DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

9 CFR Parts 303, 308, 381, and 416

[Docket No. 96–037P]

Sanitation Requirements for Official Meat and Poultry Establishments

AGENCY: Food Safety and Inspection Service.

ACTION: Proposed rule.

SUMMARY: The Food Safety and Inspection Service (FSIS) is proposing to revise its regulatory requirements concerning sanitation in official meat and poultry establishments. Specifically, FSIS is proposing to consolidate the sanitation regulations into a single part applicable to both meat and poultry establishments, eliminate unnecessary differences between the meat and poultry sanitation requirements, and convert many of the highly prescriptive requirements to performance standards.

DATES: Comments must be received on or before October 24, 1997.

ADDRESSES: Submit one original and two copies of written comments to FSIS Docket Clerk, Docket #96–037P, U.S. Department of Agriculture, Food Safety and Inspection Service, Room 102, Cotton Annex, 300 12th St. SW, Washington, DC 20250–3700. All comments submitted in response to this proposal will be available for public inspection in the Docket Clerk's Office between 8:30 a.m. and 4:30 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Patricia F. Stolfa, Assistant Deputy Administrator, Regulations and Inspection Methods, Food Safety and Inspection Service, U.S. Department of Agriculture, (202) 205–0699.

SUPPLEMENTARY INFORMATION:

Background

On December 29, 1995, FSIS announced that it had begun a comprehensive review of its regulatory procedures and requirements to determine which were still needed and which ought to be modified, streamlined, or eliminated (FSIS Docket No. 95–008A, ''FSIS Agenda for Change: Regulatory Review''; 60 FR 67469–67474). This ongoing review is an integral part of the FSIS initiative to improve the safety of meat and poultry products by modernizing the Agency's system of food safety regulation. Further, this review and the resulting regulatory revisions reflect the Agency's commitment to achieving the goals of the President's Reinvention of Government initiative: to have fewer, clearer, and more user-friendly regulations.

In the course of its review, FSIS identified the need to revise its sanitation requirements for official meat and poultry establishments. A number of the existing sanitation requirements are difficult to understand, redundant, or outdated. Also, there are unnecessary differences between the sanitation requirements for meat and poultry establishments. Further, some of the existing sanitation requirements are no longer needed in light of the Agency's recently finalized Hazard Analysis and Critical Control Point (HACCP) and Sanitation Standard Operating Procedure (SOP) requirements. Finally, some of the current sanitation regulations are unnecessarily prescriptive, may impede innovation, and blur the distinction between establishment and inspector responsibilities for maintaining sanitary conditions.

Therefore, FSIS is proposing in this document to revise its sanitation regulations. FSIS is proposing to clarify and consolidate the sanitation requirements for meat and poultry establishments, eliminate unnecessary differences between those regulations, make the existing sanitation regulations more compatible with the HACCP and sanitation SOP requirements, and convert prescriptive requirements to performance standards.

Sanitation

Proper and effective sanitation practices and conditions are an essential part of all safe food manufacturing processes. Insanitary facilities and equipment and poor food handling and personal hygiene practices by employees create an environment in which pathogens and other food safety hazards can contaminate and adulterate products. Consequently, proper sanitation is a fundamental requirement under both the Federal Meat Inspection Act (FMIA) and the Poultry Products Inspection Act (PPIA).

The FMIA and the PPIA authorize the Secretary of Agriculture to promulgate regulations regarding sanitary practices in official establishments. Meat and poultry product produced, packed, or held under insanitary conditions, where they may have become contaminated with filth or may have been rendered injurious to health, are deemed adulterated. Furthermore, if meat and poultry products consist in whole or in part of any filthy, putrid, or decomposed substance, or for any other reason are unsound, unhealthy, unwholesome, or otherwise unfit for human food, they are deemed to be adulterated.

While sanitation has improved greatly throughout the meat and poultry industries over the years, many individual establishments still have difficulty maintaining the required sanitary conditions. In fact, poor sanitation is the most frequently observed problem in meat and poultry establishments. Between September 1993 and February 1995, the Food Safety and Inspection Service (FSIS) conducted unannounced reviews of 1,014 federally inspected meat and poultry establishments, observing operations and noting deficiencies. More than 60 percent of all deficiencies documented by these reviews involved establishment sanitation. Data collected through FSIS's Performance Based Inspection System similarly documents that sanitation is the most frequent deficiency noted by inspection personnel in routine establishment visits.

FSIS inspectors examine the conditions under which meat and poultry products are produced at official establishments. Until the recent implementation of Sanitation Standard Operating Procedure (SOP's) requirements, FSIS enforced sanitation requirements primarily through a combination of prescriptive sanitation regulations, detailed guidance materials, and direct, hands-on involvement by inspectors in day-to-day pre-operational and operational sanitation procedures in establishments. This system achieved sanitation goals on a daily basis in individual establishments, but encouraged establishments to shift accountability for sanitation to the FSIS inspector.

To make establishments appropriately accountable for food safety, including the maintenance of sanitary conditions, the Agency recently finalized major changes to the meat and poultry regulations (FSIS Docket No. 93–016F, ''Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) Systems''; 61 FR 38806). Under these new regulations, every official meat and poultry establishment will be required to develop and implement HACCP, a science-based process control system designed to improve the safety of meat and poultry products. Establishments will be responsible for developing and implementing HACCP plans incorporating the controls necessary and appropriate to produce safe meat and poultry products. At the same time, HACCP is a flexible system that enables establishments to tailor their control

systems to the individual needs of their particular plants and processes.

FSIS also has required all official establishments to develop, implement, and maintain written Sanitation Standard Operating Procedures (SOP's). Sanitation SOP's must describe all procedures an official establishment conducts daily, before and during operations, to prevent direct contamination or adulteration of product(s). The format and content of Sanitation SOP's are not specified in the final regulations; so, as under HACCP, each meat and poultry establishment must analyze its own operations and identify possible sources of direct contamination or adulteration that need to be addressed in its Sanitation SOP's.

Effective establishment sanitation through the development and implementation of written Sanitation SOP's is essential to improve food safety and for the successful implementation of HACCP. Establishment compliance with the Sanitation SOP requirements will not only substantially minimize the risk of direct product contamination or adulteration, but also will improve the utilization of FSIS inspection resources by refocusing sanitation inspection on the oversight of establishment prevention and correction of conditions that cause direct product contamination or adulteration.

Performance Standards

For the HACCP and SOP requirements to be successful, FSIS believes it must reduce its reliance on detailed, command-and-control regulations. Command-and-control regulations prescribe step-by-step procedures establishments must use toward the goal of safe meat and poultry products. Such regulations can be incompatible with HACCP and the SOP requirements to the extent that they deprive establishments of the flexibility to innovate and deter them from assuming their full share of responsibility for food safety.

FSIS is engaged in a thorough review of its current regulations and, where possible, will eliminate overly prescriptive regulations and replace them with regulations that embody performance standards. Such regulations establish requirements in terms of the objective to be achieved. They specify the ends, but do not detail the means to achieve those ends. Adopting performance standards for meat and poultry products would allow establishments to develop and employ innovative and more effective sanitation or processing procedures customized to the nature and volume of their production.

FSIS also believes that the existing sanitation regulations may interfere with efforts to implement the Sanitation SOP requirements of the final Pathogen Reduction/HACCP regulation. Commenters on the proposed HACCP rule expressed their concerns about the layering of new Sanitation-SOP requirements over existing regulations. These concerns have merit. The Agency indicated in the Preamble to the Final Pathogen Reduction/HACCP regulation that ''its existing sanitation regulations contain some detailed and prescriptive provisions and that some of these regulations may be outmoded and no longer needed in light of the Agency's effort to clarify that good sanitation is the responsibility of each establishment.'' The Agency also stated that it ''* * * will continue to review, re-evaluate, and revise, as necessary , all current sanitation regulations, along with related issuances and sanitation inspection procedures, to simplify and streamline them and make them more compatible with Sanitation SOP requirements.'' In addition, at recent implementation conferences held in Washington and at six cities across the country, participants raised questions about the relationship between existing requirements and the new Sanitation SOP's.

Accordingly, FSIS is proposing to convert all of its sanitation requirements to performance standards. The proposed performance standards regarding the general sanitary conditions of an establishment would provide meat and poultry establishments with the maximum possible flexibility to innovate in facility design, construction, and operations, and allow them to tailor Sanitation SOP's to their particular circumstances. Furthermore, many of the current sanitation regulations requiring that equipment or operations be approved prior to use (such as trap and vent approval requirements in §§ 308.3(c) and 381.49(c)(1)) would be eliminated.

Explanation of the Proposed Sanitation Performance Standards

FSIS is proposing to replace all of the current sanitation regulations in 9 CFR Parts 308 and 381, Subpart H, with a single set of consolidated performance standards in new Sections 416.1 through 416.6. This is a comprehensive revision; the relationship between the current requirements and the proposed performance standards is complex. Therefore, FSIS has developed the following chart to illustrate how current sanitation requirements correspond to the proposed performance-based regulations. A description of the requirements(s), along with regulatory citations for the current and proposed regulations are given. Notably, FSIS is proposing to eliminate many of the current prescriptive sanitation requirements and replace them with a single performance standard for general sanitation. Following the chart is a more detailed explanation of the proposed revisions.

Subject	Proposed regulation	Current regulation(s)
General sanitation	§ 416.1	§§ 308.3(a), (g), 308.7, 381.45, 381.57; and all other provisions not listed below.
Establishment grounds and pest management	§ 416.2(a)	§§ 308.3 (h), 308.13, 381.49(b), 381.56(a), 381.59, and 381.60.
Establishment Construction	§ 416.2(b)	§§ 308.3(e), (f), (h), 381.46, 381.47 and 381.48.
Light	§ 416.2(c)	§§ 308.3(b), 381.52 (a) and (b).
Ventilation	§ 416.2(d)	§§ 308.3 (b) and (g), 308.8(b), 381.52 (a) and (c).
Plumbing	§ 416.2(e)	§§ 308.3(c), 381.47(b), 381.49 (a), (b) and (c).
Sewage disposal	§ 416.2(f)	§§ 308.4(c) and 381.49(c)(4).
Water supply and reuse	§ 416.2(g)	§§ 308.3(d), 381.50 and 381.53(k).
Ice and solution reuse	§ 416.2(h)	FSIS policy (explained below).
Dressing rooms, lavatories, and toilets	§ 416.2(i)	§§ 308.4 (a), (b), (d), 381.47(h), 381.51 and 381.53(c).
Equipment and utensils	§ 416.3	§§ 308.5 (a) and (g), 308.6, 308.8(c), 308.16, 381.53(a)(1), (f), (g), (h), (i), (j), (k), (l), (m), 381.54, 381.55 and 381.56(b).
Food-contact surface cleaning and sanitation	§ 416.4(a)	§§ 308.3(d)(4), 308.7, 308.8(a), 381.57 and 381.58.
Non-food-contact surface cleaning and sanitation	§ 416.4(b)	§§ 308.3(d)(4), 308.7, 308.8(a), 381.57 and 381.58.
Cleaning compounds and sanitizers	§ 416.4(c)	§ 381.60.

Subject	Proposed regulation	Current regulation(s)
Operational sanitation	§ 416.4(d)	§§ 308.3(g), 308.7, 308.8(a), 308.9, 308.10, 308.11, 308.12, 381.47(e), 381.53(d),(e), and (g)(4).
Employee hygiene	§ 416.5(a)	§§ 308.8(c),(e), 381.47(i), 381.51(g), 381.61(b),(c), and (d).
Employee clothing	§ 416.5(b)	§§ 308.8(d) and 381.61(b).
Employee disease	§ 416.5(c)	§§ 308.14 and 381.61(a).
Tagging insanitary equipment, rooms, or compartments	§ 416.6	§§ 308.15 and 381.99.

The Proposed Regulations

This proposed rule would significantly reduce the number of sanitation regulations and consolidate the sanitation requirements for meat and poultry into part 416. This consolidation would not only simplify the sanitation regulations for the user, but also would establish uniform sanitation performance standards that would provide flexibility to establishments while maintaining the rigorous sanitation standards necessary to ensure food safety. The establishment's responsibility for maintaining sanitary conditions and preventing the contamination and adulteration of product would remain unchanged. Further, in consolidating the sanitation regulations, FSIS would eliminate the unnecessary differences between the current sanitation requirements for meat and poultry establishments. In the following, FSIS has provided brief descriptions of the proposed sanitation performance standards accompanied by examples of current regulations they would replace.

General Sanitation—416.1

The current sanitation regulations for meat and poultry require in general that rooms, compartments, and other parts of the official establishment be kept clean and sanitary. New § 416.1 sets out similar requirements, but as a performance standard: ''Each official establishment must be operated and maintained in sanitary manner sufficient to ensure that product is not contaminated, adulterated, or misbranded.'' As discussed above and illustrated by the chart, FSIS is proposing to eliminate many of the current sanitation requirements and replace them with this single performance standard for general sanitation. Examples of current requirements to be replaced by the general standard are: §§ 308.3(i) and 381.59, concerning dogs, cats, and other animals on establishment premises; § 308.8(f), concerning equipment that generates gases or odors in meat establishments; and § 381.47 paragraphs (f) and (g), concerning general sanitary conditions in poultry establishment storage and boiler rooms.

Establishment Grounds and Pest Management—§ 416.2(a)

The current requirements for facility grounds are somewhat prescriptive and inconsistent. For example, § 308.13 requires that outer premises of every official meat establishment be properly paved and drained and kept in clean and orderly condition. However, the counterpart regulation in § 381.56(a) concerning the outside premises of poultry establishments does not require grounds to be paved. The proposed performance standard would eliminate this inconsistency while clarifying and retaining the intent of the current requirements: that grounds be maintained to prevent conditions that could lead to the contamination or adulteration of product or prevent FSIS program employees from performing assigned tasks.

The current requirements for pest control on establishment grounds and within establishments place much of the responsibility for pest control on the Agency. For example, §§ 308.3(h) prohibits the use of poisons for the control of pests in rooms or compartments where unpackaged product is stored or handled, unless approved in the regulations or by the circuit supervisor. Similarly, the regulations in § 381.60 prohibit the use of pest control substances in poultry establishments unless approved by the Administrator.

The proposed performance standard preserves the intent of the current requirement: establishments must implement and maintain an integrated pest control program to eliminate the harborage and breeding of pests on the grounds and within the establishment facilities and must safely and effectively use any interventions, such as pesticides, fumigants, and rodenticides. The proposed standard would eliminate requirements that pest control substances be approved by FSIS prior to use.

Finally, current § 308.3(h) specifically prohibits the use of ''so-called rat viruses'' in meat establishments. FSIS has determined that this prohibition is obsolete and therefore is proposing to delete it.

Establishment Construction—416.2(b)

The requirements concerning construction of poultry establishments are more prescriptive than the comparable requirements for red meat establishments. For example, § 381.47 prescribes numerous, specific requirements for the different areas within a poultry establishment, e.g., refuse rooms, rooms for holding carcasses for further inspection, coolers and freezers, rooms for mechanical deboning of raw poultry, storage and supply rooms, boiler rooms, toilet rooms, and lunch rooms. There are no equally prescriptive requirements in § 308.3 (e), (f), and (h) of the red meat regulations. The proposed performance standards in § 416.2(b), which set forth general requirements for construction applicable to both meat and poultry establishments, would eliminate the existing inconsistency.

The proposed performance standards allow for increased flexibility in regard to establishment construction and maintenance. FSIS recommends that establishments consult the Food and Drug Administration Food Code when designing, building, or maintaining facilities. The Food Code provides useful guidance on how to safely process and prepare food. Although the Food Code is neither federal law nor federal regulation and does not preempt state or local laws, local, state and federal regulators use the FDA Food Code as a model to help develop or update their own food safety rules and to guide the development of a consistent national food regulatory policy. Similarly, establishment operators also should consult the various national building and construction codes and standards. Such materials provide additional guidance concerning the design, construction, and maintenance of sanitary meat and poultry establishments.

Also, in a related document published in the **Federal Register** on May 2, 1996, FSIS proposed to eliminate current

requirements for prior approval by FSIS of establishment drawings, specifications, and equipment prior to their use in official establishments (FSIS Docket No. 95–032P; 61 FR 19587–19590). These amendments, like the proposed sanitation performance standards, would provide the regulated industry with the flexibility to design facilities and equipment in the manner they deem best to maintain the required sanitary environment for food production.

Light—416.2(c)

Currently, the lighting requirements for poultry establishments in § 381.52 prescribe specific light intensities for different areas of the establishment. For example, in paragraph (b) of this section, FSIS requires that all rooms in which poultry is 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) do not contain such specific requirements, stating only that meat establishments must have ''abundant light, of good quality and well distributed.'' Nevertheless, the intent of the current lighting requirements is 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 contamination, adulteration, or misbranding. Proposed § 416.2(c) would codify this intent as a single performance standard applicable to both meat and poultry establishments.

FSIS suggests that establishments consult the guidelines for light intensity contained in the Food Code. The Food Code provides useful guidance regarding necessary light intensity in food processing establishments and, in many cases, an establishment in compliance with the light intensity recommendations in the Food Code would meet the proposed performance standard for lighting.

It is important to note that FSIS is not proposing to remove from the current regulations the light intensity requirements for inspector and reprocessing stations currently set out in §§ 307.2 and 381.36. Our experience indicates that these requirements are still necessary to ensure appropriate conditions for effective inspection. FSIS will reevaluate these requirements, however, and welcomes comment on the current requirements and desirable alternatives.

Ventilation—416.2(d)

Currently both the red meat and poultry regulations addressing ventilation have the same basic requirements: all rooms must be sufficiently ventilated to eliminate objectionable odors and minimize moisture condensation, either of which could contaminate or adulterate product. FSIS is proposing a single performance standard based upon these current requirements and applicable to both meat and poultry establishments.

Plumbing—416.2(e)

The design, installation and maintenance of an adequate plumbing system is a key responsibility of the establishment. Because plumbing systems carry water into establishments and convey water, sewage, and other waste from establishments, problems with plumbing systems can easily cause product contamination or adulteration. The proposed performance standards would establish the essential condition meat and poultry establishments must achieve with their plumbing systems: plumbing systems cannot cause contamination or adulteration of product. Establishments otherwise would be allowed to build plumbing systems suitable to the nature and volume of their production. Further, prior approval requirements in the current plumbing regulations (such as the requirement in § 308.3(c) that circuit supervisors must preapprove the traps and vents installed in drains and gutters) would be eliminated.

FSIS suggests that establishments consult the National Plumbing Code published by the Building Officials & Code Administrators when designing or building a plumbing system. The National Plumbing Code is used by Federal, State, and local governments as a model for their own plumbing requirements. A plumbing system in compliance with the National Plumbing Code in most instances would meet the proposed performance standards for plumbing. Of course, establishments also should consider State and local plumbing system requirements, as well as the circumstances of their production, when designing or building a plumbing system.

Sewage Disposal—416.2(f)

The current requirements for establishment sewage disposal are unnecessarily prescriptive. For example, § 308.4(c) of the regulations requires sewage lines to be separate from all other drainage lines to a point outside the building and not be discharged into grease catch basins; § 381.49(c)(4) is similar, but allows for cross-connection if an automatic backwater check valve is installed. The intent of these requirements is to ensure that sewage does not back up into processing areas. However, this could be accomplished in other ways than through separate drainage lines for sewage and house drains. The proposed performance standard would maintain the requirement that sewage backup be prevented, but would allow the establishment flexibility in determining how best to prevent sewage backup.

As with plumbing, FSIS believes that the National Plumbing Code contains useful guidance for designing and building sewage systems that would satisfy the proposed regulatory requirements.

Water supply and reuse—416.2(g)

The current requirements regarding water supply and reuse in meat and poultry establishments (§§ 308.3(d), 381.50 and 381.53(k)) are similar, though not identical. In general, both meat and poultry establishments are required to have water supplies that are ''ample, clean, and potable, with adequate facilities for its distribution * * * and protection against contamination and pollution.'' Neither meat nor poultry establishments may use nonpotable water in areas where edible product is processed or handled and the use of nonpotable water is limited to specific areas and equipment. Further, in both meat and poultry establishments, potable water lines may not be cross-connected with nonpotable water lines, unless necessary for fire protection and approved by both FSIS and local authorities.

Restrictions on the reuse of water also are similar for both meat and poultry establishments. A few permitted ''reuses'' are specified, one in common for both meat and poultry being the reuse of water to thermally process canned product packed in hermetically sealed containers. Any other water reuse must be for the identical original purpose and must be approved by FSIS.

Finally, both the meat and poultry regulations require that an adequate supply of hot water be available for cleaning rooms and equipment.

There are a few differences between the water supply and reuse regulations for meat and poultry establishments. Under § 308.3(d)(4), meat establishments are required to have an ample supply of water of at least 180° F for cleaning equipment, floors, and walls subject to contamination by diseased meat carcasses. There is no similar requirement for poultry establishments. Because there are

substantive and material questions about the efficacy of the 180° F water for sanitization, the Agency is proposing to eliminate the requirement (see the discussion below under ''*Equipment and Utensils—416.3*'').

Also, under § 381.50(d), FSIS specifically requires that poultry establishment refuse rooms ''be provided with adequate facilities for washing refuse cans and other equipment in the rooms.'' There is no such specific requirement for meat establishments. Finally, under § 381.50(a), FSIS requires that poultry establishments obtain a water report issued under the authority of a State health agency, certifying potability, and furnish this report to FSIS upon request. Although there is no such regulatory requirement for meat establishments, FSIS believes that all meat establishments do obtain such certificates.

Proposed § 416.2(g) consolidates water supply and reuse requirements for both meat and poultry into a single section. The proposed performance standards are based on the current regulations, as well as policies found in FSIS policy documents. Also incorporated are water reuse performance standards generated over time by industry and known to be effective in ensuring that the reuse water does not cause product contamination or adulteration.

Proposed § 416.2(g), paragraph (1), sets forth a water supply performance standard based upon the general requirements in the current regulations:

> 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.). A water report, issued under the authority of the State health agency, certifying or attesting to the quality of the water supply, must be made available to the Agency upon request.

Notably, the proposed standard makes transparent a current requirement concerning potable water: that it comply with EPA 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. Because these regulations already apply to potable water used by meat and poultry establishments, the reference in the proposed performance standards would not constitute a new requirement.

The proposed performance standard also restates the current requirement that establishments must make available to FSIS, upon request, State certificates attesting to water quality. The performance standard clarifies that this requirement applies to both meat and poultry establishments. As explained above, while currently there is no such regulatory requirement for meat establishments, it is likely that all meat establishments obtain such certificates and also that they would make them available to FSIS. FSIS believes, therefore, that this provision would not impose a new requirement upon meat establishments.

Proposed § 416.2, paragraphs (g) (2) through (6) set forth performance standards for the reuse of water in meat and poultry establishments. As explained above, the regulations currently permit water to be reused only under certain circumstances and require that any other reuse be approved by the Agency in advance. The proposed performance standards are intended to account for every allowable water reuse situation and eliminate the need for prior approval.

The meat and poultry industries need great quantities of water for processing products and for cleaning. Water and water based (aqueous) solutions are widely used for product formulation, slaughter, cooking, cooling the equipment, and chilling products as well as for cleaning and sanitization. Reuse of water and solutions, therefore, can offer significant economic advantages.

Historically, FSIS and other public health agencies have required that only potable water be used in the production of meat and poultry products. However, over the past 20 years the Agency has recognized that reuse water, which does not meet all of the EPA requirements for potability, may be used safely and effectively in certain processing situations. In the early 1990's EPA, FDA, and FSIS representatives agreed that current technology will allow for the reconditioning of water for safe and effective reuse in various applications.

Reuse water can be treated to render it free of physical, microbiological, and chemical hazards. Some of the general treatment options used include: filtration, chlorination, ozonation, ultraviolet (UV) radiation, and heating. Use of these procedures can usually return water to a level of quality appropriate to its intended use. After treatment, however, such water should be tested regularly to assure continual freedom from biological, chemical, or physical hazards.

Depending upon the original use, the intended reuse, and the duration of reuse, a wide range of acceptable microbiological, chemical, or physical contaminant levels are possible in reuse water. The previous degree of exposure or potential exposure to contaminants dictates the appropriate reconditioning treatment and the allowable reuse. FSIS has based its proposed performance standards for water reuse on these factors.

Proposed § 416.2(g), paragraph (2) states:

> Water used to chill or cook ready-to-eat product may be reused for the same purpose, provided that measures are taken to ensure that it is maintained free of pathogenic organisms and fecal coliform organisms and that other physical, chemical, and microbiological contamination is reduced so as to prevent contamination or adulteration of product.

FSIS expects establishments to produce ready-to-eat products that are free of pathogens; therefore, FSIS is proposing to require that reuse water used to chill or cook ready-to-eat product be free of pathogens. FSIS is proposing to require that this reuse water be free of fecal coliforms because their presence would indicate that the water was contaminated, possibly with pathogenic organisms. Finally, FSIS is proposing that other types of contamination be reduced sufficiently to prevent contamination or adulteration of product.

Paragraph (4) of this proposed section states:

> Water 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 water which has come into contact with raw product may not be used on ready-to-eat product.

FSIS is proposing to require that physical, chemical, and microbiological contamination be reduced to minimize the risk of cross-contamination in general. FSIS also is proposing to require that water used to chill or wash raw product be reused only for the same purpose to minimize the possibility of cross-contamination between different types of products or processes. Because raw product often is initially contaminated with pathogenic microorganisms and fecal coliforms, FSIS is not proposing to require that this reuse water be free of those contaminants. Finally, FSIS is proposing to prohibit water which has come into contact with raw product from being used on ready-to-eat product so as to prevent the cross-contamination of ready-to-eat product by contaminants

or adulterants from raw product. Current regulations mandating the separation of raw and ready-to-eat product serve the same purpose.

Proposed paragraph (4) applies to meat or poultry establishments that recondition their water through an advanced wastewater treatment facility, usually either onsite or under contract. Such water meets the criteria prescribed in National Primary Drinking Water regulations (40 CFR part 141) concerning water quality. It cannot be considered ''potable,'' however, because it would not originate from the best available source. The best available source would most often be a municipal water system.

Because this reconditioned water is of such high quality, FSIS is proposing to allow it to be used ''on raw product, except in product formulation, and throughout the facility in edible and inedible production areas.'' Notably, to prevent establishments from using water from sewage lines, FSIS would not allow this water to ever have contained human waste. Further, FSIS is proposing to require that ''product, facilities, and equipment 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.'' This requirement, as well as the prohibition against the use of this water in product formulation, are redundant safeguards, already accepted by industry. They serve to further prevent contamination or adulteration of product. It is likely that establishments would use the reuse water described in this provision to wash equipment, floors, and carcasses on the kill floor, all of which can easily be rinsed.

Proposed paragraph (5) of this section permits any water to be used for any purpose in edible or inedible product areas, provided that it has never contained human waste, has been conditioned to be free of pathogenic organisms, and does not contact edible product. FSIS is proposing to require that this reuse water never have contained human waste to prevent establishments from using water from sewage lines. FSIS is proposing to require this reuse water to be reconditioned until free of pathogenic organisms to prevent the spread of pathogenic organisms throughout an establishment, which could lead to cross-contamination of product. Finally, because this reuse water may contain fecal coliforms or chemical or physical contaminants, FSIS is proposing to prohibit it from contacting edible product.

Finally, proposed paragraph (6) states that any water not meeting the conditions of § 416.2(g) paragraphs (1) through (5) may not be used, except in areas where no edible product is handled or prepared and may not be used in any manner which would allow it to contaminate or adulterate edible product.

Ice and Solution Reuse—416.2(h)

Similarly, FSIS is proposing to codify performance standards for ice and solution reuse taken from Agency policy statements (e.g. FSIS Directive 7110.4, ''Liquid Smoke Re-Use'' and ''MPI Bulletin 83–16, ''Reuse of Water or Brine Cooling Solutions on Product Following a Heat Treatment'') and accepted industry practices known to ensure that reused ice or solutions do not contaminate or adulterate product. The proposed standards for reuse of ice or solutions in § 416.2(h) are similar to those proposed for water reuse.

The performance standards proposed for reuse of ice or solutions on ready-to-eat product (§ 416.2(h)(3)) serve the same purpose as those proposed for water reuse on ready-to-eat product (§ 416.2(g)(5)). The proposed performance standards for reuse of ice or solutions on raw or partially-cooked product (§ 416.2(h)(4)) are slightly different than those proposed for water reuse on raw products (§ 416.2(g)(4)). Unlike the corresponding requirements for water reuse, ice or solutions from any source may be reused to chill raw or partially-cooked product. To minimize the possibility of cross-contamination between different types of products or processes, FSIS is proposing that such ice be free of fecal coliforms, which indicate contamination.

Dressing Rooms, Lavatories, and Toilets—416.2(i)

Certain current regulations concerning dressing rooms, lavatories, and toilets in poultry establishments are highly prescriptive. For example, § 381.51(h) prescribes the exact number of toilet bowls that should be installed within an establishment based on the number of people employed, the intent being to ensure that establishments provide an adequate number of toilet bowls, thus maintaining related sanitary conditions. The proposed performance standards would give meat and poultry establishments the responsibility and flexibility to determine how many dressing rooms, lavatories, and toilets it needs. Of course, establishments would have to meet any applicable State and local codes concerning the number of lavatories and toilets in the workplace.

Also, the current regulations for dressing rooms, lavatories, and toilets include requirements already present in other sections of the sanitation regulations. For example, ventilation is addressed in §§ 308.3(b), 308.4(a), and 308.8(b). The proposed, unified regulations eliminate such redundancies.

Equipment and Utensils—416.3

The current regulations concerning equipment and utensils are unduly prescriptive and can deprive establishments of the flexibility to innovate in regard to equipment and utensil sanitation. The proposed performance standards not only provide flexibility, but also clarify establishment responsibility for selecting and maintaining equipment and utensils in a manner that effectively prevents product contamination or adulteration:

> 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 ensure that product is not contaminated, adulterated, or misbranded during processing, handling, or storage. Equipment and utensils must be maintained in sanitary condition so as not to contaminate or adulterate product.

FSIS also is proposing to eliminate § 308.8(c) of the regulations which requires that all implements used in dressing diseased meat carcasses be cleaned either with hot water having a minimum temperature of 180° F or a disinfectant approved by the Administrator and that they then be rinsed in clean water. This requirement, and the 180 °F water requirement specified in § 308.3(d)(4), are intended as sanitization steps, effecting a reduction in microbial levels on areas subject to contamination.

However, research has raised questions about the efficacy of the 180 °F requirement. When there is organic matter present on equipment, such as that which would occur during slaughter or processing operations at meat or poultry establishments, the length of time necessary to achieve disinfection can be variable. Additionally, sometimes disinfection may not be achieved since hot water can bake organic material onto a surface, impeding the penetration of the water and diminishing the efficacy of the hot water disinfection.[1, 2]

---

[1] Peel, B., and Simmons, G.C. (1976) *Contamination of Knives as a Means of Spread of Salmonellae in Meatworks.* Proceedings of the Annual Conference of the Australian Veterinary Association, 53: 38–39.

[2] Peel, B., and Simmons, G.C. (1978) *Factors in the Spread of Salmonellae in Meatworks with*

Research also indicates that maintaining the temperature of a water spray from the nozzle to a surface is quite different from immersion of utensils in an 180 °F water bath. Husband and McPhail [3] studied the specific effects of the use of sprayed 180 °F water for cleaning boning rooms in Australia. Initial measurements of water temperature along a sprayed stream indicated that water temperature dropped rapidly with distance from the nozzle. If the initial temperature at the nozzle was 180 °F, the temperatures recorded at 1, 2, and 3 meter points along the water stream were 176 °F, 169 °F, and 163 °F respectively. A maximum temperature of only 127 °F was obtained at the boning table surface when water at an initial nozzle temperature of 180 °F was sprayed at a distance of one meter. Fogging, which results in undesirable condensation, was subjectively judged to be severe whenever nozzle temperatures exceeded 149 °F in a boning room with an initial ambient temperature of 50 °F.

Husband and McPhail [4] also claimed that water at 120 °F nozzle temperature was as effective as water at 180 °F nozzle temperature in reducing bacterial numbers on flat uncleaned and unsanitized surfaces to low levels of 40–75 cfu per 5 cm^2. These results were applicable for bacteria originating from meat smears or from dried-on suspensions of broth cultures. However, they concluded that rinse water at 131–138 °F nozzle temperature is the most suitable for all stages of an effective cleaning and sanitization procedure. This conclusion was reached in consideration of the fact that residual fat is effectively removed, fogging and its resulting condensation is reduced, and energy is conserved. The authors assert that bacteriological reduction of at least 5 logs from flat stainless steel surfaces was expected after effective cleaning and sanitization, irrespective of rinse water temperature.

Attempts to ''disinfect'' with chemical agents or 180 °F water are of limited value unless the surfaces are first thoroughly cleaned of organic residue such that the bacteria are not protected by film. Weise and Levitzow [5] demonstrated that cleaning surfaces in slaughterhouses with just 180 °F water caused coagulation of protein. Protein and fat remained on the examined metal, plastic, and ceramic tile surfaces. They recommended 165 °F water for 30 seconds to clean, but not disinfect, these surfaces in slaughterhouses.

In the 1970's, the need for energy conservation created interest in the use of chemical disinfectants in lieu of 180 °F water. While the Environmental Protection Agency (EPA) registers disinfectants under the Federal Insecticide, Fungicide and Rodenticide Act primarily for hospital use, there was concern within FSIS about whether such chemical disinfectants would ensure adequate disinfection of surfaces and equipment in meat and poultry plants, where pathogens such as tuberculosis may be present. FSIS developed a program to enable disinfectant manufacturers to apply for approval of disinfectants and for meat and poultry plants to apply for use of approved compounds in lieu of 180 °F water. The requirements were published in MPI Bulletin 77–34 (3–16–77). At this time, there are no disinfectants that meet the criteria of MPI Bulletin 77–34 and its goals. The EPA does not have a category of disinfectants specifically for use in meat and poultry plants. FSIS has since contacted EPA and requested that EPA identify hospital disinfectant(s) that might be suitable for use in red meat and poultry plants.

Therefore, because the efficacy of the 180 °F water requirement is questionable, the Agency is proposing to remove the specific requirements for the water temperature from § 308.8(c) of the regulations. The proposed performance standard also would replace other prescriptive sanitation requirements for equipment and utensils, such as the requirements in § 308.16 concerning electrical stimulating equipment and the requirements in § 381.53(f) concerning the construction of ice shovels used in poultry establishments.

FSIS also is proposing that this performance standard replace the prohibitions against equipment and utensils containing certain concentrations of liquid polychlorinated biphenyls (PCB's) in §§ 308.5(g) and 381.56(b). The new standard would effectively prohibit the use of any equipment or utensils that could lead to product contamination by PCB's.

Food-Contact Surface Cleaning and Sanitation—416.4(a)

In general, current Agency policy requires that establishments clean food contact surfaces daily. However, not all of the pertinent current meat and poultry regulations state that equipment, utensils, and rooms be maintained in a sanitary manner. Proposed § 416.4(a) clarifies and codifies Agency policy regarding daily cleaning:

> All food-contact surfaces, including food-contact surfaces of utensils and equipment, must be cleaned daily prior to starting operations and as frequently as necessary so that they are free of physical and chemical contamination and so that microbiological populations are reduced so as to prevent contamination or adulteration of product.

This proposed performance standard also clarifies the intent of the Sanitation SOP regulations in § 416.2(c), which require establishments to develop and implement SOP's that address the cleaning of food contact surfaces, equipment, and utensils.

The objective of food-contact surface cleaning requirements has always been to mitigate physical, chemical, and microbiological contamination that could contaminate or adulterate product. The proposed performance standard codifies this objective and clarifies establishment responsibility for determining how best to achieve it.

Some of the current regulations regarding food-contact surface cleaning are prescriptive and limit innovation by the establishment. For example, § 381.58(g) requires that all conveyor trays or belts which come into contact with raw poultry products be completely washed and sanitized after each use. The intent of this requirement is to minimize the growth of microorganisms on the food contact surface. There may be other more efficient procedures that would accomplish this objective, however, that are not allowed by the current requirements. The proposed performance standard would allow establishments to clean ''as frequently as necessary.'' Additionally, the current requirement in § 381.58(g) is not applicable to cutting boards used for poultry products, or conveyors and trays used for red meat products. The proposed performance standard also would remove this inconsistency and others like it.

Non-Food-Contact Surface Cleaning and Sanitation—416.4(b)

FSIS also is proposing to replace the current regulations concerning the cleaning and sanitation of non-food-contact surfaces with a performance standard. For example, § 308.3(d)(4) now requires that meat establishments use 180 °F water for cleaning of floors, and walls which are subject to contamination by the dressing or handling of diseased carcasses, their viscera, and other parts. The intent of

---

Special Reference to Contamination of Knives. Australian Veterinary Journal 54: 106-110.

[3] Husband, P. And McPhail, N.G. (1978) *The Use of 82 °C Water in Meat Plant Cleaning Operations.* CSIRO Meat Research Report No. 2/78. Commonwealth Scientific and Industrial Research Association.

[4] Ibid.

[5] Weise, E., and Levitzow , R. (1976) *Is 82 Degree C the Optimum Water Temperature for Cleaning Slaughterhouses*? Fleischwirtschaft 56(12): 1725–1728.

this regulation is to require establishments to keep floors and walls free of any physical contaminants (soil, tissue debris), chemical contaminants or biological contaminants that could contaminate or adulterate a meat and poultry product. The requirement to prevent contamination or adulteration is retained in the proposed performance standard, but without the 180 °F water provision. This gives establishments greater flexibility and responsibility for developing sanitary procedures specific to the nature of their operations and the food safety hazards which might occur.

Cleaning Compounds and Sanitizers—416.4(c)

The current regulations in § 381.60 require that FSIS approve cleaning compounds and sanitizers before they can be used within an official poultry establishment. FSIS policy has been to enforce this requirement in meat plants as well. The requirement is intended to ensure that meat and poultry products are not contaminated or adulterated with chemicals or any injurious substance. We are proposing to replace this requirement with a performance standard that would specify that ''cleaning compounds and sanitizing agents used must be safe and effective under the conditions of use and their use must not cause the contamination or adulteration of product.'' Of course, establishments would still have to meet the use requirements for the substances promulgated by other regulatory agencies, such as FDA and EPA.

Operational Sanitation—416.4(d)

The current requirements for operational sanitation (sanitation measures carried out during operations) are spread throughout a number of regulations. For example, the requirements concerning rooms and compartments in which meat product is prepared or handled can be found in both §§ 308.3(g) and 308.7. The proposed regulations would consolidate all of the operational sanitation requirements in a single place.

Further, certain current requirements for operational sanitation are unnecessarily prescriptive. For example, current § 381.47(e) stipulates that rooms where mechanical equipment for deboning of raw poultry is operated must be maintained at 50 °F or less. This requirement is intended to limit growth of microorganisms resulting from the rise in temperature of the product as a consequence of the mechanical grinding operation. Temperatures of 50 °F or less slow the growth rate of most organisms of concern, especially *Salmonella*.

However, since this requirement was promulgated, FSIS has permitted many facilities, upon request, to use heat-exchangers connected to the grinding equipment to bring about an immediate reduction in product temperature. Heat-exchangers on the equipment can more effectively reduce product temperature and limit growth of microorganisms than the requirement to maintain room temperature.

FSIS is proposing to replace the room temperature requirement with a performance standard that will allow establishments to devise their own means for limiting microbial growth in their processing operations, without requesting special approval from the Agency. The proposed performance standard states that ''Product must be protected from contamination or adulteration during processing, handling, storage, loading and unloading at and during transportation from official establishments'' and that ''ready-to-eat product must be protected from cross-contamination by pathogenic organisms.''

Under the standard, establishments would be required to protect meat and poultry products from contamination or adulteration during all phases of production. Establishments also would be specifically required to protect ready-to-eat products from cross contamination, namely by raw product. Establishments would need not only to protect product from direct contamination, but also to control the temperature of product in order to reduce microbial growth; in many instances, FSIS considers microbial growth to be indicative of insanitary conditions. Establishments would be free to take whatever measures they believe are necessary, based upon the nature and volume of their production.

Employee Hygiene—416.5(a)

The current regulations mandate specific employee hygiene practices establishments must adopt. For example, the requirements in § 308.8(e) specifically prohibit employees from spitting and from placing ''skewers, tags, or knifes'' into their mouths. Also, § 381.51(g) states that signs must be posted in each toilet room directing employees to wash their hands before returning to work. The proposed performance standard would allow establishments to develop alternative or innovative means to ensure that employee hygiene practices do not result in product adulteration or contamination.

Employee Clothing—416.5(b)

Some of the current requirements regarding employee clothing are prescriptive. For example, § 308.8(d) states that work garments shall be changed during the day when required by the inspector-in-charge. The proposed performance standard would require establishments to develop acceptable policies for prescribing when ''garments must be changed during the day ... to prevent contamination or adulteration of product.'' The other requirements of the current regulations, that garments be made of material that is readily cleaned and that clean garments be worn at the start of each day, are retained in the proposed performance standard.

Employee Disease—416.5(c)

The proposed performance standard regarding employee disease is similar to the current requirements. The revision would serve to consolidate regulations for meat and poultry into a single section.

Tagging Insanitary Equipment, Rooms, or Compartments—416.6

Similar requirements for the tagging of insanitary equipment, rooms, or compartments are found in both the meat and poultry regulations. Tagged equipment, rooms, and compartments tagged cannot be used until made acceptable. The proposed standard will not change current FSIS policy, but will consolidate requirements for meat and poultry into a single section.

FSIS is also proposing to revise § 381.99 of the poultry regulations. Section 381.99 contains both tagging provisions (which would be removed and replaced by § 416.6) and descriptions of different types of tags (which would remain in section 381.99).

Custom Slaughter Establishments

Under current § 303.1(a)(2)(i), establishments that conduct custom slaughter operations must meet all of the sanitation requirements contained in Part 308, with a few exceptions. Custom slaughter establishments currently are exempt from the following:

- §§ 308.1 and 308.2—prior approval requirements for sanitary conditions, drawings, and blueprints;
- § 308.3(d) (2) and (3)—water reuse restrictions;
- § 308.4—provisions requiring that establishments have separate toilet facilities for men and women (if a majority of the custom slaughter establishment's employees are related by blood or marriage and if this arrangement will not conflict with municipal or State requirements) and

provisions requiring that toilet soil lines be separate from house drainage lines to a point outside the buildings (if positive acting backflow devices are installed);

- § 308.12—restrictions regarding the use of second-hand tubs, barrels, and other containers;
- § 308.13—provisions requiring that driveways, approaches, yards, pens, and alleys be paved;
- § 308.16—sanitation requirements for electrical stimulating equipment; and
- any provisions of Part 308 relating to inspection or supervision of specified activities or other action by a Program employee.

FSIS is proposing to retain the exemptions in 303.1(a)(2)(i), but also to modify them for consistency with the proposed sanitation performance standards in new Part 416. FSIS is proposing to eliminate the requirements in § 308.1 regarding examination of sanitary conditions prior to inauguration of inspection; the requirements in § 308.4 regarding separation of toilet lines; the requirements in § 308.12 regarding the use of second-hand tubs, barrels, and other containers; the requirements in § 308.13 regarding surface paving; and the requirements in § 308.16 regarding the sanitation of electrical stimulating equipment. Therefore, the revised 303.1(a)(2)(i) would not refer to exemptions from these requirements. Similarly, in a recent proposal (FSIS Docket No. 95–032P; 61 FR 19587–19590), FSIS eliminated the requirements in § 308.2 concerning prior approval of establishment blueprints and drawings. The revised 303.1(a)(2)(i) therefore would not include an exemption from these requirements either.

Additional Regulatory and Policy Revisions

The comprehensive nature of this proposed rule would necessitate many changes to FSIS policy documents and regulatory references. FSIS will complete all of the needed revisions prior to the effective date of any final rule emanating from this rulemaking.

These changes fall into two categories. First, FSIS would need to revise all of the cross-references in the meat and poultry regulations to reflect the proposed deletion of §§ 308 and 381 Subpart H and the proposed addition of new §§ 416.1 through 416.6. These revisions would be nonsubstantive. Second, FSIS plans to rescind or revise many sanitation issuances and directives inconsistent with the proposed rule and with HACCP.

Much of the material contained in the rescinded or revised issuances and directives would be re-formatted and published as guidance materials providing information, advice, and suggestions on how the proposed performance standards can be met. For example, the contents of MPI Bulletin 83–16 (Re-Use of Water or Brine Cooking Solution on Product Following a Heat Treatment) will remain available from the Agency as guidance material for establishments to use in addressing the proposed performance standards.

Some of the material has been used to develop performance standards FSIS is proposing or plans to propose. For instance, material from FSIS Directive 7110.4 (Liquid Smoke Re-Use) was used to develop the proposed performance standard for solution re-use.

Issuances To Be Rescinded by the Agency

FSIS would rescind the following directives and issuances prior to the finalization of this proposal:

Approved Water Systems Guide

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 11,240.5—Plastic Cone Deboning Conveyors
FSIS Directive 11,520.2—Exposed Heat-Processed Products; Employee Dress
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° 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

Executive Order 12866 and Regulatory Flexibility Act

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

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

FSIS is proposing to revise and consolidate the sanitation regulations for meat and poultry establishments, resolve unnecessary differences between similar requirements for meat and poultry, and convert prescriptive requirements to performance standards. This proposal would affect meat and poultry establishments subject to official inspection, custom exempt red meat establishments, and consumers.

In general, the proposed streamlining, clarification, and consolidation of the sanitation regulations should benefit FSIS, the regulated industry, and consumers. User-friendly regulations would simplify compliance and therefore could bring about food safety enhancements in individual establishments. Further, consolidation of the separate sanitation requirements for meat and poultry products and the consequent elimination of unnecessary inconsistencies could enhance competition.

This proposed rule would allow individual establishments to develop and implement customized sanitation procedures other than those currently mandated, as long as those procedures produced sanitary conditions meeting the proposed performance standards. Establishments taking advantage of the performance standards to innovate thus could benefit from savings accrued through increased efficiency. However, since the currently mandated sanitation procedures meet the proposed performance standards, establishments lacking the resources to innovate could choose to continue employing current procedures. Such establishments should incur no additional expenses as a result of this rule. FSIS therefore anticipates

that sanitation performance standards would have a generally favorable economic impact on all establishments, regardless of size.

It is difficult to quantify the potential benefits of the proposed performance standards since it is not possible to predict exactly how many establishments would develop innovative processes and how these innovations reduce. However, FSIS sees the potential for an increase in the efficiency of the nation's economy in general because the proposed performance standards would stimulate innovation and encourage businesses to consider a more efficient use of resources. 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 the ability of establishments to maintain a sanitary environment through implementation of the new Sanitation SOP requirements. This proposal is part of that initiative and is intended to reduce demands on FSIS resources which could be redirected to functions more critical to improving food safety. FSIS anticipates that this proposal, along with the HACCP, Sanitation SOP, and other food safety initiatives, would produce significant economic and societal benefits by reducing the incidence of foodborne illness.

As an alternative to the present proposal, the Agency considered proposing more comprehensive and prescriptive sanitation regulations. The proposed requirements would then have included very specific definitions of terms, such as definitions for food contact surfaces or premises; 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 processes 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, due to the unnecessarily restrictive burden it would place on industry, and has made tentative decisions in these areas, on which it specifically requests comments. On the matter of definitions, the Agency has determined that within the food processing community and the meat and poultry processing industry there is an understanding of descriptive terms such as ''food contact surfaces'' and ''premises,'' and that to construct a technically accurate definition which encompassed all the possible meat and poultry establishment situations in which the term could be applied was neither useful nor likely to succeed. The Agency notes, however, that these and other terms are defined in both the Food Code and in certain FDA regulations and specifically requests comment on whether those definitions ought to be referenced in FSIS regulations.

Similarly, the Agency has made a tentative decision 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 proposed standards, which are based on the general requirement that establishments prevent product contamination or adulteration. At various other places in its regulations, the Agency has established performance standards applicable to meat and poultry products. The newest is the *Salmonella* performance standard for raw carcasses and ground product established in the Pathogen Reduction/ HACCP final regulation. Another is the zero tolerance standard for fecal material on raw carcasses. Others include the prohibition on violative levels of chemical residues and the policy that there be no *Listeria* or *Salmonella* on certain ready-to-eat products. Achieving these product-based performance standards depends on an establishment doing a number of things correctly, including correctly carrying out the sanitation responsibilities set forth in part 416.1 through 416.6. FSIS has tentatively concluded that because there are many methods and means through which establishments can ensure that product is not contaminated or adulterated, FSIS will not prescribe exactly which methods, procedures, or means must be used. FSIS requests comment on this tentative decision.

FSIS is carefully reviewing its guidance material on sanitation in an effort to develop the most comprehensive possible set of approaches which can be considered by establishments as they determine how they will go about meeting the performance standards. If that reviews yields provisions which should become parts of the performance standards, FSIS will revise its regulations accordingly. If the review yields a number of possible approaches which could be used by an establishment, they will all be included in guidance material, which FSIS expects to complete by the time this proposal is made final.

Finally, on the issue of whether there should be a list of specific prohibited practices retained in the regulations, FSIS has made a tentative decision that this is not necessary and could be misleading. Most of the prohibited practices which 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 directly applied to the surface of meat is only one of the means by which an establishment could be failing to prevent direct product contamination. Preventing direct product contamination is the performance standard. It encompasses a prohibition on using burlap as a wrap, as well as a large number of other practices. The Agency believes that a partial or outdated list of regulatory prohibitions may suggest that anything not on the list is not prohibited. FSIS prefers to communicate about unsuitable practices through its guidance material, while holding establishments directly responsible for meeting concisely defined performance standards which mitigate against a wide range of unsuitable practices.

The other alternative available to FSIS was to maintain the current sanitation requirements. However, as explained in detail above, the current requirements are to an extent inconsistent with the principles of HACCP, can impede innovation, and often can lead to confusion about FSIS and establishment responsibilities for food safety.

Executive Order 12778

This proposed rule has been reviewed under Executive Order 12778, Civil Justice Reform. States and local jurisdictions are preempted by the Federal Meat Inspection Act and the Poultry Products Inspection Act (PPIA) from imposing any marking, 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 or the PPIA. States and local jurisdictions may, however, exercise concurrent jurisdiction over meat and poultry products that are outside official establishments for the purpose of preventing the distribution of meat and poultry products that are misbranded or adulterated under the FMIA or PPIA, or, in the case of imported articles, which

are not at such an establishment, after their entry into the United States.

This proposed rule is not intended to have retroactive effect.

If this proposed rule is adopted, 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 proposed rule, if the challenge involves any decision of an FSIS employee relating to inspection services provided under the FMIA or the PPIA.

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 proposed rule on environmental and health conditions in low-income and minority communities.

This proposed rule would consolidate the sanitation regulations for meat and poultry establishments into a single part, eliminate unnecessary differences between the meat and poultry sanitation requirements, and convert many of the highly prescriptive requirements to performance standards. As explained in the economic impact analysis above, the proposed regulations should generally benefit FSIS, the regulated industry, and consumers. The proposed regulations would not require or compel meat or poultry establishments to relocate or alter their operations in ways that could adversely affect the public health or environment in low-income and minority communities. Further, this proposed rule would 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.

Paperwork Requirements

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

Under the current regulations, if meat and poultry establishments are cited for rodent or vermin infestation, FSIS requires establishments 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,'' has approved 351 burden hours for this activity.

This proposed rule would eliminate 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 would request OMB to remove the 351 burden hours approved for the development of rodent and vermin infestation corrective action reports.

Also, proposed § 416.2(g)(1) requires that establishments, upon request, make available to FSIS ''water reports issued under the authority of the State 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.''

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

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

Comments are requested by October 24, 1997. To be most effective, comments should be sent to OMB within 30 days of the publication date of this proposed rule.

List of Subjects

9 CFR Part 303

Meat inspection, Reporting and recordkeeping requirements.

9 CFR Part 308

Meat inspection.

9 CFR Part 381

Poultry and poultry products inspection, Reporting and recordkeeping requirements.

9 CFR Part 416

Sanitation.

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

PART 303—EXEMPTIONS

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

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

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

§ 303.1 Exemptions.

(a) * * *

(2) * * *

(i) Establishments conducting custom slaughter operations must be maintained and operated in accordance with the provisions of part 416 except for: §§ 416.2(g) (1) through (7), regarding water reuse; the provision in § 416.2(i) requiring that separate toilet facilities be provided where both sexes are employed (if the majority of the workers in the custom slaughter establishment are related by blood or marriage and this arrangement will not conflict with municipal or State requirements); and any provisions of part 416 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 shall apply to those operations.

* * * * *

PART 308—[REMOVED]

3.–4. Part 308 would be removed.

PART 381—POULTRY PRODUCTS INSPECTION REGULATIONS

5. The authority citation for part 381 would continue 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.

Subpart H—[Removed]

6. Subpart H would be removed.

7. Section 381.99 would be 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

8. The authority citation for part 416 would continue to read as follows:

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

9. Part 416 would be amended by adding new §§ 416.1 through 416.6, to read as follows:

§ 416.1 General rules.

Each official establishment must be operated and maintained in a sanitary manner sufficient to ensure that product is not contaminated, adulterated, or misbranded.

§ 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 contamination or adulteration of product or that could prevent FSIS programs employees from performing assigned tasks. Establishments must have in place an integrated 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 result in the contamination or adulteration of product.

(b) *Construction*. (1) 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.

(2) Walls, floors, and ceilings within establishments must be built of durable materials impervious to moisture and be cleaned, maintained, and sanitized when necessary to prevent contamination or adulteration of product.

(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.

(c) *Light.* Lighting of good quality and sufficient intensity to ensure that sanitary conditions are maintained and that product is not contaminated, adulterated or misbranded 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 eliminate odors, vapors, and condensation must be provided to prevent contamination or adulteration of product and to ensure that FSIS programs employees can perform assigned tasks.

(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 contamination or adulteration of product, water supplies, equipment, or utensils, and maintain sanitary 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; and

(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;

(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 be able to furnish FSIS with the letter of approval from that authority upon request.

(g) *Water supply and 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.). A water report, issued under the authority of the State health agency, certifying or attesting to the quality of the water supply, must be made available to the Agency upon request.

(2) Water used to chill or cook ready-to-eat product may be reused for the same purpose, provided that measures are taken to ensure that it is maintained free of pathogenic organisms and fecal coliform organisms and that other physical, chemical, and microbiological contamination is reduced so as to prevent contamination or adulteration of product.

(3) Water 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 water 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 which 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 assure 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 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, 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 which 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 which would allow it to contaminate or adulterate edible product.

(h) *Ice and solution reuse.* (1) Ice used or reused must have been originally produced from water meeting the

requirements of paragraphs (g)(1) of this section.

(2) Ice used on raw product may not be reused on ready-to-eat product.

(3) Ice or solutions (such as brine, liquid smoke, or propylene glycol) may be reused on ready-to-eat product if they are free of pathogenic and fecal coliforms and if other physical, chemical, and microbiological contamination has been reduced so as to prevent the contamination or adulteration of product.

(4) Ice or solutions may be reused on raw and partially-cooked product if they are free of fecal coliforms and if other physical, chemical and microbiological contamination has been reduced so as to prevent the adulteration of product.

(i) *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. Where both sexes are employed, separate facilities must be provided.

(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 constructed and maintained in a manner that protects against contamination or adulteration of food must be provided.

§ 416.3 Equipment and utensils.

(a) Equipment and utensils used for processing or otherwise handling edible product or ingredient must be of such material and construction to facilitate thorough cleaning and ensure that product is not contaminated, adulterated, or misbranded during processing, handling, or storage. Equipment and utensils must be maintained in sanitary condition so as not to contaminate or adulterate product.

(b) Equipment and utensils must not interfere with inspection procedures or prevent FSIS programs employees from performing assigned tasks.

(c) Receptacles used for storing inedible material must be of such material and construction that their use will not result in contamination or adulteration of any edible product or in insanitary conditions at the establishment. They 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 daily prior to starting operations and as frequently as necessary so that they are free of physical and chemical contamination and so that microbiological populations are reduced so as to prevent contamination or adulteration of product.

(b) Non-food-contact surfaces of facilities, equipment, and utensils used in the operation of the establishment must be cleaned as frequently as necessary to prevent the physical, chemical, or biological contamination or adulteration of product.

(c) Cleaning compounds and sanitizing agents used must be safe and effective under the conditions of use and their use must not cause the contamination or adulteration of product.

(d) 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.

§ 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 contamination or adulteration of product.

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

(c) *Disease control.* 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.

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

When a Program employee finds 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, he will attach to it a ''U.S. Rejected'' tag. Equipment, utensils, rooms, or compartments so tagged cannot be used until made acceptable. Only a Program employee may remove a ''U.S. Rejected'' tag.

Done in Washington, DC on: August 11, 1997.

Thomas J. Billy,

Administrator.

[FR Doc. 97–21881 Filed 8–22–97; 8:45 am]

BILLING CODE 3410–DM–P