Accordingly, part 217 of chapter I of title 8 of the Code of Federal Regulations is amended as follows:

PART 217—VISA WAIVER PILOT PROGRAM

1. The authority citation for part 217 continues to read as follows:

Authority: 8 U.S.C. 1103, 1187, 8 CFR part 2.

2. In § 217.5, paragraph (a)(1) is revised to read as follows:

§ 217.5 Designated countries.

(a)(1) *Visa Waiver Pilot Program Countries.* United Kingdom (effective July 1, 1988); Japan (effective December 15, 1988); France and Switzerland (effective July 1, 1989); Germany and Sweden (effective July 15, 1989); Italy and the Netherlands (effective July 29, 1989); Andorra, Austria, Belgium, Denmark, Finland, Iceland, Liechtenstein, Luxembourg, Monaco, New Zealand, Norway, San Marino, and Spain (effective October 1, 1991); Brunei (effective July 29, 1993); Argentina (effective July 8, 1996); and Australia [Insert date of publication in the Federal Register] have been designated as Visa Waiver Pilot Program countries based on the criteria set forth at sections 217(a)(2)(A) and 217(c) of the Act.

* * * * *

Dated: July 24, 1996.

Doris Meissner,

Commissioner, Immigration and Naturalization Service.

[FR Doc. 96–19169 Filed 7–26–96; 8:45 am]

BILLING CODE 4410–10–M

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

9 CFR Part 381

[Docket No. 92–026F]

RIN 0583–AB65

Use of Trisodium Phosphate on Raw, Chilled Poultry Carcasses

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: The Food Safety and Inspection Service (FSIS) is amending the poultry products inspection regulations to permit the application of trisodium phosphate (TSP) on raw, chilled poultry carcasses passed for wholesomeness. The TSP solution will be permitted as an antimicrobial agent on such poultry carcasses at a level of 8 to 12 percent. The solution must be maintained at a temperature of 45 °F to 55 °F and applied by spraying or dipping carcasses for up to 15 seconds. Tests conducted by industry and FSIS have shown that the use of TSP, at the above-stated concentration, temperature, and duration, reduces microbial populations on raw, chilled poultry surfaces.

EFFECTIVE DATE: August 28, 1996.

ADDRESSES: Copies of the studies, reports, letters, and publications referenced in this docket are available for public inspection in the FSIS Docket Room, USDA, 14th and Independence Avenue, SW., Room 4352, South Agriculture Building, Washington, DC 20250.

FOR FURTHER INFORMATION CONTACT: Dr. William O. James, Director, Slaughter Inspection Standards and Procedures Division, Science and Technology, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250; (202) 720–3219.

SUPPLEMENTARY INFORMATION:

Background

FSIS was petitioned by Rhône-Poulenc, Inc., Cranbury, New Jersey, to permit the use of food-grade TSP as a processing aid in post-chill poultry slaughter operations. TSP is listed in the Food and Drug Administration (FDA) regulations as generally recognized as safe (GRAS) for multiple-purpose use in accordance with good manufacturing practices (21 CFR 182.1778). The petitioner requested the use of a treatment solution consisting of TSP dissolved in water to a concentration of 10 percent, plus or minus 2 percent (8 to 12 percent). The petitioner requested exposure of the poultry to the TSP treatment solution for no more than 15 seconds, with the TSP treatment solution being maintained at 50 °F, plus or minus 5 °F (45 °F to 55 °F).

The petitioner included data in its petition demonstrating that the use of TSP is effective in reducing the levels of bacteria, including pathogenic bacteria, found on raw, chilled poultry carcasses. FSIS also conducted studies to determine the efficacy of TSP on raw, chilled poultry carcasses. These studies demonstrate that the use of TSP on raw, chilled poultry carcasses results in statistically significant reductions in the levels of bacteria.

Additionally, FDA evaluated the petitioner's request for the use of TSP as a processing aid in poultry and concluded that the treatment leaves no residues on the product which could be harmful to consumers. Therefore, in an August 25, 1992, letter to Rhône-Poulenc, Inc., FDA approved the use of TSP as a processing aid on raw poultry, under conditions to be established by FSIS.

FSIS determined that use of TSP requested by the petitioner was suitable for the intended purpose and that the use of this substance on raw, chilled poultry carcasses at the stated level would not render the treated product adulterated, misbranded, or otherwise not in accordance with the requirements of the Poultry Products Inspection Act.

On January 5, 1994, FSIS proposed to amend the poultry products inspection regulations at 9 CFR 381.147(f)(4) to add antimicrobial agents as a new class of substance for use on poultry products, and to add TSP as an approved antimicrobial agent. FSIS proposed to permit the use of TSP on raw, chilled poultry carcasses at a level of 8 to 12 percent. The TSP treatment solution would be maintained at 45 °F to 55 °F, and would be applied either by spraying or dipping the raw, chilled poultry carcasses for up to 15 seconds.

Discussion of Comments

FSIS received 21 comments in response to the proposed rule. All but 2 commenters favored the proposal. In general, those favoring the proposal stated that TSP treatment reduces bacterial levels on poultry carcasses and decreases consumer exposure to pathogens. They believed food-grade TSP has been proved safe. The following is a discussion of the relevant issues raised in all of the comments.

One commenter believed FDA's GRAS affirmation of TSP did not apply to the hydrous formulation of AvGard, a proprietary name for food-grade TSP.

In a 1979 proposed rule, FDA specifically defined TSP as containing ''* * * 1 or 12 molecules of water of hydration'' (44 FR 74845, 74857). AvGard contains 12 molecules of hydration and, therefore, is included in the definition of TSP. Citing the report of the Select Committee on GRAS Substances, FDA concurred that ''there is no evidence in the available information on * * * sodium phosphate, tribasic [TSP] * * * that demonstrates, or suggests reasonable grounds to suspect, a hazard to the public when they [GRAS phosphates] are used at levels that are now current or might reasonably be expected in the future'' (44 FR 74851–52).

It is within FDA's purview to affirm the multiple purpose GRAS status of TSP, which FDA did in the previously noted August 25, 1992, letter to Rhône-Poulenc. The Food Chemicals Codex, 3rd edition, specifically lists anhydrous and hydrous formulations of TSP as meeting the specifications for TSP.

One commenter questioned the validity of FSIS's TSP study conducted in April 1992. Since the control and treated carcass bacterial counts were low, this commenter wondered whether the results were representative.

A statistically valid number of carcasses were randomly selected by FSIS personnel over four consecutive days in April, 1992. Routine FSIS quality control checks on the ability of the nutrient broth, agar, and reagents to recover microorganisms were within normal limits. These routine FSIS quality control checks verified the accuracy of the results from the April 1992 study.

Additional data submitted with the petition, and available during the comment period, demonstrated statistically significant reductions of bacteria, including *Salmonella,* on poultry carcasses following post-chill immersion in TSP. The data showed that *Salmonella* prevalence after TSP treatment was consistently reduced from levels as high as 31 percent to levels below the laboratory limit of detection. Comparable results were obtained whether the samples were refrigerated or frozen. Similar results were found using prevalence or most probable number. Inoculation studies with *Salmonella typhimurium* showed a reduction between 95 and 100 percent. The Bender/Brodsky patented process for TSP application references similar test results.

Independent scientific studies [1],[2] also demonstrate the efficacy of TSP in reducing *Salmonella* on raw, chilled poultry carcasses. A study on the effect of TSP on *Salmonella typhimurium, Campylobacter jejuni, E. coli* 0157:H7, and *Listeria monocytogenes* showed that TSP not only reduced bacterial counts on raw poultry, but could potentially be used to reduce bacterial counts on other foods and on food and non-food contact surfaces. [3]

Therefore, FSIS has determined that information submitted by the petitioner, in the Agency's own studies, and in the scientific literature substantiates the efficacy of TSP as an antimicrobial agent on raw, chilled poultry carcasses.

On commenter questioned the petitioner's results due to unknown testing methodology and asked whether FSIS will seek comment on the experimental protocol.

Before any chemical not listed in 9 CFR 381 can be tested in official poultry establishments, the proposed conditions of use are reviewed by FSIS scientists. Only after acceptance of the testing protocol by FSIS may a trial begin. Since these trials are conducted in official establishments, supervised by FSIS personnel, and designed to address FSIS information requirements, FSIS does not routinely seek outside comment on the testing protocols.

One commenter questioned the relationship between the proposed conditions of TSP use (8–12 percent solution maintained at a temperature between 45 °F and 55 °F, and applied for up to 15 seconds) and the supporting studies.

FSIS and industry studies referenced in the proposed rule demonstrate TSP efficacy against bacteria, including pathogenic bacteria, at concentrations as low as 6 percent and temperatures as low as 42 °F. The most consistent results were achieved at TSP concentrations of 8–12 percent. Although efficacy of TSP is primarily related to solution concentration, not solution temperature, an upper 55 °F temperature limit for post-chill TSP use is consistent with the general chilling requirements in 9 CFR 381.66(b)(1), which permits a maximum internal temperature of 55 °F in processing operations, providing other requirements are met. Fifteen seconds was the time necessary to adequately apply the TSP to raw, chilled poultry carcasses on a moving line.

This commenter also asked whether these supporting studies used AvGard, a proprietary name for food-grade TSP. All TSP studies referenced in this docket used AvGard.

One commenter suggested TSP use may increase or decrease moisture absorption in poultry carcasses. Under current industry practice, broiler carcasses are chilled for approximately 60 minutes in immersion chillers. FSIS and petitioner studies have demonstrated the additional 15 second application of TSP does not result in moisture violations. As part of the poultry chilling process, poultry carcasses may gain moisture up to the levels permitted in 9 CFR 381.66(d). Poultry establishments using TSP are not exempted from the moisture absorption and retention limits contained in 9 CFR 381.66(d). Federal establishments applying TSP to raw, chilled poultry will include the TSP application in their washing, chilling, and draining method as outlined in 9 CFR 381.66(d)(8).

One commenter questioned the petitioner's claim that virtually no residue remains on or in treated poultry carcasses. The commenter referenced an abstract from an Agricultural Research Service (ARS) study, ''Effect of TSP on Salmonella Attached to Chicken Skin'' that seemed to refute the petitioner's claim. That abstract incorrectly stated that a high residual skin pH indicated the presence of TSP residue. In response to peer-review of the study, that assertion was removed when the study was published in the *Journal of Food Protection*.

Testing carcasses for pH does not directly correlate with phosphate residues. FSIS monitors meat and poultry for chemical residues by using specific analytical tests for the chemical residue in question. The 1993 FSIS Food Chemistry Guidebook recommends the quimociac method for phosphate determinations in meat and poultry. This analytical method determines phosphate levels within 0.05 percent. The petitioner used the FSIS recommended quimociac method, and, therefore, FSIS accepted the petitioner's results of virtually no residue.

One commenter asked whether use of an ''* * * FSIS approved drag through tank and attendant pump and filtration unit * * *,'' as mentioned in the petition from Rhône-Poulenc, would be required. This commenter also requested information on the significance of such equipment.

FSIS believes that requiring specific application equipment would not afford establishments sufficient flexibility in meeting good manufacturing practices (GMP) for TSP application. The Agency believes that the regulations in 9 CFR 381.53, regarding use of equipment in official establishments, are sufficient to ensure that the proper equipment is used for TSP application.

The equipment used was not significant in the results of the studies. However, it is unlikely that establishments, using current industry practices, will be able to apply TSP as a dip to raw, chilled poultry on a moving line without use of a drag-through tank. The process used in the studies is patented by Rhône-Poulenc, Inc.

One commenter expressed five concerns regarding the occupational safety of TSP. First, this commenter referenced U.S. Coast Guard and U.S. Department of Housing and Urban Development documents describing non-food-grade TSP as potentially hazardous to worker safety.

These references referred to use of non-food-grade TSP as a paint stripper on ocean vessels and for lead paint abatement in buildings. This commenter did not document any hazards from the use of food-grade TSP. TSP has been safely used for decades in a variety of food manufacturing establishments producing processed cheeses, breakfast cereals, and snack foods.

Second, the commenter referenced TSP workplace environmental exposure limits from the American Industrial

Hygiene Association, an industry group without regulatory authority, and incorrectly stated that the Occupational Safety and Health Administration (OSHA) does not have general exposure limits for TSP.

Although OSHA does not list air contaminant limits specifically for TSP, OSHA considers TSP a ''Particulate not otherwise regulated'' (PNOR) (29 CFR 1910.1000 Table Z–1). Additionally, OSHA has regulatory authority over worker and workplace safety, including those in federally inspected establishments. The OSHA regulations contained in Title 29, Code of Federal Regulations, address worker and workplace safety regarding the use of TSP.

Third, this commenter inquired about the nature of any communication regarding TSP between OSHA and FSIS.

The OSHA workplace safety levels for TSP as a PNOR are clearly codified in the above-referenced regulations, and FSIS has confirmed with OSHA that TSP is regulated as a PNOR.

Fourth, this commenter referred to U.S. Coast Guard recommendations for protective respiratory equipment for workers using non-food-grade TSP, even though OSHA does not specifically require the use of such protective respiratory equipment.

OSHA regulations state, in part, that accepted engineering control measures, such as adequate ventilation, where feasible, may be sufficient to prevent atmospheric contamination (29 CFR 1910.134).

To evaluate the safety of TSP use, FSIS contracted for industrial hygiene studies at two federally inspected establishments that are using TSP under interim approval. Because of the alkalinity of TSP, these studies recommended use of protective eyeware and gloves for FSIS employees monitoring the TSP application equipment. No medically substantiated occupational illness related to TSP use was documented from those two studies. Three TSP commercial poultry trials and 30 in-plant demonstrations, totaling more than 1,000 combined days of TSP use or testing, demonstrated no documented worker or workplace problems as a result of working in, around, or with food-grade TSP treatment facilities or TSP-treated product. As a result of the FSIS-initiated industrial hygiene studies, FSIS requires establishment management to provide FSIS employees with protective clothing or equipment. The establishment's ''Material Safety Data Sheet,'' as required under OSHA regulations, specifies the conditions under which establishment management must provide protective gear. FSIS employees have access to the Material Safety Data Sheet. The necessity of using protective equipment, such as eye wear or latex gloves, will depend on OSHA requirements (29 CFR 1910.133) and specific methods of TSP application in individual establishments.

Fifth, this commenter expressed concern over the lack of a specific antidote for any TSP-related industrial overexposure (e.g., dermal, oral, ocular, or respiratory exposure).

In fact, most substances do not have specific antidotes for overexposure. Therapy for most excessive exposures entails symptomatic treatment. As with all chemicals, especially those used in an industrial environment, caution should be exercised in handling. Protective equipment suitable for the specific application and access to means for diluting accidental chemical exposure, such as eyewashes and emergency showers, are commonly available.

One commenter expressed concern regarding the effect of TSP, an orthophosphate compound, on the environment, and referenced the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA, Title 42 U.S.C. 9601 *et seq.*) and U.S. Department of Transportation (DOT) requirements for notification of TSP release into the environment.

TSP (sodium phosphate, tribasic) is classified as a Category D hazardous substance under CERCLA (40 CFR 302.4). Category D substances, being the safest of five hazardous substance categories, are subject to CERCLA notification only for releases of 5,000 pounds. DOT regulations (49 CFR 172.101, App. A), which are based on the Superfund Amendments and Reauthorization Act of 1986 (Public Law 99–499), have an identical requirement for reporting releases of 5,000 pounds of TSP into the environment. This commenter also inquired about any communication and coordination between the U.S. Environmental Protection Agency (EPA), DOT, and FSIS on this rule. FSIS contacted EPA to affirm that CERCLA notification for TSP was 5,000 lbs. and that individual states regulate industrial effluent either directly or indirectly.

One commenter believed the disposal of TSP as an animal-feed ingredient should be required by FSIS to minimize the potential for phosphate release into the environment.

FDA, not FSIS, has the authority to determine whether TSP can be disposed of by conversion into an animal-feed ingredient. In a July 13, 1992, letter to Rhône-Poulenc, Inc., FDA stated the conditions under which it would permit TSP to be converted into an animal feed, and stated that it will consider, on a case-by-case basis, requests for the use of other by-products from the permitted recovery process. Additionally, State and local authorities have the authority to promulgate standards for phosphate discharge into the environment. Establishment effluent is regularly monitored by State or local officials with statutory authority over effluent discharge.

Another commenter questioned the safety of eating animals that have consumed calcium phosphate derived from the conversion of spent TSP.

No supporting documentation accompanied that comment. FDA stated in a July 9, 1992, letter to Rhône-Poulenc that precipitation of spent TSP with tricalcium phosphate forms calcium phosphate in accordance with the Association of American Feed Control Officials definition. FDA partially based its decision allowing this conversion of spent TSP into calcium phosphate on the known safety of the commonly used feed additive calcium phosphate to humans and animals. FSIS is not aware of any published study suggesting that use of calcium phosphate in animal feeds is a human health hazard.

One commenter questioned the safe environmental disposal of TSP and referenced a United Nations (U.N.) Environment Programme data profile for chemicals, but incorrectly stated this document reflected U.N. standards for TSP disposal. This U.N. document specifically states that it does not necessarily reflect the views or official policies of the U.N. Environment Programme. The U.N. data profiles for chemicals is intended to be used by those professionally engaged in the management of waste. The referenced data profile should not be considered on its own merit, but merely as part of an integrated body of scientific evidence. Local and state governments, not U.N. data profiles, have statutory authority over phosphate release by official establishments.

One commenter raised questions regarding pre-chill uses of TSP. Uses of TSP, other than those discussed in the proposed rule, as appropriate, will be handled through separate rulemakings.

Three commenters noted that use of TSP should not be a substitute for current inspection practices. FSIS agrees and views the use of TSP as an addition to, not a substitute for, effective inspection and process control.

One commenter stated that regular end-product testing should be

conducted to ensure the effectiveness of TSP.

FSIS does not currently plan to conduct routine microbiological monitoring of TSP-treated product. Previously referenced studies demonstrate the efficacy of TSP when applied with the FSIS-accepted concentration, time, and temperature. Industry and FSIS will monitor the TSP application process to ensure adherence to good manufacturing practices.

One commenter preferred use of ''alternate methods to reduce microorganisms,'' such as trimming contamination, slowing line speeds, and utilizing air chilling, rather than either utilizing the current method of immersion chilling or applying TSP. This commenter did not provide evidence in support of these ''alternate methods.'' FSIS is aware of several studies regarding these alternate methods. [4], [5], [6], [7] None demonstrates that removing contamination solely by trimming or line-speed reductions lowers levels of microorganisms on poultry carcasses.

Regarding air chilling, studies conducted by the Commission of the European Communities, [8] using birds from the same flock, showed that immersion-chilled and air-chilled poultry carcasses had similar numbers of *Salmonella*. However, unlike these alternate methods, use of a TSP solution has demonstrated statistically significant reductions in bacteria, including pathogenic bacteria, on poultry carcasses.

J. E. Thomson et al. [9] concluded that commercial immersion chilling of broilers, with properly used equipment and adequate water replacement, can reduce bacterial counts to lower levels than air-blast chilling. Air-blast chilling does not significantly reduce bacterial counts. Air chilling in chill-rooms or by continuous air-blast requires low scald temperatures to minimize surface drying and does not have the advantage of the washing effect of submersion chilling. Air chilling does not reduce levels of *Campylobacter* contamination dramatically, presumably because the carcass does not dry-out sufficiently on all parts of the surface, either inside or out. Air-chilled carcasses are always likely to have higher bacterial levels than those chilled in a properly controlled immersion chiller. [10] Incidence of *Campylobacter jejuni/coli* can be reduced significantly in establishments using chlorinated chiller water, however the prevalence rates for this organism have been reported in the range of 50 to 100 percent. [9]

The findings of most researchers indicate there is a potential for cross-contamination during immersion chilling, but with properly used equipment, and adequate chlorinated water replacement, the washing effect of commercial immersion chilling of broilers will reduce total bacterial counts. [11], [12], [13], [14] K.N. May [15] collected data that found immersion chilling sanitary with reduction in total bacterial counts. The work of Busta et al. [16] indicates that the number of birds contaminated with pathogens is also reduced by immersion chilling. J.E. Thomson et al. [17] and W.O. James et al. [*13*] demonstrated that chlorination of chiller water reduced or eliminated *Salmonella* cross-contamination. R.M. Blood and B. Jarvis [18] showed that bacterial levels were inversely related to the amount of fresh replacement water along with chlorine at 30–50 ppm added to the chillers.

The commenter's concern over immersion chilling cannot be supported by carefully conducted research on properly operated equipment. In the few reports showing cross-contamination of microorganisms during immersion chilling, one or more of the following existed: extremely high level of initial carcass contamination, low water overflow rates, and absence of chlorination. Air chilling is less efficient and does not improve the sanitary quality of the carcasses. [19]

Lastly, a commenter stated that the use of TSP should be indicated on the product label. TSP is classified by FDA as a multiple purpose GRAS substance. TSP is a processing aid, not an ingredient, and it leaves virtually no residue on or in poultry carcasses. FDA exempts from label declaration requirements, at 21 CFR 101.100(a)(3)(ii)(*c*), processing aids added for technical or functional effect at processing, but not present in the finished food at significant levels and which do not have any technical or functional effect in that food. Therefore, declaring TSP on product labels is not required. However, as with an optional labeling statements, FSIS would evaluate, on a case-by-case basis, requests for optional labeling statements about the purpose of TSP. Such statements must not be false or misleading.

On December 29, 1995, FSIS published in the Federal Register the proposed rule, ''Substances Approved for Use in the Preparation of Meat and Poultry Products,'' (60 FR 67459). The rule proposes to amend the meat and poultry inspection regulations to harmonize and improve the efficiency of the procedures used by FSIS and the FDA for reviewing and approving the use of substances in meat and poultry products. Under the proposed procedures, FSIS would no longer issue its own regulations listing substances it finds suitable for use in meat and poultry products. Instead, by agreement between USDA and the FDA, future FDA regulations would specify whether a substance approved for use in foods under the Federal Food, Drug, and Cosmetic Act (FFDCA) may be used in or on meat or poultry products. Current FDA regulations that approve the use of substances in foods generally, and do not preclude meat and poultry uses, will confer authority to use such substances in meat and poultry products unless expressly prohibited by USDA regulation.

Requests for meat and poultry uses of substances not permitted under title 9 or title 21 of the Code of Federal Regulations (CFR) would have to be made to FDA in the form of a petition for FDA approval. Therefore, FDA simultaneously published its proposed rule, ''Substances Approved for Use in the Preparation of Meat and Poultry Products; Food Standards of Identity, Quality and Fill of Container; Common or Usual Name Regulations,'' (60 FR 67490). FDA's rule proposes to amend FDA regulations governing the review of petitions for the approval of food additives to provide for simultaneous review of such petitions by FSIS when meat or poultry product uses are indicated. This would permit FDA listings to specify whether, and if so under what conditions, such substances may be used in USDA-inspected meat and poultry products. Such listings would eliminate the need for separate FSIS rulemaking.

FSIS would limit any future, substance-specific rulemaking to prohibitions or limitations on meat or poultry uses of specific substances that may be necessary to protect the public under the Federal Meat Inspection Act (FMIA) or Poultry Products Inspection Act (PPIA). FSIS would continue to provide evaluations upon request as to whether substances permitted for general use under current regulations are suitable for specific uses in meat and poultry products.

FSIS proposes to adopt the position that substances that are listed in title 21, CFR, Parts 182 and 184, as generally recognized as safe (GRAS) for use in food generally, with no limitation other than good manufacturing practice, would be accepted by USDA as GRAS for use in meat, meat food products, and poultry products generally, unless otherwise restricted for such use by regulation in title 9, CFR. Other GRAS substances currently permitted for general food use would be evaluated by

FSIS as to their suitability for specified uses in meat food products and poultry products on a case-by-case basis, in consultation with FDA as appropriate.

Until that proposed rulemaking is complete and final rule issued, FSIS will continue to initiate individual rulemaking to add substances to its table of approved substances.

Executive Order 12866 and Regulatory Flexibility Act

This rule has been determined to be not significant for purposes of Executive Order 12866 and therefore has not been reviewed by the Office of Management and Budget.

The Administrator, FSIS, determined this rule will not have a significant economic impact on a substantial number of small entities. The rule will permit establishments voluntary use of TSP.

Establishments choosing to use TSP as an antimicrobial agent will incur a one-time expense for the necessary equipment and an ongoing cost for purchasing TSP. In the proposed rule, the cost for equipment was estimated at $45,000 per processing line, and the cost for the TSP at ½ cent per bird. Since the proposed rule was published, additional analysis of the estimated cost of the equipment and of the TSP has provided minor changes to the cost estimations. The cost for equipment is now estimated to be $40,000 per processing line, and the cost for the TSP is estimated to average about 0.3 cents per broiler and 1.4 cents per turkey.

Executive Order 12778

This rule has been reviewed under Executive Order 12778, Civil Justice Reform. This rule will provide for the use of TSP as an antimicrobial treatment on raw, chilled poultry carcasses passed for wholesomeness.

States and local jurisdictions are preempted under the Poultry Products Inspection Act (PPIA) from imposing any requirements with respect to federally inspected premises and facilities, and operations of such establishments, that are in addition to, or different than, those imposed under the PPIA. States and local jurisdictions are also preempted under the PPIA from imposing any marking, labeling, packaging, or ingredient requirements on federally inspected poultry products that are in addition to, or different than, those imposed under the PPIA. States and local jurisdictions may, however, exercise concurrent jurisdiction over poultry products that are outside official establishments for the purpose of preventing the distribution of poultry products that are misbranded or adulterated under the PPIA or, in the case of imported articles, which are not at such an establishment, after their entry into the United States. States and local jurisdictions may also make requirements or take other actions that are consistent with the PPIA, with respect to any other matters regulated under the PPIA.

Under the PPIA, States that maintain poultry inspection programs must impose requirements on State-inspected products and establishments that are at least equal to those required under the PPIA. These States may, however, impose more stringent requirements on such State-inspected products and establishments.

In the event of its adoption, no retroactive effect will be given to this rule, and applicable administrative procedures must be exhausted before any judicial challenge to the application of these provisions. Those administrative procedures are set forth in 9 CFR 381.35.

List of Subjects in 9 CFR Part 381

Poultry and poultry products.

For the reasons set forth in the preamble, FSIS is amending the poultry products inspection regulations as follows:

PART 381—MANDATORY POULTRY PRODUCTS INSPECTION

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

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

2. In Table 1 of § 381.147(f)(4), a new class of substance, ''Antimicrobial agents,'' is added, and the substance ''Trisodium phosphate'' is added to the new class of substance, to read as follows:

§ 381.147 Restrictions on the use of substances in poultry products.

* * * * *

(f) * * *

(4) * * *

Class of substance	Substance	Purpose	Products	Amount
*	*	*	*	* * *
Anti-microbial agents	Trisodium phosphate.	To reduce microbial levels.	Raw, chilled poultry carcasses.	8 to 12 percent; solution to be maintained at 45 °F. to 55 °F. and applied by spraying or dipping carcasses for up to 15 seconds in accordance with 21 CFR 182.1778.
*	*	*	*	* * *

Done at Washington, DC, on: July 20, 1996.

Michael R. Taylor,

Acting Under Secretary for Food Safety.

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NUCLEAR REGULATORY COMMISSION

10 CFR Parts 2, 50, and 51

RIN 3150–AE96

Decommissioning of Nuclear Power Reactors

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Nuclear Regulatory Commission is amending its regulations on the decommissioning procedures that lead to the termination of an operating license for nuclear power reactors. The final amendments clarify ambiguities in the current rule and codify procedures that reduce the regulatory burden, provide greater flexibility, and allow for greater public participation in the decommissioning process. Some minor amendments pertain to non-power reactors and are for purposes of clarification and procedural simplification. The Commission believes that the final amendments will enhance efficiency and uniformity in the regulatory process of decommissioning nuclear power plants.

EFFECTIVE DATE: August 28, 1996.

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SUPPLEMENTARY INFORMATION:

Background

On June 27, 1988 (53 FR 24018), the Commission promulgated decommissioning regulations. On July 20, 1995 (60 FR 37374), the Commission issued proposed amendments to these regulations. A discussion of the current requirements and proposed amendments follows.

Current Requirements

Within 2 years after a licensee permanently ceases operation of a nuclear reactor facility, it must submit a detailed decommissioning plan to the NRC for approval, along with a supplemental environmental report that addresses environmental issues that have not already been considered. Based on these submittals, the NRC reviews the licensee's planned activities, prepares a Safety Evaluation Report (SER) and an environmental assessment (EA), and either makes a negative declaration of impact (the usual case) or prepares an environmental impact statement (EIS). Upon NRC approval of the decommissioning plan, the Commission issues an order permitting the licensee to decommission its facility in accordance with the approved plan. As part of the approval process, the opportunity for a hearing under subpart G of 10 CFR part 2, is made available to the public. Once the decommissioning process is completed and the NRC is satisfied that the facility has been radioactively decontaminated to an unrestricted release level, the NRC terminates the license.

If the licensee chooses to place the reactor in storage and dismantle it at a later time, the initial decommissioning plan submittal need not be as detailed as a plan for prompt dismantlement. However, before the licensee can begin dismantlement, a detailed plan and environmental report must be submitted and approved by the Commission.

Before the decommissioning plan is approved, the licensee cannot perform major decommissioning activities. If a licensee desires a reduction in requirements because of the permanent cessation of operation, it must obtain a license amendment for possession-only status. This is usually granted after the licensee indicates that the reactor has permanently ceased operations and fuel has been permanently removed from the reactor vessel.

A licensee is required to provide assurance that at any time during the life of the facility, through termination of the license, adequate funds will be available to complete decommissioning. For operating reactors, the amount of decommissioning funding required is generically prescribed in 10 CFR 50.75. Five years before license expiration or cessation of operations, a preliminary decommissioning plan containing a site-specific decommissioning cost estimate must be submitted and the financial assurance mechanism must be appropriately adjusted. Finally, the decommissioning plan, submitted within 2 years after permanent cessation of operations, must provide a site-specific cost estimate for decommissioning and a correspondingly adjusted financial assurance mechanism. For delayed dismantlement of a power reactor facility, an updated decommissioning plan must be submitted with the estimated cost of decommissioning and the licensee must appropriately adjust the financial assurance mechanism. Before approval of the decommissioning plan, licensee use of these funds would be determined on a case-specific basis for premature closure, when accrual of required decommissioning funds may be incomplete.

Proposed Amendments

The degree of regulatory oversight required for a nuclear power reactor during its decommissioning stage is considerably less than that required for the facility during its operating stage. During the operating stage of the reactor, fuel in the reactor core undergoes a controlled nuclear fission reaction that generates a high neutron flux and large