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

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

Done in Washington, DC: April 29, 1996.

Michael R. Taylor,

Acting Under Secretary for Food Safety.

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

BILLING CODE 3410–DM–P

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

[Docket No. 95–032P]

RIN 0583–AB93

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

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Proposed rule.

SUMMARY: The Food Safety and Inspection Service (FSIS) is proposing to amend the Federal meat and poultry products inspection regulations by removing current requirements for prior approval by FSIS of establishment drawings, specifications, and equipment prior to their use in official establishments. Requirements involving the comparison of blueprints and specifications with actual facilities and equipment would end. These amendments would provide the regulated industry with the flexibility to design facilities and equipment in the manner they deem best to maintain a sanitary environment for food production. FSIS would continue to verify through inspection that good sanitation is being achieved. Similarly, FSIS is proposing to end its prior approval of most establishment-operated partial quality control programs, which are used by establishments to control certain kinds of food processing and product characteristics. This change would make it possible for establishments to develop and implement quality control programs without first having to receive permission from FSIS to do so. This action is being taken to streamline and modernize the meat and poultry food safety regulations, to separate the roles of Government and the regulated industry, to encourage innovations that will improve food safety, and to remove unnecessary regulatory burdens on inspected meat and poultry establishments. In addition, the proposal represents an important shift away from FSIS's ''command-and-control'' regulatory approach and toward a less bureaucratic approach consistent with the Agency's food safety mission.

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

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

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

SUPPLEMENTARY INFORMATION:

Background

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

The FMIA and PPIA require the Secretary to provide, among other things, for the inspection of establishments to assure that the conditions under which meat and poultry products are produced are sanitary. The Acts also require the Secretary to prescribe rules and regulations governing the sanitary conditions of official establishments (21 U.S.C. 608 and 456). Pursuant to these provisions, the meat and poultry inspection regulations currently prescribe ''prior approval'' or approval-before-use by FSIS of facility drawings and specifications and of equipment used in official establishments. The regulations also provide for the prior approval of certain quality control programs, known as partial quality control (PQC) programs, before their use by official establishments.

Current Prior Approval Procedures

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

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

Also, prior-approval procedures exist for numerous establishment-operated partial quality control programs. This means that companies must come to FSIS for permission before they can initiate or modify processes or controls intended to ensure that products have desired characteristics and that processes are stable.

The prior-approval process is a feature of FSIS's traditional ''command-and-control'' regulatory approach. While prior approval provides assurance that equipment, facilities, or processes, as designed, meet certain requirements that are intended to assure food safety or quality, they reflect the emphasis of the current system on closely observing the means by which establishments maintain sanitation and produce safe food. This feature of the current system is an inappropriate allocation of responsibility between the Agency and establishments. It is an obstacle and too often a deterrent to innovation by establishments seeking to improve operations, and contributes to unproductive use of FSIS resources both in managing the approval system and policing establishment compliance with approved facility and equipment specifications.

In addition, elimination of prior-approval requirements is consistent with the principles articulated in FSIS's February 3, 1995, Pathogen Reduction/ Hazard Analysis and Critical Control Points (HACCP) proposal (60 FR 6774). HACCP and the FSIS food safety strategy are based on the principle that sanitary measures and science-based preventive process controls should be built into the food production system to reduce or eliminate food safety hazards. Establishment management should be responsible for designing and implementing such process controls, as well as for developing and maintaining standard operating procedures (SOP's) for its sanitation programs. However, the current system imposed by FSIS inappropriately allocates responsibility between the Agency and the industry and impedes the ability of establishment management to implement innovative food safety strategies. Establishments conducting their own hazard analyses and developing the HACCP plans to meet FSIS's food safety objectives will determine whether facility layouts, equipment operating characteristics, and other technical components of the manufacturing process will result in products that meet required standards.

FSIS's reliance on prior approvals also contrasts with both the practices of the remainder of the food industry as regulated by the U.S. Food and Drug Administration and the practices of a significant number of countries that have meat and poultry inspection systems that provide a level of food safety assurance equivalent to that of the United States. With the single exception of Canada, whose meat and poultry regulatory system is intertwined with that of the United States, none of these other countries relies on prior-approval systems to ensure that equipment does not adulterate product.

Anticipated Changes in Inspection

The elimination of the prior approval systems proposed here would change the manner in which FSIS conducts certain aspects of its inspection. Under the current prior approval system, FSIS focuses substantial attention on identifying specific design-related conditions affecting food safety, which should be the responsibility of the establishment. For example, FSIS not only performs prior approval of facility blueprints and equipment, but also inspection tasks to verify that the facility as constructed conforms to the blueprint and that equipment meets approved design specifications. This reflects the fact that the FSIS regulatory system has, in effect, taken responsibility for these matters. Similarly, many establishments currently lack a written sanitation plan and do not systematically ensure daily maintenance of good sanitation. In order to compensate for this lack, FSIS inspectors focus considerable attention on sanitation conditions and practices that are more appropriately the establishment's responsibility.

Under this proposal, FSIS would no longer control through prior approval the design specifications for buildings and equipment. Instead, FSIS would focus its regulatory and inspectional attention on determining whether an establishment is successfully meeting sanitation standards. Establishments would ensure that the design of buildings and equipment is appropriate for sanitary food production and for maintaining good sanitary conditions in accordance with broad sanitation principles. In addition, the FSIS proposal to require establishments to adopt sanitation SOP's of their own design, requires establishments to identify the elements of good sanitation required to prevent direct product contamination, carry out the SOP's on a daily basis, and achieve acceptable sanitation results. Concurrent with this action, FSIS inspection activities under SOP's and HACCP would be restructured to focus not on the building or equipment design, or on FSIS approval status, but on whether good sanitation is, in fact, being maintained.

In concert with this proposal, FSIS would review and revise its existing regulations and guidelines to avoid real or *de facto* prescriptions that are inconsistent with the approach outlined here. This review is underway and public comments on this process were invited in an advance notice of proposed rulemaking, the ''FSIS Agenda for Change,'' published in the December 29, 1995, issue of the Federal Register (60 FR 67469).

Prior-Approval Requirements To Be Eliminated

A. Establishment Facilities

The demand for Federal inspection of sanitary conditions of slaughterhouses was one of the principal concerns leading to enactment of the 1906 Meat Inspection Act. Leading experts of the day in the field of meat inspection advocated the approval of slaughterhouse plans by qualified veterinary inspectors. Facilities for slaughtering, dressing, and meat preparation that were properly designed and built with sound materials that could be effectively cleaned and not contaminate product were considered essential to help prevent the spread of disease and protect the health and safety of the animal and human populations. While the Meat Inspection Act itself did not mandate prior approval of drawings as a condition of inspection, early regulations issued under that law required the submission to the Agency of plans for new and remodeled establishments for review and approval before inspection could be granted.

The FMIA, the current law governing meat inspection, continues with slight modification the provision in the original meat act assigning to USDA the responsibility for regulating the sanitary conditions of inspected establishments (see 21 U.S.C. 608). The PPIA contains similar provisions, but neither of the Acts mandates prior approval of establishment blueprints.

As a means of assuring sanitary conditions in inspected establishments, the meat and poultry inspection regulations require that applicants for inspection submit to FSIS the drawings and specifications of establishments where inspected operations are to be conducted for review and approval (9 CFR 304.2, 381.19). The regulations also require that drawings reflecting any remodeling be submitted in advance of construction (§§ 308.2 and 381.18), and prescribe specifications for facilities of inspected establishments (at §§ 307, 308, and 381, subparts G and H). This procedure was required to help avoid costly changes in construction in the

event that FSIS determined facilities could create insanitary conditions that could lead to food adulteration.

To comply with the prior-approval regulations, the applicant completes a request form and provides a blueprint with specifications to the FSIS inspector-in-charge. The blueprint and specifications are then reviewed by the inspection circuit supervisor, the first level of supervision outside inspected establishments, and sent directly to FSIS headquarters in Washington, D.C. FSIS's area office—the second level of supervision in the field organizational structure, which stands between the circuit supervisors and the five Regional Offices—may also review plans referred to it by the circuit supervisor before sending them on to FSIS headquarters. In Washington, FSIS's facilities branch reviews the information and decides whether to approve or reject the drawings and specifications, seek further information, or return the materials to the applicant. When changes are made in the facilities of an establishment, the changes must be reflected in revised blueprints for the establishment. The remodeled facilities are then reviewed by the FSIS inspector-in-charge and the circuit supervisor to assure compliance with the approved blueprints and that there will be no product adulteration.

Currently, about 2,900 blueprints (both from new applicants and from establishments remodeling their facilities) are reviewed each fiscal year. About 38% of the submissions, or about 1,100 sets, are rejected due to various deficiencies. Most rejections result from errors in paperwork rather than design flaws that will compromise food safety. The Agency works with the submitting establishments to see that the deficiencies are corrected. Under prior approval, establishments are urged to delay construction until drawings and specifications have been approved, in order to avoid costly changes in construction or remodeling.

Experience has shown that FSIS prior approvals are of limited value in assuring good sanitation, because they are limited in both scope—dealing only with establishment facilities as presented in drawings—and time—they are given once, on the condition that establishments will maintain a sanitary operating environment after their facilities are approved. Ultimately, the establishments' implementation of good sanitation operating procedures on a continuing basis is more critical than the actual design of a facility. Also, with the elimination of prior approval requirements, production time that previously was lost in obtaining FSIS approval of blueprints and specifications would become available to the industry.

Under the proposal, establishments would continue to be expected to establish and maintain a sanitary environment for slaughtering and processing by adhering to the general principles and requirements for lighting, ventilation, drainage, plumbing, toilets, and condensation found in §§ 308.3(a)–(c), 308.4, 308.7, 308.8 (a) and (b), 381.46, and 381.47 of the meat and poultry inspection regulations.

All official establishments (about 6,200 establishments), would be affected by the proposal, except food irradiation facilities. There is no requirement for prior approval of blueprints for food irradiation facilities, because only prepackaged product is permitted to be irradiated under current regulations.

Although FSIS's prior-approval procedures for drawings and specifications would change under the proposal, its sanitation standards would not. Establishments would be responsible for ensuring that the design of facilities creates a sanitary environment and that such an environment can be and is maintained. If field inspectors carrying out their routine inspection tasks found product to be adulterated or prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth or may have been rendered injurious to health because of deficient facilities, all product subject to such conditions would be either retained and reworked or condemned, and the establishment would be required to take corrective action or cease operations. As under current regulations, such corrective action, which might involve repair or reconstruction of facilities, would be triggered only by an actual finding of product adulteration or insanitary conditions. Such a finding would constitute evidence of deviation from regulatory standards. Therefore, FSIS is proposing to remove the current requirements for prior approval of facility drawings and specifications. Requirements at 9 CFR 304.2(a), 308.2, and 381.19(a)–(f) for submission of blueprints and drawings before inspection can be granted or changes made in facilities at official establishments would be eliminated. Establishments would initiate and complete construction without prior approval by FSIS.

Although there would no longer be a requirement for an establishment to submit facility drawings and specifications in applying for a grant of Federal inspection, FSIS would continue to have a specific process through which the decision on granting inspection would be made. This process would still include an on-site review, or ''walk-through,'' of the establishment's facilities by the FSIS circuit supervisor as part of the predecisional review of the establishment's capability to produce ''complying'' product. However, the decisionmaking process would no longer include the review and prior approval of establishment facility blueprints and specifications by the Agency. The on-site review would not involve matching items on the blueprints with the actual facilities represented. Instead, the focus of the review would be on the extent to which the establishment is able to maintain a sanitary environment for food production. This change would be intended to parallel other changes in establishment-inspector relationships that FSIS is contemplating in its reinvention of meat and poultry inspection.

If this proposal is adopted, FSIS would plan to:

(1) maintain a small number of personnel who would assist inspectors in performing in their in-plant roles. These roles would eventually include the monitoring of establishment-operated sanitation SOP's and HACCP systems;

(2) provide general guidance regarding establishment layout and design to assist establishments in meeting food safety standards; and,

(3) publish one final edition of Agriculture Handbook 570, ''U.S. Inspected Meat and Poultry Packing Establishments: A Guide to Construction and Layout'', [1] and make it available to industry as a guidebook to construction of facilities. Handbook 570, an FSIS reference guide (not a set of regulatory requirements per se), is provided to assist industry, architects, and inspectors.

A small staff in Washington would maintain FSIS's technical expertise and capability in this important aspect of food science and technology. This staff would be responsible for keeping abreast of developments in the field and updating FSIS's new, HACCP-oriented guidelines and communicating technical information to Agency personnel. The Agency will not approve industry decisions in these areas.

In addition, implementation of the proposed Pathogen Reduction/HACCP rule's sanitation standard operating procedures, would render prior-approval procedures unnecessary.

[1] A copy of Agriculture Handbook 570 is on file for review in the FSIS Docket Clerk's office, 4352 South Agriculture Building, Washington DC, 20250.

Establishment-operated sanitation procedures and HACCP systems would accomplish, without prior approval, the same objectives as the FSIS prior approvals. Thus, under HACCP-based inspection, the FSIS prior approvals could no longer be considered an efficient and cost-effective way to achieve sanitation objectives.

B. Equipment Approval

As in the case of the facilities regulations, the regulations governing equipment (9 CFR 308.5, 381.53) were promulgated with a view to having the Agency assure sanitation in slaughtering, dressing, and processing operations. Requirements for sanitary equipment and utensils have been in force since the 1906 Meat Inspection Act. However, unlike prior approval of facility blueprints and drawings, the approval of types of equipment prior to use has not always been a requirement.

Under regulations that have been in force since 1975 (9 CFR 308.5, and 381.53), the FSIS Equipment Branch formally evaluates equipment and utensils proposed by manufacturers or suppliers before they can be used in official establishments to assure they can be maintained in a sanitary condition. The program focuses on identifying and correcting problems during the initial development of equipment, instead of resolving problems after equipment is put into widespread use.

FSIS's acceptance of new, modified, or reconditioned equipment for use in federally inspected meat and poultry establishments is a two-step process. First, FSIS Equipment Branch personnel evaluate the design and construction of equipment by reviewing assembly-type drawings and corresponding parts and material lists submitted to the Branch by the equipment manufacturer. Then, if necessary, FSIS inspectors review the in-establishment operation of the equipment and report their findings to the Equipment Branch. Commercially available equipment is accepted and listed in an FSIS reference guide, ''Accepted Meat and Poultry Equipment,'' [1] known as the FSIS Equipment Book. Once equipment is listed in this reference as acceptable, no further approval is needed on an establishment-by-establishment basis. Certain categories of equipment, such as simple tools and cleaning equipment, are exempt from prior approval. Among the types of equipment that are evaluated through FSIS's prior-approval procedure are clean-in-place systems, piping used with establishment machinery, automatic eviscerators, heat exchangers, smokehouses and ovens, air compressors, and water recycling equipment.

FSIS processes about 2,500 equipment applications, rejections, and acceptances each year. About 200 equipment applications are rejected on first review for lack of sufficient information. About 650 acceptance decisions are based on the results of in-plant trials. About 18 equipment applications are rejected after in-plant trials reveal deficiencies.

The principal cost of the prior-approval process to the private sector is considered to be that resulting from lost or delayed equipment sales caused by delay in obtaining approval. This cost falls mainly on equipment sellers and manufacturers and can be considerable if the introduction of promising new technology is delayed. The productivity of meat and poultry establishments could also be adversely affected by delays in approving efficient new equipment.

Furthermore, FSIS's one-time approval does not address daily operational issues such as proper maintenance and adjustment of equipment to prevent product contamination. Such issues are covered by the requirement that equipment and utensils be of such material and construction that they can be easily cleaned to prevent product adulteration (9 CFR 308.5, 381 subpart H), as well as by other general requirements, independently of any prior approval.

The prior-approval review for equipment may sometimes involve the evaluation of machinery, including scientific instrumentation, that will not itself have contact with a food product or have other direct effects on health or safety, but that may be part of an innovative approach to food processing or product safety. The Agency's review may delay testing or introduction of the innovation by weeks or months. The delay can be costly to a company in a highly competitive environment.

FSIS is therefore proposing to eliminate the requirement at 9 CFR 308.5 and 381.53 for prior evaluation and approval of equipment and utensils used in official meat and poultry establishments. The general principles and requirements for such equipment and utensils provided at 9 CFR 308.5(a) and 381.53(a) would be preserved.

Under this proposal, equipment and utensils would still have to be constructed so as to facilitate thorough cleaning and operational cleanliness and not adulterate edible product. Also, they would still have to be constructed, maintained, and used in a manner that does not interfere with inspection.

However, FSIS would no longer conduct its acceptance program before equipment could be used in an official establishment. Establishments would be able to use equipment based on their own evaluation of their ability to utilize the equipment in a sanitary way. The general requirements for equipment already in the regulations (9 CFR 308.5 and 381.53) would not change. In its inspection activities, FSIS would continue to judge establishment equipment by those same general standards. Equipment must be cleanable, it must be capable of being disassembled and inspected, and it must not interfere with inspection or adulterate product. FSIS inspectors would continue to reject equipment they find posing a sanitary hazard.

For calendar year 1996, the Agency will separate the general guidance material from its list of approved equipment and publish the guidance material separately. The final edition of the equipment list, which FSIS published in 1995, is available to current subscribers and to anyone who requests a copy before the effective date of the final rule.

Operational procedures and appropriate sanitation process controls would be developed by the inspected establishment. In this area, as in facilities, official establishments would be required to meet the general requirements prescribed in the regulations, but would be allowed the flexibility to determine the specific steps to be taken to comply with those requirements. The sanitation SOP's proposed for official establishments in FSIS's Pathogen Reduction/HACCP proposal would provide plans for applying the general principles for maintaining sanitary conditions to specific establishment situations. The establishment would also be required to maintain any controls appropriate to the HACCP plans for the establishment's products (e.g., raw beef), such as making sure the facilities and equipment (structures and machinery for evisceration) are designed, built, and operated so that any necessary action (sanitary dressing procedures) can be taken at critical control points in the HACCP plan.

The equipment prior-approval process proposed here for elimination is to be distinguished from the program, announced by FSIS last year, for reviewing experimentation with new technologies (''Guidelines for Preparing and Submitting Experimental Protocols for In-Plant Trials of New Technologies and Procedures; 60 FR 27714; May 25, 1995) under commercial conditions. The purpose of the new program is to

encourage the adoption by industry of innovative technologies that will help reduce the risk of foodborne disease. The Agency has established procedures (see FSIS Directive 10,700.1) for reviewing protocols for experimentation with new technologies in official establishments if there is a possibility the experimentation could adversely affect product, environmental, or worker safety, or interfere with inspection.

For example, in experiments involving the artificial contamination of carcasses with fecal matter to test the effectiveness of a carcass cleaning process, any products from these carcasses must be removed from commercial channels or reconditioned to be wholesome or fit for sale. Protocols for experiments involving the use of materials that could pollute the environment or affect worker safety must include appropriate regulatory citations or be accompanied by written approval of the Environmental Protection Agency or the Occupational Safety and Health Administration. Although new technologies can be expected to include the use of equipment, the FSIS review program is primarily intended to enable the experimentation to proceed rather than to approve the equipment used.

Further Regulatory Reform

As stated in FSIS Docket #95–008A, ''FSIS Agenda for Change; Regulatory Review'' (60 FR 67469; December 29, 1995), FSIS is reviewing all of its regulations, policies, and inspection procedures, including those concerning establishment sanitation (as presented in handbooks, notices, directives, etc.). Although implementation of FSIS's proposal for sanitation SOP's would not depend on revisions to the Agency's sanitation regulations, because this is an area where inspectors have traditionally exercised discretion and provided direct oversight and direction to establishments, the Agency recognizes the need to more clearly state its performance standards in this area. The Agency believes that the regulations can be made much clearer in describing the establishments' responsibilities, that doing so will relieve inspectors of much of the routine work they do that should be done by establishment employees, and that inspection resources can then be freed up and reapplied in performing new, HACCP-related food safety functions.

C. Partial Quality Control Programs

Quality control, in general, is a planned, documented system of activities intended to assure the stability of processes and uniformity of products. Quality control programs are based on the assumption that there is normal variation in any process and that the process is under control if that variation is not exceeded. Quality control is used in manufacturing to assure that components and products from ball bearings to microcomputer circuits, which are made in huge quantities, will all have the same desired characteristics. In the food industry, quality control systems are used in processing operations to make sure that each product produced, from TV dinners to hotdogs, will be exactly the same—will have the same content, flavor, color, texture, and so forth, no matter how many thousands are made in a production run.

In applications relevant to food safety, quality control programs can be used to maintain normal process variation around a standard, such as a time-temperature standard for cooked beef or a moisture-protein ratio for dry sausage. If the expected variation is exceeded, corrective action must be taken to restore process stability and ensure food safety.

Under current FSIS regulations, a company may choose to place all of the processes and products in an establishment under a comprehensive quality control system. Such a system, known as total quality control (TQC), integrates an establishment's quality development, maintenance, and improvement efforts to enable engineering, production, marketing, and service to take place at the most efficient levels that meet consumer expectations. A quality control system for only one process or product in an establishment is known as a partial quality control system (PQC). The quality control systems are, in a sense, precursors of the HACCP system FSIS envisions in that they are establishment-operated process control systems.

In 1980, FSIS promulgated regulations establishing procedures for meat and poultry establishments to follow in obtaining Agency approval of their voluntary TQC and PQC systems. FSIS approved several thousand PQC programs during the 1980's. Since 1990, FSIS has approved an additional 4,000 PQC programs and more than 3,000 amendments to those programs. There are now more than 8,200 approved PQC programs.

An approved quality control program is typically a voluntary activity in which an establishment is allowed to establish its own control procedures (provided these conform with the regulations). Approved PQC programs have provided FSIS with a tool or method for maintaining assurances that label claims, composition declarations, and many other standards are met, and that food products are safe. They also allow FSIS to regulate processes for which specific criteria have not been prescribed by the regulations. Verification inspection of the PQC programs enables FSIS to determine whether or not the programs are functioning. If they are shown to be malfunctioning, the establishment takes corrective action.

There are several types of FSIS-approved PQC programs; most are voluntary, some are mandatory. Voluntary PQC's generally fit into two broad categories. The first type includes those that need not be used to produce a product. For example, an approved PQC program for controlling the percentage of fat and water in a product is not necessary for an establishment to be allowed to make hotdogs. The establishment could produce the product without the PQC program. However, the PQC program helps assure that the establishment produces the hotdog and other products in accordance with the regulatory standards. Without a PQC program, an establishment runs a higher risk of producing noncompliant product subject to retention by the FSIS inspector.

The second type of voluntary PQC includes product labeling-related programs intended to ensure production of a product that is in compliance with a compositional requirement. For example, some PQC's are designed to meet the requirements of vignette labeling (labeling that shows an image of the food product either as it is in the container or as served, such as labeling that shows a specific number of meatballs in or pepperoni slices on a product); other PQC's are designed to comply with product composition requirements that must be met if certain labeling is used (such as the protein-fat-free requirement for a product labeled ''ham, water added'').

There are also mandatory PQC programs. Some are compulsory for certain types of food processing or are required to produce certain products; others are required for an establishment to operate under a certain inspection system. For example, the PQC for on-line carcass quality control is a mandatory component of the New Line Speeds (NELS) poultry inspection system. FSIS also requires approved PQC programs for the testing of new or not-previously-approved antimicrobial treatments in slaughtering establishments (to monitor equipment and process controls for experimental design and safety reasons); for product

identification and control during slaughter, dressing, and processing to support labeling statements; and for monitoring chlorine concentrations in product intended for export to Canada.

There are also PQC programs to control products for so-called economic factors. These programs are intended to prevent the marketing of products that are misbranded or that lack the quality or value that the product standard imposes. These economic PQC's are intended to serve two main purposes: (1) to take the place of lot inspection of product (the sampling and testing of a shift's production for certain characteristics) by the FSIS inspector; and (2) to assure that products meet requirements associated with their labeling.

Establishments operating the first type of economic PQC generate data that are subject to random verification by the FSIS inspector. Examples of these include programs for net weight, fat and water in frankfurters, and boneless meat (mainly for aesthetic defects). An establishment operating under a PQC for net weight keeps records of its checks and corrective actions to avoid lot inspection. Under PQC's for fat and water in frankfurters, establishments keep ingredient records by lot and results of laboratory tests for random verification by FSIS inspectors. An establishment operating a PQC for boneless meat inspections does its own on-line inspections and keeps records. The FSIS inspector randomly selects samples of product the establishment has already inspected to assure that the establishment's records are accurate.

Examples of the second kind of economic PQC include those for controlling the amount of added ingredients in corned beef, the amount of basting or marinating solutions in certain poultry products, and the truthfulness or accuracy of certain label claims. The PQC programs for basting or marinating solutions in certain poultry products assure that the amount of added solution in such products does not exceed the standards set forth in 9 CFR 381.169. The establishment accomplishes the objective of these programs by controlling the pumping procedure at the time of product formulation.

The PQC program for an establishment making a product bearing a label claim that only sirloin cuts have been used in the meat portion of the product must include an approved procedure with records for assuring the veracity of the claim. The PQC's for vignette labeling assure that product characteristics conform with the graphic display on the product label, in accordance with 9 CFR 317.8(a) and 381.121. If a product label shows four meat balls, the PQC for the product would have to document that each package contains four meat balls. The programs are carried out through in-plant sampling and visual inspection, with verification checks by FSIS inspectors.

Although about 70 percent of PQC's are intended to support labeling claims, not all have this purpose. Some support alternative processing procedures that have become so routine that very specific guidelines are followed in preparing the PQC program. FSIS has developed 64 guidelines detailing the essential elements of the most commonly used PQC programs. Many of these are procedures that substitute for more direct controls on economic or quality features of products such as declared count, vignette labeling, or the ''popping'' of pork rinds. These are not connected with food safety.

Under the current system, no matter how routine the preparation, review, and subsequent approval of the PQC program, each must be submitted to either the Washington office or a Regional Office and be stamped ''approved.'' FSIS has assigned 11 staff-years to the review and approval of establishment PQC programs. Approximately 1,800 quality control programs and amendments are handled each year by the Regional Offices; approximately 50 programs for complex processes or requiring specialized knowledge (such as programs for thermal processing) are approved each year by the Washington office. The purpose of the review is to assure that the programs contain all the necessary elements of a quality control program and are appropriate for their intended purpose. The programs must describe the product and process for which they are intended, and the materials to be used. They must identify any hazards, define process deviations, indicate the control points to be monitored, and procedures for checking processes. They must also state the methods for gathering data and determining results, and the corrective actions to be taken if process deviations are found. Finally, the programs must bear the names and locations of responsible establishment quality control officials and authorized USDA employees must have access to records generated by the programs. The time for a PQC prior approval to be obtained is typically 2 weeks.

FSIS considers this administrative burden on the industry and the Agency to be unnecessary to achieve food safety or nonadulteration objectives. Under HACCP-based inspection, establishments would assume responsibility for developing process control procedures in advance without having to depend on Agency approval for every step in their procedures. FSIS would evaluate or verify the effectiveness of the procedures through normal inspection operations and take action when necessary to prevent product adulteration.

By relying on general requirements for the design of all PQC programs, but not requiring prior approval of such programs, FSIS could use its resources (staff-years) more efficiently and effectively than it does now in its PQC prior-approval activities. This approach would also provide establishments with ample flexibility to develop their own process control techniques.

For these reasons, FSIS is proposing to eliminate the requirements at 9 CFR 318.4(d) and 381.145(d) for prior approval of PQC programs. Prior approval of most voluntary or ''economic'' PQC programs would be discontinued and an unnecessary regulatory burden would thus be lifted. However, the current requirements governing the content of PQC programs would remain (§§ 318.4(d)(2)(i) and 381.145(d)(2)(i)), as would existing mandatory-PQC requirements. Prior approval of PQC programs would be eliminated for all but a few of the mandatory PQC programs, such as those required for certain slaughter inspection systems, or those requiring special expertise, such as PQC's for thermal processing or other complex processing. The Agency, however, is planning to change these areas of its regulations to eliminate prior reviews and make them compatible with HACCP. This proposal would eliminate at least 90 percent of the approximately 1,900 PQC submissions made to FSIS each year. Cross-references to the existing prior-approval requirement would also be eliminated (in 9 CFR 318.7(b)(3), 318.7(c)(4), 317.21, 318.19, 318.309, 319.5, 319.104, 381.121d, and 381.309).

In addition, the regulations would be revised to provide (in 9 CFR 318.4(d)(2)(ii) and 381.145(d)(2)(ii)) for the design of PQC programs to assure, with at least 85 percent statistical confidence, that the lot or process means do not exceed the product or label limits to which the PQC programs apply. This requirement, which is already observed in the design of FSIS-approved PQC programs now in use, would also provide for control of individual sublot samples to within plus-or-minus 3 standard errors (standard deviations of the sampling distribution) of the process mean. At least 3 sublot samples representing a

production lot would have to be drawn for each lot of product subject to the PQC program. Further, each sublot sample would have to contain at least 5 samples representing the sublot. No individual sample mean or sublot-sample mean could be more than 3 standard errors above or below the process mean. (A lot is ordinarily a shift's production, but may be defined differently by different establishments. A sublot is a fraction of a lot, and may represent an hour's production, or a quarter-hour's production, or other portion of a production lot from which quality control samples may be drawn.)

For example, a PQC program prepared according to the FSIS guideline for the injection of corned beef labeled as having 30-percent added solution would be designed to assure with greater than 85 percent confidence that the 30-percent limit is not exceeded. In other words, the lot average must not be above this limit. A batch, a portion of the lot, must not be more than 1.2 percent above the declared value on the label. Samples drawn from individual batches of the production lot would have to show that the 3-standard-errors limit (in this example, 1.2 percent, or 31.2 percent added solution) is not exceeded.

PQC programs thus designed would provide process control, and hence a degree of food safety or food nonadulteration assurance, that is comparable to that provided currently by PQC programs individually approved by FSIS. Official establishments would have a less prescriptive set of conditions to meet in designing and implementing their PQC programs, and more latitude for innovation. Because the unnecessary regulatory burden of prior approval would no longer exist, establishments would be able to implement their programs sooner than the current prior-approval process allows.

Establishments would be required to comply with the requirements in proposed 9 CFR 318.4(d)(2)(ii) and 381.145(d)(2)(ii) in designing their PQC programs. Prior approval would still be required for quality control programs and systems referred to elsewhere in the regulations (e.g., 9 CFR 318.4 (c), (e), (f), and (h); and 381.145 (c), (e), (f), and (h)), including those associated with, and required for, such slaughter inspection systems as the NELS and the NTIS (9 CFR 381.76(c)). Proposals addressing these programs and systems will be published in the near future. This proposed rule would amend paragraphs 9 CFR 318.4(e) and 381.145(e) to delete references to prior approval requirements for PQC programs.

Proposed 9 CFR 318.4(d)(1) and 381.145(d)(1) would retain the current requirement for official establishments with PQC's to make the programs and data and information generated by them available to FSIS inspectors. Formal notification would not be required because establishment operators typically notify FSIS personnel of the products and processes operated under establishment-operated PQC programs during their regular interactions with FSIS personnel. Establishment operators recognize the advantage of making their quality control programs and data available to FSIS. FSIS personnel who have not been advised that a product is being produced under a PQC program would perform traditional lot inspection procedures, rather than quality control evaluation and verification tasks. The results of lot inspection may differ technically from those obtained under a PQC inspection. A product lot could be subject to retention even though the process for the product is under control, requiring no corrective action to restore controls.

FSIS, therefore, is not proposing to terminate the use of PQC's as a mechanism for organizing the collection and review of data which document outcomes. FSIS is, however, proposing to end its role as the approver of paperwork describing data collection to support alternative processing procedures.

Establishments operating under approved PQC programs would continue to keep the programs on file and available for use by FSIS employees. FSIS would adjust verification inspection tasks to reflect an approach that is appropriate to the process control procedure being used by the establishment.

It is likely that establishments will find the continued use of PQC programs to be advantageous under the inspection system envisioned by the Agency in its ''Pathogen Reduction/HACCP'' proposal. Although most PQC programs currently used by inspected establishments control products and processes for economic factors, e.g., fat and moisture content or the amount of marinating solution a product can absorb, there are some that have public health implications. Such PQC programs would be compatible with establishment-operated HACCP plans and establishments would continue to use them under HACCP-oriented inspection. Moreover, because establishments operating HACCP plans would be concerned about maintaining stability in all their processes, they would be likely to continue many of their economic PQC's or develop new ones. But they would no longer need prior approval from FSIS before implementing them.

FSIS considers relief from the prior-approval aspect of these PQC's to be the first in a series of steps to realign inspection and company responsibilities in the area of process control systems. As FSIS progresses in its review and adjustment of its inspection regulations, it will take more steps in this area. Regulations will be rewritten as performance standards, facilitating innovation. Establishments will be free to develop establishment-specific approaches as long as the regulatory objectives are met. Therefore, as FSIS reinvents its regulations in accordance with its stated plans (see docket #95–008A, ''FSIS Agenda for Change; Regulatory Review''), the need for Agency-developed guidelines should decrease. Companies will be able to call on a full range of technical resources to develop alternatives and design systems to demonstrate their efficacy.

Other Prior Approvals

This proposal addresses the removal of the requirements for prior approval of facility blueprints, equipment, and PQC programs for inspected meat and poultry establishments. In addition to the prior approvals discussed in this proposal, FSIS plans to eliminate its remaining centralized prior approval procedures. These include the procedures for: PQC's for water reuse, on-line PQC's used in the NELS and NTIS poultry inspection systems, nonfood compounds and proprietary additives, and possibly labeling. FSIS intends to publish proposals on these topics in the near future.

Like the regulations governing meat and poultry inspection, the egg products inspection regulations, promulgated under the Egg Products Inspection Act (21 U.S.C. 1031, *et seq.*) (EPIA), also contain prior-approval procedures for facilities and blueprints (7 CFR 59.146, 59.500, 59.506, 59.520, 59.538, 59.540, and 59.550), labels (7 CFR 59.411), equipment and utensils (7 CFR 59.502, 59.506, 59.515, 59.520, 59.522, 59.540, 59.540, 59.547, and 59.552), nonfood compounds (7 CFR 59.504 and 59.552), and various processing procedures for egg products. FSIS is not prepared to propose to remove these requirements because FSIS has only recently acquired responsibility for administering the EPIA and the egg products inspection regulations promulgated under that Act. FSIS has just begun reviewing the prior-approval requirements in the egg products regulations to see which, if any, are still necessary and should be maintained, and which are obsolete or burdensome and should be amended or

rescinded. As appropriate, FSIS will propose changes in the egg products inspection regulations.

Executive Order 12778

This proposed rule has been reviewed under Executive Order 12778, Civil Justice Reform. States and local jurisdictions are preempted under the Federal Meat Inspection Act (FMIA) and the Poultry Products Inspection Act (PPIA) from imposing any marking or packaging requirements on federally inspected meat and poultry products that are in addition to, or different than, those imposed under the FMIA or 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 rule, if the challenge involves any decision of an FSIS employee relating to inspection services provided under the FMIA or PPIA.

Executive Order 12866 and Effect on Small Entities

This proposed rule has been determined to be significant and was reviewed by OMB under Executive Order 12866.

FSIS is proposing to eliminate prior approval requirements for establishment drawings and specifications, equipment, and certain partial quality control programs. Concurrent with this proposal, FSIS would restructure inspection activities to focus more attention on the ability of establishments to maintain a sanitary environment. These actions, in addition to implementation of the sanitary standard operating procedures, which were proposed by the Agency as part of the Pathogen Reduction/HACCP proposal, would provide the industry the flexibility for creating and maintaining a sanitary working environment without prescriptive command-and-control requirements.

Removing these requirements would affect establishments subject to official inspection, firms producing and selling equipment currently subject to prior approval, firms providing expediting services to businesses seeking prior approval, and consumers. The proposal would reduce demands on FSIS resources which could be redirected to functions more critical to improving food safety.

Alternatives to this rulemaking that FSIS considered for facilities and equipment prior approvals included development by FSIS of detailed standards to be published in booklets with periodic updates, recognizing industry organizations as prior approval authorities, and establishing general performance standards similar to FDA-recognized good manufacturing practices. Another alternative which would have provided these services on a voluntary, user-fee basis, was considered but not adopted. FSIS has chosen the option of eliminating prior approval requirements while maintaining the general food safety standards in the existing regulations.

For PQC prior approvals, the alternatives to no rulemaking were market sampling of finished products, mandating additional in-plant controls, sampling of finished products for chemical analysis, and maintaining general requirements and a standard for the design of PQC programs. The last option was chosen because it would provide official establishments with the most flexibility in implementing PQC programs.

Benefits of the Rule

Approximately 6,200 federally inspected meat and poultry establishments would no longer be required to submit blueprints, drawings, and specifications to FSIS for review and approval. FSIS reviewed about 2,900 submissions in FY 1994. The cost of receiving FSIS approval for drawings and specifications and changes they represent includes the administrative, mailing, and labor costs associated with preparing the required Agency forms. The labor cost is estimated at 30 minutes for each submission. Assuming an hourly wage or per-hour salary of $20-$25 for each person submitting blueprints and specifications and the FSIS form, the annual cost to the industry for making these submissions is in the range of $30,000 to $40,000. This, then, is an estimate of the savings accruing to industry from removing the requirement for prior approval that FSIS is proposing.

As many as 1,500 establishments per year submit for approval PQC programs or amendments to PQC programs. FSIS receives a total of 1,900 submissions each year. A typical PQC program, prepared according to FSIS guidelines, can be written up in about 4 hours by an individual earning $20 to $25 per hour. Thus, removing the requirement for prior approval of PQC plans is estimated to save the industry $150,000 to $190,000 per year.

FSIS receives approximately 2,500 submissions for approval of equipment each year. The costs of these applications generally fall on equipment manufacturers rather than the meat and poultry firms subject to inspection, although a few meat and poultry establishments make some of their own equipment or equipment modifications. FSIS has no estimate that specifically pertains to the costs to manufacturers of applying for equipment approval, but these costs are assumed to be comparable to the costs to official establishments of submitting blueprint and establishment specification approvals. FSIS recognizes that actual costs to firms seeking equipment approval may differ and welcomes comments on this. Based on 30 minutes per submission, a labor cost of $20–$25 per hour, and 2,500 submissions annually, the annual cost savings from removing the prior approval requirement for equipment would be in the range of $25,000 to $32,500. In addition, approximately 650 applications for approval are contingent on in-plant trials. These trials involve some added costs to manufacturers and meat and poultry establishments, but the Agency has no estimates of these costs to include in this analysis. FSIS invites commenters to present information indicating what these costs are.

The proposal to eliminate blueprint prior approvals would remove a source of income for approximately 20 small firms that represent official establishments for the purpose of labeling and blueprint approval. These firms are known as ''expediters.'' It is estimated that approximately 20 percent of the annual blueprint submissions (about 600) are made to the Agency using the services of expediters. The estimated annual total value of blueprint expediting is about $240,000 for the companies involved. While this would be lost income to the expediters, it would be a transfer to meat and poultry firms, which is not a social cost of the proposed rule.

The social benefits directly resulting from the elimination of prior approval requirements as proposed in this rulemaking are indicated in Table 1. There would be additional but unquantifiable social benefits from the proposals to eliminate prior approvals.

These benefits derive from efficiencies arising from fewer demands on management, greater incentives to adopt innovative practices, and the enhanced ability to make changes quickly which the prior approval system and its inherent delays inhibit. Also, the delays inherent in the prior approval process, which can be translated into lost production time, would be eliminated.

However, it is unlikely that an inspection finding of adulterated product or insanitary conditions under the amended regulations would result in increased costs to the industry for rebuilding or remodeling facilities. Establishments planning substantial investments in new construction typically consult with local authorities and experts with up-to-date knowledge of food establishment construction before beginning major projects.

In addition to the benefits to firms from elimination of these prior approval requirements, FSIS could be expected to benefit by reallocating about $2.3 million to high priority food safety needs. Currently, the Agency allocates about 15 staff-years ($750,000) to reviews of equipment, 20 staff-years (about $1 million) to reviews of drawings and specifications, and 11 staff-years ($550,000) to review and approval of PQC programs. The true social benefits to be expected are the improvements in food safety that would logically flow from reallocating these resources to more important food safety-related tasks.

Costs of the Proposed Rule

As is currently the practice, inspectors would continue to require establishments to take corrective action or cease operations if any product has been adulterated or prepared, packed or held under insanitary conditions whereby it may have been contaminated with filth or may have been rendered injurious to health, because of deficient facilities and equipment. Corrective action, which might include reconstruction, remodeling, and redesign would only be triggered by an actual finding of product adulteration or insanitary conditions. However, it is unlikely that this proposal will increase the level of inspection findings that result in reconstruction, remodeling, and redesign of facilities and equipment.

Currently, facility and equipment plans submitted to FSIS for prior approval are rejected due either to errors in paperwork or to deviation from specific design criteria developed by FSIS. Under the proposal, establishments would not have to submit applications for approval. Instead, establishments would be permitted to initiate and complete construction or introduce new equipment without submitting any paperwork to FSIS. In addition, FSIS would eliminate design-related criteria currently utilized to evaluate the acceptability of facilities and equipment. Inspectors would no longer require establishments to incur costs for reconstruction, remodeling, and redesign, because the actual facility or piece of equipment does not match a specified design criterion, blueprint, or equipment specification.

In the absence of prior approval, FSIS would focus inspection on whether establishments are maintaining a sanitary environment. Under this proposal and the proposed rule on sanitation standard operating procedures, establishments would assume greater control over their production practices to ensure that a sanitary environment is maintained. Currently, many establishments utilize the services of knowledgeable architects, engineers, and other experts to design facilities and equipment for use in meat and poultry establishments. Under prior approval, these experts ensure, among other things, that FSIS design specifications are met. Without prior approval, establishments may require these experts to provide more information on the procedures necessary for maintaining facilities and equipment in a sanitary condition, which could increase the costs for these services. However, this is consistent with the need for the industry to assume greater responsibility for its operations. Any cost increases for these services would be commensurate with the transfer of responsibility from FSIS to the industry, and would not be a social cost attributable to the rule.

TABLE 1.—BENEFITS TO FIRMS FROM ELIMINATING PRIOR APPROVAL REQUIREMENTS

Action	Firms with more than 500 employees	Firms with fewer than 500 employees	All firms
Remove blueprint and specification approval	$1,800–$2,400	$28,200–$37,600	$30,000–$40,000
Remove equipment approval	$2,500–$3,250	$22,500–$29,250	$25,000–$32,500
Remove PQC approval	$9,000–$11,400	$141,000–$178,600	$150,000–$190,000
Total	$13,300–17,050	$191,700–$245,450	$205,000–262,500

Regulatory Flexibility Assessment

The Administrator has determined that, for the purposes of the Regulatory Flexibility Act (5 U.S.C. 601–12), this proposed rule would not have a significant economic impact on a substantial number of small entities. The entities that would be affected by this proposal are inspected meat and poultry establishments, equipment suppliers, and companies representing official establishments to the Agency for the purpose of obtaining blueprint approvals. Most of these are small entities.

The proposed rule is expected to have a beneficial effect on small and large entities, on both those regulated under the FMIA and PPIA and some that are not regulated under the inspection laws but which are affected by the Agency's review of their products, e.g., suppliers of equipment used in inspected meat and poultry establishments.

There are about 5,800 federally inspected small establishments. In this analysis, FSIS is using the Small Business Administration (SBA) business size standards (at 13 CFR 121.601) for meat packing establishments, establishments that produce sausages and other prepared meats, and poultry slaughtering and processing establishments. A small establishment in any of these categories is considered to be one with 500 or fewer employees. Under current regulations, all official establishments are required, as a condition of receiving inspection services, to submit blueprints, drawings, and specifications of new or remodeled facilities to FSIS for review and approval. Under this proposal, the establishments would, of course, not be spared the cost of preparing for themselves blueprints and specifications for construction and major installations. However, they would no longer bear the cost of submitting these drawings and specifications to the Agency for review

because the requirement to do so would be eliminated.

The savings to be obtained by eliminating FSIS approval for drawings and specifications and the changes they represent includes the administrative and mailing costs and the time (resources) required to fill out the required Agency form (''Submission and Approval of Plans and Specifications,'' FSIS –5200–S), which is estimated at 30 minutes each submission. As mentioned above, the annual savings to the meat and poultry products industry from eliminating the requirement of making the submissions would be in the neighborhood of $30,000–40,000. FSIS does not consider this savings to be significant. But in addition to such direct savings, the largest potential savings to the industry resulting from the prior approval process for blueprints and specifications would be those associated with the elimination of delays—of up to several weeks per submission—in obtaining approval. This estimated delay includes the time needed to resolve disagreements over plans and specifications, should such disagreements arise between the Agency and the establishment. This savings could be significant for some small entities, but there is no information to indicate that it would be so for a substantial number of them.

The savings would not be significant for at least two reasons. First, establishments engaged in construction projects plan for the eventuality of an FSIS review, or at least are advised by knowledgeable food establishment architects and engineers to build FSIS review time into their project timelines. Costs are minimized because delays that do occur are anticipated. Second, under the current prior review and approval system, the Agency is able to exercise discretion expediting reviews of blueprints and facilities in specific cases to prevent economic hardship from occurring. The proposal is intended to eliminate the costs attributable to the delays associated with prior review and approval.

While eliminating the cost of blueprint prior approvals to small establishments producing meat and poultry products, the proposal would at the same time remove a source of income for about 20 small expediting firms that represent official establishments for the purpose of labeling and blueprint approvals. These expediters are frequently able to shorten the time for these approvals and reduce the rejection rate on submissions because of their knowledge of Agency requirements and proximity to Agency offices. As mentioned above, the estimated annual total value of blueprint expediting is about $240,000 for the companies involved. This is a small part of the expediters' total business, which is mainly that of expediting label approvals and consulting work. These 20 entities, in any event, do not constitute a substantial number of small entities unfavorably affected by this rule.

By the same reasoning that the Agency used to determine that these prior approvals do not serve to increase the safety of meat and poultry products, the expediting activities of these firms that will be reduced by the rule would no longer be a productive use of resources. These firms may, however, experience an increased demand for their consulting services from inspected establishments who depended upon the Government's prior approval to assure they were in compliance with the regulations, who now need help from a third party to assure they are in compliance with the regulations.

The equipment acceptance procedure principally affects manufacturers or other vendors of equipment. The equipment manufacturers range in size from small to large concerns and, under the current regulations, depend on FSIS prior approval to be able to sell their products to inspected establishments. It is estimated that up to 90 percent of the equipment manufacturers and other applicants for FSIS equipment acceptance are small entities. According to the SBA business size standards (13 CFR 121.601), a small food products machinery manufacturer is one that employs 500 or fewer people.

Also favorably affected by the approval process are inspected establishments that may require machinery or other equipment to improve or continue their operations. As is the case in the blueprint review process for inspected facilities, the savings from avoiding a delay before installation and operation of a newly developed piece of equipment, although it could be significant for a few entities, large or small, but will not be significant for most establishments.

Finally, FSIS has determined that the proposal to eliminate prior approval of most voluntary PQC programs would not have a significant economic impact on a substantial number of small entities. Both large and small establishments subject to FSIS inspection would be permitted to continue to develop and implement PQC programs for their products and processes but would no longer be required to submit the PQC's to FSIS for review and approval in advance of use. Accordingly, the administrative delay for review that occurs under the present system would be eliminated.

It takes a minimum of 2 weeks for the Agency to review a typical PQC program, and as many as 1,500 establishments per year submit such programs or amendments to programs—a total of nearly 1,900 submissions per year—and about 90 percent of these establishments could be regarded as small entities. Therefore, roughly 1,100 establishments would avoid the costs associated with having to wait a minimum of 2 weeks for PQC approval, but it is not possible to identify what costs would be saved under these circumstances.

For these reasons, the Administrator has determined that this proposal would not result in a significant economic impact on a substantial number of small entities. The economic impact on such entities would in most cases involve the elimination of certain costs—some quantifiable, some not quantifiable—associated with doing business subject to Federal regulation and hence would be beneficial to those entities. Though non-quantifiable, increasing the benefits that come from reducing an establishment's dependence on Government decisions is an important objective of the proposed rule.

Paperwork Requirements

FSIS has reviewed the paperwork and recordkeeping requirements in this proposed rule in accordance with the Paperwork Reduction Act. This proposed rule would substantially reduce ''reporting'' requirements for official establishments and other entities. FSIS estimates the total reduction in reporting to be 4,291 burden hours. The reductions would occur in the following information collection reports:

- 0583–0082, ''Meat and Poultry Inspection; Application for Inspection, Sanitation, and Equipment Requirements and Exemptions'': Establishments subject to inspection would no longer have to submit blueprints and specifications along with Form FSIS–5200–5. The response time is estimated to be 30 minutes, and there are 701 total burden hours approved by the Office of Management and Budget (OMB) for this activity. Therefore, FSIS would request OMB to remove the 701 approved burden hours.
- 0583–0082, ''Meat and Poultry Inspection; Application for Inspection, Sanitation, and Equipment Requirements and Exemptions'': FSIS prior approval would no longer be required for the products of these companies that are used in official establishments. The response time is

estimated to be 30 minutes for the prior approval of equipment. There are 2,990 total burden hours approved by OMB for this activity. Therefore, FSIS would request OMB to remove the 2,990 approved burden hours.

• 0583–0089, ''Processing Procedures and Quality Control Systems'': Establishments could continue to develop and implement PQC programs according to Agency guidelines. These establishments, with the exception of poultry irradiation facilities, would no longer be required to submit a letter requesting approval of a proposed PQC program and a copy of the program to the Agency for approval prior to implementation. The response time is estimated to be 30 minutes for writing the request letter and sending the PQC program to FSIS. There are 600 total burden hours approved by OMB for this activity. In consideration of poultry irradiation facilities 60 hours of burden would remain. FSIS does not foresee more than two irradiation facilities requesting FSIS approval of PQC programs. Therefore, FSIS would request OMB to remove 540 approved burden hours. The burden hours for PQC program development and reporting would remain the same.

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 to the Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20253.

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

List of Subjects

9 CFR 304

Drawings, Information to be furnished, Grant or refusal of inspection, Meat inspection.

9 CFR 308

Meat inspection, Sanitation.

9 CFR 317

Meat inspection, Reporting and recordkeeping requirements.

9 CFR 318

Meat inspection, Establishment-operated quality control.

9 CFR 319

Food grades and standards, food labeling.

9 CFR 381

Poultry and poultry products.

For the reasons set forth in the preamble, FSIS is proposing to amend 9 CFR Chapter III, the Federal meat and poultry inspection regulations, as follows:

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

1. The authority citation for Part 304 would be revised to read as follows:

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

2. The heading of section 304.2 would be revised to read as follows:

§ 304.2 Information to be furnished; grant or refusal of inspection.

* * * * *

3. Section 304.2 would be amended by removing paragraph (a) and redesignating paragraphs (b) through (f) as paragraphs (a) through (e), respectively.

PART 308—SANITATION

4. The authority citation for Part 308 would be revised to read as follows:

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

§ 308.2 [Removed]

5. Section 308.2 would be removed and reserved.

6. Section 308.5 would be amended by removing '', in the judgment of the Administrator,'' from the first and third sentences of paragraph (a); removing paragraphs (b) through (f); redesignating paragraph (g) as (b); and revising the section heading to read as follows:

§ 308.5 Equipment and utensils to be easily cleaned; those for inedible products to be so marked; PCB-containing equipment.

* * * * *

PART 317—LABELING, MARKING DEVICES, AND CONTAINERS

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

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

8. Section 317.21 would be amended by removing the words ''or Partial Quality Control Program'' from paragraph (b).

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

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

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

10. Paragraph (d) of § 318.4 would be revised to read as follows:

§ 318.4 Preparation of products to be officially supervised; responsibilities of official establishments; plant operated quality control.

* * * * *

(d) *Partial Quality Control Programs.* (1) Any owner or operator of an official establishment preparing meat food products who is using a quality control program for a product, operation, or part of an operation shall make the written program and data and information generated by the program available to Program employees.

(2) (i) Such quality control program shall include, as appropriate for the product, operation, or part of an operation which the program concerns, detailed information on: raw material control, the critical check or control points, the nature and frequency of tests to be made, the charts and records that will be used, the length of time such charts and records will be maintained in the custody of the official establishment, the limits which will be used and the points at which corrective action will be taken to prevent recurrence of a loss of control, and the nature of the corrective action—ranging from the least to the most severe.

(ii) Such quality control program shall be designed so as to provide, with at least 85 percent statistical confidence, that the lot mean (process mean) is within the product or label limit used and that, of a minimum of 3 sublot samples representing the lot, with each sublot sample containing at least 5 samples representing the sublot, no

individual sample mean or sublot-sample mean shall be greater than three standard errors above, nor less than three standard errors below, the process mean.

* * * * *

11. Paragraph (e) of § 318.4 would be amended by removing the words ''or Partial Quality Control'' from the paragraph heading, the words ''or (d)'' from the first sentence of paragraph (e)(1) and both occurrences of the words ''or partial quality control program'' from the second sentence of the same paragraph (e)(1); by removing the words ''or program'' from the first and second sentences of paragraph (e)(2); by removing the words ''or partial quality control program'' from paragraph (e)(3); and by revising the heading of paragraph (g) and removing the words ''or partial quality control program'' from paragraphs (g)(1) and the introductory text of (g)(2) and revising paragraph (g)(3) to read as follows:

§ 318.4 Preparation of products to be officially supervised; responsibilities of official establishments; establishment operated quality control.

* * * * *

(g) *Termination of Total Establishment Quality Control.*

* * * * *

(3) If approval of the total establishment quality control system has been terminated in accordance with the provisions of this section, an application and request for approval of the same or a modified total establishment quality control system will not be evaluated by the Administrator for at least 6 months from the termination date.

* * * * *

12. Paragraphs (b)(3)(i) and (b)(3)(ii) of § 318.7 would be revised to read as follows:

§ 318.7 Approval of substances for use in the preparation of products.

* * * * *

(b) * * *

(3) * * *

(i) 100 ppm ingoing (potassium nitrite at 123 ppm ingoing); and 500 ppm sodium ascorbate or sodium erythorbate (isoascorbate) shall be used; provided that the establishment has a partial quality control program as provided in § 318.4(d) such as to result in compliance with this provision, or

(ii) 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 growth of botulinum toxin at a level sufficient for the purpose of preventing the growth of botulinum toxin; provided that the establishment has a partial quality control program as provided in § 318.4(d) such as to result in compliance with this provision.

* * * * *

13. In the table in § 318.7(c)(4) under the Class of substance ''Miscellaneous,'' the entry under the Substance ''Ascorbic Acid, erythorbic acid, citric acid, sodium ascorbate, and sodium citrate'' would be revised to read as follows:

§ 318.7 Approval of substances for use in the preparation of products.

* * * * *

(c) * * *

(4) * * *

Class of substance	Substance	Purpose	Product	Amount
*	*	*	*	* * *
Miscellaneous	Ascorbic acid, erythorbic acid, citric acid, sodium ascorbate and sodium citrate, singly or in combination under quality control.	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).
*	*	*	*	* * *

14. Section 318.19 would be amended by removing the words ''or partial quality control program'' from paragraph (e).

15. Paragraph (a) of § 318.309 would be amended by removing the words ''an approved'' and ''program'' and paragraphs (b) and (c) of § 318.309 would be amended by removing ''and submitted to the Administrator for approval''.

PART 319—DEFINITIONS AND STANDARDS OF IDENTITY OR COMPOSITION

16. The authority citation for Part 319 would continue to read as follows:

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

17. Section 319.5 would be amended by removing the second sentence of paragraph (e)(2) and revising the first sentence to read as follows:

§ 319.5 Mechanically Separated (Species).

* * * * *

(e) * * *

(2) A prerequisite for label approval for products consisting of or containing ''Mechanically Separated (Species)'' is that such ''Mechanically Separated (Species)'' shall have been produced by an establishment under a establishment quality control system. * * *

18. The last sentence in footnote 3 to the chart in § 319.104 would be amended by removing the words ''approved by the Administrator under § 318.4 of this subchapter.''

PART 381—POULTRY PRODUCTS INSPECTION REGULATIONS

19. The authority citation for Part 381 would be revised to read as follows:

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

20. Section 381.19 would be revised to read as follows:

§ 381.19 Application for inspection; irradiation facilities.

All applicants for inspection whose operations include irradiation and other processing would submit, to the Administrator, a proposed quality control system as specified in § 381.149.

§ 381.20 [Amended]

21. Section 381.20 would be amended by removing ''the approved drawings,

specifications, and'' from the first sentence.

22. Section 381.53 would be amended by removing paragraph (b); redesignating paragraphs (c) through (m) as paragraphs (b) through (l), respectively; and revising paragraph (a) to read as follows:

§ 381.53 Equipment and utensils.

(a) Equipment and utensils used for processing or otherwise handling any edible poultry product or ingredient thereof, in any official establishment, shall comply with any applicable provisions of paragraphs (b) through (l) of this section and otherwise shall be of such material and construction as will facilitate their thorough cleaning, insure cleanliness in the preparation and handling of all edible poultry products, and avoid adulteration and misbranding of such products. In addition to these requirements, equipment and utensils shall not in any way interfere with or impede inspection procedures. Receptacles used for handling inedible products shall be of such material and construction that their use will not result in adulteration of any edible product or in unsanitary conditions at the establishment, and they shall bear conspicuous and distinctive marking to identify them as only for such use and shall not be used for handling any edible poultry products.

* * * * *

§ 381.121d [Amended]

23. Section 381.121d would be amended by removing the words ''or Partial Quality Control Program'' from paragraph (b).

24. The section heading and paragraph (d) of § 381.145 would be revised to read as follows:

§ 381.145 Preparation of products to be officially supervised; responsibilities of official establishments; establishment operated quality control.

* * * * *

(d) *Partial Quality Control Programs.* (1) Any owner or operator of an official establishment preparing meat food products who is using a quality control program for a product, operation, or part of an operation shall make the written program and data and information generated by the program available to Program employees.

(2) (i) Such quality control program shall include, as appropriate for the product, operation, or part of an operation which the program concerns, detailed information on: raw material control, the critical check or control points, the nature and frequency of tests to be made, the charts and records that will be used, the length of time such charts and records will be maintained in the custody of the official establishment, the limits which will be used and the points at which corrective action will be taken to prevent recurrence of a loss of control, and the nature of the corrective action—ranging from the least to the most severe.

(ii) Such quality control program shall be designed so as to provide, with at least 85 percent statistical confidence, that the lot mean (process mean) is within the product or label limit used and that, of a minimum of 3 sublot samples representing the lot, with each sublot sample containing at least 5 samples representing the sublot, no individual sample mean or sublot-sample mean shall be greater than three standard errors above, nor less than three standard errors below, the process mean.

* * * * *

25. Paragraph (e) of § 381.145 would be amended by removing the words ''Programs or'' from the paragraph heading, the words ''or (d)'' from the first sentence of paragraph (e)(1) and both occurrences of '', partial quality control program,'' from the second sentence of the same paragraph (e)(1); by removing the words ''or program'' from the first and second sentences of paragraph (e)(2); by removing '', partial quality control program,'' from paragraph (e)(3); by revising the heading of paragraph (g) and removing the words ''or a partial quality control program'' from paragraph (g)(1); by removing '', partial quality control program,'' from paragraph (g)(2) introductory text and the words ''or program'' from the first sentence of paragraph (g)(2)(ii); and by revising paragraph (g)(3) to read as follows:

§ 381.145 Preparation of products to be officially supervised; responsibilities of official establishments; establishment operated quality control.

* * * * *

(g) *Termination of Total Establishment Quality Control.*

* * * * *

(3) If approval of the total establishment quality control system has been terminated in accordance with the provisions of this section, an application and request for approval of the same or a modified total establishment quality control system will not be evaluated by the Administrator for at least 6 months from the termination date.

* * * * *

§ 381.309 [Amended]

26. Paragraph (a) of § 381.309 would be amended by removing the words ''an approved'' and ''program'' and paragraphs (b) and (c) of § 381.309 would be amended by removing ''and submitted to the Administrator for approval''.

Done, at Washington, DC April 25, 1996.

Michael R. Taylor,

Acting Under Secretary for Food Safety.

[FR Doc. 96–10795 Filed 5–1–96; 8:45 am]

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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Airspace Docket No. 96–AGL–5]

Establishment of Class E Airspace; Sturgis, SD

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking.

SUMMARY: This notice proposes to establish Class E airspace at Sturgis, SD. A Global Positioning System (GPS) standard instrument approach procedure (SIAP) to Runway 29 has been developed for the Sturgis Municipal Airport. Controlled airspace extending upward from 700 feet above ground level (AGL) is needed for aircraft executing the approach.

DATES: Comments must be received on or before June 6, 1996.

ADDRESSES: Send comments on the proposal in triplicate to: Federal Aviation Administration, Office of the Assistant Chief Counsel, AGL–7, Rules Docket No. 96–AGL–5, 2300 East Devon Avenue, Des Plaines, Illinois 60018.

The official docket may be examined in the Office of the Assistant Chief Counsel, Federal Aviation Administration, 2300 East Devon Avenue, Des Plaines, Illinois. An informal docket may also be examined during normal business hours at the Air Traffic Division, Operations Branch, Federal Aviation Administration, 2300 East Devon Avenue, Des Plaines, Illinois.

FOR FURTHER INFORMATION CONTACT: John A. Clayborn, Air Traffic Division, Operations Branch, AGL–530, Federal Aviation Administration, 2300 East Devon Avenue, Des Plaines, Illinois 60018, telephone (847) 294–7459.