

Final Rule

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Part II

**Department of
Agriculture**

Food Safety and Inspection Service

**9 CFR Parts 381 and 424
Irradiation of Meat Food Products; Final
Rule**

DEPARTMENT OF AGRICULTURE**Food Safety and Inspection Service****9 CFR Parts 381 and 424**

[Docket No. 97-076F]

Irradiation of Meat Food Products**AGENCY:** Food Safety and Inspection Service**ACTION:** Final rule.

SUMMARY: The Food Safety and Inspection Service (FSIS) is amending its 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 foodborne pathogens and to extend shelf-life. FSIS also is revising the regulations governing the irradiation of poultry products so that they will be as consistent as possible with the regulations for the irradiation of meat food products.

EFFECTIVE DATES: February 22, 2000.

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SUPPLEMENTARY INFORMATION:**Background**

On February 24, 1999, the Food Safety and Inspection Service (FSIS) published a proposal (64 FR 9089) to permit the use of ionizing radiation for treating refrigerated or frozen uncooked meat, meat byproducts, and certain other meat food products (hereafter referred to as "meat food products" when discussed as a group) to reduce levels of foodborne pathogens and to extend shelf-life. FSIS also proposed to revise the regulations governing the irradiation of poultry products so that they will be as consistent as possible with the regulations for the irradiation of meat food products. FSIS initially provided 60 days for public comment, ending the comment period on April 26, 1999. Because of the great interest in this proposal, FSIS reopened the comment period for 15 days on June 2, 1999 (64 FR 29602). FSIS announced that it would consider all comments received between April 27, 1999 and June 17, 1999. In this document, FSIS makes final the proposed regulations, with some revision in response to comments.

Food Irradiation

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 term "food additive" means any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food (including any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food; and including any source of radiation intended for any such use), if such substance is not generally recognized * * * to be safe under the conditions of its intended use * * *.

The Food and Drug Administration (FDA) of the Department of Health and Human Services has the primary responsibility for determining whether food additives are safe for particular uses. FDA lists uses of food additives it has concluded are safe in 21 CFR parts 172 through 179.

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 refrigerated meat, and that a maximum dose of 7.0 kGy be established for the irradiation of frozen meat.

After an evaluation of available data, FDA concluded that there was a reasonable certainty of no harm from the irradiation of meat food products under the conditions requested in the petition and that irradiation would not adversely affect the nutritional adequacy of these products. On December 3, 1997, FDA published a final rule (FDA Docket No. 94F-0289; 62 FR 64107) granting the Isomedix petition. In that publication, FDA expanded the list of products (21 CFR 179.26(b)) for which ionizing irradiation may be safely used to include: refrigerated and frozen uncooked meat, as defined by FSIS in 9 CFR 301.2(rr); meat byproducts (e.g., edible organs, such as the liver and the kidneys), as defined by FSIS in 9 CFR 301.2(tt); and certain meat food products (e.g., ground beef and hamburger) 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.

The FSIS Proposal

As stated above, on February 24, 1999, FSIS proposed regulations governing the irradiation of refrigerated and frozen, uncooked meat food products and also proposed to revise the poultry irradiation regulations for consistency. Specifically, FSIS proposed the following:

Dosage

FSIS proposed that the defined meat food products could be treated with ionizing irradiation at dosages of up to 4.5 kiloGrays (kGy), if refrigerated, and 7 kGy, if frozen. FSIS proposed no minimum dosage.

Process Control

FSIS proposed to require that official establishments irradiate meat food products for food uses only in accordance with a Hazard Analysis and Critical Control Point (HACCP) system or, if not yet operating under HACCP requirements, in accordance with a process schedule validated by a process authority.

Dosimetry

FSIS proposed to require that official establishments that irradiate meat food products have in place a dosimetry system to measure the absorbed dose of radiation. The dosimetry system would

ensure that each lot of treated product has received the dose defined in the process schedule or HACCP plan. The proposed requirements mandated that each dosimetry system included:

- Procedures for determining the absorbed radiation dose value from the dosimeter;
- 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.

Documentation

FSIS proposed to require official establishments that irradiate meat food products to have on file the following documents that relate to the establishment's compliance with other Federal requirements concerning irradiation:

- Documentation that an irradiation facility that possesses gamma radiation sources is licensed with the Nuclear Regulatory Commission (NRC) or the appropriate State government acting under authority granted by the NRC, and that a worker safety program addressing OSHA regulations is in place;
- Documentation that an irradiation facility that uses machine radiation sources is registered with the appropriate State government, if applicable;
- 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;
- Certification by the operator that the irradiation facility's personnel are operating under the supervision of a person who has successfully completed a course of instruction for operators of food irradiation facilities;
- Certification by the operator that the key irradiation personnel have been trained in food technology, irradiation processing, and radiation health and safety; and
- Guarantees from the suppliers of all food-contact packaging materials that may be subject to irradiation, that those materials comply with the FFDC (21 U.S.C. 301 *et seq.*).

Labeling

FSIS proposed that labeling for packaged meat food products irradiated in their entirety bear the radura logo along with a statement such as "Treated with radiation" or "Treated by

irradiation." FSIS proposed that the logo be placed prominently and conspicuously in conjunction with the required statement and that the statement appear as a qualifier contiguous to the product name. Also, FSIS proposed to require that inclusion of an irradiated meat food product ingredient in any multi-ingredient product be reflected in the ingredient statement on the finished product labeling. Finally, FSIS stated that it would allow optional labeling statements about the purpose for radiation processing to be included on the product label in addition to the above stated requirements. Statements indicating a specific reduction in microbial pathogens would have to be substantiated by processing documentation.

FSIS proposed to require that for unpackaged meat food products irradiated in their entirety, the required logo and a statement must be prominently and conspicuously displayed to purchasers either through labeling on a bulk container or some other appropriate device.

Poultry

FSIS also proposed to revise the existing regulations governing the irradiation of poultry products to make them as consistent as possible with the regulations proposed for meat food products. FSIS proposed to eliminate the regulations requiring that establishments irradiate poultry products only in accordance with Partial Quality Control programs and to instead require that poultry establishments, like meat establishments, irradiate product in accordance with HACCP plans or process schedules. FSIS also proposed to eliminate the provision that stated that only packaged poultry products may be treated with irradiation. FSIS had adopted this requirement to ensure that the antimicrobial effects of irradiation would be maintained throughout the processing and distribution of the poultry products. However, because under the proposal all poultry establishments would be required to develop and implement HACCP plans, this prescriptive packaging requirement would no longer be necessary.

FSIS could not, however, propose to rescind the FDA requirement in 21 CFR 179.26(b)(6) 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*. In light of the

new HACCP requirements, 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 submitted a petition to FDA on August 19, 1999, to eliminate this packaging requirement.

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

FSIS could not propose to revise the FDA limits on the maximum absorbed radiation dose for poultry products. However, it is possible that poultry products could be safely treated with higher doses of radiation than those that are currently allowed. Higher doses could achieve greater reductions in pathogens. In the August 19, 1999, petition mentioned above, FSIS asked FDA to reconsider and raise the limit on the maximum absorbed dose of radiation in poultry products.

FSIS proposed to eliminate two of the labeling requirements in § 381.135(a): the requirement that the radura logo on irradiated poultry product labels 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 poultry products, without affecting the information content of such labels.

Because FSIS proposed to allow unpackaged poultry product to be irradiated, it also proposed 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)).

Also, because FSIS proposed to allow irradiated poultry products to be used as ingredients in further processed products, FSIS also proposed to require that the ingredient statement on such products reflect the inclusion of irradiated poultry products (§ 381.135(b)). For example, under the proposal, 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."

Comments and Responses

By the close of the comment period, FSIS received about 1,100 comments from consumers, consumer advocacy organizations, academia, trade and professional associations, scientific organizations, the meat and poultry products industries, the irradiation equipment industry, industry consultants, and State governments. Generally, industry, academia, and professional organizations supported the proposal. These commenters expressed concerns about the proposed labeling requirements, which they believe are too prescriptive, about the length of time it took to publish the proposal, and made recommendations for broadening the scope of the proposal. Consumer advocacy groups, for the most part, expressed qualified support for the proposal. All expressed concern that establishments will use irradiation to treat product produced under insanitary conditions and all wanted FSIS to require explicit and conspicuous product labeling. Many of the individual consumers and a few organizations opposed the irradiation of meat food products altogether, but demanded explicit and conspicuous product labeling in the event FSIS allowed it. Summaries of issues raised by commenters and Agency responses follow.

Safety of Irradiation

Comment: Numerous consumers questioned the research regarding the safety of irradiated food. Some demanded more research before irradiation is allowed; some opposed irradiation altogether. Several opposed irradiation because they believe it will significantly degrade the nutritional quality of treated food.

A few commenters opposed irradiation because, they asserted, its use would increase the risk of accidents involving radioactive material. Some raised concerns about worker safety and

environmental issues related to irradiation. One consumer advocacy group argued that the rule's potential impact on the environment must be reviewed under the National Environmental Policy Act (NEPA, 42 U.S.C. 4321 *et seq.*). Finally, a few consumers requested that parents be asked to give their permission before their children are served irradiated food in the school lunch program.

Response: The safety and efficacy of food irradiation, as demonstrated by numerous experiments and studies, is widely accepted by Federal regulatory agencies and national and international food and public health organizations. Before listing the uses of sources of ionizing radiation permitted on meat food products, as well as on other foods, FDA examined numerous studies on the chemical effects of radiation, the impact of radiation on nutrient content of foods, potential toxicity concerns, and effects on microorganisms in or on irradiated products. FDA concluded that irradiation is safe in reducing disease-causing microbes in or on meat food products and that it does not compromise the nutritional quality of treated products. Furthermore, the World Health Organization, the Food and Agriculture Organization, the American Medical Association, and the American Dietetic Association endorse food irradiation.

FSIS has examined the potential impacts of food irradiation in a review of risk analysis literature made available with the proposed rule. This literature review is available from the FSIS Docket Clerk's Office (see **ADDRESSES** above) and from the FSIS Internet world wide web page at <http://www.fsis.usda.gov/OA/topics/irrad-risk.htm>.

From this review of recent studies, FSIS concluded that the proposed regulations permitting the irradiation of meat food products and the revision of the regulations governing the irradiation of poultry products would pose no significant risk to worker or transportation safety. FSIS concluded that oversight by other Federal and State agencies will ensure the safety of food irradiation facilities:

In summary, proper design and operating procedures of commercial irradiators have been shown to operate without significant radiation risk to workers or the public. NRC [Nuclear Regulatory Commission] has set stringent environmental protection requirements for any facilities that use radionuclide sources (10 CFR Parts 20, 30, 51, and 71). There are special carrier requirements for transport of hazardous materials (such as the radionuclides used at the facility) set by the DOT [Department of Transportation]. Any extraneous radiation from radionuclides would be contained in

plants by shielding required by the NRC and the Bureau of Radiological Health at FDA. The risk of radiation exposure to workers is very low with adherence to the required NRC, OSHA, and other safety requirements. And finally, FSIS ensures that the risks from food irradiation are insignificant by its requirement that all irradiation facilities adhere to the safety regulations of the NRC, DOT, and FDA.

Furthermore, FSIS employees will receive training from FSIS in radiation health and safety and will be required to wear dosimetry devices. The Agricultural Research Service (ARS) will issue the devices as part of their radiological safety program for all USDA employees. Radiation exposure records for FSIS employees will be maintained and monitored by ARS, and kept indefinitely.

Concerning NEPA, USDA has determined that FSIS programs and activities have been found to have no individual or cumulative effect on the human environment. Accordingly FSIS is categorically excluded from the preparation of an Environmental Assessment (EA) or Environmental Impact Statement unless the Administrator determines that an action may have a significant environmental effect (7 CFR 1b.4). The irradiation of various food products has been permitted and safely conducted for over 30 years. The irradiation of poultry products has been permitted and safely conducted since 1992. Therefore, the Administrator has not determined that circumstances dictate the need for preparation of an EA for the voluntary use of irradiation in meat food products.

FSIS works closely with the other agencies within USDA responsible for the school lunch program. Should USDA or individual school districts choose to purchase irradiated products for the school lunch program, FSIS would support that decision. Irradiation can significantly reduce the levels of pathogenic microorganisms in treated meat food and poultry products. Therefore, irradiated food products would be ideal for the school lunch program, which serves children, a population particularly vulnerable to foodborne illness. FSIS sees no need for any special notification of the parents of children participating in a school lunch program that serves irradiated meat food or poultry products because FSIS agrees with FDA's finding that food irradiation poses no toxicological or microbiological risks for consumers and does not affect the nutritional adequacy of treated product.

Efficacy of Irradiation

Comment: Several commenters from industry and academia requested that FSIS either maintain a minimum absorbed dose requirement or, if there is to be no required minimum dose, require establishments that irradiate product to achieve a minimum level of pathogen reduction (one irradiator suggested 1-log¹⁰ reduction of the pathogen of concern in a product). One commenter argued that unscrupulous processors could irradiate product with a minimal dosage, achieving an insignificant antimicrobial effect, merely to accrue the benefit of the label and extended product shelf-life. This commenter also maintained that consumers would be misled by product labeled as irradiated, but treated with only a negligible dose. Another industry commenter maintained that although FSIS should not mandate irradiation, FSIS should mandate that all official establishments achieve the level of pathogen reduction resulting from irradiation, regardless of the antimicrobial intervention they use.

Several consumer advocacy organizations recommended that FSIS maintain the minimum dose requirement for treated poultry and establish a minimum dose for meat food products so as to ensure specific reductions in pathogens.

Response: FSIS will allow meat and poultry establishments to determine what level of irradiation (subject to a maximum level) and what consequent reduction of pathogens is appropriate within their HACCP systems. Depending on the processing environment, the type of meat food or poultry product, and the type of radiation source employed, varying dosages of radiation will be appropriate. A required minimum dosage would undercut the flexibility needed for the successful implementation of HACCP.

Furthermore, FSIS finds that it is unnecessary to establish a minimum level of pathogen reduction to be achieved by irradiation or by any other specific antimicrobial intervention. Establishments must determine what level of pathogen reduction is necessary from a particular intervention based on the results of the hazard analysis they conduct when developing their HACCP plan. Establishments are required to meet specific pathogen reduction performance standards for numerous meat food and poultry products and FSIS plans to propose more standards to eventually cover every processing category. FSIS will ensure that safe meat food and poultry products are produced through compliance with these

standards, but need not hinder processing innovation by mandating the use of specific antimicrobial interventions, or specific results from specific interventions.

Comment: Several consumer advocacy organizations argued that FSIS should require establishments that irradiate product, and especially establishments not yet under HACCP, to conduct regular micro-testing prior to irradiation. One organization requested that FSIS require end-product microbial testing of irradiated product. This testing would discourage establishments from using irradiation to treat “dirty” product or operate under insanitary conditions. Another suggested that FSIS clarify in the final rule that irradiation would in no way satisfy the “zero-fecal” policy. Finally, another organization argued that FSIS should allow meat food products to be irradiated only after final packaging, to prevent any recontamination of the treated product.

Response: Irradiation is just one of the many antimicrobial interventions available to establishments. As with other interventions, its use in no way exempts establishments from meeting statutory sanitation requirements. Moreover, FSIS emphasizes that establishments that employ irradiation still must meet the zero-tolerance requirements for visible fecal matter on meat or poultry carcasses.

FSIS will neither require special microbial testing nor conduct such testing in establishments that irradiate product (although FSIS may conduct microbial testing to verify pathogen reduction claims or for enforcement purposes). Compliance with the HACCP requirements, along with other FSIS requirements governing sanitation, will preclude the irradiation of product produced under insanitary conditions, as well as the adulteration of product after an irradiation treatment.

Finally, in order to promote processing flexibility and innovation that will lead to improvements in food safety, FSIS did not propose to require that meat food products be irradiated only after final packaging. Using a HACCP system, an establishment must control the conditions under which product is held from initial processing through irradiation and packaging to ensure and preserve the intended antimicrobial effects of irradiation. By law, establishments must produce unadulterated meat food and poultry products regardless of whether or when they irradiate within their processing systems.

Comment: Numerous commenters opposed irradiation of meat food and poultry products because they believe

irradiation will allow establishments to clean up insanitary meat food and poultry products resulting from “factory farming” (concentrated animal production methods), which they believe is unethical and inhumane. They argue, therefore, that irradiation would indirectly promote the expansion of “factory farming.”

Response: As stated above, the use of irradiation in no way exempts establishments from meeting statutory and regulatory sanitation requirements. Establishments are not permitted to produce meat food or poultry products under insanitary conditions, regardless of whether they irradiate. Furthermore, FSIS prohibits the inhumane handling and slaughter of livestock. Under the Humane Slaughter Act (7 U.S.C. 1901–1906), FSIS personnel may suspend inspection of an official establishment if the Agency determines that the method by which livestock is slaughtered is inhumane, as defined by the Humane Slaughter Act.

As part of its “farm-to-table” food safety strategy, FSIS is interested in effects of concentrated animal production methods on food safety, as well as humane handling and slaughter. Notably, no data was submitted that supported comments concerning concentrated animal production. FSIS would welcome and thoroughly review any such data.

Comment: One consumer advocate organization requested that FSIS provide information on how it intends to redeploy inspection program employees to irradiation facilities.

Response: As stated in the proposal, facilities that irradiate meat food and poultry products are considered by FSIS to be official establishments. As such, they are subject to inspection as provided for by the Federal Meat Inspection Act (FMIA) and Poultry Products Inspection Act (PPIA). FSIS will deploy inspection program employees to irradiation facilities based on a number of factors, such as inspection force workload and the type of activities conducted at the individual facilities (e.g., product irradiation only, irradiation and additional processing, slaughter and irradiation) Assignment of FSIS program personnel to irradiation facilities will not differ from assignment to other types of official establishments.

Irradiation and HACCP

Comment: A few establishments and trade associations argued that FSIS should not mandate a critical control point (CCP) for irradiation, as they believed that the preamble implied that FSIS will mandate a CCP for irradiation.

Response: FSIS did not mandate any specific CCP or critical limit in the proposed rule language, although the Agency did give some examples. Because most, if not all, establishments will irradiate product specifically to reduce microbial pathogens (identified hazards), they would include irradiation as a CCP in their HACCP plans. 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. Dosage, ambient temperature, oxygen levels or other factors that affect the antimicrobial efficacy of irradiation will likely be monitored to determine if the critical limits for an irradiation CCP are being met.

In accordance with the FDA regulation on the use of irradiation, establishments could irradiate product solely to extend shelf-life. In its proposal to provide for the use of irradiation on meat food products, FSIS stated that it therefore might be possible for an establishment to irradiate product solely to extend shelf-life and not account for effects of the treatment on pathogens in its HACCP plan:

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.

(64 FR 9091-9092)

FSIS still maintains this position, but notes that there is a safety factor inherent in product shelf-life determination. Pathogenic and non-pathogenic microorganisms, including spoilage organisms, compete for nutrients in food products. Non-pathogenic and spoilage organisms generally are more plentiful than pathogenic organisms. Increasing the shelf-life of a product involves reducing the levels of the spoilage organisms. Although most antimicrobial treatments, including irradiation, reduce microbial levels fairly proportionately, an establishment must ensure that its treatment does not give a competitive advantage to pathogenic organisms, allowing for their disparate growth.

More specifically, irradiation can affect the levels and projected growth of microbial pathogens, which would be

identified by establishments as hazards. Establishments should take into account the levels and projected growth of microbial pathogens in meat food and poultry products when determining product shelf-life. Therefore, in its HACCP plan, an establishment would need to account for the reduction of pathogens (and possibly the reduction of competing microorganisms) resulting from irradiation conducted solely to extend product shelf-life. Nonetheless, FSIS is not mandating the specific CCP or critical limit to be employed.

Comment: Numerous industry groups and establishments argued that facilities that only irradiate packaged product should not be considered official establishments, since, in their view, such establishments would not be processing product (traditionally considered to be grinding, salting, etc.). A few of these commenters noted that FSIS does not currently consider certain warehouses that freeze packaged meat food and poultry products to destroy parasites to be official establishments. One commenter suggested that third party irradiators be required to implement HACCP anyway; several suggested that irradiation conducted at a remote facility be considered under the HACCP plan of the establishment that provides the meat food or poultry products for irradiation.

Response: FSIS disagrees and will consider any facility that irradiates meat food or poultry products to be an official establishment. Sources of radiation used to treat food are defined as food additives under § 201(s) of the FFDCFA. FSIS believes that the act of using any food additive constitutes processing, and the processing of meat food and poultry products may only take place in official establishments subject to FSIS inspection and regulation.

In regard to the freezing of meat food and poultry products to kill internal parasites, it is true that FSIS has allowed certain warehouses to freeze beef and pork for this purpose, without being designated as official establishments. FSIS is now reviewing this policy decision to determine whether this freezing constitutes processing and will designate these facilities as official establishments if it concludes that it does.

Because facilities that irradiate product will be designated as official establishments, FSIS will not permit such establishments to operate under other establishments' HACCP plans. Each official establishment must develop and implement its own.

Comment: Several commenters contended that the validation requirement for process schedules is

inadequate, since irradiation is so complicated and relatively new to the meat food product industry. They suggested FSIS require that radiation specialists review process schedules and HACCP plans. One consumer advocacy organization suggested that FSIS should validate HACCP plans that include irradiation.

Response: FSIS disagrees. Food irradiation has been practiced in the United States for over 30 years. Further, the irradiation of poultry products has been permitted and safely conducted since 1992. Industry possesses the expertise and the resources to safely and effectively irradiate meat food products.

FSIS is requiring certain employees of official establishments conducting irradiation to be trained in various aspects of food irradiation and radiation safety (new § 424.22(c)(3)(v) and (vi)); FSIS already requires this training for personnel at establishments that irradiate poultry.

In regard to the proposed requirements for process schedule validation, because all official meat and poultry establishments will be operating under the HACCP requirements by the time the regulations are in effect, FSIS has not carried forward the proposed process schedule requirements (meant for establishments not yet operating under HACCP) into this final rule. FSIS does not validate establishment HACCP plans, regardless of the processing systems employed. In accordance with § 417.4(a) of the regulations, it is the responsibility of an establishment to validate its HACCP plan's adequacy in controlling the identified food safety hazards. FSIS does review HACCP plans for conformance with the HACCP regulations. Further, FSIS and establishments are responsible for verifying that HACCP plans are adequate and working on a day-to-day basis. Establishments must monitor and verify the performance of the controls in their HACCP plans and maintain records of this monitoring and verification. FSIS evaluates the HACCP plan's adequacy and successful operation as part of the inspection process.

Scope of Meat Food and Poultry Products That May Be Irradiated

Comment: Several commenters requested that FSIS specifically provide for irradiation as an acceptable treatment for raw, non-intact beef products contaminated with *Escherichia coli* O157:H7.

Response: On January 19, 1999, FSIS published a notice in the **Federal Register** (54 FR 2803; "Beef Products Contaminated With *Escherichia Coli*

O157:H7") clarifying that non-intact beef products, as well as intact cuts of muscle that are to be further processed into non-intact product prior to distribution for consumption, that are contaminated with *E. coli* O157:H7 are adulterated under the Federal Meat Inspection Act unless the products are further processed to destroy this pathogen. Also in that notice, FSIS stated that it was considering irradiation as an option for effectively eliminating *E. coli* O157:H7 from contaminated beef products, since the only type of effective processing available at the time of the notice was cooking. Now, under the regulations in this final rule, establishments may use irradiation as a means of eliminating *E. coli* O157:H7 from contaminated beef products.

An establishment that irradiates beef product known to be contaminated with *E. coli* O157:H7 and intended for distribution as a non-intact product must have controls in place to ensure that the pathogen is eliminated from the product prior to its distribution for consumption. The establishment also must document its actions to eliminate *E. coli* O157:H7 from the product in accordance with applicable regulations. Establishments should refer to the above mentioned notice, as well as guidance available from the FSIS Internet site (www.fsis.usda.gov), for further clarification on the Agency's policy in regard to the treatment of beef products containing *E. coli* O157:H7.

Comment: Consumer and industry groups asked FSIS to broaden the scope of the final rule to provide for the irradiation of processed products, especially ready-to-eat products. Many commenters believed that the FDA finding in regard to the Isomedix petition allows FSIS to do this without petitioning FDA again. Also, several commenters criticized FSIS and FDA for failing to cooperate more closely in regard to approving the irradiation for various products. They suggested that:

- FSIS should act quickly to petition FDA to make the regulations for irradiating poultry consistent with those for meat and to allow for the irradiation of hot-boned meat.

- FSIS and FDA should expedite the approval of new packaging materials for product irradiated while packaged.

- FSIS should make final and implement Docket No. 88-026P ("Substances Authorized for Use in the Preparation of Meat and Poultry Products"; 60 FR 67459) so as to end the need for duplicative rulemaking by FDA and FSIS when approving food additives, including the use of sources of ionizing radiation.

Response: FDA's authority to regulate the uses of ionizing radiation on food is clear under § 409 of the FFDCA. FDA has approved the use of sources of ionizing radiation only on the uncooked meat food products described above. Until FDA approves the use of ionizing radiation on other meat food products, including processed or cooked products, FSIS will not provide for the irradiation of such products.

In August 23, 1999, a consortium of organizations, including the National Food Processor's Association (NFPA), petitioned FDA to allow for the use of approved sources of ionizing radiation on processed meat food and poultry products. Because the irradiation treatment is intended to significantly reduce the levels of pathogens in food, FDA is reviewing this petition in an expedited clearance process. FSIS will cooperate with FDA in reviewing this petition. Further, On August 19, 1999, FSIS petitioned FDA to clarify that sources of ionizing radiation may be used on "hot-boned" (unrefrigerated) meat food products and to revise the dosage and packaging restrictions on the irradiation of poultry products for consistency. FDA also is reviewing these petitions in an expedited clearance process.

FDA is also working to expedite the process for reviewing packaging materials to be used during food product irradiation and FSIS will cooperate with FDA in reviews of such packaging for poultry and meat food products. Under its new Premarket Notification Program, FDA will continue to review all food contact substances, including food packaging materials intended for use during irradiation, but will no longer necessarily list those permitted in the Code of Federal Regulations.

In regard to the approval of food additives in meat food and poultry products, elsewhere in this issue of the **Federal Register**, FSIS has published a final rule (FSIS Docket No. 88-026F; "Substances Authorized for Use in the Preparation of Meat and Poultry Products") that ends duplicative approval by both FDA and FSIS. Requests to approve the use of food additives in or on meat food and poultry products not permitted now must be sent to FDA. Although FDA will receive and review such petitions, FDA also intends to amend its regulations to provide for FSIS review of petitions for uses of food additives in or on meat food or poultry products. These actions will eliminate the need for separate FSIS rulemakings. FSIS will limit substance-specific rulemakings to those necessary to establish prohibitions or

limitations on the use of substances in meat food or poultry products that are necessary to protect public health or to achieve other consumer protection benefits, such as to prevent product misbranding.

In this final rule, FSIS is consolidating its regulations governing irradiation into a single set of generic regulations under new § 424.22(c), applicable to the irradiation of all types of meat food and poultry products (FSIS proposed separate, but identical sets of regulations for meat and poultry). Therefore, in the future, when FDA lists new uses of ionizing radiation on various types of meat food and poultry products, unless FSIS needs to establish a prohibition or restriction, establishments may immediately take advantage of the newly approved usage of irradiation without waiting for additional FSIS rulemaking.

Consumer Acceptance of Irradiation

Comment: Numerous industry groups argued that FSIS should actively promote irradiation and implement a consumer education program regarding its benefits.

Response: Recognizing the diversity of meat food and poultry products and processing environments, FSIS does not mandate or actively promote any single intervention or antimicrobial technology. The meat food and poultry product industries, as well as consumer and public health organizations, have the primary responsibility for promoting irradiation and educating the public about the benefits and limitations of irradiation. However, FSIS recognizes the potential of irradiation to safely and effectively reduce foodborne pathogens in meat food and poultry products and therefore is eager to provide for its use as one of the many antimicrobial treatments that may be used within a HACCP system.

Labeling

Comment: Numerous commenters requested that FSIS make its labeling requirements for irradiated meat food and poultry products identical with FDA's requirements. Several commenters noted that the proposed labeling requirements regarding placement of the statement and radura, as well as the proposed disclosure requirements for irradiated meat food or poultry ingredients contained in multi-ingredient products, are inconsistent with FDA labeling requirements and with the Food and Drug Administration Modernization Act (FDAMA) of 1997 (Pub. L. 105-115). Many commenters argued that the proposed requirements are unworkable and expensive and

therefore will prevent the wide scale adoption of irradiation. A few trade associations maintained that establishments producing multi-ingredient meat food and poultry products will have to maintain two sets of labeling, since they will not always be using irradiated meat food or poultry products as ingredients.

Commenters suggested numerous and varied revisions to the proposed labeling requirements:

- One trade association requested that FSIS require the radura but not the statement on product irradiated in its entirety;

- An irradiator suggested that FSIS not require the irradiation statement to be contiguous to the product name and argued that the radura should be voluntary;

- A few commenters requested that FSIS require "irradiated" to be part of the product name. One commenter suggested that FSIS should then eliminate other labeling requirements, while another suggested this be an additional requirement;

- Several commenters asked that FSIS require the radura with a qualified statement indicating the beneficial effects of irradiation;

- One commenter requested that FSIS allow labeling that indicates the source of radiation, i.e., gamma or machine source;

- One trade association suggested that multi-ingredient products containing irradiated meat food or poultry product ingredients be labeled with the radura and statement such as "contains beef products treated with irradiation;"

- One company maintained that the proposed labeling requirements for multi-ingredient products are inconsistent with FDA requirements in 21 CFR 101.100(a)(3)(i), which exempt from labeling disclosure "Substances that have no technical or functional effect but are present in a food by reason of having been incorporated into the food as an ingredient in another food, in which the substance did have a functional or technical effect."

- An irradiator suggested that there be no required disclosure in multi-ingredient products unless the irradiated component makes up more than 50% of the total product;

- One scientific organization argued that no irradiation labeling should appear on product irradiated before its final packaging. They contended that the treated product would not maintain the antimicrobial effects of irradiation and therefore, that any labeling implying otherwise would be misleading;

- Numerous individual consumers and consumer advocacy organizations commented in favor of explicit and conspicuous labeling disclosing that product has been irradiated or contains an irradiated ingredient. Two organizations submitted poll results suggesting that a majority of consumers are in favor of explicit and conspicuous disclosure of irradiation. Many of these commenters generally supported the labeling requirements FSIS proposed and opposed efforts at consistency with FDA regulations and the requirements of the FDAMA.

- Consumer advocacy groups and numerous consumers argued that, in the interest of the visually impaired, FSIS should not rescind the existing letter size requirements for the irradiation statement on treated poultry and should apply this same requirement to irradiated meat food products.

- One consumer advocacy group argued that multi-ingredient products with an irradiated poultry or meat food product ingredient making up more than 50% of the total weight should be labeled with the irradiation statement, as well as disclosure in the ingredient statement.

Response: FSIS proposed to require that the radura be contiguous to the irradiation statement and the statement to be contiguous to the name. In § 317.2(c)(1) of the regulations, FSIS requires that product names be on the principal display panel. Therefore, under the proposed regulations the statement and the radura would be required to be on the principal display panel. FDA, however, in response to the FDAMA, recently amended its regulations to clarify that the statement does not have to be any more prominent than the ingredients statement; that is, the statement and the radura can appear somewhere other than the principal display panel.

In response to comments and as part of an effort to make FSIS labeling requirements more consistent with those of FDA, FSIS will not require, as proposed, that the irradiation statement and the radura be any more prominent than the ingredients statement on the labeling of irradiated meat food and poultry products. Thus, the statement and the radura may appear somewhere other than on the principal display panel. The requirement in § 317.2(b) that any statement must be placed and in such terms so as to "render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use" will still apply to the irradiation statement, however. This requirement prohibits labeling of irradiated product in a

manner that would intentionally mislead consumers.

FSIS disagrees with the comment that it should have letter size requirements for irradiation disclosure statements in the interest of the visually impaired. FSIS is working with FDA and other agencies to make food labeling regulations consistent. Maintaining the existing or proposing new letter size requirements solely for irradiated meat food and poultry products would counter these efforts. However, FSIS will continue to examine methods for improving the communication of food safety and other relevant information to all consumers.

Also in response to public comment, FSIS will allow the word "irradiated" to be part of the name of irradiated meat food or poultry product. FSIS will not require the irradiation statement on the labeling of product that has the word "irradiated" as part of its name. Having "irradiated" in a product name will be as meaningful to consumers as labeling irradiated product with the statement.

Although FDA does not exempt irradiated product from being labeled with the statement when "irradiated" is included in the product name, it is considering this issue as part of its ongoing reexamination of labeling requirements for irradiated foods. FDA recently solicited comment on possible revisions to the labeling requirements for irradiated food in an advance notice of proposed rulemaking ("Irradiation in the Production, Processing, and Handling of Food"; February 17, 1999; 64 FR 7834). During the comment period on for this notice, FSIS informed FDA of this revision to the labeling requirements for irradiated meat food and poultry products. If FDA ultimately does not adopt this labeling approach, FSIS will reassess its labeling requirements for irradiated products to determine how to best improve consistency between the requirements of the two agencies.

FSIS will allow labeling statements and claims regarding the beneficial effects of irradiation, provided they are truthful and not misleading. FSIS already has approved such claims for the labeling of irradiated poultry and FDA allows for such claims on the labeling of other irradiated foods. As proposed, any claims must be substantiated by processing documentation. The specificity and complexity of the documentation required will vary and depend on the specificity of the claim. For example, a general labeling claim, such as a statement that product was irradiated "to reduce pathogens such as *Salmonella*," could be easily

substantiated by the establishment's HACCP plan and monitoring records. *Salmonella* and other microbial pathogens would need to be identified as a hazard in the establishment's HACCP plan and plan validation and monitoring records would demonstrate the claimed reduction. If an establishment wished to claim that a particular pathogen had been eliminated from the product as a result of irradiation, more specific documentation substantiating this would be required. This type of claim is discussed further below in the response to comments concerning the claimed elimination of *E. coli* O157:H7 from an irradiated product.

FSIS will allow labeling statements disclosing the specific source of radiation (gamma or machine source). FDA already allows such statements on irradiated food (e.g. "Treated by electron beam irradiation").

FSIS is making final the proposed requirement that inclusion of an irradiated meat food product ingredient in any multi-ingredient product be reflected in the ingredient statement on the finished product labeling. The FMIA and PPIA, like the FFDCa, require that food labeling not be false or misleading. In determining whether labeling is false or misleading under these statutes, FSIS must consider not only representations made or suggested by elements of the label, but also the failure to reveal material facts in light of such representations.

FSIS views the irradiation of meat and poultry products as a "material fact" that must be disclosed in product labeling, even if the irradiated meat and poultry products are used as ingredients in multi-ingredient products. Under this final rule, establishments may irradiate meat food or poultry products only to control foodborne pathogens or to extend product shelf-life. In FSIS's view, effects on pathogen levels or product shelf-life, whether achieved in single-ingredient or multi-ingredient meat or poultry products, are material facts that would not be evident to consumers in the absence of labeling. Moreover, some, and probably much, of the antimicrobial effect and extension of shelf-life achieved through irradiation is likely to persist in irradiated meat and poultry used as ingredients in multi-ingredient products, especially considering that FSIS anticipates that products in which irradiated meat or poultry are likely to be used as ingredients are also likely to contain a significant amount of these ingredients.

Thus, FSIS concludes that irradiation of a meat or poultry ingredient in a multi-ingredient product must be

disclosed. FSIS will, however, continue to monitor how irradiation is used. As new information based on experience in the marketplace becomes available, and should FDA approve other uses of irradiation for meat and poultry products, FSIS may revisit whether irradiation of ingredients for those uses is a material fact that requires disclosure.

FSIS disagrees with the comment that disclosure of the irradiated ingredient will mislead consumers about the product's safety because, according to the commenter, multi-ingredient products with irradiated meat or poultry ingredients would be no different microbiologically than those without. FSIS acknowledges that the antimicrobial effects of irradiation will be maintained at varying levels in a multi-ingredient meat food or poultry product, depending on the type of product, how it is processed, whether it is combined with other non-irradiated ingredients, or if specific microorganisms are reintroduced. However, some antimicrobial effect from the irradiation would be maintained in the irradiated meat food or poultry product ingredient and that would not be apparent to consumers without labeling.

FSIS disagrees with the comment that the this disclosure requirement is inconsistent with FDA regulations in 21 CFR 101.100(a)(3)(i), which exempt from labeling disclosure "Substances that have no technical or functional effect but are present in a food by reason of having been incorporated into the food as an ingredient in another food, in which the substance did have a functional or technical effect." FDA applies this requirement only to food ingredients. FDA consider sources of radiation to be additives, but not ingredients.

In regard to the possibility of requiring this disclosure on the basis of the percentage of the irradiated meat food or poultry product ingredient in a multi-ingredient product, FSIS, in cooperation with FDA, will continue to examine the issue. Although numerous commenters suggested labeling disclosure options based on a percentage, no data was submitted. FSIS is aware that Canada requires labeling disclosure only if the irradiated ingredient comprises more than 15 percent of a multi-ingredient product. FSIS is reviewing this Canadian policy.

FSIS could revise the labeling requirements in the future. In fact, as discussed in the next two comments and response, FSIS and FDA are considering the option of eventually

revising some of the labeling requirements.

Comment: Numerous industry groups requested that FSIS plan to sunset all labeling requirements related to irradiation within 5 years or sooner. They note that FDA discusses this possibility in the recent notice (64 FR 7834).

Response: FSIS is consulting with FDA on this issue and will review the comments on the FDA notice. Central to the option of revising any of the labeling requirements will be consumer awareness and understanding of food irradiation. FSIS also will continue to assess the impact and effectiveness of its labeling requirements for irradiated meat food and poultry products. Interested persons may wish to submit information on this issue to FSIS.

Comment: A few commenters argued that labeling of irradiated product should be voluntary. They argued that demand for irradiated products will give producers and retailers incentive to disclose that their products were irradiated. Further, numerous commenters claimed that consumers will regard the statement and radura as a warning and not purchase the product and argued that irradiation, therefore, will not be widely adopted by industry. A few commenters claimed that if irradiation is not widely employed by the food industry as result of labeling requirements and other perceived regulatory impediments, significant reductions in foodborne illness will not occur.

Response: As explained above, to prevent misleading labeling, the FMIA, PPIA, and FFDCa require disclosure of facts material to food products. Irradiation can affect food in a manner that is not obvious to consumers in the absence of labeling. Antimicrobial effects, changes in product shelf-life, and in some cases, changes in characteristics of food (taste, smell, texture) can result from irradiation. FSIS views irradiation of meat and poultry, therefore, as a material fact that must be disclosed in product labeling. However, both FSIS and FDA are continuing to examine their labeling requirements and the options for revising these requirements so as to better convey information to consumers.

Although FSIS acknowledges that labeling may initially have some effect on consumer acceptance of irradiated meat food and poultry products, FSIS expects that as consumer awareness increases, the demand for these products will expand and the labeling will serve to promote these products. FSIS will continue to examine ways to remove regulatory impediments to

advances in food safety technologies, including irradiation, but it is the responsibility of industry to promote irradiated meat food and poultry products. FSIS does not agree that its labeling requirements will decrease the level of possible reductions in foodborne illness that may result from the use of irradiation. Potential reduction in foodborne illness are examined in detail below in the discussion of the economic impact of these regulations.

Comment: FSIS noted in the proposed rule that it had received a petition from NFPA regarding labeling requirements for irradiated food. In the petition, NFPA requested that FSIS address whether labeling requirements concerning the disclosure of irradiation are warranted for meat food and poultry products and how such labeling affects consumer acceptance of irradiation. In a subsequent comment on the irradiation proposal, NFPA demanded that FSIS publicly respond to each issue raised in its petition and ask for public comment on each issue, although they added that the FSIS's actions should not delay a final rule.

In its petition and subsequent comment, NFPA requested that FSIS address several labeling issues discussed elsewhere in this document, including: whether labeling of irradiated product is "constitutionally, statutorily, and scientifically unwarranted;" whether disclosure of radiation would contribute to unfounded apprehension among consumers and therefore preclude widespread use of irradiation; and whether FSIS and FDA labeling requirements for irradiated products should be identical. NFPA cited case law (*International Dairy Food Association v. Amestoy*, 92 F.3d 67, 73 (2d. Cir. 1996) and *Central Hudson Gas & Elec. Corp. v. Public Service Commission*, 447 U.S. 557 (1980)) in support of its argument that consumer desire to know how food was processed is not alone sufficient to justify mandatory disclosure of the processing. NFPA also requested that FSIS address whether irradiation is a material fact under section 403(a)(1) of the FFDC; that is, should irradiated meat food or poultry products be labeled as such since otherwise, consumers would be unaware of the material fact that the products had been processed with radiation?

Response: All the labeling issues raised by NFPA in its petition and in its subsequent comment were also raised in other comments and FSIS has responded to them in this document. Furthermore, FDA has requested comment on these and other labeling

issues in its recent notice and FSIS will review those comments. FSIS sees no need, therefore, to again solicit public comment on these labeling issues, and, NFPA did request that the response to their petition not delay any final regulations.

In response to NFPA questions regarding the legal basis for requiring disclosure, FSIS has reviewed the Supreme Court standards for governmental regulation of commercial speech as announced in *Central Hudson Gas & Elec. Corp. v. Public Service Commission* and summarized in the dissenting opinion in *International Dairy Food Association v. Amestoy*:

At the outset, commercial speech enjoys no First Amendment protection at all unless it is not misleading (and related to lawful activity). If the speech passes that test, it is nonetheless subject to regulation if the government has a substantial interest in regulating the speech, the regulation directly advances that interest, and it is no more intrusive than necessary to accomplish its goal. 447 U.S. at 566, 100 S.Ct. at 2351. The Supreme Court later clarified that government's power to regulate commercial speech includes the power to compel such speech. *Zauderer v. Office of Disciplinary Counsel*, 471 U.S. 626, 651, 105 S.Ct. 2265, 2281-82, 85 L.Ed.2d 652 (1985). *International Dairy Food Association v. Amestoy*, 92 F.3d 67, 77 (2d. Cir. 1996).

FSIS does have a substantial interest in requiring the disclosure that meat or poultry products have been irradiated; such irradiation is a material fact that must be disclosed to consumers through labeling to avoid deception, since it can affect the meat or poultry products in a manner that is not obvious to consumers in the absence of labeling. Disclosure of irradiation through labeling is the most direct way to advance this interest. FSIS believes that the labeling requirements contained in this regulation are the least intrusive possible, but still accomplish the goal of disclosure. Therefore, FSIS is requiring labeling that indicates meat and poultry products have been treated with irradiation.

Comment: Numerous industry and academic commenters requested that FSIS allow alternative, euphemistic statements on irradiated products that would be more appealing to consumers, such as "cold," "electronic," and "ionizing" pasteurization. Several of these commenters cited or submitted consumer polling data to support the use of their claims. One food processor suggested that any euphemistic labeling statements containing the word "pasteurization" be contingent upon specific levels of pathogen reductions. Consumers and consumer advocacy organizations, for the most part,

maintained that alternative and euphemistic statements would be misleading and erroneous and opposed them.

Response: FSIS will review, on a case-by-case basis, labels with alternative or euphemistic statements regarding irradiation. FSIS is requiring, however, that labels of meat food or poultry products that have been irradiated in their entirety be labeled with statements such as "Treated with irradiation" or "Treated by irradiation," or, that the word "Irradiated" be part of the product name. FSIS will allow the terms "cold," "electronic," and "ionizing" to be used in conjunction with term "irradiation," if truthful.

At this time, however, labeling statements or claims for irradiated product that include the term "pasteurization" probably would be misleading. "Pasteurization" implies the destruction of all vegetative microorganisms in the product as a result of irradiation. At the maximum dosages allowed by FDA and FSIS, it would be highly unlikely that all of the vegetative microorganisms in irradiated product would be destroyed.

For example, an establishment irradiates refrigerated, raw beef round or chuck using a gamma radiation source. They determine that they will achieve a 2:1 overdose ratio¹ using the maximum allowed dosage of 4.5 kGy. That is, the irradiation treatment will achieve at least a minimum absorbed dosage of 2.25 kGy throughout the product.

According to the International Consultative Group on Food Irradiation², the dosage necessary to eliminate 90 percent of *Salmonella sp.* in a gram of product (the "D value," which is equivalent to $1-\log_{10}$), ranges from 0.48 kGy to 0.7 kGy. Therefore, this establishment, by achieving a minimum absorbed dosage of 2.25 kGy throughout the product, also would effect a minimum reduction of *Salmonella sp.* ranging between $4.7-\log_{10}$ and $3.2-\log_{10}$ per gram of product, throughout the product. These hypothetical reductions are significant

¹ Product shape, density, and its distance from the source of radiation, as well as other factors, influence the absorbed dosage in an irradiated product. Therefore, it is difficult to achieve a uniform absorbed dosage in irradiated products, especially if the product is densely packed in large quantities. To achieve specific absorbed dosages of radiation in treated products, irradiators calculate a maximum/minimum "overdose ratio." Using this ratio they are able to irradiate product so as to accurately predict that while some of the treated product will have absorbed the maximum dosage, all will have absorbed at least the minimum dosage.

² International consultative Group on Food Irradiation, "Irradiation of red meat: A compilation of technical data for its authorization and control," August 1996.

and would greatly reduce the risk of foodborne illness from treated product. However, these reductions are well below the levels necessary to achieve a ready-to-eat roast beef product. FSIS recently established that it is necessary to achieve at least a 6.5-log₁₀ reduction of *Salmonella* sp. throughout a roast beef product to consider that product ready-to-eat (64 FR 732; 9 CFR 318.17).

FSIS acknowledges that if an establishment were to greatly minimize the pathogen load on incoming whole muscle meat product, it could possibly use irradiation combined with stringent process controls to produce a ready-to-eat, though uncooked, meat product, such as steak tartar. In such a case, irradiation would effectively pasteurize the product. FSIS would allow "pasteurized" to be in the labeling statement on such a product. However, under the current regulations, FSIS would require that the product also be labeled with statements such as "Treated with irradiation" or "Treated by irradiation," or, that the word "Irradiated" be part of the product name. FSIS will continue to examine these requirements in light of developments in irradiation technology and FDA policy.

Comment: Commenters from industry overwhelmingly supported incentive labeling (labeling claims regarding the benefits of irradiation) and most suggested that FSIS clarify what types of substantiating documentation would be required for using it. Most consumer advocacy groups expressed concerns about incentive labeling and requested that FSIS require stringent levels of pathogen reduction as prerequisites for making any claims, as well as regular microbial testing. One group argued that FSIS should allow claims only on product irradiated in its final packaging.

All of the consumer advocacy groups that commented, as well as a few industry commenters, opposed the use of labels claiming that a product is "free" of any pathogen as a result of irradiation treatment. Many cited concerns about post-processing contamination of treated and labeled product. Several commenters argued that consumers, misled by labeling claims, would mishandle treated product, believing that it is free of all pathogens.

One consumer advocacy organization suggested that FSIS put in place special "trace back" mechanisms for irradiated product. The organization is concerned that consumers, misled by claims concerning the efficacy of irradiation, may mishandle irradiated product that still contains pathogens. Special "trace back" mechanisms would ensure that

establishments label irradiated products so as not to mislead consumers regarding the safety of those products.

Response: As proposed, FSIS will allow labeling statements on irradiated meat food and poultry products that indicate general or specific reductions in microbial pathogens, provided they can be substantiated by processing documentation. The amount and specificity of the required documentation will vary depending on the statement or claim.

Also in the proposal, FSIS discussed the possibility of product being labeled as "free" of the pathogen *E. coli* O157:H7:

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-log₁₀ reduction of *E. coli* O157:H7).

(64 FR 9094)

Irradiation, as provided for in this rule, could eliminate *E. coli* O157:H7 from products with an appropriate margin of safety. Therefore, FSIS will allow labeling of sufficiently irradiated product to state that processing has been conducted to eliminate *E. coli* O157:H7. As with any labeling statement that claims a specific reduction of pathogens resulting from irradiation, FSIS is requiring establishments claiming that *E. coli* O157:H7 has been eliminated from their products to have processing documentation substantiating this.

FSIS agrees with commenters that stringent processing controls (probably including monitoring of pathogen load on incoming product and the prevention of product recontamination and post processing temperature abuse) would be needed to substantiate a label claiming that a product was "free" of *E. coli* O157:H7. FSIS will expect establishments that treat product known to be adulterated with *E. coli* O157:H7 to implement such controls. FSIS emphasizes that it will closely assess any requests for labeling that a product is free of *E. coli* O157:H7 and, through

inspection, will verify that processes to eliminate the pathogen are under control.

FSIS does not now have the data necessary to establish in the regulations a minimum level of reduction of *E. coli* O157:H7 that establishments must achieve in order to label products as being free of *E. coli* O157:H7. The FSIS Office of Public Health and Science currently is conducting a risk assessment concerning *E. coli* O157:H7. Using the results of this risk assessment, as well as other data that may be developed, FSIS may, in the future, propose to require that any such labeling claims be used only if establishments achieve a specific, minimum level of reduction of *E. coli* O157:H7 within treated product.

In the interim, establishments may want to note that for certain ready-to-eat products, establishments have been processing to achieve a 5-log₁₀ reduction in *E. coli* O157:H7. For example, the cooking requirements for meat patties in § 318.23 of the regulations achieve an approximate 5-log₁₀ reduction in *E. coli* O157:H7 and that compliance with the regulations in this section results in the production of a ready-to-eat meat patty. Further, since 1995, FSIS has encouraged establishments manufacturing ready-to-eat fermented sausage products to implement processes validated to achieve at least a 5-log₁₀ reduction of *E. coli* O157:H7. Several outbreaks of food borne illness attributable to *E. coli* O157:H7 in fermented, shelf-stable sausage products led FSIS, in cooperation with the Agricultural Research Service, meat and poultry industry representatives, and members of the National Advisory Committee on Microbiological Criteria for Food (NACMCF) to develop a policy for ensuring the safety of ready-to-eat fermented sausages. This group developed several processing options that would ensure a 5-log₁₀ reduction of *E. coli* O157:H7 in fermented sausages. In an August 21, 1995 correspondence, FSIS wrote to establishments producing fermented sausages and strongly encouraged that they implement one of the validated processing options contained in the document or that they validate their processes to ensure the processing used achieves at least a 5-log₁₀ reduction of *E. coli* O157:H7. This specific level of reduction may not be adequate for all products or processes and establishments should carefully evaluate the specific product and processes at issue when developing treatments to eliminate *E. coli* O157:H7 from meat products.

In regard to consumer perceptions regarding pathogen reduction claims,

irradiated raw ground beef still must carry the safe handling instruction, regardless of the claimed pathogen reduction. FSIS recognizes that it may be asked to reconsider its requirements regarding safe handling instructions in the event establishments develop methods to pasteurize raw meat food and poultry products through irradiation or other means.

Comment: One commenter requested that FSIS permit irradiated meat and poultry to be labeled as being "organic." A comment from an organic food cooperative opposed any such designation.

Response: The Organic Foods Production Act (OFPA) of 1990 requires USDA to develop national standards and regulations for organically produced agricultural products and to assure consumers that agricultural products marketed as "organic" are consistent with these standards. The OFPA also provides for USDA to establish an organic certification program based on recommendations received from a 14-member National Organic Standards Board (NOSB). Although the OFPA did not specifically address the use of irradiation, the NOSB has recommended, consistent with most existing State and private certification agency organic standards, that the use of irradiation be prohibited in handling organic products. This issue is most appropriately resolved in the agency rulemaking process under OFPA.

Comment: Several industry groups recommended that FSIS explicitly allow product irradiated at a separate establishment to be fully labeled before shipment to that facility. One trade organization asked that FSIS no longer require such product to be shipped under seal. Several industry commenters requested that FSIS specifically exempt irradiation facilities from using their marks of inspection over those of the originating plant and instead allow the irradiator to use a separate stamp, so as to facilitate trace-back.

Response: Meat food or poultry products may be packaged and labeled as being irradiated before shipment to an irradiation facility, provided that the shipping establishment implements controls to prevent the labeled, but as yet not irradiated, product from being distributed to consumers. Most establishments could control the shipment of such product through the maintenance and verification of records, such as bills of lading. FSIS inspection personnel will verify that these controls are implemented.

FSIS does not and will not require irradiators or other processors to place

their marks of inspection over those of the establishments from which the product originated. In regard to which inspection legend and establishment number would be placed on an irradiated product, different scenarios are possible. For example, if bulk shippers of trimmings or cuts are received by an irradiator, irradiated, and then repackaged in smaller units such as retail trays, the irradiator will be required to declare its establishment number on the retail package. However, if an irradiator receives packaged and labeled products for irradiation, the legend and number of the originating establishment will be declared on the retail package label. FSIS would expect that the irradiator would place its legend on the shipper container in which it packs the product, even if the irradiator uses the same shipper in which the product was received. In all cases, every establishment that processes the product must maintain records, as part of its HACCP paperwork, showing where the product originated, where it was processed, and where it was distributed for consumption. Any necessary trace-back will be facilitated by review of these records.

Comment: Numerous consumers requested that FSIS extend required disclosure to restaurants and institutions that serve irradiated meat food and poultry products.

Response: Historically, FSIS has not extended its regulations regarding meat food and poultry product labeling or misbranding to restaurant and institutional menus. Requiring and enforcing disclosure that restaurant or institutional food has been irradiated would require a heavy expenditure of Agency resources for as yet indeterminate benefits. FSIS will continue to examine this issue. FSIS is aware that a restaurant in Florida has been disclosing on its menu that it serves irradiated poultry products. Possibly, other restaurants and institutions may want to disclose this information for marketing or other purposes.

Technical Concerns

Comment: One commenter stated that the hypothetical reduction of *E. coli* O157:H7 given in the preamble is misleading, as it does not take minimum/maximum ratios into account.

Response: The example of pathogen reduction given in the preamble was hypothetical and intended to emphasize the potential effectiveness of irradiation against pathogens. This level of reduction would be possible under the

permitted dosages, though costly and probably unnecessary.

Comment: Several commenters requested that FSIS clarify its proposed training requirements for irradiation facility managers and "key personnel." One commenter claimed that existing short courses available in North America are inadequate because they either concern only electron beam irradiation or are too simplistic and argued that "in-house" training should satisfy the intent proposed requirement. Another requested clarification as to who "key personnel" are and suggested that the "key personnel" include the facility manager, QC manager, an external consultant, or corporate management.

Response: FSIS proposed to require establishments that irradiate meat food products to have on file "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," as well as "certification by the operator that the key irradiation personnel have been trained in food technology, irradiation processing, and radiation health and safety." These requirements already are in effect for poultry establishments.

The intent of the first training requirement is to ensure that supervisors of irradiation facilities gain an understanding about the process controls necessary when irradiating food, as well as the requirements set forth in FSIS regulations. FSIS is aware of numerous irradiation facilities that plan to irradiate meat food and poultry products, but that have previously irradiated only medical devices and other non-food products. Supervisors of such establishments certainly need and would benefit from food irradiation training.

The second training requirement is intended to ensure that "key" personnel in an establishment also have instruction in the safe and proper operation of an irradiation facility. Key personnel would include managers, supervisors, or other personnel of the facility who monitor or control daily operations. Key personnel must be knowledgeable about the environmental safeguards and worker safety precautions necessary in any irradiation facility and required by other Federal and State agencies. FSIS is revising § 424.22(c)(3)(vi) to clarify the term "key irradiation personnel."

FSIS is aware of several available food irradiation training courses, but does not intend to review or endorse any specific training course. Further, FSIS

agrees that in-house training in food irradiation or radiation safety could be adequate to meet the requirements. FSIS will verify that establishments have records confirming that the required training was received by the establishment personnel.

Comment: One irradiator objected to proposed §§ (318.11(b)(6) and 381.149(b)(6) which appear to prescriptively specify minimum dosimeter placements. They suggested FSIS instead allow for statistically based validation and dose mapping to determine the number and placement of dosimeters.

Response: FSIS agrees and will revise the requirement in § 424.22(c)(2)(vi) accordingly. FSIS recommends that establishments consult some of the various technical guides on dosimetry when developing their systems. The American Society for Testing and Materials and the International Consultative Group on Food Irradiation both have published guides on food irradiation dosimetry.

Comment: Another irradiator asked that FSIS revise proposed §§ 318.11(b)(7) and 381.149(b)(7) to account for dosimetry from machine sources of radiation.

Response: The proposed provisions (a single provision in this final rule, § 424.22(c)(2)(vii)) did account for machine sources of irradiation in that they required establishments to have in place "Procedures for verifying the relationship of absorbed dose as measured by the dosimeter to time exposure of the product unit to the radiation source." The radiation source could be a machine source of radiation, such as an electron beam accelerator. This requirement remains unchanged.

Comment: One commenter suggested that establishments employing irradiation be exempted from pathogen reduction (*Salmonella*) and process control microbial testing (generic *E. coli*) requirements for raw meat food and poultry products. This commenter argued that irradiation will reduce pathogens to immeasurable levels and testing would therefore be unnecessary. The commenter also maintained that such an exemption would bring about cost savings to industry in excess of \$100 million.

Response: FSIS disagrees. The microbial testing requirements are still necessary for measuring an establishment's performance in process control and pathogen reduction, even if an establishment irradiates its product. Establishments may irradiate product at any point in their processing system, including before the required testing for *Salmonella* or generic *E. coli*. Irradiation

of raw product before testing could not only significantly improve a single establishment's performance, but also could lower the national baselines, compelling improvements in process control and pathogen reduction by all establishments. Although rescission of these testing requirements (or any regulatory requirements, for that matter) might result in cost savings to the regulated industry, FSIS has determined that these requirements are a necessary and cost-effective means for improving the safety of meat food and poultry products.

Costs and Benefits of Irradiation

Comment: A few commenters recommended revisions to the Agency's cost/benefit and economic impact analyses in the proposal. One commenter questioned FSIS's estimate of the cost of shipping irradiated products, arguing that the Agency underestimated the costs by an order of magnitude. Several commenters maintained that the required labeling would be perceived by consumers as a warning and, as discussed, would prevent the wide-scale acceptance of irradiated product. Many of these commenters argued that labeling should be voluntary, since demand for irradiated products would create adequate incentives for labeling.

Response: FSIS addresses the comments and reviews the submitted cost data below in the economic impact analyses.

Summary of the Final Rule

FSIS is amending its regulations to provide for irradiation of uncooked meat food and poultry products under the following conditions:

- Meat food products may be treated with ionizing irradiation, for purposes of reducing pathogens and extending shelf-life, at dosages up to 4.5 kiloGrays (kGy), if refrigerated, and 7 kGy, if frozen.

- Establishments may irradiate meat food and poultry products only in accordance with a HACCP system.

- Establishments that irradiate meat food products must have in place a dosimetry system to measure the absorbed dose of radiation.

- Establishments that irradiate meat food products must have on file documents that relate to other compliance with the requirements of Federal Agencies with jurisdiction over irradiation, such as NRC and OSHA.

- Labeling of meat food and poultry products irradiated in their entirety must bear the international radura logo. Also, either the product name must include the word "Irradiated" or the

labeling must bear a disclosure statement such as "Treated with radiation" or "Treated by irradiation." The logo must be placed in conjunction with the disclosure statement, if the disclosure statement is used. The radiation disclosure statement is not required to be more prominent than the declaration of ingredients.

- The inclusion of irradiated meat food or poultry product in a multi-ingredient product must be reflected in the ingredient statement on the finished product labeling.

- Optional labeling statements about the purpose for radiation processing may be included on the product label in addition to the above stated requirements. Statements that there has been a specific reduction in microbial pathogens must be substantiated by processing documentation.

- The regulations governing the irradiation of poultry products are now entirely consistent with the regulations governing the irradiation of meat food products but for the maximum dosage allowed (3 kGy) and the requirement that if packaged poultry product is irradiated, that packaging must be air permeable.

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 final 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) and from the FSIS Internet world wide web page at <http://www.fsis.usda.gov/OA/topics/irrad-risk.htm>.

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

Executive Order 12988

This final rule has been reviewed under Executive Order 12988, Civil Justice Reform. States and local jurisdictions are preempted by the Federal Meat Inspection Act (FMIA) and the Poultry Products Inspection Act (PPIA) from imposing any marking, 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 the PPIA. States and local jurisdictions may, however, exercise concurrent jurisdiction over meat and poultry products that are within their jurisdiction and 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 rule is not intended to have retroactive effect.

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

Compliance With Executive Order 12866—Final 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.

FSIS is amending 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 revising the existing regulations governing the irradiation of poultry so as to render them more consistent with the proposed regulations for meat. In the proposal preceding this final action, FSIS requested comment concerning the potential economic effects of the proposed regulations, as well as data concerning the costs of and benefits from irradiation of meat and poultry. FSIS received only a few comments that included economic data or questioned the economic analysis included in the proposal. These comments are addressed below.

FSIS believes that the net benefits of this action will be positive. As discussed in the preamble, irradiation can reduce the levels of pathogens in meat food and poultry products significantly. Further, the use of irradiation is voluntary. If an 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. However, the current lack of quantification of both the benefits and costs of irradiation make comparison difficult.

FSIS endeavors to develop regulations 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 proposed requirements that allow for significant flexibility in integrating irradiation into processing operations. In this final rule, FSIS has been able to provide for even greater flexibility through revisions based upon the comments received in response to proposal.

Although FSIS recognizes the capability of irradiation treatment to reduce pathogens below current regulatory performance standards for pathogen reduction, these regulations do not change the existing performance standards. With standards unchanged, the primary benefit of the regulations to

establishments is the increased processing 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 the proposed regulation: (1) Not allowing for the irradiation of meat food products and (2) allowing the irradiation of meat food products only under very limited conditions, similar to those previously prescribed for the irradiation of poultry products. FSIS rejected these two alternatives for reasons explained below.

FSIS did not consider alternatives that would not be permissible under current FDA regulations, such as allowing irradiation at higher doses or allowing the irradiation of ready-to-eat meat and poultry products. FSIS believes that the regulations in this final rule are the most permissive possible under current FDA regulations. Also, as explained in the preamble above, FSIS has petitioned FDA to raise the allowable absorbed dosage for poultry, to remove certain requirements regarding the packaging for irradiated poultry, and to specifically allow the irradiation of unrefrigerated ("hot-boned") meat food products. Further, an industry consortium has petitioned FDA to allow the irradiation of processed meat and poultry products.

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 provide for the irradiation of meat food products and has rejected the option of disallowing irradiation.

Notably, the irradiation of meat food products is 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 previous requirements governing the irradiation of poultry were fairly prescriptive in that they mandated a minimum dosage and required 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 previous requirements mandating minimum dosages and packaging for irradiated poultry products, originally intended to ensure that the effects of irradiation were maintained, are no longer necessary in light of the new HACCP requirements. Therefore, FSIS is making final no minimum irradiation dose and no specific packaging requirements for meat food products, rescinding the minimum dose requirements for irradiated poultry, and revising the packaging requirements for poultry, where possible.

Benefits

FSIS has concluded that the meat industry may accrue numerous benefits from the use of irradiation. As with other antimicrobial treatments, FSIS is allowing irradiation to be used at any point within a HACCP system and is requiring no minimum dosage. Establishments employing irradiation may accrue benefits from this flexibility. 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.

Further, through the use of irradiation, product shelf-life can be increased. Andrews, *et al.* (1998), reviewed five studies encompassing shelf lives of different types of red meat products.³ Their results suggest that shelf life of products treated with irradiation increase considerably compared to untreated products.

Society also may realize benefits from these final regulations if the use of irradiation results in a reduction of illnesses beyond what is achieved by current technologies. Several types of harmful 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 allowed by this action can reduce the levels of these pathogens substantially. Economic benefits associated with these

reductions would be decreases in the diseases associated with these pathogens. The reductions in the disease rates would translate into a reduction in the number of visits to physicians and hospitals.

FSIS believes that ground beef is likely to be the first meat product irradiated in great quantity. It is likely that ground beef will be irradiated in relatively large quantities initially because irradiation is a means for establishments to effectively eliminate *E. coli* O157:H7 from raw ground beef without cooking it. 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. Until now, establishments could distribute ground beef containing *E. coli* O157:H7 only after they had thoroughly cooked it, so as to eliminate the pathogen. Establishments, therefore, are likely to benefit from the availability of irradiation as an additional treatment for rendering adulterated raw ground beef product safe. Of course, other types of raw meat and poultry products also may be irradiated to reduce or eliminate pathogens.

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, a USDA Economic Research Service 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. In that study, Morrison, *et al.* (1997), estimated the annual pre-HACCP economic value of the health costs and productivity losses attributable to *E. coli* O157:H7 and salmonellosis to be between \$226 and \$552 million.⁴ If 25 percent of all ground beef were irradiated, the benefits could range between \$56.5 and \$138 million.

An assumption that only 25% of ground beef will be irradiated may be 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.⁵ 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."

One consumer advocacy organization requested clarification regarding FSIS use of the estimates of benefits from Morrison (1997). The group questioned whether Morrison assumed that ground beef would be irradiated only after final packaging, as was required for poultry irradiated at the time of the study. The group suggested that if Morrison made such an assumption, the estimated reductions in foodborne illness would be inflated if applied to the proposed regulations, which allow ground beef to be irradiated before final packaging. The group claimed that because the ground beef could be re-contaminated after irradiation and before final packaging, reductions in pathogens and consequently, foodborne illness, would not be so high.

FSIS disagrees. Morrison did not specify whether their estimates of benefits applied only to ground beef irradiated in its final packaging. However, FSIS is allowing meat and poultry product to be irradiated only in accordance with a HACCP system of process controls, regardless of when it is packaged. HACCP controls will considerably lessen, and likely prevent, the possibility that meat and poultry product will be re-contaminated after irradiation and before packaging. Therefore, these estimates of reductions in foodborne illness are applicable to these final regulations.

Another commenter suggested that the proposed labeling requirements could prevent the wide-scale acceptance of irradiated products by consumers, who will view the required labeling as a warning, and therefore diminish the potential benefits from reductions in foodborne illnesses. This commenter suggested the use of voluntary instead of mandatory labeling and argued that demand for irradiated product will give producers and retailers incentive to disclose that their products were irradiated.

As discussed above, disclosure of facts material to food products is required by the FMIA, PPIA, and the FFDC. Irradiation can affect food in a manner that is not obvious to consumers in the absence of labeling and therefore is a material fact that must be disclosed to consumers to prevent misleading labeling. FSIS is requiring that irradiation of meat or poultry products be disclosed in product labeling. FSIS will consider, however, revising some or all of its labeling requirements as consumer awareness grows.

FSIS has made some revisions to the proposed labeling requirements that

⁴ Morrison, R.M., *et al.*, "Irradiating Ground Beef to Enhance Food Safety," *Food Review*, January-April 1997, pp. 33-37.

⁵ American Meat Institute Foundation, "Consumer Awareness, Knowledge, and Acceptance of Food Irradiation," November, 1993.

³ Andrews, L.S., *et al.* "Food Preservation Using Ionizing Radiation," *Review of Environmental Contaminant Toxicology*, Vol. 154, 1998, pp. 1-53.

will increase flexibility for processors and could represent some minimal cost savings. First, FSIS is requiring that single ingredient meat or poultry products irradiated in their entirety be labeled with a radura and either a statement indicating that the product was irradiated or the inclusion of the word "irradiated" in the product name. Allowing establishments to use the word "irradiated" as part of the product name instead of including a labeling statement was suggested in industry comments as a means of providing more labeling flexibility.

Also, in response to comments and as part of an effort to make FSIS labeling requirements more consistent with those of FDA, FSIS will not require, as proposed, that the irradiation statement and the radura be any more prominent than the ingredients statement on the labeling of irradiated meat food and poultry products. Thus, the statement and the radura may appear somewhere other than on the principal display panel.

Finally, the same commenter estimated the annual net social welfare gains from irradiation, without HACCP, to be \$900 million, *i.e.*, almost ten times the benefits presented above. This higher estimate of benefits was based on an assumption that demand for irradiated ground beef would be similar to the potential demand for irradiated poultry as estimated by Fox and Olson (1998) from market surveys conducted between 1995 and 1996.⁶ FSIS views this comment as further evidence that there could be benefits in excess of the health costs savings estimated by Morrison (1997).

Incremental Costs

In the proposed rule, using estimates from Morrison (1997) and other sources, FSIS estimated the incremental costs of irradiation to range from 2 to 6 cents/lb. of ground beef in 1995 dollars. These estimates included the cost of labels and of transportation of the ground beef products from establishments to third-party irradiators. Assuming that 25 percent of the total annual sales of ground beef (1.75 billion lbs.) would be irradiated, FSIS estimated the annual cost of irradiation to range from \$35 to \$105 million in 1995 dollars.

These costs are likely to be overestimated for two reasons. First, the cost estimates are based on the assumption that irradiation of ground beef would take place in the smallest plants, which have the capacity to

irradiate only 52 million pounds per year. Second, FSIS assumed that only 25 percent of ground beef would be irradiated. Any increase in the irradiated quantity would tend to reduce costs considerably.

Buzby and Morrison⁷ (1999) recently published updated cost estimates for ground beef for irradiation. They employed two estimates of costs, 1.6 cents/lb. and 5.0 cents/lb. in 1996 dollars. Again assuming that 25 percent of ground beef would be irradiated, they estimated that the costs of irradiation would range from \$28.6 million to \$89.3 million. Their new estimates fall within the range of costs estimated by FSIS in the proposed rule.

In the analysis included with the proposal, FSIS assumed the costs of transporting ground beef from slaughter houses or processing plants to and from irradiating facilities to be 0.2 cents/lb. A commenter suggested that this estimate was "too low by more than one order of magnitude." In response to this comment, FSIS recalculated the transportation costs to be twice the amount originally estimated, that is 0.4 cents/lb. instead of 0.2 cents/lb. This assumption would increase the irradiation costs to range from 2.2 to 6.2 cents/lb. FSIS believes that these possible cost increases are too small to significantly decrease the net benefits of meat irradiation.

In conclusion, although FSIS has incomplete data regarding the costs and benefits of the rule, FSIS believes that the net benefits of this action will be positive. As discussed above, irradiation can reduce the levels of pathogens in meat food and poultry products significantly. Further, the meat industry may accrue numerous benefits from the use of irradiation.

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 final rule will 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 will not be affected adversely by the irradiation requirements because the use of irradiation is voluntary.

The industry may 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 of these products would reduce demand by only 0.3611 percent.⁸

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.⁹ An increase in price of any one 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 the long term, small establishments may have to irradiate 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. However, FSIS believes that eventually technological innovations may reduce the cost of in-plant accelerators and that the increased availability of such devices could help small firms compete with the larger firms.

This final rule may 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

⁸ Huang, Kao S., *A Complete System of U.S. Demand for Food*, ERS Technical Bulletin No. 1821, 1993, p. 24.

⁹ Hahn, 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.

⁶ Fox, John A. and Dennis G. Olson, "Market Trials of Irradiated Chicken," *Radiation Physical Chemistry*, 52 (1–6), 1998, pp. 63–66.

⁷ Buzby, Jean C. and Rosanna M. Morrison, "Food Irradiation—An Update" *Food Review*, May–August 1999, p. 21–22.

that these entities purchase irradiated meat products, they could be affected somewhat by an increase in price.

Finally, FSIS is revising the regulatory requirements concerning the irradiation of poultry for consistency with HACCP and with the requirements proposed for meat food products. Significantly, FSIS is eliminating 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.

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

This rule allows 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 regulations should generally benefit consumers and the regulated industry. The 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 rule does 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 are 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 ensures 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.

Public Notification and Request for Data

FSIS requests information regarding the impact of this final rule on minorities, women, and persons with disabilities, including information on the number of minority-owned meat and poultry establishments, the makeup of establishment workforces, and the communities served by official establishments.

Public involvement in all segments of rulemaking and policy development are important. FSIS provides a weekly FSIS Constituent Update, which is communicated via fax to over 300 organizations and individuals. In addition, the update is available on line through the FSIS web page located at <http://www.fsis.usda.gov>. The update is used to provide information regarding FSIS policies, procedures, regulations, **Federal Register** notices, FSIS public meetings, recalls, and any other types of information that could affect or would be of interest to our constituents/ stakeholders. The constituent fax list consists of industry, trade, and farm groups, consumer interest groups, allied health professionals, scientific professionals, and other individuals that have requested to be included. Through these various channels, FSIS is able to provide information to a much broader, more diverse audience. For more information and to be added to the constituent fax list, fax your request to the Congressional and Public Affairs Office, at (202) 720-5704.

Paperwork Requirements

In response to comments and as part of an effort to make FSIS labeling requirements more consistent with those of FDA, FSIS will not require, as proposed, that the irradiation statement and the radura be any more prominent than the ingredients statement on the labeling of irradiated meat food and poultry products. Thus, the statement and the radura may appear somewhere other than on the principal display panel. Because of this change the 2-hour label development that FSIS included in the original paperwork analysis has been decreased to 1 hour. This change will decrease the overall burden estimate by 100 hours. Therefore, FSIS resubmitted an information collection

request to OMB requesting approval for 2,601 burden hours, not 2,701.

The Office of Management and Budget (OMB) has approved the reporting and recordkeeping requirements associated with this final rule under OMB control number 0582-0115.

List of Subjects

9 CFR Part 381

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

9 CFR Part 424

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

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

PART 381—POULTRY PRODUCTS INSPECTION REGULATIONS

1. 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]

2. Section 381.19 is removed.

§ 381.135 [Removed]

3. Section 381.135 is removed.

4. In § 424.22, paragraph (c) is added to read as follows:

§ 424.22 Certain other permitted uses.

* * * * *

(c) Irradiation of meat food and poultry products.

(1) *General requirements.* Meat food and poultry products may be treated to reduce foodborne pathogens and to extend product shelf-life by the use of sources of ionizing radiation as identified in 21 CFR 179.26(a). Official establishments must irradiate meat food and poultry products in accordance with 21 CFR 179.26(b), the Hazard Analysis and Critical Control Point (HACCP) system requirements in part 417 of this chapter, and the provisions of this section.

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

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

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

(iii) 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.

(iv) 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.

(v) 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).

(vi) Procedures for verifying routine dosimetry, i.e., assuring each production lot receives the total absorbed dose. Establishments may either position one dosimeter 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 in each production lot or use statistically based validation and dose mapping to determine the number and placement of dosimeters in each production lot.

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

(viii) 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.

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

(i) 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.

(ii) Documentation that the machine radiation source irradiation facility is registered with the appropriate State government, if applicable.

(iii) Documentation that a worker safety program addressing OSHA regulations (29 CFR chapter XVII) is in place.

(iv) 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.

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

(vi) A certification by the operator that the key irradiation personnel, who monitor or control daily operations, have been trained in food technology, irradiation processing, and radiation health and safety.

(vii) 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.*).

(4) *Labeling.*

(i) The labels on packages of meat food and poultry products irradiated in their entirety, in conformance with this section and with 21 CFR 179.26(a) and (b), must bear the logo shown at the end of this paragraph (c)(4)(i). Unless the word "Irradiated" is part of the product name, labels also must bear a statement such as "Treated with radiation" or "Treated by irradiation." The logo must be placed in conjunction with the required statement, if the statement is used. The statement is not required to be more prominent than the declaration of ingredients required under § 317.2(c)(2). Any label bearing the logo or any wording of explanation with respect to this logo must be approved as required by Section 317.4. of this chapter or subparts M and N of part 381.



(ii) For meat food or poultry products that have been irradiated in their entirety, but that are not sold in packages, the required logo must 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. Unless the word "Irradiated" is part of the product name, the labeling counter sign, card, or other device also must bear a statement such as "Treated with radiation" or "Treated by irradiation." The logo must be placed in conjunction with the required statement, if the statement is used.

(iii) The inclusion of an irradiated meat food or poultry product ingredient in any multi-ingredient meat food or poultry product must be reflected in the ingredient statement on the finished product labeling.

(iv) 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, provided that such statements are not false or misleading. Statements that there has been a specific reduction in microbial pathogens must be substantiated by processing documentation.

Done in Washington, DC, on December 13, 1999.

Thomas J. Billy,
Administrator.

[FR Doc. 99-32660 Filed 12-22-99; 8:45 am]

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