

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

9 CFR Parts 301, 317, 318, 320, and 381

[Docket No. 95-033F]

Performance Standards for the Production of Certain Meat and Poultry Products

AGENCY: Food Safety and Inspection Service, Agriculture.

ACTION: Final rule.

SUMMARY: The Food Safety and Inspection Service (FSIS) is amending the Federal meat and poultry products inspection regulations by converting into performance standards the regulations governing the production of cooked beef, roast beef, and cooked corned beef products, fully and partially cooked meat patties, and certain fully and partially cooked poultry products. Unlike the previous requirements for these products, which mandated step-by-step processing measures, the new performance standards spell out the objective level of food safety performance that establishments must meet, but allow establishments to develop and implement processing procedures customized to the nature and volume of their production. Establishments that do not wish to change their processing practices may continue following the previous requirements for these products, which will be disseminated as "safe harbors" in Agency guidance materials.

Establishments that have not yet developed and implemented a HACCP (Hazard Analysis and Critical Control Point) plan are required to develop and maintain on file a documented process schedule that has been approved by a process authority for safety and efficacy. The process schedule must include control, monitoring, verification, validation, and corrective action activities to be performed by the establishment during production. Establishments operating under HACCP are not required to develop a processing schedule. FSIS expects such establishments will develop and implement HACCP plans incorporating critical limits that achieve the new performance standards.

FSIS is not making final the lethality performance standards proposed for ready-to-eat, uncured meat patties. Instead, FSIS will be proposing revised lethality performance standards for this product in a future, separate rulemaking.

EFFECTIVE DATES: March 8, 1999.

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SUPPLEMENTARY INFORMATION:

Background

On May 2, 1996, FSIS published in the *Federal Register* (61 FR 19564-19578) a proposal to convert into performance standards the regulations governing the production of cooked beef, roast beef, and cooked corned beef; fully cooked, partially cooked, and char-marked uncured meat patties; and certain fully and partially cooked poultry products. FSIS also proposed to maintain in the regulations the then current processing requirements as examples of how an establishment might comply with the proposed performance standards ("safe harbors"). Establishments wishing to continue current manufacturing practices could follow these safe harbor examples and meet the proposed performance standards.

FSIS anticipated that establishments operating under HACCP and using processing methods other than those described in the safe harbors would incorporate into their HACCP plans CCP's and critical limits that would achieve the performance standards. Of course, such establishments would be required to meet all of the applicable HACCP requirements, such as plan validation, as well as the performance standards. Importantly in such cases, validation would ensure not only that a HACCP plan was functioning as intended, but also that performance standards were being met.

FSIS proposed to require establishments choosing to develop and use procedures different from those provided in the safe-harbors, but not yet operating under HACCP, to develop and maintain on file a process schedule approved by a process authority for safety and efficacy. Similar to a HACCP plan, the process schedule would include control, monitoring procedures, verification, validation, and corrective action activities to be performed by the establishment. This requirement would sunset as establishments developed and implemented HACCP systems.

Ready-to-Eat Products

FSIS proposed to require that certain ready-to-eat products (cooked/roast beef products, fully cooked, uncured meat patties, and certain fully cooked poultry products) meet three performance

standards: lethality, stabilization, and handling. FSIS determined that ready-to-eat, cooked products meeting these three standards would contain no viable pathogenic microorganisms of concern, the intent of the then current regulations.

Lethality

To meet the first standard, lethality, FSIS proposed that establishments treat ready-to-eat product so as to ensure a specific, significant reduction in the number of *Salmonella* microorganisms, therefore eliminating or adequately reducing other vegetative pathogenic microorganisms from the product. FSIS did not propose to require that any particular means be used to meet the lethality standard, although for cooked products FSIS did propose to require a heat treatment. FSIS emphasized that cooking did not need to be the sole means by which lethality would be achieved. Other applicable treatments, such as curing or other controls, might be used in combination with cooking to achieve the required lethality.

FSIS proposed to measure the reduction of pathogenic microorganisms in "x-decimal" reductions, where x is a number. In this regulation, a single "1-decimal" reduction represents an expected 90% reduction in the number of organisms, i.e., the number of organisms would be expected to be reduced by a factor of 10. A "5-decimal" reduction reduces the number of organisms by an expected factor of 10⁵ or 100,000.

In terms of a common logarithm (log₁₀) scale, an "x-decimal" reduction is the same as saying an "x-log₁₀" reduction. In the proposed regulation, FSIS referred to an "x-log₁₀" reduction as "decimal" or "D" reduction. However, FSIS feels that it is clearer and more descriptive to use the phrase "x-log₁₀." Therefore, throughout the remainder of this document and in the final rule language, FSIS will describe pathogen reduction values as "x-log₁₀" reductions rather than "x-decimal" or "D" reductions. Thus, a "x-log₁₀" reduction means that the number of organisms would be expected to be reduced by a factor of 10^x. In terms of probability distributions, this means that the probability, p, that a given organism will survive a "x-log₁₀" lethality reduction is $p = (1/10^x)$.¹

For the cooked beef, roast beef, and cooked corned beef products described in § 318.17 and the cooked poultry

¹ More generally, it is assumed that the distribution of the number of surviving organisms given N initial organisms is a binomial distribution with parameters N and p.

products described in § 381.150, FSIS proposed that the lethality performance standard be a 7-log₁₀ reduction in *Salmonella*. Traditionally, the primary pathogenic microorganism of concern in these cooked products has been *Salmonella*. Furthermore, the thermal destruction of *Salmonella* in cooked beef products would indicate the destruction of most other pathogens.

In the proposal, FSIS noted that though a 7-log₁₀ reduction in *Salmonella* would eliminate or adequately reduce vegetative pathogenic microorganisms from these cooked products, a 7-log₁₀ reduction in *Salmonella* also may be overly conservative in certain processing environments. FSIS also recognized that developments in processing technology may indicate that a safe, ready-to-eat cooked beef or poultry product could be produced with a different level of lethality. The Agency stated, therefore, that it would consider revising the lethality performance standard and safe harbor example for these products if presented with compelling data and invited submissions on this lethality standard.

For fully cooked, uncured meat patties, as described in § 318.23, FSIS proposed that the lethality performance standard be a 5-log₁₀ reduction in *Salmonella*. FSIS identified *Salmonella* as the target pathogenic microorganism in fully cooked uncured meat patties, as in fully cooked beef products. FSIS had assumed that a 5-log₁₀ reduction in *Salmonella* in cooked, uncured meat patties would effectively eliminate most other bacterial pathogens of concern.

At the time of the proposal, the processing requirements for ready-to-eat cooked beef, roast beef, and cooked corned beef, meat patties, and cooked poultry products all contained heat treatment requirements that, if followed, ensured products met the proposed lethality performance standards. FSIS proposed to retain those requirements in the regulations as examples of processing methods that would achieve the performance standards. And, as stated above, establishments wishing to continue their current manufacturing practices could follow these safe harbor examples and meet the performance standards.

Stabilization

FSIS proposed to require that establishments producing any of the ready-to-eat products meet the second performance standard, stabilization, by preventing growth of spore-forming bacteria that may produce toxin either in the product or in the human intestine after consumption. If allowed to grow in

number, these bacteria can cause food borne illness. Means applied to products to bring about the lethality of certain pathogenic microorganisms, particularly heat treatment, can create a model environment for the multiplication of spore-forming bacteria. Spores of *Clostridium botulinum*, *Clostridium perfringens*, and other spore-forming bacteria can survive cooking and, in fact, thrive in the warm product following cooking after competitive microorganisms, such as *Salmonella*, have been eliminated.

FSIS proposed to require that establishments stabilize each of the ready-to-eat products to prevent the germination and multiplication of toxigenic microorganisms such as *C. botulinum*, and allow no more than a 1-log₁₀ multiplication of *C. perfringens*. Limiting the allowable growth of *C. perfringens* to a 1-log₁₀ multiplication would effectively limit the multiplication of other, slower growing spore-forming bacteria, such as *Bacillus cereus*. FSIS anticipated that most establishments would meet the stabilization performance standards by rapidly cooling products following cooking.

At the time of the proposal, the regulations for cooked beef products and cooked meat patties (§§ 318.17 (h)(10) and 318.23(b)) contained chilling requirements to inhibit the growth of spore-forming bacteria. Compliance with these requirements would allow establishments to meet the proposed stabilization performance standard, so FSIS proposed to retain these requirements in the regulations as safe harbors. Consequently, meat establishments wishing to continue their current manufacturing practices could follow these safe harbor examples.

The regulations for cooked poultry products in § 381.150, however, did not contain chilling requirements. FSIS proposed to codify as safe harbors the chilling recommendations in FSIS Directive 7110.3, "TIME/TEMPERATURE GUIDELINES FOR COOLING HEATED PRODUCTS." FSIS determined that this chilling directive would constitute a safe harbor because compliance would yield cooked poultry products that meet the stabilization performance standard and because most, if not all, establishments were already following this directive.

Handling

To meet the third performance standard for the ready-to-eat products, FSIS proposed to require that establishments handle product to preclude recontamination by infectious

pathogenic microorganisms. The proposed standard required that no infectious pathogens be introduced into the product following processes ensuring lethality or stabilization, or after final packaging.

At the time of the proposal, the regulations for cooked beef products (§ 318.17(i), (j), and (k)) and for cooked meat patties (§ 318.23(b)(4)) required that these cooked products be handled throughout processing in a manner precluding their recontamination by infectious pathogenic microorganisms. FSIS proposed to retain these requirements in the regulations as safe harbors. Consequently, meat establishments wishing to continue their current manufacturing practices could follow these safe harbor examples and meet the performance standards.

The regulations for ready-to-eat poultry products in § 381.150, however, did not contain handling requirements. FSIS proposed to codify the handling regulations already in place for cooked beef products and cooked meat patties as the safe harbor handling requirements for cooked poultry products. As with the proposed chilling requirements, FSIS determined that these proposed handling requirements for ready-to-eat poultry would constitute safe harbors because they represent current good manufacturing practices (GMP's) accepted and in general use by industry.

Performance Standards for Partially Cooked and Char-Marked Meat Patties and Partially Cooked Poultry Breakfast Strips

Unlike the fully cooked, ready-to-eat products described above, partially cooked and char-marked uncured meat patties and partially cooked poultry breakfast strips are essentially raw, and require adequate cooking prior to consumption. FSIS determined that a lethality performance standard, therefore, would not apply to partially cooked and char-marked products, since FSIS does not require that these products be ready-to-eat. Neither would a handling performance standard apply, since these raw products might contain infectious pathogenic microorganisms after processing and prior to cooking. FSIS proposed, therefore, that establishments producing these products meet a stabilization performance standard identical to the stabilization standard proposed above for fully cooked products.

During processing, these products are partially cooked and then cooled, which creates a model environment for the growth of *Clostridium perfringens*, *Clostridium botulinum*, and other spore-

forming, toxigenic bacteria. Cooking by the consumer, retailer, or other end-user may not eliminate these bacteria from these products. Therefore, it is important that bacterial growth be controlled in these products to the extent possible while they remain at the producing establishment.

At the time of the proposal, the regulations for partially cooked and char-marked uncured meat patties (§ 318.23(b)(1)(ii) and (iii)) and partially cooked poultry breakfast strips (§ 381.150(a)) required that these products be quickly chilled following partial cooking or char-marking, in order to inhibit the growth of spore-forming bacteria. When applied, these chilling requirements produce partially cooked and char-marked products that meet the stabilization performance standard. FSIS proposed to retain these requirements in the regulations as safe harbors. Consequently, establishments wishing to continue their current manufacturing practices could follow these safe harbor examples and meet the proposed stabilization performance standard.

FSIS currently requires that partially cooked and char-marked meat patties, as well as partially cooked poultry breakfast strips, be labeled with cooking directions. It is imperative that consumers fully cook these products, as they are essentially raw, and may contain viable pathogenic microorganisms. Therefore, FSIS proposed to retain these labeling requirements in the regulations.

Process Schedule Approval and Validation

FSIS proposed to require that prior to its development and implementation of a HACCP plan, an establishment choosing to develop and use processing procedures different from those provided in the safe-harbor examples have on file a written process schedule describing the specific operations employed by the establishment to accomplish the objectives of the performance standards. This process schedule also would be required to contain the related control, monitoring, verification, validation, and corrective action activities associated with the establishment's procedures. These activities would be similar, if not identical, to the control, monitoring, verification, validation, and corrective action activities eventually developed by the establishment as part of its HACCP plan. Accordingly, FSIS proposed to sunset these process schedule requirements as establishments implemented HACCP.

FSIS also proposed to require that the process schedule be evaluated and approved for safety and efficacy by a process authority—a person or organization with expert knowledge in meat and poultry process control and relevant regulations. FSIS did not propose to preapprove the procedures deemed acceptable by the establishment's process authority. The process authority would evaluate the establishment's prospective processing procedures and, after using such devices as laboratory challenge studies or comparison to peer-reviewed and -accepted procedures, approve, in writing, the safety and efficacy of the establishment's prospective procedures. The process authority must have access to the establishment in order to evaluate the safety of that establishment's planned production processes.

Also, FSIS proposed to require that prior to the implementation of HACCP, establishments validate the process schedule by holding and testing product to determine that it meets the applicable performance standards. Testing would have to be conducted in accordance with a sampling program designed by the process authority to assure, with at least 95 percent statistical confidence, that an establishment's process schedule will produce product that meets applicable performance standards. Establishments could not release product for commercial use until testing confirmed that the process schedule was producing product meeting applicable performance standards. FSIS proposed to require that results of the product testing, as well as the sampling regimen, be made available as the validation activities contained in the process schedule. And, like the proposed requirements concerning the development, approval, and maintenance of the process schedule, FSIS proposed to sunset the process schedule validation requirement as establishments implemented HACCP.

FSIS noted that this particular form of validation may not be appropriate in every circumstance and invited comment on the validation requirement proposed in this document, specifically as to whether FSIS should prescribe a specific method of validation for these process schedules, and, whether the proposed testing requirement was, in fact, appropriate for ensuring that an establishment's products meet food safety performance standards.

Safe Handling Labels

Sections 317.2(l) and 381.125(b) of the regulations require that safe handling instructions be provided for beef products, meat patties, and poultry

products not heat processed in a manner that conforms to the time and temperature combinations listed in §§ 318.17, 318.23, and 381.150, respectively. FSIS proposed, however, to allow ready-to-eat products to be processed by means other than the time and temperature requirements prescribed in these sections, as long as they met the performance standards proposed. Therefore, as a result of the proposal, safe handling label requirements might not be necessary for all ready-to-eat products processed by means other than those prescribed time/temperature combinations. Accordingly, FSIS proposed to amend §§ 317.2(l) and 381.125(b), to exempt from the labeling requirements ready-to-eat products meeting the proposed performance standards.

Comments and Agency Responses

FSIS received nine comments on the proposed rule from industry and an industry consultant, trade associations, a veterinary medical association, and a State government. Several of the commenters requested that the initial comment period, which was to end on July 1, 1996, be extended. Commenters were concerned that there might be conflicts between the final HACCP rule and codification of safe harbors and GMP's. Also, there was a request for more time to develop data to support lower lethality values. The Agency responded by extending the comment period for this proposal until September 9, 1996. Meanwhile, the HACCP rule was published on July 25, 1996, which gave commenters time to consider this proposal in light of the final HACCP rule.

All of the commenters expressed general support for the Agency's stated intent to move away from command-and-control regulations. One reviewer felt that the proposal provided for adequate assurance of food safety while allowing innovation in processing procedures. Some commended the Agency for promoting the move towards a HACCP approach and welcomed the flexibility to vary production schedules, as long as performance standards were met. However, some commenters stated that the goal of moving away from command-and-control regulations into a HACCP environment was not fully realized in the proposal. Their specific objections and Agency responses follow.

Performance Standards and HACCP

Comment: Several of the commenters were opposed to the Agency establishing the type of safety standard that was embodied in the proposed performance standards. These

commenters maintained that the proposal could inhibit innovation and flexibility and that allowing each plant to develop and specify their individual performance standards or food safety objectives would be more consistent with HACCP.

Response: FSIS has determined that HACCP-based process controls combined with appropriate food safety performance standards are the most effective means available for controlling and reducing harmful bacteria on meat and poultry products. In the final rule establishing HACCP and pathogen reduction requirements for all official meat and poultry establishments, FSIS explained the role played by HACCP and pathogen reduction performance standards in its food safety strategy:

FSIS has concluded that HACCP-based process control, combined with appropriate food safety performance standards, is the most effective means available for controlling and reducing harmful bacteria on raw meat and poultry products. HACCP provides the framework for industry to set up science-based process controls that establishments can validate as effective for controlling and reducing harmful bacteria. Performance standards tell establishments what degree of effectiveness their HACCP plans will be expected to achieve and provide a necessary tool of accountability for achieving acceptable food safety performance. Science-based process control, as embodied in HACCP, and appropriate performance standards are inextricably intertwined in the Agency's regulatory strategy for improving food safety. Neither is sufficient by itself, but, when combined, they are the basis upon which FSIS expects significant reductions in the incidence and levels of harmful bacteria on raw meat and poultry products and, in turn, significant reductions in food borne illness.

(61 FR 38811)

In this rule, FSIS replaces existing, prescriptive cooking and cooling requirements for ready-to-eat products with pathogen reduction performance standards. These standards set forth the required level of food safety performance for specific types of meat and poultry processing, but allow for significant flexibility in achieving those levels of safety. Allowing individual establishments to develop their own performance standards would not provide sufficient accountability for achieving an acceptable level of food safety performance.

FSIS is providing more flexibility in meeting the lethality performance standards than that which was proposed by allowing establishments to use alternative, and presumably lower, lethality standards. An establishment may develop and use an alternative lethality if it can demonstrate, within its

validated HACCP plan or process schedule, that its process yields finished, ready-to-eat meat or poultry products with reductions of *Salmonella* and other pathogens equivalent to the reductions achieved through compliance with the lethality performance standards explicitly provided for in the regulations. Alternative lethality standards are explained further in the following responses.

Lethality

Comment: Most commenters agreed that the Agency was scientifically justified in proposing that a 5-log₁₀ reduction in *Salmonella* be achieved in ready-to-eat meat patties, but contended that the proposed 7-log₁₀ lethality for whole muscle products (ready-to-eat cooked beef and poultry products) was excessive. These commenters argued that a 5-log₁₀ reduction in *Salmonella* would adequately ensure the safety of all of the fully-cooked meat and poultry products. They maintained that achieving a 5-log₁₀ reduction in *Salmonella* would eliminate other pathogens of concern, which generally are more sensitive to heat treatment. Also, they stated that they expect to see relatively low numbers of pathogens on incoming raw products.

One commenter stated that "obviously, the surface of products, which are cooked to achieve a specified internal lethality value, are subject to much, much higher lethality." The commenter implied that a lethality applicable to the interior of a whole cut product resulted in a greater lethality on the outside surfaces, where the bacteria lie. The commenter specifically suggested that the lethality requirement for cooked meat products be reduced from a 7-log₁₀ to a 5-log₁₀ reduction. The justification of this commenter's recommended reduction was based on the measured "high value" of 240 Most Probable Number (MPN)/cm² of *Salmonella* reported by FSIS in "baseline" surveys, and a "safety" factor of 100.

Response: In the proposal, FSIS acknowledged that both the current cooking requirements and the proposed performance standards for ready-to-eat whole muscle meat and poultry products, each of which achieves a 7-log₁₀ reduction in *Salmonella*, may be overly conservative in certain processing environments. Accordingly, FSIS specifically requested comment on whether to revise the proposed lethality performance standards and regulatory safe harbors for these products.

Although establishing a single lethality performance standard for all ready-to-eat products, as suggested by

commenters, would greatly simplify the regulations, the commenters did not present information that would substantiate a single lethality requirement for all ready-to-eat products. Furthermore, data collected in FSIS's national microbiological "baseline" surveys of raw whole and ground meat and poultry products² indicate that different ready-to-eat products require different lethality standards. Because the baseline data shows higher levels of *Salmonella* in poultry than in meat, FSIS is establishing higher lethality performance standards for ready-to-eat poultry products than for meat. This difference is necessitated by need for lethality standards that will render raw poultry into ready-to-eat poultry products safe for consumption. FSIS already has established different *Salmonella* standards for different types raw products owing to the different prevalences of *Salmonella* found in the baselines for raw meat and poultry (§§ 310.25(b)(1) and 381.381.94(b)(1)).

After considering the comments and information collected from the baseline studies, FSIS is requiring that establishments achieve a 7-log₁₀ reduction of *Salmonella* or an equivalent probability that no viable *Salmonella* organisms remain in the finished product in ready-to-eat poultry products and a 6.5-log₁₀ reduction of *Salmonella* or an equivalent probability that no viable *Salmonella* organisms remain in the finished product in ready-to-eat cooked beef, roast beef, and cooked corned beef products. Effectively, processing that achieves these specific lethality standards or their equivalents will result in ready-to-eat products that pose no health risks to consumers.³

FSIS is not finalizing the lethality performance standards proposed for ready-to-eat comminuted meat patty products. Compliance with the current requirements concerning the production of ready-to-eat meat patties effectively achieves a 5-log₁₀ reduction in *Salmonella*. FSIS proposed to retain this same level of pathogen reduction in both the performance standard and the

² Copies of reports on FSIS's Nationwide Microbiological Baseline Data Collection Programs are available in the FSIS Docket Room, U.S. Department of Agriculture, Room 102, Cotton Annex, 300 12th St. SW, Washington, DC 20250-3700.

³ A technical report explaining the lethality performance standards and their equivalent probabilities, "Lethality and Stabilization Performance Standards for Certain Meat and Poultry Products: Technical Paper," is available from the FSIS Docket Room, U.S. Department of Agriculture, Room 102, Cotton Annex, 300 12th St. SW, Washington, DC 20250-3700.

safe harbor for this product. However, in the course of developing this final regulation, after examining the baseline surveys of raw ground meat products, FSIS has concluded that a higher lethality may be necessary to produce ready-to-eat meat patties that pose no health risk to consumers. Therefore, FSIS is considering establishing a new lethality performance standard for ready-to-eat meat patties. Until further rulemaking, the current heat-processing requirements for ready-to-eat meat patties will remain in effect.

In this rule, FSIS is finalizing lethality performance standards that, effectively, ensure that even a "worst case" product presents no health risk to consumers. The Agency defined worst case product by considering data from the FSIS's national baseline studies. Specifically, the worst case was defined as an approximate 97.5% upper bound for the number of organisms in a sample with the highest measured density from each baseline survey. This approach of determining a "worst case" is more appropriate from a scientific and statistical standpoint than using an arbitrary 2-log_{10} safety factor over a given "high value" measurement (another common approach), in that it allows FSIS to better address any uncertainty associated with the "worst case" value.

As stated above, FSIS used the baseline surveys for both raw whole and ground products in defining "worst case product" and determining the necessary lethality. The "worst case" definition and lethality for ready-to-eat poultry products were determined using the raw ground poultry surveys. FSIS recognizes that the raw ground product survey data has certain limitations. For example, the raw ground product surveys did not cover all of the summer months and therefore do not completely represent possible seasonal variations in the prevalence and levels of pathogenic microorganisms. Nevertheless, the raw ground product surveys represent the most complete, recent data set available for the Agency's purposes.

Furthermore, FSIS has concluded that the raw ground product surveys are more appropriate as a basis for these performance standards than are epidemiological data, such as quantitative data from meat and poultry products implicated in outbreaks of food borne illness. Products implicated in outbreaks often have been temperature abused. Because the cause of the temperature abuse, as well as the bacterial levels in the implicated product prior to the abuse, are often unknown, outbreak data were not

deemed useful in developing these performance standards.

To assure that "worst case" product subjected to the finalized lethality requirements (with subsequent proper handling) would present, effectively, no health risk to the consumers, FSIS calculated the probability distribution for the number of organisms that survive cooking. These calculations demonstrate that it is highly unlikely that worst case product subjected to the required lethality would ever contain more than a very few *Salmonella* organisms in 100 grams of product. FSIS also emphasizes that, even though it employed probability calculations regarding the survival of *Salmonella* in finished, ready-to-eat product to develop the performance standards, if it were to find viable pathogens of concern in any ready-to-eat product, FSIS would consider that product to be adulterated.

In regard to the comment contending that whole muscle meat products are inherently safer than comminuted meat products, no conclusive information was presented to FSIS that demonstrated that the distributions of bacteria on ground and whole product produced under good manufacturing practices would present comparatively higher or lower risks to consumers. In fact, research suggests that in some situations risks could be higher in whole products than in ground products.

Research has suggested that the lethality on the outside surface might not always be greater than that of the interior of product during cooking. Blankenship has shown, through an inoculation study,⁴ that roast beef cooked in an oven at 229°F resulted in no *Salmonella* being recovered from the roast's center, while *Salmonella* survived on the roast's surface, even though an internal temperature of 147.5°F was achieved. The reason for this phenomenon was elucidated by Goodfellow and Brown⁵ who showed that without adequate conditions of humidity, *Salmonella* could survive on dry roasted beef surfaces during low temperature dry roasting. Therefore, the research shows that, under some circumstances, cooking does not always result in a higher lethality on the surface of a product versus the interior of the product. It was for this reason that the previous cooked beef, roast beef, and cooked corned beef regulations (9 CFR

318.23) required humidity to be controlled during the cooking process, and the lethality performance standards for this regulation were clarified by adding the phrase "throughout the product."

Further, it is possible for intact whole muscle cuts, sectioned and formed products, and chunked and formed products, to have high microbial levels on small portions of the product ("hot spots").⁶ A piece of meat with high levels of *Salmonella* could end up anywhere in the chunked/formed roast, resulting in an uneven distribution of *Salmonella*. This uneven distribution is in sharp contrast to the more even distribution of *Salmonella* that would be expected in ground product such as ground beef. Therefore, in such a case, the amount of lethality needed to reduce *Salmonella* for a given amount in whole muscle cuts and in chunked/formed product may exceed that needed for ground product.

Therefore, because in some situations risks could be higher in whole muscle and chunked/formed products than in ground products, FSIS will continue to require a higher lethality reduction in *Salmonella* for cooked beef, roast beef, and cooked corned beef than that which is currently required for meat patties. However, as mentioned above, FSIS is reconsidering the lethality reduction in *Salmonella* currently required for ready-to-eat meat patties.

Comment: A few commenters recommended that the industry be allowed to set plant- and process-specific lethality performance standards, since HACCP requires a hazard analysis resulting in appropriate food safety process controls. These commenters claimed that the proposed performance standards would limit an establishment's flexibility in employing alternative lethality values and inhibit innovation in pathogen reduction. One commenter said explicitly that "there must be an option for use of other scientifically valid lethality values." This commenter suggested how other scientifically valid lethality values could be derived, by allowing "a lower level of lethality as long as the food safety objectives are met (i.e., a similar probability of survival of the pathogens of concern)." The same commenter also stated that "The Agency must provide a clear and reasonable mechanism for review and acceptance of alternative values."

⁴ Blankenship, L.C. 1978. Survival of a *Salmonella typhimurium* Experimental Contaminant During Cooking of Beef Roasts. Appl. Environ. Microbiol. 35:1160.

⁵ Goodfellow, S.J. and Brown, W.L. 1978: Fate of *Salmonella* inoculated into beef for cooking. J. Food Protect. 41:598-605.

⁶ Surkiewicz, B.F., et al. (1975) *Bacteriological Survey of Raw Beef Patties Produced at Establishments under Federal Inspection*, Applied Microbiology, p. 331-334.

Response: The Agency agrees and will allow establishments to design and employ processes with lethality different from, but effectively equivalent to, those specifically provided for in this rule. FSIS did not intend to limit an establishment's flexibility in designing processes that would produce safe food. FSIS stated in the preamble to the proposed rule that it "recognizes * * * that a safe, ready-to-eat * * * product could be produced with a different level of lethality." An establishment that develops and uses an alternative lethality will be required to demonstrate, within its validated HACCP plan or process schedule, that its process yields finished, ready-to-eat meat or poultry products with reductions of *Salmonella* and other pathogens equivalent to the reductions achieved through compliance with the lethality performance standards explicitly provided for in the regulations. As suggested by the commenter, establishments will need to evaluate processes using alternative lethality with criteria based on calculated probabilities of surviving pathogens following processing.

To develop criteria for evaluating the effectiveness of processes using alternative lethality, it will be necessary for the processor to define, using associated statistical criteria, the expected characteristics of the treated product after processing for assumed pre-processing product conditions. For example, an establishment using an alternative lethality would specify that the probability of there being more than x surviving organisms in the finished product is no more than p , given that the "worst case," pre-processed product contained at least y organisms. Of course, establishments would need to use an alternative lethality that results in a finished product that is as safe as product produced using the lethality explicitly set out in this regulation (a 6.5 or 7 \log_{10} reduction of *Salmonella*).

The performance standards describe a property of the actual process: the lethality performance standards in this rule require that processing achieve an x - \log_{10} lethality reduction in *Salmonella*. Practical difficulties would have been created for a large portion of the industry if this regulation were stated purely in terms of the statistical criteria that would indicate an adequate reduction of *Salmonella*. It would be difficult for many establishments to demonstrate that a process achieves an adequate reduction of *Salmonella* using statistical criteria. Such a demonstration would entail extensive scientific research beyond the capability of most establishments. Therefore, to allow for

processing flexibility while ensuring product safety, FSIS is finalizing specific lethality performance standards in the regulations, but allowing establishments to use alternative lethality that achieve an equivalent probability that no viable *Salmonella* organisms remain in the finished product.

As explained in the previous response, FSIS determined that processes meeting the finalized lethality performance standards will render "worst case" raw product, as defined by FSIS's national baseline studies, into finished product that, effectively, poses no health risk to the consumer. In determining that processes meeting the performance standards will ensure a safe product, the Agency made conservative assumptions concerning the actual lethality achieved throughout the product. The Agency acknowledges that it might be possible for producers to scientifically demonstrate that these lethality assumptions or the Agency's defined "worst case" would not be applicable for their particular processing situation. An establishment could then design a process with lethality values that are different from those provided in this rule, but that would still yield a product that meets the final conditions equivalent to those achieved by the lethality performance standard.

An establishment developing an alternative lethality treatment or treatments and assuming an initial product condition other than the "worst case" would need to include in its HACCP plan or process schedule scientific data and statistical validation that would justify the assumed initial conditions and ensure that these would not change. For example, an establishment may be able to demonstrate that the number of *Salmonella* is not uniformly distributed throughout a particular type of product. The establishment also might demonstrate that due to husbandry and slaughter practices, the worst case product processed within an establishment differs from the worst case scenarios developed for this rule. Demonstrations of initial product conditions solely by statistical means will be unacceptable.

Generally, an establishment will need to demonstrate in its HACCP plan or process schedule how its alternative lethality treatment(s) provides for a level of safety in its finished product equivalent to that provided for by compliance with the lethality performance standards explicitly provided in this rule. The establishment will need to demonstrate the

relationships between the lethality treatment(s) and the specific characteristics of a product, such as physical and chemical properties. This demonstration could involve the use of heat transfer equations and should account for all variables that would affect lethality (e.g., size of product, humidity, density, thermal conductivity, specific heat, shape, product composition, and strain of organism).

Finally, establishments employing alternative lethality will need to demonstrate, within their HACCP plans or process schedules, that they have validated their processes as being effective in ensuring product safety. Section 417.4(a)(1) of the HACCP regulations sets forth the "initial validation" requirements for establishments under HACCP:

Upon completion of the hazard analysis and development of the HACCP plan, the establishment shall conduct activities designed to determine that the HACCP plan is functioning as intended. During this HACCP plan validation period, the establishment shall repeatedly test the adequacy of the CCP's, critical limits, monitoring and recordkeeping procedures, and corrective actions set forth in the HACCP plan. Validation also encompasses reviews of the records themselves, routinely generated by the HACCP system, in the context of other validation activities.

FSIS will expect establishments employing alternative lethality, but not yet operating under HACCP, to undertake similar actions as part of the validation activities documented in their process schedules.

As mentioned above, FSIS is making available a technical paper explaining the derivation of the lethality performance standards.⁷ Establishments are encouraged to use this paper when developing alternative lethality. In the paper, FSIS explains the methodology used to calculate the probability of remaining *Salmonella* organisms in treated product.

Comment: Some commenters suggested that it would be appropriate to allow combinations of treatments or alternatives to achieve a level of safety equivalent to that provided by the specified lethality.

Response: The Agency agrees and will allow combinations of treatments or alternatives to meet the performance standards for lethality, so long as a cooking step is included and process schedules are validated by a knowledgeable processing authority.

⁷ "Lethality and Stabilization Performance Standards for Certain Meat and Poultry Products: Technical Paper" is available from the FSIS Docket Room (see footnote 3).

FSIS has amended the lethality performance standards to clarify that one or more controlled intermediate steps applied to raw product may form part of the basis for equivalency with the specified lethality. Importantly, the net, or overall, effect of the entire process must be demonstrated to effect a required reduction in *Salmonella*. The following example, provided in part by one of the commenters, clarifies the Agency's intent:

A controlled intermediate step(s) applied to the untreated raw product may form part of the basis for the equivalency. Assume that a 7- \log_{10} reduction is required. A 3- \log_{10} attained by an anti-microbial spray treatment is followed immediately by a 4- \log_{10} reduction using a heat treatment. The combined 3- \log_{10} plus 4- \log_{10} reduction could result in a net 7- \log_{10} reduction. This 7- \log_{10} reduction should be confirmed with reference to the level of *Salmonella* on the initial raw product compared to the level attained after the second or final treatment. This confirmation is needed because there may be an interactive effect between the treatments. A primary treatment could, for example, increase or decrease the heat resistance of *Salmonella* if heat were the second treatment. Secondly, certain conditions, such as time/temperature abuse between the steps could have an unanticipated negative affect, allowing pathogens to grow between treatments.

If treatments or interventions (organic rinses, steam vacuuming, steam pasteurization, etc.) are used in combination with a heat treatment, it is the responsibility of the establishment and processing authority to ensure not only the cumulative equivalency of a 6.5- \log_{10} or 7- \log_{10} lethality for *Salmonella* in ready-to-eat beef or poultry products, respectively, but also the reduction/inactivation of all other food borne pathogens of concern. The Agency has revised the lethality performance standard to clarify this point. The lethality performance standard now states that establishments are responsible not only for the required reduction in *Salmonella*, but also for the "reduction of other pathogens and their toxins or toxic metabolites necessary to prevent adulteration, * * * throughout the product" This phrase was added to clarify that, while *Salmonella* is the reference organism and its destruction in most cases will indicate adequate reduction of other pathogens of concern, it is the responsibility of the establishment to demonstrate and ensure that the final product is ultimately safe. "Throughout the product" is added to indicate FSIS's intent that the process cannot affect only the surface or restricted portions of the product.

Stabilization

Comment: As with the lethality standards, a few commenters recommended that the industry be allowed to set establishment- and process-specific stabilization performance standards, since HACCP requires a hazard analysis resulting in appropriate food safety process controls.

Response: The Agency has decided to maintain the performance standards with regard to multiplication of *Clostridium perfringens* and *Clostridium botulinum*. As noted in the HACCP final rule, *Clostridium perfringens* is ubiquitous in the environment so that controls at slaughter would not necessarily be effective in controlling the occurrence of this organism in raw product. Therefore, product cooling or stabilization is a critical factor in preventing the multiplication of this organism.

Comment: One commenter suggested that FSIS allow 1.5 logs of multiplication of *Clostridium perfringens*. The commenter stated he had data to support this level of reduction, but has yet to provide it. This commenter also recommended that the Agency convene a technical conference of appropriate scientists to develop a consensus on the stabilization performance standard and have the performance standard addressed by the NACMCF.

Another commenter suggested allowing 10 generations (approximately 3 logs) of *Clostridium perfringens* multiplication as the performance standard. This commenter's reason for permitting a 3 log increase is based on an assumed surviving spore population, after cooking, of 10 *Clostridium perfringens* per gram, and the commenter's assumption that 10⁴ per gram is generally considered to be the upper acceptable limit for finished product.

Response: The performance standard provides that any more than 1- \log_{10} multiplication of *Clostridium perfringens* will adulterate the product for the following reasons: First, viable counts of 10⁵ or greater of *Clostridium perfringens*/gram have been recommended by the U.S. Centers for Disease Control and Prevention as one criteria for incriminating *Clostridium perfringens* as the causative agent of food borne illness in finished product⁸ (although foods responsible for *Clostridium perfringens* outbreaks usually contain at least 10⁶ vegetative *Clostridium perfringens* cells per

gram^{9,10}). Second, in the FSIS ground product surveys, some samples were found to contain more than 1000 *Clostridium perfringens*/gram (the level on one ground chicken sample was 11,000 CFU/gram). Thus, there is some probability that greater than 10⁴ *Clostridium perfringens*/gram can occur in raw product on rare occasions. It is a conservative assumption (with respect to public health) that the great majority of *Clostridium perfringens* in the raw product are spores. Heating activates the spores which during the cooling become vegetative cells that can multiply to hazardous levels. Given that there can be more than 10⁴ *Clostridium perfringens* (spores) per gram on raw product, it is possible that there could be as many as 10⁴ vegetative *Clostridium perfringens*/gram of these surviving, after cooking, in the product.¹¹ Therefore, the Agency, using the aforementioned CDC criteria as an upper limit that should not be exceeded, determined that a limit of no more than 1 \log_{10} growth of *Clostridium perfringens* is appropriate to ensure that there would be no more than 10⁵ *Clostridium perfringens* per gram on the finished product after cooling.

Finally, although the Agency has not convened a technical conference to develop this performance standard, the Agency did informally discuss the standard with several experts in the field of clostridial research. These experts agreed that limiting relative growth of *Clostridium perfringens* to no more than 1- \log_{10} would be reasonable with respect to product safety, albeit somewhat conservative.

Comment: Some commenters felt that there was little justification for including *Clostridium botulinum* as part of the performance standard. They maintained that it is unlikely to be present in meat and poultry with its sparse distribution (about 1/1000 gram) in raw meat; that the risk of *Clostridium botulinum* is low; limiting *Clostridium perfringens* would effectively limit growth of the other spore formers (e.g., *Clostridium botulinum* and *Bacillus cereus*), since *Clostridium perfringens* has a shorter generation time and

⁹Hauschild, A. (1975) *Criteria and Procedures for Implicating Clostridium Perfringens in Food-borne Outbreaks*. Canadian Journal of Public Health. 66: 388-392.

¹⁰McClane, B.A. (1992) *Clostridium Perfringens Enterotoxin: Structure, Action, and Detection*. Journal of Food Safety. 12:237-252.

¹¹For further detail refer to the "Compliance Guidelines" concerning stabilization performance attached to this document.

⁸Labbe, R. (1989) *Clostridium perfringens*. In M. Doyle (ed.), *Food borne Bacterial Pathogens*, Marcel Dekker, Inc., New York. pp. 210, 213.

broader range of temperature growth; and, that the germination of *Clostridium botulinum* spores, per se, without multiplication, was not dangerous.

Response: The Agency is resolved to keep *Clostridium botulinum* in the performance standard because severe cooling deviations could potentially allow *Clostridium botulinum* multiplication resulting in toxin production. However, the term "germination" has been removed from the performance standard as suggested, since it is expected that processors could not completely prevent germination. While in recent years few, if any, cases of botulism have resulted from commercially produced fully cooked uncanned meat and poultry products, many food scientists feel that the risk has increased with the advent of vacuum-packaged products. While the risk still may remain low, the consequences of botulism are often catastrophic.

Although both *Clostridium perfringens* and *Clostridium botulinum* will remain in the performance standard, a process authority may choose to consider *Clostridium perfringens* as a reference organism to demonstrate that the performance standard was met. That is, if time, temperature, and intrinsic properties of the product have been shown to preclude over one log multiplication of *Clostridium perfringens*, then multiplication of *Clostridium botulinum*, which multiplies much more slowly, would be unlikely to have occurred.

Comment: Some of the commenters strongly objected to proposed codification of cooling guidelines for cooked poultry products (FSIS Directive 7110.3, "Time/Temperature Guidelines for Cooling Heated Products") as safe harbors. One commenter agreed that the application of this Directive to partially cooked poultry breakfast strips may be acceptable, but felt that the proposal implies the Directive is applicable to all poultry products. For instance, the commenter claimed that the guidelines in Directive 7110.3 "are not physically attainable" for cooked turkey roasts and other similar large mass products because they were developed from data derived from 50 ml samples of ground chili-type product in polyethylene tubes. This commenter contended that the roast beef rules in 9 CFR 318.17 (h)(10) are more applicable to turkey roasts, but may not be applicable to all poultry products, hence this part of the safe harbor should be subjected to further scientific study. This commenter also stated that relative to cooling, it was imperative that the Agency clarify its intent with respect to poultry

products. Finally, some commenters stated that the application of the cooling guidelines to partially cooked and char-marked meat patties was especially unwarranted, because these products pose no more hazard than other raw products.

Response: There has been no constraint against using the cooling requirements in the roast beef regulation for chilling whole poultry products. Further, there is no reason why any of the cooling safe harbors for fully cooked and partially cooked products could not be used across product categories (whole, ground or comminuted), regardless of the species of origin of the tissue. Research conducted by the Agricultural Research Service demonstrates that the cooling control points specified in the roast beef regulation could safely be applied to ground beef.¹² It must be understood that though these cooling guidelines and regulations were written at different times, effective use of any of them will satisfy the performance standard. Therefore, it is the intent of this rule that the cooling guidelines and regulations can freely be interchanged among product categories without requiring the approval of a processing authority.

The safe harbors for achieving the stabilization performance standards have withstood the test of time; no cases of food borne illness due to the clostridia when these times and temperatures are followed have been documented. Admittedly, the current safe harbors for cooling contain a margin of safety in meeting the performance standard. However, barring mechanical or electrical failure of equipment, the time/temperature combinations in the safe harbors for cooling are easily achieved.

Implicit and of paramount importance is that cooling be continuous between the stated temperature control points. Also important is that cooling between the temperatures of 130 °F and 80 °F, the range of most rapid *Clostridium* multiplication, be accomplished quickly, as suggested in Directive 7110.3. The upper limit for growth of *Clostridium perfringens* is about 125–126 °F.¹³

Finally, in response to the comment that stabilization performance standards for partially cooked poultry products are

unwarranted, FSIS disagrees and the standards will be adopted as proposed. Partial cooking can allow heat shocking of clostridial spores, which can germinate during cooling and become vegetative cells that multiply. Therefore, the consumer potentially could receive a partially cooked product containing a high number of vegetative clostridial cells. If the consumer undercooked the product, there would be an increased risk that the number of vegetative clostridial cells would survive and increase to hazardous levels. Consequently, it is important that processors control clostridial growth as required by the performance standard.

Handling

Comment: There were a number of comments concerning the proposed provisions for sanitary handling. Many of the commenters insisted that this performance standard was unnecessary, being adequately covered by both the Agency requirement for Sanitation SOP's and GMP's that are already accepted by the industry. One stated that the requirement for Sanitation SOP's was in itself contrary to the principles of HACCP, and that the Agency should allow individual plants to determine necessary sanitation procedures. Nevertheless, this commenter stated they could support the requirement for Sanitation SOP's if it were not overlaid with this additional performance standard. This commenter also reminded the Agency of a phrase in the background to the final HACCP rule stating that current GMP's, already accepted by industry, encompass the proposed handling performance standards. Also, some commenters questioned the necessity of this performance standard for poultry, stating that handling requirements for poultry were based on GMP's.

Some of the commenters felt that the safe harbors for handling remained in the realm of command-and-control regulations, and contrary to HACCP principles, especially in regard to the stated specifications concerning the use of sanitizers and outer garments. One commenter suggested that the Agency should not prescribe how to reduce cross contamination. Instead the commenter suggested that the rule should have a performance standard stating that cross-contamination should be less than one pathogen per 100 grams of finished product.

Response: The Agency had many reservations concerning the addition of this performance standard, anticipating that it would be perceived as redundant and duplicative of other requirements. However, the Agency was also

¹²Juneja, V.K., et al. (1994) "Influence of Cooling Rate on Outgrowth of *Clostridium perfringens* Spores in Cooked Ground Beef." J. Food Prot. 57(12):1063–1067.

¹³Juneja, V.K., et al. 1996. "Interactive Effects of Temperature, Initial pH, Sodium Chloride, and Sodium Pyrophosphate on the Growth Kinetics of *Clostridium perfringens*." J. Food Prot. 59(9):963–968.

concerned that handling GMP's, while widely practiced by industry, were not required by regulation. Further, though FSIS is now requiring establishments to develop and implement Sanitation SOP's, there is no specific requirement as to their level of detail, which will vary in accordance with the needs, requirements, and complexity of the specific plant and its operations. Therefore the Agency was concerned that handling might be inadequately addressed by some establishments.

Ultimately, in consideration of the numerous comments, the Agency decided that it is consistent with HACCP principles for establishments to be free to devise the specific actions, practices, and procedures necessary to ensure a safe final product. Also, the Agency agrees that at least general provisions for handling and sanitation are contained in the Sanitation SOP requirements, and it did not want to impose duplicative requirements that would be burdensome in most cases. Accordingly, all handling performance standards have been removed from the requirements finalized in this rule.

Process Authority

Comment: Commenters raised concerns about insufficient detail regarding the qualifications required of persons acting as process authorities. Also, two commenters were concerned that FSIS inspection personnel may not have the qualifications to evaluate the procedures recommended by the process authority.

Response: The Agency has defined "process authority" as a person or organization with expert knowledge in meat or poultry production, process control, and relevant regulations. The Agency has decided that further specifications regarding the qualifications of a process authority would limit the flexibility needed by industry to develop customized, effective processes and process controls. In regard to inspection personnel qualifications, FSIS does not intend for its inspectors to evaluate the process authority-approved procedures for efficacy. FSIS has, however, initiated an aggressive national training effort for all inspection personnel regarding their roles in verifying HACCP plans and plant performance.

Testing and Other Validation Activities

Comment: Several commenters felt that the validation requirements for processing schedules were too prescriptive and poorly defined in the rule, although somewhat better defined in the preamble. Some of the commenters maintained that the hold

and test requirement would inhibit flexibility and be burdensome, costly, and contrary to the principles of HACCP. One commenter stated that it could result in false conclusions of product safety, because the process is designed to handle extremes greater than that which would be presented in everyday samples. One commenter, citing the alternatives the Agency previously presented for *E. coli* O157:H7 testing of dry and semi-dry sausages, stated that a flexible precedent was already set.

A few commenters stated that challenge studies could also be construed as another costly and inflexible requirement. They claimed that ultimately this requirement would not allow a processing authority to validate new or altered processing schedules by other means, such as material gleaned from the scientific literature, heat distribution or penetration studies, or any other available, scientifically supportable means to assure product safety. One commenter stated that this requirement would require validation studies for food borne pathogens that did not pose a relevant risk for the intended product. And, two commenters maintained that this requirement implies that the Agency expected challenge studies to be conducted in the establishment, before or even after product release. Such studies could irresponsibly expose equipment, product, and ultimately the consumer to food borne pathogens.

Response: The Agency agrees with the comment regarding the hold and test requirements and is removing this requirement from the rule. Otherwise, the Agency is adopting the validation requirements. FSIS intends for processing authorities to have the flexibility to validate new or altered processes by any reasonable and scientifically supportable means.

It was not the intent of FSIS to require challenge studies and the Agency does not expect such studies to be conducted in the plant. This would indeed risk equipment contamination, product contamination, plant workers, and ultimately the public health. Challenge studies, while often appropriate and definitive, should be conducted only in the laboratory under the auspices of a process authority. The Agency has modified the regulations to accommodate these concerns and clarify the intent relative to process validation.

Safe Harbors and Performance Standards

Comment: Many of the commenters fully supported the concept of establishing performance standards that

allow flexibility in processing while retaining regulatory safe harbors for use by establishments that prefer to follow existing procedures already accepted by the Agency as providing adequate food safety. Some, however, argued that the proposed safe harbors are prescriptive, inflexible, and inconsistent with HACCP. One commenter supported performance standards, but felt that safe harbors were too reminiscent of the command-and-control mode of inspection.

Response: By proposing performance standards that could be met through adherence to the earlier regulations, FSIS intended to create regulatory safe harbors for establishments that wished to follow procedures already accepted by the Agency as providing adequate food safety. The Agency proposed to retain these safe harbors in the regulations as examples of how to produce meat and poultry products that meet the performance standards. FSIS believed that these examples would assist small or new establishments that do not have the resources to develop customized process schedules. FSIS acknowledged that the regulatory safe harbors contained many prescriptive requirements, but made clear they would be provided only as examples of how to meet the performance standards; they would not be requirements.

To alleviate concerns of commenters, FSIS will not retain the safe harbors in the regulations, but instead provide them as compliance guidelines. The safe harbor compliance guidelines for ready-to-eat cooked, roast, and corned beef products, fully and partially cooked meat patties and poultry products are attached to this rule as Appendices A and B ("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)"). Also, the Agency is currently developing a process to ensure that the safe harbor guidelines will be readily available to all interested parties.

FSIS also had proposed to exempt establishments that followed the regulatory safe harbors from the proposed process schedule requirements. However, because FSIS is removing the safe harbors from the regulations and issuing them as guidelines, such an exemption is impossible; establishments cannot be exempted from a regulatory requirement based on compliance with a nonregulatory guideline.

Establishments choosing to follow the safe harbor guidelines may use those

guidelines as their process schedules. FSIS will consider such process schedules validated, since they will consist of processing methods already accepted by the Agency as effective. As proposed, therefore, establishments affected by this rule should not have to change their current processing practices.

Comment: One commenter suggested that it would be appropriate to replace safe harbors with Hazard Control Performance Standards that would prescribe specific numerical standards for reduction of pathogens on hands and food contact surfaces. Another recommended that the Agency codify only "food safety objectives," and that neither performance standards nor safe harbors should be codified as they would inhibit flexibility and innovation.

Response: Promulgation of only quantifiable hazard control performance standards, such as determining microbial counts on food contact surfaces or fingertips, would require extensive resources to implement and monitor. The Agency has determined that this would be an unreasonable and unnecessary burden for industry, especially since other alternatives would be equally effective.

In regard to establishing only food safety objectives, FSIS has determined that clearly-defined performance standards and HACCP are both necessary for improving food safety. Performance standards and HACCP provide meat and poultry establishments with the incentive and flexibility to adopt innovative, science-based processing procedures and controls, ensure safety for consumers, and provide objective, measurable standards, compliance with which can be verified through Agency inspectional oversight.

Comment: Some commenters maintained that having safe harbors would discourage establishments from conducting hazard analyses and from taking responsibility for the safety of their processes for specific products.

Response: Compliance with the safe harbors will effectively exempt some establishments from developing process schedules prior to developing and implementing HACCP plans; establishments following safe harbor guidelines may use the guidelines as validated process schedules. However, all official establishments will be required to conduct hazard analyses as part of HACCP plan development regardless of whether they follow the safe harbor examples. Further, FSIS considers following a safe harbor example to be a legitimate way of taking

responsibility for ensuring the safety of meat and poultry products. The safe harbors are examples of processing methods proven to ensure the production of safe meat and poultry products.

Comment: Commenters also expressed concerns that inspection personnel would be less willing and able to evaluate or accept alternatives to safe harbors.

Response: The Agency is providing training for all inspection personnel to assure a knowledgeable and capable work force that will be prepared to deal with questions concerning performance standards and safe harbors. A technical support center, staffed with highly experienced personnel to provide clarification and guidance to inspection personnel, has been established.

Recommended Amendments to Specific Safe Harbors

Comment: Several commenters submitted recommendations for revising the processing requirements in the safe harbors. For example, one commenter recommended that the time-temperature combinations in the table "Permitted Heat-Processing Temperature/Time Combinations for Fully-Cooked Patties" should be amended to include temperatures as low as 130°F to enable lower temperature heat treatment processes such as sous vide to be used.

Response: FSIS has revised the safe harbor guidelines for ready-to-eat cooked, roast, and corned beef products to include processes ensuring a 6.5 log₁₀ reduction in *Salmonella*, as well as the 7-log₁₀ reduction required by the previous regulations. Otherwise, unless safe harbor requirements are found to be insufficient for producing meat and poultry products meeting the performance standards, FSIS sees no need to revise these provisions. If an establishment wishes to manufacture meat or poultry products by means other than those contained in the safe harbors, it may do so, provided they comply with the applicable requirements (e.g., meeting performance standards, developing and validating a process schedule, or operating under HACCP).

In response to the suggestion that temperatures as low as 130 °F be allowed for processing ready-to-eat meat patties, the Agency will consider this comment as it reconsiders lethality requirements for ready-to-eat meat patties. In general, any time/temperature combination that will achieve the lethality performance standard would be acceptable. However, establishments employing processing methods other

than those described in the safe harbors will be required to develop and implement process schedules or HACCP plans. FSIS does not plan to regularly amend the safe harbors to account for processing variations. The safe harbors are only examples of how an establishment can meet the performance standards.

Comment: One commenter argued that humidity is not a significant control factor in achieving lethality and, therefore, requirements regarding humidity should be removed from the safe harbors. The commenter claimed that there has been no link established between the failure to control humidity and the incidence of food borne disease.

Response: The Agency does not agree. In the late 1970's there were several food borne disease outbreaks caused by the consumption of "rare" roast beef. At the time of these outbreaks, there were no regulations specifying the minimum internal temperature and humidity requirements for the type of roasts involved in the outbreaks. Published articles have demonstrated that dry heat has a lower lethality than moist heat in killing *Salmonella*.^{14,15} Blankenship¹⁶ demonstrated that *Salmonella* survived on the surface of the roast even though an internal temperature of 147.5 °F was attained in a gas-fired oven with no control for humidity. Another researcher showed that dry oven temperatures below 250 °F permitted *Salmonella* survival on the surface, but that when steam was injected for 30 minutes into a 175 °F oven, *Salmonella* was eliminated on the surface of the roasts cooked to an internal temperature of 130 °F or higher.¹⁷

Until 1977, the outbreaks of salmonellosis attributable to commercially produced precooked roast beef occurred frequently, particularly in the northeast.¹⁸ In 1977 and 1978, cooking requirements for cooked beef and roast beef involving time, temperature, and in some cases, relative humidity were established. Following the implementation of the cooking requirements, one outbreak of

¹⁴ Blankenship, L.C. (1978) Survival of a *Salmonella typhimurium* experimental contaminant during cooking of beef roasts. Appl. Environ. Microbiol. 35:1160.

¹⁵ Goodfellow, S.J., and Brown, W.L. (1978) Fate of *Salmonella* inoculated into beef for cooking. J. Food Protect. 41-598.

¹⁶ Blankenship, L.C.

¹⁷ Goodfellow, S.J., and Brown, W.L.

¹⁸ Centers for Disease Control (1981) Multi state Outbreak of Salmonellosis Caused by Precooked Roast Beef. MMWR 30:391-2.

salmonellosis occurred in 1978 due to a deviation from the cooking requirements. No further outbreaks were reported until 1981. Investigation showed that the 1981 outbreaks of salmonellosis resulted from processing procedures unrelated to humidity control. The processors either did not use one of the prescribed cooking time/temperature combinations or failed to maintain good sanitary practices (e.g., failed to maintain adequate separation of raw and cooked product).¹⁹

Comment: One commenter suggested that FSIS have the same cooking standard for roasts weighing less than 10 pounds as for those weighing more than 10 pounds.

Response: FSIS does not agree. Research has been done to determine the effect of product size on *Salmonella* survival on the surface of beef roasts. The results of the research showed that beef rounds of 10 pounds and larger can be dry roasted safely; beef rounds of 5 pounds or less cannot be safely dry roasted to the rare state (<135°F or 57.2 °C internal temperature).²⁰

Disposition of Products Not Meeting Performance Standards

Comment: One commenter stated that the disposition of products not meeting the performance standards was not addressed in this rule. The commenter recommended that as deviations occur, the establishment should assess product safety as one activity of corrective action; and the establishment may seek the advice of a process authority in this regard. This commenter declared that under HACCP, the Agency role in assuring product safety is in verification.

In a comment related to disposition of product produced under extreme conditions, a commenter recommended that "come-up time" during the cooking process be addressed as a performance standard. He suggested that the performance standard be less than 10 generations of multiplication of *Clostridium perfringens* when heating product from 50 °F to over 130 °F.

Response: FSIS agrees that the proposal did not include provisions for determining the disposition of product that did not meet the performance standards. FSIS also agrees that under HACCP, it will be the establishment's responsibility to determine the disposition of product not meeting performance standards. The Agency realizes that the determination of

disposition of such a product can often be a vexing problem. Most important may be the question of whether or not the product can be reprocessed to make it safe for consumption.

Heating deviations are generally related to the issue of "come-up time." Computer modeling as a tool to address problems related to excessive time to temperature is somewhat problematic. One of the primary difficulties of modeling specific occurrences is that current programs only allow modeling under only unfluctuating temperature conditions. Currently, the Agency has been using the ARS Pathogen Modeling Program Version 4.0 to model growth conditions. Further discussion on "come-up time" is contained in the attached Compliance Guides.

With respect to addressing cooling deviations, the Agency has been using another program that estimates the relative growth of *Clostridium perfringens* and *Clostridium botulinum* to provide an initial rough assessment of the severity of a cooling deviation. In cooperation with ARS, efforts are underway to improve this program. In the future, the Agency would like to make this program available to the industry and will welcome comments towards further advancing its capabilities and usefulness.

Following an initial assessment, some establishments may want to sample product to determine whether or not the specific lot of finished product meets the performance standard for stabilization. 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. After obtaining the test results from the samples, the disposition of the product can be determined. There are three possibilities: the lot should be destroyed; recooking will render the product safe for consumption; or the lot is safe for consumption and no reprocessing is necessary.

Further guidance concerning cooling deviations is available in Appendix B, "Compliance Guidelines for Cooling Heat-Treated Meat and Poultry Products (Stabilization)."

Other Issues

Comment: A commenter pointed out that *Staphylococcus aureus* was incorrectly identified as a spore former.

Response: FSIS has corrected this error in this document.

Comment: A commenter stated that the word "cooked" is inappropriately used throughout this document, arguing that "pasteurized" or "fully pasteurized" would be more correct,

referring to the reduction of vegetative pathogens to a safe level.

Response: The word "cooked" is commonly used and understood; "pasteurized" or "fully pasteurized" would be confusing.

Comment: A commenter contended that the words "stabilization" and "handling" are unnecessary. The operator only need describe the process, steps, and then limits for process variables at each step to control hazards, minimizing risk.

Response: The term "stabilization" is useful in describing the performance standard established in this rulemaking and will be retained. The handling performance standard is not being finalized, so the term "handling" does not appear in these regulations.

Comment: A commenter stated that it is not possible to prevent germination of spore-forming bacteria after cooking as indicated in the proposal; only multiplication can be controlled.

Response: FSIS agrees; the term "germination" has been removed from the stabilization performance standard.

Comment: One of the commenters applauded the Agency's recent efforts to extend food safety concerns to the restaurant and institutional settings, especially with regards to the shifting of resources outside the environment of meat and poultry establishments. This commenter also supported and applauded efforts toward broad application of FDA's Food Code in these areas.

Response: Harmonization of regulations and initiatives towards HACCP principles with those of FDA and other government bodies has been a worthwhile effort. Ultimately, State, local, and municipal authorities will be operating under harmonious principles. To this end, the Agency has also been involved in working through Association of Food and Drug Officials (AFDO) committees to encourage State adoption of acceptable uniform standards presented in the Food Code. In addition, FSIS has devoted resources to educating the public in food safety concerns. Today, it is important that consumers know how to safely store and prepare their food, and particularly important that they be aware of and follow good sanitary practices in the kitchen.

The Final Rule

FSIS is adopting the proposal as a final rule, with changes made in response to comments and noted above. In summary, the substantive changes are:

- The lethality performance standard for all of the ready-to-eat cooked beef,

¹⁹ Houston, D.L. (1982) Production Requirements for Cooked Beef, Roast Beef, and Cooked Corned Beef. FR 47:31854.

²⁰ Goodfellow, S.J., and Brown, W.L. (1978) Fate of *Salmonella* Inoculated Into Beef for Cooking. J. Food Protect. 41:598.

roast beef, and cooked corned beef, is a 6.5 log₁₀ reduction in *Salmonella*.

- The lethality performance standard proposed for ready-to-eat, uncured meat patties is not being finalized. A revised lethality standard will be proposed in an upcoming **Federal Register** publication. (Section 318.23 is being amended in this document, however, by replacing cooling requirements with stabilization performance standards for fully-cooked, partially-cooked, and char-marked meat patties.)

- The lethality performance standards now clarify establishment responsibility not only for reducing *Salmonella*, but also for the "reduction of other pathogens and their toxins or toxic metabolites necessary to prevent adulteration," * * * throughout the product."

- The lethality performance standards now explicitly provide for the optional use of a combination of controlled, intermediate steps to achieve the required lethality throughout ready-to-eat products.

- Establishments may produce ready-to-eat roast beef or poultry products using lethalties other than those prescribed in the regulations, as long as they demonstrate in a validated process schedule that the processes used achieve an equivalent probability that no viable *Salmonella* organisms remain in the finished product.

- The handling performance standards proposed for ready-to-eat cooked beef, roast beef, and cooked corned beef and for fully cooked meat patty and poultry products are not being finalized. The handling requirements for ready-to-eat, uncured meat patties are being removed from the regulations.

- Establishments will not be required to hold and test product.

- The safe harbors will not be retained in the regulations as proposed, but instead will be issued as compliance guidelines. Establishments following the safe harbor guidelines may use them as process schedules; FSIS will consider such process schedules already validated as being effective.

Executive Order 12866 and Regulatory Flexibility Act

This rule has been reviewed under Executive Order 12866. The rule has been determined to be significant for the purposes of Executive Order 12866 and, therefore, has been reviewed by the Office of Management and Budget.

This rule allows meat and poultry establishments to employ processing methods other than those previously mandated, as long as those methods yield products that meet the performance standards set forth in this

rule. However, FSIS also will allow establishments to meet the performance standards by following the previously mandated production methods, which are being disseminated in compliance guidelines by FSIS as "safe harbors." Therefore, establishments can choose to continue using their current methods of processing and probably incur no new expenses (or savings or income) as a result of this rule.

As explained above, the safe harbor compliance guidelines for fully cooked poultry contain chilling requirements currently contained in FSIS Directive 7110.3, since previously there were no regulatory chilling requirements for the poultry products covered under § 381.150. FSIS has determined, however, that all establishments producing cooked poultry products are meeting the chilling requirements in FSIS Directive 7110.3. FSIS anticipates, therefore, that establishments choosing the safe harbor guidelines for producing fully cooked poultry would experience no economic effect, positive or negative.

The rule will have a favorable economic impact on all establishments, regardless of size. When an establishment voluntarily elects to use a processing method other than one of those contained in the safe harbors, it is likely that it expects to receive increased revenues, greater than the cost of implementing and validating the processing method, as a result. Also, changes made in response to comments received on the proposed rule have reduced costs of adopting alternative processing methods, providing even greater incentive for innovation. The increased flexibility to innovate allowed by the rule will encourage competition, which is a benefit to consumers.

It is difficult to quantify the potential benefits of this rule since it is not possible to predict what effect innovations will have on revenues to the establishments or on benefits to consumers. Under the previous regulations, FSIS required that ready-to-eat poultry products reach specific, minimum internal temperatures before being removed from a cooking medium. The products lose water during cooking at these temperatures and consequently, establishments must add water and other ingredients both to make the products palatable and to restore lost yield. FSIS anticipates that most establishments initially taking advantage of the proposed performance standards would develop customized process schedules for ready-to-eat poultry products that minimize lost yield.

As an alternative to this rulemaking, FSIS considered merely expanding the

list of time/temperature combinations previously allowed for processing ready-to-eat meat and poultry products, but otherwise maintaining the detailed processing requirements. While this option would have expanded flexibility in regard to heat treatment, establishments still would have been constrained by the remaining prescriptive processing requirements, which are inconsistent with the principles of HACCP and can impede innovation. FSIS, therefore, has chosen an option it believes will both maximize flexibility and encourage innovation: establishments may employ innovative or unique processing procedures customized to the nature and volume of their production, provided they meet the designated performance standards for pathogen reduction.

Executive Order 12778

This rule has been reviewed under Executive Order 12778, Civil Justice Reform. States and local jurisdictions are preempted by the Federal Meat Inspection Act (FMIA) and the Poultry Products Inspection Act (PPIA) from imposing any marking or packaging requirements on federally inspected meat and poultry products that are in addition to, or different than, those imposed under the FMIA or the PPIA. States and local jurisdictions may, however, exercise concurrent jurisdiction over meat and poultry products that are outside official establishments for the purpose of preventing the distribution of meat and poultry products that are misbranded or adulterated under the FMIA or PPIA, or, in the case of imported articles, which are not at such an establishment, after their entry into the United States.

This rule is not intended to have retroactive effect.

Administrative proceedings will not be required before parties may file suit in court challenging this rule. However, the administrative procedures specified in 9 CFR §§ 306.5 and 381.35 must be exhausted prior to any judicial challenge of the application of the provisions of this rule, if the challenge involves any decision of an FSIS employee relating to inspection services provided under the FMIA or the PPIA.

Paperwork Requirements

In the proposal preceding this final rule, FSIS proposed "hold and test" requirements for treated product and a handling performance standard, both of which would account for some of the estimated paperwork burden. In response to comments requesting that FSIS allow establishments more flexibility in meeting the proposed

performance standards, FSIS decided not to make final the "hold and test" and handling requirements. Therefore, the paperwork burden is decreased, though not significantly. FSIS has not adjusted the estimated paperwork burden. The paperwork and recordkeeping requirements in this final rule are approved under OMB control number 0583-0109.

List of Subjects

9 CFR Part 301

Meat inspection.

9 CFR Part 317

Food labeling.

9 CFR Part 318

Meat inspection, Reporting and recordkeeping requirements.

9 CFR Part 320

Meat inspection, Reporting and recordkeeping requirements.

9 CFR Part 381

Poultry and poultry products inspection, Reporting and recordkeeping requirements.

Accordingly, title 9, chapter III, of the Code of Federal Regulations is amended 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:

§ 301.2 Definitions.

* * * * *

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.

* * * * *

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 § 317.2, paragraph (l) introductory text is revised to read as follows:

§ 317.2 Labels: definition; required features.

* * * * *

(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 § 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 § 318.23, except as exempted under paragraph (l)(4) of this section.

* * * * *

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:

§ 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-log₁₀ 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-log₁₀ 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 § 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:

§ 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	66.168	41
152	66.754	32
153	67.243	26
154	67.834	20
155	68.327	16
156	68.922	13
157 (and up)	69.4 (and up)17	10

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

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

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

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

(2) For each meat patty product produced using a stabilization process other than one conducted in accordance with the Hazard Analysis and Critical

Control Point (HACCP) system requirements in part 417 of this chapter, an establishment must develop and have on file, available to FSIS, a process schedule, as defined in § 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.

§ 320.1 [Amended]

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

320.4 [Amended]

10. In § 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.

* * * * *

§ 381.125 [Amended]

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

14. Section 381.150 is revised to read as follows:

§ 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-log₁₀ 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 log₁₀ 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 § 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 § 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.

Done in Washington, DC: December 29, 1998.

Thomas J. Billy,

Administrator, Food Safety Inspection Service.

The following are appendices to the preamble of the Final Rule.

Note: The following appendices will not appear in the Code of Federal Regulations.

Appendix A—Compliance Guidelines for Meeting Lethality Performance Standards for Certain Meat and Poultry Products

Introduction

Establishments producing ready-to-eat roast beef, cooked beef and corned beef

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

To assist establishments in meeting the lethality requirements, FSIS is issuing these compliance guidelines, which are based upon the time/temperature requirements contained in previous regulations.

Establishments may choose to employ these guidelines as their process schedules. FSIS considers these guidelines, if followed precisely, to be validated process schedules, since they contain processing methods already accepted by the Agency as effective.

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

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

1. Cooked beef and roast beef, including sectioned and formed roasts, chunked and formed roasts, and cooked corned beef can be prepared using one of the following time and temperature combinations to meet either a 6.5-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 at least the stated time.

Minimum internal temperature		Minimum processing time in minutes or seconds after minimum temperature is reached	
Degrees fahrenheit	Degrees centigrade	6.5-log ₁₀ lethality	7-log ₁₀ lethality
130	54.4	112 min	121 min.
131	55.0	89 min	97 min.
132	55.6	71 min	77 min.
133	56.1	56 min	62 min.
134	56.7	45 min	47 min.
135	57.2	36 min	37 min.
136	57.8	28 min	32 min.
137	58.4	23 min	24 min.
138	58.9	18 min	19 min.
139	59.5	15 min	15 min.
140	60.0	12 min	12 min.
141	60.6	9 min	10 min.
142	61.1	8 min	8 min.
143	61.7	6 min	6 min.
144	62.2	5 min	5 min.
145	62.8	4 min	4 min.*
146	63.3	169 sec	182 sec.

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
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	11 sec	12 sec.
159	70.6	10 sec	10 sec.
160	71.1	10 sec	10 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.

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

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

- Heating roasts of 10 pounds or more in an oven maintained at 250 °F (121 °C) or higher throughout a process achieving one of the time/temperature combinations in (1) above;

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

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

4. Establishments producing cooked beef, roast beef, or cooked corned beef should have sufficient monitoring equipment, including recording devices, to assure that the time

(accuracy assured within 1 minute), the temperature (accuracy assured within 1 °F), and relative humidity (accuracy assured within 5 percent) limits of these processes are being met. Data from the recording devices should be made available to FSIS program employees upon request.

Guidelines for Cooked Poultry Rolls and Other Cooked Poultry Products

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

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

Discussion

Heating Deviations and Slow Come Up Time

Determining the appropriate disposition of products following heating deviations can be even more difficult than determining the disposition of product after a cooling deviation. Heating deviations, which most often involve slow come-up time or an inordinate dwell time within the optimum temperature range for microorganism growth, can foster the multiplication of many pathogens. This multiplication sometimes can be so prodigious that even re-cooking may be ineffective in rendering the product safe. Also, certain toxigenic bacteria can release toxins into the product. Some of these toxins,

such as those of *Staphylococcus aureus*, are extremely heat stable and are not inactivated by normal re-cooking temperatures.

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

Depending on the circumstances, establishments may want to use computer modeling to estimate the relative multiplication of bacteria. For example, in a past incident involving an extreme heating deviation, product was put in an oven in which the temperature was inadvertently set to 95°F for about 12 hours. Computer modeling was easily applied in this case because much of the dwell time was at one temperature. The Agency determined that within a 6 hour time frame (with other growth conditions assumed to be favorable), the relative multiplication of many pathogens of concern could have exceeded five logs. Clearly the product could not be salvaged by reprocessing and was therefore destroyed.

Under changing conditions of temperature, however, computer modeling becomes more difficult. One approach is to average lag/log times over small increments such as 5° and add these times to get an approximation of possible total relative growth over a larger increment of time. Establishments must keep in mind that the population of bacteria before processing is generally unknown and that assumptions in the high range often are used as input parameters in the modeling.

Establishments should ultimately rely upon the expertise of a processing authority to determine the severity of heating deviations and subsequent appropriate disposition of the product in question. Dwell times of greater than 6 hours in the 50°F to 130°F range should be viewed as especially hazardous, as this temperature range can foster substantial growth of many pathogens of concern. And, a knowledge of the specific product and factors that would favor or

inhibit the growth of various bacteria is essential.

Computer Modeling Program Availability

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

Customized Processes

Although compliance with these guidelines will yield product that meets the lethality performance standards, some establishments may want to develop customized processing procedures that meet the codified lethality performance standards: 6.5 \log_{10} of *Salmonella* in ready-to-eat beef products and 7 \log_{10} in ready-to-eat poultry products. Establishments also may want to develop and implement processes using alternative lethality standards. 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 standards that meet the performance standards by using information obtained from the literature and/or by comparing their methods with established processes. However, statistical calculations on results obtained from sampling alone are not sufficient to demonstrate that product satisfies reduced initial product conditions or that product meets the performance standards. Rather, the demonstration should be based on scientific rationale, supported by experimental data.

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

Appendix B—Compliance Guidelines for Cooling Heat-Treated Meat and Poultry Products (Stabilization)

Introduction

Establishments producing ready-to-eat roast beef, cooked beef and corned beef products, fully cooked, partially cooked, and char-marked meat patties, and certain partially cooked and ready-to-eat poultry products are required by FSIS to meet the stabilization performance standards for

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

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

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

Stabilization Guidelines

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

1. During cooling, the product's maximum internal temperature should not remain between 130 °F and 80 °F for more than 1.5 hours nor between 80 °F and 40 °F for more than 5 hours. This cooling rate can be applied universally to the products and is preferable to (2) below.

2. Product consisting of pieces of intact muscle, such as beef, turkey breast or pork loin, may be cooled as follows: 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 and the product not packed for shipment before it has reached 40°F (4.4°C)

This cooling guideline was derived from the former ("Roast Beef Regulation", 9 CFR 318.17(h)(10)), which originally applied to cooked beef, cooked corned beef, and cooked roast beef. However, if this cooling rate is used as a guideline it remains important that cooling be rapid between 130°F and 80°F.

Discussion

Cooling Deviations

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

The recommended time/temperature combinations in these guidelines incorporate

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

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

1. Notify the inspector, the QC unit, and other concerned units, such as refrigeration maintenance and production.
2. Hold the involved product and determine the potential adulteration by bacteria, particularly clostridial pathogens. If adulteration is confirmed or appears to be likely, inform the inspector.
3. Postpone further product manufacturing using that chill facility until the processor has:

- a. determined the cause of the deviation;
- b. completed adjustments to assure that the deviation will not recur; and
- c. informed the inspector and the production units of the determinations and adjustments and make any needed amendments in the written processing procedures.

Computer Modeling and Sampling

In the event that a cooling deviation does occur, the product may often be salvaged if the results of computer modeling and/or sampling can ensure product safety. Because of a lack of information concerning the distribution of *C. perfringens* in product, sampling may not be the best recourse for determining the disposition of product following cooling deviations. However, computer modeling can be a useful tool in assessing the severity of a cooling deviation. While computer modeling cannot provide an exact determination of the possible amount clostridial growth, it can provide a useful estimate.

A technical document (available from the FSIS Docket Room¹) 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 *Clostridium perfringens*, without any multiplication

¹ FSIS Docket Room, U.S. Department of Agriculture, Room 102, Cotton Annex, 300 12th St. SW, Washington, DC 20250-3700.

(remains in lag phase) of *Clostridium botulinum*, then the establishment can choose to recook or sample the product.

Recook only when:

- All product was either immediately refrigerated after the deviation or can be immediately recooked after the deviation; and
- The recooking procedure can achieve a final internal product temperature of at least 149 °F (65 °C) for two minutes. Subsequent to recooking, the product must be cooled in strict conformance to existing guidelines. When the product is to be reworked with another raw product, the recooking procedure for the combined product must achieve a minimum internal temperature of 149 °F, to address the cooling deviation, and further to an increased time/temperature if necessary to be in accord with any other requirement relative to microbiological safety for the intended final product. Subsequent to recooking, the product must be cooled in strict conformance to existing guidelines.

Custom Stabilization Processes

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

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

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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 98-ANE-75-AD; Amendment 39-10968; AD 99-01-01]

RIN 2120-AA64

Airworthiness Directives; General Electric Company CF6-80C2 Series Turbofan Engines

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule; request for comments.

SUMMARY: This amendment adopts a new airworthiness directive (AD) that is applicable to General Electric Company CF6-80C2 series turbofan engines. This action requires a one-time visual inspection to ensure the correct accessory gearbox (AGB) idler adapter inserts are installed, and, if necessary, removal of AGB idler adapters with the improper inserts. This amendment is prompted by a report of a failure of a fuel tube flange connection due to improper AGB idler adapter inserts that resulted in a high pressure fuel leak and engine fire. The actions specified in this AD are intended to identify and remove AGB idler adapters with improper inserts, which can result in an engine fire and damage to the aircraft.

DATES: Effective January 21, 1999.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of January 21, 1999.

Comments for inclusion in the Rules Docket must be received on or before March 8, 1999.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), New England Region, Office of the Regional Counsel, Attention: Rules Docket No. 98-ANE-75-AD, 12 New England Executive Park, Burlington, MA 01803-5299. Comments may also be sent via the Internet using the following address: "9-ad-engineprop@faa.gov". Comments sent via the Internet must contain the docket number in the subject line.

The service information referenced in this AD may be obtained from General Electric Aircraft Engines, c/o Commercial Technical Publications, 1 Neumann Way, Rm. 230, Cincinnati, OH 45215-1988; telephone (513) 552-2005, fax (513) 552-2816. This information may be examined at the FAA, New England Region, Office of the Regional Counsel, 12 New England Executive

Park, Burlington, MA; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

FOR FURTHER INFORMATION CONTACT: Ian Dargin, Aerospace Engineer, Engine Certification Office, FAA, Engine and Propeller Directorate, 12 New England Executive Park, Burlington, MA 01803-5299; telephone (781) 238-7178, fax (781) 238-7199.

SUPPLEMENTARY INFORMATION: The Federal Aviation Administration (FAA) has received a report of an engine fire on an Airbus A300 aircraft with General Electric Company (GE) Model CF6-80C2A5 turbofan engines installed. The investigation into the cause of the fire identified a high pressure fuel leak at the fuel cross-over tube to accessory gearbox (AGB) idler adapter flange interface. The fuel leak occurred due to shearing of the idler adapter threads by the threaded inserts, allowing the inserts to pull out. This was attributed to incorrect Service Bulletin (SB) instructions which created a situation where a repair station installed improper inserts into the AGB idler adapter housing at a previous maintenance shop visit.

The maintenance on the idler adapter was performed using GE SB 72-743, dated August 25, 1994, that provided instructions for AGB idler adapter rework on P/N 9395M78G06 adapters to improve the reliability and correct a fuel leak problem that had been identified on engines in revenue service. Idler adapters that were reworked were required to be remarked to P/N 9395M78G08. The instructions in SB 72-743 were incorrect and could have resulted in repair stations installing improper inserts into the idler adapter. GE issued supplemental instructions by way of Repair Document 032-273-S1, dated April 8, 1998, which addresses the problem in SB 72-743 and has proven to be an acceptable repair procedure. Furthermore, GE has published SB 72-743, Revision 1, dated November 2, 1998, to cancel the rework of any AGB idler adapter in accordance with the original issue of the SB. Presently, the total number of GE CF6-80C2 engines that have incorporated SB 72-743 and that could have improper inserts installed is not known. Therefore, work performed using SB 72-743 by any repair facility is suspect at this time. This condition, if not corrected, can result in shearing of the idler adapter threads and pullout of the threaded inserts from the AGB idler adapter which could result in a high pressure fuel leak leading to a potential engine fire and damage to the aircraft.