compliance would be highly speculative and essentially be a requirement that FDA perform a worst-case analysis when evaluating the potential environmental impact of an agency action. This is simply not what NEPA requires (see *Robertson* v. *Methow Valley Citizens Council*, 490 U.S. 332, 355 (1989)).

Importantly, the poultry final rule, in and of itself, does not permit any additional building or operation of irradiation facilities, and thus, does not directly result in any increased risk of accidents at such facilities. Before an irradiation facility is built, other regulatory agencies with oversight regarding its site design, location, licensing, and radiation control procedures (such as the NRC) must issue permits. The evaluation of the environmental impact of the construction and operation of these facilities is, under NEPA, the responsibility of the licensing agency or agencies. FDA's environmental evaluation in this case, and thereby FDA's FONSI, was not intended to reassess the environmental impact issues that are the responsibility of other regulatory agencies. In fact, under NEPA, an agency is not required to assess the environmental impact of a portion of a project where a second agency has jurisdiction over such portion (see *State of N.C.* v. *City of Virginia Beach*, 951 F.2d 596 (4th Cir. 1991)).

Accordingly, even if there have been accidents at irradiation facilities, or even if there would be an increased risk of such accidents as a result of the poultry final rule, these facts have no bearing on FDA's EA of its action. Thus, FDA is denying a hearing on this issue because a hearing will not be granted on factual issues that are not determinative with respect to the action requested (§ 12.24(b)(4)).

d. *Alleged contradiction*. FWI also objects to FDA's FONSI on the grounds of an alleged contradiction between information in FSIS's EA and other FSIS documents and cites an article from *The Food and Drug Letter* (April 28, 1989) in support of its objection. According to FWI, FSIS declared in its EA that alternatives to irradiation need not be discussed when considering the environmental impact of the technology and yet, in the article in *The Food and Drug Letter*, did not mention irradiation as one of the research areas for potentially solving the bacterial problem.

The material cited by FWI does not support its contention. In preparing an EA, petitioners are required, under § 25.31a(a)(11), to consider alternatives to the proposed action if potential adverse environmental impacts have been identified for the proposed action (§ 25.31a(a)(11)). After evaluating the FSIS' EA, the agency found that irradiation of poultry in compliance with existing laws and regulations will not lead to a significant impact on the environment. Because no adverse impacts are expected, the agency did not require, and FSIS did not address, alternatives to the proposed action under format item 11 of the EA. It should also be noted that, contrary to FWI's contention, FSIS did not claim in its EA that irradiation is the only solution to food-borne pathogens.

The article referred to by FWI from *The Food and Drug Letter* discusses areas identified by FSIS for future research for potential solutions to the problem of microbial contamination in poultry; at that time, irradiation had already been a subject of research as a potential solution to this problem. Thus, there is no contradiction between the statements made by FSIS in its EA and in the article in *The Food and Drug Letter*.

In order to justify a hearing on this issue, FWI would need to provide credible evidence that challenges FDA's conclusion that the irradiation of poultry in compliance with existing regulations will not lead to a significant impact on the environment (see § 12.24(b)(2)). FWI has not done so and, thus, has failed to meet a threshold burden of tendering evidence that suggests a need for a hearing (*Costle* v. *Pacific Legal Foundation*, *supra*, 445 U.S. at 214).

V. Summary and Conclusions

The safety of poultry irradiated at up to 3 kGy has been thoroughly tested and the data have been reviewed by the agency. As discussed previously, FDA concluded that the available studies establish the safety of poultry irradiated at doses up to 3 kGy for human consumption.

The petitioner has the burden to demonstrate safety before FDA can approve the use of a food additive. Nevertheless, once the agency makes a finding of safety in an approval document, the burden shifts to an objector, who must come forward with evidence that calls into question FDA's conclusion (*American Cyanamid Co.* v. *FDA*, 606 F2d. 1307, 1314–1315 (D.C. Cir. 1979)).

None of those objecting to the final rule has identified any information in the record that was misconstrued by FDA to support the objector's claim that the agency incorrectly concluded that consumption of poultry irradiated at up to 3 kGy is safe. Nor has any objector established that the agency overlooked significant information in reaching its conclusion. Indeed, none of the objections presented any relevant evidence that has not already been carefully reviewed and weighed by the agency. The agency has determined that the objections do not raise any genuine and substantial issue of fact that would justify an evidentiary hearing on any of the objections raised (§ 12.24(b)). Accordingly, FDA is overruling the objections and is denying the requests for a hearing. In addition, FWI's request for a stay of the effectiveness of the May 2, 1990, regulation until a hearing is held is moot because FDA is denying all hearing requests.

FDA is confirming May 2, 1990, as the effective date of the regulation.

VI. Reference

The following reference has been placed on display in the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. FDA, Bureau of Foods, ''Toxicological Principles for the Safety Assessment of Direct Food Additives and Color Additives Used in Food,'' Appendix III, p. 18, 1982.

Dated: November 26, 1997.

Michael A. Friedman

Lead Deputy Commissiner for the Food and Drug Administration.

[FR Doc. 97–31739 Filed 12–2–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 179

[Docket No. 94F–0289]

Irradiation in the Production, Processing and Handling of Food

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the safe use of a source of radiation to treat refrigerated or frozen uncooked meat, meat byproducts, and certain meat food products to control foodborne pathogens and extend product shelf-life. This action is in response to a petition filed by Isomedix, Inc.

DATES: Effective December 3, 1997; written objections and requests for a hearing by January 2, 1998.

ADDRESSES: Submit written objections to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Patricia A. Hansen, Center for Food Safety and Applied Nutrition (HFS–206), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3093.

SUPPLEMENTARY INFORMATION:

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I. Introduction

In a notice published in the **Federal Register** of August 25, 1994 (59 FR 43848), FDA announced that a food additive petition (FAP 4M4428) had been filed by Isomedix, Inc., 11 Apollo Dr., Whippany, NJ 07891, proposing that part 179 *Irradiation in the Production, Processing and Handling of Food* (21 CFR part 179) be amended to provide for the safe use of a source of radiation to treat the fresh or frozen raw edible tissue of domesticated mammalian human food sources for purposes of reduction of parasites and microbial pathogens, and extension of product shelf-life.

Several letters, from members of academia and from a trade group, were received in response to the filing of the petition. The letters urged FDA to approve irradiation of beef and other meats, and expressed the belief that the use of irradiation could benefit public health and improve the safety of meat by controlling foodborne pathogens. Because the letters expressed general support for the agency's action, but provided no substantive information, these comments will not be addressed further.

The comments illustrate, however, a heightened public awareness of the health threat posed by pathogens in or on meat. Among these, *Escherichia coli* O157:H7, *Salmonella* sp., and *Clostridium perfringens* are of primary concern from a public health standpoint; *E. coli* O157:H7 because of the severity of the illness associated with the organism, and *Salmonella* and *C. perfringens* because of the high number of outbreaks and individual cases of foodborne illness associated with these pathogens (Refs. 1 and 2).[1]

Although proper handling practices and cooking to recommended internal temperatures are effective interventions in preventing foodborne illness associated with meat products, much effort has gone into the development of other interventions aimed at reducing microbial pathogens. Irradiation has been proposed as one such additional tool.

The subject petition requests that FDA amend the food additive regulations to authorize the use 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 also specifies that the proposed foods are to be ''primarily from bovine, ovine, porcine, and equine sources.'' The petition requests that a maximum dose of 4.5 kiloGray (kGy) be established for the irradiation of fresh (chilled, not frozen) meat, and that a maximum dose of 7.0 kGy be established for the irradiation of frozen meat.

In this final rule, FDA is adding refrigerated and frozen uncooked meat, meat byproducts (e.g., edible organs such as the liver and the kidneys) and certain meat food products (e.g., ground beef and hamburger) to the list of foods that are authorized (under § 179.26(b)) for treatment with ionizing radiation. In addition, FDA is establishing 4.5 kGy as the maximum permitted dose for irradiation of refrigerated meat, meat byproducts, and certain meat food products; and 7.0 kGy as the maximum permitted dose for irradiation of frozen meat, meat byproducts and certain meat food products.

The foods that are set forth in the regulation below are all subject to the Federal Meat Inspection Act (21 U.S.C. 601, *et seq.*), and are defined by the U.S. Department of Agriculture/Food Safety and Inspection Service (USDA/FSIS) in title 9 of the Code of Federal Regulations. These foods include meat, as defined by USDA/FSIS in 9 CFR 301.2(rr),[2] meat byproducts, as defined by USDA/FSIS in 9 CFR 301.2(tt),[3] and certain meat food products[4] from among those defined by USDA/FSIS in 9 CFR 301.2(uu).

In the text of this document, the term ''meat'' will be used to refer collectively to meat, meat byproducts, and applicable meat food products. When, in the text of this document, the discussion is also applicable to foods that might, in common usage, be referred to as a meat or as a type of meat (e.g., chicken, turkey, or fish), but that

[1] *E. coli* O157:H7 causes hemorrhagic colitis, a severe illness, the symptoms of which include high fever, vomiting, and bloody diarrhea, with consequent dehydration. In patients with weakened or immature immune systems, the infection can progress to hemolytic uremic syndrome (HUS), a life-threatening kidney disease with a mortality rate of 6 percent (Ref. 3). The number of outbreaks in the United States reported to be associated with *E. coli* O157:H7 has increased from 4 in 1992 to 30 in 1994; *E. coli* O157:H7 has been estimated to cause more than 20,000 infections and 250 deaths each year (Ref. 4).

Salmonella sp. are a leading reported cause of foodborne bacterial diseases (Ref. 5) and have been reported to be associated with 48 percent of beef-related outbreaks (Ref. 2). *C. perfringens* is also an important agent of foodborne microbial disease, with a projected incidence of 652,000 cases and 7.6 deaths per year. During 1973 to 1987, beef accounted for 30 percent of all *C. perfringens* type A food poisoning outbreaks (Ref. 6).

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

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

[3] *Meat byproduct.* Any part capable of use as human food, other than meat, which has been derived from one or more cattle, sheep, swine, or goats. This term, as applied to products of equines, shall have a meaning comparable to that provided in this paragraph with respect to cattle, sheep, swine, and goats.

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

do not conform to the definitions of meat, meat byproducts, or meat food products in title 9 of the Code of Regulations, the term ''flesh food(s)'' will be used instead.

II. Evaluation of Safety

Under section 201(s) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 321(s)), a source of radiation used to treat food is defined as a food additive:

> * * * 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) * * *.

Under section 409(c)(3)(A) of the act (21 U.S.C. 348(c)(3)(A)), a food additive cannot be approved for a particular use unless a fair evaluation of the evidence establishes that the additive is safe for that use. The concept of safety embodied in the Food Additives Amendment of 1958 (the Amendment) is explained in the legislative history of the provision: ''Safety requires proof of a reasonable certainty that no harm will result from the proposed use of the additive. It does not—and cannot—require proof beyond any possible doubt that no harm will result under any conceivable circumstance'' (H. Rept. 2284, 85th Cong., 2d sess. 4 (1958)). This concept of safety has been incorporated into FDA's food additive regulations (21 CFR 170.3(i)).

The legislative history of the Amendment clearly reflects that Congress recognized that it is impossible to establish with complete certainty the absolute harmlessness of any chemical substance. The concept of safety contained in the Amendment has, as its focus, the reduction of uncertainty about the safety of an additive to the point where the agency can reasonably conclude that no harm will result from its proposed use.

The statute does not prescribe the safety tests to be performed but leaves that determination to the discretion and scientific expertise of FDA. Not all food additives require the same amount or type of testing. The amount and type of testing required to establish the safety of an additive will vary depending on the particular additive and its intended use.

In this particular case, the additive is not, literally, added to food. Instead, a source of radiation is used to process or treat food such that, analogous to other food processes, its use can affect the characteristics of the food. In the subject petition, the intended technical effect is a change in the microbial load of the food, specifically, a reduction in the numbers of microorganisms, both pathogenic and nonpathogenic, in or on meat. It is important to realize, however, that the petitioner is not required to show, nor is FDA permitted to consider, that irradiation of meat has benefits, health or otherwise, for consumers of irradiated meat. The legislative history of the Amendment is clear on this point:

> The question of whether an additive produces such [a technical] effect (or how much of an additive is required for such an effect) is a factual one, and does not involve any judgement on the part of the Secretary whether such effect results in any added 'value' to the consumer of such food or enhances the marketability from a merchandising point of view.

S. Rept. 2422, 85th Cong., 2d sess. 7 (1958). Accord: H. Rept. 2284, 85th Cong., 2d sess. 6 (1958)

Thus, in evaluating the safety of a source of radiation to treat meat intended for human consumption, FDA cannot consider the possible benefits to consumers or to food processors. Instead, the agency must identify the various effects that can result from irradiating this food and assess whether any of these effects may pose a human health risk. In this regard, three areas of concern need to be addressed: potential toxicity, nutritional adequacy, and potential microbiological risk. Each of these areas is discussed in detail in section III of this document.

III. Evaluation of Safety of the Petitioned Use of a Source of Radiation

The petitioner submitted a large number of published articles and other study reports containing data and information in the areas of radiation chemistry,[5] dietary consumption patterns, toxicology, nutrition, and microbiology. FDA has reviewed the data and studies submitted in the petition, as well as other information in its files relevant to the safety and nutritional adequacy of meat treated with ionizing radiation. Specifically, the agency evaluated information concerning:

1. Studies of the radiation chemistry of food components and whole foods, including chemical analyses of irradiated flesh foods.

2. Toxicity studies of flesh foods, including studies of irradiated beef, pork, horse meat, chicken, and fish.

3. Studies of nutrient levels in, and information regarding dietary consumption patterns of, irradiated flesh foods.

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

A. General Framework

To determine whether the use of a food additive is safe, FDA typically considers the chemical identity and amount of the additive that will be ingested in light of what is known regarding its toxicity. In the case of substances added directly to food, the agency estimates the amount of the additive that will be ingested from the proposed use levels of the additive in particular foods or food types along with consideration of consumption patterns of those foods. Information about the chemical structure of an additive and an assessment of the likely consumption levels of the additive, together with information obtained from toxicological testing, forms the basis for evaluating safety.

In the case of food irradiation, the effects of this form of processing on the characteristics of the treated foods are a direct result of the chemical reactions induced by the absorbed radiation. Research has established that the types and amounts of products generated by radiation-induced chemical reactions (hereinafter referred to as ''radiolytic products'') depend on the chemical constituents of the food and on the conditions of irradiation. Information regarding the chemical structures and the amounts of radiolytic products in particular food types, together with the information obtained from toxicological testing, forms a sound basis for evaluating the toxicological safety of an irradiated food.

In the case of food irradiation, the nutritional adequacy and the microbiological safety of the treated foods must also be evaluated. Research has shown that the principles of radiation chemistry govern the extent of changes both in the nutrient levels and in the microbial load of irradiated foods. Key factors include the specific nutrient or microorganism of interest, the food, and the conditions of irradiation.

[5] The term ''radiation chemistry'' refers to the chemical reactions that occur as a result of the absorption of ionizing radiation. Like all chemical reactions, these radiation-induced reactions depend on the nature of the reactants and on the energy supplied to the system. In the context of food irradiation, the radiation-induced reactions depend on the chemical constituents of the food and such factors as the ambient atmosphere (which also contains potential reactants), the physical state of the food, the ambient temperature, and the radiation dose. Radiation-induced chemical reactions can affect the detailed chemical composition of the food and the cellular components of the microorganisms in or on the food.

B. Radiation Chemistry

Scientists have compiled an enormous body of data regarding the effects of ionizing radiation on different foods under various conditions of irradiation. Because of the complexity in the composition of any food and the large numbers of specific radiation-induced reactions that can occur, the agency will limit its discussion here to the broad principles that are applicable to this decision.[6] These broad principles provide the basis for extrapolation and generalization from data obtained in specific foods irradiated under specific conditions to draw conclusions regarding foods of a similar type irradiated under different, yet related, conditions.

1. Factors Affecting the Radiation Chemistry of Foods

Apart from the chemical composition of the food itself, the factors, or irradiation conditions, that are most important in considering the radiation chemistry of a given food include the radiation dose, the physical state of the food (e.g., the solid or frozen versus the liquid or nonfrozen state), and the ambient atmosphere (air, reduced oxygen, vacuum, etc.).

With respect to dose, the amounts of radiolytic products generated in a particular food have been shown to be directly proportional to the radiation dose (Refs. 7, 8, and 9). Thus, it is entirely sound to extrapolate from data obtained at high radiation doses to draw conclusions regarding the amounts of radiolytic products expected to be generated at lower doses.

The radiation chemistry of food is also strongly influenced by the physical state of the food. If all other conditions, including dose and ambient atmosphere, are the same, the extent of chemical change that occurs in a particular food in the frozen state is less than the change that occurs in the same food in the nonfrozen state. This is a result of the reduced mobility, in the frozen state, of the initial products of irradiation (free radicals, which are highly energetic, unstable molecules). Because of their reduced mobility, these free radicals tend to recombine to form the original substance rather than to diffuse through the food to react with other components of the food matrix and thereby form different substances (Refs. 9 and 10). Thus, both the types and the amounts of radiolytic products are affected by the physical state of the food, and, for a given food, higher radiation doses are needed to effect the same degree of chemical change in frozen versus nonfrozen food. Higher radiation doses are also needed to accomplish the same antimicrobial technical effect in a frozen food versus a nonfrozen food of the same type.

The formation of radiolytic products in a given food is also affected by the ambient atmosphere. Irradiation in an atmosphere of high oxygen content generally produces both a greater variety, and greater amounts, of radiolytic products in the food than would be produced in an atmosphere of lower oxygen content. This is because irradiation initiates certain oxidation reactions, reactions that occur with greater frequency in foods with high fat content (Refs. 11 and 12). The final products of radiation-induced oxidation reactions in foods are similar to those produced by oxidation reactions induced by other processes (e.g., storage or heating in air).

In general, the types of products generated by irradiation are similar to those produced by other food processing methods. Radiation-induced chemical changes, if sufficiently large, however, may cause changes in the organoleptic properties of the food. Because food processors wish to avoid undesirable effects on taste, odor, color, or texture, there is an incentive to minimize the extent of these chemical changes in the food. Thus, irradiation is often conducted under reduced oxygen levels or on food in the frozen state.

2. Radiation Chemistry of the Major Components of Flesh Foods

The major components of all foods are water, carbohydrates, proteins, and lipids. Flesh foods, as a group, have very little carbohydrate content, and are comprised primarily of water, proteins, and lipids. The radiation chemistry of these components is well established.

In foods of relatively high water content, such as flesh foods, free radicals produced by radiolysis of water form the majority of the initial products of the radiation-induced chemical reactions. These free radicals, in turn, react with the other components of the food to form the final, stable, radiolytic products.

With respect to proteins, several types of reactions can occur as a result of irradiation. One type of reaction is the breaking of a small number of peptide bonds to form polypeptides of shorter length than the original protein (Refs. 13 and 14).[7] Radiation-induced aggregation or cross-linking of individual polypeptide chains can also occur; these processes result in protein denaturation (Refs. 13 through 16). In irradiated flesh foods, most of the radiolytic products derived from proteins have the same chemical composition but are altered in their secondary and tertiary structures. These changes are similar to those that occur as a result of heating, but in the case of irradiation, such changes are far less pronounced and the amounts of reaction products generated are far lower.

A third type of reaction that can occur when proteins are irradiated involves the reaction of amino acids in the polypeptide chain with the free radicals produced from water, without the breaking of peptide bonds (Refs. 17 and 18). The compounds produced by such reactions, like the other radiolytic products derived from proteins, are similar or identical to those found in foods that have not been irradiated. The radiolytic products resulting from this third type of reaction occur in very small amounts; various studies have established that there is little change in the amino acid composition of flesh foods irradiated at doses below 50 kGy (Refs. 19 and 20), a dose approximately seven times greater than the highest dose set forth in the regulation below.

The radiation chemistry of lipids (fats) is also well established.[8] Numerous studies have been performed with various oils and fats and also on the lipid fraction of irradiated foods (see, e.g., Refs. 21 through 25). A variety of radiolytic products derived from lipids have been identified, including fatty acids, esters, aldehydes, ketones, alkanes, alkenes, and other hydrocarbons (Refs. 7, 22, 23, 25, and 26a through 26c).[9] All of these types of

[6] Several books provide more detailed discussions of radiation chemistry with references to the large number of original research studies, particularly in the area of food irradiation. Sources that can be consulted for further information include, but are not limited to: *Radiation Chemistry of Major Food Components*, edited by P. S. Elias and A. J. Cohen, Elsevier, Amsterdam, 1977; *Recent Advances in Food Irradiation*, edited by P. S. Elias and A. J. Cohen, Elsevier, Amsterdam, 1983; and Diehl, J. F., ''Chemical Effects of Ionizing Radiation,'' Ch. 3 in *Safety of Irradiated Foods*, Marcel Dekker, New York, 1995.

[7] Proteins are composed of amino acids joined by peptide bonds. The characteristic sequence of amino acids in a particular protein is known as the primary structure. The extent and nature of the coiling or pleating of different segments of the protein is known as the secondary structure. The three dimensional shape of the coiled or pleated protein is known as the tertiary structure. Denaturation refers to structural changes that result in a loss of biological properties; these are usually changes in the secondary or tertiary structures.

[8] The fat in meat is composed primarily of triglycerides, each molecule of which contains three fatty acids. The predominant fatty acids in the triglycerides of flesh foods are oleic, palmitic, linoleic, and stearic acid.

[9] One major effort to determine whether radiolytic products in a flesh food presented any risk to human health is described in a report entitled ''Evaluation of the Health Aspects of Certain Compounds Found in Irradiated Beef,'' prepared by the Life Sciences Research Office of the Federation

compounds are also found in foods that have not been irradiated. These types of compounds are also produced by heating foods, and, in the case of heating, are produced in amounts far higher than the trace amounts that result from irradiating foods (Refs. 23 and 27).

In summary, the results obtained from chemical analyses of irradiated flesh foods establish that there would be very small amounts of individual radiolytic products generated by radiation doses comparable to those proposed in the petition. In addition, most of these radiolytic products are either the same as, or structurally very similar to, compounds found in foods that have not been irradiated. Because of their structural similarities to compounds found in foods that have not been irradiated, these radiolytic products would be expected to be toxicologically similar to such compounds as well. Thus, the available information regarding the radiation chemistry of the major components of flesh foods supports the proposition that there is no reason to suspect a toxicological hazard due to consumption of an irradiated flesh food.

3. Flesh Foods as a Generic Class

As noted above, flesh foods are comprised primarily of water, proteins, and lipids.[10] While the proportions of the individual amino acids in the proteins and the individual fatty acids in the lipid fraction vary somewhat among the different flesh foods, the same chemical components provide the basis for any chemical reactions in flesh foods caused by the absorption of ionizing radiation. Because of this, the same compounds (in slightly varying proportions) will constitute the majority of radiolytic products in all irradiated flesh foods.

The large number of studies on the radiation chemistry of food and food components, taken together, support this conclusion regarding commonality in the chemistry and predictability of the types and amounts of radiolytic products (see, e.g., Refs. 14, 18, and 30). Accordingly, it is scientifically sound to generalize from the data obtained in studies of a variety of specific irradiated flesh foods to draw conclusions regarding the irradiation of flesh foods as a class (Ref. 30). Because of the foregoing, FDA has determined that, to evaluate the safety of foods that are the subject of this petition (i.e., meat and meat byproducts as defined in 9 CFR 301.2(rr) and (tt), and certain meat food products from among those defined in 9 CFR 301.2(uu)), it is entirely appropriate to consider the available data from all flesh foods, irradiated under a variety of conditions. Details of the agency's analysis are presented below.

C. Toxicological Considerations

As discussed previously, all of the available information from the results of chemical analyses suggests that there is no reason to suspect a toxicological hazard due to consumption of an irradiated food. However, while chemical analyses have not identified the presence of any particular radiolytic products in amounts that would raise a toxicological concern, the agency notes that the large body of data from studies where irradiated flesh foods were fed to laboratory animals provides an independent way to assess toxicological safety. Thus, the agency has also examined all the available data from toxicological studies that are relevant to the safety of irradiated meat, namely, all of those with flesh foods.

This includes the data relied on by the agency in its previous evaluation of the safety of poultry irradiated at doses up to 3 kGy (discussed in the **Federal Register** of May 2, 1990 (55 FR 18538)), as well as additional data in FDA files from studies of irradiated meat, poultry, and fish. The agency's analysis incorporates the principle that toxicological data collected from studies on foods irradiated at high doses can be applied to the toxicological evaluation of foods of the same generic class receiving lower doses (Refs. 14 and 30). The agency's analysis also takes into account the known effects of other conditions of irradiation, such as the physical state of the food and the ambient atmosphere, to compare the results of different studies. A summary of that analysis is presented below.

1. Toxicity Studies of Flesh Foods Relied Upon by FDA in Previous Safety Evaluations

In the early 1980's, as part of a regulatory initiative on irradiation of minor dry ingredients (e.g., spices and seasonings) and foods irradiated at low doses, the agency conducted a review of all toxicological studies of irradiated foods that were available at that time. In order to come to timely closure on that rulemaking, the agency limited its analysis to whether individual studies could stand alone to support a safety decision and to whether the studies showed any evidence of toxicity attributable to irradiation. The agency found no evidence of toxicity that could be attributed to irradiation of food and amended its regulations to authorize the use of irradiation on foods at low doses (no greater than 1 kGy) and on minor dry ingredients at doses no greater than 30 kGy (51 FR 13376 at 13378, April 18, 1986).

However, FDA concluded that it could not, at that time, expand approval to higher doses for foods other than minor dry ingredients because most of the individual studies had limitations in design or conduct. The agency did not attempt to determine whether the available toxicological studies, taken as a whole, could complement each other and thus compensate for weaknesses in any individual study or whether additional information could be obtained to supplement the available reports. In addition, FDA had not, at that time, assessed the nutritional and microbiological ramifications of irradiating major dietary components at doses above 1 kGy.

Although, as noted, many of the animal feeding studies were not fully adequate by modern toxicology standards, the agency found that several studies were fully adequate in design and conduct and could stand alone in support of safety. One of these studies examined the effects of feeding an irradiated flesh food to animals; specifically, rats were fed beef stew or evaporated milk, each food irradiated at 27.9 and 55.8 kGy (51 FR 13376 at

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of American Societies for Experimental Biology under contract with the U.S. Army (''the FASEB/LSRO report'' and supplements, Refs. 26a through 26c).

This report presented the results of chemical analyses performed on frozen beef irradiated under vacuum at a dose of 56 kGy. Sixty-five volatile radiolytic products were identified, most of which originated from the lipid fraction. This study established that these 65 radiolytic products were either identical or structurally similar to substances found in foods that have not been irradiated, and that these individual radiolytic products were produced in very small amounts (generally 1 to 700 parts per billion of irradiated beef), even at a radiation dose eight times higher than the highest dose requested in the petition.

[10] The proximate composition of flesh foods does not vary widely. Beef and lamb, for example, are composed of approximately 17 to 20 percent protein, 15 to 25 percent fat, and 56 to 65 percent water, depending on the cut. Chicken, depending on the cut and whether the skin is included, is approximately 18 to 25 percent protein, 5 to 19 percent fat, and 57 to 75 percent water. Fish, depending on the species, is approximately 16 to 27 percent protein, 1 to 20 percent fat, and 60 to 75 percent water.

The predominant fatty acids in the triglycerides of flesh foods are oleic, palmitic, linoleic, and stearic acid. The saturated fatty acids (palmitic and stearic acid) contribute approximately 8 to 12 percent of the fat content in both beef and lamb. The fat in chicken (skin on) and pork is composed of approximately 2 to 9 percent saturated fatty acids. The amino acid content of flesh foods also does not vary widely. In beef, pork, lamb, and chicken, tryptophan contributes the smallest weight percentage and lysine the greatest weight percentage to the amino acid content (see Refs. 28 and 29).

13384).[11] The data showed that no treatment-related adverse effects were observed with either irradiated food.

Subsequent to the agency's review of all animal feeding studies, discussed above, FDA further evaluated a series of feeding studies of irradiated poultry, obtaining additional information on some of the studies and analyzing the results in greater detail.[12] The agency has previously discussed the findings of, and its conclusions regarding, these studies in its decision authorizing the irradiation of poultry at doses no greater than 3 kGy (55 FR 18538, May 2, 1990).[13] Briefly, the agency concluded that three animal feeding studies of high quality (a multigeneration study in rats, a chronic study in rats, and a 1-year study in beagle dogs), in which chicken was irradiated at 3 or 6 kGy and administered at a level of 35 percent of the diet, showed no evidence of adverse toxicological effects attributable to irradiation (55 FR 18538 at 18539 and 18540). At that time, the agency also reviewed all other toxicity data on irradiated poultry and found the results to be consistent with a conclusion that irradiated poultry does not present a toxicological hazard.[14]

[11] Although the agency cited this as one study, it would be more accurately described as one report where the results of two chronic feeding studies of irradiated beef stew, one in rats and one in dogs, and two chronic studies of irradiated evaporated milk, also one in rats and one in dogs, were described. The two studies in rats were fully accepted by the agency. The two studies in dogs were not fully accepted in the agency's early review solely because of the small number of animals used.

[12] The earlier review had not fully accepted some of these studies because the reports did not contain a complete discussion of all relevant details. In addition, FDA had not fully addressed the possible significance of the use of an antioxidant to prevent rancidity from developing during drying of the meat for storage. The agency subsequently concluded that the studies were acceptable after receiving additional information from the laboratory, and after determining that the antioxidant could not have changed the effects due to irradiation because it was added after the chicken was irradiated (see 55 FR 18538 at 18539 and 18540).

[13] Following publication of the final rule, FDA received several letters and two submissions within the 30-day objection period. The submissions sought revocation of the final rule and requested a hearing. Elsewhere in this issue of the **Federal Register**, FDA is denying the objections and requests for a hearing because they do not raise issues of material fact that justify a hearing or otherwise provide a basis for revoking the final rule.

[14] The agency evaluated several other studies in which animals were fed radiation-sterilized chicken and one in which mice were fed chicken irradiated at 7 kGy. No treatment-related adverse effects were seen in any of these studies (55 FR 18538 at 18540). However, because, in the studies of radiation-sterilized chicken, the conditions of irradiation were different from what would be used in commerce under the regulation sought by the petitioner, and because of deficiencies in the data from the study of chicken irradiated at 7 kGy, FDA did not rely explicitly on these studies.

In summary, the agency has previously found that the following toxicological studies of irradiated flesh foods, tested in fully adequate animal feeding studies, demonstrated no adverse health effects that could be attributed to irradiation: beef (as a component of stew) irradiated at doses of 27.9 and 55.8 kGy and tested in a chronic study in rats; chicken irradiated at doses of 3 kGy and 6 kGy and tested in a three generation reproduction study in rats, a chronic study in rats, and a 1-year study in dogs.

2. Additional Analyses of Toxicity Data

In 1980, a Joint FAO/IAEA/WHO Expert Committee[15] concluded that irradiation of any food commodity at an average dose of up to 10 kGy presents no toxicological hazard (Ref. 31). Based in part on the Expert Committee's conclusion regarding the absence of toxicological hazard (as well as conclusions on the nutritional adequacy and microbiological safety of irradiated foods), the Codex Alimentarius Commission (Codex), in 1984, recommended that member nations adopt the Codex finding that the ''wholesomeness of foods irradiated so as to have absorbed an overall average dose of up to 10 kGy, is not impaired'' (Ref. 32). FDA did not adopt the Codex recommendation in its 1986 rulemaking because, as noted, it had not yet analyzed the issues of nutritional adequacy and microbiological safety in a sufficiently comprehensive way and had not pursued the analysis of toxicity data beyond the examination of individual studies.

Subsequently, WHO, at the request of one of its member States, conducted a new review and analysis of the safety data on irradiated food (Ref. 33). WHO considered the extent to which data on one food type can be extrapolated to other foods and the extent to which individual studies of irradiated foods can be integrated into one large database to be evaluated as a whole, as opposed to separate evaluations of a series of individual studies.

This review included all the studies in FDA's files that the agency considered as reasonably complete, as well as those studies that appeared to be acceptable but had deficiencies interfering with interpretation of the data (see 51 FR 13376 at 13378). The WHO review also included data from USDA and from the Federal Research Centre for Nutrition at Karlsruhe, Germany. WHO explicitly documented, in detail, the data relied on for its conclusion that the integrated toxicological database is sufficiently sensitive to evaluate safety and that no adverse toxicological effects due to irradiation were observed in the dose ranges tested (Ref. 33).

[15] FAO is the Food and Agriculture Organization of the United Nations, IAEA is the International Atomic Energy Agency, and WHO is the World Health Organization.

FDA has previously reviewed the individual studies that are cited in the WHO report and found no evidence of toxicity attributable to irradiation. FDA has now also reexamined these studies to determine whether the integrated toxicological database derived from this body of work, together with the information regarding radiation-induced chemical changes, establishes the toxicological safety of meat irradiated under the conditions set forth in the regulation below.

FDA finds that, while many of these studies cannot individually establish safety,[16] they still provide important information that, evaluated collectively, supports a conclusion that there is no reason to believe that irradiation of flesh foods presents a toxicological hazard (Refs. 34a and 34b). The overwhelming majority of studies reported no adverse toxicological effects due to consumption of irradiated flesh foods; equally important, the few effects observed were not reproduced in other studies.[17] In addition, FDA notes that many of the feeding studies were conducted using flesh foods irradiated at doses far higher than those proposed in the petition, providing some exaggeration in terms of the amounts of radiolytic products consumed.

Details regarding the important features of both WHO's and FDA's recent analyses are presented below. FDA has evaluated all relevant data to ensure that any potential evidence of toxicity would not be overlooked. However, because of the large number of studies in the total database, this document focuses on the types of

[16] For example, the number of animals used in many of the early studies is smaller than that commonly used today. Complete histopathology was not always done or reported. For some studies, the data are available only in brief summary form.

[17] If the radiolytic products in flesh foods irradiated under test conditions were of any toxicological significance, consistent effects, particularly in those tests where the foods were irradiated at comparable doses and under comparable conditions, should have been observed. It is also important to note that at the time many of these studies were conducted, scientists did not fully understand the nutritional ramifications of modifying an animal's diet by feeding it large amounts of foods not normally consumed by laboratory animals. The few adverse effects observed in certain of the studies are consistent with what one could expect based on the nutritional composition of the test diet (Refs. 33 and 35).

studies of irradiated flesh foods that provide the greatest opportunity for detecting a treatment-related effect rather than attempting an exhaustive discussion of all the available studies.[18] In addition, this document concentrates on those studies that were conducted at radiation doses greater than, or comparable to, the doses requested in the subject petition.

3. Chronic Feeding Studies

Both FDA and WHO evaluated chronic studies in which various flesh foods, irradiated at doses ranging from 6 to 74 kGy, were fed to animals (Ref. 36). These include those studies, discussed previously, on which FDA has relied in previous safety evaluations of irradiated foods. The studies in which no adverse effects were reported include the following: (1) Studies in which rats were fed beef irradiated at 56 kGy; pork at 56 kGy; chicken at 6 kGy; fish at 6 kGy; horse meat at 6.5 kGy; fish at 56 kGy; beef stew at 56 kGy; a mixture of beef, pork, fish, and other foods at 28 kGy; pork brain and egg at 93 kGy; and pork at 74 kGy; (2) studies in which mice were fed chicken irradiated at 59 kGy; bacon and bacon fat at 56 kGy; chicken at 7 kGy; fish and beef at 56 kGy; pork brain and egg at 93 kGy; and pork and chicken at 56 kGy; and (3) studies in which dogs were fed chicken irradiated at 59 kGy; chicken, beef, and jam at 56 kGy; bacon and cabbage at 56 kGy, beef at 56 kGy; and chicken at 6 kGy.

In addition to the studies listed above, four chronic studies reported observations that merit further discussion. FDA has concluded that the effects reported in these four studies were either not attributable to irradiation or were otherwise not of toxicological significance.

In one study (Ref. 37), weanling rats fed a mixture of radiation-sterilized (56 kGy) chicken stew and irradiated (6 kGy) cabbage for 19 days were reported to have reduced levels of alkaline phosphatase in duodenal tissue. However, this effect was not seen in weanling rats fed either (but not both) radiation-sterilized chicken stew or irradiated cabbage for 19 days and was not seen in other rats that were fed the irradiated chicken stew/cabbage mixture for 150 days. Additionally, no adverse histopathological findings that would indicate a toxic effect were reported. FDA concludes that the observed decrease in alkaline phosphatase levels in weanlings is not of toxicological significance for three reasons: (1) The effect observed in weanling rats was not observed in rats maintained on the same diet into adulthood, (2) the effect was not reproduced when either of the two irradiated foods was fed individually, and (3) no other reported observations indicate a toxic effect (Ref. 38).

In a second study (Ref. 39), a diet composed of a mixture of nine foods, including bacon, beef, ham, and fish was radiation-sterilized (56 kGy) and fed to rats. This study reported a decreased weight gain for third generation females, but not for males. FDA has concluded that this effect cannot be attributed to irradiation because it was accompanied by breeding problems that significantly reduced the sizes of the groups of rats fed the control diet as well as the groups of rats fed the irradiated diet, an observation that is indicative of overall dietary deficiencies unrelated to radiation treatment (Ref. 35).

A third study (Ref. 40) reported a significant increase in heart lesions (auricular dilatations) in mice fed radiation-sterilized (56 kGy) pork and chicken. FDA has determined that this effect cannot be attributed to the irradiated flesh foods because a replicate study with nearly 5,000 mice of the same strains showed no such lesions. (Refs. 34a and 38).

Finally, a chronic study in dogs fed irradiated (8 kGy) soft shell clams reported a decrease in blood urea nitrogen (BUN) in the males but not in the females (Ref. 41). FDA has concluded that the decreased BUN levels in this study were not of toxicological significance for the following reasons. FDA notes that, while an elevated BUN level could be a sign of kidney malfunction (urea is a metabolite of protein excreted by the kidney), a decrease in BUN level may simply indicate less protein consumed. No significant findings were reported, however, with respect to clinical chemistry parameters other than BUN levels, or in the histopathological examinations. Moreover, given that the normal range of BUN levels in dogs is quite wide, the observed decrease in BUN level is likely to represent an artifact of the low statistical power of the study and is not of toxicological significance (Ref. 38).

In summary, a large number of chronic feeding studies have been conducted in rats, mice, and dogs with flesh foods irradiated at doses between 6 and 74 kGy. In these studies, no toxic effects that can be attributed to radiation treatment were consistently observed.

4. Reproduction and Teratology Studies

FDA has also reviewed the following reproduction/teratology studies (Ref. 42) in which flesh foods, irradiated at doses of 6 kGy or higher, were fed to laboratory animals: (1) Studies in which rats were fed pork irradiated at 56 kGy; chicken and green beans irradiated at 59 kGy; and fish irradiated at 6 kGy (two separate studies with fish); (2) a multigeneration reproduction study and a teratology study in which mice were fed chicken irradiated at 59 kGy and 45 kGy, respectively; (3) two studies in which dogs were fed beef irradiated at 56 kGy; (4) a study in which hamsters were fed chicken irradiated at 45 kGy; and (5) a study in which rabbits were fed chicken irradiated at 45 kGy.

All of these studies, except one, showed no adverse effects. In one of the two studies in which fish irradiated at 6 kGy was fed to rats (''the Shillinger study,'' Ref. 43), rats in the treated group were reported to have an increased incidence of testicular atrophy and prolonged estrous cycles, among other findings. The authors reported no significant difference between experimental and control groups with regard to such standard indices of reproductive function as time of first births, fertility index, number of offspring in the litter, or weight of offspring at birth or at 1 month of age. In addition, no toxic effects on the growth or development of three generations were reported. The authors stated that some of the findings point to a protein deficiency.[19] However, the second reproduction study with fish irradiated at the same dose (''the Hickman study,'' Ref. 44) reported no adverse effects. FDA has concluded that the effects reported in the Shillinger study are not attributable to irradiation for three reasons: (1) The irradiated fish was stored under inappropriate conditions, (2) the results of measurements of blood protein levels

[18] Chronic toxicity studies and reproductive toxicity studies are generally considered to be the most sensitive tools for detecting treatment-related toxicological effects when there is no basis, *a priori*, to expect a particular adverse effect. This is because treatment over the lifetime of the animal in a chronic study allows the longest time for a subtle effect to be manifested, and because the developing organism in reproduction and teratology studies can be particularly sensitive to toxic effects.

[19] Although the irradiated fish was not irradiated at a sterilizing dose or treated to inactivate enzymes that could lead to decomposition, it was stored under refrigeration for up to 2 months. Fish fed to the control group, however, was stored frozen until incorporated into the diet. Irradiated fish, stored under refrigeration, had greater opportunity to undergo decomposition or other spoilage before consumption. The authors did not report addition of vitamins or minerals to the diets and did not report actual nutrient levels in the diet. The authors also reported a higher incidence of pneumonia and parasitic infections in the treated group, varying blood and liver enzyme activities in the different generations, and a lower albumin/globulin ratio (a sign of protein deficiency) in the treated group.

are consistent with a nutritionally inadequate diet, and (3) similar effects were not seen in the Hickman study.

In summary, the agency concludes that the available studies of irradiated flesh foods show no adverse effects on reproductive or developmental endpoints that can be attributed to radiation treatment.

5. Genetic Toxicity Studies

Although chronic feeding studies are the primary basis for assessing potential carcinogenicity of a substance, genetic toxicity tests are often used to screen for possible carcinogenic effects. A large variety of genetic toxicity studies with irradiated chicken, ham, beef, or fish have been conducted (Ref. 45). All of these studies report that no genotoxic effects were observed. FDA agrees that these studies demonstrate that irradiated flesh foods are not genotoxic.

6. Summary of the Toxicological Assessment

As noted previously, chemical analyses and toxicity studies provide independent means for assessing whether there is a reasonable certainty that irradiation of meat will not present a toxicological hazard. Chemical analyses are used to identify substances produced by irradiation that might present a risk. Animal feeding studies and genetic toxicity studies are used to determine whether toxicants may be present in irradiated foods, even if not identified, at levels that would be harmful.

The agency has carefully reviewed the data and information submitted in the petition. The agency has also considered all the available data and studies in its files regarding the radiation-induced chemical changes in flesh foods and the toxicological effects of irradiated meat and other irradiated flesh foods (e.g., chicken and fish) when consumed in the diet.

All the available results of chemical analyses of irradiated flesh foods support the conclusion that a toxicological hazard due to consumption of irradiated flesh foods is highly unlikely, because no substance resulting from irradiation has been found at levels that would suggest any reason for toxicological concern. The results of the available toxicological studies of irradiated flesh foods also demonstrate that a toxicological hazard is highly unlikely because no toxicologically significant adverse effects attributable to consumption of irradiated flesh foods were observed in any of these studies. Thus, the results of the chemical analyses and the toxicological studies are entirely consistent. The agency therefore concludes, based on all the evidence before it, that irradiation of meat under the conditions set forth in the regulation does not present a toxicological hazard.

D. Nutritional Considerations

The nutritional adequacy of an irradiated food may be affected by radiation-induced reductions in the amounts of essential nutrients in the food. FDA has carefully reviewed the data and information submitted in the petition, as well as other information in its files, to determine whether irradiation would have an adverse effect on the nutritional value of meat.

1. Nutrients in Meat

Flesh foods are consumed primarily as sources of protein. The so-called ''red meats,'' beef in particular, are also rich sources of iron and phosphorus. Flesh foods, including red meats, also contribute significantly to the dietary intake of B vitamins, except for thiamine.

Most individual flesh foods, including meats, provide only a minor portion of the dietary intake of thiamine (Ref. 46). The exception to this rule is pork, which contributes approximately 9 percent of the thiamine in the American diet (Refs. 46 and 47). The largest contributors to thiamine intake in the human diet, however, are grains in various foods (e.g., cereals; flour in bread, other baked goods, and pasta) and legumes.

2. Effects of Irradiation on the Nutrients in Meat

It is well known that the nutrient value of the macronutrients in the diet (proteins, fats, and carbohydrates) is not significantly altered by irradiation at the petitioned doses (Refs. 19, 48, and 49). Minerals (e.g., iron, phosphorus, and calcium) are also unaffected by irradiation (Refs. 48 and 49).

Levels of certain vitamins may be reduced, however, as a result of irradiation. The extent to which this occurs depends on the specific vitamin, the food type, and the conditions of irradiation. Not all vitamin loss is significant, however. The extent to which a reduction in a specific vitamin level is significant depends on the relative contribution from the food in question to the dietary intake of the vitamin.

Most of the nutrition-related studies submitted in the petition presented analyses of vitamin levels in irradiated flesh foods. These studies covered a wide range of foods, vitamins, and irradiation conditions. Most of these studies focused on the levels of B vitamins because, as noted, meats and certain edible organs (e.g., the liver and the heart) are better sources of B vitamins than of other vitamins, such as vitamins C or D, for example. For the same reason, FDA's evaluation of the nutritional adequacy of irradiated meat and meat byproducts, which considered all relevant vitamins, focused on the effects of irradiation on the levels of B vitamins. In FDA's evaluation, thiamine levels received particular attention because thiamine is one of the vitamins most susceptible to radiation (Refs. 46 and 50).

In general, the available studies have reported insignificant effects on the levels of B vitamins other than thiamine when flesh foods were irradiated at dose levels comparable to those proposed in the subject petition (Refs. 50, 51, and 52). For example, pork irradiated at a dose of 6.7 kGy showed no detectable loss in cobalamin level and, when irradiated at 5 kGy, showed no detectable loss in niacin level (''the first Fox study,'' Ref. 47). Similar results have been obtained in studies of the effects of irradiation on other B vitamins such as pyridoxine and pantothenic acid (Ref. 52).

Another recently conducted study by Fox et al., (''the second Fox study,'' Ref. 53) compared radiation-induced reductions in B vitamin levels in beef, lamb, pork, and turkey, all of which were irradiated at 5 °C in the presence of oxygen, conditions which would tend to maximize vitamin loss. The authors reported that, even under such conditions, losses of riboflavin resulting from irradiation were virtually undetectable at radiation doses up to 3 kGy and that the losses did not differ significantly among the various flesh foods. The average incremental loss of riboflavin at radiation doses above 3 kGy was reported to be 2.5 percent per kGy, which was judged by the authors as insignificant. FDA agrees that this reduction in riboflavin is insignificant in the context of the total diet (Refs. 46 and 51).

Losses in thiamine levels resulting from irradiation were also measured in the second Fox study. Thiamine losses were detectable at all irradiation doses tested and differed among the flesh foods tested, but the range was fairly narrow: from a low of 8 percent loss per kGy in lamb to a high of 16 percent loss per kGy in beef. The incremental thiamine loss in pork was approximately 11 percent per kGy above 3 kGy when irradiated at 5 °C in the presence of oxygen. These results were consistent with the results of the first Fox study in which pork irradiated at 4.5 kGy at 0 °C (frozen) sustained losses

in thiamine levels of circa (ca.) 40 percent (Ref. 47).

Other studies of the effect of irradiation on thiamine levels in flesh foods, conducted under a variety of irradiation conditions, show losses ranging from approximately 10 to 50 percent over a dose range of 0.6 to 7.3 kGy (Refs. 46, 52, 54, and 55), which is comparable to the dose range that could, in actual practice, be used under the limitations set forth in the regulation. It is important to note that the highest thiamine losses (ca. 50 percent for some, but not all, flesh foods) have occurred when foods were irradiated at the higher doses in this range (ca. 7 kGy), in the nonfrozen state, and/or in the presence of oxygen.

Irradiation of meat is likely to be carried out on products that are in prepackaged form. Meat is commonly packaged under vacuum or reduced oxygen levels at the wholesale level and stored and shipped either refrigerated or frozen (Ref. 2). As discussed previously, irradiation of food in the frozen state (or at reduced temperatures) and under reduced oxygen levels tends to minimize vitamin losses (Ref. 48). Thus, irradiation of most meat, which is likely to be carried out in an atmosphere of reduced oxygen content and at low temperature or in the frozen state, will tend to result in thiamine losses that are far less than 50 percent.

Nevertheless, the agency has conducted an ''extreme case'' assessment of the potential effect on the dietary intake of thiamine that would result if all flesh foods (i.e., meat, poultry, and fish) were irradiated under conditions that would tend to maximize thiamine loss (i.e., such that thiamine levels in all these foods would be reduced by 50 percent). The agency has determined that even in such extreme and unlikely circumstances, the average thiamine intake would still be above the recommended daily allowance (RDA) and, thus, there would be no deleterious effect on the total dietary intake of thiamine as a result of irradiating flesh foods, including meat (Ref. 46).

3. Summary of the Nutritional Assessment

As discussed, FDA has concluded that the effects of irradiation on thiamine, under the conditions set forth in the regulation below, will not result in an adverse effect on the dietary intake of thiamine. Because the effects of irradiation on B vitamins other than thiamine are far less than the effects on thiamine, FDA also concludes that there will be no deleterious effect on the total dietary intake of these other B vitamins (e.g., riboflavin, niacin, cobalamin). In addition, as noted, irradiation does not affect mineral levels, nor, at the doses set forth in the regulation, the nutritional quality of the protein in meat.

FDA therefore concludes, based on all the evidence before it, that irradiation of meat under the conditions set forth in the regulation below will not have an adverse impact on the nutritional adequacy of a person's diet.

E. Microbiological Considerations

Irradiation at the doses requested in the petition will reduce, but not entirely eliminate, the microorganisms in or on meat. Further, because different microorganisms are affected by irradiation to different degrees, irradiation of meat will change the relative amounts of different microorganisms present (the microbiological profile). The microbiological profile and the storage conditions of meat influence the growth patterns of the various microorganisms found in or on this food. Because microorganisms remaining in food after irradiation processing can multiply, FDA has assessed whether irradiation of meat under the conditions set forth in the regulation is likely to alter the growth patterns of any surviving microorganisms in such a way as to result in an increased microbiological hazard (from increased growth of pathogens) compared to meat that has not been irradiated.

1. Microbiological Profile of Raw Meat

Meat is a nutrient-rich substrate that can support the growth of a variety of microorganisms. During the initial processing steps (e.g., slaughter, skinning, cutting of primals) these microorganisms are diverse. They include a wide variety of nonpathogenic spoilage bacteria, including organisms from the *Pseudomonas-Moraxella-Acinetobacter* group, *Lactobacillus* sp., and others. Pathogenic (illness-causing) microorganisms, including *Salmonella* sp., *E. coli* O157:H7, *Listeria monocytogenes*, *Staphylococcus aureus*, and others, have also been isolated from raw meat, generally at relatively low levels (see Refs. 2, 56, and 57).

Spores[20] of certain other pathogenic microorganisms have been isolated from raw meat as well. The most commonly occurring spores in meat are those of *C. perfringens* (Refs. 2 and 6). Spores of *Clostridium botulinum* have also been isolated from raw meat; the available data indicate that both the incidence and the numbers of *C. botulinum* spores are extremely low (Refs. 58, 59, and 60).

Fungal species (i.e., yeasts and molds) have also been isolated from the surfaces of raw meat, presumably as a result of airborne contamination. Various parasites, including *Toxoplasma gondii* and *Trichinella spiralis*, both of which can cause serious foodborne illness, may also be found in meat.

2. Effects of Irradiation on Microorganisms in or on Meat

The petitioner provided reports and published articles describing the effects of irradiation on the microorganisms in or on flesh foods. These reports and published articles provide data on several microorganisms of relevance, including various species of *Salmonella*; *E. coli* O157:H7; *C. perfringens*; *S. aureus*; *L. monocytogenes*; *Bacillus cereus*; *Campylobacter jejuni*; and the protozoan parasite *T. gondii*. Taken together, the available reports and published articles establish that the radiation dose necessary to reduce the initial population of any of the bacterial pathogens by 90 percent (i.e., the ''D value'') ranges from 0.1 kGy to just under 1 kGy. For any individual pathogen, the D value varies depending on such factors as the specific food, physical state (frozen versus nonfrozen) of the food, temperature, and ambient oxygen level.

The D value for *Salmonella*, for example, ranges from approximately 0.4 kGy to 0.8 kGy, depending on the microbial strain and the other factors mentioned above (Refs. 61, 62, 63, and 64). *E. coli* O157:H7 is more radiation sensitive than *Salmonella*, with a D value range of approximately 0.2 to 0.4 kGy, depending on the type of flesh food and the conditions of irradiation (Refs. 62, 63, and 65). Other studies of a variety of different pathogens in different flesh foods yield comparable results.[21]

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[20] Spores are the so-called ''resting stage'' of certain bacteria in which the bacterial cell becomes enclosed in a tough, resistant coat as a response to adverse environmental conditions. On return to less adverse conditions, the spore can germinate and revert to the normal vegetative form of the organism. Under favorable conditions, the vegetative cells can multiply and, in the case of certain spore-forming bacteria, produce toxin. Growth rates of the vegetative cells are influenced by several factors including temperature, ambient oxygen level, pH, and the size of the spore inoculum (numbers of spores present).

[21] For example, the D values of both *L. monocytogenes* and *S. aureus* fall in the range of 0.40 to 0.48 kGy when irradiated in beef, pork, or lamb at 5 °C (see, e.g., Refs. 62 and 66). *C. jejuni* is more radiation sensitive, with D values in the range of 0.16 to 0.24 kGy depending on the particular meat and the conditions of irradiation (see, e.g., Refs. 63 and 67).

T. gondii tissue cysts are inactivated at a radiation dose of approximately 0.4 kGy (Ref. 68).

D values for the principal nonpathogenic microorganisms (spoilage bacteria) commonly found in or on meat cover a wide range, from approximately 0.3 to 2.0 kGy (Refs. 69, 70, and 71). *Lactobacillus* sp. are among the more radiation-resistant nonpathogenic spoilage bacteria; the D values for these bacteria range from approximately 1 to 2 kGy, depending on the microbial strain and the conditions of irradiation (Ref. 71).

In the case of spore-forming bacteria, the spores and vegetative cells are affected by irradiation to different degrees. Spores are generally more resistant to the effects of radiation than vegetative cells. For example, the D values for vegetative cells of various strains of *C. perfringens* range from 0.6 to 0.8 kGy (Refs. 72 and 73), comparable to the D values for most of the pathogens discussed above, while the D values for the spores of *C. perfringens* range from 1.2 to 1.8 kGy (Ref. 74). The spores of *C. botulinum* are more radiation-resistant; the D values for the spores of various strains of *C. botulinum* range from approximately 2 to 4 kGy (Refs. 60 and 74).

The agency has reviewed the data and information described previously as well as other information in its files and has determined that irradiation at doses of up to 4.5 kGy for refrigerated product and doses of up to 7.0 kGy for frozen product will significantly reduce the number of pathogenic microorganisms in or on meat (Ref. 75). Under the conditions set forth in the regulation below, reductions in *Salmonella* levels, for example, could be approximately 100,000-fold in refrigerated beef irradiated at 4.5 kGy. Because *E. coli* is more sensitive to the effects of irradiation, reductions in the levels of that microorganism would be even greater in beef irradiated under these same conditions. The levels of most spoilage microorganisms on meat will also be significantly reduced at the petitioned doses, resulting in an extension of the shelf-life of the product.

However, while irradiation at the petitioned doses significantly reduces the numbers of many pathogenic and spoilage bacteria, its effect in reducing the numbers of relatively radiation-resistant spores of other pathogenic bacteria (e.g., *C. botulinum*, with D values of approximately 2 to 4 kGy), is less. Therefore, FDA has carefully examined the effects of radiation-induced changes in the microbiological profile of meat on the growth patterns of surviving microorganisms to determine whether the microbiological safety of meat irradiated under the conditions set forth in the regulation would be adversely affected. In FDA's evaluation, *C. botulinum* received particular attention both because *C. botulinum* spores are the most radiation-resistant of the pathogens found in meat and because the illness induced by botulinal toxin is so severe.

3. Growth Patterns of Microorganisms in or on Raw Meat

As noted previously, meat is a substrate that can, in principle, support the growth of a variety of microorganisms. The conditions under which meat is stored (e.g., temperature, ambient atmosphere, pH) influence the growth patterns of different microorganisms, however, affecting both the types and numbers of different microorganisms that are likely to be found in or on meat at any given time.

Meat is chilled and subsequently stored under refrigeration (generally 37 to 45 °F) immediately following the initial processing steps. During cold storage, the predominant microorganisms are the spoilage bacteria, primarily *Pseudomonas* sp., that are capable of growth at these temperatures. If the chilled meat is packaged in an environment of reduced oxygen content, other spoilage bacteria, such as *Lactobacillus* sp., *Brochothrix thermosphacta*, and other lactic acid-producing microorganisms, predominate (Refs. 2 and 56).

The growth of *C. perfringens*, *Salmonella*, and *E. coli* is well controlled by cooling meat quickly after slaughter and maintaining the product at refrigerated temperatures during subsequent transport and storage. None of these pathogens is normally capable of growth in meat stored under refrigeration. In addition, competition with the more numerous and faster-growing spoilage bacteria that predominate at refrigeration temperatures further inhibits the growth of these pathogens. Both *Salmonella* and *E. coli* O157:H7 are capable of significant growth, however, in meat stored above refrigeration temperatures (''temperature abuse'' conditions; above 50 °F). Temperature control is thus a primary tool in reducing the growth of, and consequently, the risk from, these pathogens.

Growth of *C. botulinum* is influenced by several factors in addition to temperature, including the availability of oxygen, pH of the food, and the numbers of *C. botulinum* spores in relation to the types and numbers of competing microorganisms. Temperature control is, however, the single most important factor in controlling the growth of the strains of *C. botulinum* that have been most frequently (albeit still rarely and in low numbers) isolated from meat in the United States (Refs. 59, 60, and 76) In this regard, the same temperature control regimen used to control the growth of other pathogens such as *Salmonella*, *E. coli* O157:H7, and *C. perfringens* also works well to inhibit growth of, and toxin production by, *C. botulinum* in meat. Temperature abuse can lead to growth and toxin production by *C. botulinum*; however, this typically takes several weeks to occur, even at temperatures of approximately 60 °F. By this time, signs of spoilage (e.g., putrid odor, slimy texture), produced primarily by the faster-growing and more numerous nonpathogenic spoilage bacteria, are evident. The objectionable odor and texture of spoiled meat is a signal that typically inhibits consumers from eating the product. Reports of botulism resulting from consumption of such meat are rare and, generally, have been limited to ethnic groups that favor these foods (see Refs. 59, 76, and 77).

In summary, maintaining meat at low storage temperatures is the primary method for controlling the growth of pathogenic microorganisms and, thus, for reducing the risk of disease from pathogenic microorganisms in or on meat.

4. Effects of Irradiation on Growth Patterns of Microorganisms in or on Meat

As noted above, radiation-induced changes in the microbiological profile of meat have the potential to affect the growth patterns of the various microorganisms in or on meat. FDA has evaluated whether irradiation would result in significantly altered microbial growth patterns in meat (e.g., significantly increased growth of pathogens) such that irradiated meat would present an increased microbiological hazard compared to meat that had not been irradiated. The agency has reviewed data and information submitted in the petition, as well as other information in its files, regarding the effects of irradiation, temperature abuse conditions, and ambient oxygen levels on the microbiological profile of meat.

Because *C. botulinum* spores are the most resistant to the effects of irradiation and would thus be more likely to survive irradiation than other pathogens and most spoilage bacteria, and because the illness associated with botulinal toxin is so severe, FDA, in its evaluation, focused particularly on the effects of irradiation on the probability of significantly increased growth of, and subsequent toxin production by, *C. botulinum*.

With respect to most of the significant pathogens found in or on meat, other than *C. botulinum* (e.g., *Salmonella* and *E. coli* O157:H7), FDA concludes that the probability of significant growth of these pathogens in irradiated meat stored under adequate temperature control is extremely remote for two reasons. First, these pathogens typically require temperatures of 50 °F or higher for significant growth. Second, as noted above, most of the pathogens in or on meat are more sensitive to the effects of irradiation than many of the common spoilage microorganisms (e.g., *Lactobacillus*, with D values of 1 to 2 kGy). Because these pathogens are sensitive to the effects of irradiation, FDA expects that irradiation under the conditions set forth in the regulation below will reduce the numbers of these pathogens to a far greater extent than it will reduce the numbers of the faster-growing spoilage microorganisms that compete with, and inhibit the growth of, pathogens at refrigeration temperatures.

Nevertheless, FDA has also considered the effects of temperature abuse on growth of these pathogens (e.g., *Salmonella*, *E. coli* O157:H7, *C. perfringens*) in irradiated meat. In one of the studies submitted in the petition (Ref. 72), pork was packaged and irradiated at 1.75 kGy under a modified atmosphere containing no oxygen following inoculation with high levels of any one of several pathogens. In this study, the authors reported that growth of these pathogens (*Salmonella*, *E. coli*, and *C. perfringens*, among others), was, in fact, decreased by irradiation even when temperature conditions were favorable for growth (approximately 60 °F).

With respect to *C. botulinum*, FDA concludes that the probability for significant growth of, and toxin production by, *C. botulinum* in irradiated meat stored under adequate temperature control (properly refrigerated or frozen) is extremely remote for several reasons. First, as noted, *C. botulinum* spores occur with extremely low frequency and in extremely low numbers in meat; these numbers will be further reduced by irradiation at the petitioned doses. Research has established that the size of the spore inoculum (numbers of spores present in the food) is an important factor in the growth of, and toxin production by, *C. botulinum*; reduced numbers of spores generally result in a decreased probability that growth sufficient for toxin production will occur (Ref. 59).

Second, most strains of *C. botulinum* that have been found in meat do not grow and produce toxin under refrigeration conditions appropriate for transport and storage of flesh foods. The available data show that growth and subsequent toxin production by *C. botulinum* in meat requires significantly elevated temperatures (50 to 55 °F, or higher) (Refs. 59, 60, and 77). Even under reduced ambient oxygen levels (conditions that favor the growth of *C. botulinum*), elevated temperatures are still required for significant growth and toxin production. Irradiation does not enable *C. botulinum* to grow at refrigeration temperatures; elevated temperatures on the order of 50 to 55 °F are required, whether meat is irradiated or not. Nevertheless, the agency has also considered whether, in the absence of temperature control, irradiation could increase the likelihood that *C. botulinum* could grow and produce toxin without the signs of spoilage familiar to the consumer that discourage consumption of spoiled meat.

One study submitted in the petition (Ref. 78) investigated the effect of irradiation, at a dose of 3 kGy, on the patterns of microbial growth and spoilage in vacuum-packaged pork loins stored under conditions of proper refrigeration (2 to 4 °C to simulate wholesale storage, and 5 to 7 °C to simulate retail storage) and under conditions of severe temperature abuse (24 to 25 °C). Shelf-life of pork stored under refrigeration conditions was extended by irradiation. The authors found that both irradiated pork and pork that had not been irradiated spoiled rapidly under conditions of severe temperature abuse and that the same types of microorganisms were responsible for spoilage in both irradiated pork and pork that had not been irradiated. The authors concluded that the concurrent and similar increases that they observed in the numbers of *lactobacilli* and other bacteria in the temperature-abused, vacuum-packaged irradiated pork indicated that sufficient spoilage organisms survived irradiation to bring about spoilage after severe temperature mishandling. FDA concurs in these conclusions (Ref. 77).

In several other studies submitted in the petition (''the Lambert studies,'' Refs. 79a through 79c), pork was packaged and irradiated at a dose of 1 kGy under reduced ambient oxygen levels following inoculation with high levels of *C. botulinum* spores. In these studies, storage at elevated temperatures, equivalent to approximately 60 °F, was required for *C. botulinum* to grow and produce toxin; no toxin was detected in pork stored at approximately 41 °F . The authors concluded that irradiation at 1 kGy significantly delayed toxin production by *C. botulinum* (Refs. 79a and 79b). The authors of these studies also reported that signs of spoilage in the irradiated pork appeared at least 1 week before, and under certain conditions, up to 5 weeks before, toxin was detected (Ref. 79a).

The data and information in the Lambert studies show that even when the levels of *C. botulinum* spore inoculum are high and the ambient oxygen level low (conditions that, as noted, would tend to increase growth and toxin production), toxin production was preceded by signs of spoilage in the irradiated meat. These data also demonstrate that storage at sustained elevated temperatures, for several weeks, are required for growth of, and toxin production by, *C. botulinum* in irradiated pork.

Third, other data and information also show that various species of other microorganisms commonly found on meat, particularly spoilage bacteria (e.g., *Lactobacillus* sp.[22] and others), survive irradiation in sufficient numbers to grow and inhibit growth of, and toxin production by, *C. botulinum* in both refrigerated and temperature-abused irradiated meats (Refs. 71, 80, and 81).

5. Summary of the Microbiological Assessment

FDA has reviewed the data and information submitted in the petition and has considered all the available data and information in its files relevant to an assessment of the microbiological safety of the irradiation of meat. In particular, FDA has carefully examined the effects of radiation-induced changes in the microbiological profile of meat on the growth patterns of any surviving microorganisms, including *C. botulinum*, to determine whether the microbiological safety of meat would be adversely affected by irradiation under the conditions set forth in the regulation below.

As discussed previously in this document, the agency has determined that irradiation of meat and meat byproducts under the conditions set forth in the regulation below will not result in any additional health hazard from *C. botulinum* (Ref. 75). Likewise, as discussed previously, FDA has also determined that irradiation will not result in any additional hazard from common pathogens other than *C. botulinum*. Therefore, the agency concludes, based on all the evidence before it, that irradiation of meat under

[22] In the case of *Lactobacillus*, production of lactic acid, which lowers the pH of the meat, is a contributing factor in inhibiting the growth of various pathogens, including *C. botulinum* (see, e.g., Refs. 59 and 71).

the conditions set forth in the regulation below will not result in a microbiological hazard.

IV. Current Good Manufacturing Practice Considerations

As noted, the proper processing, handling, and storage of meat and meat byproducts, irradiated or not, are necessary to ensure their safety. With respect to the processing and handling of both meat and poultry, USDA/FSIS has recently established specific requirements applicable to meat and poultry establishments designed to reduce the occurrence and numbers of pathogenic microorganisms on meat and poultry products and thus, to reduce the incidence of foodborne illness associated with these products (61 FR 38806, July 25, 1996). Among other things, these new regulations require that each meat and poultry establishment develop and implement written standard operating procedures for sanitation (Sanitation SOP's, SSOP's) and that each establishment also develop and implement a system of preventive controls, known as HACCP (Hazard Analysis and Critical Control Points), which is designed to improve the safety of their products.

FSIS has stated that it intends to use HACCP systems as a framework for the modernization of the meat and poultry inspection system (61 FR 33806). HACCP systems are not intended to replace good manufacturing practices (GMP's), but rather to be used as the basis of an approach to food safety that focuses on hazard prevention and control. HACCP, GMP's, SSOP's, and other tools and interventions all have a place in ensuring the safety of meat. FSIS has stated that it anticipates that the adoption of HACCP systems by the meat industry as a whole will significantly increase the safety of meat products and reduce the risk of foodborne illness (61 FR 33806).

A. Temperature control

As noted previously, proper temperature control is critical in ensuring the safety of meat, meat byproducts, and meat food products, whether or not they are irradiated. FDA's regulations regarding CGMP's (part 110 (21 CFR part 110)) stipulate that the temperature of refrigerated foods not exceed 45 °F (§ 110.80(b)(3)(i)). With respect to meat products specifically, FDA's Model Food Code, which is offered for adoption by States and other government entities that exercise primary regulatory authority over food service, retail food stores, and food vending machine operations, recommends that meat products be stored at 41°F or less. There are no data or other information that suggest that, in order to ensure their safety, irradiated meat products require different temperature controls than meat products that have not been irradiated.

Moreover, FSIS, under its regulatory authority over meat processing plants, can establish specific requirements with respect to temperature control of irradiated meat, meat byproducts, and meat food products.[23] FDA concludes that its regulation should allow for flexibility in this regard. Therefore, the regulation does not establish specific requirements with respect to temperature control of irradiated meat, meat byproducts, and meat food products.

B. Consideration of the Need for Establishment of a Minimum Dose

FDA has established, in § 179.25, general provisions defining CGMP for the use of irradiation in the treatment of food. This regulation discusses requirements such as recordkeeping and the need for a scheduled process for food irradiation. Among other things, § 179.25 also requires that ''Food treated with ionizing radiation shall receive the minimum radiation dose reasonably required to accomplish its intended effect * * *.'' (Section 179.25(b).)

FDA notes that the minimum dose necessary to control pathogenic organisms on food can vary with the particular microorganism, the specific food, and with the microbial load on the food. In its decision to permit the irradiation of poultry at doses up to 3 kGy, FDA explicitly considered these facts and noted that FSIS, based on its regulatory authority over poultry processing plants, could establish a minimum dose, consistent with CGMP, for controlling pathogenic organisms in or on the products processed in such plants. The agency also concluded that FSIS should be free to do so without having to submit a new petition for an amendment to the regulation, as long as any requirements complied with the applicable sections of part 179.

Similarly, with respect to the processing of meat, meat byproducts, and meat food products, FDA is not establishing a minimum required dose. The agency concludes that different doses could be appropriate, in different circumstances, for achieving the desired technical effect and that FDA's regulation should allow for flexibility in this regard. Moreover, FSIS, under its regulatory authority over meat processing plants, can establish a minimum dose, consistent with GMP, for controlling pathogenic organisms in or on the products processed in these plants. FSIS should be free to do so without having to submit a petition for an amendment to FDA's regulation, as long as any FSIS requirements comply with the applicable sections of part 179.

V. Labeling

Meat, meat byproducts, and meat food products are subject to the Federal Meat Inspection Act (21 U.S.C. 601 *et seq.*). Therefore, the labeling of these products irradiated under the conditions set forth in the regulation must comply with any requirements imposed by USDA/FSIS under its authority to approve the labeling of such products.

VI. Conclusion of Safety

FDA has evaluated the data in the petition and other material in its files relevant to the proposed use of a source of radiation to treat meat, meat byproducts, and certain meat food products. Based on all the evidence before it, FDA concludes that irradiation of these products under the conditions set forth in the regulation below will not present a toxicological hazard, will not present a microbiological hazard, and will not adversely affect the nutritional adequacy of such products. Therefore, the agency concludes that irradiation of meat, meat byproducts, and meat food products under the conditions set forth in the regulation below is safe. Accordingly, FDA has determined that part 179 should be amended.

In accordance with § 171.1(h) (21 CFR 171.1(h)), the petition and the documents that FDA considered and relied upon in reaching its decision to approve the petition are available for inspection at the Center for Food Safety and Applied Nutrition by appointment with the listed contact person. As provided in § 171.1(h), the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

[23] In the preamble to the rule that established the new requirement for the development and implementation of HACCP systems in meat and poultry plants, FSIS addressed the need for cooling and chilling requirements for raw meat and poultry. In the final rule, FSIS stated that, with respect to regulation of time and temperature control, it would be best to have, as a performance standard, a maximum temperature for products being shipped into commerce, and at which raw products in commerce must be maintained. This standard would be applicable to all persons who handle such product before the product reaches the consumer. FSIS concluded, however, that development of such a performance standard required the acquisition of additional information, and indicated that it would engage in further rulemaking in this area.

VII. Environmental Impact

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

VIII. Objections

Any person who will be adversely affected by this regulation may at any time on or before January 2, 1998 file with the Dockets Management Branch (address above) written objections thereto. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents shall be submitted and shall be identified with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

IX. References

The following sources are referred to in this document. References marked with an asterisk (*) have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday. References without an asterisk are not on display; they are available as published articles and books.

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List of Subjects in 21 CFR Part 179

Food additives, Food labeling, Food packaging, Radiation protection, Reporting and record keeping requirements, Signs and symbols.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 179 is amended as follows:

PART 179—IRRADIATION IN THE PRODUCTION, PROCESSING AND HANDLING OF FOOD

1. The authority citation for 21 CFR part 179 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 343, 348, 373, 374.

2. Section 179.26 is amended in the table in paragraph (b) by adding a new entry ''8.'' under the headings ''Use'' and ''Limitations'' to read as follows:

§ 179.26 Ionizing radiation for the treatment of food.

* * * * *

(b) * * *

Use	Limitations
* * *	* * * *
8. For control of foodborne pathogens in, and extension of the shelf-life of, refrigerated or frozen, uncooked products that are meat within the meaning of 9 CFR 301.2(rr), meat byproducts within the meaning of 9 CFR 301.2(tt), or meat food products within the meaning of 9 CFR 301.2(uu), with or without nonfluid seasoning, that are otherwise composed solely of intact or ground meat, meat byproducts, or both meat and meat byproducts..	Not to exceed 4.5 kGy maximum for refrigerated products; not to exceed 7.0 kGy maximum for frozen products.

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Dated: November 26, 1997.

Michael A. Friedman,

Lead Deputy Commissioner for the Food and Drug Administration.

[FR Doc. 97–31740 Filed 12–2–97; 8:45 am]

BILLING CODE 4160–01–F