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DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

9 CFR Parts 317, 318, 319, 381, and 424

[Docket No. 97–001F]

RIN 0583–AC35

Elimination of Requirements for Partial Quality Control Programs

AGENCY: Food Safety and Inspection Service.

ACTION: Final rule.

SUMMARY: The Food Safety and Inspection Service (FSIS) is amending the meat and poultry products inspection regulations by removing the remaining requirements pertaining to partial quality control (PQC) programs. A PQC program controls a single product, operation, or part of an operation in a meat or poultry establishment. FSIS is removing the design requirements for PQC programs and the requirements for establishments to have PQC programs for certain products or processes. For example, poultry slaughtering establishments operating under the New Line Speed (NELS) inspection system and the New Turkey Inspection System (NTIS) will no longer be required to operate PQC programs in conjunction with those systems. FSIS also is removing from the thermal processing regulations all requirements concerning PQC programs, the requirements for case-by-case FSIS approval of systems and devices not specified in the regulations, and several other prior approval requirements. The amended regulations will be more consistent with the Pathogen Reduction (PR)/Hazard Analysis and Critical Control Points (HACCP) regulations and inspected establishments will have greater flexibility to adopt new technologies and methods that will improve food safety and other consumer protections.

EFFECTIVE DATE: August 28, 2000. The material incorporated by reference is approved by the Director of the Federal Register as of August 28, 2000.

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SUPPLEMENTARY INFORMATION:

Background

FSIS carries out programs designed to ensure that meat, poultry, and egg products are wholesome, not adulterated, and properly marked, labeled, and packaged. FSIS is implementing the ''Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) Systems'' final rule published July 25, 1996 (61 FR 38806), to reduce the risk of foodborne illness associated with the consumption of meat and poultry products to the maximum extent possible. The Pathogen Reduction (PR)/HACCP final rule requires establishments to take appropriate and feasible measures to prevent or reduce the likelihood of physical, chemical, and microbiological hazards in the production of meat and poultry products. Specifically, the PR/HACCP final rule: (1) Requires each official meat and poultry establishment to develop and implement written sanitation standard operating procedures (Sanitation SOP's); (2) requires regular microbial testing (for generic *Escherichia coli*) by slaughter establishments to verify the adequacy of the establishment's process controls for the prevention and removal of fecal contamination and associated bacteria; (3) establishes pathogen reduction performance standards for Salmonella that slaughter establishments producing raw ground products must meet; and (4) requires that all meat and poultry establishments develop and implement a system of preventive controls designed to improve the safety of their products, known as HACCP.

HACCP is a conceptually simple, science-based process control system by which food processors identify and evaluate hazards to the production of safe products, institute controls necessary to reduce or eliminate those hazards, monitor the performance of these controls, and maintain records of this monitoring.

FSIS is reviewing its regulations to determine how they can be revised to conform with the PR/HACCP regulations and the regulatory approach they embody. This approach favors performance-based standards over prescriptive, command-and-control regulations. In its December 29, 1995, advance notice of proposed rulemaking (ANPR) ''FSIS Agenda for Change: Regulatory Review'' (60 FR 67469), FSIS said that by eliminating unnecessary regulations and replacing command-and-control prescriptions with performance standards, inspected establishments would have greater flexibility to adopt innovations that can yield food safety benefits. Identified as candidates for modification or elimination were those regulations that delimit processing and treatment methods intended to address specific food safety hazards and requirements that establish quality control programs.

Under FSIS regulations, a company may choose to place all of the processes and products in a plant under a comprehensive, or total, quality control (TQC) system, or the company may choose to place only individual products or processes under quality control. A quality control program for only one process or product in a plant is known as a partial quality control, or PQC, program. This final rule addresses PQC programs.

Some PQC programs control potential health and safety problems; others focus on economic or quality factors. PQC programs controlling for safety factors include those for thermally processed products, which are intended primarily to prevent toxin formation in the processed product. The programs for cooked beef products are intended to ensure that the processing of the products meets the regulatory requirements for handling, processing (time, temperature, and relative humidity), and storage to prevent pathogen formation in the products. PQC programs that control for product safety have been superseded by required HACCP plans.

PQC programs that control for economic or non-food safety factors include those used to control the fat and water content of hotdogs; the number of

meatballs in or pepperoni slices on, a product; and the moisture or protein-fat-free (PFF) content of a product labeled ''ham, water added.'' The quality control program for mechanically separated (species) (MS(S)) is intended to control bone particle size, calcium content, fat and protein content, and protein efficiency ratio (9 CFR 319.5). The programs for pressed ham and spiced ham products are intended to ensure that the products meet the PFF regulatory requirements of § 319.104.

PQC programs to control products for economic factors are intended to prevent the marketing of products that are misbranded or that lack the quality or value that consumers expect. A plant operating under a PQC program for net weight keeps records of its checks and corrective actions to avoid lot inspection. Under PQC programs for fat and water in frankfurters, plants keep ingredient records by lot and results of laboratory tests for verification by FSIS inspectors. A plant operating a PQC program for boneless meat inspection does its own on-line inspection and keeps records. The FSIS inspector randomly selects samples of product that the plant has already inspected to ensure that the records are accurate.

FSIS regulations have required establishments to have PQC programs for certain products or processes, such as the one for MS(S), just mentioned. A PQC program for on-line carcass quality control has been required for an establishment operating under either the NELS or the NTIS poultry inspection system (9 CFR 381.76(c)).

In 1997, the Agency published a final rule that, among other things, removed the requirement for FSIS prior approval of most PQC programs (62 FR 45016; August 25, 1997). FSIS now thinks it appropriate to take the further step of eliminating the remaining PQC requirements so that establishments will have the flexibility they need to be innovative, consistent with HACCP and the Agency's regulatory policy.

On May 18, 1999, FSIS proposed to amend the meat and poultry products inspection regulations by removing requirements pertaining to PQC programs, except programs for poultry product irradiation plants (64 FR 26892). The December 23, 1999, final rule ''Irradiation of Meat Food Products'' removed requirements for quality control programs in such irradiation plants (64 FR 72165).

Comments Received

FSIS received six letters in response to the May 18, 1999, proposal. All were from the regulated industry and all supported the proposal. Some commenters wanted clarification of matters addressed in the preamble of the proposal, and one requested the removal of additional regulatory restrictions. The substantive comments and the Agency's responses are summarized below.

Comment: An organization representing the food processing industry supported the proposed removal from the thermal processing regulations of requirements for FSIS prior approval of systems and devices not specified in the regulations and of all requirements concerning PQC programs. This commenter also recommended the removal from these regulations of additional command-and-control provisions. The commenter asked that, in the regulations on the handling of containers after closure (9 CFR 318.301(f)(2) and 381.301(f)(2)), approval by a processing authority replace the need to obtain the FSIS Administrator's permission for a time lapse between container closing and initiation of thermal processing of greater than two hours.

Response: FSIS set the regulatory maximum 2-hour time period between container closure and initiation of the thermal process in its 1984 canning regulation amendments. The Agency did so to prevent adulteration from the holding of unprocessed products for an extended period, and because it was aware of several documented incidents of illness from staphylococcal enterotoxin in such products. The commenter's suggested change would place the judgment whether to alter the specified time interval between closure and the initiation of thermal processing with the process authority rather than the FSIS Administrator.

A processing authority is an individual or organization with expert knowledge of thermal processing requirements for foods in hermetically sealed containers, having access to facilities for making such determinations, and designated by the establishment to perform certain functions required by the regulations. FSIS already requires the processing authority to perform the vital function of developing and determining the process schedule and specifying the critical factors in the process.

The change suggested by the commenter is consistent with the Agency's stated aim of making the meat and poultry canning regulations more consistent with the Agency's new, non-command-and-control regulatory approach by eliminating some prior approval requirements. With respect to the canning regulations, however, this rulemaking addresses only PQC programs and prior approval requirements other than the one addressed by the commenter. FSIS therefore considers the commenter's request to be outside the scope of this rulemaking.

Comment: The same commenter requested the addition to the regulations on pH measurement in canning plants (9 CFR 318.304(e) and 381.304(e)) of a provision allowing use of colorimetric or other methods in addition to potentiometric methods, provided that the methods are sufficiently accurate to ensure product safety and stability. The commenter also asked for the removal of the requirement for approval by the FSIS Administrator of methods other than the potentiometric. In addition, the commenter requested the removal of the requirement at 9 CFR 318.305(h)(2) and 381.305(h)(2) for approval by the FSIS Administrator for the use in cooling canal water of chemicals other than chlorine that have a bactericidal effect equivalent to that of chlorine.

Response: As stated in the previous response, FSIS proposed to make the thermal processing regulations more consistent with its new regulatory approach by eliminating provisions concerning PQC programs and certain prior approval requirements. FSIS did not propose changes in its requirements for pH measuring devices or chemicals used in cooling canal water. These suggested changes are outside the scope of this rulemaking, and, accordingly, FSIS is not making them in this final rule.

Regarding the regulation on chemicals in cooling canal water, FSIS announced in early 1998 that it was ending its prior approval system for all non-food compounds and proprietary substances (63 FR 7319; February 13, 1998). These classes of substances include water treatment compounds. The program was ended because the Agency considered it to be redundant with those of other Federal agencies and because of the program's inconsistency with the PR/HACCP regulations.

Since establishments are responsible for developing and implementing HACCP plans incorporating the controls necessary and appropriate to produce safe meat and poultry products, FSIS is not responsible for determining whether the nonfood compounds and proprietary substances they use are safe and effective. Therefore, establishments need not obtain the approval of the Administrator to use chemicals other than chlorine in cooling canal water.

Nevertheless, FSIS retains the discretionary authority to prevent the use of such substances in official establishments if the Agency finds, through its normal inspection activities,

that the substances directly or indirectly contaminate edible product. FSIS expects establishments to use only compounds that are safe and that have the intended technical effect when used appropriately in a food preparation environment. The Agency expects establishments to keep on file any information provided by chemical manufacturers (written approvals from other agencies, letters of guaranty, etc.) as part of their sanitation SOP, HACCP, or other records.

Comment: The same commenter requested the removal of two other prior-approval requirements in the canning regulations: first, the requirement (in 9 CFR 318.305(a)(2)(ii) and 381.305(a)(2)(ii))for FSIS Administrator approval of recording devices other than temperature/time recording devices; and second, the requirement at 9 CFR 318.305(d)(5) and 381.305(d)(5) that the FSIS Administrator be notified of the use of any batch retorts with steam/air circulation systems.

Response: FSIS proposed the elimination of the requirement for prior-approval of thermometric measuring devices other than mercury-in-glass thermometers (proposed §§ 318.305(a)(1)(ii) and 381.305(a)(1)(ii)). The Agency also proposed the elimination of prior approval requirements for automated process monitoring and recordkeeping systems not specified in the canning processing regulations (proposed §§ 318.307(b) and 381.307(b)). The commenter's suggestion to remove the requirement in §§ 318.305(a)(2)(ii) and 381.305(a)(2)(ii) for prior approval of time/temperature recording devices other than chart-type devices is consistent with the Agency's proposals regarding temperature measurement and automatic process monitoring devices. Accordingly, FSIS is making the requested change to the regulations in this final rule.

Regarding the prior approval of batch retorts with steam-air cooling, FSIS finds the commenter's request to be consistent with the Agency's proposal to eliminate the requirement for prior approval of thermal processing systems other than those delineated in §§ 318.305 and 381.305 of the canning regulations (proposed §§ 318.305(f) and 381.305(f)). FSIS is therefore adopting the requested change in this final rule.

Comment: The same commenter—the organization representing the food processing industry—questioned the intent of the Agency's statement in the preamble of the proposal regarding alternative documented procedures for handling process deviations or finished product inspections. FSIS stated, at 64 FR 26894, that such procedures ''would have to ensure that only safe, stable product is shipped in commerce.'' The procedures would have to ensure that the product is free of microorganisms of public health significance and is not adulterated by other types of bacteria, such as ''flat-sour'' bacteria or other spoilage organisms.

The commenter thought that the Agency's statement could be misinterpreted to mean that a product might be adulterated if spoilage organisms were merely present in a product not likely to be subject to conditions that would lead to the growth of the organisms and deterioration of the product. Citing the regulatory definition of shelf stability (at 9 CFR 318.300 and 381.300), the commenter pointed out that the presence in low numbers of flat-sour bacteria or other spoilage organisms that would not grow under intended conditions of distribution and storage would not render the product adulterated. However, the growth of spoilage organisms to high numbers that affected product characteristics before or after processing would adulterate the finished product. The product then would not be cleared by a processing authority or released into commerce.

Response: The commenter has accurately explained the intended meaning of the phrase ''adulterated by * * * spoilage organisms'' in the preamble of the proposal (at 64 FR 26894). In stating the conditions for use of procedures alternative to the existing prescriptive requirements (9 CFR 318.308(d) and 381.308(d); 9 CFR 318.309(d) and 381.309(d)), FSIS assumed the current regulatory definitions of ''shelf stability.''

Comment: The same commenter questioned whether the Agency's example of an establishment's incorporation of a PQC program for raw materials in the establishment's HACCP plan (at 64 FR 26896) might imply that non-food safety regulatory concerns might become part of HACCP systems, which only address food safety issues.

Response: FSIS agrees with the commenter that HACCP systems are only intended to control food safety hazards. The Agency recognizes the potential for misunderstanding that can arise when PQC programs and HACCP systems are discussed because PQC programs may address either safety or quality issues or both. The context of the statements to which the commenter refers was the analysis of benefits of the rule. One benefit to establishments is a possible efficiency gain through integration of some facets of quality control with HACCP. FSIS meant to suggest by its example that a food safety-related PQC program or other food safety process control could be used in the context of an establishment's HACCP plan. The HACCP plan would include a critical control point for raw materials only if the hazard analysis identified a food safety hazard associated with raw materials. Raw material control is identified as a CCP in many HACCP plans and is not so identified in others. A PQC program for raw materials or any other step in processing a product would be relevant to HACCP and be subject to being subsumed in or superseded by a HACCP plan only if it were food safety-related.

Comment: The food-processing industry organization also read proposed § 318.308(b)(2) and § 381.308(b)(2) as inadvertently depriving very small establishments of the option of using the alternative procedures for handling process deviations (§ 318.308(d) and § 381.308(d)).

Response: The proposal language did not exclude any canning establishment without a HACCP plan that addresses microbial hazards from using the procedures in paragraph (d) of § 318.308 or § 381.308. Further, under the final rule, these procedures will continue to be available to establishments whose HACCP plans do not address microbial hazards.

Comment: Three of the commenters—the food-processing industry organization, an organization representing the Nation's turkey industry, and a producer of processed meat and poultry products—wanted FSIS to continue to recognize the value of PQC programs, and particularly of those programs that the Agency has previously approved. The food-processing industry organization expressed concern that such programs might automatically become invalid when the final rule goes into effect. The organization wanted the Agency to address this matter in implementing notices or directives to the FSIS field force lest previously approved procedures have to be re-documented.

Response: FSIS has not changed its policy of encouraging establishments to adopt statistically sound quality control systems. FSIS recognizes, however, that product formulations, processing operations, and technology may change over time, and that establishments should have the ability to change the variables and parameters of their control programs without seeking Agency revalidation of those programs. The Agency is therefore removing the

prescriptive, command-and-control regulatory requirements that may inhibit innovation—especially innovation that may yield food safety benefits. The Agency's approval process for PQC programs was part of that old command-and-control system.

Obviously, a PQC program that the Agency approved in the past may still be regarded as useful if no significant changes have been made in the process or product controlled. However, the proof of the program's effectiveness must be found primarily in the data collected under the program or other studies of the product or process controlled and not in an old approval letter. This is particularly the case with respect to food safety-related PQC programs. Where food safety is concerned, FSIS will be relying primarily on its verification of HACCP systems to determine whether official establishments are taking sound control measures.

Regarding the enforcement of this final rule, FSIS will issue appropriate instructions to its field force. Many of the changes necessary to carry out this final rule have already been instituted with the revision of the Agency's automated system for directing inspection program activities.

Comment: An organization representing the meat and poultry canning industry supported the proposal but thought the preamble should have expanded on how and why the elimination of PQC programs would not diminish consumer confidence. The commenter thought that FSIS should have furnished a more comprehensive explanation of PR/HACCP for readers unfamiliar with it, and of why and how PR/HACCP systems make PQC programs redundant. The commenter also thought the explanation for the elimination of specific PQC requirements was insufficient to allay consumer skepticism or fears about eliminating such requirements. In particular, a more substantial justification should have been given for removing FSIS case-by-case approval of thermal processing systems not specifically delineated in the regulations. In this context, the commenter thought that FSIS should have discussed the fact that scientific evaluation of all new processes by competent experts is a long-established practice of the canned food industry.

Response: FSIS made an editorial decision to limit the explanation of the PR/HACCP final rule and its underlying principles because they had been fully discussed in previous Agency publications and at the many public meetings and media events conducted since 1995. The PR/HACCP final rule and the other documents referred to in the preamble of the proposal were made available for public viewing in the FSIS Docket Room at the address given in the proposal. Nevertheless, in response to the commenter's suggestion, FSIS has added, near the beginning of this preamble, a summary of the main features of the PR/HACCP final rule.

While FSIS may not have provided a discussion of PR/HACCP sufficient to satisfy the commenter, the Agency did state in the proposal that requirements for PQC programs that control for product safety have been superseded by required HACCP plans (64 FR 26893, col. 1). The Agency also stated that requirements pertaining to PQC programs that control food safety factors are inconsistent with PR/HACCP (64 FR 26894, col. 3). The Agency further stated or implied in a number of places (64 FR 26892, col. 3; 26893, col. 3; 26894, col. 1, col. 3; 26895, col. 2, col. 3; and 26896, col. 2) that regulatory requirements for PQC programs tend to restrict innovation and perpetuate the command-and-control approach to food inspection and regulation. Such regulatory requirements are not in keeping with the Agency's new approach of defining industry compliance with performance-related objectives.

On the matter of consumer protection, the Agency stated that the proposed rule was intended to provide inspected establishments with flexibility and to encourage them to adopt new technologies and methods that will improve food safety and other consumer protections (64 FR 26892, 26895 col. 2). The Agency also stated, with respect to PQC programs required to ensure compliance with regulatory limits on certain restricted ingredients (64 FR 28693, col. 3) and with product standards, that the limits and standards themselves, as well as product labeling requirements, would continue to protect consumers (64 FR 26894, col. 3; 26895, col. 1).

FSIS stated that PQC programs were not necessary to ensure food safety protection where HACCP plans were in operation (64 FR 26894, col.2). It may be that FSIS could have said more about its regulatory provisions for continued consumer protection, but in the Agency's judgment, what it said was sufficient for the purposes of the rulemaking.

On the elimination of case-by-case approval of new types of thermal processing systems in 9 CFR 318.305(f) and 381.305(f), new systems must still meet the applicable requirements governing equipment and heat processing procedures and be capable of producing shelf-stable products consistently and uniformly. FSIS stated in the preamble of the proposal (at 64 FR 26894) that these requirements reflect the basic purposes of the canning regulations.

The canning regulations continue to address such matters as: container integrity before and after fill; container closure; thermal processing schedules; critical factors; operations in the thermal processing area; processing and production records; deviations in processing; finished product standards; recalls; and the role of the processing authority. FSIS has recognized that the thermal processing regulations are HACCP-consistent with respect to the control of microbial hazards and has supplemented them with a requirement for HACCP plans that address physical and chemical hazards. The Agency also realizes, however, that many of these regulations are excessively prescriptive and in its December 29, 1995, ANPR, cited above, listed them among candidates for revision or removal in conjunction with HACCP implementation.

The commenter's statement about the canning industry's practice of having all new processes evaluated scientifically by competent experts is a point well taken. Both the FDA and the FSIS regulations governing thermally processed, low-acid foods in hermetically sealed containers require thermal process schedules to be established by qualified persons—processing authorities—who have expert knowledge of thermal processing requirements for such foods and access to the facilities to make the necessary determinations (21 CFR 113.83; 9 CFR 318.302, 381.302). These requirements remain in effect for canned products. Also, FSIS has thought well enough of the process-authority concept to make use of it in the final rule ''Performance Standards for the Production of Certain Meat and Poultry Products'' (64 FR 732; January 6, 1999). Under that final rule, affected products not produced under a HACCP plan must be produced according to a process schedule approved in writing by a process authority for safety and efficacy in meeting the performance standards applicable to the product.

Regarding the interest commenters have shown in the few changes in the canning regulations to be made in this final rule, FSIS notes that in the December 29, 1995, ANPR cited above, FSIS listed the requirements for canning and canned products as candidates for reform. Possible actions to be taken were the conversion of these requirements to performance standards

and clarifying the role of inspection program employees. A future rulemaking to reform the canning regulations remains under consideration.

Regulation Changes Adopted

FSIS is eliminating the requirement in 9 CFR 317.21(b) that establishments have, as an alternative to State or local certification of scales, PQC programs or total quality control system provisions for checking the accuracy of scales. The Agency will simply require that there be a certification of accuracy from State or local authorities or from a State-registered or -licensed scale repair firm or person. Establishments can, of course, continue to maintain scale-checking provisions in their QC programs and systems.

The Agency is removing from the meat and poultry inspection regulations the design requirements for partial quality control programs (9 CFR § 318.4(d), § 381.145(d)).

FSIS also is removing quality control requirements governing the use of nitrites in bacon curing and the use of certain organic acids singly or in combination to delay the discoloration of fresh meat cuts (9 CFR 424.21–.22). Such requirements are incompatible with the Agency's regulatory objectives because they specify a manner of compliance rather than simply a performance standard. Both the nitrite and the organic acid regulations clearly state the maximum limits of use of the substances they concern. Also, the consumer is informed by product labeling of the presence of the substances in products. The regulations provide clear limits and adequate consumer protections without the quality control requirements. In addition, the Agency is improving the accuracy of the regulation by using the term ''production of botulinum toxin'' rather than ''growth of botulinum toxin'' (see 9 CFR 424.22(b)(1)(ii)(B)).

FSIS is eliminating a number of prior-approval requirements from the meat and poultry canning regulations. The Agency is replacing the requirement that the Agency approve temperature-indicating devices other than mercury-in-glass thermometers (at §§ 318.305(a)(1)(ii) and 381.305(a)(1)(ii)) before they could be used. The devices must meet known standards of accuracy for such devices, but the Agency is not prescribing the frequency of testing for accuracy.

The Agency is removing the requirement for FSIS prior-approval of the use of time/temperature recording devices other than chart-type devices. The alternative devices must meet known standards of accuracy (9 CFR 318.305(a)(1)(ii) and (a)(2)(ii); 9 CFR 381.305(a)(1)(ii) and (a)(2)(ii)).

In response to comments, the Agency is removing the requirement at 9 CFR 318.305(d)(5) and 381.305(d)(5) that the FSIS Administrator be notified of the use of any batch retorts with steam/air circulation systems. As explained previously in this document, FSIS regards this action as consistent with the proposed rule.

As proposed, the Agency is removing the requirement for FSIS case-by-case evaluation and prior approval of systems for thermally processing canned product other than those systems specifically delineated in the regulations. Such alternative systems must still be adequate for producing shelf-stable product consistently and uniformly. (9 CFR 318.305(f), 381.305(f).)

FSIS is removing from the thermal processing regulations (9 CFR 318.307(b) and 381.307(b)) requirements for FSIS approval of automated process monitoring and recordkeeping systems.

The Agency also is removing from the thermal processing regulations the requirements in §§ 318.308 and 309 and §§ 381.308 and 309 concerning partial quality control programs to control process deviations and establishment finished product inspection procedures. The Agency finds that these requirements are unnecessary. The remaining provisions in these sections, which are based on HACCP principles, remain as acceptable protections against potential microbial contamination.

The proposal would have provided additional options for establishments, such as handling the deviations under an approved total quality control system or using alternative documented procedures until the PR/HACCP rule became applicable to the establishment. The alternative documented procedures could have included partial quality control programs or other documented corrective action, monitoring, or recordkeeping procedures developed by or for the establishment, but not subject to FSIS approval. Such food safety-related PQC programs were to be integrated in or superseded by the establishment's HACCP plan. Because the effective date of the final rule is after January 25, 2000, however, the PR/HACCP regulations will be applicable to all establishments that are subject to the final rule. Thus, there is no need to provide options for establishments that are not yet subject to the PR/HACCP requirements. Deviations in processing will need to be handled according to a HACCP plan that addresses hazards associated with microbial contamination or by the alternative procedures for handling deviations during processing or through record review (§§ 318.308(d) and 381.308(d)).

A thermal processing establishment will have available at least three alternatives for handling finished product inspections. The finished product inspections could be handled under: (1) The existing regulations (§§ 318.309(d) and 381.309(d)); (2) a HACCP plan; or (3) alternative documented procedures for handling finished product inspections. The alternative documented procedures can be PQC programs or the HACCP plan provisions.

In any case, any alternative procedures for handling process deviations or finished product inspections will have to ensure that only safe, stable product is shipped in commerce. The procedures will have to ensure that the product is free of microorganisms of public health significance, and that it does not contain other types of microorganisms, such as ''flat-sour'' bacteria or other viable spoilage organisms, that could cause adulteration under intended conditions of distribution and storage of the product. This requirement is consistent with the aims of HACCP and with the statutory prohibitions against the distribution of adulterated and misbranded meat and poultry products in commerce.

These amendments and revisions will make the thermal processing regulations more consistent with the PR/HACCP final rule by explicitly providing a HACCP-plan alternative (consistent with §§ 417.2(b)(3)) to the prescriptive procedures in §§ 318.309(d) and 381.309(d). The amended and revised regulations also include, as an option for handling process deviations or final product inspections, alternative documented procedures that ensure that only safe and stable products are shipped in commerce. This option will provide the establishment with the flexibility to use PQC programs or other procedures that meet a regulatory public health standard.

It should be noted that, under the HACCP regulations, an establishment's HACCP plan does not have to address potential microbial hazards in thermally processed/commercially sterile product if the establishment is following the current regulatory requirements for such product. However, the HACCP plan must address physical and chemical hazards to which the product may be subject.

Besides removing the requirements pertaining to PQC programs that control food safety factors, which are

inconsistent with PR/HACCP, FSIS is removing the requirements affecting economic or quality-related PQC programs. FSIS considers both the food safety-related and the economic PQC requirements to be too prescriptive. They tend to perpetuate the command-and-control approach to food inspection and regulation. They are not in keeping with the Agency's new regulatory approach, which is oriented more toward monitoring industry compliance with performance-related objectives.

FSIS is removing the QC system requirements from the regulations and requirements governing the identity and composition of MS(S) product and label approval of the product (9 CFR 319.5). The MS(S) regulations specify the maximum calcium content, the minimum protein content, the protein efficiency ratio, the maximum fat content, and the maximum bone particle size for the product. The regulations also specify the elements that the QC system must contain, including a written description of the methods used by the establishment to maintain uniformity of raw materials used in manufacturing product and to control handling and processing of the raw materials and finished product. The regulations also specify the sample size and sampling frequency for food-chemistry analysis of product to determine compliance with the standards. FSIS regards these provisions as overly prescriptive and believes that, to achieve the purposes of the MS(S) regulations, it is sufficient to set the product standards for fat, protein, calcium content, and bone particle size.

The Agency also is updating the provision for finished product samples to be analyzed according to methods of the Association of Official Analytical Chemists (AOAC) or methods listed in the FSIS ''Chemistry Laboratory Guidebook'' to reflect use of the most recent edition of the AOAC compendium. In addition, establishments will have the latitude to use validated scientific methods equivalent to, but not listed in, the AOAC and FSIS references. They will have the flexibility to choose the most appropriate means of ensuring that MS(S) meets the compositional and labeling identity requirements of the regulations. The Agency cautions, however that, if the establishment is to adequately protect its interests, it should ensure that the method that it uses will produce results comparable to the relevant AOAC or FSIS method.

Second, FSIS is eliminating the quality control program requirements from the protein-fat-free (PFF) percentage regulations (§§ 319.104 and 319.105) for various ''finely divided'' cured ham products, such as patties, chopped or pressed ham, and spiced ham. Establishments, however, must continue to comply with the PFF percentage limits for these products.

Finally, FSIS is removing the requirement that poultry slaughtering establishments operating under the NELS and NTIS inspection systems have PQC programs for carcass defects. The establishments will now have the flexibility to adopt quality control programs or other measures for ensuring the quality of their products. Removing the prior-approval aspect of these requirements contributes to clarifying the respective roles of the inspection service and the regulated industry—a necessary task in making the requirements consistent with HACCP.

FSIS inspectors will continue to check poultry in NELS and NTIS plants for visible contamination and carcass trimming defects.

Executive Order 12866 and Regulatory Flexibility Act

This final rule has been determined to be significant, though not economically significant, and was reviewed by the Office of Management and Budget under Executive Order 12866.

FSIS is eliminating the regulatory requirements pertaining to establishment-operated PQC programs. This action removes regulatory obstacles to innovation and command-and-control requirements, which are inconsistent with the Agency's new regulatory approach and the objectives of the PR/HACCP regulations. In the Agency's August 25, 1997, final rule ''Elimination of Prior Approval Requirements for Establishment Drawings and Specifications, Equipment, and Certain Partial Quality Control Programs'' (62 FR 45016), the requirements for FSIS prior approval of most PQC programs were eliminated. This action was taken to facilitate the transition to HACCP in official establishments producing the greatest portion of meat and poultry products consumed in the United States. FSIS is now taking the additional step of eliminating the remaining requirements for establishments to have PQC programs for specific products or processes, as well as design requirements affecting PQC programs.

The alternatives to this rulemaking that FSIS considered were, in addition to the alternative of no rulemaking, those of mandating additional in-plant controls and mandating general requirements and standards for PQC programs.

The alternative of no rulemaking would impose no additional regulatory burdens on establishments, which would continue to have the assurance that their PQC programs meet basic design criteria. However, the Agency rejected this alternative. The failure to change the regulations would leave in place a prescriptive regulatory regime for process controls and PQC programs that also conflicts in a material way with the objectives of the PR/HACCP final rule. Under HACCP, establishments assume responsibility for building science-based, preventive process controls into the food production system to reduce or eliminate food safety hazards. This responsibility includes ensuring that processes conform with sound food safety performance standards. Establishments need to be able to implement better and more innovative food safety and other consumer-protection strategies, including having flexibility to design a PQC program and determine its content and implementation date.

The alternative of mandating additional in-plant controls, whether in addition to or in lieu of PQC requirements, would add regulatory assurances that processes are under control and that products are safe, wholesome, and not misbranded. However, this alternative would add prescriptive, command-and-control requirements and restrict the scope for establishment food safety initiatives, contradicting the Agency's new regulatory approach. The additional requirements also would likely not result in food safety improvement.

The alternative of mandating new general requirements or standards for PQC programs would differ little in its effects from the current requirements for PQC programs to have certain features and for process control under the programs to be based on generally accepted statistical principles (9 CFR 318.4(d); 381.145(d)). Even if the current requirements were condensed, they would still be inconsistent with the PR/HACCP regulations and with the Agency's new regulatory approach, establishments would continue to incur a substantial recordkeeping burden, and the Agency would have nearly the same burden as it now does of verifying establishment compliance with the requirements.

FSIS chose the option of eliminating regulatory requirements for all PQC programs except QC programs for the irradiation of poultry products. (As mentioned previously, the final rule ''Irradiation of Meat Food Products'' removed requirements for poultry irradiation QC programs.) This option provides establishments with the most

flexibility in implementing process control programs in a HACCP environment.

This final rule will affect, overall, as many as 72 poultry slaughtering establishments and about 3,550 establishments that process meat and poultry products beyond slaughtering, dressing, and cut-up. The most far-reaching effect of the rule will be to increase the flexibility establishments have in controlling their processes. This benefit arises from eliminating the required PQC program elements in §§ 318.4(d) and 381.145(d).

With or without this final rule, establishment HACCP plans will supersede or incorporate the few PQC programs that control food safety factors. Under the final rule, most establishments that have PQC programs that control for non-food safety factors will continue to use the programs. In all likelihood, in developing new PQC programs, they will continue to include the information now required by FSIS. They will also be free to adopt other methods of process control and different techniques of observation, measurement, documentation, recordkeeping, and evaluation than are prescribed in the current regulations. They are likely to change their PQC-controlled operations to coordinate their food quality process control more effectively with their HACCP system operations to improve overall efficiency. Thus, raw material control, which has been a required element in PQC programs, could be handled under a HACCP plan with a CCP for raw materials, and other process controls for food safety could be handled in the same manner. Similarly, the records requirements for PQC programs could be superseded by more efficient and appropriate establishment-developed systems. Establishments would thus be able to achieve unquantifiable gains in efficiency that would yield food safety and other consumer-protection benefits.

FSIS-inspected establishments develop about 1,900 PQC programs a year according to regulatory design specifications. Assuming that a PQC program is developed by a QC manager earning about $26 an hour, and that it takes about 20 hours, on average, to develop a PQC program, the cost to an establishment of developing such a program is about $520. FSIS estimates that the cost to the regulated industry of developing such programs is about $1,000,000 per year.

This cost of developing PQC programs according to FSIS requirements, plus $13 million in annual operating costs for about 1,852 mandatory (required by regulation) PQC programs ($26/hr. × 260 hrs./yr./program × 1,852 programs), add up to about $14 million in costs to the regulated industry.

For most establishments, the final rule will not yield immediate, direct savings from removal of burdens associated with developing PQC programs because most PQC programs are voluntarily adopted by establishments. Establishments likely will continue the use of QC methods in their operations, so the removal of the regulatory requirement for establishments to follow the regulatory design specifications will not immediately yield a savings to establishments. Further, a substantial proportion of the costs of complying with this regulation was removed with the publication of the final rule eliminating prior approvals for facilities, equipment, and PQC programs (62 FR 45016; August 25, 1997).

However, FSIS currently requires that if establishments adopt PQC programs, the programs must meet certain design specifications and must contain certain specified information. Some establishments that are required to have PQC programs for certain products and processes would benefit from the removal of burdens associated with developing PQC programs. These establishments, including those involved in producing MS(S), meat cuts treated with organic acids, and other processing, may benefit from shifting some portion of their PQC program development and operation costs into HACCP-related or other activities.

Also, under the final rule, establishments would have greater freedom to innovate. An indeterminate proportion of the annual burden of developing PQC programs according to FSIS specifications could eventually be channeled into more efficient and effective use of industry resources, especially where PQC programs have been operated.

Thus, although there will not be a direct savings from the removal of the regulatory requirements governing PQC programs, the industry potentially will be able to make more efficient and effective use of the $1 million or so in annual costs of developing the programs.

Finally, the final rule will permit FSIS to reallocate field inspection and headquarters resources now used in oversight of establishment-operated PQC programs to higher priority food safety-related activities.

Regulatory Flexibility Act

The Administrator of FSIS has determined that this final rule will not have a significant effect on a substantial number of small entities. The final rule will affect about 72 poultry slaughtering establishments, most of which are large business enterprises. It also will affect as many as 3,550 official meat and poultry processing establishments, of which a substantial majority, 3,330, are considered small entities under Small Business Administration criteria (500 or fewer employees per establishment). However, the rule will not have a significant effect on these establishments. It will impose no new regulatory requirements necessitating investments or other resource commitments by establishments but would, by removing a number of existing regulatory requirements, permit more efficient resource utilization, especially to support establishment HACCP systems.

The final rule will remove the remaining requirements for establishments to have PQC programs for certain products or processes and the general requirement concerning the design of such programs. The final rule will give inspected establishments greater flexibility to innovate and to introduce new processes or products that meet HACCP or other consumer protection objectives. As a result, the final rule will theoretically provide several thousand dollars of regulatory relief annually per establishment.

The final rule will enable establishments to avoid the costs associated with developing and implementing PQC programs that address regulatory requirements for the use of certain substances in preparation of meat and poultry products, such as the use of organic acids to delay discoloration of fresh meat cuts. Thermal processing establishments (of which there are about 130) will avoid the costs associated with developing PQC programs according to Agency specifications and the costs associated with obtaining Agency prior approvals.

As many as 3,330 small establishments will no longer be required to operate PQC programs for certain processes (such as PQC programs for processing cooked beef) and products (such as mechanically separated, or ''deboned,'' product). Small and large establishments will save about $520 per PQC program in development costs for 310 mandatory PQC programs, or $161,720 total. Out of this total, small establishments will save about $151,320.

Operating costs of PQC programs vary widely. A simple PQC program to verify the accuracy of scales, for example, may require that tests be performed only several times a year, at little cost in operator time. A PQC program for a complex process, on the other hand,

may require daily tests and data collection and recordkeeping tasks lasting up to 4 hours. For the purposes of this document, PQC programs are each assumed to require up to 1 hour's worth of daily attention by the establishment QC specialist. The removal of the PQC requirements will relieve small establishments of these burdens.

Assuming, for example, that small establishments incur annual costs of about $12,000,000 in operating mandatory PQC programs (solely in operating the QC evaluation process of such programs, and not including laboratory analysis or special facilities that may be required to determine whether products are in compliance with the regulations), each establishment will save about $3,600 in PQC program operations.

In addition, small establishments will benefit from savings (at the rate of $300 per establishment) that accrue from the removal of regulatory design requirements for both mandatory and voluntary PQC programs. They will have flexibility to develop and implement HACCP-consistent or other process control systems, beyond the flexibility that was provided by the FSIS final rule that removed prior approval requirements for blueprints, equipment, and certain PQC programs (62 FR 45016; August 25, 1997).

Thus, at least $3,900 in recurring savings is available to each small meat and poultry establishment. However, because many, if not most, affected establishments will be likely to continue to operate PQC programs that help in producing products with consistent and uniform characteristics, establishments may not choose to reap the savings that could result from adopting alternatives to their PQC programs. The effect of the final rule on the substantial number of affected small establishments is therefore not likely to be significant.

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 or packaging requirements on federally inspected meat and meat products or poultry products that are in addition to, or different than, those imposed under the FMIA and 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 or 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 final rule is not intended to have retroactive effect.

There are no applicable administrative procedures that must be exhausted prior to any judicial challenge to the provisions of this final rule. However, the administrative procedures specified in 9 CFR 381.35 must be exhausted prior to any judicial challenge of the application of the provisions of this final rule, if the challenge involves any decision of an FSIS employee relating to inspection services provided under the FMIA or PPIA.

Executive Order 12898

Pursuant to Executive Order 12898 (59 FR 7629; February 16, 1994), ''Federal Actions to Address Environmental Justice in Minority 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 final rule will remove the requirements pertaining to PQC programs in federally inspected meat and poultry establishments. It will also remove from the canning regulations all requirements concerning PQC programs, the requirements for case-by-case FSIS approval of systems and devices not specified in the regulations, and several other prior-approval requirements.

As explained in the economic impact analysis, the regulations should generally benefit firms that process meat, meat food products, and poultry products. The regulations will 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 final rule will 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. The benefits of this final rule from ensuring that products are not adulterated or misbranded will accrue to the members of all classes of the public, including minorities, women, and persons with disabilities.

About 4 percent of official meat and poultry establishments are under female or minority ownership. FSIS does not believe that the effects of this rulemaking, whether beneficial or adverse, on such establishments will be disproportionate. however, the Agency welcomes any data or information that would contribute to an understanding of the effects of this rule on minorities, women, or persons with disabilities.

Additional Public Notification

Public awareness of all stages of rulemaking and policy development is important. Consequently, in an effort to better ensure that minorities, women, and persons with disabilities are aware of this final rule, FSIS will announce it and provide copies of this **Federal Register** publication in the weekly FSIS Constituent Update. FSIS communicates the Constituent Update by fax to over 300 organizations and individuals. In addition, the update is available on line through the FSIS web page located at ''http://www.fsis.usda.gov''. The update is used to provide information regarding FSIS policies, procedures, regulations, **Federal Register** notices, FSIS public meetings, recalls, and other information that could affect or would be of interest to the Agency's constituents/ stakeholders. The constituent fax list consists of industry, trade, and farm groups, consumer interest groups, allied health professionals, scientific professionals, and other individuals who have requested to be included. Through these various channels, FSIS is able to provide information to a much broader, more diverse audience. For more information and to be added to the constituent fax list, readers of this document may fax their requests to the Congressional and Public Affairs Office, at (202) 720–5704.

Paperwork Requirements

Title: Processing Procedures and Quality Control Systems.

Type of Collection: Revision.

Abstract: FSIS has reviewed the paperwork and recordkeeping requirements in this final rule in accordance with the Paperwork Reduction Act. This final rule will substantially reduce reporting requirements for official establishments. The final rule will remove the design requirements affecting most PQC programs that establishments have and most requirements for establishments to have PQC programs for certain products or processes. Currently, there are 624,465 burden hours associated with the PQC program requirements. FSIS will request OMB to eliminate all these burden hours from the information collection request 0583–0089.

List of Subjects

9 CFR Part 317

Meat inspection, Reporting and recordkeeping requirements.

9 CFR Part 318

Meat inspection, Reporting and recordkeeping requirements.

9 CFR Part 319

Food labeling, Incorporation by reference, Meat inspection.

9 CFR Part 381

Poultry and poultry products, Reporting and recordkeeping requirements.

9 CFR Part 424

Food additives, Food packaging, Meat inspection, Poultry and poultry products.

For the reasons set forth in the preamble, FSIS is amending 9 CFR chapter III, the Federal meat and poultry inspection regulations, as follows:

PART 317—LABELING, MARKING DEVICES, AND CONTAINERS

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

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

§ 317.21 [Amended]

2. Paragraph (b) of § 317.21 is amended by removing the comma and all words following the word ''person''.

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

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

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

§ 318.4 [Amended]

4. Paragraph (d) of § 318.4 is removed and reserved.

5. In § 318.305, paragraph (d)(5) is removed, and paragraphs (a)(1)(ii), (a)(2)(ii), and (f) are revised to read as follows:

§ 318.305 Equipment and procedures for heat processing systems.

(a) * * *

(1) * * *

(ii) *Other devices.* Temperature-indicating devices, such as resistance temperature detectors, used in lieu of mercury-in-glass thermometers, shall meet known, accurate standards for such devices when tested for accuracy. The records of such testing shall be available to FSIS program employees.

(2) * * *

(ii) *Other devices.* Temperature/time recording devices or procedures used in lieu of chart-type devices must meet known accurate standards for such devices or procedures when tested for accuracy. Such a device must be accurate enough for ensuring that process time and temperature parameters have been met.

* * * * *

(f) *Other systems.* All other systems not specifically delineated in this section and used for the thermal processing of canned product shall be adequate to produce shelf-stable products consistently and uniformly.

* * * * *

6. Paragraph (b) of § 318.307 is revised to read as follows:

§ 318.307 Record review and maintenance.

* * * * *

(b) *Automated process monitoring and recordkeeping.* Automated process monitoring and recordkeeping systems shall be designed and operated in a manner that will ensure compliance with the applicable requirements of § 318.306.

* * * * *

7. In § 318.308, paragraph (b) is revised, paragraph (c) is removed and reserved, and paragraph (d) introductory text is revised to read as follows:

§ 318.308 Deviations in processing.

* * * * *

(b) Deviations in processing (or process deviations) must be handled according to:

(1)(i) A HACCP plan for canned product that addresses hazards associated with microbial contamination, or

(ii) Paragraph (d) of this section.

(c) [Reserved]

(d) Alternative procedures for handling process deviations.

* * * * *

8. In § 318.309, paragraph (a) is revised, paragraphs (b) and (c) are removed and reserved, and paragraph (d) introductory text is revised, to read as follows:

§ 318.309 Finished product inspection.

(a) Finished product inspections must be handled according to:

(1) A HACCP plan for canned product that addresses hazards associated with microbiological contamination;

(2) An FSIS-approved total quality control system;

(3) Alternative documented procedures that will ensure that only safe and stable product is shipped in commerce; or

(4) Paragraph (d) of this section.

(b) [Reserved]

(c) [Reserved]

(d) Alternative procedures for handling finished product inspections.

* * * * *

PART 319—DEFINITIONS AND STANDARDS OF IDENTITY OR COMPOSITION

9. The authority citation for part 319 continues to read as follows:

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

10. Paragraph (e)(2) of § 319.5 is revised to read as follows:

§ 319.5 Mechanically Separated (Species).

* * * * *

(e) * * *

(2) Analytical methods used by establishments in verifying the fat, protein, and calcium content of product consisting of or containing Mechanically Separated (Species) shall be among those listed in ''Official Methods of Analysis of the Association of Official Analytical Chemists (AOAC),'' 16th edition, 1995, §§ 960.39, 976.21, 928.08 (Chapter 39), and 940.33 (Chapter 45), which is incorporated by reference, or, if no AOAC method is available, in the ''Chemistry Laboratory Guidebook,'' U.S. Department of Agriculture, Washington, D.C., March 1986 edition, sections 6.011–6.013, Revised June 1987 (pages 6–35 through 6–65), or by appropriate methods validated by scientific bodies in collaborative trials. The ''Official Methods of Analysis of the Association of Official Analytical Chemists,'' Chapter 39 and Chapter 45, subsection 45.2.06 (AOAC Official Method 940.33), 16th edition, 1995, are incorporated by reference with the approval of the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR Part 51.

§ 319.104 [Amended]

11. Section 319.104 is amended in paragraph (a) by removing the last sentence of footnote 3 to the chart.

§ 319.105 [Amended]

12. Section 319.105 is amended in paragraph (a) by removing the last sentence of footnote 2 to the chart.

PART 381—POULTRY PRODUCTS INSPECTION REGULATIONS

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

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

14. Section 381.76 is amended follows:

a. Paragraph (b)(1)(ii)(*b*) is revised.

b. Paragraph (b)(1)(iii)(*b*) is revised.

c. Paragraph (b)(4)(i)(*a*) introductory text is revised.

d. Paragraph (b)(4)(i)(*b*) is revised.

e. Paragraph (b)(4)(ii) is removed and reserved.

f. Paragraph (b)(4)(iii) is removed and reserved.

g. Paragraph (b)(5)(i)(*a*) introductory text is revised.

h. Paragraph (b)(5)(i)(*b*) is revised.

i. Paragraph (b)(5)(ii) is removed and reserved.

j. Paragraph (b)(5)(iii) is removed and reserved.

k. Paragraph (c) is removed.

The revisions read as follows:

§ 381.76 Post-mortem inspection, when required; extent; traditional, Streamlined Inspection System (SIS), New Line Speed (NELS) Inspection System and the New Turkey Inspection (NTI) System; rate of inspection.

* * * * *

(b)(1) * * *

(ii) * * *

(*b*) The Administrator determines that the establishment has the intent and capability to operate at line speeds greater than 70 birds per minute, and meets all the facility requirements in § 381.36(d).

(iii) * * *

(*b*) The Administrator determines that the establishment meets all the facility requirements in § 381.36(e).

* * * * *

(4) * * *

(i) * * *

(*a*) *Post-mortem inspection.* The establishment shall provide three inspection stations on each eviscerating line in compliance with the facility requirements § 381.36(d)(1). The three inspectors shall inspect the inside, viscera, and outside of all birds presented. Each inspector shall be flanked by two establishment employees—the presenter and the helper. The presenter shall ensure that the bird is properly eviscerated and presented for inspection and the viscera uniformly trailing or leading. The inspector shall determine which birds shall be salvaged, reprocessed, condemned, retained for disposition by the veterinarian, or allowed to proceed down the line as a passed bird subject to reinspection. Poultry carcasses with certain defects not requiring condemnation of the entire carcass shall be passed by the inspector, but shall be subject to reinspection to ensure the physical removal of the specified defects. The helper, under the supervision of the inspector, shall mark such carcasses for trim when the defects are not readily observable. Trimming or birds passed subject to reinspection shall be performed by:

* * * * *

(*b*) A reinspection station shall be located at the end of each line. This station shall comply with the facility requirements in § 381.36(d)(2). The inspector shall ensure that the establishment has performed the indicated trimming of carcasses passed subject to reinspection by visually monitoring, checking data, or gathering samples at the station or at other critical points on the line.

(ii) [Reserved]

(iii) [Reserved]

(5) * * *

(i) * * *

(*a*) *Post-mortem inspection.* Each inspection station must comply with the facility requirements in § 381.36(e)(1). Each inspector shall be flanked by and establishment employee assigned to be the inspector's helper. The one inspector on an NTI–1 Inspection System shall be presented every bird. Each inspector on an NTI–2 Inspection System line shall be presented every other bird on the line. An establishment employee shall present each bird to the inspector properly eviscerated with the back side toward the inspector and the viscera uniformly trailing or leading. Each inspector shall inspect the inside, viscera, and outside of all birds presented. The inspector shall determine which bird shall be salvaged, reprocessed, condemned, retained for disposition by a veterinarian, or allowed to proceed down the line as a passed bird subject to reinspection. Turkey carcasses with certain defects not requiring condemnation of the entire carcass shall be passed by the inspector, but shall be subject to reinspection to ensure the physical removal of the specified defects. The helper, under the supervision of the inspector, shall mark such carcasses for trim when the defects of birds passed subject to reinspection shall be performed by:

* * * * *

(*b*) *Reinspection.* A reinspection station shall be located at the end of the lines. This station shall comply with the facility requirements in § 381.36(e)(2). The inspector shall ensure that establishments have performed the indicated trimming of each carcass passed subject to reinspection by visually monitoring, checking data, and/or sampling product at the reinspection station and, if necessary, at other points, critical to the wholesomeness of product, on the eviscerating line.

(ii) [Reserved]

(iii) [Reserved]

§ 381.121d [Amended]

15. Paragraph (b) of § 381.121d is amended by removing the comma and all words following the word ''person.''

§ 381.145 [Amended]

16. Paragraphs (d) and (e) of § 381.145 are removed and reserved.

17. In § 381.305, paragraph (d)(5) is removed, and paragraphs (a)(1)(ii), (a)(2)(ii), and (f) are revised to read as follows:

§ 381.305 Equipment and procedures for heat processing systems.

(a) * * *

(1) * * *

(ii) *Other devices.* Temperature-indicating devices used in lieu of mercury-in-glass thermometers, such as resistance temperature detectors, shall meet known, accurate standards for such devices when tested for accuracy. The records of such testing shall be available to FSIS program employees.

(2) * * *

(ii) *Other devices.* Temperature/time recording devices or procedures used in lieu of chart-type devices must meet known accurate standards for such devices or procedures when tested for accuracy. Such a device must be accurate enough for ensuring that process time and temperature parameters have been met.

* * * * *

(f) *Other systems.* All other systems not specifically delineated in this section and used for the thermal processing of canned product shall be adequate to produce shelf-stable products consistently and uniformly.

* * * * *

18. Paragraph (b) of § 381.307 is revised to read as follows:

§ 381.307 Record review and maintenance.

* * * * *

(b) *Automated process monitoring and recordkeeping.* Automated process monitoring and recordkeeping systems shall be designed and operated in a manner which will ensure compliance with the applicable requirements of § 381.306.

* * * * *

19. In § 381.308, paragraph (b) is revised, paragraph (c) is removed and reserved, and paragraph (d) introductory text is revised to read as follows:

§ 381.308 Deviations in processing.

* * * * *

(b) Deviations in processing (or process deviations) must be handled according to:

(1) A HACCP plan for canned product that addresses hazards associated with microbial contamination; or

(2) Paragraph (d) of this section.

(c) [Reserved]

(d) Alternative procedures for handling process deviations.

* * * * *

20. In § 381.309, paragraph (a) is revised, paragraphs (b) and (c) are removed and reserved, and paragraph (d) introductory text is revised, to read as follows:

§ 381.309 Finished product inspection.

(a) Finished product inspections must be handled according to:

(1) A HACCP plan for canned product that addresses hazards associated with microbiological contamination; or

(2) An FSIS-approved total quality control system; or

(3) Alternative documented procedures that will ensure that only product that is safe and stable is shipped in commerce; or

(4) Paragraph (d) of this section.

(b) [Reserved]

(c) [Reserved]

(d) Alternative procedures for handling finished product inspections.

* * * * *

PART 424—PREPARATION AND PROCESSING OPERATIONS

21. The authority citation for part 424 continues to read as follows:

Authority: 7 U.S.C. 450, 1901–1906; 21 U.S.C. 451–470, 601–695; 7 CFR 2.18, 2.53.

22. In the table in § 424.21(c), under the Class of substance ''Miscellaneous,'' the entry for the Substance ''Ascorbic acid, erythorbic acid, citric acid, sodium ascorbate, and sodium citrate, singly or in combination'' is revised to read as follows:

§ 424.21 Use of food ingredients and sources of radiation.

* * * * *

(c) * * *

Class of substance	Substance	Purpose	Products	Amount
*	*	*	*	* * *
Miscellaneous	Ascorbic acid, erythorbic acid, citric acid, sodium ascorbate and sodium citrate, singly or in combination.	To delay discoloration.	Fresh beef cuts, fresh lamb cuts, and fresh pork cuts.	Not to exceed, singly or in combination, 500 ppm or 1.8 mg/sq inch of product surface of ascorbic acid (in accordance with 21 CFR 182.3013), erythorbic acid (in accordance with 21 CFR 182.3041), or sodium ascorbate (in accordance with 21 CFR 182.3731); and/or not to exceed, singly or in combination, 250 ppm or 0.9 mg/sq inch of product surface of citric acid (in accordance with 21 CFR 182.6033), or sodium citrate (in accordance with 21 CFR 182.6751).
*	*	*	*	* * *

* * * * *

23. In § 424.22, paragraphs (b)(1)(ii)(A) and (B) are revised to read as follows:

§ 424.22 Certain other permitted uses.

* * * * *

(b) * * *

(1) * * *

(ii) * * *

(A) 100 ppm ingoing (potassium nitrite at 123 ppm ingoing); and 550 ppm sodium ascorbate or sodium erythorbate (isoascorbate) shall be used; or

(B) A predetermined level between 40 and 80 ppm (potassium nitrite at a level between 49 and 99 ppm); 550 ppm sodium ascorbate or sodium erythorbate (isoascorbate); and additional sucrose or other similar fermentable carbohydrate at a minimum of 0.7 percent and an inoculum of lactic acid producing bacteria such as *Pediococcus acetolactii* or other bacteria demonstrated to be equally effective in preventing the production of botulinum toxin at a level sufficient for the purpose of preventing the production of botulinum toxin.

* * * * *

Done at Washington, DC, on May 12, 2000.

Thomas J. Billy,

Administrator.

[FR Doc. 00–12659 Filed 5–26–00; 8:45 am]

BILLING CODE 3410–DM–P

FEDERAL RESERVE SYSTEM

12 CFR Part 261a

[Docket No. R–1071]

Rules Regarding Access to Personal Information Under the Privacy Act

AGENCY: Board of Governors of the Federal Reserve System.

ACTION: Final rule.

SUMMARY: In accordance with the Privacy Act, the Board of Governors of the Federal Reserve System (Board) is amending its Rules Regarding Access to Personal Information under the Privacy Act to include a new system of records, entitled Multi-rater Feedback Records (BGFRS–25) to the list of system of records that is exempt from certain required disclosures. Notice of the new system of records is published elsewhere in this **Federal Register**.

EFFECTIVE DATE: June 28, 2000.

FOR FURTHER INFORMATION CONTACT: Elaine M. Boutilier, Senior Counsel, Legal Division (202/452–2418), or Chris Fields, Manager, Human Resources Function, Management Division (202/452–3654), Board of Governors of the Federal Reserve System, 20th Street and Constitution Avenue, NW, Washington, DC 20551. For users of the Telecommunications Device for the Deaf (TDD) only, contact Janice Simms at 202/452–4984.

SUPPLEMENTARY INFORMATION:

The Board is instituting a feedback program for its managers and officers. Under this Multi-rater Feedback program, Board employees who work for or with a particular manager or officer are asked to complete a voluntary, confidential questionnaire regarding the performance of that manager/officer and send it directly to a consultant hired by the Board for this program. The consultant analyzes the completed questionnaires and compiles a report for the manager/officer that summarizes the comments from the questionnaires. This report does not identify individual comments or those who completed the questionnaires. The report is given only to the manager/officer being evaluated; no other Board