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This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

9 CFR Parts 317, 318, and 381

[Docket No. 97-076P]

RIN 0583-AC50

Irradiation of Meat and Meat Products

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Proposed rule.

SUMMARY: The Food Safety and Inspection Service (FSIS) is proposing to amend the meat inspection regulations to permit the use of ionizing radiation for treating refrigerated or frozen uncooked meat, meat byproducts, and certain other meat food products to reduce levels of food borne pathogens and to extend shelf-life. FSIS is proposing this action in light of the Food and Drug Administration's recent final rule which amended its food additive regulations to provide for the safe use of ionizing irradiation sources to treat these same meat food products. FSIS also is proposing to revise the regulations governing the irradiation of poultry so that they will be as consistent as possible with the proposed regulations for the irradiation of meat food products.

DATES: Comments must be received on or before April 26, 1999.

ADDRESSES: Submit one original and two copies of written comments to FSIS Docket #97-076P, U.S. Department of Agriculture, Food Safety and Inspection Service, Room 102, Cotton Annex, 300 12 St., SW, Washington, DC 20250-3700. All comments submitted in response to this proposed rule will be available for public inspection in the Docket Clerk's Office between 8:30 a.m. and 4:30 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Daniel L. Engeljohn, Ph.D., Director, Regulation Development and Analysis Division, Office of Policy, Program Development, and Evaluation, Food Safety and Inspection Service, U.S.

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SUPPLEMENTARY INFORMATION:

Background

Food irradiation is the process of exposing food to high levels of radiant energy. Forms of radiant energy include: microwave and infrared radiation that heat food during cooking; visible light or ultraviolet light used to dry food or kill surface microorganisms; and ionizing radiation, resulting from cobalt-60, cesium-137, x-ray machines, or electron accelerators, that penetrates deeply into food, killing insect pests and microorganisms without raising the temperature of the food significantly. Food is most often irradiated commercially to extend shelf-life, eliminate insect pests, or reduce numbers of pathogenic microorganisms. Food irradiation for these purposes is practiced in many countries, including the United States.

Section 201(s) of the Federal Food, Drug and Cosmetic Act (FFDCA) defines sources of radiation used to treat food as "food additives." The Food and Drug Administration (FDA) of the Department of Health and Human Services has the primary responsibility for determining whether or not food additives are safe for particular uses. FDA lists uses of food additives it has concluded are safe in 21 CFR parts 172 through 180.

On August 25, 1994 (59 FR 43848), FDA announced that it had received a petition from Isomedix, Inc., requesting that FDA amend the food additive regulations in 21 CFR part 179 (Irradiation in the Production, Processing and Handling of Food). The petition requested that FDA authorize the safe use of sources of ionizing radiation to:

control microbial pathogens in raw, fresh-chilled, and frozen intact and comminuted edible tissue of the skeletal muscle and organ meat of domesticated mammalian food sources; with concomitant control of infectious parasites, and, extension of acceptable edible/marketable life of chilled/refrigerated and defrosted meat through the reduction in levels of spoilage microorganisms.

The petition further specified that the proposed foods were to be "primarily from bovine, ovine, porcine, and equine sources." Also, Isomedix requested that a maximum dose of 4.5 kiloGray (kGy) be established for the irradiation of fresh (chilled, not frozen) meat, and that a

maximum dose of 7.0 kGy be established for the irradiation of frozen meat.

On December 3, 1997, FDA published a final rule (FDA Docket No. 94F-0289; 62 FR 64107) granting this petition. In that publication, FDA expanded the list of products (21 CFR 179.26(b)) for which ionizing irradiation may be safely used to control food borne pathogens and extend shelf life to include: refrigerated and frozen uncooked meat; meat byproducts (e.g., edible organs, such as the liver and the kidneys); and certain meat food products (e.g., ground beef and hamburger). Specifically, the foods that may be irradiated are: meat, as defined by FSIS in 9 CFR 301.2(rr); meat byproducts, as defined by FSIS in 9 CFR 301.2(tt); and other meat food products within the meaning of 9 CFR 301.2(uu), with or without nonfluid seasoning, that are otherwise composed solely of intact or ground meat or meat byproducts, or of both.

FDA's Evaluation of the Safety of Irradiation

Under § 409(c)(3)(A) of the FFDCA, a food additive cannot be listed for a particular use unless a fair evaluation of the evidence establishes that the additive is safe for that use. In response to the Isomedix petition, FDA identified the various effects that could result from the irradiation of meat food products and then assessed whether any of these effects could pose a human health risk. FDA did not consider whether irradiation of meat would bring about health or other benefits for consumers.

FDA examined the data and studies submitted by Isomedix, as well as other information in its files relevant to the safety and nutritional adequacy of meat treated with irradiation. Specifically, FDA evaluated:

- Studies of the radiation chemistry of food components and whole foods, including flesh foods ("radiation chemistry" refers to the chemical reactions that occur as a result of absorbing radiation);
- Toxicity studies of irradiated beef, pork, chicken, and fish;
- Studies of the nutritional adequacy of irradiated products derived from livestock and poultry, in light of the dietary consumption patterns for these products; and

• Studies of the effects of irradiation on both pathogenic and nonpathogenic microorganisms.¹

Based on its evaluation of available data, FDA concluded that irradiation of meat, meat byproducts, and certain other meat food products under the conditions requested in the petition would not present toxicological or microbiological hazards and would not adversely affect the nutritional adequacy of these products. FDA therefore granted the petition and added meat, meat byproducts, and certain other meat food products to the list in 21 CFR 179.26(b) of foods that may be treated with ionizing radiation to reduce levels of food borne pathogens and to extend shelf-life.

Under § 318.7 of the meat inspection regulations, FSIS may approve a substance for use in the preparation of meat food products if the substance has been previously approved by FDA and if FSIS has determined that:

- Its use is in compliance with applicable FDA requirements;
- The use of the substance will not render the product in which it is used adulterated or misbranded or otherwise not in compliance with the requirements of the Federal Meat Inspection Act; and
- Its use is functional and suitable for the product and it is permitted for use at the lowest level necessary to accomplish the stated technical effect as determined in specific cases. FSIS has made these determinations and therefore, in this document is proposing to amend its meat inspection regulations to provide for the safe use of ionizing radiation for the treatment of meat, meat byproducts, and certain other meat food products. FSIS also is proposing labeling requirements for these same products.

Irradiation as a Food Additive in Meat and Poultry

Pathogenic microorganisms are the most significant cause of food borne illness. Ionizing radiation will reduce, and in some circumstances eliminate, pathogenic microorganisms in or on meat and poultry. FSIS therefore recognizes irradiation as a important technology for helping to ensure the safety of meat and poultry. FSIS already has listed ionizing radiation as an approved additive in pork carcasses or

fresh or previously frozen cuts of pork carcasses that have not been cured or heat-processed for the control of *Trichinella spiralis* (9 CFR 318.7); and as an approved additive in fresh or frozen, uncooked, packaged poultry products and mechanically separated poultry for the purpose of reducing pathogenic microorganisms (9 CFR 381.147). In fact, FSIS originally petitioned FDA to allow the irradiation of poultry.

Available scientific data indicate that ionizing radiation can significantly reduce the levels of many of the pathogenic microorganisms of concern in meat food products, including various species of *Salmonella*; *E. coli* O157:H7; *Clostridium perfringens*; *Staphylococcus aureus*; *Listeria monocytogenes*; *Campylobacter jejuni*; and the protozoan parasite *Toxoplasma gondii*. The available reports and published articles establish that the radiation dose necessary to reduce the initial population of many of the bacterial pathogens by 90 percent (the "D value," which is equivalent to 1-log₁₀) ranges from 0.1 kGy to just under 1 kGy. The following chart lists the approximate D values for some of the pathogens of concern in meat food products.²

Pathogen	Irradiation D values
<i>C. jejuni</i>	0.18 kGy (in refrigerated product) to 0.24 kGy (in frozen product).
<i>C. perfringens</i>	0.586 kGy (in refrigerated product).
<i>E. coli</i> O157:H7.	0.25 kGy (in refrigerated product) to 0.45 kGy (in frozen product).
<i>L. monocytogenes</i> .	0.4 kGy to 0.64 kGy.
<i>Salmonella</i> spp.	0.48 kGy to 0.7 kGy.
<i>S. aureus</i>	0.45 kGy.
<i>T. gondii</i>	0.4 kGy to 0.7 kGy.
<i>T. spiralis</i>	0.3 kGy to 0.6 kGy.

These approximate ranges of D values are all well beneath the maximum dosages of irradiation authorized by FDA and proposed by FSIS for refrigerated and frozen meat food products (4.5 kGy and 7 kGy, respectively). Treating product with a maximum dose of irradiation, therefore, could result in a significant reduction or even the elimination of certain pathogens. For example, given the highest approximate D value for *E. coli*

O157:H7 from the table above, irradiation of a frozen meat food product at 7 kGy could achieve an approximate 15 log₁₀ per gram reduction of *E. coli* O157:H7. That is, approximately 99.99999999999999 percent of the pathogen could be eliminated from the product. Considering that *E. coli* O157:H7 is usually found at levels of 3 log₁₀ per gram or lower in ground meat products³, there is a high probability that irradiation of frozen ground meat products with a 7 kGy dose could eliminate *E. coli* O157:H7 from the product.

It is important to remember, however, that the D value for any individual pathogen varies depending on such factors as the type of food to be irradiated, the physical state (frozen versus nonfrozen) of the food, product temperature, and ambient oxygen level. For example, higher radiation doses are needed to achieve the same antimicrobial effect in a frozen food versus a nonfrozen food of the same type (hence the two different maximum doses for refrigerated and frozen product approved by FDA and proposed in this document by FSIS). Further, the load of pathogens on incoming product can vary widely, due to animal husbandry and sanitation practices, as well as other factors. Regardless, it is apparent that irradiation would be a highly effective antimicrobial treatment for meat food products.

Finally, as mentioned in footnote 1, the pathogen *C. botulinum* is very resistant to irradiation. Spores have D values of approximately 3.45 to 3.6 kGy in refrigerated product and 3.73 to 3.85 kGy in frozen product.⁴ However, in its microbiological assessment of irradiation, FDA determined that the probability for significant growth of, and toxin production by, *C. botulinum* in irradiated meat stored under adequate temperature control (properly refrigerated or frozen) is extremely remote for several reasons. First, *C. botulinum* spores occur with extremely low frequency and in extremely low numbers in meat, and these numbers will be further reduced by irradiation at the permitted doses. Second, most strains of *C. botulinum* that have been found in meat do not grow and produce toxin under refrigeration conditions appropriate for transport and storage of

¹ Because *Clostridium botulinum* spores are very resistant to the effects of irradiation and would be more likely to survive irradiation than other pathogens and most spoilage bacteria, and because the illness associated with botulinum toxin is so severe, FDA, in its evaluation, focused particularly on the effects of irradiation on the probability of significantly increased growth of, and subsequent toxin production by, *C. botulinum*. FDA determined that irradiation of meat food products under the conditions set forth in its regulation will not result in any additional health hazard from *C. botulinum* or from other common pathogens.

² These approximate D-values are from: "Irradiation of red meat: A compilation of technical data for its authorization and control," International Consultative Group on Food Irradiation, August 1996.

³ National Advisory Committee on Microbiological Criteria for Foods, Meat and Poultry Subcommittee Report, November 20, 1997.

⁴ "Irradiation of red meat: A compilation of technical data for its authorization and control," International Consultative Group on Food Irradiation August 1996.

flesh foods. Third, various species of other microorganisms commonly found on meat, particularly spoilage bacteria (e.g., *Lactobacillus* spp. and others), survive irradiation in sufficient numbers to grow and inhibit growth of, and toxin production by, *C. botulinum* in both refrigerated and temperature-abused irradiated meats. FDA concluded, therefore, that irradiation of meat food products under the conditions set forth in its regulation will not result in any health hazard from *C. botulinum* additional to that which may be found in non-irradiated product.

Irradiation and HACCP

On July 25, 1996, FSIS published a final rule that requires every meat and poultry establishment to develop and implement Hazard Analysis and Critical Control Point (HACCP), a science-based process control system designed to improve the safety of meat and poultry products (FSIS Docket No. 93-016F, "Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) Systems"; 61 FR 38806). Under this final rule, meat and poultry establishments are responsible for developing and implementing HACCP plans incorporating the controls determined by the establishment to be necessary and appropriate to produce safe products. HACCP is a flexible system that enables establishments to tailor their control systems to the needs of their particular plants and processes. In the paragraphs that follow, FSIS outlines how irradiation could be used within a HACCP system by poultry establishments and, if FSIS finalizes this rule, by meat establishments.

To meet the HACCP requirements, establishments must first conduct a hazard analysis to identify and list the food safety hazards reasonably likely to occur in a production process, as well as the preventive measures necessary to control the hazards. A food safety hazard is any biological, chemical, or physical property that may cause a food to be unsafe for human consumption. Establishments that identify microbial pathogens as hazards within their processes could choose irradiation as a method to reduce or even eliminate such pathogens.

Next, establishments must establish critical control points (CCP's). A CCP is a point, step, or procedure at which control can be applied so that a food safety hazard can be prevented, eliminated, or reduced to an acceptable level. Meat and poultry establishments choosing to irradiate product would integrate irradiation into their HACCP systems as a CCP.

Establishments then must establish critical limits for their CCP's. Critical limits are most often based on process parameters such as temperature, time, physical dimensions, humidity, moisture level, water activity, pH, and survival of target pathogens. Establishments that irradiate product probably would have as some of their critical limits radiation dosage, product temperature, and ambient oxygen level. By ensuring that specific limits for each of these parameters were met, establishments could be reasonably sure that a predetermined reduction in pathogens had been achieved within the irradiated product. Establishments would be free to establish any critical limits appropriate for their HACCP systems, as long as they remain in compliance with the FSIS and FDA regulations governing irradiation, such as the regulatory limits on maximum dosage.

The remaining HACCP requirements include monitoring of CCP's, plans for corrective action in the event of processing deviations, record keeping, and HACCP plan verification. It is likely that establishments that irradiate product would meet these requirements no differently than other official establishments. Establishments that irradiate meat or poultry product should keep in mind, however, that their HACCP plans must address all processing, from receiving to shipment. Therefore, an establishment that ships product to a separate facility for irradiation would need to address the conditions of shipment (handling, packaging, refrigeration, etc.) within its HACCP plan. Similarly, the irradiation facility would need to address shipment and receiving of the product, as well as the irradiation treatment itself, in its HACCP plan. Controlling the conditions of product from initial processing through irradiation and packaging will be necessary to ensure and preserve the intended antimicrobial effects of irradiation.

There are numerous possible scenarios involving the use of irradiation within a HACCP system and FSIS could not enumerate them all in this document. There is available from FSIS, however, a generic HACCP model for irradiation developed by the International Meat and Poultry HACCP Alliance. The model, entitled "Generic HACCP Model for Irradiation," is available from the FSIS Docket Room (see ADDRESSES above) and from the Texas A&M University World Wide Web site at <http://ifse.tamu.edu/alliance/haccpmodels.html>.

To account for the numerous possible processing situations and to allow for

maximum flexibility and innovation in developing HACCP systems incorporating irradiation, FSIS is proposing only those requirements necessary to ensure product safety. For example, FSIS is proposing no minimum dose for the irradiation of meat products. FDA did not establish a minimum irradiation dose for meat food products in its final rule, although they stated that FSIS could establish a minimum dose without petitioning FDA. FDA concluded that different doses could be appropriate, in different circumstances, for achieving a desired technical effect and that its regulation should allow for flexibility in this regard. FSIS agrees. FSIS also is proposing to eliminate the minimum dose that it currently requires for poultry. The minimum dosage for poultry was intended to ensure a certain reduction of pathogens. Under the HACCP requirements, FSIS wants to allow poultry establishments, like meat establishments, to determine what level of irradiation (subject to a maximum level) and consequent reduction of pathogens is appropriate within their HACCP systems.

Furthermore, FSIS is proposing no specific handling or packaging requirements for the irradiation of meat food products. Under this proposal, establishments will be responsible for determining, within their HACCP systems, what sort of handling and packaging is appropriate for ensuring that irradiated product is not adulterated. FSIS also is proposing to revise the packaging requirements for irradiated poultry to maximize processing flexibility and innovation. The proposed revisions are explained in detail below under "Revision of the Requirements for Irradiated Poultry."

Finally, FSIS is proposing no restrictions on the specific function of irradiation as a CCP within a HACCP system. If this proposal is finalized, some establishments may choose to irradiate packaged ground product at high dosages to achieve maximal pathogen reduction throughout the product. Other establishments may choose to irradiate only a few millimeters into whole muscle products to control pathogenic bacterial contamination on the surface. These types of pathogen reduction treatments and others will be allowed under the proposed regulations.

FDA did approve irradiation of meat food products as a means to extend product shelf-life, as well as a means to reduce pathogens. FSIS is proposing to allow irradiation for this purpose too. Were an establishment to irradiate meat food products solely for the purpose of

extending shelf-life, it is conceivable, although highly unlikely, that the establishment could disregard any amount of pathogen reduction achieved by the irradiation and therefore not list irradiation as a CCP in its HACCP plan. However, such an establishment still would have to meet the other requirements for irradiation facilities promulgated by FSIS and other Federal and State agencies, such as requirements for dosimetry and documentation. FSIS does not anticipate that any establishment will irradiate product solely to extend shelf life and not account for the antimicrobial effects of irradiation in its HACCP plan.

Products Affected by the Proposed Rule

FSIS worked with FDA during its review of the Isomedix petition, primarily to identify the various types of meat food products suitable for irradiation, in light of the petitioner's request and FDA restrictions concerning the irradiation of ingredients (e.g. water, brine, spices) contained in certain meat products. FSIS also consulted with FDA regarding which forms of comminuted meats (e.g. low-temperature rendered meat, advanced meat recovery system meat, finely textured meat) would be suitable for irradiation. As a result of those consultations, FDA approved ionizing irradiation as an additive for the following types of uncooked, refrigerated or frozen meat food products:

- Meat, as defined in 9 CFR 301.2(rr):

(1) The part of the muscle of any cattle, sheep, swine, or goats, which is skeletal or which is found in the tongue, or in the diaphragm, or in the heart, or in the esophagus, with or without the accompanying and overlying fat, and the portions of bone, skin, sinew, nerve, and blood vessels which normally accompany the muscle tissue and which are not separated from it in the process of dressing. It does not include the muscle found in the lips, snout, or ears. This term, as applied to products of equines, shall have a meaning comparable to that provided in this paragraph with respect to cattle, sheep, swine, and goats.

(2) The product derived from the mechanical separation of the skeletal muscle tissue from the bones of livestock using the advances in mechanical meat/bone separation machinery and meat recovery systems that do not crush, grind, or pulverize bones, and from which the bones emerge comparable to those resulting from hand-deboning (i.e., essentially intact and in natural physical conformation such that they are recognizable, such as loin and rib bones, when they emerge from the machinery) which meets the criteria of no more than 0.15 percent or 150 mg/100 gm of product for calcium (as a measure of bone solids content) within a tolerance of 0.03 percent or 30 mg.

- Meat byproducts, as defined in 9 CFR 301.2(tt):

Any part capable of use as human food, other than meat, which has been derived from one or more cattle, sheep, swine, or goats. This term, as applied to products of equines, shall have a meaning comparable to that provided in this paragraph with respect to cattle, sheep, swine, and goats. (This category of byproducts would include blood and blood plasma.)

- Meat food products within the meaning of 9 CFR 301.2(uu), with or without nonfluid seasoning, that are otherwise composed solely of intact or ground meat and/or meat byproducts (e.g., ground beef as in 9 CFR 319.15(a); hamburger as in 9 CFR 319.15(b); certain defatted beef or pork products as in 9 CFR 319.15(e) and 9 CFR 319.29(a), respectively; mechanically separated (species) as in 9 CFR 319.5).

FSIS's proposed irradiation requirements would be applicable to these same meat food products.

It has come to the attention of the Agency that several establishments may wish to irradiate "hot-boned" meat. Hot-boned meat is meat carcasses or parts that are deboned immediately following slaughter and then chilled. It is likely that an establishment wishing to irradiate hot-boned meat would irradiate between the deboning and the chilling of the carcasses or parts. The meat, therefore, would not have been refrigerated prior to irradiation and FDA has listed ionizing irradiation as an additive only for refrigerated or frozen, uncooked meat products.

FSIS believes that the irradiation of hot-boned meat poses no unique risks and further, that the assessment conducted by FDA regarding the safety of irradiating refrigerated meat is completely applicable to hot-boned meat. In the proposed regulatory text, FSIS has specified only refrigerated and frozen meat food products as products that may be irradiated in § 318.7(c)(4). However, FSIS currently is consulting with FDA to determine what action is necessary and appropriate in regard to the possible irradiation of hot-boned meat. FSIS requests public comment on this issue as well. Depending upon these consultations with FDA and other information submitted by the public, FSIS may specifically provide for the irradiation of hot-boned meat in the final rule that succeeds this document.

Addition of Irradiation to the Table of Substances Approved for Use in the Preparation of Meat Food Products

FSIS is proposing to amend the table in § 318.7(c)(4) of its meat inspection regulations by adding ionizing radiation as a substance suitable for controlling food borne pathogens in the meat, meat byproducts, and other meat food products described above. In accordance with the FDA final rule, FSIS is

proposing a maximum absorbed dosage of 4.5 kGy for refrigerated products and 7 kGy for frozen products. As explained above, FSIS is proposing no minimum dosage.

This addition to the table would supercede the current entry allowing the use of ionizing radiation from gamma rays for the control of *Trichinella spiralis* in pork. Current FSIS regulations permit the use of ionizing irradiation from cobalt-60 and cesium-137 for control of *Trichinella spiralis* in specified pork products. Additionally, the regulation specifies minimum and maximum dosages. Under this proposal, establishments could continue to irradiate pork for the control of trichinae, but could employ higher doses, as well as ionizing radiation from machine sources. In its recent final rule, FDA did not remove the entry allowing the use of ionizing radiation for the control of *Trichinella spiralis* in pork from the table in 21 CFR 179.26(b). However, FDA's addition of sources of radiation as a treatment for meat food products seems to supercede the entry for *Trichinella spiralis*. FSIS will consult with FDA to clarify the intent of its new rule on this issue.

Processing Requirements for the Irradiation of Meat Food Products

FSIS is proposing to amend § 318.11 (currently reserved) by establishing processing requirements specific to the irradiation of specified meat food products. Of primary importance is that the irradiation of meat food products be conducted only in accordance with written procedures. Absorbed radiation dosage cannot be measured in treated product. Only through adherence to written procedures can establishments ensure that product receives doses of radiation within the regulatory limits.

To this end, FSIS is proposing to require that establishments conduct irradiation of meat and meat products only in accordance with either a HACCP plan, as defined in Part 417 of the FSIS meat and poultry inspection regulations, or a process schedule validated for efficacy by a processing authority (proposed § 318.11(a)). Written irradiation procedures must describe the specific, sequential operations employed by the establishment in the irradiation and associated processing of meat food products, including the control, validation, monitoring, and corrective action activities.

Because the smallest meat and poultry establishments will not be required to implement HACCP until January 25, 2000, it is possible that there will be establishments ready to irradiate meat food products before they have

implemented HACCP. FSIS would prefer that establishments develop and implement HACCP plans sooner than required. The Agency is proposing however, that establishments desiring to irradiate meat food products before they have implemented HACCP, have on file a written process schedule describing the specific operations employed by the establishment to accomplish the objectives of irradiation. FSIS is proposing to require that this process schedule contain the control, validation, monitoring, and corrective action activities associated with the establishment's irradiation procedures (proposed § 318.11(a)(2)). These activities are the safety, sanitation, and basic good manufacturing practices generally regarded as essential prerequisites for the production of safe food. Further, these activities are likely to be similar, if not identical, to the control, monitoring, validation, and corrective action activities developed by the establishment as part of its HACCP plan.

Under this proposal, the process schedule will have to be evaluated and approved for safety and efficacy by a process authority. A "process authority" is defined in § 301.2 of the regulations as "A person or organization with expert knowledge in meat production process control and relevant regulations." The process authority will evaluate the establishment's prospective irradiation and related processing procedures using appropriate validation methods such as laboratory challenge studies or comparison to peer-reviewed and -accepted procedures. The process authority must approve in writing the safety and efficacy of the irradiation procedures. The process authority must have access to the establishment in order to evaluate the safety of that establishment's planned production processes.

FSIS is proposing to sunset these proposed process schedule requirements after all establishments have been required to develop and implement HACCP plans. These requirements will be duplicative of what is required by HACCP and an establishment would not need both an approved process schedule and a validated HACCP plan for the same process. FSIS anticipates that if an establishment develops a process schedule for irradiating meat food products prior to implementing HACCP, it would incorporate elements of that process schedule into its HACCP plan.

Dosimetry

FSIS also is proposing to require in § 318.11(b) that any establishment

irradiating meat food products have in place a dosimetry system. Dosimetry is the process of measuring an absorbed dose of radiation. FSIS is proposing to require establishments to implement a dosimetry system to ensure that each lot of treated product has received the dose defined in the process schedule or HACCP plan.

FSIS is proposing dosimetry requirements for the irradiation of meat food products that are almost identical to the dosimetry requirements currently in place for the irradiation of poultry food products. Under current and proposed requirements, establishments that irradiate poultry or meat food products must have in place: procedures for determining the absorbed radiation dose value from the dosimeter(s); procedures for calibrating dosimeters and other means of measurement (e.g., time clocks and weight scales); procedures for ensuring specific absorbed dosages of irradiation by product unit and product lot; and procedures for verifying the integrity of the radiation source and the processing procedure. The current and proposed dosimetry requirements are based upon standards promulgated by the American Society for Testing and Materials (ASTM).

It is likely that establishments will incorporate many dosimetry procedures into their HACCP plans. For example, procedures for verifying routine dosimetry (i.e., ensuring each product lot receives the total absorbed dose) could be incorporated into an HACCP plan as critical limits for the irradiation process. Also, calibration of dosimeters and other instruments could be incorporated as ongoing verification activities.

Documentation Requirements

Finally, FSIS is proposing to require that any establishment irradiating meat food products have on file, along with its validated process schedule or HACCP plan, the following documents that relate to its compliance with other Federal requirements concerning irradiation. These are almost identical to the documentation requirements currently in place for the irradiation of poultry products.

- Documentation that the irradiation facility is licensed and possesses gamma radiation sources registered with the Nuclear Regulatory Commission (NRC) or the appropriate State government acting under authority granted by the NRC (proposed § 318.11(c)(2)).
- Documentation that the machine radiation source irradiation facility is registered with the Occupational Safety and Health Administration (OSHA) or the

appropriate State government acting under authority granted by OSHA, and that a worker safety program addressing OSHA regulations is in place (proposed § 318.11(c)(3)).

- Citations or other documents that relate to the instances in which the establishment was found not to comply with Federal or State agency requirements for irradiation facilities (proposed § 318.11(c)(4)).

- Certification by the operator that the irradiation facility personnel are operating under supervision of a person who has successfully completed a course of instruction for operators of food irradiation facilities (proposed § 318.11(c)(5)).

- Certification by the operator that the key irradiation personnel have been trained in food technology, irradiation processing, and radiation health and safety (proposed § 318.11(c)(6)).

- Guarantees from the suppliers of all food-contact packaging materials that may be subject to irradiation, that those materials comply with the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) and with regulations in 21 CFR 179.45 for food irradiation processing (proposed § 318.11(c)(7)).

Labeling Requirements for Irradiated Meat Food Products

FSIS is proposing to amend § 317.14 by establishing requirements for the labels and labeling of irradiated meat and meat products. For meat and meat products irradiated in their entirety (as opposed to a multi-ingredient product that merely contains an irradiated ingredient), FSIS is proposing to require that package labels contain the radura symbol and a statement indicating that the product was treated with irradiation. The symbol must be placed prominently and conspicuously in conjunction with the required statement. The statement must appear as a qualifier contiguous to the product name. Further, FSIS is proposing to require that for unpackaged meat food products irradiated in their entirety, the required logo and a statement must be placed prominently and conspicuously displayed to purchasers either through labeling on a bulk container or some other appropriate device. These proposed requirements are consistent with those promulgated by FSIS for poultry and by FDA for meat and poultry.

Under this proposal, establishments could use irradiated meat food products as ingredients in multi-ingredient meat food products. FSIS is proposing to require that the ingredient statement on such products reflect the inclusion of irradiated meat food product ingredients. For example, an ingredient statement for a sausage product containing irradiated pork would be required to include an entry such as, "irradiated pork" or "pork, treated by

irradiation." Consumers and consumer advocacy groups have requested that such information be disclosed in the labeling of multi-ingredient food products.

Further, disclosure of processing is consistent with current FSIS labeling policy. For example, § 317.2(e) of the meat inspection regulations requires that "Product which has been prepared by salting, smoking, drying, cooking, chopping, or otherwise shall be so described on the label unless the name of the product implies, or the manner of packaging shows that the product was subjected to such preparation." Unlike the effects of these other forms of processing, the effects of irradiation processing upon meat usually would not be detectable by the consumer. However, some of the effects brought about by irradiation, such as antimicrobial effects and certain changes to product quality, are similar to the effects of other forms of processing, especially cooking. Furthermore, the use of treatments has been considered part of the common or usual name for various ingredients in meat food products, such as "dehydrated onions" and "reconstituted potatoes."

Because FDA has not promulgated a similar requirement, and because FSIS anticipates opposition from certain sectors of the meat industry, FSIS specifically requests comment on this proposed labeling requirement. Notably, in a recently published Advance Notice of Public Rulemaking, FDA has requested public comment on this same issue and other issues related to the labeling of irradiated food products. FDA's labeling requirements and this recent notice are further discussed below under "Other Labeling Issues."

Incentive Labeling for Irradiated Meat Food Products

FSIS would consider for approval labeling statements for meat food products indicating the elimination or reduction of certain pathogens. Under 9 CFR 381.135(c), FSIS already allows qualifiers on labels of irradiated poultry, e.g., "Treated by irradiation to reduce *Salmonella* and other pathogens." The prerequisite for such labeling statements on meat and poultry products would be a HACCP plan or process schedule validated as achieving, through irradiation, the specific elimination or reduction in pathogens indicated by the labeling. FSIS is proposing to require that labeling statements indicating a specific reduction in microbial pathogens be substantiated by processing documentation. Further, FSIS is proposing to require that such

labeling meet all other applicable labeling requirements contained in § 317.

Several representatives of the meat and poultry industries have stated to FSIS that they would like to label product as being free of certain pathogens as a result of irradiation, e.g., "Free of *E. coli* O157:H7." It may be possible for an establishment to determine the pathogen load on incoming product, irradiate the product to completely eliminate those pathogens with an appropriate margin of safety, and ensure that the product remains free of that pathogen until it reaches the consumer. FSIS requests comment on whether to allow this type of incentive labeling. Specifically, FSIS is interested in whether it should establish performance standards for labeling statements that reflect a specific reduction of pathogens. For example, FSIS could require that to use such labeling, establishments must achieve, through a validated HACCP system incorporating irradiation, a specific reduction of a pathogen of concern (e.g., an $x\text{-log}_{10}$ reduction of *E. coli* O157:H7). FSIS requests comment on this regulatory option, as well as any others, concerning the truthful labeling of irradiated meat and poultry products.

Currently, FSIS does not have the scientific data necessary to propose regulations that specifically address the necessary preconditions for an "*E. coli* O157:H7 free" label or similar labels indicating the elimination of other pathogens. Based upon comments and other data FSIS receives, FSIS would consider a modified version of the proposed labeling requirements in § 317.2(c) that would allow the labeling of meat products as being free of *E. coli* O157:H7 or other pathogens. Following an evaluation of submitted comments and data, FSIS will determine whether to provide for such labeling.

Other Labeling Issues

On November 21, 1997, President Clinton signed into law the FDA Modernization Act (FDAMA) of 1997 (Pub. L. 105-115). Section 306 (Disclosure of Irradiation) of FDAMA amends the Federal Food, Drug, and Cosmetic Act (FFDCA) by adding a new section 403C, as follows:

(a) No provision of section 201(n), 403(a), or 409 shall be construed to require on the label or labeling of a food a separate radiation disclosure statement that is more prominent than the declaration of ingredients required by section 403(i)(2).

(b) In this section, the term "radiation disclosure statement" means a written statement that discloses that a food has been intentionally subject to irradiation.

FDA's regulations currently do not specify how prominent a radiation disclosure statement must be. However, FDA believed that there was merit to amending 21 CFR 179.26 to include the prominence specification of the new statutory provision. Accordingly, FDA has amended its labeling provisions for irradiated foods in 21 CFR 179.26 to reflect that a radiation disclosure statement is not required to be any more prominent than the declaration of ingredients required under the applicable regulation promulgated under section 403(i)(2) of the FFDCA. The labeling requirements proposed in this document for irradiated meat and poultry products are consistent with these FDA provisions.

Also, the Joint Explanatory Statement of the Committee of Conference that accompanied the FDAMA directed FDA to publish for public comment proposed changes to current regulations relating to the labeling of foods treated with ionizing radiation. In response, on February 17, 1997, FDA published an Advance Notice of Proposed Rulemaking concerning possible revisions to the labeling requirements for irradiated food (64 FR 7834). In keeping with the FDAMA joint statement, FDA is specifically requesting comments on two issues: (1) Whether the wording of the current radiation disclosure statement should be revised and (2) whether such labeling requirements should expire at a specified date in the future. FDA also is requesting comments on other possible revisions to other labeling requirements for irradiated food, including the possibility of requiring disclosure of irradiated ingredients in multi-ingredient food products. FSIS will continue to consult with FDA on their labeling requirements and will also review the comments submitted in response to their notice. As is necessary and appropriate, FSIS will make any final labeling requirements for irradiated meat and poultry products that are consistent with the labeling requirements promulgated by FDA.

Finally, in the course of developing this proposal, FSIS received a petition from the National Food Processors Association (NFPA) regarding labeling requirements for irradiated food. Specifically, NFPA requested that FSIS address whether labeling requirements concerning the disclosure of irradiation are warranted for meat and poultry, and how such labeling affects consumer acceptance of irradiation. FSIS is reviewing this petition and will respond following its review of comments on this proposed rule.

Other Requirements

Establishments that irradiate meat food products are "official establishments," as defined by § 301.2(zz) of the regulations. Consequently, irradiation facilities will have to comply with all of the applicable regulatory requirements governing the processing of meat food products, including requirements concerning grants of inspection, sanitation, and the development and implementation of Sanitation Standard Operating Procedures and HACCP plans.

Revision of the Requirements for Irradiated Poultry

FSIS's regulations governing the irradiation of meat and poultry products must be based upon FDA's requirements for the use of ionizing radiation as an additive in those products. FDA's requirements for the use of ionizing radiation as an additive in poultry are far more restrictive than their recently issued requirements for the use of ionizing radiation as an additive in meat food products. Therefore, until FDA changes certain requirements concerning ionizing radiation as an additive in poultry, FSIS will be unable to make its requirements for irradiated poultry entirely consistent with those for irradiated meat. For example, FSIS cannot propose to change the restrictions on the maximum irradiation dose for poultry, the types of poultry products allowed to be irradiated, and certain packaging requirements. However, FSIS is proposing other permissible changes to the poultry regulations to make them as consistent as possible with the meat regulations and with HACCP.

First, FSIS is proposing to eliminate the requirements in §§ 381.19 and 381.149 that establishments irradiate poultry only in accordance with Partial Quality Control programs (PQC's). Instead, FSIS is proposing to require that, like meat establishments, poultry establishments irradiating product develop and implement process schedules or HACCP plans that account for the irradiation treatment. PQC's contain all or most of the elements required in a process schedule or HACCP plan, and all poultry establishments eventually will be required to implement HACCP. Consequently, FSIS anticipates that this conversion, if this proposal is finalized, will be relatively simple and pose no significant burden.

FSIS also is proposing to eliminate the requirement that only packaged poultry may be treated with irradiation.

FSIS adopted this requirement to ensure that the antimicrobial effects of irradiation would be maintained throughout the processing and distribution of the poultry:

To best ensure a reduction of the microbial load on poultry product, FSIS believes that all irradiated poultry would be packaged, in compliance with 21 CFR 179.25 and 179.26, prior to irradiation and remain in the same package through the distribution in commerce to the point of purchase.

(57 FR 19463; May 6, 1992)

Because FSIS is requiring all poultry establishments to develop and implement HACCP plans, this prescriptive packaging requirement is no longer necessary. Under the HACCP requirements, poultry establishments have both the responsibility and the flexibility to determine the best means for reducing hazards within a specific processing environment. A poultry establishment with irradiation as a CCP within its HACCP plan may choose whatever means is appropriate to preserve the antimicrobial effects of irradiation throughout processing and distribution. One result of this proposed revision will be that, as with irradiated meat food products, irradiated poultry products can be used as ingredients in further processed products.

FSIS cannot, however, propose to rescind the FDA requirement in 21 CFR 179.26(b)(6) which mandates that if packaged poultry product is irradiated, that packaging be air permeable: "* * * any packaging used shall not exclude oxygen." FSIS originally requested that FDA establish this requirement for control of the pathogen *C. botulinum*. FDA agreed, noting that "use of air-permeable packaging materials provides an extra margin of safety from *C. botulinum* toxin production and spoilage in chicken incubated both aerobically (with oxygen) and anaerobically (without oxygen)" (57 FR 19463; May 6, 1992). In light of the new HACCP requirements, FSIS believes that this prescriptive requirement is no longer necessary. Under HACCP, poultry establishments have both the responsibility and the flexibility to determine the best means for controlling any hazards resulting from the irradiation of product in anaerobic packaging. FSIS plans to petition FDA to eliminate this packaging requirement.

FSIS is proposing to eliminate the minimum dose requirement for irradiated poultry contained in § 381.147(f)(4). FSIS adopted this requirement to ensure that the irradiation of poultry, which may occur only after the product is packaged for retail sale, does in fact achieve a specific

reduction in pathogens. However, as stated above, FDA and FSIS have concluded that different doses of ionizing radiation can be appropriate, in different circumstances, for achieving different technical effects and, therefore, that to continue to require a minimum dose of irradiation for poultry would limit the flexibility needed for the successful implementation of HACCP. FSIS considers irradiation to be just one of many treatments that could be used within a HACCP system to achieve a compounded reduction in pathogens.

The optional labeling statements currently allowed for irradiated poultry in § 381.135(c) are premised upon an establishment employing the minimum dose. As with meat food products, FSIS is proposing instead to approve qualifiers based upon whether a poultry establishment has in place a HACCP plan or process schedule validated as achieving, through irradiation, the elimination or reduction of pathogens indicated on the label (proposed § 381.135(c)).

FSIS cannot propose to revise the FDA limits on the maximum absorbed radiation dose for poultry. However, it is possible that poultry may be safely treated with higher doses of radiation than that which are currently allowed. Higher doses could achieve greater reductions in pathogens. FSIS intends to petition FDA to reconsider and raise the limit on the maximum absorbed dose of radiation in poultry.

FSIS is proposing to eliminate two of the labeling requirements in § 381.135(a): the requirement that the radura logo on irradiated poultry labels must be colored green and the requirement that "letters used for the qualifying statement shall be no less than one-third the size of the largest letter in the product name." The elimination of these requirements will make FSIS requirements consistent with FDA requirements and provide more flexibility for labeling irradiated meat and poultry products, without affecting the information content of such labels.

Because FSIS is proposing to allow irradiated poultry products to be used as ingredients in further processed products, FSIS also is proposing to require that the ingredient statement on such products reflect the inclusion of irradiated poultry products (§ 381.135(b)). For example, an ingredient statement for a sausage product containing irradiated poultry would be required to include an entry such as, "irradiated poultry" or "poultry, treated by irradiation." Consumers and consumer advocacy groups have requested that such information be disclosed in the labeling

of multi-ingredient food products. This proposed disclosure requirement is identical to the requirement proposed in this document for irradiated meat used as an ingredient. Because FDA has not promulgated a similar requirement for irradiated meat or poultry, and because FSIS anticipates strong opposition from certain sectors of the meat and poultry industries, FSIS specifically requests comment on this proposed labeling requirement.

Further, because FSIS is proposing to allow unpackaged poultry product to be irradiated, it is proposing labeling requirements for unpackaged, irradiated poultry product sold at the retail level (proposed § 318.135(b)). The proposed labeling requirements are consistent with those proposed for unpackaged, irradiated meat food products and with FDA labeling requirements for irradiated products sold in bulk (21 CFR 179.26(c)(2)).

Finally, to further streamline and clarify the regulations governing the irradiation of poultry, FSIS is proposing to remove the "Definitions" section from those regulations (current § 381.149(a)). These definitions serve as general references for the PQC requirements that FSIS is proposing to remove from the regulations. Further, these definitions are already acknowledged and understood by irradiation facilities, as they are a paraphrase of those provided by ASTM.

Combination Meat and Poultry Products

Under the proposed requirements, FSIS will allow products composed of both meat and poultry to be irradiated. Such products would have to meet the requirements in proposed § 318.7(c)(4) and in existing § 381.147(f)(4) concerning the types of meat and poultry products that may be irradiated. Furthermore, establishments that irradiate combination product in its entirety will be required to meet the more restrictive requirements of the FSIS poultry irradiation regulations, namely the maximum radiation dose requirement in 9 CFR 381.147(f)(4) and the air-permeable packaging requirement in 9 CFR 381.149(c)(7). FSIS anticipates that establishments producing low-fat products, such as pepperoni or salami composed of both meat and poultry, will be especially interested in irradiation as an antimicrobial treatment.

Risk Analysis

Section 304 of the Federal Crop Insurance Reform and Department of Agriculture Reorganization Act of 1994 (P.L. 103-354) requires any regulation published by USDA concerning human

health, safety, or the environment, and having an annual economic impact of at least \$100 million in 1994 dollars, contain a risk assessment and cost-benefit analysis. The risk assessment and cost-benefit analysis must be "performed consistently and use reasonably obtainable and sound scientific, technical, economic, and other data." The USDA Office of Risk Assessment and Cost-Benefit Analysis (ORACBA), also established by the 1994 Act, must ensure that major rules include such analyses.

ORACBA and FSIS have agreed that FDA has already conducted a definitive risk analysis concerning the safety of meat food products treated with ionizing radiation in developing their final rule, "Irradiation in the Production, Processing and Handling of Food" (62 FR 64107; December 3, 1997). Therefore, FSIS and ORACBA are adopting the FDA finding as their risk assessment. Further, FSIS and ORACBA also have agreed that the cost-benefit and economic impact analyses that FSIS has performed for this proposed rule, as required by E.O. 12866 and the Regulatory Flexibility Act, satisfy the cost-benefit analysis requirements of the Reorganization Act. Consequently, FSIS, with assistance from ORACBA, has produced only an analytical literature review addressing existing research and risk assessments on the safety of food irradiation for consumers and the related risks posed by irradiation, including worker safety and environmental concerns. This literature review is available from the FSIS Docket Clerk's Office (see ADDRESSES above).

In this document, FSIS is proposing revisions to the current regulations governing the irradiation of poultry to make them more consistent with the proposed regulations for meat and with HACCP. These proposed revisions to the poultry regulations would pose no new risks to human health, the environment, or worker safety. Therefore, FSIS has not addressed these changes in a separate risk assessment or in the above mentioned literature review.

Executive Order 12988

This proposed rule has been reviewed under Executive Order 12988, Civil Justice Reform. States and local jurisdictions are preempted by the Federal Meat Inspection Act (FMIA) and the Poultry Products Inspection Act (PPIA) from imposing any marking, labeling, packaging, or ingredient requirements on federally inspected meat and poultry products that are in addition to, or different than, those imposed under the FMIA and PPIA. States and local jurisdictions may,

however, exercise concurrent jurisdiction over meat 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 and PPIA, or, in the case of imported articles, that are not at such an establishment, after their entry into the United States.

This proposed rule is not intended to have retroactive effect.

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

Compliance With Executive Order 12866—Preliminary Analysis

This action has been reviewed for compliance with Executive Order 12866. As this action is determined to be economically significant for purposes of Executive Order 12866, the Office of Management and Budget has reviewed it.

On December 3, 1997, FDA granted a petition from Isomedix, Inc. requesting that FDA permit the use of ionizing radiation to treat the fresh or frozen raw edible tissue of domesticated mammalian human food sources for purposes of reduction of parasites and microbial pathogens and extension of product shelf-life. Accordingly, in this document, FSIS is proposing to amend its meat inspection regulations to allow for the safe use of ionizing radiation for the treatment of meat, meat byproducts, and certain other meat food products. FSIS also is proposing to revise the existing regulations governing the irradiation of poultry so as to render them more consistent with the proposed regulations for meat.

FSIS has endeavored to propose regulations for the irradiation of meat food products that set forth performance objectives, rather than prescribe specific processing methods. For the irradiation of meat food products, and where possible for the irradiation of poultry products, FSIS has proposed requirements that allow for significant flexibility in integrating irradiation into the processing environment. It is possible that FSIS will be able to provide for even greater flexibility based upon the comments received in response to this proposal.

If this proposal is made final, the use of ionizing irradiation as a treatment for meat food products will be voluntary. Although FSIS recognizes the capability of irradiation treatment to reduce pathogens below current performance standards for pathogen reduction, the proposed rule does not change the performance standards. With standards unchanged, the primary benefit of the proposed rule to establishments is the increased flexibility they are allowed with this rule.

Alternatives

Executive Order 12866 requires that FSIS identify and assess alternative forms of regulation. FSIS considered two alternatives to this proposed regulation: (1) not proposing to allow for the irradiation of meat food products and (2) proposing to allow the irradiation of meat food products only under very limited conditions, similar to those currently prescribed for the irradiation of poultry products. FSIS rejected these two alternatives for reasons explained below.

No Action

Central to the FSIS food safety strategy are efforts to reduce the level of microbiological pathogens in raw meat and poultry products. Irradiation has been shown to be a highly effective method for reducing the levels of microbiological pathogens in raw meat food products. Further, FDA has concluded that irradiation of meat food products, under the conditions requested by Isomedix, Inc. and granted by FDA, would not present toxicological or microbiological hazards and would not adversely affect the nutritional adequacy of these products. FSIS, therefore, sees compelling reasons to propose regulations providing for the irradiation of meat food products and has rejected the option of disallowing irradiation.

Notably, the irradiation of meat food products would be voluntary. Although it is an effective antimicrobial treatment, irradiation may not be appropriate, feasible, or affordable in certain processing environments. Also, in certain situations, other antimicrobial treatments may be more effective. FSIS, therefore, is not requiring that raw meat food products be irradiated.

Irradiation of Meat Food Products Under Limited Conditions

The existing requirement for the irradiation of poultry are fairly prescriptive in that they mandate a minimum dosage and require that only packaged product be irradiated. FSIS could have proposed similar

requirements for the irradiation of meat food products. However, as explained above, FSIS believes that the minimum dosage and packaging requirements for irradiated product, intended to ensure that the effects of irradiation are maintained, are no longer necessary in light of the new HACCP requirements. Therefore, FSIS is proposing no minimum irradiation dose and no specific packaging requirements for meat food products and is proposing to rescind the minimum dose requirements for irradiated poultry and to revise the packaging requirements, where possible.

Furthermore, such an action would not meet FSIS' goal to propose regulations for the irradiation of meat food products that set forth performance objectives, rather than prescribe specific processing methods. For the irradiation of meat food products, and where possible for the irradiation of poultry products, FSIS has proposed requirements that allow for significant flexibility in integrating irradiation into the processing environment. It is possible that FSIS will be able to provide for even greater flexibility based upon the comments received in response to this proposal.

Benefits

An establishment's decision to irradiate will be based on whether the net return on an investment in irradiation is positive. If an official establishment chooses to irradiate its meat food products, it can be assumed from the establishment's decision to incur the expense of irradiation that it expects the economic benefits of the investment in irradiation to exceed the costs of that investment. In that sense, the rule could have favorable economic consequences for firms that choose to irradiate.

The meat industry may accrue numerous qualitative benefits from the use of irradiation. For example, slaughter establishments will gain added flexibility in treating products so as to meet pathogen reduction performance standards. Similarly, processors may use irradiated meat in further processed products. Product shelf life could be increased, the market for meat products could expand, and exports of irradiated products could increase. These benefits and others are discussed more fully under the section "Net Benefits."

In its final rule requiring that official meat and poultry establishments to develop and implement HACCP, the Agency estimated a range of public health benefits that could result from the consequent reduction of food borne microbial pathogens (61 FR 38858).

Society may realize further benefits from this proposal if the use of irradiation results in a reduction of illnesses beyond what could be achieved by the implementation of HACCP alone. Several types of microbial pathogens can be present in meat food products, including *E. coli* O157:H7, *Salmonella*, *Clostridium perfringens*, and the protozoan parasite *Toxoplasma gondii*. Irradiation at the dose levels proposed in this action can reduce the levels of these pathogens substantially. The economic benefits associated with these reductions would be decreases in the diseases associated with these pathogens, as well as productivity losses associated with them that would not have occurred with the implementation of HACCP. The reductions in the disease rates would translate into a reduction in the number of visits to physicians and hospitals.

This analysis focuses on the irradiation of ground beef. FSIS believes that ground beef is likely to be the first meat product irradiated in great quantity. Furthermore, ground beef constitutes a significant proportion of beef consumption. For example, according to an industry source, of the per capita consumption of beef at 68 pounds (in 1998), ground beef comprised of 40 percent and another 5 to 10 percent was consumed as hamburger or other ground products. FSIS is aware, however, of industry plans to irradiate other types of raw meat and poultry products, including vacuum-packed primal cuts of meat, steaks, prime ribs, and bulk poultry. If, during the comment period, FSIS receives data concerning the types and volumes of meat and poultry products to be irradiated under the proposed regulations, FSIS will be able to develop an expanded cost-benefit analysis for inclusion in a final rule.

Following a 1993 outbreak of food borne illness associated with *E. coli* O157:H7 in hamburger, FSIS implemented a policy under which it considers raw ground beef containing *E. coli* O157:H7 to be adulterated. Currently, establishments can distribute ground beef containing *E. coli* O157:H7 only after they have thoroughly cooked it, so as to eliminate the pathogen. If irradiation is permitted, establishments will have a means to effectively eliminate *E. coli* O157:H7 from raw ground beef without cooking it. Establishments, therefore, would likely benefit from the availability of irradiation as an additional treatment for rendering adulterated raw ground beef product safe.

To give some sense of the potential benefit from the reduction of illnesses

that may occur as a result of the irradiation of ground beef, an USDA Economic Research Service (ERS) study on the use of irradiation to reduce *E. coli* O157:H7 and *Salmonella* in ground beef, conducted before the implementation of HACCP, is instructive. Morrison, et al. (1997), of ERS estimated the annual pre-HACCP economic value of the health costs and productivity losses attributable to *E. coli* O157:H7 to be between \$196 million and \$441 million.⁵ These figures are also reported in Table 1 (row 1). ERS calculated the annual, pre-HACCP medical costs and productivity losses associated with salmonellosis to range

from \$30 million to \$111 million (Table 1, row 2). Irradiation of ground beef is unlikely to completely eliminate the diseases associated with consumption of ground beef because not all ground beef is likely to be irradiated; initially acceptance of irradiated ground beef may be slow. After consumers are informed about the safety of irradiated ground beef, however, acceptance is likely to increase. Morrison, et al., 1997 assumed that market acceptance, the associated reductions in pathogens, and the decrease in the incidence of associated diseases would be 25% over the next 20 years. It was also assumed that the reduction in the incidence of the

number of illnesses would be directly proportional to the acceptance of irradiated ground beef, i.e., 25%. Based on these assumptions, Table 1 (row 3 and 4) reports the extent of pre-HACCP health and economic benefits associated with reductions of *E. coli* O157:H7 and salmonellosis. (The higher number of cases of salmonellosis, but lower economic benefits of their reduction relative to that of *E. coli* O157:H7, is due to the fact that the former is less severe compared to the latter.) The last row of Table 1 shows that the total pre-HACCP economic benefits of reduction in these two diseases would range from \$56.5 million to \$138 million.

TABLE 1.—HEALTH AND ECONOMIC BENEFITS OF IRRADIATING GROUND BEEF PRE-HACCP

	Low estimate of annual illnesses	High estimate of annual illnesses	Low estimate of health costs in col. (1) in 1995\$ million	High estimate of health costs in col. (2) in 1995\$ million
Total Annual Incidence of <i>E. coli</i> O157:H7 due to consumption of ground beef	4,900	9,800	\$196.0	\$441.00
Total Annual Salmonellosis cases due to consumption of ground beef	24,000	120,000	30.0	111.00
Estimated benefits of 25% reduction in <i>E. coli</i> O157:H7 cases due to irradiation	1,225	2,450	49.0	110.25
Estimated benefits of 25% reduction in Salmonellosis cases due to irradiation	6,000	30,000	7.5	27.75
Total benefits from reductions in <i>E-coli</i> and Salmonellosis	7,225	32,450	56.5	138.00

Because these estimates were developed prior to the implementation of the HACCP requirements, and due to the lack of data on benefits resulting from HACCP implementation so far, these estimated benefits are most likely higher than the benefits that would actually occur in the current HACCP environment.

FSIS, like Morrison, et al., (1997), is assuming that 25% of consumers will accept irradiated ground beef products. This assumption is conservative in light of a 1993 survey, conducted by the American Meat Institute Foundation, which reported that 54 percent of respondents said that they would buy irradiated beef rather than non-irradiated beef after being told that irradiation can kill pathogens in raw meat.⁶ This survey also reported that 60 percent of respondents said that they were willing to pay ten cents more per pound for hamburger sold at \$2/lb. if bacteria levels were "greatly reduced by irradiating the meat."

The experience with poultry irradiation also indicates that the benefits from poultry irradiation have been slow in being realized because only about 1% of poultry production has been irradiated since the final rule

was published. One reason that only a small percentage of poultry has been irradiated is that poultry primarily is sold through product differentiation, that is, brand names of major producers (Perdue, Holly Farms, etc.), and most of these major producers have not irradiated their products. In the case of beef in general and ground beef in particular, there are hardly any brand names, so that lack of brand loyalty is likely to accelerate acceptance of irradiated beef.

Furthermore, it is likely that the current restrictions governing the irradiation of poultry (packaging and minimum dosage requirements) have limited the cost-effectiveness of irradiation. FSIS is proposing to repeal these restrictive requirements, where possible, in this document. FSIS anticipates that numerous establishments, if granted the processing flexibility proposed in this rule, will choose to employ irradiation as an antimicrobial treatment for their raw poultry products.

Incremental Costs

As explained above, if an official establishment chooses to irradiate its meat food products, it can be assumed

from the establishment's decision to incur the expense of irradiation that it expects the economic benefits of the investment in irradiation to exceed the costs of that investment. Irradiation of meat food products will be voluntary. The meat industry will not be required to have their products irradiated, nor will consumers be forced to purchase irradiated meat and products.

This analysis assumes that meat and poultry plants would contract out their irradiation requirements to centralized plants. Therefore, the costs would include fees or prices charged by these facilities. Since irradiation of meat food products is not currently permitted, information on prices of irradiating meat food products is not available. If prices of irradiation were available, one would add other incidental costs to meat establishments such as the costs of marketing, labeling, and transportation to and from irradiation facilities to estimate comprehensive costs of irradiation. In the absence of prices for irradiation, one has to estimate annualized costs (in cents per pound of meat or poultry) of irradiation to the irradiating facility.

The annualized cost of irradiation depends on fixed costs, such as the cost

⁵Morrison, R.M., et al., "Irradiating Ground Beef to Enhance Food Safety," *Food Review*, January-April 1997, pp. 33-37.

⁶American Meat Institute Foundation, "Consumer Awareness, Knowledge, and Acceptance of Food Irradiation," November, 1993.

of Cobalt-60 irradiators and variable costs of electricity to power the electron accelerators. The latter costs vary by throughput rate (quantity of meat to be irradiated), the dose (kilograys or kGy), the amount of the beam power actually absorbed by the product or the net utilization efficiency, and the number of workers employed in a plant. The number of workers employed in these plants is small because the processes are highly automated.

Assuming a dosage of 2.5 kGy, Morrison (1989) estimated the annualized per pound cost of irradiating poultry and ground beef (the annual average of fixed and operating costs) to range from 1.2 cents/lb. for a plant having the capacity to irradiate 52 million pounds annually to 0.51 cents/lb. for a plant that irradiates 416 million pounds annually.⁷ Morrison, et al. (1997), updated these annualized cost estimates and concluded that the annualized costs for a plant that irradiates 52 million pounds would be 1.6 cents/lb. in 1995 dollars. This estimate assumes an annualized, constant charge after initial costs are incurred.⁸ The 1.6 cents/lb. estimate does not include costs of marketing the irradiated products such as labels or the costs of transporting the product from the slaughter houses/processing establishments to an irradiating facility.

To estimate the cost of labels, FSIS assumes that about 50 beef plants would participate in the irradiation program with about 10 labels each. The cost of making the initial labeling plate would be \$800 per label, if the label were without any color, and printing costs in the out years. Therefore, the initial cost of these labels would amount to \$400,000 ($50 \times 10 \times \$800 = \$400,000$). If FSIS were to continue to require that the labels be green, the cost of making the initial labeling plate would be \$1,500, and the estimated total cost would be \$750,000 ($50 \times 10 \times \$1500 = \$750,000$). These costs would be distributed over 1.7 billion pounds of ground beef (7 billion pounds of ground beef were sold in 1995; twenty-five per cent would be 1.7 billion pounds). FSIS assumed that the labeling costs would add about 0.2 cents/lb. to the irradiation

costs. Such an addition would increase the irradiation cost from 1.6 to 1.8 cents/lb. (in 1995 dollars).

FSIS is proposing to require that single ingredient meat or poultry products irradiated in their entirety be labeled with a radura and a statement indicating that the product was irradiated. FSIS also is proposing to require disclosure, in the ingredients statements, that multi-ingredient products contain irradiated meat or poultry ingredients. FSIS also is considering the possibility of allowing irradiated meat or poultry products to be labeled as being free of certain pathogens, under certain circumstances. FSIS requests comments on these estimated labeling costs, as well as comments on the economic effects of changes to the proposed labeling requirements and the possible use of incentive labeling for irradiated meat and poultry products.

FSIS conservatively assumes the costs of transporting ground beef from slaughter houses/processing plants to and from irradiating facilities at 0.2 cents/lb. Therefore, the incremental cost of irradiation would amount to 2.0 cents/lb. ($1.6 + 0.2 + 0.2$). These costs are shown in Table 2. The last column of Table 2 reveals that the cost of irradiating 1.7 billion pounds of ground beef at 2 cents/lb. would amount to \$35 million. It must be noted that these costs refer to a dose of 2.5 kGy and hence are underestimated compared to the costs of irradiating at 4.5 or 7 kGy as permitted under the proposed rule. Information on extrapolating costs for irradiation at these levels is not available. FSIS requests comments on the costs of transporting meat to and from irradiation facilities.

A second estimate of the cost of irradiating meat was available from an engineering consulting firm. This estimate was developed as a conceptual design by this firm for one of their meat processing clients. The assumptions included an average dose of 3 kGy, a production rate of 2.4 million lbs./week, a product configuration of boxed frozen ground beef patties, employment of 20 workers and 4 supervisors, capital cost of \$14.2 million, and operating cost of \$1.9 million/year. The resulting cost estimate, determined by estimating discounted present value of future costs, amounted to 2.2 cents/lb. An addition of

0.2 cents/lb. for labeling and another 0.2 cents/lb. for transportation would increase this cost to 2.6 cents/lb. It must be noted that the plant size assumption of 2.4 million lbs./week translates to a plant size of 124.8 million lbs./year. This plant is more than double the size assumed by Morrison et al., (1997) at 52 million lbs./year. The cost estimates in Table 2, therefore, relate to different plant sizes with different levels of utilization of capacity. It also must be noted that these costs refer to a dose of 3kGy and hence are lower than the costs of irradiating at 4.5 or 7 kGy, as permitted under the rule. Information on extrapolating costs for irradiation at these levels is not available.

A third estimate of cost can be developed from the current approximate cost of irradiating poultry, obtained from an industry source. For this estimate, it is assumed that the cost of irradiating meat food products would be the same as the cost of irradiating poultry, since the irradiation method is the same. The current cost of irradiating poultry, for an establishment operating at only 5% of capacity, is approximately 6 cents/lb. Any increase in utilization of capacity would spread the costs over a larger volume of production and hence tend to reduce irradiation costs. This high cost scenario, reported in Table 2, suggests that the incremental cost of irradiating 1.7 billion pounds of ground beef would amount to \$105 million (in 1995 dollars).

The preceding cost estimate is higher than the costs FSIS originally estimated for irradiating poultry—about a penny a pound. In estimating the cost of irradiating poultry, ERS had assumed that 10% of all poultry products would be irradiated. The current costs are higher because only around one percent of poultry is being irradiated. The lower volume of irradiation results in higher costs. Since FSIS is proposing to remove many of the restrictions governing the irradiation of poultry and is not proposing any similar restrictions on the irradiation of meat, and because the demand for irradiated meat and poultry may increase, it is very unlikely that such high costs will continue to be incurred by the industry. FSIS anticipates that the lower cost estimates are more likely to reflect the true future costs.

⁷Morrison, R.M., "An Economic Analysis of electron accelerators and Cobalt-60 for Irradiating Food," ERS Publication No. 1762, June 1989.

⁸Morrison, et al., (1989) p. 28.

TABLE 2.—ESTIMATED COSTS OF IRRADIATING GROUND BEEF

Cost scenario	Irradiation cost cents/lb	Quantity of ground beef irradiated (25% of total sales) billion pounds	Irradiation costs \$ million (1995\$)
Low cost	2.0	1.75	\$35
Midrange cost	2.6	1.75	\$46
High cost	6.0	1.75	\$105

Net Benefits

Executive Order 12866 requires the proposed action maximize net benefits to society, including potential economic, environmental, public health and safety benefits, distributional impacts and equity. FSIS believes that the net benefits of the proposed action are positive. However, the current lack of quantification of both benefits and costs would make comparison meaningless at this time. As discussed above, the benefit estimates are incomplete. First, several indirect benefits have been excluded. As mentioned above, the meat industry may accrue qualitative benefits from the use of irradiation. Slaughter establishments will gain added flexibility in treating products so as to meet pathogen reduction performance standards. Similarly, processors may use irradiated meat in further processed products. Non-quantified industry benefits would also include a decrease in the number of potential court cases

for product liability from avoidance of illnesses associated with pathogens in their products. Also, the market for meat products could expand; consumers desiring meat products with reduced numbers of pathogens could increase the demand for irradiated products. Market expansion could also take place via increased exports, especially to numerous European and Asian countries, where irradiation of poultry products already is permitted and practiced. The potential increase in exports cannot be estimated for a lack of data. Only one of the meat products, ground beef accounting for about one-half of the beef industry, is analyzed. Inclusion of other meat products would tend to increase the estimated benefits. The analysis also does not account for the indirect benefits to consumers that include the avoidance of costs of pain and suffering associated with the diseases. These costs are generally greater than the direct costs of treatment of illnesses and productivity losses. Second, FSIS has not calculated the

benefits from the reduction in illness that might occur with the use of ionizing irradiation in meat products within the context of HACCP implementation. Though the ground beef example discussed above is informative, FSIS expects that substantial reductions in these pathogens will be made with HACCP without the use of irradiation. Therefore, any analysis of benefits from this action must account for those reductions in illnesses and the associated costs that would have occurred without this action.

Finally, another important economic benefit to industry, as well as to consumers, is the extended shelf life of irradiated products. Andrews, et al. (1998), reviewed five studies encompassing shelf lives of different types of red meat products.⁹ Their results suggest that shelf life of products treated with irradiation increase considerably (d log extension) compared to untreated products. These results are reported in Table 4.

TABLE 4.—SHELF LIFE EXTENSION OF IRRADIATED RED MEAT

Meat product	Dose (kGy)	Untreated shelf life (d)	Irradiated Shelf life (d)
Beef	2.5	2-3	9
Beef top round	2.0	8-11	28
Beef burgers	1.54	8-10	26-28
Beef cuts	2.0	1X	2X
Beef cuts irradiated under vacuum	2.0	NA	70
Corned beef	4.0	14-21	35
Lamb, whole and minced	2.5	7	28-35

Source: Andrews et al., (1998), p. 26.

As with the estimates of benefits, the cost estimates also are incomplete. The costs estimated in this analysis of the potential irradiation of ground beef are likely to be overestimated for three reasons. First, the cost estimates are

based on the assumption that irradiation of ground beef would take place in the smallest, and hence the least efficient, plant having the capacity to irradiate only 52 million pounds per year. An increase in capacity to, for instance, 416

million pounds per year would reduce annualized operating costs to less than half the estimated costs (from 1.2 cents for 52 million pounds size to 0.51 cents for 416 million pounds). Second, the cost estimation assumes that all beef

⁹ Andrews, L.S., et al. "Food Preservation Using Ionizing Radiation," *Review of Environmental Contaminant Toxicology*, Vol. 154, 1998, pp. 1-53.

slaughtering/processing plants would ship their products to an independent irradiating facility. To save the shipping costs, it is possible that large slaughter/processing plants might set up their own on-line irradiating facilities, using electron accelerators instead of Cobalt 60. These on-line irradiation facilities are likely to have lower operating costs. For example Morrison (1989) notes that electron accelerators or machine irradiators have significantly declining unit costs at annual throughput between 50 and 100 million pounds, and even between 100 and 200 million pounds. Third, this analysis assumes that only 25 percent of ground beef would be irradiated. Any increase in the irradiation quantity would tend to reduce costs considerably.

Furthermore, because this proposal will allow for the irradiation of numerous meat food products other than ground beef and numerous poultry products which previously could not be irradiated, it is possible that the social and economic benefits of the proposed regulations have been underestimated in this analysis. As stated above, FSIS is aware of industry plans to irradiate several other types of raw meat and poultry products. Again, FSIS requests comments specific to this analysis, as well as any additional relevant data. Using such data, FSIS will develop an expanded cost-benefit analysis for inclusion in a final rule.

Compliance With Regulatory Flexibility Act of 1996

The Administrator has determined that, for the purposes of the Regulatory Flexibility Act (5 U.S.C. 601-612), this proposed rule would not have a significant economic impact on a substantial number of small entities.

Data from the U.S. Bureau of Census, Survey of Industries, 1994, indicate that the beef industry is predominated by small firms and establishments. For example, based on the U.S. Small Business Administration definition of small business by the number of employees (fewer than 500), 96% of 1,226 firms comprising this industry are small. Similarly, 90% of individual meat establishments or plants in this industry are small. In 1994, these small businesses accounted for 19% of total employment in the industry. Their share of payroll was 18% of the total payroll of \$2.8 billion and their revenues were 16% of the total revenues of \$55.8 billion. FSIS believes that these small businesses would not be affected adversely by the proposed irradiation requirements since the use of irradiation would be voluntary; no meat establishments, large or small, would be

required to irradiate their product under this rule.

In the long term, however, these small establishments may start irradiating their products to keep their market shares. In so doing, they may be affected relative to large size establishments because of economies of scale in irradiation. For example, bulk discounts provided by irradiating facilities would be realized mainly by the large size establishments. FSIS requests comment and data regarding the impact of the proposed regulations on small businesses.

Purchase of irradiated ground beef also is voluntary for consumers. Moreover, the estimated impact of the incremental cost of 2 to 6 cents per pound of irradiated ground beef is an insignificant proportion of the approximate price of ground beef, \$2 per pound. Above all, the industry would be able to pass through the cost of irradiation to consumers without losing its market share significantly because demand for beef products is very inelastic. Huang (1993) analyzed a group of meats and other animal proteins consisting of products including beef and veal, pork, other meats, chicken, turkey, fresh and frozen fish, canned and cured fish, eggs and cheese. He concluded that price elasticity of demand for this group of products was (-0.3611), i.e., a one percent increase in price for one of these products would reduce demand by only 0.3611 percent.¹⁰

Review of about a dozen recent studies annotated by William Hahn of the Economic Research Service reveals that estimates of price elasticity of demand for most beef products (ground beef, steak, chuck roast, etc.) is less than one.¹¹ This implies that demand for beef products is price-insensitive because an increase in price of any one of these products by one percent would result in a decrease in its demand by less than one percent. In short, consumers are unlikely to reduce their demand for beef significantly when beef price is increased by a few pennies a pound. In fact, some consumers may demand irradiated product, even at higher prices per pound. Therefore, the small businesses in this industry are unlikely to be impacted adversely by an increase in price associated with irradiation.

¹⁰Huang, Kao S., *A Complete System of U.S. Demand for Food*, ERS Technical Bulletin No. 1821, 1993, p. 24.

¹¹Hahn, William F., *An Annotated Bibliography of Recent Elasticity and Flexibility Estimates for Meat and Livestock*, Staff Paper, Commercial Agriculture Division, Economic Research Service, July 1996, pp. 1-19.

The supply of beef products also is likely to be very price elastic. The high elasticity of supply is attributable to the presence of over 1,200 firms in this industry, 96 percent of whom are small businesses. Any single producer cannot raise prices of its products without losing its market share significantly.

The proposed action would have a negligible economic impact on other small organizations or entities that are not engaged in the business of processing meat and meat products. To the extent that these entities purchase irradiated meat products, they could be impacted somewhat by an increase in price.

Finally, FSIS is proposing to revise the regulatory requirements concerning the irradiation of poultry for consistency with HACCP and with the requirements proposed for meat food products. Significantly, FSIS is proposing to eliminate the minimum dosage requirements, certain packaging requirements, and the requirement that poultry establishments develop and implement PQC's addressing irradiation. All poultry establishments are required to develop and implement HACCP; the costs of HACCP will probably offset any benefits from the elimination of the PQC requirements. However, FSIS assumes that large and small poultry establishments will realize benefits from the reduction in the cost of compliance with some of the packaging requirements and the minimum dosage for irradiated poultry. In addition, the industry will also benefit from the expansion in its market for other poultry products that could be irradiated under this proposal. Consumers also could benefit from the availability of a wider variety of irradiated poultry products.

Executive Order 12898

Pursuant to Executive Order 12898, "Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations," FSIS has considered potential impacts of this proposed rule on environmental and health conditions in low-income and minority communities.

This proposed rule would allow the use of ionizing radiation for treating fresh or frozen uncooked meat, meat byproducts, and certain meat food products to reduce levels of pathogens. As explained in the economic impact analysis above, the proposed regulations should generally benefit FSIS, the regulated industry, and consumers. The proposed regulations would not require or compel meat or poultry establishments to relocate or alter their

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

Establishments choosing to irradiate meat or meat products would be required to comply not only with FSIS and FDA requirements regarding the safety of irradiated product, but also with NRC, EPA, OSHA, DOT, and State and local government requirements governing the operation of irradiation facilities. Compliance with these requirements would ensure the maintenance of appropriate environmental, worker safety, and public health protections, thus further reducing the probability that this rule would have any disparate impact on low-income or minority communities. FSIS currently is investigating the possibility of developing stronger partnerships with these Federal, State, and local agencies so as to better ensure the maintenance of environmental, worker safety, and public health protections.

Paperwork Requirements

Title: Irradiation of Meat and Poultry Products

Type of Collection: New

Abstract: FSIS has reviewed the paperwork and record keeping requirements in this proposed rule in accordance with the Paperwork Reduction Act. Under this proposed rule, FSIS is requiring several information collection and record keeping activities. FSIS is proposing to require that establishments conduct irradiation of meat and meat products only in accordance with either an HACCP plan, as defined in Part 417 of the FSIS meat and poultry inspection regulations, or a process schedule validated for efficacy by a processing authority (proposed § 318.11(a)). Written irradiation procedures must describe the specific, sequential operations employed by the establishment in the irradiation and associated processing of meat food products, including the control, validation, monitoring, and corrective action activities. FSIS also is proposing to require that establishments implement a dosimetry system to measure the dosage of radiation absorbed by product. FSIS also is requiring that any establishment irradiating meat food products have on

file a number of documents as identified in the section "Documentation Requirements." Finally, products irradiated by establishments would need to be properly labeled.

FSIS inspection personnel would initially, and periodically as required, review the records from the process schedule or HACCP plan, the required documentation, and the product labels. FSIS personnel would not evaluate the procedures for efficacy.

Estimate of Burden: FSIS estimates that the development of a HACCP plan or process schedule would take an average of 2 days (16 hours) and 5 minutes to file. FSIS estimates that an establishment will spend about 5 minutes a day developing an average of 8 monitoring records, per HACCP plan or process schedule, and 2 minutes a day filing each record. These monitoring records are highly likely to include records of dosimetry measurements, since establishments that irradiate product will probably select dosimetry as the monitoring step for an irradiation CCP. FSIS estimates that it would take an establishment 30 minutes for the preparation of each of the necessary documents discussed in the "Required Documentation" section of this preamble and about 5 minutes to file each document. FSIS estimates that an establishment would develop about 10 new product labels and each label would be developed in about 2 hours. Because of the elimination of the partial quality control requirements for poultry irradiation, FSIS would request OMB to delete the 60 hours of burden approved for poultry irradiation under the OMB approval number 0583-0090.

Respondents: Meat and poultry product establishments and irradiation facilities.

Estimated Number of Respondents: 10 (this number represents the current number of facilities with the capability to irradiate meat and poultry products).

Estimated Number of Responses per Respondent: 4009.

Estimated Total Annual Burden on Respondents: 2,730 hours.

Copies of this information collection assessment can be obtained from Lee Puricelli, Paperwork Specialist, Food Safety and Inspection Service, USDA, 112 Annex, 300 12th St., SW, 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, see address above, and the Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20253.

Comments are requested by April 26, 1999. To be most effective, comments should be sent to OMB within 30 days of the publication date.

List of Subjects

9 CFR Part 317

Food labeling, Food packaging, Meat inspection, Reporting and recordkeeping requirements.

9 CFR Part 318

Food additives, Food packaging, Meat inspection, Reporting and recordkeeping requirements, Signs and symbols.

9 CFR Part 381

Food labeling, Poultry and poultry products, Reporting and recordkeeping requirements, Signs and symbols.

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

PART 317—LABELING, MARKING DEVICES, AND CONTAINERS

1. 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.

2. Section 317.14 would be added to read as follows:

§ 317.14 Irradiated meat food products.

(a) The labels on packages of meat food products irradiated in their entirety, in conformance with § 318.7(c)(4) of this chapter, must bear the following logo along with a statement such as "Treated with radiation" or "Treated by irradiation." The logo must be placed prominently and conspicuously in conjunction with the required statement. The statement must appear as a qualifier contiguous to the product name. Any label bearing the logo and any wording of explanation with respect to this logo must be approved as required by § 317.4. This

requirement applies only to meat food products irradiated in their entirety, not to multi-ingredient products that merely contain an irradiated ingredient. The logo is as follows:



(b) For meat food products irradiated in their entirety, but not in package form, the required logo and a statement such as "Treated with radiation" or "Treated by irradiation" shall be displayed to the purchaser with either

the labeling of the bulk container plainly in view or a counter sign, card, or other appropriate device bearing the information that the product has been treated with radiation. In either case, the information must be prominently and conspicuously displayed to purchasers. This requirement applies only to meat food products irradiated in their entirety, not to multi-ingredient products that merely contain an irradiated ingredient.

(c) The inclusion of an irradiated meat food product ingredient in any multi-ingredient meat food product must be indicated in the ingredient statement on the finished product labeling.

(d) Optional labeling statements about the purpose for radiation processing may be included on the product label in addition to the stated requirements elsewhere in this section. Such statements must not be false or misleading. Statements indicating a

specific reduction in microbial pathogens must be substantiated by processing documentation.

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

3. The authority citation for part 318 would continue 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.

4. Section 318.7(c)(4) would be amended by removing the entry for "Sources of radiation" in the chart of substances and adding an entry for "Radiation sources" in alphabetical order, to read as follows:

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

- * * * * *
- (c) * * *
- (4) * * *

Class of substance	Substance	Purpose	Products	Amount
*	*	*	*	*
Radiation sources.	Ionizing radiation sources approved in 21 CFR 179.26(a).	For control of food borne pathogens and the extension of shelf-life..	Refrigerated or frozen, uncooked meat, as defined in 9 CFR 301.2(rr); meat byproducts, as defined in 9 CFR 301.2(tt); and other meat food products within the meaning of 9 CFR 301.2(uu), with or without nonfluid seasoning, that are otherwise composed solely of intact or gound meat and/or meat byproducts.	No more than 4.5 kiloGrays (450 kilorads) for refrigerated products and no more than 7 kiloGrays (700 kilorads) for frozen product.
*	*	*	*	*

* * * * *
5. Section 318.11 would be added to read as follows:

§ 318.11 Irradiation of meat food products.

(a) *General requirements.* (1) Meat food products may be treated to reduce food borne pathogens by the use of ionizing radiation as identified in § 318.7(c)(4). Official establishments may irradiate meat food products for food uses only in accordance with § 318.7(c)(4) and the Hazard Analysis and Critical Control Point (HACCP) system requirements in part 417 of this chapter or, if not yet operating under HACCP, in accordance with a process schedule, as defined in § 301.2 of this chapter.

(2) Each process schedule must be approved in writing by a process authority for safety and efficacy. A process authority must have access to the establishment in order to evaluate and approve the safety and efficacy of each process schedule. Under the auspices of a processing authority, an establishment must validate new or altered process schedules by

scientifically supportable means, such as information gleaned from the literature or by challenge studies conducted outside the plant.

(b) *Dosimetry.* Official establishments that irradiate meat food products must have the following procedures in place:

(1) Laboratory operation procedures for determining the absorbed dose value from the dosimeter.

(2) Calibration criteria for verifying the accuracy and consistency of any means of measurement (e.g., time clocks and weight scales).

(3) Calibration and accountability criteria for verifying the traceability and accuracy of dosimeters for the intended purpose, and the verification of calibration at least every 12 months. To confirm traceability, establishments must relate, through documentation, the end point measurement of a dosimeter to recognized standards.

(4) Procedures for ensuring that the product unit is dose mapped to identify the regions of minimum and maximum absorbed dose and such regions are consistent from one product unit to another of like product.

(5) Procedures for accounting for the total absorbed dose received by the product unit (e.g., partial applications of the absorbed dose within one production lot).

(6) Procedures for verifying routine dosimetry (i.e., assuring each production lot receives the total absorbed dose). Each production lot must have at least one dosimeter positioned at the regions of minimum and maximum absorbed dose (or at one region verified to represent such) on at least the first, middle, and last product unit.

(7) Procedures for verifying the relationship of absorbed dose as measured by the dosimeter to time exposure of the product unit to the radiation source.

(8) Procedures for verifying the integrity of the radiation source and processing procedure. Aside from expected and verified radiation source activity decay for radionuclide sources, the radiation source or processing procedure must not be altered, modified, replenished, or adjusted without repeating dose mapping of

product units to redefine the regions of minimum and maximum absorbed dose.

(c) *Documentation.* Official establishments that irradiate meat products must have the following documentation on premises, available to FSIS:

(1) The validated process schedule, if the establishment is not operating under HACCP.

(2) Documentation that the irradiation facility is licensed or possesses gamma radiation sources registered with the Nuclear Regulatory Commission (NRC) or the appropriate State government acting under authority granted by the NRC.

(3) Documentation that the machine radiation source irradiation facility is registered with the Occupational Safety and Health Administration (OSHA) or the appropriate State government acting under authority granted by OSHA, and that a worker safety program addressing OSHA regulations (29 CFR chapter XVII) is in place.

(4) Citations or other documents that relate to incidences in which the establishment was found not to comply with Federal or State agency requirements for irradiation facilities.

(5) A certification by the operator that the irradiation facility personnel would operate under supervision of a person who has successfully completed a course of instruction for operators of food irradiation facilities.

(6) A certification by the operator that the key irradiation personnel have been trained in food technology, irradiation processing, and radiation health and safety.

(7) Guarantees from the suppliers of all food-contact packaging materials that may be subject to irradiation that those materials comply with the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 *et seq.*) and with regulations in 21 CFR 179.45 for food irradiation processing.

PART 381—POULTRY PRODUCTS INSPECTION REGULATIONS

6. The authority citation for part 381 would continue to read as follows:

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

§ 381.19 [Removed and Reserved]

7. Section 381.19 would be removed and reserved.

8. Section 381.135 would be revised to read as follows:

§ 381.135 Irradiated poultry product.

(a) The labels on packages of poultry food products irradiated in their entirety, in conformance with § 381.147(f)(4), must bear the following

logo along with a statement such as “Treated with radiation” or “Treated by irradiation.” The logo must be placed prominently and conspicuously in conjunction with the required statement. The statement must appear as a qualifier contiguous to the product name. Any label bearing the logo and any wording of explanation with respect to this logo must be approved as required by subparts M and N of this part. This requirement applies only to meat food products irradiated in their entirety, not to multi-ingredient products that merely contain an irradiated ingredient. The logo is as follows:



(b) For poultry food products irradiated in their entirety, but not in package form, the required logo and a statement such as “Treated with radiation” or “Treated by irradiation” shall be displayed to the purchaser with either the labeling of the bulk container plainly in view or a counter sign, card, or other appropriate device bearing the information that the product has been treated with radiation. In either case, the information must be prominently and conspicuously displayed to purchasers. This requirement applies only to poultry food products irradiated in their entirety, not to multi-ingredient products that merely contain an irradiated ingredient.

(c) The inclusion of an irradiated poultry food product ingredient in any multi-ingredient poultry food product must be indicated in the ingredient statement on the finished product labeling.

(d) Optional labeling statements about the purpose for radiation processing may be included on the product label in addition to the stated requirements elsewhere in this section. Such statements must not be false or misleading. Statements indicating a specific reduction in microbial pathogens must be substantiated by processing documentation.

§ 381.147 [Amended]

9. In § 381.147(f)(4), the entry for “Radiation Sources” in Table 1 would be amended by removing the phrase “,

packaged” from the sentence under the “Products” column; and, by revising the sentence under the “Amount” column to read “A maximum absorbed dose of 3.0 kiloGray (300 kilorads).”.

10. Section 381.149 would be revised to read as follows:

§ 381.149 Irradiation of poultry products.

(a) *General requirements.* (1) Poultry products may be treated to reduce food borne pathogens by the use of ionizing radiation as identified in § 381.147(f)(4). Official establishments may irradiate poultry product for food uses only in accordance with § 381.147(f)(4) and the Hazard Analysis and Critical Control Point (HACCP) system requirements in part 417 of this chapter, or if not yet operating under HACCP, in accordance with a process schedule, as defined in § 381.1(b).

(2) Each process schedule must be approved in writing by a process authority for safety and efficacy. A process authority must have access to the establishment in order to evaluate and approve the safety and efficacy of each process schedule. Under the auspices of a processing authority, an establishment must validate new or altered process schedules by scientifically supportable means, such as information gleaned from the literature or by challenge studies conducted outside the plant.

(b) *Dosimetry.* Official establishments that irradiate poultry products must have the following procedures in place:

(1) Laboratory operation procedures for determining the absorbed dose value from the dosimeter.

(2) Calibration criteria for verifying the accuracy and consistency of any means of measurement (e.g., time clocks and weight scales).

(3) Calibration and accountability criteria for verifying the traceability and accuracy of dosimeters for the intended purpose, and the verification of calibration at least every 12 months. To confirm traceability, establishments must relate, through documentation, the end point measurement of a dosimeter to recognized standards.

(4) Procedures for ensuring that the product unit is dose mapped to identify the regions of minimum and maximum absorbed dose and such regions are consistent from one product unit to another of like product.

(5) Procedures for accounting for the total absorbed dose received by the product unit (e.g., partial applications of the absorbed dose within one production lot).

(6) Procedures for verifying routine dosimetry (i.e., assuring each production lot receives the total

absorbed dose). Each production lot must have at least one dosimeter positioned at the regions of minimum and maximum absorbed dose (or at one region verified to represent such) on at least the first, middle, and last product unit.

(7) Procedures for verifying the relationship of absorbed dose as measured by the dosimeter to time exposure of the product unit to the radiation source.

(8) Procedures for verifying the integrity of the radiation source and processing procedure. Aside from expected and verified radiation source activity decay for radionuclide sources, the radiation source or processing procedure must not be altered, modified, replenished, or adjusted without repeating dose mapping of product units to redefine the regions of minimum and maximum absorbed dose.

(c) *Documentation.* Official establishments that irradiate poultry products must have the following documentation on premises, available to FSIS:

(1) The validated process schedule, if the establishment is not operating under HACCP.

(2) Documentation showing that the irradiation facility is licensed and/or possesses gamma radiation sources registered with the Nuclear Regulatory Commission (NRC) or the appropriate State government acting under authority granted by the NRC.

(3) Documentation showing that the machine radiation source irradiation facility is registered with the Occupational Safety and Health Administration (OSHA) or the appropriate State government acting under authority granted by OSHA, and that a worker safety program addressing OSHA regulations (29 CFR chapter XVII) is in place.

(4) Citations or other documents that relate to incidences in which the establishment was found not to comply with Federal or State agency requirements for irradiation facilities.

(5) A certification by the operator that the irradiation facility personnel would operate under supervision of a person who has successfully completed a course of instruction for operators of food irradiation facilities.

(6) A certification by the operator that the key irradiation personnel have been trained in food technology, irradiation processing, and radiation health and safety.

(7) Guarantees from the suppliers of all food-contact packaging materials that may be subject to irradiation that those materials comply with the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301

et seq.) and with regulations in 21 CFR 179.45 for food irradiation processing and that the food-contact packaging material is air-permeable, but does exclude moisture and microorganisms from penetrating the package barrier.

Done in Washington, DC on: February 18, 1999.

Thomas J. Billy,

Administrator.

[FR Doc. 99-4401 Filed 2-18-99; 3:37 pm]

BILLING CODE 3410-DM-P

FEDERAL RESERVE SYSTEM

12 CFR Part 229

[Regulation CC; Docket No. R-1034]

Availability of Funds and Collection of Checks

AGENCY: Board of Governors of the Federal Reserve System.

ACTION: Proposed rule.

SUMMARY: The Board is requesting comment on options for amending Subpart C of Regulation CC, which contains rules governing the collection and return of checks. The proposed options would amend Subpart C's provisions on sending notices in lieu of returning the original checks. The proposal is intended to provide more flexibility to depository institutions to experiment with methods to return checks electronically.

DATES: Comments must be submitted on or before April 30, 1999.

ADDRESSES: Comments, which should refer to Docket No. R-1034, may be mailed to Ms. Jennifer J. Johnson, Secretary, Board of Governors of the Federal Reserve System, 20th and C Streets, NW, Washington, D.C. 20551. Comments addressed to Ms. Johnson also may be delivered to the Board's mail room between 8:45 a.m. and 5:15 p.m. and to the security control room outside of those hours. Both the mail room and the security control room are accessible from the courtyard entrance on 20th Street between Constitution Avenue and C Street, NW. Comments may be inspected in Room MP-500 between 9:00 a.m. and 5:00 p.m.

FOR FURTHER INFORMATION CONTACT: Oliver I. Ireland, Associate General Counsel (202/452-3625), Stephanie Martin, Senior Counsel (202/452-3198), Legal Division. For the hearing impaired *only*, contact Diane Jenkins, Telecommunications Device for the Deaf (TDD) (202/452-3544), Board of Governors of the Federal Reserve System, 20th and C Streets, NW, Washington, D.C. 20551.

SUPPLEMENTARY INFORMATION:

Background

Subpart C of the Board's Regulation CC (12 CFR Part 229) contains rules governing the collection and return of checks. These rules are intended to expedite the check collection and return process, thereby reducing risk to banks¹ and their customers. Regulation CC was designed to work in accord with the state law check-collection rules in Articles 3 and 4 of the Uniform Commercial Code (U.C.C.), although in some areas the regulation preempts the U.C.C.

When a paying bank decides to return a check, the U.C.C. and Regulation CC require it to send the check or a notice within certain deadlines.² If a check is unavailable for return, U.C.C. 4-301(a) allows a paying bank to charge back the check by revoking provisional settlement based on a "notice of dishonor" (or a "notice of nonpayment" where the check is returned for reasons other than dishonor). The U.C.C. would appear to allow a paying bank to return a notice when a check has been truncated. The Official Comment to U.C.C. 4-301 states that an item may be considered unavailable for return if it is retained by the collecting bank in accordance with a bank check retention plan.

Regulation CC (§§ 229.30(f) and 229.31(f)) establishes a "notice in lieu of return," which substitutes for the original check and carries value. The "notice-in-lieu" provisions of Regulation CC provide that the paying (or returning) bank must return the original check unless the check is unavailable, in which case the bank may return a copy of the front and back of the check, or, if no such copy is available, a written notice containing specified information about the check. The Commentary to §§ 229.30(f) and 229.31(f) states that notice in lieu of return is permitted only when a bank does not have and cannot obtain possession of the check or must retain possession of the check for protest. The Commentary explains that a check is not unavailable for return if it is merely difficult to retrieve from a filing system or from storage by a keeper of checks in a truncation system.

¹ In Regulation CC and its Commentary, as well as in this docket, the term "bank" refers to all depository institutions, including commercial banks, savings institutions, and credit unions.

² The paying bank must initiate the return by midnight of the banking day following the day the check was presented (U.C.C. 4-301). The paying bank must return the check so that it reaches the depository bank expeditiously, in accordance with § 229.30(a) of Regulation CC.