

they have met the requirements of the standards contained in the "Uniform Methods and Rules—Bovine Tuberculosis Eradication" by tracing all potential sources of infection and maintaining an adequate level of slaughter surveillance. Therefore, we are amending the regulations by removing California, Pennsylvania, and Puerto Rico from the list of modified accredited States in § 77.1 and adding them to the list of accredited-free States in that section.

Immediate Action

The Administrator of the Animal and Plant Health Inspection Service has determined that there is good cause for publishing this interim rule without prior opportunity for public comment. Immediate action is warranted to change the regulations so that they accurately reflect the current tuberculosis status of California, Pennsylvania, and Puerto Rico as accredited-free States. This will provide prospective cattle and bison buyers with accurate and up-to-date information, which may affect the marketability of cattle and bison since some prospective buyers prefer to buy cattle and bison from accredited-free States.

Because prior notice and other public procedures with respect to this action are impracticable and contrary to the public interest under these conditions, we find good cause under 5 U.S.C. 553 to make this action effective less than 30 days after publication. We will consider comments that are received within 60 days of publication of this rule in the **Federal Register**. After the comment period closes, we will publish another document in the **Federal Register**. The document will include a discussion of any comments we receive and any amendments we are making to the rule as a result of the comments.

Executive Order 12866 and Regulatory Flexibility Act

This rule has been reviewed under Executive Order 12866. For this action, the Office of Management and Budget has waived its review process required by Executive Order 12866.

Cattle and bison are moved interstate for slaughter, for use as breeding stock, or for feeding. California has approximately 2,650 dairy herds and 12,158 beef herds with a combined total of approximately 5,968,679 cattle. Approximately 98 percent of herd owners would be considered small businesses. Pennsylvania has approximately 10,920 dairy herds and 11,237 beef herds with a combined total of approximately 1,672,295 cattle. Approximately 99 percent of herd

owners would be considered small businesses. Puerto Rico has approximately 1,982 dairy herds and 3,957 beef herds with a combined total of approximately 386,980 cattle. Approximately 99 percent of herd owners would be considered small businesses. Changing the status of California, Pennsylvania, and Puerto Rico may enhance the marketability of cattle and bison from those States, since some prospective cattle and bison buyers prefer to buy cattle and bison from accredited-free States. This may result in some beneficial economic effect on some small entities. However, based on our experience in similar designations of other States, the effect should not be significant.

Under these circumstances, the Administrator of the Animal and Plant Health Inspection Service has determined that this action will not have a significant economic impact on a substantial number of small entities.

Executive Order 12372

This program/activity is listed in the Catalog of Federal Domestic Assistance under No. 10.025 and is subject to Executive Order 12372, which requires intergovernmental consultation with State and local officials. (See 7 CFR part 3015, subpart V.)

Executive Order 12988

This interim rule has been reviewed under Executive Order 12988, Civil Justice Reform. This rule: (1) Preempts all State and local laws and regulations that are in conflict with this rule; (2) has no retroactive effect; and (3) does not require administrative proceedings before parties may file suit in court challenging this rule.

Paperwork Reduction Act

This interim rule contains no information collection or recordkeeping requirements under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

List of Subjects in 9 CFR Part 77

Animal diseases, Bison, Cattle, Reporting and recordkeeping requirements, Transportation, Tuberculosis.

Accordingly, we are amending 9 CFR part 77 as follows:

PART 77—TUBERCULOSIS

1. The authority citation for part 77 continues to read as follows:

Authority: 21 U.S.C. 111, 114, 114a, 115–117, 120, 121, 134b, and 134f; 7 CFR 2.22, 2.80, and 371.2(d).

2. In § 77.1, in the definition of *Accredited-free state*, paragraph (2) is amended by adding "California," immediately after "Arkansas," and by adding "Pennsylvania, Puerto Rico," immediately after "Oregon," and in the definition of *Modified accredited State*, paragraph (2) is revised to read as follows:

§ 77.1 Definitions.

* * * * *

Modified accredited State.

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(2) Modified accredited States: New Mexico and Texas.

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Done in Washington, DC, this 14th day of October 1999.

Richard L. Dunkle,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 99–27322 Filed 10–19–99; 8:45 am]

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DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

9 CFR Parts 303, 304, 307, 308, 312, 314, 327, 331, 350, 381, and 416

[Docket No. 96–037F]

Sanitation Requirements for Official Meat and Poultry Establishments

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: The Food Safety and Inspection Service (FSIS) is revising its regulatory requirements concerning sanitation in official meat and poultry establishments. Specifically, FSIS is consolidating the sanitation regulations into a single part applicable to both official meat and poultry establishments, eliminating unnecessary differences between the sanitation requirements for meat and poultry processing, and converting many of the highly prescriptive sanitation requirements to performance standards. **EFFECTIVE DATES:** January 25, 2000.

FOR FURTHER INFORMATION CONTACT: Daniel L. Engeljohn, Ph.D., Director, Regulation Development and Analysis Division, Office of Policy, Program Development, and Evaluation, Food Safety and Inspection Service, U.S. Department of Agriculture (202) 720–5627.

SUPPLEMENTARY INFORMATION:

Background

As a result of a recent, comprehensive review of its regulatory procedures and

requirements, FSIS identified the need to revise its sanitation requirements for official meat and poultry establishments. The Agency's tentative view was that a number of the sanitation requirements were difficult to understand, redundant, or outdated. Also, the Agency found that there were unnecessary differences between the sanitation regulations for official meat and poultry establishments. Finally, the Agency could not justify the retention of the sanitation regulations that were inconsistent with the Agency's recently finalized Hazard Analysis and Critical Control Point (HACCP) and Sanitation Standard Operating Procedure (Sanitation SOP) regulations. These sanitation requirements were unnecessarily prescriptive, impeded innovation, and blurred the distinction between establishment and inspection program employee responsibilities for maintaining sanitary conditions.

Therefore, on August 25, 1997, FSIS published in the **Federal Register** a proposal to revise its sanitation requirements for official meat and poultry establishments (62 FR 45045). FSIS proposed to consolidate the sanitation regulations into a single part applicable to both official meat and poultry establishments, eliminate unnecessary differences between the meat and poultry sanitation requirements, and convert many of the highly prescriptive sanitation requirements into performance standards. FSIS initially solicited comment on the proposal for a 60-day period ending October 24, 1997.

Shortly after the comment period for that proposal opened, FSIS mistakenly released information that mischaracterized the provisions of the proposal concerning the use of nonfood compounds and proprietary substances. In order to alleviate any confusion regarding the sanitation proposal and to clarify FSIS policy in regard to nonfood compounds and proprietary substances, FSIS published a retraction of the erroneous information in the **Federal Register** (FSIS Docket No. 97-062N; 62 FR 55996). Further, in order to ensure that the public had ample opportunity to submit meaningful comments on the sanitation proposal and its provisions concerning nonfood compounds and proprietary substances, FSIS reopened the comment period for that proposal for 15 days, from October 28, 1997, to November 10, 1997 (FSIS Docket 96-037R; 62 FR 55997).

By the close of the second comment period, FSIS had received 51 comments from meat and poultry establishments, trade and professional associations, academia, consumer advocacy groups,

State governments, and FSIS inspection program employees. Two of these comments included requests for a 90-day extension of the original comment period. FSIS believed the original 60-day comment period was sufficient and did not extend it, except for the 15-day period discussed above.

About two-thirds of the commenters opposed the proposal in general. Many of these commenters characterized the proposal as "deregulation" that would weaken inspection program employee authority and reduce the consumer food safety protections in the existing prescriptive regulations. Most of these commenters argued that there should be no, or only minimal, change to the existing sanitation regulations.

The other third of the commenters generally supported the proposal to revise the sanitation requirements for official meat and poultry establishments. These commenters commended FSIS efforts to streamline and consolidate the sanitation requirements, to make the requirements consistent with the HACCP and Sanitation SOP regulations, and to grant establishments greater flexibility to innovate. Many of these commenters, however, did raise objections to and recommend revisions for specific provisions in the proposed rule.

FSIS responses to all of the relevant comments follow.

General Opposition

Comment: Many of the commenters opposed to the proposal characterized the performance standards as "deregulation" that would weaken FSIS enforcement authority and endanger consumers. Some of these commenters maintained that the proposed performance standards are too general to be enforceable, as they would allow for multiple interpretations of the sanitation standards. Several commenters also argued that by replacing with performance standards the existing sanitation requirements that contain prohibitions against specific activities, such as the prohibition in §308.8(e) against "placing skewers, tags, or knives in the mouth," FSIS would be impairing inspection program employees' ability to take action as necessary to prevent product adulteration.

Response: The sanitation performance standards are "deregulatory" in the sense that they remove obstacles to innovation previously caused by overly prescriptive, and in some cases obsolete, sanitation regulations. For establishments to fully and successfully meet the HACCP and Sanitation SOP requirements, they must be able to

innovate, or at least customize their operating procedures, to control food safety hazards and ensure that product does not become adulterated within their unique processing environments. The sanitation performance standards established in this rule not only will provide meat and poultry establishments with the flexibility to innovate in facility design, construction, and operations, but also will articulate the standards for good sanitation and for food product safety that must be met by establishments.

The sanitation performance standards are not subject to multiple interpretations. Regardless of the area or activity any individual performance standard governs, all of the sanitation standards have the same intent: An official meat or poultry establishment must operate under sanitary conditions, in a manner that ensures that product is not adulterated and that does not interfere with FSIS inspection and its enforcement of such standards. However, because the sanitation performance standards define the results to be achieved by sanitation, but not the specific means to achieve those results, the sanitation performance standards can be met by establishments in different ways. Regardless of the means by which establishments comply with the standards, the required results will be the same for all establishments.

The sanitation performance standards do not lessen the authority of FSIS inspection program employees nor in any way weaken the statutory and regulatory requirements that official meat and poultry establishments maintain sanitary conditions and ensure that product is not adulterated. Section 8 of the Federal Meat Inspection Act (FMIA) states that the "Secretary shall cause to be made by experts in sanitation or other competent inspectors, such inspection * * * as may be necessary to inform himself of the sanitary conditions* * * of * * * establishments." It also provides that "where the sanitary conditions of any such establishment are such that the meat or meat food products are rendered adulterated, (the Secretary of Agriculture) shall refuse to allow said meat or meat food products to be labeled, marked, stamped, or tagged as 'inspected and passed.'" Likewise section 7 of the Poultry Products Inspection Act (PPIA) requires that every official poultry establishment subject to inspection be operated according to sanitary practices "required by regulations promulgated by the Secretary (of Agriculture) for the purpose of preventing the entry into * * * commerce * * * of poultry

products which are adulterated” and directs the Secretary of Agriculture to refuse inspection “to any establishment whose premises, facilities, or equipment, or the operation thereof, fail to meet the (sanitation) requirements of this section.”

FSIS does not need to specifically prohibit every action that could possibly lead to product adulteration or insanitary conditions. It would, in fact, be impossible to compile such a list of prohibited practices. FSIS inspection program employees currently have the authority to withhold the mark of inspection if an establishment fails to ensure that product is not adulterated or fails to maintain sanitary conditions, even if the failure in question is not specifically prohibited in the regulations. This authority remains unchanged under the new performance standards. For example, were an establishment employee to place a knife used on inspected product in his mouth, that action would be a violation of § 416.5(a), “All persons working in contact with product, food-contact surfaces, and product-packaging materials must adhere to hygienic practices while on duty to prevent adulteration of product.”

Comment: Several commenters objected to the proposed rescission of the regulations requiring that various systems (such as plumbing and sewage systems) and activities (such as the use of sanitizers, pesticides, and other chemicals) be prior-approved by circuit supervisors or other FSIS program employees. These commenters claimed that many serious sanitation problems can be prevented only through prior-approval of such systems and activities by experienced FSIS program employees. Further, these commenters maintained that without prior approval, establishments will negligently use pesticides and other chemicals, adulterating product.

Response: FSIS disagrees. In regard to the prior approval of establishment plumbing, sewage, and other systems, FSIS has made the determination that it should afford establishments the flexibility to determine what is appropriate and sufficient for maintaining sanitary conditions and preventing the adulteration of product. FSIS will verify that these systems meet the sanitation performance standards through inspection. FSIS already has rescinded the requirements for prior approval of establishment drawings, specifications, and equipment used in official establishments (62 FR 45015; August 25, 1997).

In regard to the use of pesticides, sanitizers, and other chemicals, FSIS

has determined that it is the establishment’s responsibility to ensure that the chemicals it uses are safe and appropriate for use in its particular meat or poultry processing environment. Establishments will be required to account for the safety and appropriate use of these chemicals in their written HACCP plans, Sanitation SOP’s, or in other documentation. A full discussion of this issue can be found below under the section entitled “Cleaning Compounds and Sanitizers.”

Comment: Finally, two commenters argued that the proposed performance standards could have a deleterious impact on trade. One stated that European countries with more stringent sanitation requirements would ban imports of U.S. meat and poultry products if the proposed performance standards were made final.

Response: FSIS disagrees. Many of the United States’ major agricultural trading partners have already implemented or are currently developing meat and poultry inspection systems incorporating performance standards or food safety objectives, rather than prescriptive, “command-and-control” regulations. Further, because the sanitation performance standards do not lower the existing food safety standards for meat and poultry, but instead only allow for increased flexibility and innovation to meet the prescribed standards, other countries would not be justified in imposing any new restrictions in response. Thus, FSIS anticipates that these new regulations will have no adverse impact on trade.

General Sanitation: Proposed § 416.1

Comment: Several commenters questioned the proposed performance standard language in § 416.1 and elsewhere requiring that establishments be operated in a sanitary manner sufficient to prevent product from being “misbranded.” These commenters argued that there could never be a situation where insanitation by itself could lead to misbranding and, therefore, that the requirement is unnecessary.

Response: FSIS agrees that it would be highly unlikely for any meat or poultry product to be misbranded as a result of insanitation and has removed the references to misbranding from §§ 416.1, 416.2(c), and 416.3. Establishments should keep in mind, however, that the misbranding of meat or poultry products is prohibited by the FMIA, the PPIA, and the regulations promulgated under those Acts. FSIS will take action in accordance with its statutory authority and the regulations

any time it determines that meat or poultry products have been misbranded.

Comment: Similarly, several commenters questioned the proposed rule language requiring that establishments operate in a sanitary manner in order to prevent both “adulteration” and “contamination.” These commenters argued that “contamination” is a very broad term that can describe problems with product quality or composition, as well as those associated with product safety. They maintained that a requirement to prevent “adulteration” would be sufficient, as “adulteration” is defined by both the FMIA and the PPIA.

Response: FSIS agrees that the term “contamination” may cause some confusion and has removed the references to “contamination” throughout the rule language. FSIS emphasizes, however, that establishments must maintain sanitary conditions within their processing facilities, as insanitary conditions do lead to the adulteration of product. While the references to “contamination” have been removed, FSIS has added to the regulations the requirement that processing activities and the use of chemicals and equipment must not create insanitary conditions.

Establishment Grounds and Pest Management: Proposed § 416.2(a)

Comment: Several commenters objected to the language of proposed § 416.2(a) regarding establishment grounds: “The grounds about an establishment must be maintained to prevent conditions that could lead to contamination or adulteration of product or that could prevent FSIS program employees from performing assigned tasks.” The commenters contended that the phrase “grounds about an establishment” is inconsistent with recent FSIS policy that establishment management is responsible for defining the boundaries of their facilities. Specifically, commenters cite recent FSIS Directive 7640.1, “Inspection Duties Related to Facilities and Equipment, and Plant Operated Quality Control Programs,” which states that inspection program employees are to request from establishment management written designation of the official premises’ boundaries. Therefore, these commenters have suggested that “grounds about an establishment” be revised to read “grounds as designated by the establishment.”

Response: FSIS disagrees. The Agency sees no inconsistency between the directive and the performance standard as proposed. Proper maintenance of the

grounds about an establishment is essential for ensuring good sanitation. FSIS inspection program employees request written designation of establishment boundaries only to facilitate their inspection of the establishment. Establishments are responsible for preventing adulteration of product even if the sources are outside the designated boundaries of the establishment. Revising the performance standard to address only areas within the designated boundaries could mislead establishments into believing that they are not responsible for preventing such adulteration, especially when it originates from areas outside of the designated boundaries of the processing operations, but under the control of the establishment. Accordingly, FSIS is not making any changes to the rule language as proposed.

Comment: FSIS proposed to require that establishments "have in place an integrated pest management program to prevent the harborage and breeding of pests on the grounds and within establishment facilities." One commenter suggested that FSIS delete the word "integrated," arguing that it is confusing and unnecessary.

Response: Integrated pest management (IPM) is a widely recognized system of agricultural pest control that takes into account pest ecology and the effect of pesticides and other pest control chemicals on the environment and on food. For the most part, IPM has been used within agricultural production systems. However, IPM also is applicable to meat and poultry processing.

FSIS has rethought its tentative view that meat and poultry establishments should implement IPM systems. Although FSIS encourages establishments to develop or adopt IPM, FSIS has concluded that IPM is not absolutely necessary to ensure the production of unadulterated meat or poultry products. In this final rule, FSIS is requiring that any pest control system used by an establishment be designed and implemented so as to ensure that product is not adulterated either by pests or by the products designed to control them and, further, that the pest control system does not create insanitary conditions.

Comment: The remaining comments on pest control addressed the proposal to eliminate the requirements that pesticides and rodenticides be approved by FSIS prior to their use in official establishments. Several commenters argued that without prior approval of pesticides and prescriptive requirements concerning their use,

establishments will adulterate product or create insanitary conditions that could lead to adulteration.

Response: FSIS' review and approval of pesticides and rodenticides prior to their intended use provided some assurance to meat and poultry processors that proper use of these compounds would not result in the adulteration or contamination of food products. However, FSIS has concluded after careful consideration of the issue that this prior approval program is unnecessary and inconsistent with HACCP. Under the HACCP regulations, establishments are responsible for developing and implementing HACCP plans incorporating the controls necessary and appropriate to produce safe meat and poultry products. Consequently, establishments are responsible for ensuring that the pesticides and rodenticides they use are safe and effective.

Further, FSIS prior approval of pesticides and rodenticides has been somewhat redundant with the Environmental Protection Agency (EPA) requirements and review programs for these compounds. Under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), EPA reviews pesticide formulation, intended use, and other information; registers all pesticides for use in the United States; and prescribes labeling, use, and other regulatory requirements to prevent unreasonable adverse effects on the environment, including humans, wildlife, plants, and property. Any meat or poultry establishment using a pesticide must follow the FIFRA requirements.

FSIS is requiring that documentation substantiating the safety of pesticides and rodenticides be available to FSIS inspection program employees for review (§ 416.4(c)). The documentation will need to include proof of EPA registration and could also include other any information, such as letters of guaranty from the manufacturer, labels, application instructions, and records of use that establish the safe and effective use of these products. FSIS inspection program employees will review these records as necessary, as well as observe the application and storage of pesticides and rodenticides to ensure the maintenance of sanitary conditions and that product is not adulterated. (For further discussion of prior approval of pesticides and other chemicals, see the section "Cleaning Compounds and Sanitizers" below.)

Establishment Construction: Proposed § 416.2(b)

Comment: Several commenters objected to the language of the proposed

provision: "Establishment buildings, including their structures, rooms, and compartments must be of sound construction, kept in good repair, and be of sufficient size to allow for the sanitary processing, handling, and storage of product." Commenters argued that the requirement regarding "sufficient size" constitutes a new standard for sanitation. Commenters also argued that the phrase "sanitary processing, handling, and storage of product" is too general; they suggested that the construction standard be based upon preventing adulteration of product.

Response: FSIS disagrees that the requirement that rooms in an official establishment be of "sufficient size" constitutes a new standard. Although the previous regulations did not explicitly require rooms to be any particular size, the requirement that rooms be of sufficient size to prevent the adulteration of product was implicit. Moreover, this requirement is fully consistent with the FMIA and PPIA. An establishment would very likely be in violation of the statutory and regulatory prohibitions against product adulteration if its processing or storage rooms were so small that adequate separation of raw and ready-to-eat product were impossible. FSIS is merely making this requirement explicit in this performance standard.

FSIS agrees that the proposed language regarding "sanitary processing, handling, and storage of product" should be revised to make clear the obligation specified in this regulation. For clarity and consistency with the other performance standards, FSIS is revising this performance standard to read: "Establishment buildings, including their structures, rooms, and compartments must be of sound construction, be kept in good repair, and be of sufficient size to allow for processing, handling, and storage of product in a manner that does not result in product adulteration or the creation of insanitary conditions."

Comment: A few commenters stated that while large establishments might be able to innovate effectively under the proposed performance standards for construction, many small establishments lack the expertise to innovate in facility construction and design and need to follow specific requirements in order to maintain sanitary operations that produce safe meat and poultry products.

Response: FSIS disagrees. The design or alteration of facility construction or layout is well within the capability of most, if not all, meat and poultry establishments, regardless of size.

Moreover, in this rule, FSIS is not requiring establishments to innovate in regard to facility construction or layout. Establishments currently maintaining sanitary conditions will not need to make any changes to their construction or layout as a result of this performance standard. Further, FSIS is making available a compliance guide for the sanitation performance standards, including the standards for construction. Establishments remodeling or undertaking new construction may consult this guide or the various national building and construction codes, State and local laws and codes, and other relevant resources available from trade associations, consultants, and nonprofit organizations.

Comment: One commenter questioned FSIS' recommendation that establishments consult the Food Code, as well as national building and construction codes, when designing or building facilities. The commenter maintained that because these documents have no force of law, establishments do not have to follow their guidance, and further, that these documents are not always applicable to the unique requirements of meat and poultry processing establishments. This commenter concluded that specific design and construction requirements are necessary to ensure that meat and poultry establishments are built properly.

Response: FSIS does not agree that specific requirements for establishment design and construction are necessary to ensure that meat and poultry are not adulterated. FSIS is adopting performance standards for construction that provide establishments, regardless of size, the flexibility to design facilities and equipment in the manner they deem best to maintain the required sanitary environment for food production. Further, as stated above, if establishments are maintaining sanitary conditions, there is no reason to believe that they will not be in compliance with the new performance standards for design and construction, as long as their facilities are maintained in good repair. Also, as stated above, they may follow the recommendations in the Food Code or the national building and construction codes, many of which have been adopted as requirements by State and local governments. If establishments do so, they should be in compliance with the standards.

Comment: One commenter requested that FSIS delete the examples of vermin given in proposed § 416.2(b)(3): "Walls, floors, ceilings, doors, windows, and other outside openings must be

constructed and maintained to prevent the entrance of vermin, such as flies, rats, and mice." The commenter argued that these examples are unnecessary.

Response: These examples are illustrative of the types of vermin known to commonly infest meat and poultry establishments and, therefore, FSIS is retaining them in the regulations.

Comment: Finally, although no commenter specifically addressed the proposed standard concerning the separation of edible and inedible product, FSIS believes that the proposed standard could be misunderstood and is making a revision to clarify its intent. FSIS proposed to require that "Rooms or compartments in which edible product is processed, handled, or stored must be separate and distinct from rooms or compartments in which inedible product is processed, handled, or stored." FSIS did not intend to imply that rooms where edible product is processed, handled, or stored could never be used for the processing, handling or storage of inedible product. FSIS has allowed, and will continue to allow, establishments to process, handle, or store edible and inedible product in the same room as long as they are separated by time or space, in a manner sufficient to prevent the adulteration of the edible product or the creation of insanitary conditions.

Response: FSIS is adopting a revised standard that states: "Rooms or compartments in which edible product is processed, handled, or stored must be separate and distinct from rooms or compartments in which inedible product is processed, handled, or stored, to the extent necessary to prevent product adulteration and the creation of insanitary conditions."

Light: Proposed § 416.2(c)

Comment: A few commenters opposed the proposed performance standard that establishments provide "Lighting of good quality and sufficient intensity to ensure that sanitary conditions are maintained and that product is not adulterated * * *". These commenters maintained that by allowing establishments to determine whether light quality and intensity is sufficient, FSIS, in fact, would be allowing establishments to provide lighting that is not sufficient to ensure sanitation. One commenter doubted that establishments would follow the recommendations for lighting contained in the Food Code, as suggested by FSIS. Another commenter recommended that FSIS maintain the existing 30-foot candle requirement for light intensity at poultry working surfaces and extend the

same requirement to meat establishments.

Response: FSIS disagrees. FSIS does not believe it is necessary to prescribe specific light intensities to ensure sanitation in meat and poultry processing areas because establishments must determine what light intensities are appropriate to ensure sanitation in different operational contexts. Importantly, however, as with all of the sanitation performance standards, FSIS will continue to verify through inspection that the lighting meets the performance standard.

The previous requirements for lighting in poultry establishments in § 381.52 prescribed specific light intensities for different areas of the establishment. For example, FSIS required that all rooms in which poultry was killed, eviscerated, or otherwise processed have 30-foot candles of light intensity on all working surfaces. The comparable regulations for red meat establishments in § 308.3(b) did not contain such specific requirements, but required only that meat establishments have "abundant light, of good quality and well distributed." However, the intent of these requirements was the same for both meat and poultry establishments: there must be enough light of adequate quality to monitor sanitary conditions and processing operations and to examine product for evidence of adulteration. New § 416.2(c) establishes this intent as a single performance standard applicable to both meat and poultry establishments, which is wholly consistent with the purpose of the current regulations.

It also is important to note that FSIS is not rescinding the specific light intensity requirements for inspection program employee and reprocessing stations set out in §§ 307.2 and 381.36. FSIS has determined that these specific requirements are still necessary to ensure appropriate conditions for effective inspection.

Ventilation: Proposed § 416.2(d)

Comment: FSIS proposed that meat and poultry establishments provide "ventilation adequate to eliminate odors, vapors, and condensation." Several commenters maintained that it would be impossible for establishments to "eliminate" odors, vapors, and condensation. They suggested that the standard be revised to require that ventilation be adequate to control odors, vapors, and condensation to the extent necessary to prevent the adulteration of product.

Response: FSIS agrees and has revised the standard to require that ventilation be adequate to control odors, vapors,

and condensation to the extent necessary to prevent adulteration of product and to prevent the creation of insanitary conditions which can lead to product adulteration.

*Plumbing and Sewage Disposal:
Proposed §§ 416.2(e) and (f)*

Comment: In the preamble to the proposed rule, FSIS recommended that establishments consult the National Plumbing code when designing or building a plumbing system and stated that "a plumbing system in compliance with the National Plumbing Code in most instances would meet the proposed performance standards for plumbing." One commenter supported the use of the National Plumbing Code by establishments but questioned whether there were certain provisions in the Code that FSIS has determined would be inadequate to meet the performance standard.

Response: FSIS has not determined that any of the provisions of the National Plumbing Code are inappropriate or inadequate as models for plumbing systems in meat and poultry establishments. However, compliance with the National Plumbing Code or any other code does not necessarily establish compliance with FSIS regulations. For instance, it could be possible to build a plumbing system that meets the standards of the National Plumbing Code but also creates insanitary conditions that could cause the adulteration of product. FSIS continues to recommend that meat and poultry establishments consult the National Plumbing Code when designing or building a plumbing system, but also encourages establishments to keep in mind the relevant requirements of FSIS, other Federal Agencies, and State and local governments.

Comment: A few commenters opposed the removal of requirements that features of plumbing and sewage systems, such as traps and vents, be prior-approved by FSIS program employees for safety and efficacy.

Response: As the Agency has stated throughout this document, FSIS fundamentally disagrees with those commenters who oppose the elimination of prior approval requirements. It is the responsibility of the establishment to ensure that plumbing and sewage systems provide an adequate supply of potable water for processing and other purposes and move waste and sewage from the establishment without adulterating product or creating insanitary conditions. There are many ways to achieve these goals that are consistent

with FSIS regulations, State and local laws, and the Food Code. Required prior approval of these systems undercuts this objective and would deprive establishments of the flexibility to innovate and create sound, effective plumbing and sewage systems that ensure sanitary operating conditions. FSIS will continue to verify, through inspection, that plumbing and sewage systems neither adulterate product nor create insanitary conditions.

Water Supply and Reuse: Proposed § 416.2(g)

Comment: One commenter believed that FSIS suggested in the preamble to the proposal that compliance with the EPA standard for water potability might not be sufficient to ensure that water used by meat and poultry establishments is potable.

Response: FSIS proposed a water supply performance standard intended to make transparent the current requirement that potable water comply with EPA's National Primary Drinking Water regulations. These regulations are promulgated under section 1412 of the Public Health Service Act, as amended by the Safe Drinking Water Act, and are applicable to public water systems. The EPA standard of water potability is sufficient and FSIS is adopting the performance standard as proposed.

Comment: Another commenter questioned the proposed requirement that establishments make available to FSIS any water reports "issued under the authority of the State health agency, certifying or attesting to the quality of the water supply." The commenter argued that this requirement would be ineffective as an indicator of water potability unless FSIS specified the frequency at which an establishment must have its water supply tested.

Response: The EPA National Primary Drinking Water regulations, contained in 40 CFR part 141, require testing of drinking water for fecal coliforms and other contaminants at specified frequencies. Because FSIS is requiring that water used by meat and poultry establishments meet the EPA requirements, which include testing requirements, FSIS does not need to promulgate separate testing requirements. Certifications of water potability provided by State or local governments or other responsible entities will show whether water meets the EPA requirements.

Some meat and poultry establishments use private wells for their water supply. EPA classifies private wells as "noncommunity" water sources and does not require testing for potability. It also is unlikely that State

or local governments would test such wells for potability. If an establishment uses a private well, FSIS is requiring that the establishment make available to FSIS documentation, renewed at least semi-annually, certifying the potability of its private well water. Most establishments will obtain this documentation from private laboratories.

FSIS is finalizing this requirement concerning the potability of well water in response to the above comment. Although the Agency did not specifically propose this approach, it is consistent with the proposal, which focused on how to ensure the potability of water used in all establishments. Moreover, it is not a new requirement. It is the codification of a policy that FSIS has been enforcing under FSIS Directive 11,000.1, the "Sanitation Handbook for Meat and Poultry Inspection." This Directive was rescinded by FSIS Notice 3-98 on January 16, 1998. Another FSIS document concerning this policy, entitled "Approved Water Systems," will be rescinded upon the effective date of this rule.

Comment: Several commenters objected to the proposed performance standards for water reuse because, they argued, the proposed standards would allow establishments to wash raw product, equipment, and utensils with non-potable water, and the possibility of product adulteration would therefore be greatly increased. One commenter suggested that FSIS require water to be "heat pasteurized" before reuse on raw or ready-to-eat product.

Response: In many circumstances, establishments can reuse water in a manner that will neither adulterate product nor create insanitary conditions. FSIS already permits certain uses of nonpotable water. For example, water is recirculated in tanks to chill raw poultry; water treated by an advanced wastewater treatment system can be used to wash equipment or raw product, if followed by a potable water rinse; and nonpotable, reuse water can be used to wash floors or equipment in areas where edible product is not handled. FSIS is making final performance standards that will provide for the reuse of water in numerous processing contexts, provided that the establishment takes actions necessary to ensure that product is not adulterated by the water and that sanitation is not compromised. Establishments are required to document and monitor water reuse activities either in their Sanitation SOP's or HACCP plans.

Comment: One commenter expressed concern about the proposed requirement

that water used or reused to chill or cook ready-to-eat product be free of pathogens. This commenter and others stated that the stated goal of the performance standards for water, processing solution, and ice reuse should be to prevent meat and poultry products from becoming adulterated by pathogens, rather than preventing water, ice, or solutions from being contaminated with pathogens, fecal coliforms, and other hazardous substances. These commenters maintained that establishments will control pathogens in the processing environment, in this case water, through HACCP and Sanitation SOP's and recommended that the performance standards for water, ice, and solutions reuse be revised accordingly.

Response: FSIS does not agree with the commenters' suggestion. In many cases, the presence of fecal coliforms, pathogens, or other contaminants in reuse water, ice, or processing solutions indicates insanitation that may, in fact, lead to the adulteration of meat and poultry products. The control of pathogens in water used in processing, therefore, is essential for ensuring that meat and poultry products do not become adulterated. The performance standards establish the necessary conditions to ensure that water, ice, and solution reuse do not compromise sanitation or cause the adulteration of product. Establishment Sanitation SOP's and HACCP plans must provide for compliance with these sanitation standards.

Ice and Solution Reuse: Proposed § 416.2(h)

Comment: Several commenters maintained that the hazards inherent in ice and solution reuse were identical to those in water reuse and suggested, therefore, that the performance standards be combined for consistency.

Response: FSIS agrees and has made final a single set of reuse performance standards applicable to water, ice, and solutions. However, because of the different physical characteristics and uses of water, ice, and solutions, it is expected that establishments will meet the performance standards for these substances in different ways. For example, an establishment recirculating water in a chill tank for raw poultry might add chlorine to the water to reduce the number of pathogens. An establishment reusing ice to chill raw poultry might bag the ice to prevent it from contacting product.

Dressing Rooms, Lavatories, and Toilets: Proposed § 416.2(i)

Comment: Numerous commenters opposed the proposed performance standard concerning the number of lavatories and toilet facilities in official establishments:

Dressing rooms, toilet rooms, and urinals must be sufficient in number, ample in size, conveniently located, and maintained in a sanitary condition and in good repair at all times to ensure cleanliness of all persons handling any product. They must be separate from the rooms and compartments in which products are processed, stored, or handled. Where both sexes are employed, separate facilities must be provided.

These commenters claimed that many establishments have crowded, insanitary conditions now, and, if given this performance standard instead of a more prescriptive requirement, establishments would not provide a sufficient number of lavatories and toilet facilities. One commenter, however, argued that the standard is, in fact, too prescriptive in that it requires separate facilities for both sexes. This commenter stated that Federal, State, and local labor laws already provide for this.

Response: As the Agency has stated throughout this document, it is prudent and reasonable to replace prescriptive sanitation requirements with performance standards that articulate the objectives or results that establishments must achieve. Thus, FSIS is replacing the prescriptive requirements concerning establishment lavatories, toilet facilities, and their sanitation with a performance standard. Furthermore, other Federal law already does govern lavatories and toilet facilities in places of employment.

The Occupational Safety and Health Administration (OSHA) of the Department of Labor has promulgated regulations concerning toilet facilities in the workplace in 29 CFR 1910.141, "Sanitation." Paragraph (c)(1)(i) of this regulation sets forth requirements for the number of toilet facilities in all permanent places of employment. Official meat and poultry establishments are governed by these requirements. Thus, FSIS has determined that it is not necessary to add a more specific provision regarding the number of toilets to the performance standard it proposed.

In regard to the issue of requiring separate toilet facilities for men and women, OSHA also has set forth requirements, again in 29 CFR 1910.141(c)(1)(i): "toilet facilities, in toilet rooms separate for each sex, shall be provided in all places of

employment," and, further, "Where toilet rooms will be occupied by no more than one person at a time, can be locked from the inside, and contain at least one water closet, separate toilet rooms for each sex need not be provided." For consistency with this OSHA requirement, FSIS has removed the proposed provision requiring separate lavatories and toilet facilities.

Equipment and Utensils: Proposed § 416.3

Comment: Numerous commenters objected to the proposed elimination of the requirement in §§ 308.3(d)(4) and 308.8 that utensils and equipment used to dress diseased meat carcasses be cleaned with either 180 °F water or an approved disinfectant. Several commenters contended that the use of 180 °F water has been the method "proven" to be effective for sanitizing implements. These commenters submitted no supporting data, however. A few commenters recommended that FSIS require a minimum water temperature of at least 155 °F to 160 °F, as water in this temperature range is purported to kill *E. coli* O157:H7. Several commenters questioned the studies cited by FSIS as support for rescinding the 180 °F requirement. These commenters recommended that FSIS commission or conduct a new study to determine the water temperature that is most effective for controlling bacteria in a slaughter environment. Finally, one commenter argued that by rescinding the 180 °F water requirement, FSIS is contradicting its other policy of "promoting" the use of steam cabinets as a processing step to kill bacteria.

Response: For HACCP systems to be effective, meat and poultry establishments must be afforded the flexibility to take whatever actions are necessary to produce safe products. Meat establishments must determine what is necessary, in the particular context of their processing environment, to clean implements used to dress diseased carcasses so that those implements will not adulterate product. Under the performance standard, many meat establishments are likely to continue using 180 °F water for this purpose, but others will use different means that they will have determined are more suitable and as effective.

The studies summarized by FSIS in the proposal raise significant questions about the efficacy of 180 °F water for the cleaning of implements used to dress diseased carcasses. FSIS cited these studies to emphasize that this prescribed treatment may not be effective in every processing

environment and, therefore, that a performance standard would be more appropriate for ensuring that meat establishments maintain proper sanitation within their operations. FSIS is not planning to conduct or sponsor any additional studies at this time, but certainly will evaluate any research developments in this area.

Finally, FSIS has endorsed the use of steam pasteurization as an antimicrobial treatment for the surfaces of meat carcasses. FSIS has not prescribed, however, a specific temperature for the steam or a specific method for its application. Similarly, FSIS will no longer require a specific method for the cleaning of implements used to dress diseased carcasses.

Comment: Several commenters opposed the proposed performance standard regarding equipment and FSIS inspection program employees: "Equipment and utensils must not interfere with inspection procedures or interfere with inspection by FSIS inspection personnel." These commenters argued that this standard is unnecessary because the general requirement that establishments not interfere with FSIS inspection is implicit in all of the regulations.

Response: The FMIA, PPIA, and the regulations specifically prohibit the forcible interference with FSIS program employees performing inspection or any other duties prescribed by the FMIA, PPIA, or the regulations. Moreover, the requirement that establishments not interfere with FSIS inspection is implicit throughout FSIS regulations. However, it is important to establish a performance standard regarding the inspection of the sanitary condition of equipment. Equipment in an official establishment must not be constructed or operated in a manner that would prevent FSIS inspection program employees from determining whether the equipment is in sanitary condition. If meat or poultry processing equipment is built, located, or operated in a manner that prevents it from being inspected to determine whether it has been cleaned or sanitized so as to ensure that it will not be the cause of product adulteration, FSIS may withhold the mark of inspection from product processed using that equipment. FSIS has revised the proposed performance standard, as follows, to clarify this intent: "Equipment and utensils must not be constructed, located, or operated in a manner that prevents FSIS inspection program employees from inspecting equipment or utensils to determine whether they are in sanitary condition."

Food Contact Surface Cleaning and Sanitation: Proposed § 416.4(a)

Comment: Numerous commenters objected to the proposed requirement that "all food-contact surfaces, including food-contact surfaces of utensils and equipment, must be cleaned daily prior to starting operations * * *." Commenters stated that many establishments currently operate successfully for extended periods (more than 24 hours), cleaning and sanitizing as necessary. Also, several commenters noted that certain types of equipment, such as blast freezers and high temperature ovens, can be operated over extended periods without posing a significant food safety risk. Finally, a few commenters suggested that an establishment's Sanitation SOP or HACCP plan should dictate frequency of cleaning food contact surfaces.

Response: FSIS agrees that it is possible for an official establishment to safely operate for an extended period (more than 24 hours) without re-sanitizing all food contact surfaces. It is also true that more frequent sanitizing may be necessary. Accordingly, FSIS is finalizing a performance standard for operational sanitation requiring that "All food-contact surfaces, including food-contact surfaces of utensils and equipment, must be cleaned and sanitized as frequently as necessary to prevent the creation of insanitary conditions and the adulteration of product." The regulation, as revised, is consistent with the Sanitation SOP and HACCP requirements. Establishments must comply with the Sanitation SOP requirements regarding food contact surfaces in § 416.12(c): "Procedures in the Sanitation SOP's that are to be conducted prior to operations shall be identified as such, and shall address, at a minimum, the cleaning of food contact surfaces of facilities, equipment, and utensils."

Non-Food Contact Surface Cleaning and Sanitation: Proposed § 416.4(b)

Comment: Several commenters stated that the language proposed for the performance standard for non-food contact surfaces was unnecessarily prescriptive and inconsistent with the other performance standards because it required that such surfaces be cleaned "as necessary to prevent the physical, chemical, or biological contamination or adulteration of product," rather than simply to prevent adulteration of product.

Response: FSIS agrees and has revised the standard to be consistent with the revised standard in § 416.4(a): "Non-

food-contact surfaces of facilities, equipment, and utensils used in the operation of the establishment must be cleaned and sanitized as frequently as necessary to prevent the creation of insanitary conditions and the adulteration of product." Obviously, during the normal course of an establishment's operations, meat and poultry products should not come in contact with "non-food contact surfaces." Therefore, as long as such contact did not occur, it would be unlikely that these surfaces would ever directly adulterate product. However, if non-food contact surfaces are insufficiently cleaned or sanitized, insanitary conditions within the establishment can result, potentially leading to product adulteration. FSIS has revised this performance standard by deleting the specific reference to "physical, chemical, or biological contamination" and by requiring that non-food contact surfaces be cleaned and sanitized as necessary to prevent the creation of insanitary conditions and the adulteration of product.

Comment: One commenter claimed that non-food contact surfaces in establishments, such as floors, drains, and walls, are highly contaminated. This commenter suggested that FSIS revise the performance standard to require daily cleaning and sanitizing of non-food contact surfaces.

Response: In many establishments, daily cleaning and sanitizing of non-food contact surfaces may not be necessary for the maintenance of sanitary conditions or the prevention of product adulteration. FSIS will not, therefore, mandate specific time intervals for this requirement. If the conditions in an establishment are such that floors, drains, walls, and other non-food contact surfaces are highly contaminated on a regular basis, the establishment may need to provide for the appropriate frequency of cleaning and sanitizing of those surfaces in either its HACCP plan or Sanitation SOP's. FSIS is confident that insanitary conditions of non-food contact surfaces in official establishments will be detected by FSIS inspection program employees during verification of an establishment's HACCP plans and written Sanitation SOP's.

Cleaning Compounds and Sanitizers: Proposed § 416.4(c)

FSIS proposed to eliminate the regulatory requirements mandating that certain nonfood compounds and proprietary substances be approved by the Agency prior to their use. Specifically, FSIS proposed to rescind the following regulations:

§ 308.3(h)—requirements that FSIS approve pesticides, rodenticides, and insecticides prior to use in certain areas of meat establishments;

§ 308.8(c)—requirements that FSIS approve, prior to use, disinfectants used to clean implements that have contacted diseased meat carcasses; and

§ 381.60—requirements that germicides, insecticides, rodenticides, detergents, wetting agents, and similar compounds be approved by FSIS prior to use in poultry establishments.

FSIS did not propose to discontinue its policy of approving other proprietary substances or nonfood compounds prior to their use in official establishments. As a matter of policy, FSIS has reviewed and approved, prior to use, most other nonfood compounds and proprietary substances, including: branding and tattoo inks; poultry and hog scald agents; rendering agents; certain cleaning compounds; paint removers; antimicrobial agents; hand washing and sanitizing agents; water treatments; solvent cleaners; sewer and drain cleaners; and lubricants. Following its review, FSIS has listed all approved nonfood compounds and proprietary substances in Miscellaneous Publication Number 1419, *List of Proprietary Substances and Nonfood Compounds*.

Shortly after FSIS published the proposal to revise the sanitation regulations, FSIS mistakenly released information that mischaracterized the proposal's provisions concerning the prior approval of nonfood compounds and proprietary substances. On September 11, 1997, the FSIS Compound and Packaging Review Branch mailed a notice to chemical manufacturers and other businesses announcing a change of address. Included with that notice was a facsimile of the first page of a proposed rule, incorrectly identified as the sanitation proposal, FSIS Docket No. 96-037P, announcing that the Agency was discontinuing its policy of approving *all* nonfood compounds and proprietary substances prior to their use in official meat and poultry establishments.

In order to clear up any confusion regarding the matter, FSIS published a notice in the **Federal Register** (FSIS Docket No. 97-062N; 62 FR 55995) explaining the situation and correcting the erroneous information. Further, in order to ensure that the public had ample opportunity to submit comments on the sanitation proposal and its provisions concerning nonfood compounds and proprietary substances, FSIS reopened the comment period for that proposal for 15 days, from October

28, 1997, to November 10, 1997 (FSIS Docket 96-037R; 62 FR 55997).

On February 13, 1998, FSIS announced in a notice (FSIS Docket No. 97-007N; 63 FR 7319) that it did, in fact, intend to discontinue approving all nonfood compounds and proprietary substances prior to their use in official meat and poultry products establishments. FSIS emphasized that it would continue to require that meat and poultry products be neither adulterated nor misbranded through the misuse of proprietary additives and nonfood compounds. Further, FSIS also explained its plan to maintain a small staff with expertise in nonfood compounds and proprietary substances. This staff will keep abreast of developments in chemical manufacturing and use, maintain liaison with outside organizations that have an interest in this matter, and issue technical guidance, particularly to small meat and poultry plants, as circumstances warrant. Finally, FSIS requested comment on possible alternatives to the FSIS prior approval program, including the option of third party review and approval of nonfood compounds and proprietary substances.

The comments FSIS received on this issue, whether in response to the sanitation proposal, the letter distributed by the Compounds and Packaging Review Branch, or the February 13 notice, do not differ substantively. While a few commenters supported the proposed regulatory and policy changes, most of the comments were submitted by chemical manufacturers, and most were in opposition to ending the prior approval program for all nonfood compounds and proprietary substances. In response to the letter, FSIS received 68 comments. Because these commenters believed that they were responding to an FSIS proposed rulemaking, FSIS maintained their comments on file in the FSIS Docket Room. In response to the February 13 notice, FSIS received 35 comments. Below, FSIS responds to all of the issues raised in all of the comments concerning the FSIS plan to eliminate the prior approval program.

Comment: The majority of commenters opposed to ending the prior approval program argued that without prior approval, unscrupulous chemical manufacturers will market unsuitable and possibly dangerous chemicals to meat and poultry establishments and that the use of such chemicals would inevitably lead to the adulteration of product. Further, they argued that it would be difficult for FSIS inspection program employees to prevent such adulteration since they would not be

able to consult the *List of Proprietary Substances and Nonfood Compounds*. Several commenters contended that without the *List of Proprietary Substances and Nonfood Compounds*, FSIS inspection program employees will make inconsistent or arbitrary decisions in regard to what compounds establishments may use.

Response: FSIS disagrees. The FMIA and PPIA require that meat and poultry products be neither adulterated nor misbranded through the use of proprietary substances and nonfood compounds. Meat and poultry establishments are responsible for ensuring that all proprietary substances and nonfood compounds are safe for their intended use and used appropriately. In light of these requirements, FSIS anticipates that establishments considering purchasing and using nonfood compounds or proprietary substances will demand formulation or other information from chemical manufacturers before making purchase decisions. Manufacturers who fail to provide such information could lose their market share.

FSIS inspection program employees will continue to verify that proprietary substances and nonfood compounds do not adulterate meat and poultry products. Enforcement activities in this regard will include, but will not be limited to, direct observation of establishment operations and inspection of an establishment's premises and product, as well as sampling of product for chemical residues, as necessary, and review of establishment records. Establishments will document the use of proprietary substances and nonfood compounds in a variety of records, depending on the nature of the compound and its use. FSIS inspection program employees will review Sanitation SOP's, HACCP plans, use directions, pest control certifications, letters of guarantee, and other materials furnished to establishments by chemical manufacturers and suppliers.

In response to comments, FSIS is finalizing an additional regulatory requirement in regard to the use of nonfood compounds and proprietary substances in § 416.4(c): "Documentation substantiating the safety of a chemical's use in a food processing environment must be available to FSIS inspection program employees for review." FSIS is not requiring that establishments make available any specific type of documentation since, as stated above, documentation substantiating the safety of a chemical varies with the nature and intended uses of that chemical. For example, for a pesticide, an

establishment should have documentation showing that the compound is registered with EPA and the label information for the pesticide. For a chemical sanitizer used on food contact surfaces, an establishment should have documentation showing that the compound complies with the relevant Food and Drug Administration (FDA) regulations in 21 CFR 178.1010. For an antislip agent, an establishment may satisfy the regulations with a letter of guarantee and use instructions from the manufacturer certifying that if used in accordance with directions, the compound will neither adulterate product nor create insanitary conditions. This documentation requirement not only will assist FSIS inspection program employees in determining whether the use of given compound is proper and safe, but also will ensure that meat and poultry establishments have adequately reviewed and evaluated the chemicals used in their food processing environments.

FSIS inspection program employees may, of course, disallow a specific use of a chemical in an official establishment if documentation is not available or is inadequate, if the establishment misuses the nonfood compound or proprietary substance, or if there is reason to believe a specific use will lead to insanitation or product adulteration. FSIS program employees will be instructed to direct any questions or concerns regarding the use of nonfood compounds and proprietary substances to the FSIS Technical Services Center. Further, FSIS is publishing a new Directive to assist inspection program employees in verifying the safety of the use of nonfood compounds and proprietary substances in official meat and poultry establishments.

Comment: Some commenters maintained that small establishments lack the resources and technical expertise to determine whether chemical compounds are safe and effective and, therefore, would be adversely affected by the elimination of FSIS review and approval. Several of these commenters urged FSIS to provide guidance material to industry concerning the appropriate formulation and use of nonfood compounds and proprietary substances.

Response: FSIS does not anticipate that the elimination of its prior approval program will substantially affect small meat and poultry establishments. These establishments are or should be already aware of which chemicals have been approved by FSIS. Moreover, competition will compel chemical

manufacturers to provide meat and poultry establishments of all sizes with data that establish that their compounds are safe and effective. Likewise, FSIS is making available guidelines for compliance with the sanitation performance standards that explicitly address the appropriate formulation and safe use of nonfood compounds and proprietary substances. The guidelines are based upon the FSIS's regulatory experience, the requirements of other Federal agencies, and the criteria previously used by FSIS for reviewing and approving nonfood compounds and proprietary substances. Establishments should refer to those guidelines. Furthermore, although the guidelines are directed primarily to regulated meat and poultry establishments, chemical manufacturers may find them useful in developing and marketing their products.

Comment: A few commenters, including several non-government standard-setting organizations, strongly supported third-party review and certification of nonfood compounds and proprietary substances.

Response: FSIS encourages third-party standards organizations and independent laboratories to develop systems for testing and certifying nonfood compounds and proprietary substances. Such certification would encourage the development and marketing of effective, safe, and innovative products. Chemical manufacturers whose products meet FSIS performance standards and other agency requirements will have ample incentive to publicize the fact that their products are approved by third party organizations or independent laboratories. It is not likely that FSIS will officially sanction any particular organization's certification as definitive evidence of compliance with FSIS requirements. However, FSIS would obviously give careful consideration to valid third-party certifications when questions arise regarding the safety of a nonfood compound or proprietary substance.

Comment: Several commenters noted that some of the nonfood compounds and proprietary substances previously approved by FSIS, including general cleaners, hand soaps, sewer and drain cleaners, and certain water treatments, are not, in fact, reviewed or approved by other Federal agencies. These commenters contended that, consequently, continued review and approval of these compounds by FSIS is necessary. In one comment, FDA raised specific concerns regarding the proposed discontinuation of prior approval for hand cleaners and

sanitizers. Although some hand treatments are considered over-the-counter drug products and therefore regulated by FDA, others are not.

Response: FSIS does not agree that prior approval of these chemicals is necessary to ensure the safety of meat and poultry products. Meat and poultry establishments have the responsibility of ensuring that the nonfood compounds and proprietary substances that they use will not adulterate product or create insanitary conditions. As stated above, FSIS will verify that these chemicals are being used appropriately through inspection, review of documentation substantiating the safety of the chemicals, and if necessary, sampling and testing. FSIS anticipates that competition will compel chemical manufacturers to demonstrate to meat and poultry establishments that their products are safe and satisfy the standards established in these regulations.

Specifically in regard to the use of hand treatments and sanitizers, FSIS prior approval is unnecessary. Hand care products formulated with chlorhexidene gluconate and intended to be used as an antimicrobial hand cleaner or hand sanitizer/dip in food handling and processing, as well as hand care treatments intended for use as a "barrier" or "shield" to prevent or mitigate human disease by protecting skin from exposure to toxic chemicals or pathogenic microorganisms, are considered "drugs" and possibly "new drugs" under the Federal Food, Drug, and Cosmetic Act (FFDCA). Consequently, FDA regulates and registers these hand treatments. Establishments using such chemicals should keep registrations on file for review by FSIS inspection program employees.

Other hand treatments, however, are not currently regulated or registered by FDA. It is the responsibility of establishments to ensure that such treatments do not adulterate product or create insanitary conditions. As with other chemicals, FSIS will verify that hand treatments are being used appropriately through inspection, review of documentation substantiating the safety of the chemicals, and if necessary, sampling and testing. FSIS is publishing guidance on the appropriate use of hand treatments in the sanitation performance standards compliance guide. FSIS also is continuing to consult with FDA regarding the appropriate use of hand treatments, and will modify the compliance guide in the event of changes in FDA policies.

Comment: One trade association cited concerns regarding labeling and

marketing claims for nonfood compounds and proprietary substances previously approved and listed by FSIS. This commenter requested that FSIS explicitly allow manufacturers of previously approved chemicals to market them as such.

Response: FSIS will neither approve nor disapprove marketing claims or labeling for the nonfood compounds and proprietary substances used in establishments. Chemical manufacturers may market or label their products as being previously approved by FSIS, as long as their claims are truthful and not misleading, as is required by applicable law. Meat and poultry establishments should keep in mind that since FSIS is discontinuing its prior approval program for these products, previous approval of a product by FSIS does not necessarily mean that it is safer or more effective than a new product that has not been reviewed and approved.

Documentation required to be available under the regulation may cite that products were previously approved by FSIS for a particular use and that the formulation of that product has not changed. This information may facilitate decisions by FSIS program employees when reviewing documentation that substantiates the safety of a nonfood compound or proprietary substance.

Comment: A few commenters argued that in regard to the proposed elimination of its prior approval program, FSIS must perform environmental impact analyses pursuant to the requirements of the National Environmental Policy Act (NEPA, 42 U.S.C. 4321 *et seq.*) and the Council for Environmental Quality regulations in 40 CFR parts 1500–1508. These commenters noted that FSIS has been granted a categorical exclusion from NEPA requirements by USDA regulation (7 CFR 1b.4), unless “the agency head determines that an action may have a significant environmental effect.” They concluded that the elimination of prior approval for nonfood compounds and proprietary substances in general, and specifically for pesticides, could have a significant, adverse impact on human health and the environment and therefore that FSIS should conduct an environmental assessment or impact analysis as required by NEPA. Two commenters also claimed that FSIS’s planned elimination of its prior approval program is inconsistent with the intent of E.O. 13045, which encourages Federal agencies to “identify and assess environmental health risks and safety risks that may disproportionately affect children” and result from regulatory action.

Response: The Administrator of FSIS has determined that the elimination of prior approval of nonfood compounds and proprietary substances will not have an adverse impact on the environment or human health, and therefore, that it is not necessary for FSIS to perform an environmental impact assessment for this action. As stated above, FSIS is continuing to require that meat and poultry products be neither adulterated nor misbranded through the use of proprietary substances and nonfood compounds and that the use of these substances and compounds must not create insanitary conditions. FSIS inspection program employees will verify that these chemicals are being used appropriately and are not adulterating product through inspection, review of documentation substantiating the safety of the chemicals, and if necessary, sampling and testing. Other Federal and state requirements concerning the use, storage, or disposal of these chemicals will not be affected by this rule. There is no reason to believe, therefore, that the discontinuation of the FSIS prior approval program for nonfood compounds and proprietary substances will allow meat and poultry establishments to use these chemicals in any manner that would have an adverse impact on human health and the environment.

Finally, because FSIS has determined that this action will not have any significant impact on the environment or on human health, FSIS has similarly determined that this action will not have a disproportionately adverse impact on the health of children and is, therefore, consistent with the intent of E.O. 13045.

Denaturants

During the course of reviewing the comments, FSIS discovered that it had not proposed to rescind in §§ 314.3 and 381.95, which require establishments to use only prior approved denaturants for condemned meat and poultry, even though FSIS has listed approved denaturants in the *List of Proprietary Substances and Nonfood Compounds*. Denaturants are chemicals used to color or affect condemned meat and poultry products in a manner that readily identifies them as inedible to establishment employees and FSIS inspection program employees, so that the product will not be processed, shipped, or marketed as edible product. In the near future, FSIS will publish a proposal to rescind these prior approval requirements for denaturants and replace them with a performance standard. The standard that FSIS

intends to propose will take into account FDA policy regarding denaturants applied to condemned meat and poultry products used for animal feed. Until the FSIS proposal is published and made final, the requirements regarding prior approval of denaturants will remain in effect.

Operational Sanitation: Proposed 416.4(d)

Comment: Several commenters opposed the proposal to replace with a performance standard § 381.47(e), which required that rooms where mechanical equipment is operated for the deboning of raw poultry be maintained at 50 °F or less. FSIS considered this requirement to be overly prescriptive and proposed to allow establishments to devise their own means for limiting microbial growth in their processing operations. Commenters claimed that the prescriptive temperature requirement is imperative for preventing microbial growth and contended that small establishments lack the resources and expertise to innovate in this area.

Response: As stated in the proposal, in response to requests, FSIS has permitted many establishments to use methods other than reducing ambient temperature to control microbial growth in raw poultry. Several establishments have used heat-exchangers connected to the grinding equipment to bring about an immediate reduction in product temperature. Use of heat-exchangers on the equipment can more effectively reduce product temperature and limit growth of microorganisms than strict adherence to the requirement to maintain a specific room temperature. The performance standard for operational sanitation will allow establishments to devise their own means for limiting microbial growth in their processing operations, without requesting special approval from the Agency.

Small establishments will not have to innovate in this area. If they choose, small establishments may continue to maintain the temperature in poultry deboning rooms at 50 °F. Since this measure has been proven to adequately control microbial growth in this processing situation, it will continue to meet the performance standard for operational sanitation, until new or better data suggest otherwise.

Comment: Also in regard to operational sanitation, FSIS proposed the following performance standard: “Product must be protected from contamination or adulteration during processing, handling, storage, loading, and unloading at and during

transportation from official establishments; ready-to-eat product must be protected from cross-contamination by pathogenic organisms." Several commenters argued that the standard regarding cross-contamination of ready-to-eat product was redundant, unnecessary, and only an example of one kind of product adulteration. They requested that FSIS make final only the first, more general standard.

Response: FSIS agrees that the proposed standard concerning cross-contamination is redundant and thus, for clarity, will not finalize it. Establishments already are specifically required to prevent the cross-contamination of ready-to-eat product by the first half of this proposed standard. FSIS also is revising this standard by removing the prohibition against product contamination, because, as explained above, such a standard is unnecessary.

Employee Hygiene: Proposed § 416.5(a)

Comment: Several commenters argued that the proposed performance standards for employee hygiene were too prescriptive. Specifically, these commenters objected to the proposed requirement that "All persons working in contact with * * * product-packaging materials must adhere to hygienic practices while on duty to prevent adulteration of product." They maintained that insanitary contact with certain packaging materials, such as canned product shipping containers, could never lead to product adulteration. These commenters suggested that FSIS clarify that the standard only applies to "product-contact-packaging."

Response: Although the unhygienic handling of certain packaging materials that do not come in contact with product may not lead to direct contamination of the product contained therein, such handling could contribute to the creation of insanitary conditions within an official establishment. FSIS is revising the performance standard to reflect this concern. The finalized § 416.5(a) states: "All persons working in contact with product, food-contact surfaces, and product-packaging materials must adhere to hygienic practices while on duty to prevent adulteration of product and the creation of insanitary conditions."

Comment: Conversely, several commenters opposed rescinding the existing regulatory prohibitions against specific, unhygienic employee activities and replacing them with performance standards. As discussed above in the "General Opposition" section, these

commenters asserted that FSIS inspection program employees' enforcement authority will be weakened without specific prohibitions against such actions as "placing skewers, tags, or knives in the mouth" (§ 308.8(e)). Further, these commenters cited multiple anecdotal examples of employee actions that could lead to the adulteration of product.

Response: FSIS does not need to specifically enumerate every action by establishment personnel that could possibly lead to product adulteration or insanitary conditions. It would, in fact, be impossible to compile such a list of prohibited practices. FSIS program employees have always had the authority, and will continue to have the authority, to take action whenever establishment personnel fail to ensure that product is not adulterated or fail to maintain sanitary conditions, even if the problem identified is not specifically delineated in a regulation. This authority remains unchanged under the new performance standard for employee hygiene in § 416.5(a).

Employee Clothing: Proposed § 416.5(b)

Comment: FSIS proposed a performance standard requiring that all employee outer clothing be readily cleanable. Several commenters from industry stated that their employees use disposable clothing, which is both sanitary and cost-effective, and requested that FSIS revise the standard to specifically allow for the use of disposable clothing.

Response: FSIS agrees that disposable clothing can be appropriately sanitary and has revised the standard to read, in part: "Aprons, frocks, and other outer clothing worn by persons who handle product must be of material that is disposable or readily cleaned."

Employee Disease: Proposed § 416.5(c)

Comment: FSIS proposed a performance standard requiring that:

Any person who has or appears to have an illness, open lesion, including boils, sores, or infected wounds, or any other abnormal source of microbial contamination must be excluded from any operations which could result in product contamination or adulteration until the condition is corrected.

One commenter requested that the word "illness" be replaced with the word "disease."

Response: FSIS agrees and has replaced the word "illness" with the phrase "infectious disease." "Illness" is a general term that could describe a disease or condition that is not infectious and therefore would pose no risk of product adulteration. The phrase

"contamination or" also is removed for reasons explained above.

Tagging Insanitary Equipment, Utensils, Rooms or Compartments: Proposed § 416.6

Comment: In regard to tagging insanitary equipment, utensils, rooms or compartments, FSIS proposed that its inspection program employees take such action when they find "that any equipment, utensil, room, or compartment at an official establishment is unclean or that its use would be in violation of any of the regulations in this subchapter." Several commenters objected to the word "unclean," arguing that it constituted a new standard and that its vagueness would lead to highly subjective enforcement by FSIS inspection program employees.

Response: The proposed language is not new and, in fact, is almost identical to the previous tagging regulation, § 308.15. Nevertheless, FSIS agrees that the regulation can be improved and for consistency with the sanitation requirements has replaced the word "unclean" with the word "insanitary." As stated above, under the FMIA and PPIA, FSIS must take action when an official establishment operates in a manner that leads to insanitary conditions and product adulteration. Accordingly, FSIS is revising the requirement to state that an FSIS inspection program employee will tag equipment, utensils, rooms, or compartments at an official establishment if they are "insanitary or [their] use could cause the adulteration of product."

Custom Slaughter Establishments

Comment: One commenter suggested that the proposed revisions to language exempting custom establishments from certain sanitation requirements were too restrictive, as they would apply only to custom slaughter operations and not to custom processing operations.

Response: FSIS agrees. This error was unintentional and the exemption in § 303.1(a)(2)(i) has been revised so as to apply to establishments "that conduct custom operations," rather than only to "establishments conducting custom slaughter operations."

Miscellaneous Changes

In the proposal preceding this final rule, FSIS stated that it needed "to revise all of the cross-references in the meat and poultry regulations to reflect the proposed deletion of Part 308 and 381 Subpart H and the proposed addition of new §§ 416.1 through 416.6." FSIS is making those revisions

in this final rule. References to specific sanitation requirements contained in sections of previous Part 308 or 381 Subpart H are replaced with references to the relevant sanitation performance standards in Part 416.

FSIS also is making a few revisions to the regulations for consistency with the new sanitation performance standards. Although FSIS did not propose these specific revisions, they are necessary to avoid conflict within the meat and poultry inspection regulations. These changes will impose no new regulatory burden on establishments.

First, Section 381.36(c)(1)(viii) of the poultry regulations states that "Online handrinsing facilities with a continuous flow of water conforming to section 381.51(f) shall be provided for and within easy reach of each inspector and each establishment helper." Section 381.51(f), which will be deleted by this final rule, stated:

An adequate number of hand washing facilities shall be provided in areas where poultry products are prepared. Hand washing facilities accepted in accordance with the procedures set forth in section 381.53 may be used in such areas, provided that if hand-activated facilities are used, the hand-contact element must be rinsed automatically with a sufficient volume of water to remove all fat, tissue, debris, and other extraneous material from the hand contact element after each use. Both hot and cold running water shall be available at each inspection station on the eviscerating line and shall be delivered through a suitable mixing device controlled by the inspector. Alternatively, water for hand washing shall be delivered to such inspection stations at a minimum temperature of 65 degrees F.

Although FSIS is deleting from § 381.36(c)(1)(viii) the reference to the deleted § 381.51(f), it is not rescinding the requirements for hand washing facilities at inspection stations in official poultry establishments. The specific requirements for hand washing equipment and water temperatures previously contained in § 381.51(f) are now contained in § 381.36(c)(1)(viii). Similarly, in this final rule, although FSIS is replacing with a performance standard the prescriptive light intensity requirements for official poultry establishments (previous § 381.52), it is not rescinding the specific light intensity requirements for inspector and reprocessing stations currently contained in §§ 307.2 and 381.36. FSIS has determined that although official establishments are responsible for determining what light intensities and types of hand washing equipment are necessary to maintain sanitary conditions, the specific requirements for light intensities and hand washing facilities at inspection stations are still

necessary to ensure appropriate conditions for effective inspection.

Second, FSIS is revising the regulations in §§ 314.2 and 314.4 regarding the adulteration of edible meat and poultry product by inedible meat and poultry products. Specifically, FSIS is removing references to Part 308 and converting to performance standards prescriptive requirements regarding the prevention of product adulteration through contact with inedible product or odors from inedible product. These revisions are entirely consistent with the performance standards for establishment construction, operations, and the suppression of odors.

Elimination of Directives

Comment: Several commenters objected to the proposed rescission of numerous FSIS Directives and Issuances concerning sanitation in official establishments, particularly FSIS Directive 11,000.1, the "Sanitation Handbook for Meat and Poultry Inspection." These commenters claimed that these Directives are needed by FSIS inspection program employees to ensure that establishments maintain adequate sanitation and do not adulterate product.

Response: The FSIS Issuances and Directives in question are based upon the prescriptive sanitation regulations that are being rescinded and replaced by this rule. Therefore, retention of these documents would only generate conflict and confusion regarding the sanitation requirements official establishments must meet and how FSIS inspection program employees are to enforce these new requirements. For consistency with the HACCP and Sanitation SOP requirements and with the recent elimination of prior approval of establishment blueprints and equipment, FSIS already has rescinded the following Directives concerning sanitation (FSIS Notice 3-98; January 16, 1998):

FSIS Directive 7110.4—Liquid Smoke Re-Use
 FSIS Directive 11,100.1—Sanitation Handbook
 FSIS Directive 11,000.2—Plant Sanitation
 FSIS Directive 11,000.4—Paints and Coatings in Official Establishments
 FSIS Directive 11,210.1—Protecting Potable Water Supplies on Official Premises
 FSIS Directive 11,220.2—Guidelines for Sanitization of Automatic Poultry Eviscerating Equipment
 FSIS Directive 11,520.2—Exposed Heat-Processed Products; Employee Dress

Further, in a forthcoming FSIS Directive concerning the new performance standards, FSIS will rescind these remaining Directives:

FSIS Directive 11,240.5—Plastic Cone Deboning Conveyors
 FSIS Directive 11,520.4—Strip Doors in Official Establishments
 FSIS Directive 11,540.1—Use of Certain Vehicles as Refrigeration or Dry Storage Facilities
 MPI Bulletin 77-34—Chemical Disinfection in Lieu of 180 deg. °F Water
 MPI Bulletin 77-129—Water Conservation and Sanitation
 MPI Bulletin 79-68—Use of Iodine in Processing Water
 MPI Bulletin 81-38—Equipment and Procedure Requirements for Processing Gizzards
 MPI Bulletin 83-14—Monitoring Chlorine Concentration in Official Establishments
 MPI Bulletin 83-16—Re-Use of Water or Brine Cooking Solution on Product Following a Heat Treatment
 As stated above, FSIS is issuing a new Sanitation Directive to accompany this rule. Although the Directive is written for FSIS inspector program employees, it will be available to the public. In addition, FSIS also will be issuing a compliance guide to assist establishments in complying with the new sanitation performance standards.

Compliance With Executive Order 12866 and the Regulatory Flexibility Act of 1996

This 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.

FSIS is revising and consolidating the sanitation regulations for official meat and poultry establishments, resolving unnecessary differences between similar rules for meat and poultry processing, and converting prescriptive requirements to performance standards. This action affects meat and poultry establishments subject to official inspection, custom exempt meat and poultry establishments, and consumers. In the proposal preceding this final action, FSIS requested comment concerning the potential economic effects of the proposed sanitation performance standards. FSIS specifically requested information that would allow the Agency to determine the number and kind of small entities that may incur benefits or costs resulting from issuance of this final rule.

FSIS received no comments that specifically addressed this issue. However, several commenters opposed

to the proposed sanitation performance standards maintained that small meat and poultry establishments do not have the resources to innovate in order to take advantage of the flexibility provided by the performance standards. Further, these commenters argued that small establishments need prescriptive requirements to ensure that they know how to maintain sanitary conditions and produce safe, unadulterated products. FSIS disagrees. Establishments currently maintaining sanitary conditions may choose to continue their current practices and be assured that they will be found in compliance with the new performance standards. In addition, FSIS will be making available a compliance guide that will contain much of the information contained in previous sanitation regulations and Directives, to assist establishments of all sizes in meeting the new sanitation performance standards.

In general, the streamlining, clarification, and consolidation of the sanitation regulations should benefit FSIS, the regulated industry, and consumers. User-friendly regulations employing performance standards simplify compliance and, therefore, should bring about food safety enhancements in individual establishments. Further, consolidation of the separate sanitation requirements for meat and poultry establishments and the consequent elimination of unnecessary inconsistencies will better ensure that enforcement policies are consistent and equitable and that competition is enhanced.

The performance standards allow individual establishments to develop and implement customized sanitation procedures other than those currently mandated, as long as those procedures produce and maintain sanitary conditions that meet the performance standards. Establishments taking advantage of the performance standards to innovate may benefit from savings accrued through increased efficiency. Since the previously mandated sanitation procedures meet the performance standards established by this final rule, establishments may continue employing their current procedures. There is no discernable reason that establishments would incur any additional expenses as a result of this rule. As a matter of fact, FSIS anticipates that the adoption of these sanitation performance standards will present numerous opportunities for cost savings and believes that this rule will have a favorable economic impact on all establishments, regardless of size.

It is difficult to quantify the potential benefits of the sanitation performance

standards since it is not possible to predict exactly how many establishments will take advantage of the flexibility provided and develop innovative processes and how these innovations will reduce costs and increase efficiency. However, FSIS sees the potential for a more efficient use of resources by official establishments. Also, the possibility of subsequently 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.

Finally, FSIS is restructuring inspection activities to focus more attention on whether establishments maintain a sanitary environment in accordance with the Sanitation SOP requirements and these sanitation performance standards. This action should reduce demands on FSIS resources which could be redirected to functions more critical to improving food safety. FSIS anticipates that this restructuring of inspection, along with these performance standards and the HACCP, Sanitation SOP, and other food safety initiatives, will produce significant economic and societal benefits by reducing the incidence of food borne illness.

In response to comments, FSIS is finalizing a new requirement in regard to the use of nonfood compounds and proprietary substances in § 416.4(c): "Documentation substantiating the safety of a chemical's use in a food processing environment must be available to FSIS inspection program employees for review." FSIS is not requiring that establishments make available any specific type of documentation since the specific documentation substantiating the safety of a chemical will almost certainly vary as to the nature and use of that chemical. Most, if not all, of the nonfood compounds and proprietary substances used by meat and poultry establishments already are sold with documentation substantiating their safety and efficacy. Pesticides, for example, have labels and documentation demonstrating registration with EPA; chemical sanitizers used on food contact surfaces often are accompanied by documentation, such as letters of guarantee, stating that the compound complies with the relevant FDA regulations in 21 CFR 178.1010. Therefore, FSIS has concluded that the finalized documentation requirement will place no new economic burden on

the manufacturers or consumers of most of these compounds.

FSIS recognizes that certain compounds, such as general cleaners and antislip agents, are not currently regulated or reviewed by any Federal agency and therefore may not be sold with documentation attesting to the safety and efficacy of their use in food processing establishments. Manufacturers will be compelled, therefore, to make such documentation available to their customers, if they are not doing so already. However, FSIS estimates that the economic impact of this requirement on these manufacturers will be minimal. Until the recent discontinuation of the FSIS prior approval program, these manufacturers had been required to supply FSIS with documentation attesting to the safety of their products. Now they will instead make this or similar documentation available to their customers. The paperwork burden of this new documentation requirement is discussed below under the section *Paperwork Requirements*.

As an alternative to the proposed sanitation performance standards, the Agency considered proposing more comprehensive and prescriptive sanitation regulations. The proposed requirements would then have included more prescriptive performance standards than those proposed, such as microbial criteria for recently cleaned and sanitized food contact surfaces; detailed requirements currently contained in Agency guidance materials, such as an ambient temperature requirement for rooms in which certain types of food processing are conducted; and a list of specific regulatory prohibitions, again largely drawn from existing regulatory and guidance material.

The Agency did not choose this more detailed and prescriptive alternative, because of the burden it would place on industry. The Agency believes that a proliferation of prescriptive standards applicable to the establishment environment or its features, like ambient temperature or microbial characteristics of cleaned equipment, would not be a useful addition to the sanitation performance standards.

FSIS already has established performance standards applicable to meat and poultry products, such as the Salmonella performance standard for raw carcasses and ground product established in the Pathogen Reduction/HACCP final regulation and the zero tolerance standard for fecal material on raw carcasses. Achieving these product-based performance standards depends on an establishment doing a number of

things correctly, including meeting the sanitation performance standards set forth in part 416.1 through 416.6. FSIS has concluded that because there are many methods and means through which establishments can ensure that products are not adulterated, FSIS will not prescribe exactly which methods, procedures, or means must be used.

Finally, on the issue of whether there should be a list of specific prohibited practices retained in the regulations, FSIS has concluded that this is not necessary and that such a list could be misleading. Most of the prohibited practices that are mentioned in the current sanitation regulations represent only one or a small fraction of the ways in which establishments could fail to meet a performance standard. For example, using burlap as a wrap by directly applying it to the surface of meat is only one of the means by which an establishment could be failing to prevent product adulteration. The Agency believes that a partial or outdated list of regulatory prohibitions in the regulations could be misconstrued to mean that anything not on the list is not prohibited. FSIS has concluded that it is better regulatory policy to communicate to industry examples of the types of practices that could result in insanitary conditions in guidance material.

The other alternative available to FSIS was to maintain the previous sanitation requirements. However, as explained in detail above, these requirements were to an extent inconsistent with the principles of HACCP, needlessly reduced flexibility in accomplishing good sanitation, and may have substantially impeded innovation.

Executive Order 12898

Pursuant to Executive Order 12898 (59 FR 7629, February 16, 1994), "Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations," FSIS has considered potential impacts of this final rule on environmental and health conditions in low-income and minority communities.

This rule consolidates the sanitation regulations for official meat and poultry establishments into a single part, eliminates unnecessary differences between the meat and poultry sanitation requirements, and converts many highly prescriptive requirements to sanitation performance standards. As explained in the economic impact analysis above, the new regulations should generally benefit FSIS, the regulated industry, and consumers. The regulations do not require or compel meat or poultry establishments to relocate or

significantly alter their operations in ways that could adversely affect the public health or environment in low-income and minority communities. Further, this rule does not exclude any persons or populations from participation in FSIS programs, deny any persons or populations the benefits of FSIS programs, or subject any persons or populations to discrimination because of their race, color, or national origin.

Executive Order 12988

This final rule has been reviewed under Executive Order 12988, Civil Justice Reform. States and local jurisdictions are preempted by the Federal Meat Inspection Act (FMIA) and the Poultry Products Inspection Act (PPIA) from imposing any marking, labeling, packaging, or ingredient requirements on federally inspected meat and poultry products that are in addition to, or different than, those imposed under the FMIA and the PPIA. States and local jurisdictions may, however, exercise concurrent jurisdiction over meat and poultry products that are within their jurisdiction and outside official establishments for the purpose of preventing the distribution of meat and poultry products that are misbranded or adulterated under the FMIA and PPIA, or, in the case of imported articles, that are not at such an establishment, after their entry into the United States.

This rule is not intended to have retroactive effect.

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

Paperwork Requirements

Abstract: FSIS has reviewed the paperwork and recordkeeping requirements in this proposed rule in accordance with the Paperwork Reduction Act.

Under the previous regulations, if meat and poultry establishments were cited for rodent or vermin infestation, FSIS required them to develop a written corrective action report. The Office of Management and Budget (OMB) under control number O583-0082, "Meat and Poultry Inspection and Application for Inspection," had approved 351 burden hours for this activity.

This final rule eliminates the requirement that establishments develop rodent and vermin infestation corrective action reports. Corrective action measures for rodent and vermin infestation will be part of establishments' Sanitation SOP's. The burden hours reported for Sanitation SOP's includes the development of these corrective actions. Therefore, FSIS is requesting OMB to remove the 351 burden hours approved for the development of rodent and vermin infestation corrective action reports.

Also, § 416.2(g)(1) requires that establishments, upon request, make available to FSIS "water reports issued under the authority of the State or local health agency certifying or attesting to the quality of the water supply." This paperwork collection requirement already is in place under the current regulations and is approved under OMB control number O583-0082, "Meat and Poultry Inspection and Application for Inspection."

Finally, the Agency is adding a new information collection requirement in § 416.4(c): "Documentation substantiating the safety of a chemical's use in a food processing environment must be available to FSIS inspection program employees for review." FSIS is not requiring that establishments make available any specific type of documentation since documentation substantiating the safety of a chemical varies as to the nature and use of that chemical. Further, most, if not all, of the nonfood compounds and proprietary substances used by meat and poultry establishments already are sold with documentation substantiating their safety and efficacy. Nevertheless, manufacturers will be compelled to make such documentation available to their customers, if they are not doing so already. FSIS estimates that the impact of this requirement on these manufacturers will be quite minimal, since until the recent discontinuation of the FSIS prior approval program, these manufacturers had been required to supply FSIS with documentation attesting to the safety of their products.

FSIS estimates that there are approximately 8,000 chemical manufacturers selling about 115,000 compound and substances to official meat and poultry establishments. There are approximately 6,186 official meat and poultry establishments. The following calculations were based upon the assumption that each chemical manufacturer sells, and each official establishment uses, an average of 14 compounds and substances.

Estimate of Burden: The public reporting burden for this collection of

information is estimated to average 30 minutes for chemical manufacturers to provide documentation and 10 minutes for establishments to file the information.

Respondents: Meat and poultry establishments and chemical manufacturers.

Estimated Number of Respondents: 14,186.

Estimated Number of Responses per Respondent: 14.

Estimated Total Annual Burden on Respondents: 132,403 hours.

Copies of this information collection assessment can be obtained from Lee Puricelli, Paperwork Specialist, Food Safety and Inspection Service, USDA, Cotton Annex Building, Room 109, Washington, DC 20250.

Comments are invited on: (a) Whether the 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) or the Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20253.

Comments are requested by December 20, 1999. To be most effective, comments should be sent to OMB within 30 days of the publication date of this final rule.

List of Subjects

9 CFR Parts 303, 304, and 307

Meat inspection, Reporting and record keeping requirements.

9 CFR Part 308, 312, 314, 327,, 331, and 350

Meat inspection.

9 CFR Part 381

Poultry and poultry products inspection, Reporting and record keeping requirements.

9 CFR Part 416

Sanitation.

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

PART 303—EXEMPTIONS

1. The authority citation for part 303 continues to read as follows:

Authority: 21 U.S.C. 601–695; 7 CFR 2.17, 2.55.

2. Section 303.1 is amended by revising paragraph (a)(2)(i) to read as follows:

§ 303.1 Exemptions.

(a) * * *

(2) * * *

(i) Establishments that conduct custom operations must be maintained and operated in accordance with the provisions of §§ 416.1 through 416.6, except for: § 416.2(g) (2) through (6) of this chapter, regarding water reuse and any provisions of part 416 of this chapter relating to inspection or supervision of specified activities or other action by a Program employee. If custom operations are conducted in an official establishment, however, all of the provisions of Part 416 of this chapter of shall apply to those operations.

* * * * *

§ 303.1 [Amended]

3. In § 303.1, paragraph (c), the second sentence is amended by removing the phrase “in part 308 of this subchapter, except §§ 308.1, 308.2, and 308.15” and adding the phrase “in part 416, §§ 416.1 through 416.5 of this chapter” in its place.

PART 304—APPLICATION FOR INSPECTION; GRANT OR REFUSAL OF INSPECTION

4. The authority citation for part 304 continues to read as follows:

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

§ 304.2 [Amended]

5. In § 304.2(b), the first sentence is amended by removing the phrase “308” and adding the phrase “Part 416, §§ 416.1 through 416.6 of this chapter” in its place.

Part 307—FACILITIES FOR INSPECTION

6. The authority citation for part 307 continues to read as follows:

Authority: 7 U.S.C 394, 21 U.S.C. 601–695; 7 CFR 2.17, 2.55.

7. Section 307.2 is amended by revising paragraph (l) to read as follows:

§ 307.2 Other facilities and conditions to be provided by the establishment.

* * * * *

(l) Sanitary facilities and accommodations as prescribed by §§ 416.2(c), (d), (e), (f), and (h) of this chapter.

* * * * *

8. Section 307.3 is revised to read as follows:

§ 307.3 Inspectors to furnish and maintain implements in a sanitary condition.

Inspectors shall furnish their own work clothing and implements, such as flashlights and triers, for conducting inspection and shall maintain their implements in sanitary condition as prescribed by § 416.3(a) of this chapter.

9. Section 307.7, paragraph (a), is revised to read as follows:

§ 307.7 Safety requirements for electrical stimulating (EST) equipment.

(a) *General.* Electrical stimulating (EST) equipment is equipment that provides electric shock treatment to carcasses for the purpose of accelerating rigor mortis of facilitating blood removal. These provisions do not apply to electrical equipment used to stun and/or slaughter animals or to facilitate hide removal. Electrical stimulating equipment consists of two separate pieces—the control system and the applicator. The EST control system contains the circuitry to generate pulsed DC or AC voltage for stimulation and is separate from the equipment used to apply the voltage to the carcass. The voltage is applied by inserting a probe that penetrates the carcass or is inserted in the rectum, placing a clamp in the nose, a carcass rub-bar, a conveyor with energized surfaces traveling with the carcass, or any other acceptable method.

* * * * *

PART 308—[REMOVED AND RESERVED]

10–11. Remove and reserve part 308, consisting of §§ 308.1–308.16.

PART 312—OFFICIAL MARKS, DEVICES AND CERTIFICATES

12. The authority citation for part 312 continues to read as follows:

Authority: 21 U.S.C. 601–695; 7 CFR 2.17, 2.55.

13. In § 312.6, paragraphs (a), and introductory text and (a)(3) are revised to read as follows:

§ 312.6 Official marks and devices in connection with post-mortem inspection and identification of adulterated products and insanitary equipment and facilities.

(a) The official marks required by parts 310 and 416 of this chapter for use in post-mortem inspection and identification of adulterated products and insanitary equipment and facilities are:

* * * * *

(3) The "U.S. Rejected" mark which is used to identify insanitary buildings, rooms, or equipment as prescribed in part 416, § 416 of this chapter and is applied by means of a paper tag (Form MP-35) bearing the legend "U.S. Rejected."

* * * * *

PART 314—HANDLING AND DISPOSAL OF CONDEMNED OR OTHER INEDIBLE PRODUCTS AT OFFICIAL ESTABLISHMENTS

14. The authority citation for part 314 continues to read as follows:

Authority: 21 U.S.C. 601-695; 7 CFR 2.17, 2.55.

15. Section 314.2 is revised to read as follows:

§ 314.2 Tanking and other facilities for inedible products to be separate from edible product facilities.

All tanks and equipment used for rendering, otherwise preparing, or storing inedible products must be in rooms or compartments separate from those used for preparing or storing edible products. There may be a connection between rooms or compartments containing inedible products and those containing edible products as long as it does not cause the adulteration of edible product or create insanitary conditions.

16. Section 314.4 is revised to read as follows:

§ 314.4 Suppression of odors in preparing inedible products.

Tanks, fertilizer driers, and other equipment used in the preparation of inedible product must be operated in a manner that will suppress odors incident to such preparation which could adulterate edible product or create insanitary conditions.

PART 327—IMPORTED PRODUCTS

17. The authority citation for part 327 continues to read as follows:

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

§ 327.6 [Amended]

18. In § 327.6, paragraph (e) is amended by removing the phrase "

308.3, 308.4, 308.5, 308.6, 308.7, 308.8, 308.9, 308.11, 308.13, 308.14, 308.15" and adding the phrase "416.1 through 416.6 of this chapter" in its place.

PART 331—SPECIAL PROVISIONS FOR DESIGNATED STATES AND TERRITORIES; AND FOR DESIGNATION OF ESTABLISHMENTS WHICH ENDANGER PUBLIC HEALTH AND FOR SUCH DESIGNATED ESTABLISHMENTS

19. The authority citation for part 331 continues to read as follows:

Authority: 21 U.S.C. 601-695; 7 CFR 2.17, 2.55.

20. Section 331.3, paragraph (c), is revised to read as follows:

§ 331.3 States designated under paragraph § 301(c) of the Act; application of regulations.

* * * * *

(c) Sections 416.2(c), (d), (e), (f), and (h) of this chapter shall apply to such establishments.

* * * * *

PART 350—SPECIAL SERVICES RELATING TO MEAT AND OTHER PRODUCTS

21. The authority citation for part 350 continues to read as follows:

Authority: 21 U.S.C. 1622, 1624; 7 CFR 2.17, 2.55.

§ 350.3 [Amended]

22. Section 350.3, paragraph (a)(2) is amended by removing the phrase "part 308" and adding the phrase "part 416, §§ 416.1 through 416.6 of this chapter" in its place.

PART 362—VOLUNTARY POULTRY INSPECTION REGULATIONS

23. The authority citation for part 362 continues to read as follows:

Authority: 21 U.S.C. 1622, 1624; 7 CFR 2.17 (g) and (i), 2.55.

§ 362.2 [Amended]

24. The second sentence of § 362.2(a) is amended by removing the phrase "subchapter C of this chapter" and adding the phrase "subchapter A and subchapter E, part 416, §§ 416.1 through 416.6 of this chapter" in its place.

PART 381—POULTRY PRODUCTS INSPECTION REGULATIONS

25. The authority citation for part 381 continues to read as follows:

Authority: 7 U.S.C. 138f; 7 U.S.C. 450, 21 U.S.C. 451-470; 7 U.S.C. 2.18, 2.53.

26. In § 381.1, paragraph (b)(39) is removed.

27. Section 381.36, is amended as follows:

a. Paragraph (c)(1)(iv) is revised,
b. Paragraph (c)(1)(vi), is amended by removing the phrase "complying with § 381.53(g)(4) of this part",

c. Paragraphs (c)(1)(vii), (viii) and (x) are revised,

d. In Paragraph (d)(1)(vi), the first sentence is amended by removing the phrase "complying with § 381.53(g)(4) of this part",

e. In paragraph (d)(1)(viii), the first sentence is amended by removing the phrase ", notwithstanding the requirement of § 381.52(b)",

f. Paragraph (d)(1)(xi) is revised,

g. In paragraph (e)(1)(v), the first sentence is amended by removing the phrase "complying with § 381.53(g)(4)", and

h. Paragraph (e)(1)(ix) is revised.

These revisions to § 381.36 read as follows:

§ 381.36 Facilities required.

* * * * *

(c) * * *

(1) * * *

(iv) Each inspector's station shall have a platform that is slip-resistant and can be safely accessed by the inspector. The platform shall be designed so that it can be easily and rapidly adjusted for a minimum of 14 inches vertically while standing on the platform. The platform shall be a minimum length of 4 feet and have a minimum width of 2 feet; the platform shall be designed with a 42-inch high rail on the back side and with 1/2-inch foot bumpers on both sides and front to allow safe working conditions. The platform must have a safe lift mechanism and be large enough for the inspector to sit on a stool and to change stations during breaks or station rotation.

* * * * *

(vii) A minimum of 200-footcandles of shadow-free lighting with a minimum color rendering index value of 85 where the birds are inspected to facilitate inspection.

(viii) Online handrinsing facilities with a continuous flow of water must be provided for and within easy reach of each inspector and each establishment helper. The hand-contact element must be rinsed automatically with a sufficient volume of water to remove all fat, tissue, debris, and other extraneous material from the hand contact element after each use. Both hot and cold running water shall be available at each inspection station on the eviscerating line and shall be delivered through a suitable mixing device controlled by the inspector. Alternatively, water for hand washing shall be delivered to such

inspection stations at a minimum temperature of 65 degrees F.

(ix) * * *

(x) Each inspection station shall be provided with receptacles for condemned carcasses and parts. Such receptacles shall comply with the performance standards in § 416.3(c) of this chapter.

* * * * *

(d) * * *

(1) * * *

(xi) Each inspection station shall be provided with receptacle for condemned carcasses and parts. Such receptacles shall comply with the performance standards in § 416.3(c) of this chapter.

* * * * *

(e) * * *

(1) * * *

(ix) Each inspection station shall be provided with receptacles for condemned carcasses and parts. Such receptacles shall comply with the performance standards in § 416.3(c) of this chapter.

* * * * *

§§ 381.45–381.61 (Subpart H)—Sanitation [Removed and reserved]

28. Remove and reserve Subpart H, consisting of §§ 381.45–381.61.

29. Section 381.99 is revised to read as follows:

§ 381.99 Official retention and rejection tags.

The official marks for use in post-mortem inspection and identification of adulterated products, insanitary equipment and facilities are:

(a) A paper tag (a portion of Form MP-35) bearing the legend "U.S. Retained" for use on poultry or poultry products under this section.

(b) A paper tag (another portion of Form C&MS 510) bearing the legend "U.S. Rejected" for use on equipment, utensils, rooms and compartments under this section.

PART 416—SANITATION

30. The authority citation for part 416 continues to read as follows:

Authority: 21 U.S.C. 451–470, 601–680; 7 U.S.C. 450; 7 CFR 2.18, 2.53.

31. Part 416 is amended by adding new §§ 416.1 through 416.6, as follows:

§ 416.1 General rules.

Each official establishment must be operated and maintained in a manner sufficient to prevent the creation of insanitary conditions and to ensure that product is not adulterated.

§ 416.2 Establishment grounds and facilities.

(a) *Grounds and pest control.* The grounds about an establishment must be maintained to prevent conditions that could lead to insanitary conditions, adulteration of product, or interfere with inspection by FSIS program employees. Establishments must have in place a pest management program to prevent the harborage and breeding of pests on the grounds and within establishment facilities. Pest control substances used must be safe and effective under the conditions of use and not be applied or stored in a manner that will result in the adulteration of product or the creation of insanitary conditions.

(b) *Construction.* (1) Establishment buildings, including their structures, rooms, and compartments must be of sound construction, be kept in good repair, and be of sufficient size to allow for processing, handling, and storage of product in a manner that does not result in product adulteration or the creation of insanitary conditions.

(2) Walls, floors, and ceilings within establishments must be built of durable materials impervious to moisture and be cleaned and sanitized as necessary to prevent adulteration of product or the creation of insanitary conditions.

(3) Walls, floors, ceilings, doors, windows, and other outside openings must be constructed and maintained to prevent the entrance of vermin, such as flies, rats, and mice.

(4) Rooms or compartments in which edible product is processed, handled, or stored must be separate and distinct from rooms or compartments in which inedible product is processed, handled, or stored, to the extent necessary to prevent product adulteration and the creation of insanitary conditions.

(c) *Light.* Lighting of good quality and sufficient intensity to ensure that sanitary conditions are maintained and that product is not adulterated must be provided in areas where food is processed, handled, stored, or examined; where equipment and utensils are cleaned; and in hand-washing areas, dressing and locker rooms, and toilets.

(d) *Ventilation.* Ventilation adequate to control odors, vapors, and condensation to the extent necessary to prevent adulteration of product and the creation of insanitary conditions must be provided.

(e) *Plumbing.* Plumbing systems must be installed and maintained to:

(1) Carry sufficient quantities of water to required locations throughout the establishment;

(2) Properly convey sewage and liquid disposable waste from the establishment;

(3) Prevent adulteration of product, water supplies, equipment, and utensils and prevent the creation of insanitary conditions throughout the establishment;

(4) Provide adequate floor drainage in all areas where floors are subject to flooding-type cleaning or where normal operations release or discharge water or other liquid waste on the floor;

(5) Prevent back-flow conditions in and cross-connection between piping systems that discharge waste water or sewage and piping systems that carry water for product manufacturing; and

(6) Prevent the backup of sewer gases.

(f) *Sewage disposal.* Sewage must be disposed into a sewage system separate from all other drainage lines or disposed of through other means sufficient to prevent backup of sewage into areas where product is processed, handled, or stored. When the sewage disposal system is a private system requiring approval by a State or local health authority, the establishment must furnish FSIS with the letter of approval from that authority upon request.

(g) *Water supply and water, ice, and solution reuse.* (1) A supply of running water that complies with the National Primary Drinking Water regulations (40 CFR part 141), at a suitable temperature and under pressure as needed, must be provided in all areas where required (for processing product, for cleaning rooms and equipment, utensils, and packaging materials, for employee sanitary facilities, etc.). If an establishment uses a municipal water supply, it must make available to FSIS, upon request, a water report, issued under the authority of the State or local health agency, certifying or attesting to the potability of the water supply. If an establishment uses a private well for its water supply, it must make available to FSIS, upon request, documentation certifying the potability of the water supply that has been renewed at least semi-annually.

(2) Water, ice, and solutions (such as brine, liquid smoke, or propylene glycol) used to chill or cook ready-to-eat product may be reused for the same purpose, provided that they are maintained free of pathogenic organisms and fecal coliform organisms and that other physical, chemical, and microbiological contamination have been reduced to prevent adulteration of product.

(3) Water, ice, and solutions used to chill or wash raw product may be reused for the same purpose provided that measures are taken to reduce physical, chemical, and microbiological

contamination so as to prevent contamination or adulteration of product. Reuse that which has come into contact with raw product may not be used on ready-to-eat product.

(4) Reconditioned water that has never contained human waste and that has been treated by an onsite advanced wastewater treatment facility may be used on raw product, except in product formulation, and throughout the facility in edible and inedible production areas, provided that measures are taken to ensure that this water meets the criteria prescribed in paragraph (g)(1) of this section. Product, facilities, equipment, and utensils coming in contact with this water must undergo a separate final rinse with non-reconditioned water that meets the criteria prescribed in paragraph (g)(1) of this section.

(5) Any water that has never contained human waste and that is free of pathogenic organisms may be used in edible and inedible product areas, provided it does not contact edible product. For example, such reuse water may be used to move heavy solids, to flush the bottom of open evisceration troughs, or to wash antemortem areas, livestock pens, trucks, poultry cages, picker aprons, picking room floors, and similar areas within the establishment.

(6) Water that does not meet the use conditions of paragraphs (g)(1) through (g)(5) of this section may not be used in areas where edible product is handled or prepared or in any manner that would allow it to adulterate edible product or create insanitary conditions.

(h) *Dressing rooms, lavatories, and toilets.* (1) Dressing rooms, toilet rooms, and urinals must be sufficient in number, ample in size, conveniently located, and maintained in a sanitary condition and in good repair at all times to ensure cleanliness of all persons handling any product. They must be separate from the rooms and compartments in which products are processed, stored, or handled.

(2) Lavatories with running hot and cold water, soap, and towels, must be placed in or near toilet and urinal rooms and at such other places in the establishment as necessary to ensure cleanliness of all persons handling any product.

(3) Refuse receptacles must be constructed and maintained in a manner that protects against the creation of insanitary conditions and the adulteration of product.

§ 416.3 Equipment and utensils.

(a) Equipment and utensils used for processing or otherwise handling edible product or ingredients must be of such material and construction to facilitate

thorough cleaning and to ensure that their use will not cause the adulteration of product during processing, handling, or storage. Equipment and utensils must be maintained in sanitary condition so as not to adulterate product.

(b) Equipment and utensils must not be constructed, located, or operated in a manner that prevents FSIS inspection program employees from inspecting the equipment or utensils to determine whether they are in sanitary condition.

(c) Receptacles used for storing inedible material must be of such material and construction that their use will not result in the adulteration of any edible product or in the creation of insanitary conditions. Such receptacles must not be used for storing any edible product and must bear conspicuous and distinctive marking to identify permitted uses.

§ 416.4 Sanitary operations.

(a) All food-contact surfaces, including food-contact surfaces of utensils and equipment, must be cleaned and sanitized as frequently as necessary to prevent the creation of insanitary conditions and the adulteration of product.

(b) Non-food-contact surfaces of facilities, equipment, and utensils used in the operation of the establishment must be cleaned and sanitized as frequently as necessary to prevent the creation of insanitary conditions and the adulteration of product.

(c) Cleaning compounds, sanitizing agents, processing aids, and other chemicals used by an establishment must be safe and effective under the conditions of use. Such chemicals must be used, handled, and stored in a manner that will not adulterate product or create insanitary conditions. Documentation substantiating the safety of a chemical's use in a food processing environment must be available to FSIS inspection program employees for review.

(d) Product must be protected from adulteration during processing, handling, storage, loading, and unloading at and during transportation from official establishments.

§ 416.5 Employee hygiene.

(a) *Cleanliness.* All persons working in contact with product, food-contact surfaces, and product-packaging materials must adhere to hygienic practices while on duty to prevent adulteration of product and the creation of insanitary conditions.

(b) *Clothing.* Aprons, frocks, and other outer clothing worn by persons who handle product must be of material that is disposable or readily cleaned. Clean

garments must be worn at the start of each working day and garments must be changed during the day as often as necessary to prevent adulteration of product and the creation of insanitary conditions.

(c) *Disease control.* Any person who has or appears to have an infectious disease, open lesion, including boils, sores, or infected wounds, or any other abnormal source of microbial contamination, must be excluded from any operations which could result in product adulteration and the creation of insanitary conditions until the condition is corrected.

§ 416.6 Tagging insanitary equipment, utensils, rooms or compartments.

When an FSIS program employee finds that any equipment, utensil, room, or compartment at an official establishment is insanitary or that its use could cause the adulteration of product, he will attach to it a "U.S. Rejected" tag. Equipment, utensils, rooms, or compartments so tagged cannot be used until made acceptable. Only an FSIS program employee may remove a "U.S. Rejected" tag.

Done in Washington, DC on October 6, 1999.

Thomas J. Billy,
Administrator.

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DEPARTMENT OF ENERGY

10 CFR Part 600

RIN 1991-AB53

Assistance Regulations; Technical and Administrative Amendments

AGENCY: Department of Energy.

ACTION: Final rule.

SUMMARY: The Department of Energy (DOE) is amending the Department of Energy Assistance Regulations to make technical and administrative changes. These changes include: revising a definition for clarity, updating titles and addresses, changing an approval authority, eliminating provisions that contain internal procedures for DOE officials, removing obsolete coverage, eliminating redundant coverage, and correcting a typographical error. These changes are technical and administrative in nature and have no significant impact on non-agency persons, such as recipients or applicants. The uniform administrative requirements for grants and cooperative agreements with institutions of higher