

# Proposed Rules

Federal Register

Vol. 61, No. 86

Thursday, May 2, 1996

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

## DEPARTMENT OF AGRICULTURE

### Food Safety and Inspection Service

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

[Docket No. 95-033P]

#### Performance Standards for the Production of Certain Meat and Poultry Products

**AGENCY:** Food Safety and Inspection Service, USDA.

**ACTION:** Proposed rule.

**SUMMARY:** The Food Safety and Inspection Service (FSIS) is proposing to amend the Federal meat and poultry inspection regulations by converting the current regulations governing the production of cooked beef products, uncured meat patties, and certain poultry products into performance standards. The proposed performance standards spell out the objective level of performance establishments must meet during their operations in order to produce safe products, but allow the use of plant-specific processing procedures other than the procedures prescribed in the current regulations.

Performance standards set forth requirements in terms of what is to be achieved by a given regulatory requirement. They represent a shift in focus from "command-and-control" regulations in that they specify the ends to be achieved (producing safe meat and poultry products), but not the means to achieve those ends. The command-and-control provisions in the current regulations prescribe the means for producing safe meat and poultry products, specifying step-by-step procedures to be followed by establishments.

All of the command-and-control provisions in the current regulations meet the proposed performance standards. FSIS proposes to maintain the current provisions in the regulations as examples of how an establishment might comply with the proposed performance standards ("safe harbors"). Therefore, establishments would not be

required to change any current practices in response to this proposed rule.

The specific categories of products affected follow: 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. Any establishment producing these products and choosing to develop and use procedures different from those provided in the safe-harbor example would be required to maintain on file a documented process schedule that has been approved by a process authority for safety and efficacy, as required by the performance standard. The process schedule would include control, monitoring, validation, and corrective action activities to be performed by the establishment.

**DATES:** Comments must be received on or before July 1, 1996.

**ADDRESSES:** Submit one original and two copies of written comments to Docket Clerk, U.S. Department of Agriculture, Food Safety and Inspection Service, Room 4352-S, Washington, DC 20250-3700. Please refer to docket number 95-033P in your comments. Any person desiring an opportunity for oral presentation of views as provided under the Poultry Products Inspection Act should contact Dr. Paula M. Cohen at (202) 720-7164 so that arrangements can be made. All comments submitted in response to this proposal will be available for public inspection in the Docket Clerk's Office between 8:30 a.m. and 1:00 p.m., and 2:00 p.m. and 4:30 p.m., Monday through Friday. To review the research and other background information used by FSIS in developing this document, persons may visit the Docket Clerk's office during the times listed above.

**FOR FURTHER INFORMATION CONTACT:** Patricia F. Stolfa, Acting Deputy Administrator, Science and Technology, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250-3700; (202) 205-0699.

#### SUPPLEMENTARY INFORMATION:

##### Background

Under the Federal Meat Inspection Act (FMIA; 21 U.S.C. 601 *et seq.*) and the Poultry Products Inspection Act (PPIA; 21 U.S.C. 451 *et seq.*), FSIS issues regulations governing the production of meat and poultry

products prepared for distribution in interstate and foreign commerce. Many of these regulations employ the command-and-control approach, prescribing a precise sequence of steps to be followed to produce food that is safe and not adulterated.

Since 1972, FSIS has promulgated several regulations ensuring the safety of various cooked and partially cooked meat and poultry products. These regulations (9 CFR 318.17, 318.23, and 381.150) prescribe specific steps establishments must follow to ensure harmful bacteria are killed, growth of spore-forming bacteria is controlled, and recontamination of the product is prevented. By describing detailed safety procedures, this approach to rulemaking has provided clear direction and ensured that all establishments are subject to the same rules.

However, command-and-control regulations often do not account for the uniqueness of individual processing procedures and needs within different establishments. FSIS command-and-control regulations require all establishments to produce meat and poultry products in the same manner. Such prescriptive regulations are burdensome in many settings.

Further, command-and-control regulations can have disparate economic effects on establishments producing different volumes of the same product. By mandating the use of specific processes or technologies, FSIS often inadvertently imposes economic burdens on small businesses. Small establishments producing meat and poultry products at low volumes often must pay a high cost per product unit when required to employ a specific process or technology, while large establishments are able to spread the cost over their higher production volumes.

FSIS is now proposing to convert these regulations to performance standards. Performance standards spell out the objective level of performance establishments must meet during their operations in order to produce safe and nonadulterated products, but allow the use of plant-specific processing procedures, other than those prescribed in the current regulations. Accordingly, establishments could employ innovative or unique processing procedures customized to the nature and volume of their production.

The conversion of command-and-control regulations to performance standards is also an important element of the Agency's HACCP (Hazard Analysis and Critical Control Points) initiative.

#### *Performance Standards and HACCP*

In the Federal Register of February 3, 1995 (60 FR 6774), FSIS described a new food safety strategy based on clearly defining the responsibility of meat and poultry establishments to produce products that meet FSIS-established food safety performance standards. As a central element of this new food safety strategy, FSIS has proposed that all establishments adopt the science-based system of preventive controls to ensure food safety, known as HACCP. Under HACCP, establishments will be responsible for developing and implementing HACCP plans incorporating the controls determined by the establishment to be necessary and appropriate to produce safe products. HACCP is a flexible system that enables establishments to tailor their control systems to the needs of particular plants and processes.

Clearly defined food safety performance standards and HACCP are both powerful tools for improving food safety. Under FSIS proposals to implement performance standards and HACCP, establishments would have the incentive and flexibility to adopt innovative, science-based food safety processing procedures and controls. Furthermore, by focusing on inspectional oversight of the manner in which establishments are implementing HACCP plans and achieving performance standards, FSIS will have a more effective means of ensuring that establishments are meeting their food safety responsibilities.

Moreover, for HACCP to be successful, FSIS must reconsider its current reliance on command-and-control regulations. As a general matter, such regulations are incompatible with HACCP and the new food safety strategy because they deprive plants of the flexibility to innovate, one of the advantages of HACCP, and undercut the clear delineation of responsibility for food safety on which the FSIS strategy is based. Therefore, to prepare for the implementation of HACCP, FSIS is conducting a thorough review of its current regulations and, to the maximum extent possible, converting its command-and-control regulations to performance standards. This proposal to convert the current regulations governing the production of certain cooked beef products, uncured meat patties, and certain poultry products

into performance standards is an important part of this effort.

#### *The Integration of Performance Standards Into Establishment HACCP Plans*

Establishments would have the option of developing customized processing procedures designed to meet performance standards prior to their implementation of the HACCP requirements. These establishments would incorporate elements of their customized processing procedures into their HACCP plans and, in fact, probably would develop these processing procedures with HACCP in mind. Specifically, establishments would incorporate the means they use to meet the performance standards into their HACCP plans as critical limits.

When developing a HACCP plan, an establishment must first carry out a hazard analysis to identify and list the physical, biological, or chemical food safety hazards reasonably likely to occur in the production process for a particular product and the preventive measures necessary to control the hazards. The establishment then must identify the critical control points (CCP—s) in each of its processes. A CCP is a point, step, or procedure at which control can be applied and a food safety hazard can be prevented, eliminated, or reduced to an acceptable level.

Next, the critical limits for preventive measures associated with each identified CCP must be established. A critical limit is the maximum or minimum value to which a process control measure must be controlled at a CCP to prevent, eliminate, or reduce to an acceptable level the identified food safety hazard. Critical limits are most often based on process parameters such as temperature, time, water activity, or humidity. Critical limits must be designed to satisfy relevant FSIS regulations (including performance standards), FDA tolerances, and action levels where appropriate.

The proposed performance standards set out quantifiable microbiological pathogen reduction requirements for cooked beef products, uncured meat patties, and certain fully and partially cooked poultry products. Therefore, establishments would develop critical limits based upon these performance standards. Of course, during hazard analysis, establishments probably would identify other hazards not addressed by these performance standards and would be required to develop CCP's and critical limits accordingly. An example of how an establishment might use performance standards to develop critical limits follows.

Establishment X produces ready-to-eat poultry products and, as a result of this proposal, would be required to meet three performance standards: lethality, stabilization, and handling. To meet the lethality standard, the establishment must achieve a 7-D reduction in the microbiological pathogen *Salmonella* (explained below) in their poultry products. As would most, if not all establishments, Establishment X achieves this reduction in *Salmonella* through cooking. Establishment X cooks its poultry at 155 °F for 16 seconds to achieve a 7-D lethality.

As part of its HACCP plan, Establishment X must develop critical limits for the preventive measures addressing the hazards associated with producing ready-to-eat poultry products. *Salmonella* is identified as one of those hazards by the lethality performance standard. Therefore, Establishment X would incorporate the time/temperature combination used to meet the lethality performance standard into its HACCP plan as critical limits.

To meet the second performance standard, stabilization, Establishment X must prevent the germination and multiplication of toxigenic microorganisms such as *C. botulinum* and allow no more than a 1-decimal log multiplication of *C. perfringens* within its ready-to-eat poultry products (further explained below). To meet this performance standard, Establishment X decides to chill its poultry products following cooking, to 80 °F within 1.5 hours and to 40 °F within 5 hours. *C. botulinum* and *C. perfringens* are identified by the stabilization performance standard as hazards that must be addressed during the production of ready-to-eat poultry products. Therefore, Establishment X would incorporate the time/temperature combination used to meet the stabilization performance standard into its HACCP plan as critical limits.

To meet the third performance standard for ready-to-eat poultry, handling, Establishment X must ensure that no infectious pathogens are introduced into the product following processes ensuring lethality and stabilization and after final packaging. To meet the handling standard, Establishment X cooks the packaged, raw poultry product in a room physically separated from other rooms in which raw poultry and ingredients are handled and packaged. Further, Establishment X assures that raw materials entering the room for processing are stored separately from the finished, ready-to-eat product. Finally, Establishment X monitors the integrity of the packaged, ready-to-eat

product to ensure that there are no punctures or incomplete seals that may cause contamination.

#### *The Proposed Performance Standards and Commercial Sterility*

As stated above, the performance standards proposed set out quantifiable pathogen reduction requirements for cooked beef products, uncured meat patties, and certain fully and partially cooked poultry products. In the interest of further simplifying the food safety regulations governing these products, FSIS might have proposed a single performance standard: commercial sterility, or the elimination of all microorganisms from these products.

However, achieving commercial sterility within cooked beef products, uncured meat patties, and certain fully and partially cooked poultry products would not be feasible. It would be technically impossible for establishments to produce versions of these products that are both commercially sterile and marketable. For example, using current technology, it would be impossible to produce a ready-to-eat, rare roast beef product that is commercially sterile.

The quantifiable pathogen reduction performance standards proposed for these products would both ensure the production of safe food, with an ample margin of safety, and be readily achievable by industry. Further, as explained in the following section, these proposed performance standards are intrinsic to the current regulations.

#### *Safe Harbors*

Products produced in accordance with the command-and-control provisions in the current regulations governing cooked beef products, uncured meat patties, and certain fully and partially cooked poultry products would meet the proposed performance standards. Establishments producing these products therefore would not be required to change any current practices in response to this proposed rule. By proposing performance standards that may be met through adherence to the current regulations, FSIS creates a regulatory "safe harbor" for establishments that wish to continue operating as is currently required.

FSIS proposes to retain these regulatory safe harbors in the Code of Federal Regulations (CFR), as examples of how establishments can produce cooked beef products, uncured meat patties, and certain fully and partially cooked poultry products that meet the performance standards. Such examples would assist small or new establishments that do not have the

resources to develop customized process schedules for these products. Though these regulatory safe harbors contain many prescriptive and possibly obsolete requirements, the Agency wants to provide options that allow establishments to continue operating as they do under the current regulations. Therefore, in this proposal, the regulatory safe harbors are presented with few changes from the current regulations.

FSIS has announced a comprehensive review of regulatory procedures and requirements to determine which are still needed and which ought to be reconsidered, streamlined, or eliminated. As well as identifying regulatory candidates for reform and repeal in general, this review will establish priorities for revising regulations for compatibility with HACCP and the new FSIS food safety strategy. As explained above, under the new food safety strategy and HACCP, establishments will be responsible for developing and implementing HACCP plans incorporating the controls determined by the establishment to be necessary and appropriate to produce safe products.

Many of the command-and-control provisions, inherent in the current regulations and thus in the proposed safe harbors, must therefore be eliminated, revised, or converted to performance standards. Command-and-control regulations are generally incompatible with HACCP and the new food safety strategy because they deprive establishments of the flexibility to innovate and undercut the clear delineation of responsibility for food safety on which the FSIS strategy is based. FSIS will focus its review of the proposed regulatory safe harbors on the most prescriptive provisions, especially those concerning prior approval of customized processes or product disposition by FSIS program officials. These prior approval requirements would be incompatible with FSIS inspection under HACCP and would need to be eliminated before HACCP implementation. Further, FSIS proposes to retain the safe harbors only as examples of processes establishments can use to produce product meeting the performance standard.

The safe harbors included in this proposal still contain provisions requiring prior approval by FSIS program officials of customized processes or product disposition. As stated above, FSIS must remove these provisions prior to the implementation of HACCP. FSIS invites comment on precisely how safe harbors should be revised in light of HACCP and the new

FSIS food safety strategy. FSIS also invites comment on whether the Agency should provide regulatory safe harbors at all, and if so, whether their retention in the Code of Federal Regulations is necessary.

#### *Process Schedule Approval and Validation*

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 would be required to have on file, available to FSIS, a written process schedule describing the specific operations employed by the establishment to accomplish the objectives of the performance standards (FSIS would amend the relevant information requirements in 9 CFR part 320). This process schedule also would be required to contain the related control, monitoring, validation, and corrective action activities associated with the establishment's procedures. These activities are the good sanitation and basic good manufacturing practices generally regarded as essential prerequisites for the production of safe food. Further, these activities would be similar, if not identical, to the control, monitoring, validation, and corrective action activities developed by the establishment as part of its HACCP plan. Accordingly, so not to place duplicative requirements on establishments, FSIS would sunset these process schedule requirements as HACCP is implemented.

The process schedule would have to be evaluated and approved for safety and efficacy by a process authority. FSIS does not propose to preapprove the procedures deemed acceptable by the establishment's process authority. The proposed regulations define a process authority as a person or organization with expert knowledge in meat and poultry process control and relevant regulations.

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.

As stated above, FSIS proposes to sunset these proposed process schedule requirements as establishments develop and implement HACCP plans. These requirements would be duplicative of

what is required by HACCP, that is, an establishment would not need both an approved process schedule and a validated HACCP plan for the same process. FSIS anticipates that if an establishment developed a process schedule for producing one of the aforementioned meat or poultry products prior to implementing HACCP, it would incorporate elements of that process schedule into its HACCP plan.

Also, FSIS proposes to require that prior to the implementation of HACCP, establishments validate the process schedule by 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 would 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.

It is an industry convention to confirm that new production processes are safe and effective by holding and testing product prior to its commercial release. Therefore, FSIS believes that this proposed testing requirement for customized and essentially new process schedules would not be burdensome for meat and poultry establishments.

Validation of process schedules through sampling prior to the implementation of HACCP is a necessary step establishments must take to ensure that their processes are producing safe food for commercial distribution. FSIS realizes, however, that this particular form of validation may not be appropriate in every circumstance. Therefore, FSIS invites comment on the validation requirement proposed in this document, specifically as to whether FSIS should prescribe this specific method of validation for these process schedules, and, whether the proposed testing requirement is in fact appropriate for ensuring that an establishment's products meet food safety performance standards.

Like the proposed requirements concerning the development, approval, and maintenance of the process schedule, the process schedule validation requirement would be sunsetted as HACCP is implemented. FSIS would not require an

establishment with a validated HACCP plan producing meat and poultry products that meet performance standards also to have on file a validated process schedule.

#### *FSIS Inspection*

After a process authority has approved an establishment's planned procedures and before the production of lots to be held and tested, an establishment would be required to notify FSIS that it is implementing procedures different than those contained in the safe harbor provisions of the regulations. This notification would facilitate FSIS inspection in regard to these procedures. FSIS personnel would continue to perform inspection tasks as scheduled by the Performance Based Inspection System, as they do under the current regulations, in order to verify that the product is processed according to the procedures on file and meets the performance standards. FSIS in-plant inspection personnel would not be evaluating the process authority-approved procedures for efficacy, except through these in-plant verification tasks. FSIS inspection of an establishment employing process authority-approved procedures would be as rigorous as inspection of an establishment employing safe-harbor procedures.

At all establishments, FSIS personnel would retain the authority to sample product for verification or to take action on the process in cases where noncompliance with Agency regulations is suspected or when the process is not properly controlled. FSIS personnel would sample products made with process authority-approved procedures at the same frequency they sample products made with safe-harbor procedures.

Should an establishment wish to alter its approved procedures, the process authority must evaluate and approve, in writing, the proposed alterations prior to their implementation. The process authority would approve only alterations that result in the continued production of product meeting performance standards. Prior to the commercial release of any product produced by process authority-approved, altered procedures, testing requirements would again apply.

It is possible that the same process authority may service several establishments owned by a single company. The process authority could approve the same procedures for use at all of the establishments. FSIS would allow such an arrangement, as long as the process authority-approved procedure is on file at each

establishment and each establishment complies with the applicable testing provisions for the product in question.

Any establishment operating under a Total Quality Control (TQC) system (§ 318.4) and desiring to employ a processing procedure approved by a process authority would be required to submit the approved procedure through normal channels for incorporation into its TQC system. FSIS would evaluate only the format of the approved procedure, to allow its incorporation into the official FSIS-held copies of the TQC system procedures.

#### *Performance Standards for Cooked/ Roast Beef Products, Cooked Uncured Meat Patties, and Certain Cooked Poultry Products*

To meet the proposed performance standards for cooked/roast beef products, fully cooked, uncured meat patties, and certain fully cooked poultry products, establishments would need to continue to eliminate pathogenic microorganisms from these products. FSIS is proposing three performance standards reflecting this goal: lethality, stabilization, and handling. An establishment meeting these three standards would produce ready-to-eat, cooked products containing no viable pathogenic microorganisms.

#### *Lethality*

To meet the first standard, lethality, establishments must treat ready-to-eat product so as to ensure a specific, significant reduction in the number of pathogenic microorganisms in the product, effectively eliminating the pathogenic microorganisms from the product. FSIS is not proposing to require that any particular means be used to meet the lethality standard. For these cooked products, FSIS would continue to require a heat treatment. However, FSIS is not proposing to require that cooking be the sole means by which lethality is to be achieved. Other applicable treatments, such as curing, might be used in combination with cooking to achieve the required lethality.

For the purpose of the lethality standard, reduction of pathogenic microorganisms would be measured in D-values. A D-value indicates the time required to reduce the viable microbial population by one log<sub>10</sub> unit at a given temperature:

$$D = t / \log a - \log b$$

where "t" is the time of heating, "a" the number of viable organisms at "t"=0 minutes, and "b" the number of surviving organisms. A "7-D" process for *Salmonella*, for example, would

reduce *Salmonella* contamination by a factor of 10 million and would ensure the effective elimination of *Salmonella* in a product contaminated with as many as 10 million ( $10^7$ ) organisms per gram.

For cooked beef, roast beef, and cooked corned beef products, FSIS is proposing that the lethality performance standard be a 7-D reduction in *Salmonella*. Traditionally, the pathogenic microorganism of concern in cooked beef products has been *Salmonella*. Although *E. coli* 0157:H7 has emerged as a significant pathogen of concern in meat products, *Salmonella* is generally slightly more resistant to heat than *E. coli* 0157:H7. Furthermore, while *Salmonella* is not as heat resistant as *Listeria monocytogenes*, the presence of *L. monocytogenes* in finished product is primarily a result of recontamination and the expected levels of *L. monocytogenes* are much lower than those expected of *Salmonella*. Therefore, the thermal destruction of *Salmonella* in cooked beef products would indicate the destruction of the other two pathogens. (To review the research and other background information used by FSIS in developing this document, see ADDRESSES above.)

When the current regulations for cooked beef products were promulgated, available research indicated that due to the microbiological profile of beef and other factors, a 7-D reduction in *Salmonella* was necessary to produce a safe cooked beef product, free of pathogens. A 7-D reduction in *Salmonella* does effectively eliminate all pathogenic microorganisms from cooked beef products and provides a significant margin of safety. However, the Agency recognizes that the required 7-D reduction in *Salmonella* may be overly conservative in certain processing environments. For example, if an establishment with an effective system of process controls were processing high quality raw product into roast beef, it might not need to achieve a 7-D reduction in *Salmonella* in order to produce safe product. Given the variety of establishments producing cooked beef products, however, requiring a 7-D reduction of *Salmonella* in these products provides for a significant margin of safety throughout the industry.

FSIS also recognizes that developments in processing technology now may indicate that a safe, ready-to-eat cooked beef product could be produced with a different level of lethality. Raw beef is rarely contaminated with *Salmonella* at levels in excess of three or four logs (1,000–10,000 organisms) per gram of product. It is thus probable that a 3-D or 4-D

reduction in *Salmonella* would effectively eliminate all pathogens from a cooked beef product.

The Agency invites submissions on this lethality standard. FSIS would consider revising the lethality performance standard and safe harbor example for cooked beef products in general if presented with compelling data. FSIS also might consider revising the lethality performance standard for cooked beef products produced under certain combinations of conditions, such as those presented in the example above. Such revisions would grant further flexibility to cooked beef processors and encourage innovation, while ensuring the safety of the food produced.

The current regulations in § 318.17, governing the production of cooked beef, roast beef, and cooked corned beef products, require, among other things, that these products be cooked at certain temperatures for certain periods of time (the table in paragraph (a) of § 318.17 lists the approved time/temperature combinations). When applied, all of these time/temperature combinations produce a 7-D lethality. Therefore, as a result of this proposal, establishments continuing to follow the current regulations (the proposed safe harbors) would produce cooked beef products that meet the 7-D lethality standard presented in this document. And, notably, establishments that choose to produce cooked beef products using procedures other than those retained in the safe harbor regulations would be required to meet the same rigorous measure of lethality.

For fully cooked, uncured meat patties, FSIS is proposing that the lethality performance standard be a 5-D reduction in *Salmonella*. FSIS has identified *Salmonella* as the target pathogenic microorganism in fully cooked uncured meat patties, as in fully cooked beef products, because its elimination indicates the elimination of other pathogenic microorganisms. A 5-D reduction in *Salmonella* in cooked, uncured meat patties effectively eliminates all pathogenic microorganisms, provides a significant margin of safety, and allows for the production of a marketable product (achieving a 7-D reduction of *Salmonella* in fully cooked meat patties, as is mandated for cooked beef or poultry products, would require a degree of processing that would render the patties burnt, dry, and unacceptable to consumers).

As in the cooked beef product regulations, the regulations in § 318.23 governing the production of cooked, uncured meat patties require that these

products be cooked at certain temperatures for certain periods of time (Table A, in paragraph (b)(1)(i) of § 318.23 lists the approved time/temperature combinations). When applied, all of these time/temperature combinations produce a 5-D lethality. Therefore, as a result of this proposal, establishments continuing to follow the current regulations (the proposed safe harbors) would produce cooked meat patties that meet the 5-D lethality standard proposed in this document. And, establishments that choose to produce cooked meat patties using procedures other than those retained in the safe harbor regulations would be required to meet the same rigorous measure of lethality.

For the cooked poultry products described in § 381.150, FSIS is proposing that the lethality performance standard be a 7-D reduction in *Salmonella*. FSIS has identified *Salmonella* as the target pathogenic microorganism in cooked poultry products, as in fully cooked beef and uncured meat patties, because its elimination indicates the elimination of other pathogenic microorganisms. When the current regulations for cooked poultry products were promulgated, available research indicated that due to the microbiological profile of poultry and other factors, a 7-D reduction in *Salmonella* was necessary to produce a safe cooked poultry product, free of pathogens. (To review the research and other background information used by FSIS in developing this document, see ADDRESSES above.) A 7-D reduction in *Salmonella* does effectively eliminate all pathogenic microorganisms from cooked poultry products and provides a significant margin of safety.

The Agency recognizes that the required 7-D reduction in *Salmonella* may be overly conservative in certain processing environments. For example, if an establishment with an effective system of process controls were processing high quality raw product into ready-to-eat cooked poultry, it might not need to achieve a 7-D reduction in *Salmonella* in order to produce safe product. Given the variety of establishments producing cooked poultry products, however, requiring a 7-D reduction of *Salmonella* in these products provides for a significant margin of safety throughout the industry.

Further, FSIS recognizes that developments in processing technology now may indicate that in general, safe, ready-to-eat cooked poultry products could be produced with a different level of lethality. It is possible, for example, that a 3-D or 4-D reduction in

*Salmonella* would effectively eliminate all pathogens from cooked poultry products.

The Agency invites submissions on the lethality standard for cooked poultry products. FSIS would consider revising the lethality performance standard and safe harbor example for cooked poultry products in general if presented with compelling data. FSIS also might consider revising the lethality performance standard for cooked poultry products produced under certain combinations of conditions, such as those presented in the example above.

The regulations in § 381.150(b) governing the production of cooked poultry products require that these products reach certain internal temperatures prior to being removed from the cooking medium. Meeting these internal temperature requirements ensures a 7-D reduction of *Salmonella*. Therefore, as a result of this proposal, establishments continuing to follow the current regulations (the proposed safe harbors) would produce cooked poultry products that meet the 7-D lethality standard proposed in this document. And, establishments that choose to produce cooked poultry products using procedures other than those retained in the safe harbor regulations would be required to meet the same rigorous measure of lethality.

#### Stabilization

In order to meet the second performance standard, stabilization, establishments must prevent vegetative spore-forming bacteria from growing within product and producing toxin. If allowed to grow in number, these bacteria can produce high concentrations of toxin, which cause foodborne illness.

Means applied to products to bring about the lethality of certain pathogenic microorganisms, such as *Salmonella*, can create a model environment for the multiplication of spore-forming bacteria. For example, cooking or heat processing is likely to be applied to a product in order to eliminate *Salmonella* and other pathogenic microorganisms. *Clostridium botulinum* spores, *Clostridium perfringens* spores, and spores from other vegetative and spore-forming bacteria can survive cooking and, in fact, thrive in the warm product following cooking when competitive microorganisms, such as *Salmonella*, have been eliminated.

Therefore, it is important that the stabilization conditions are implemented so that vegetative, spore-forming bacteria do not have an opportunity to grow within the product.

Accordingly, FSIS is proposing that stabilization, likely to be rapid cooling following cooking, must prevent the germination and multiplication of toxigenic microorganisms such as *C. botulinum*, and allow no more than a 1-decimal log multiplication of *C. perfringens*. Limiting the allowable growth of *C. perfringens* to a 1-decimal log multiplication would effectively limit the multiplication of other, slower growing spore-forming bacteria, such as *Bacillus cereus* and *Staphylococcus aureus*.

The current regulations for cooked beef products and cooked meat patties require, among other things, that these cooked products be quickly cooled following cooking, in order to inhibit the growth of vegetative, spore-forming bacteria. Section 318.17(h)(10) requires that establishments begin chilling cooked beef products within 90 minutes of heat processing. The products must be chilled from 120 °F to 55 °F in no more than 6 hours, chilling must continue until shipment, and the product cannot be packed for shipment until it has reached 40 °F. Section 318.23(b) requires that cooked meat patties be cooled to an internal temperature of 40 °F or below within 2 hours of heat processing. When applied, the chilling requirements for both cooked beef products and cooked meat patties prevent the germination and multiplication of toxigenic microorganisms such as *C. botulinum* and allow no more than a 1-decimal log multiplication of *C. perfringens*, that is, they produce cooked products that meet the stabilization performance standard presented in this document.

The chilling requirements for the cooked poultry products concerned in this proposal are not set out in the regulations for these products, § 381.150, but instead in FSIS Directive 7110.3, "TIME/TEMPERATURE GUIDELINES FOR COOLING HEATED PRODUCTS." This directive states that following heat treatment, cooked poultry products should be chilled to 80 °F within 1.5 hours, and to 40 °F within 5 hours. When applied, this chilling prevents the germination and multiplication of toxigenic microorganisms such as *C. botulinum* and allows no more than a 1-decimal log multiplication of *C. perfringens*, that is, it produces cooked poultry products that meet the stabilization performance standard presented in this document.

Therefore, as a result of this proposal, establishments continuing to follow the current regulations regarding the chilling of cooked beef and meat patty products or the directive regarding the chilling of cooked poultry products (the

proposed safe harbors) would produce cooked products that meet the stabilization standard for cooked products presented in this document. And, establishments that choose to produce cooked products using procedures other than those retained in the proposed safe harbors would be required to meet the same rigorous measure of stabilization.

FSIS is proposing to amend the current regulations in § 381.150 (the proposed safe harbor for certain cooked poultry products) by adding the chilling requirements for cooked poultry currently contained in FSIS Directive 7110.3. This proposed amendment would help to clarify and complete in a single section of the Poultry Products Inspection Regulations the proposed safe harbor regulations for certain cooked poultry products.

#### Handling

To meet the third performance standard for cooked products, establishments would need to handle product to preclude its recontamination by infectious pathogenic microorganisms. This standard requires that no infectious pathogens are introduced into the product following processes ensuring lethality, stabilization, or final packaging.

The current regulations for cooked beef products and cooked meat patties require, among other things, that these cooked products be handled, throughout processing, in a manner precluding their recontamination by infectious pathogenic microorganisms. Section 318.17, paragraphs (i), (j), and (k) require that establishments take various measures to ensure that cooked beef products are not recontaminated by contact with raw product, unsanitary work surfaces or machines, employee gloves or garments, and other sources of contamination. Section 318.23, paragraph (b)(4) requires establishments to take similar measures to ensure that cooked meat patties are not recontaminated.

Therefore, as a result of this proposal, establishments continuing to follow the current regulations regarding handling of cooked beef and meat patty products (the proposed safe harbors) would produce cooked beef products and cooked meat patties that meet the handling standard for cooked products proposed in this document. And, establishments that choose to produce cooked beef products and cooked meat patties using procedures other than those retained in the proposed safe harbors would be required to meet the same rigorous measure of handling.

Section 381.150 of the regulations contains no specific handling requirements for cooked poultry products. FSIS is proposing to amend the regulations contained in § 381.150 by adding specific handling requirements for cooked poultry products. These proposed handling requirements are modeled after those currently in place for cooked beef products and cooked meat patties. Consequently, adherence to these proposed handling requirements for cooked poultry products would assure establishment compliance with the proposed handling performance standard. The addition of these handling requirements to the proposed regulatory safe harbor would clarify existing sanitation requirements and assist establishments that do not have the resources to develop customized process schedules for these products.

FSIS experience with establishments producing the cooked poultry products defined under § 381.150 indicates that the proposed handling requirements represent current good manufacturing practices (GMPs) accepted by industry. These handling GMPs, including the separation of raw and cooked product, sanitation of work surfaces, and appropriate packaging, are generally regarded as essential for preventing the direct and indirect contamination of cooked product.

Poultry establishments already following the proposed handling safe harbor requirements would not have to change their handling procedures in order to meet the proposed handling performance standards. These establishments may wish to take advantage of the flexibility afforded by the proposed performance standards, however, and develop handling procedures that more closely match their unique production practices. Establishments that do not have handling procedures in place that meet the proposed safe harbor requirements, would be required to either adhere to the proposed safe harbor handling requirements or develop procedures that meet the proposed handling performance standard. FSIS is requesting comment on the possible economic impact of these proposed handling requirements (see "Executive Order 12866 and Regulatory Flexibility Act," below).

#### *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. 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 may contain infectious pathogenic microorganisms after processing and prior to cooking. FSIS is proposing, however, 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 *C. perfringens*, *C. 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. Accordingly, FSIS is proposing that in partially cooked and char-marked uncured meat patties and partially cooked poultry breakfast strips, establishments prevent the germination and multiplication of toxigenic microorganisms such as *C. botulinum*, and allow no more than a 1-decimal log multiplication of *C. perfringens*.

The current regulations for partially cooked and char-marked uncured meat patties and partially cooked poultry breakfast strips require, among other things, that these products be quickly chilled following partial cooking or char-marking, in order to inhibit the growth of vegetative, spore-forming bacteria. Section 318.23, paragraph (b)(1)(ii) requires that partially cooked meat patties be cooled to a maximum internal temperature of 40 °F within 2 hours following partial cooking. Section 318.23, paragraph (b)(1)(iii) requires that char-marked meat patties be char-marked and then cooled to a maximum internal temperature of 40 °F within 2 hours. Section 381.150, paragraph (a) requires that following partial cooking, partially cooked poultry breakfast strips be cooled to 80 °F within 1.5 hours and to 40 °F within 5 hours. When applied, these chilling requirements prevent the germination and multiplication of toxigenic microorganisms such as *C. botulinum* and allow no more than a 1-decimal log multiplication of *C. perfringens*, that is, they produce partially cooked and char-marked

products that meet the stabilization performance standard presented in this document.

Therefore, as a result of this proposal, establishments continuing to follow the current regulations regarding the chilling of partially cooked and char-marked uncured meat patties and partially cooked poultry breakfast strips (the proposed safe harbors) would produce cooked products that meet the stabilization standard for partially cooked products proposed in this document. And, establishments that choose to produce these products using procedures other than those retained in the proposed safe harbors would be required to meet the same rigorous measure of stabilization.

FSIS 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 is proposing that these labeling requirements remain in the regulations governing partially cooked and char-marked meat patties and partially cooked poultry breakfast strips.

#### *Miscellaneous*

Section 317.2, paragraph (l) and § 381.125, paragraph (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. This proposal, however, would allow ready-to-eat products to be processed by means other than the time and temperature requirements currently prescribed in these sections, as long as they met the performance standards proposed. Therefore, as a result of this proposal, safe handling label requirements would not be applicable to all ready-to-eat products processed by means other than the currently prescribed time and temperature combinations. FSIS proposes to amend 317.2, paragraph (l) and § 381.125, paragraph (b), to reflect this change.

Executive Order 12866 and Regulatory Flexibility Act

This proposed 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.

In accordance with 5 U.S.C. 603, we have performed an Initial Regulatory Flexibility Analysis, which is set out below, regarding the impact of this rule on small entities. However, we do not currently have all the data necessary for a comprehensive analysis of the effects of this rule on small entities. Therefore, we are inviting comments concerning potential effects. In particular, we are interested in determining the number and kind of small entities that may incur benefits or costs from implementation of this proposed rule.

This rule would allow individual establishments to employ processing methods other than those currently mandated, as long as those methods yield products that meet the performance standards set out in this rule. Since the currently mandated methods meet the performance standards and would be retained as "safe harbors," establishments could choose to continue using their current methods and probably incur no new expenses (or savings or income) as a result of this rule. Therefore, we anticipate that the rule would have a favorable economic impact on all establishments, regardless of size.

As stated above, FSIS is proposing to amend the current regulations in § 381.150 (the proposed safe harbor for certain cooked poultry products) by adding the chilling requirements for cooked poultry currently contained in FSIS Directive 7110.3. This proposed amendment would help to clarify and complete in a single section of the Poultry Products Inspection Regulations the proposed safe harbor regulations for certain cooked poultry products. Because establishments producing cooked poultry products already must meet the chilling requirements set forth in FSIS Directive 7110.3, FSIS anticipates that codifying these requirements in the regulations would have no economic impact.

Also, because currently there are no explicit handling regulations for cooked poultry products, some establishments may be required to develop new procedures in order to meet the proposed handling performance standard for cooked products. Establishments already following the proposed handling safe harbor requirements would not have to change their handling procedures in order to meet the proposed handling performance standards. These establishments may wish to take advantage of the flexibility afforded by the proposed performance standards, however, and develop handling procedures that more closely match their unique production practices.

Establishments that do not have handling procedures in place that meet the proposed safe harbor requirements, would be required to either adhere to the proposed safe harbor handling requirements or develop procedures that meet the proposed handling performance standard.

FSIS anticipates that any impact on these firms would be minimal, because the proposed handling requirements for cooked poultry products represent current GMPs accepted and in general use by industry. Data necessary for a comprehensive analysis of the effects of these proposed handling safe harbors on poultry establishments is not currently available to FSIS. Therefore, FSIS invites public comment concerning potential economic effects of these proposed requirements.

When an establishment wants to use a processing method other than those contained in the safe harbors, either because it will be more efficient or improve its product, we can assume by its decision to incur the expense of using that method (only a small part of which would be to meet the requirements of the proposed rule) that it expects to receive increased revenues in the future from the investment in the method. In that sense, the rule could have favorable economic consequences for firms that choose to innovate. Also, the increased flexibility to innovate allowed by the rule could encourage competition and benefit consumers with lower prices or higher quality products.

It is difficult to quantify the potential benefits of this proposal since it is not possible to predict exactly how many establishments would develop innovative processes and how these innovations would generate revenues or benefits to consumers. There are approximately 1,000 establishments currently producing the cooked beef products, uncured meat patties, and poultry products addressed by this proposal. FSIS expects that only about five to ten percent of these establishments would choose to develop customized process schedules prior to the implementation of HACCP. FSIS anticipates that most, if not all, of these establishments would develop alternative process schedules for the production of ready-to-eat poultry products.

Under the current regulations, FSIS requires 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.

Therefore, FSIS anticipates that most establishments initially taking advantage of the proposed performance standards would develop customized process schedules for ready-to-eat poultry products and would benefit from some cost savings. FSIS expects that most establishments producing roast beef and meat patty products would not develop customized process schedules prior to implementing HACCP, as it would be less duplicative and more cost-effective to use the proposed performance standards to develop critical limits within HACCP plans.

Finally, there is the potential for an increase in the efficiency of the nation's economy in general because the proposed rule encourages businesses to consider a more efficient use of resources. Also, the possibility of reduced prices of meat or poultry products are economic factors that could produce a more efficient use of resources in the economy as a whole. These effects would be small for individual firms and consumers, but could be substantial in the aggregate.

#### Executive Order 12778

This proposed rule has been reviewed under Executive Order 12778, Civil Justice Reform. States and local jurisdictions are preempted by the Federal Meat Inspection Act 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 proposed rule is not intended to have retroactive effect.

There are no applicable administrative procedures that must be exhausted prior to any judicial challenge to the provisions of this proposed 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 proposed rule, if the challenge involves any decision of an FSIS employee relating to inspection



services provided under the FMIA or the PPIA.

#### Paperwork Requirements

*Title:* Performance Standards for Certain Meat and Poultry Products.

*Type of Collection:* New.

*Abstract:* FSIS has reviewed the paperwork and recordkeeping requirements in this proposed rule in accordance with the Paperwork Reduction Act. Under this proposed rule, establishments choosing to meet performance standards for certain cooked beef products, uncured meat patties, and certain fully and partially cooked poultry products either by means other than those described in the current regulations or under the HACCP requirements, would be required to develop a written process schedule and maintain a copy of the process schedule on file.

The process schedule would detail all the specific, sequential operations that compose the process used by each establishment to produce its specific products. The process schedule would also contain the related control, monitoring, validation, and corrective action activities associated with the procedure. Further, this process schedule must have been evaluated and approved for safety, efficacy, and equivalency by a process authority.

FSIS inspectors would initially, and periodically as required, review the process schedule and any other relevant records to ensure that the product is processed according to the procedures on file. FSIS personnel would not evaluate the process authority-approved procedures for efficacy.

Again, developing and implementing processing procedures different from those in the current regulations would be optional. FSIS assumes that an establishment would develop and implement such processing procedures only if the resulting economic advantages outweighed the accompanying costs, including the paperwork burden.

FSIS is proposing to amend the current regulations in § 381.150 (the proposed safe harbor for certain cooked poultry products) by adding the chilling requirements for cooked poultry currently contained in FSIS Directive 7110.3. The paperwork burden hours for FSIS Directive 7110.3 are approved under OMB control number 0583-0089.

Finally, because currently there are no explicit handling regulations for cooked poultry products, some establishments may be required to develop new procedures in order to meet the proposed handling performance standard for cooked products. FSIS has

accounted for the paperwork and recordkeeping burden hours resulting from the proposed handling requirements in the estimate of burden for process schedules below.

*Estimate of Burden:* FSIS estimates that the process schedule would take an average of 2 days (16 hours) to develop and 5 minutes to file. The written description of the establishment validation procedures, whether conducted for new or altered process schedules, would take no more than 1 day (8 hours) to complete and 5 minutes to file.

*Respondents:* Meat and poultry product establishments.

*Estimated Number of Respondents:* 1,000 (this number represents the total number of establishments that could change their operations).

*Estimated Number of Responses per Respondent:* 1.

*Estimated Total Annual Burden on Respondents:* 24,166 hours.

Copies of this information collection assessment can be obtained from Lee Puricelli, Paperwork Specialist, Food Safety and Inspection Service, USDA, South Agriculture Building, Room 3812, Washington, DC 20250.

Comments are invited on: (a) whether the proposed collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility; (b) the accuracy of the Agency's estimate of the burden of the proposed collection of information including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology. Comments may be sent to Lee Puricelli, Paperwork Specialist, see address above, and Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20253.

Comments are requested by July 1, 1996. To be most effective, comments should be sent to OMB within 30 days of the publication date of this proposed rule.

#### 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 would be amended as follows:

#### PART 301—DEFINITIONS

1. The authority citation for part 301 would be 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 would be amended by removing the paragraph designations (a) through (yyy) and adding, in alphabetical order, new definitions for "Process Schedule" and "Process authority" 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 this part.

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

\* \* \* \* \*

#### PART 317—LABELING, MARKING DEVICES, AND CONTAINERS

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

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

4. In § 317.2, paragraph (l) would be revised to read as follows:

##### § 317.2 Labels: definition; required features.

\* \* \* \* \*

(l) Safe handling instructions shall be provided for: All meat and meat products of cattle, swine, sheep, goat, horse, or other equine not heat processed in a manner that conforms to the time and temperature combinations in the Table for Time/Temperature

Combination For Cooked Beef, Roast Beef, and Cooked Corned Beef in § 318.17 of this chapter, or that have not undergone other processing that would render them ready-to-eat; and all comminuted meat patties not processed in accordance with the standard for fully cooked patties in § 318.23 of this chapter; except as exempted under paragraph (l)(4) of this section.

\* \* \* \* \*

**PART 318—ENTRY INTO OFFICIAL ESTABLISHMENTS; REINSPECTION AND PREPARATION OF PRODUCTS**

5. The authority citation for part 318 would be revised to read as follows:

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

6. Section 318.17 would be 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 7-decimal log reduction of *Salmonella* must be achieved within the product. The lethality process must include a cooking step.

(2) *Stabilization*. There can be no germination and multiplication of toxigenic microorganisms such as *Clostridium botulinum*, and no more than a 1-decimal log multiplication of *Clostridium perfringens* within the product.

(3) *Handling*. There can be no recontamination of product by infectious pathogens at any time from processing through the final packaging.

(b) For each product produced using a process other than the process provided as an example in paragraph (e) of this section or a process conducted in accordance with the Hazard Analysis and Critical Control Point (HACCP) system requirements set, 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.

(c) Establishments must validate the process schedule by producing and testing product against applicable

performance standards, in accordance with a statistically valid sampling program designed by the process authority. No product can be released for commercial use until samples are tested and found to meet the applicable performance standards. After a process authority has approved an establishment's process schedule and before the production of lots to be held and tested, the establishment must notify FSIS that it is implementing a process other than that described in paragraph (e) of this section.

(d) Should an establishment wish to alter any procedures contained in an approved process schedule, a process authority must evaluate and approve, in writing, the proposed alterations prior to their implementation. The process authority can approve only alterations that result in the continued production of product meeting applicable performance standards. Prior to the commercial release of any product produced by approved, altered procedures, the establishment must validate the altered process schedule by sampling and testing product in accordance with a statistically valid sampling program designed by the process authority; the tested product must meet applicable performance standards.

(e) *Example*. An establishment may produce cooked beef, roast beef, and cooked corned beef products using the processes described in the following example, which meets the performance standards listed in paragraph (a) of this section:

(1) Cooked beef and roast beef, including sectioned and formed roasts and chunked and formed roasts, and cooked corned beef shall be prepared by one of the time and temperature combinations in the following table. The stated temperature is the minimum which shall be produced and maintained in all parts of each piece of meat for at least the stated time:

**TABLE FOR TIME/TEMPERATURE COMBINATION FOR COOKED BEEF, ROAST BEEF, AND COOKED CORNED BEEF**

Minimum internal temperature		Minimum processing time in minutes after minimum temperature is reached
Degrees Fahrenheit	Degrees Centigrade	
130 .....	54.4	121
131 .....	55.0	97
132 .....	55.6	77

**TABLE FOR TIME/TEMPERATURE COMBINATION FOR COOKED BEEF, ROAST BEEF, AND COOKED CORNED BEEF—Continued**

Minimum internal temperature		Minimum processing time in minutes after minimum temperature is reached
Degrees Fahrenheit	Degrees Centigrade	
133 .....	56.1	62
134 .....	56.7	47
135 .....	57.2	37
136 .....	57.8	32
137 .....	58.4	24
138 .....	58.9	19
139 .....	59.5	15
140 .....	60.0	12
141 .....	60.6	10
142 .....	61.1	8
143 .....	61.7	6
144 .....	62.2	5
145 .....	62.8	(1)

<sup>1</sup> Instantly.

(2) Cooked beef, including sectioned and formed roasts and chunked and formed roasts, and cooked corned beef shall be moist cooked throughout the process or, in the case of roast beef or corned beef to be roasted, cooked as provided in paragraph (e)(3) of this section. The moist cooking may be accomplished by placing the meat in a sealed, moisture impermeable bag, removing the excess air, and cooking, completely immersing the meat, unbagged, in water throughout the entire cooking process, or 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 shall be cooked by one of the following methods:

(i) Heating roasts of 10 pounds or more in an oven maintained at 250 degrees F. (121 degrees C.) or higher throughout the process;

(ii) Heating roasts of any size to a minimum internal temperature of 145 degrees F. (62.8 degrees 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

(iii) Heating roasts of any size in an oven maintained at any temperature that will satisfy the internal temperature and time requirements of paragraph (e)(1) of this section 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.

(iv) The relative humidity may be achieved by use of steam injection or by sealed ovens capable of producing and maintaining the required relative humidity.

(4)(i) Except as provided in paragraph (e)(4)(ii) of this section, establishments producing cooked beef, roast beef, or cooked corned beef shall have sufficient monitoring equipment, including recording devices, to assure that the time (within 1 minute), the temperature (within 1 degree F.), and relative humidity (within 5 percent) limits of these processes are being met. Data from the recording devices shall be made available to a program employee upon request.

(ii) In lieu of recording devices, establishments may propose in the written procedures prescribed in paragraph (e)(6) of this section, an alternative means of providing inspection personnel with evidence that finished product has been prepared in compliance with the humidity requirements of paragraphs (e)(2) and (e)(3) of this section, and the 145 degrees F. (62.8 degrees C.) temperature requirements of paragraph (e)(1) of this section.

(5) Each package of finished product shall be plainly and permanently marked on the immediate container with the date of production either in code or with the calendar date.

(6) In order to assure that cooked beef, roast beef, and cooked corned beef are handled, processed, and stored under sanitary conditions, the establishment shall submit a set of written procedures through the inspector-in-charge for approval by the Regional Director. The written procedures shall include the following information:

(i) The temperature to which raw frozen product is thawed and the time required.

(ii) The lot identification procedure for lots of product during processing.

(iii) The storage time and temperature combinations which the establishment intends to use before cooking, the cooking time and temperature the establishment intends to use, and the time, if any, the establishment intends to wait after cooking and before cooling.

(iv) If a code, instead of the calendar date, is used on the immediate container of the finished product, its meaning shall also be included.

(v) Any other critical control points in the procedures which could affect the safety of the product.

(vi) In lieu of recording devices, the alternate means permitted by paragraph (e)(4)(ii) of this section for providing evidence to inspection personnel that the finished product will be prepared in compliance with temperature or humidity requirements.

(vii) Any other alternate procedure used that is permitted in this section.

(7) The establishment shall maintain records and reports which document the time, temperature, and humidity at which any cooked beef, roast beef, or cooked corned beef is cooked and cooled at the establishment. Such records shall be kept by the establishment for 6 months or for such further period as the Administrator may require for purposes of any investigation or litigation under the Act, by written notice to the person required to keep such records. Such records shall be made available to the inspector or any duly authorized representative of the Secretary upon request.

(8) The handling and processing of cooked beef, roast beef, and cooked corned beef before, during, and after cooking shall be such as to prevent the finished product from being adulterated. As a minimum, they shall be controlled as follows:

(i) The establishment shall notify the inspector-in-charge which processing procedure will be used on each lot, including time and temperature.

(ii) In order to assure uniform heat penetration and consequent adequate cooking of each piece of beef, individual pieces of raw product in any one lot shall either not vary in weight by more than 2 pounds or not vary in thickness by more than 2 inches at the thickest part. Alternate methods of assuring uniform heat penetration may be submitted in writing for approval to the Regional Director.

(iii) A water-based solution that is used for injecting or immersing the meat shall be refrigerated to 50 degrees F. (10 degrees C.) or lower from the time it contacts the meat, and shall be filtered each time it is recirculated or reused.

(iv) A nonmeat ingredient, including the water-based solution in paragraph (e)(8)(iii) of this section, which has contacted meat shall be discarded at the end of that day's production unless it is in continuous contact with one batch of product.

(v) Product prepared for cooking shall be entered into the cooking cycle within 2 hours of completion of precooking preparation, or be placed immediately in a cooler at a temperature of 40 degrees F. (4.4 degrees C.) or lower.

(vi) The time and temperature requirements shall be met before any product in the lot is removed from the

cooking units. Unless otherwise specified in the written procedures approved in accordance with paragraph (e)(6) of this section, the heat source shall not be shut off until these requirements are met.

(vii) Other than incidental contact caused by water currents during immersion cooking or cooling, product shall be placed so that it does not touch or overlap other products. This provision does not apply to product that is stirred or agitated to assure uniform heat transfer.

(viii) Temperature sensing devices shall be so placed that they monitor product in the coldest part of the cooking unit; and when an oven temperature is required by paragraph (e)(3) of this section, the oven temperature shall also be monitored in the coldest part of the cooking unit.

(ix) If a humidity sensing device is required in an oven, it shall be placed so that it measures humidity in either the oven chamber or at the exit vent.

(x) Chilling shall begin within 90 minutes after the cooking cycle is completed.

(A) All product shall be chilled from 120 degrees F. (48.8 degrees C.) to 55 degrees F. (12.7 degrees C.) in no more than 6 hours.

(B) Chilling shall continue and the product shall not be packed for shipment until it has reached 40 degrees F. (4.4 degrees C.).

(xi) Any establishment that has experienced a cooking process deviation during preparation of product may either reprocess the product completely, continue the heating to 145 degrees F. (62.8 degrees C.), or contact the Regional Director for a review of the process schedule for adequacy and, if needed, for a cooking schedule to finish that one batch of product.

(xii) An establishment that has experienced a cooling deviation after the product has been cooked shall contact the Regional Director to determine the disposition of that retained product.

(9) Cooked beef, roast beef, and cooked corned beef shall be so handled as to assure that the product is not recontaminated by direct contact with raw product. To prevent direct contamination of the cooked product, establishments shall:

(i) Physically separate areas where raw product is handled from areas where exposed cooked product is handled, using a solid impervious floor to ceiling wall;

(ii) Handle raw and exposed cooked product at different times, with a cleaning of the entire area after the raw material handling is completed and

prior to the handling of cooked product in that area; or

(iii) Submit a written procedure for approval through the inspector-in-charge to the Circuit Supervisor detailing the steps to be taken which would avoid recontamination of cooked product by raw product during processing.

(10) To prevent indirect contamination of cooked product:

(i) Any work surface, machine, or tool which contacts raw product shall be thoroughly cleaned and sanitized with a solution germicidally equivalent to 50 ppm chlorine before it contacts cooked product;

(ii) Employees shall wash their hands and sanitize them with a solution germicidally equivalent to 50 ppm chlorine whenever they enter the heat processed product area or before preparing to handle cooked product, and as frequently as necessary during operations to avoid product contamination; and

(iii) Outer garments, including aprons, smocks, and gloves, shall be especially identified as restricted for use in cooked product areas only, changed at least daily, and hung in a designated location when the employee leaves the area.

(11) Cooked product shall not be stored in the same room as raw product unless it is first packaged in a sealed, water-tight container or is otherwise protected by a covering that has been approved, upon written request, by the Circuit Supervisor.

7. Section 318.23 would be revised to read as follows:

**§ 318.23 Requirements for the production of uncured meat patties.**

(a) Fully cooked, uncured meat patties must be produced using processes ensuring that the products meet the following performance standards:

(1) *Lethality*. A 5-decimal log reduction of *Salmonella* must be achieved within the product. The lethality process must include a cooking step.

(2) *Stabilization*. There can be no germination and multiplication of toxigenic microorganisms such as *Clostridium botulinum*, and no more than a 1-decimal log multiplication of *Clostridium perfringens* within the product.

(3) *Handling*. There can be no recontamination of product by infectious pathogens at any time from processing through the final packaging.

(b) Partially cooked and char-marked meat patties must be produced using processes ensuring that the products meet the performance standard listed in paragraph (a)(2) of this section.

(1) 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, 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.

(2) 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.

(c) For each product produced using a process other than the process described in paragraph (f) of this section or a process conducted in accordance with the Hazard Analysis and Critical Control Point (HACCP) system requirements, 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.

(d) Establishments must validate the process schedule by producing and testing product against applicable performance standards, in accordance with a statistically valid sampling program designed by the process authority. No product can be released for commercial use until samples are tested and found to meet the applicable performance standards. After a process authority has approved an establishment's process schedule and before the production of lots to be held and tested, the establishment must notify FSIS that it is implementing a process other than that described in paragraph (f) of this section.

(e) Should an establishment wish to alter any procedures contained in an approved process schedule, a process authority must evaluate and approve, in

writing, the proposed alterations prior to their implementation. The process authority can approve only alterations that result in the continued production of product meeting applicable performance standards. Prior to the commercial release of any product produced by approved, altered procedures, the establishment must validate the altered process schedule by sampling and testing product in accordance with a statistically valid sampling program designed by the process authority; the tested product must meet applicable performance standards.

(f) *Example*. An establishment may produce uncured meat patties using the processes described in this example, which meet the applicable performance standards listed in paragraph (a) of this section.

(1) *Definitions*. For purposes of § 318.23, the following definitions shall apply:

(i) *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.

(ii) *Heat-processed*. Treatment by a heat source, including, but not limited to, frying, broiling, baking, or roasting, which results in a fully-cooked, partially-cooked, or char-marked product.

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

(2) *Processing procedures for heat-processed patties*. Fully-cooked, partially-cooked, or char-marked patties shall be processed as follows:

(i) *Heat processing*. (A) Official establishments which manufacture fully-cooked patties shall utilize the following heat-processing procedures:

**PERMITTED HEAT-PROCESSING TEMPERATURE/TIME COMBINATIONS FOR FULLY-COOKED PATTIES**

Minimum internal temperature at the center of each patty		Minimum holding time after maximum temperature is reached	
Degrees Fahrenheit	Degrees Centigrade	Minutes	Seconds
151 .....	66.1 .....	0.68	41
152 .....	66.7 .....	.54	32
153 .....	67.2 .....	.43	26
154 .....	67.8 .....	.34	20
155 .....	68.3 .....	.27	16
156 .....	68.9 .....	.22	13
157 (and up).	69.4 (and up).	.17	10

(B) Official establishments which manufacture partially-cooked patties

shall raise the internal temperature at the center of each patty to a minimum internal temperature of 140 degrees F. and then cool it to a maximum internal temperature of 40 degrees F. within 2 hours.

(C) Official establishments which manufacture char-marked patties (if marked by a heat source) may raise the temperature at the center of each patty, but not above 70 degrees F., when the char-marks are applied to the patty. The process of char-marking the patty and cooling the patty to a maximum internal temperature of 40 degrees F. shall be completed within 2 hours or less.

(D) The official establishment shall measure the holding time and temperature of at least one heat-processed 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 degrees F.

(ii) *Cooling.* (A) Fully-cooked patties shall be cooled to an internal temperature of 40 degrees F. or below within 2 hours after heat-processing.

(B) Cooling requirements for partially-cooked and char-marked patties are combined with those for heat-processing and are contained in paragraph (f)(2)(i)(B) and (C) of this section.

(C) The internal temperature measuring device shall be accurate within 1 degrees F.

(iii) *Cooking instruction label requirement.* (A) Partially-cooked patties shall bear the labeling statement "Partially-cooked: 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.

(B) Char-marked patties shall 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.

(iv) *Sanitary handling and storage practices.* Fully-cooked patties shall be

handled in accordance with the following provisions so as to assure that the patties are not recontaminated.

(A) To prevent direct contamination of fully-cooked patties, official establishments shall:

(1) Physically separate areas where unpackaged, fully-cooked patties are handled from areas where less-than-fully-cooked products are handled using a solid impervious floor to ceiling wall;

(2) Handle unpackaged, fully-cooked patties and less-than-fully-cooked product at different times, and cleaning the entire area after handling other products before handling unpackaged, fully-cooked patties; or

(3) Submit a written procedure through the inspector-in-charge to the Regional Director detailing the steps to be taken which would avoid recontamination of fully-cooked patties by less-than-fully-cooked product during processing.

(B) To prevent indirect contamination of fully-cooked patties:

(1) Any work surface, machine, or tool which contacts other product shall be cleaned and sanitized before it contacts unpackaged fully-cooked patties. The sanitizer shall be germicidally equivalent to 50 ppm chlorine.

(2) Employees shall wash their hands with soap and water and sanitize their hands whenever they enter the fully-cooked patty area or before handling unpackaged, fully-cooked patties. They must also wash and sanitize their hands whenever they become contaminated during operations to avoid contamination of fully-cooked patties. The sanitizer shall be germicidally equivalent to 50 ppm chlorine.

(3) All employee outer garments, including aprons, smocks, and gloves shall be identified as restricted for use in the fully-cooked area only. The employee shall change garments at least daily. The garments shall be hung in a designated location before the employee leaves the area.

(C) Fully-cooked patties stored in the same room with other product, shall first be packaged or covered to prevent microbial contamination.

(D) Fully-cooked, partially-cooked, and char-marked patties shall be stored at a chamber temperature of 40 degrees F. or below.

(3) Requirements for Handling Heating or Cooling Deviations.

(i) If for any reason a heating or cooling 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 representative of the

Secretary, a report of the investigation, the cause of the deviation, and the steps taken to prevent recurrence; and

(ii) In addition, in the case of a heating deviation, the official establishment may reprocess the affected product, by a method in paragraph (f)(2)(i)(A) in this section; use the affected product as an ingredient in another product processed to one of the temperature and time combinations in paragraph (f)(2)(i)(A) 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 partially-cooked requirements in paragraph (f)(2)(i)(B) of this section.

(iii) In addition, in the case of a cooling deviation, contact the Regional Director to determine the disposition of the product.

#### **PART 320—RECORDS, REGISTRATION, AND REPORTS**

8. The authority citation for part 320 would be 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), the phrase "§ 318.17(d)" would be removed and the phrase "§ 318.17(e)(4)" would be added in its place.

##### **§ 320.4 [Amended]**

10. In § 320.4, the first sentence would be 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 would be 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 would be amended by adding new paragraphs (b)(63) and (b)(64) to read as follows:

##### **§ 381.1 Definitions.**

\* \* \* \* \*

(b) \* \* \*

(63) *Process schedule.* A process schedule is 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,

validation, and corrective action activities associated with production.

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

\* \* \* \* \*

**§ 381.125 [Amended]**

13. In § 381.125, the introductory text of paragraph (b) would be amended by removing the phrase “§ 381.150(b)” and by adding the phrase “§ 381.150(f)(2)(i)” in its place; and by removing the word “further”.

14. Section 381.150 would be revised to read as follows:

**§ 381.150 Requirements for the production of cooked poultry products and partially cooked poultry breakfast strips.**

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

(1) *Lethality.* A 7-decimal log reduction of *Salmonella* must be achieved within the product. The lethality process must include a cooking step.

(2) *Stabilization.* There can be no germination and multiplication of toxigenic microorganisms such as *Clostridium botulinum*, and no more than a 1-decimal log multiplication of *Clostridium perfringens* within the product.

(3) *Handling.* There can be no recontamination of product by infectious pathogens at any time from processing through the final packaging.

(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 section 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 ½ 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 the process described in paragraph (f) of this section or a process conducted in accordance with the Hazard Analysis and Critical Control Point (HACCP) system requirements, an establishment must develop and have on file, available to FSIS, a process schedule, as defined in § 381.1. 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) Establishments must validate the process schedule by producing and testing product against applicable performance standards, in accordance with a statistically valid sampling program designed by the process authority. No product can be released for commercial use until samples are tested and found to meet the applicable performance standards. After a process authority has approved an establishment's process schedule and before the production of lots to be held and tested, the establishment must notify FSIS that it is implementing a process other than that described in paragraph (f) of this section.

(e) Should an establishment wish to alter any procedures contained in an approved process schedule, a process authority must evaluate and approve, in writing, the proposed alterations prior to their implementation. The process authority can approve only alterations that result in the continued production of product meeting applicable performance standards. Prior to the commercial release of any product produced by approved, altered procedures, the establishment must validate the altered process schedule by sampling and testing product in accordance with a statistically valid sampling program designed by the process authority; the tested product must meet applicable performance standards.

(f) *Example.* An establishment may produce partially cooked poultry breakfast strips and cooked poultry products using the processes described in the following example, which meet the applicable performance standards listed in paragraph (a) of this section.

(1) Poultry breakfast strips are cured and smoked products which require special handling during distribution and additional cooking before consumption. These products shall be heated to an internal temperature of 140 degrees F. After heating in the establishment, these products must be cooled to 80 degrees F. within 1.5 hours and to 40 degrees F. with 5 hours. Labeling for these products shall comply with § 381.125. In addition, the statement “Partially Cooked: For Safety, Cook Until Well Done” shall appear on the principal display panel in letters no smaller than ½ the size of the largest letter in the product name. Detailed cooking instructions shall be provided on the immediate container of the products.

(2) Except for product produced in accordance with paragraph (f)(1) of this section, poultry rolls and other poultry products produced in accordance with this example shall meet the following requirements:

(i) *Heat processing.* Poultry rolls and other poultry products that are heat processed in any manner shall reach an internal temperature of at least 160 degrees F. prior to being removed from the cooking medium, except that cured and smoked poultry rolls and other cured and smoked poultry products shall reach an internal temperature of at least 155 degrees F. prior to being removed from the cooking medium. Notwithstanding the other provisions of this section, product to which heat will be applied incidental to a subsequent processing procedure may be removed from the media for such processing provided it is immediately fully cooked to the required 160 degrees F. internal temperature.

(ii) *Cooling.* After heating in the establishment, these products must be cooled to 80 degrees F. within 1.5 hours and to 40 degrees F. with 5 hours.

(iii) *Handling.* The product must be so handled as to assure that the cooked product is not recontaminated. To prevent direct contamination of the cooked product, establishments shall:

(A) Physically separate areas where raw product is handled from areas where exposed cooked product is handled, using a solid impervious floor to ceiling wall.

(1) Handle raw and exposed cooked product at different times, with a cleaning of the entire area after the raw material handling is completed and prior to the handling of cooked product in that area; or

(2) Submit a written procedure for approval through the inspector-in-charge to the Circuit Supervisor detailing the steps to be taken which would avoid recontamination of cooked product by raw product during processing.

(B) To prevent indirect contamination of cooked product:

(1) Any work surface, machine, or tool which contacts raw product shall be thoroughly cleaned and sanitized with a solution germicidally equivalent to 50 ppm chlorine before it contacts cooked product;

(2) Employees shall wash their hands and sanitize them with a solution germicidally equivalent to 50 ppm chlorine whenever they enter the heat processed product area or before preparing to handle cooked product, and as frequently as necessary during operations to avoid product contamination; and

(3) Outer garments, including aprons, smocks, and gloves, shall be especially identified as restricted for use in cooked product areas only, changed at least daily, and hung in a designated location when the employee leaves the area.

(C) Cooked product shall not be stored in the same room as raw product unless it is first packaged in a sealed, water-tight container or is otherwise protected by a covering that has been approved, upon written request, by the Circuit Supervisor.

Done in Washington, DC: April 29, 1996.  
Michael R. Taylor,

*Acting Under Secretary for Food Safety.*

[FR Doc. 96-10796 Filed 5-01-96; 8:45 am]

BILLING CODE 3410-DM-P

## 9 CFR Parts 304, 308, 317, 318, 319, and 381

[Docket No. 95-032P]

RIN 0583-AB93

### Elimination of Prior Approval Requirements for Establishment Drawings and Specifications, Equipment, and Certain Partial Quality Control Programs

**AGENCY:** Food Safety and Inspection Service, USDA.

**ACTION:** Proposed rule.

**SUMMARY:** The Food Safety and Inspection Service (FSIS) is proposing to amend the Federal meat and poultry products inspection regulations by removing current requirements for prior approval by FSIS of establishment drawings, specifications, and equipment prior to their use in official establishments. Requirements involving the comparison of blueprints and specifications with actual facilities and equipment would end. These amendments would provide the regulated industry with the flexibility to design facilities and equipment in the manner they deem best to maintain a sanitary environment for food production. FSIS would continue to verify through inspection that good sanitation is being achieved. Similarly, FSIS is proposing to end its prior approval of most establishment-operated partial quality control programs, which are used by establishments to control certain kinds of food processing and product characteristics. This change would make it possible for establishments to develop and implement quality control programs without first having to receive permission from FSIS to do so. This action is being taken to streamline and modernize the meat and poultry food

safety regulations, to separate the roles of Government and the regulated industry, to encourage innovations that will improve food safety, and to remove unnecessary regulatory burdens on inspected meat and poultry establishments. In addition, the proposal represents an important shift away from FSIS's "command-and-control" regulatory approach and toward a less bureaucratic approach consistent with the Agency's food safety mission.

**DATES:** Comments must be received on or before: July 1, 1996.

**ADDRESSES:** Please send an original and two copies of comments on this proposed rule to FSIS Docket Clerk, DOCKET #93-032P, Room 4352 South Agriculture Building, Washington, DC 20250-3700. Oral comments, as provided under the Poultry Products Inspection Act, should be directed to the person listed under **FOR FURTHER INFORMATION CONTACT**. Copies of FSIS reference materials cited in this proposal are available for review in the FSIS docket room.

**FOR FURTHER INFORMATION CONTACT:** Ms. Patricia F. Stolfa, Acting Deputy Administrator, Science and Technology, FSIS, Room 402 Annex Building, Washington, DC 20250-3700; (202) 205-0699.

#### SUPPLEMENTARY INFORMATION:

##### Background

The Federal Meat Inspection Act (FMIA) (21 U.S.C. 601 *et seq.*), and the Poultry Products Inspection Act (PPIA) (21 U.S.C. 451 *et seq.*) direct the Secretary of Agriculture to maintain inspection programs designed to assure the public that meat and meat food products (meat products) and poultry and poultry products (poultry products) are safe, wholesome, not adulterated, and properly marked, labeled, and packaged. FSIS carries out the mandates of these statutes by administering a continuous in-establishment inspection program for meat and poultry products that are shipped in interstate and foreign commerce or in "designated" States. A number of the States operate meat and poultry inspection programs for product shipped intrastate. Under the FMIA and PPIA, such programs must impose requirements "at least equal" to the Federal requirements.

The FMIA and PPIA require the Secretary to provide, among other things, for the inspection of establishments to assure that the conditions under which meat and poultry products are produced are sanitary. The Acts also require the Secretary to prescribe rules and

regulations governing the sanitary conditions of official establishments (21 U.S.C. 608 and 456). Pursuant to these provisions, the meat and poultry inspection regulations currently prescribe "prior approval" or approval-before-use by FSIS of facility drawings and specifications and of equipment used in official establishments. The regulations also provide for the prior approval of certain quality control programs, known as partial quality control (PQC) programs, before their use by official establishments.

#### Current Prior Approval Procedures

Currently, applicants seeking Federal inspection must submit to FSIS blueprints and drawings with specifications that exactly illustrate the applicant's establishment as it exists or is proposed to exist (9 CFR 304.2(a), 308.2, and 381.19). Before inspection is granted, FSIS officials in the field and in Washington, D.C., review the blueprints and drawings and the facility they represent to determine whether the facility meets the requirements of the meat and poultry inspection regulations, which are intended to ensure that products can be produced in a sanitary environment. Owners or operators of establishments intending to add structures or remodel their existing facility must also submit blueprints and drawings with specifications to FSIS for review before beginning any new construction (9 CFR 404.2, 308.2, and 381.19). During FY 1994, FSIS technical personnel reviewed about 2,900 sets of blueprints for new or modified facilities.

Federally inspected establishments or equipment manufacturers must go through a similar process of prior submission for review and approval of most equipment used in preparing or handling edible meat and poultry products or ingredients (9 CFR 308.5 and 381.53). FSIS requires that establishment owners or operators wishing to use new equipment submit any information FSIS needs to review new equipment, including assembly-type drawings and a list showing the materials of which parts are made. The primary objectives of the FSIS review are to determine whether the equipment can be readily cleaned and inspected for its sanitary condition. In some instances, FSIS also requires that the equipment be used on a trial basis before approval is granted (9 CFR 308.5(d) and 381.53(a)(4)). FSIS technical personnel review more than 2,500 submissions of equipment specifications each year, and approximately 650 pieces of new equipment require a trial installation before being accepted for use.