

ionizing radiation source. Accordingly, this final rule should not be construed to be a statement that ionizing radiation used to treat meat, if introduced or delivered for introduction into interstate commerce, would not violate section 301(ll) of the FD&C Act. Furthermore, this language is included in all food additive final rules and therefore, should not be construed to be a statement of the likelihood that section 301(ll) of the FD&C Act applies.

X. References

The following sources are referred to in this document. References marked with an asterisk (*) have been placed on display at the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday, and are available electronically at <http://www.regulations.gov>. References without asterisks are not on display; they are available as published articles and books.

- ionizing radiation source. Accordingly, this final rule should not be construed to be a statement that ionizing radiation used to treat meat, if introduced or delivered for introduction into interstate commerce, would not violate section 301(l) of the FD&C Act. Furthermore, this language is included in all food additive final rules and therefore, should not be construed to be a statement of the likelihood that section 301(l) of the FD&C Act applies.

X. References

The following sources are referred to in this document. References marked with an asterisk (*) have been placed on display at the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday, and are available electronically at <http://www.regulations.gov>. References without asterisks are not on display; they are available as published articles and books.

 - Memorandum for FAP 9M4695 from K. Morehouse, FDA, to L. Highbarger, FDA, dated August 10, 2010.*
 - Diehl, J. F., "Chemical Effects of Ionizing Radiation," pp. 43–88, in *Safety of Irradiated Foods*, Second Edition, Marcel Dekker, Inc., New York, 1995.
 - Elias, P. S. and A. J. Cohen, "Recent Advances in Food Irradiation," Elsevier Biomedical, Amsterdam, 1983.
 - World Health Organization, "High-Dose Irradiation: Wholesomeness of Food Irradiated With Doses Above 10 kGy," World Health Organization Technical Report Series No. 890, pp. 9–37, Geneva, 1999.
 - Preservation of Food by Ionizing Radiation*, edited by E. S. Josephson, and M. S. Peterson, Vol. II, CRC Press, Boca Raton, 1982.
 - Diehl, J. F., "Radiolytic Effects in Foods," pp. 279–357, in *Preservation of Food By Ionizing Radiation*, Vol. I, edited by E. S. Josephson, and M. S. Peterson, CRC Press, Boca Raton, 1982.
 - Crone, A. V. J., *et al.*, "Effect of Storage and Cooking on the Dose Response of 2-Dodecylcyclobutanone, a Potential Marker for Irradiated Chicken," *Journal of the Science of Food and Agriculture*, 58:249–252, 1992.
 - Gadgil, P., K. A. Hachmeister, J. S. Smith, and D. H. Kropf, "2-Alkylcyclobutanones as Irradiation Dose Indicators in Irradiated Ground Beef Patties," *Journal of Agriculture and Food Chemistry*, 50:5746–5750, 2002.
 - Seibersdorf Project Report, International Programme on Irradiation of Fruit and Fruit Juices, Chemistry and Isotopes Department, National Centre for Nuclear Energy, Madrid, Spain, Vol. 8, 1966.
 - Memorandum for FAP 9M4695 from K. Morehouse, FDA, to L. Highbarger, FDA, dated May 18, 2009.*
 - Locas, C.; and V. A. Yaylayan, "Origin and Mechanistic Pathways of Formation of the Parent Furan—a Toxicant," *Journal of Agricultural and Food Chemistry*, 52:6830–6836, 2005.
 - Fan, X., and K. J. B. Sokorai, "Effect of Ionizing Radiation on Furan Formation in Fresh-Cut Fruits and Vegetables," *Journal of Food Science*, 73(2): C79–C83, 2008.
 - Memorandum from Food Additives Evaluation Branch, FDA (HFS–156), to C. Takaguchi, Petition Control Branch, FDA, December 28, 1982.*
 - Memorandum for FAP 9M4696 from E. Jensen, FDA, to R. Alrefai, FDA, dated December 10, 1999.*
 - Memorandum to the file for FAP 4M4428, from D. Hattan, FDA, dated November 18, 1997.*
 - Underdal, B., J. Nordal, G. Lunde, and B. Eggum, "The Effect of Ionizing Radiation on the Nutritional Value of Fish (Cod) Protein," *Lebensmittel Wissenschaft Technologie*, 6:90–93, 1973.
 - Diehl, J. F., "Nutritional Adequacy of Irradiated Foods," pp. 241–282, in *Safety of Irradiated Foods*, Marcel Dekker, New York, 1995.
 - Memorandum for FAP 9M4695 from R. Merker, FDA, to L. Highbarger, FDA, dated May 26, 2010.*
 - Merritt, C., Jr., P. Angelini, E. Wierbicki, and G. W. Shults, "Chemical Changes Associated With Flavor in Irradiated Meat," *Journal of Agricultural and Food Chemistry*, 23:1037–1041, 1975.

List of Subjects in 21 CFR Part 179

Food additives, Food labeling, Food packaging, Radiation protection, Reporting and recordkeeping 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 "13," under the headings "Use" and "Limitations" to read as follows:

§ 179.26 Ionizing radiation for the treatment of food.

*	*	*	*	*
(b)	*	*	*	*

List of Subjects in 21 CFR Part 179

Food additives, Food labeling, Food packaging, Radiation protection, Reporting and recordkeeping 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 “13.” under the headings “Use” and “Limitations” to read as follows:

§ 179.26 Ionizing radiation for the treatment of food.

(b) *

Use	Limitations
* * * * * 13. For control of foodborne pathogens, and extension of shelf-life, in unrefrigerated (as well as refrigerated) uncooked meat, meat byproducts, and certain meat food products.	Not to exceed 4.5 kGy.

* * * * *

Dated: November 27, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012-28967 Filed 11-29-12; 8:45 am]

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**DEPARTMENT OF HEALTH AND
HUMAN SERVICES**

Food and Drug Administration

21 CFR Part 179

**[Docket No. FDA-1999-F-1267 (Formerly
Docket No. 1999F-5322)]**

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 increase the maximum dose of ionizing radiation permitted in the treatment of poultry products, to include specific language intended to clarify the poultry products covered by the regulations, and to remove the limitation that any packaging used during irradiation of poultry shall not exclude oxygen. This action is in response to a petition filed by the U.S. Department of Agriculture, Food Safety and Inspection Service (USDA/FSIS).

DATES: This rule is effective November 30, 2012. Submit either electronic or written objections and requests for a hearing by December 31, 2012. See section VIII of this document for information on the filing of objections.

ADDRESSES: You may submit either electronic or written objections and requests for a hearing identified by Docket No. FDA-1999-F-1267 (formerly Docket No. 1999F-5322) by any of the following methods:

Electronic Submissions

Submit electronic objections in the following way:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments.

Written Submissions

Submit written objections in the following ways:

- *FAX:* 301-827-6870.
- *Mail/Hand delivery/Courier (for paper or CD-ROM submissions):* Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the Agency name and Docket No. FDA-1999-F-1267 for this rulemaking. All objections received will be posted without change to <http://www.regulations.gov>, including any personal information provided. For detailed instructions on submitting objections, see the "Objections" heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or objections received, go to <http://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Lane A. Highbarger, Center for Food Safety and Applied Nutrition (HFS-255), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240-402-1204.

SUPPLEMENTARY INFORMATION:

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I. Background

In a notice published in the **Federal Register** of December 21, 1999 (64 FR 71461), FDA announced that a food additive petition (FAP 9M4696) had been filed by the USDA/FSIS, 300 12th St. SW., rm. 112, Washington, DC 20250 (currently, Food Safety and Inspection Service, Stop Code 3782, Patriots Plaza III, Cubicle 8-163A, 1400 Independence Ave. SW., Washington, DC 20250-3700). The petition proposed to amend the food additive regulation, *Ionizing radiation for the treatment of food* (§ 179.26 (21 CFR 179.26)) in item 6 of the table in paragraph (b) to: (1) Increase the maximum dose of ionizing radiation permitted in the treatment of poultry products; (2) include specific language intended to clarify the poultry products covered by the regulations; and (3) remove the limitation that any packaging used during irradiation of poultry shall not exclude oxygen.

FDA's current regulation under § 179.26(b)(6) permits the irradiation of fresh or frozen, uncooked poultry products that are: (1) Whole carcasses or disjointed portions of such carcasses that are "ready-to-cook poultry" within the meaning of 9 CFR 381.1(b)(44) or (2) mechanically separated poultry product (a finely comminuted ingredient produced by the mechanical deboning of poultry carcasses or parts of carcasses) up to a maximum absorbed dose of 3.0 kiloGray (kGy) with the restriction that any packaging used shall not exclude oxygen.

The amended regulation clarifies the range of poultry products that may be irradiated, increases the maximum dose of ionizing radiation permitted in the treatment of covered poultry products, and will remove the requirement that the packaging for covered poultry products must not exclude oxygen. The amended regulation clarifies that the regulation covers fresh (refrigerated or unrefrigerated) or frozen, uncooked poultry products that are: (1) Whole carcasses or disjointed portions (or other parts) of such carcasses that are "ready-to-cook poultry" within the meaning of 9 CFR 381.1(b) (with or without nonfluid seasoning; includes, e.g., ground poultry) or (2) mechanically separated poultry product (a finely comminuted ingredient produced by the mechanical deboning of poultry carcasses or parts of carcasses). In this document, the term "poultry" will be

used to refer collectively to all of these products.

This amendment will bring the poultry regulation into conformity with the current regulation permitting the irradiation of refrigerated or frozen, uncooked products that are meat, meat byproducts, or meat food products; i.e., it permits a maximum absorbed dose of 4.5 kGy for non-frozen products and 7.0 kGy for frozen products (§ 179.26(b)(8)), and provides no limitation that the packaging shall not exclude oxygen, which would allow the use of packaging including modified atmosphere packaging and vacuum packaging.

II. Safety Evaluation

FDA has previously evaluated the safety of irradiated protein food products in a variety of applications. Discussions of these applications have been presented in various **Federal Register** documents (see 51 FR 13376, April 18, 1986; 55 FR 18538, May 2, 1990; 62 FR 64107, December 3, 1997; 65 FR 45280, July 21, 2000; and 70 FR 48057, August 16, 2005). FDA specifically reviewed the irradiation of flesh foods and concluded that the irradiation of refrigerated flesh foods is safe at the absorbed doses that were reviewed (see 62 FR 64107 at 64111). FDA has also updated its review of the safety of irradiation of food with a thorough review of the literature to the present time and found no new studies on the irradiation of poultry (Ref. 1).

Under section 201(s) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 321(s)), a source of radiation used to treat food is a food additive. The additive is not added to food literally but is rather a source of radiation used to process or treat food such that, analogous to other food processing technologies, its use can affect the characteristics of the food. Under section 409(c)(3)(A) of the FD&C 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 under the conditions of that use. Importantly, 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 to establish safety. The testing and data required to establish the safety of an additive will vary depending on the particular additive and its intended use.

In evaluating the safety of a source of radiation to treat food intended for human consumption, the Agency must identify the various effects that may result from irradiating the food and

assess whether any of these effects pose a public health concern. In doing so, the following three general areas need to be addressed: (1) Potential toxicity, (2) nutritional adequacy, and (3) effects on the microbiological profile of the treated food. Each of these areas is discussed in this document.

The term "radiation chemistry" refers to the chemical reactions that occur as a result of the absorption of ionizing radiation. Because an understanding of radiation chemistry is fundamental in addressing the three areas noted in this document, key aspects of radiation chemistry are also discussed.

FDA has fully considered the data and studies submitted in the subject petition as well as other relevant data and information. The safety data that have been obtained from irradiating various foods under various conditions support conclusions about the safety of irradiating the poultry products covered in this rule (Refs. 2 and 4 through 7).

A. Radiation Chemistry

The conditions under which foods are irradiated are important in considering the radiation chemistry of a given food. These conditions include: The radiation dose, the physical state of the food (e.g., frozen or dried), and the atmosphere in the package.

The radiolysis products generated in any food are directly proportional to the absorbed radiation dose (Ref. 2). Radiation-induced chemical changes may cause changes in the organoleptic properties of the food, and the radiation chemistry of food is strongly influenced by the physical state of the food. If all other conditions, including radiation 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 non-frozen state. This is because of the reduced mobility, in the frozen state, of the initial radiolysis products, which will tend to recombine rather than diffuse and react with other food components. For similar reasons, if all other conditions are the same, the extent of chemical change that occurs in the dehydrated state is less than the change that occurs in the fully hydrated state (62 FR 64107 at 64110 and references cited therein).

1. Radiation Chemistry of the Major Components of Poultry

FDA has previously determined that flesh foods, including poultry, can be considered a single group for the purposes of evaluating the safety of irradiation because they are similar in composition (62 FR 64107 at 64111). Specifically, the approximate

composition of beef and lamb is 17 percent to 20 percent protein, 15 percent to 25 percent fat, and 56 percent to 65 percent water. Chicken (depending on cut and whether or not skin is included) is about 18 percent to 25 percent protein, 5 percent to 19 percent fat, and 57 percent to 75 percent water (Ref. 3). Fatty acids in the triglycerides from all flesh foods are comprised of the same predominant species: Oleic, palmitic, linoleic, and stearic acid.

Because of the commonality in the chemistry of the components of flesh foods and the predictability of the types and amounts of radiolytic products produced when food is irradiated, the Agency determined in the 1997 rule permitting the irradiation of meat, meat byproducts, and certain meat food products, that the conclusions regarding the irradiation of specific flesh foods can be used to draw conclusions about the irradiation of flesh foods as a class (62 FR 64107 at 64111). The effects of irradiation on non-frozen poultry irradiated at levels up to 4.5 kGy and in frozen poultry irradiated at levels up to 7.0 kGy are similar to the effects that occur in irradiated meat and have been shown to be safe.

a. *Protein*. As noted previously in this document, FDA has previously provided detailed discussions of the radiation chemistry of proteins in its rulemakings on the use of ionizing radiation to treat meat, meat byproducts, and certain meat food products (62 FR 64107 at 64110) and molluscan shellfish (70 FR 48057 at 48059–48060). Studies conducted with high-protein foods (e.g., meat, poultry, and seafood) have established that most of the radiolysis products derived from food proteins have the same amino acid composition as the original protein and are altered only in their secondary and tertiary structures (i.e., they are denatured, Ref. 2). These changes are similar to those that occur as a result of heating, but in the case of irradiation, even at doses up to 50 kGy and when food is irradiated at temperatures ranging from –168 °C to 60 °C in various studies, such changes are far less pronounced than heating and the amounts of reaction products generated are far lower (62 FR 64107 at 64110). Based on these studies, FDA concludes that there will be no significant change in the amino acid composition of poultry that is irradiated at absorbed doses not to exceed 4.5 kGy for non-frozen products and not to exceed 7.0 kGy for frozen products.

b. *Lipid*. FDA has also previously provided a detailed discussion of the radiation chemistry of lipids in the rules to permit the irradiation of meat, meat byproducts, and certain meat food

products (62 FR 64107 at 64110–64111) and molluscan shellfish (70 FR 48057 at 48060). Those discussions also support this rule.

To summarize the previous discussions, a variety of radiolysis products derived from lipids have been identified. These include the following: Fatty acids, esters, aldehydes, ketones, alkanes, alkenes, and other hydrocarbons (Ref. 2). Identical or analogous products are also found in foods that have not been irradiated. In particular, heating food produces generally the same types of products, but in amounts far greater than the trace amounts produced by irradiating food (62 FR 64107 at 64111 and references cited therein).

A class of radiolysis products that is derived from lipids, 2-alkylcyclobutanones (2-ACBs), has been reported to form in small quantities when fats are exposed to ionizing radiation. Any 2-ACB formed will depend on the fatty acid composition of the food, e.g., 2-dodecylcyclobutanone (2-DCB) is a radiation byproduct of palmitic acid. (Refs. 8 and 9). In the molluscan shellfish rule, the Agency noted the reported creation of 2-DCB in irradiated chicken and ground beef, which contain triglycerides with esterified palmitic acid. FDA did not find that the presence of low levels of 2-DCB raised a safety issue (70 FR 48057 at 48060).

2. Furan

During the course of reviewing the chemical effects of irradiation, FDA became aware of a report that suggested that the irradiation of apple juice may produce furan (Ref. 10). Because furan has been shown to cause tumors in laboratory animals, FDA has extensively researched the occurrence of furan in irradiated foods over the last 10 years.

FDA has confirmed that certain foods form furan in low quantities when irradiated (Ref. 11). Studies conducted by FDA scientists and other researchers show that some foods form furan when heated and still other foods form furan during storage at refrigeration temperatures (Refs. 11 and 13). Testing of irradiated poultry found no furan at the limit of detection in the tests and detected no furan above the background levels of natural furan formation during storage (Refs. 11, 12, and 13). Therefore, the Agency concludes that the irradiation of poultry at the requested maximum absorbed dose will not increase the amount of furan in the diet and does not present a toxicological hazard under the conditions proposed in the USDA/FSIS petition.

B. Toxicological Considerations

As discussed previously in this document, the available information from chemical analyses of irradiated foods suggests that there is no reason to suspect a toxicological hazard due to consumption of an irradiated food (Ref. 5). The Agency notes that the large body of data from studies where irradiated foods were fed to laboratory animals provides an independent way to assess toxicological safety. These studies include those relied on by the Agency in previous evaluations of the safety of irradiated foods (see 51 FR 13376, April 18, 1986; 55 FR 18538, May 2, 1990; 62 FR 64107; 65 FR 45280, July 21, 2000 and 70 FR 48057, August 16, 2005). Additionally, FDA has looked at data and information in FDA files summarized by the Bureau of Foods Irradiated Food Committee (Refs. 14 and 15).

In summary, FDA has reviewed data relevant to the assessment of potential toxicity of irradiated poultry. While all of the studies are not of equal quality or rigor, the Agency has concluded that the quantity and breadth of testing and the number and significance of endpoints assessed would have identified any meaningful risk. Based on the totality of the evidence, FDA concludes that irradiation of poultry under the conditions proposed in the petition does not present a toxicological hazard.

C. Nutritional Considerations

It has been established that the nutrient values of the macronutrients in the diet (protein, fats, and carbohydrates) are not significantly altered by irradiation at the petitioned doses (62 FR 64107 at 64114 and Refs. 16 and 17). Minerals (e.g., calcium and iron) are also unaffected by irradiation (62 FR 64107 at 64114 and Ref. 17). Levels of certain vitamins may be reduced as a result of irradiation. The extent to which this reduction occurs depends on the specific vitamin, the type of food, and the conditions of irradiation. Not all vitamin loss is nutritionally significant; the extent to which the reduction in a specific vitamin level is significant depends on the relative contribution of the food in question to the total dietary intake of the vitamin (62 FR 64107 at 64114).

FDA has made the following finding with respect to the nutritional impact of consuming non-frozen flesh foods irradiated at levels up to 4.5 kGy and frozen flesh foods irradiated at levels up to 7.0 kGy: The effects of irradiation on the nutritional adequacy of irradiated flesh foods, which includes poultry, at or above the petitioned doses have been

considered previously. Although the meat final rule (62 FR 64107, December 3, 1997), codified only the irradiation of red meat at up to the petitioned doses, the safety evaluation took into account the effects on the diet of irradiating all flesh foods. The Agency concluded that permitting the irradiation of poultry at the petitioned levels will not affect the nutritional status of poultry consumers (Ref. 3).

In summary, based on the available data and information, FDA concludes that amending the regulations, as set forth in this document, to allow for the use of ionizing radiation to treat poultry up to a maximum absorbed dose of 4.5 kGy for non-frozen products and not to exceed 7.0 kGy for frozen products will not have an adverse impact on the nutritional adequacy of the overall diet.

D. Microbiological Considerations

In the 1990 final rule for irradiation of poultry (55 FR 18538), FDA determined that while irradiation at a dose of 3 kGy reduces the number of many pathogenic and spoilage bacteria, it does not eliminate the relatively radiation-resistant spore-forming bacteria such as *Clostridium botulinum* (55 FR 18541). FDA also determined in the final rule that *C. botulinum*, if present, would not render fresh poultry irradiated at 3 kGy toxic before normal signs of spoilage became apparent (55 FR 18542).¹ As an extra margin of safety, however, the final rule established the limitation that packaging shall not exclude oxygen with respect to poultry, because *C. botulinum* does not grow in oxygenated environments (Ref. 18).

Since the final rule permitting the irradiation of poultry was published in 1990, the Agency notes that poultry production practices have changed, making *C. botulinum* contamination and growth less of a concern.² As part of the 1990 rulemaking, the Agency considered the fact that *C. botulinum* type E could potentially contaminate fish meal, which was typically used in chicken feed. Currently, however, fish meal has almost been completely replaced with high protein soybean and corn meal. Additionally, *C. botulinum* does not produce toxin when held at 10 °C (Ref. 19), and current USDA/FSIS regulations generally require that poultry plants maintain poultry at temperatures below 10 °C during processing (9 CFR 381.66(b)(1)). Finally, controlling microbiological

contamination, including contamination from *C. botulinum*, is now required under mandatory USDA/FSIS poultry processing Hazard Analysis Critical Control Point plans (9 CFR part 417).

In addition to the changes in poultry production practices after the issuance of the 1990 final rule, a study published after the issuance of the 1990 poultry regulation demonstrates that lactic acid producing bacteria predominate on irradiated raw chilled meat at doses up to 5 kGy (Ref. 20) and flourish in an anaerobic environment that could potentially allow *C. botulinum* to grow. The growth of *C. botulinum* and other pathogens is inhibited by these non-pathogenic lactic acid producing bacteria (such as *Lactobacillus* species).

All of the previously mentioned factors would render it unlikely that *C. botulinum* could either grow or produce toxin in poultry under the conditions of irradiation specified in the regulation as amended by this final rule, including removal of the restriction on packaging that excludes oxygen (Ref. 18). Further, the presence of spoilage bacteria will warn consumers of spoilage before any *C. botulinum* present would produce toxin.

In summary, based on the available data and information, FDA concludes that irradiation of poultry under the conditions in this amended regulation will reduce or eliminate bacterial populations with no increased microbial risk from pathogens that may survive the irradiation process in either an aerobic or anaerobic atmosphere (Ref. 18).

III. Labeling

Poultry products are subject to the Poultry Products Inspection Act (21 U.S.C. 451, *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.

IV. Comments

FDA has received numerous comments, primarily form letters, from individuals that state their opinions regarding the potential dangers and unacceptability of irradiating food. FDA has also received several comments from individuals or organizations that state their opinions regarding the potential benefits of irradiating food and urging FDA to approve the petition. Additionally, FDA received several comments from Public Citizen (PC) and the Center for Food Safety (CFS) requesting the denial of this and other food irradiation petitions.

¹ We note that *C. botulinum* is not able to grow at temperatures below freezing.

² We note that *C. botulinum* generally occurs in very low numbers in chicken.

Overall, the comments were of a general nature and not necessarily specific to the requests in the individual petitions, and did not contain any substantive information that could be used in a safety evaluation of irradiated poultry. Many of the comments from PC and CFS were also submitted to the docket for the Agency rulemaking on irradiation of molluscan shellfish (Docket No. 1999F-4372, FAP 9M4682). The topics raised in these comments included the following: Studies reviewed in the 1999 Food and Agriculture Organization of the United Nations/International Atomic Energy Agency/World Health Organization (FAO/IAEA/WHO) report on high-dose irradiation; a review article that analyzed studies of irradiated foods performed in the 1950s and 1960s; the findings of a 1971 study in which rats were fed irradiated strawberries; the findings regarding reproductive performance in a 1954 study in which mice were fed a special irradiated diet; issues regarding mutagenicity studies; certain international opinions; issues related to 2-ACBs, including purported promotion of colon cancer; the findings of certain studies conducted by the Indian Institute of Nutrition in the 1970s; general issues regarding toxicity data; FDA's purported failure to meet certain statutory requirements; data from a 2002 study purportedly showing an irradiation-induced increase in trans fatty acids in ground beef; studies regarding purported elevated hemoglobin levels and their significance; and an affidavit describing the opinions of a scientist regarding the dangers of irradiation and advocating the use of alternative methods for reducing the risk of foodborne disease. These comments have all been addressed by FDA in a previous rulemaking. For a detailed discussion of the Agency's response to each of the previously mentioned general comments, the reader is referred to the molluscan shellfish rule (70 FR 48057 at 48062 through 48071). Because these comments do not raise issues specific to irradiated poultry, and the previous responses are sufficient to address these issues as they pertain to the rule to permit the irradiation of poultry as described in this document, the Agency will not address these comments further here.

V. Conclusions

Based on the data and studies submitted in the petition and other information in the Agency's files, FDA concludes that the proposed use of irradiation to treat fresh (refrigerated and unrefrigerated) poultry food

products³ with absorbed doses that will not exceed 4.5 kGy and frozen poultry products not to exceed 7.0 kGy is safe with no need for a requirement that the packaging shall not exclude oxygen, and therefore, § 179.26 should be amended as set forth in this document.

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 use of irradiation of poultry in response to the petition will be made available for inspection at the Center for Food Safety and Applied Nutrition by appointment with the information contact person (see **FOR FURTHER INFORMATION CONTACT**). 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.

VI. Paperwork Reduction Act of 1995

This final rule does not provide for collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

VII. Environmental Impact

The Agency has carefully considered the potential environmental effects of this action. The Agency has determined under 21 CFR 25.32(j) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VIII. Objections

Any person who will be adversely affected by this regulation may file with the Division of Dockets Management (see **ADDRESSES**) either electronic or written objections. 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

³The term "fresh poultry" is defined by USDA to include both refrigerated and unrefrigerated poultry food products.

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. It is only necessary to send one set of documents. Identify documents 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 Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

IX. Section 301(l) of the Federal Food, Drug, and Cosmetic Act

FDA's review of this petition was limited to section 409 of the FD&C Act. This final rule is not a statement regarding compliance with other sections of the FD&C Act. For example, the Food and Drug Administration Amendments Act of 2007, which was signed into law on September 27, 2007, amended the FD&C Act to, among other things, add section 301(l) (21 U.S.C. 331(l)). Section 301(l) of the FD&C Act prohibits the introduction or delivery for introduction into interstate commerce of any food that contains a drug approved under section 505 of the FD&C Act (21 U.S.C. 355), a biological product licensed under section 351 of the Public Health Service Act (42 U.S.C. 262), or a drug or biological product for which substantial clinical investigations have been instituted and their existence has been made public, unless one of the exceptions in section 301(l)(1) to (l)(4) of the FD&C Act applies. In our review of this petition, FDA did not consider whether section 301(l) of the FD&C Act or any of its exemptions apply to the ionizing radiation source. Accordingly, this final rule should not be construed to be a statement that ionizing radiation used to treat poultry products, if introduced or delivered for introduction into interstate commerce, would not violate section 301(l) of the FD&C Act. Furthermore, this language is included in all food additive final rules and therefore, should not be construed to be a statement of the likelihood that section 301(l) of the FD&C Act applies.

X. References

The following sources are referred to in this document. References marked with an asterisk (*) have been placed on display at the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday, and are available electronically at <http://www.regulations.gov>. References without asterisks are not on display; they are available as published articles and books.

1. Memorandum for FAP 9M4696 from K. Morehouse, FDA, to L. Highbarger, FDA, dated August 10, 2010.*
2. Diehl, J. F., "Chemical Effects of Ionizing Radiation," pp. 43–88, in *Safety of Irradiated Foods*, second edition, Marcel Dekker, Inc., New York, 1995.
3. Memorandum for FAP 9M4696 from E. Jensen, FDA, to R. Alrefai, FDA, dated December 10, 1999.*
4. Elias, P.S. and A.J. Cohen, "Recent Advances in Food Irradiation," Elsevier Biomedical, Amsterdam, 1983.
5. World Health Organization, "High-Dose Irradiation: Wholesomeness of Food Irradiated With Doses Above 10 kGy," World Health Organization Technical Report Series No. 890, pp. 9–37, Geneva, 1999.
6. *Preservation of Food by Ionizing Radiation*, edited by E.S. Josephson and M.S. Peterson, Vol. II, CRC Press, Boca Raton, 1982.
7. Diehl, J.F., "Radiolytic Effects in Foods," pp. 279–357, in *Preservation of Food By Ionizing Radiation*, Vol. I, edited by E.S. Josephson and M.S. Peterson, CRC Press, Boca Raton, 1982.
8. Crone, A.V.J., et al., "Effect of Storage and Cooking on the Dose Response of 2-Dodecylcyclobutanone, a Potential Marker for Irradiated Chicken," *Journal of the Science of Food and Agriculture*, 58:249–252, 1992.
9. Gadgil, P., K.A. Hachmeister, J.S. Smith, and D.H. Kropf, "2-Alkylcyclobutanones as Irradiation Dose Indicators in Irradiated Ground Beef Patties," *Journal of Agriculture and Food Chemistry*, 50:5746–5750, 2002.
10. Seibersdorf Project Report, International Programme on Irradiation of Fruit and Fruit Juices, Chemistry and Isotopes Department, National Centre for Nuclear Energy, Madrid, Spain, Vol. 8, 1966.
11. Memorandum for FAP 9M4697 from K. Morehouse, FDA, to L. Highbarger, FDA, dated February 20, 2008.*
12. Locas, C. and V.A. Yaylayan, "Origin and Mechanistic Pathways of Formation of the Parent Furan—a Toxicant," *Journal of Agricultural and Food Chemistry*, 52:6830–6836, 2005.
13. Fan, X., and K.J.B. Sokorai, "Effect of Ionizing Radiation on Furan Formation in Fresh-Cut Fruits and Vegetables," *Journal of Food Science*, 73(2):C79–C83, 2008.
14. Memorandum from Food Additives Evaluation Branch, FDA (HFS–156), to C. Takaguchi, Petition Control Branch, FDA, December 28, 1982.*
15. Memorandum to the file for FAP 4M4428, from D. Hattan, FDA, dated November 18, 1997.*
16. Underdal, B., J. Nordal, G. Lunde, and B. Eggum, "The Effect of Ionizing Radiation on the Nutritional Value of Fish (Cod) Protein," *Lebensmittel Wissenschaft Technologie*, 6:90–93, 1973.
17. Diehl, J.F., "Nutritional Adequacy of Irradiated Foods," pp. 241–282, in *Safety of Irradiated Foods*, Marcel Dekker, New York, 1995.
18. Internal Memorandum for FAP 9M4696 from J. Newland, FDA, to the file, dated July 7, 2000.*
19. Firstenberg-Eden, R., D.B. Rowley, and G.E. Shattuck, "Factors Affecting Growth and Toxin Production by Clostridium Botulinum Type E on Irradiated (0.3 Mrad) Chicken Skins," *Journal of Food Protection*, 47:867–870, 1982.
20. Matilla-Sandholm, T. and E. Skytta, "The Effect of Spoilage Flora on the Growth of Food Pathogens in Minced Meat Stored at Chilled Temperature," *Lebensmittel-Wissenschaft Technologie*, 24:116–120, 1991.

List of Subjects in 21 CFR Part 179

Food additives, Food labeling, Food packaging, Radiation protection, Reporting and recordkeeping 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 revising entry "6." under the headings "Use" and "Limitations" to read as follows:

§ 179.26 Ionizing radiation for the treatment of food.

* * * * *

(b) * * *

Use	Limitations
* * * * 6. For control of food-borne pathogens in fresh (refrigerated or unrefrigerated) or frozen, uncooked poultry products that are: (1) Whole carcasses or disjointed portions (or other parts) of such carcasses that are "ready-to-cook poultry" within the meaning of 9 CFR 381.1(b) (with or without nonfluid seasoning; includes, e.g., ground poultry), or (2) mechanically separated poultry product (a finely comminuted ingredient produced by the mechanical deboning of poultry carcasses or parts of carcasses). * * * *	Not to exceed 4.5 kGy for non-frozen products; not to exceed 7.0 kGy for frozen products. * * * *

* * * *

Dated: November 27, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012-28968 Filed 11-29-12; 8:45 am]

BILLING CODE 4160-01-P

PENSION BENEFIT GUARANTY CORPORATION

29 CFR Part 4044

Allocation of Assets in Single-Employer Plans; Valuation of Benefits and Assets; Expected Retirement Age

AGENCY: Pension Benefit Guaranty Corporation.

ACTION: Final rule.

SUMMARY: This rule amends the Pension Benefit Guaranty Corporation's regulation on Allocation of Assets in Single-Employer Plans by substituting a new table for determining expected retirement ages for participants in pension plans undergoing distress or involuntary termination with valuation dates falling in 2013. This table is needed in order to compute the value of early retirement benefits and, thus, the total value of benefits under a plan.

DATES: *Effective Date:* January 1, 2013.

FOR FURTHER INFORMATION CONTACT:

Catherine B. Klion, Assistant General Counsel for Regulatory Affairs, Pension Benefit Guaranty Corporation, 1200 K

Street NW., Washington, DC 20005, 202-326-4024. (TTY/TDD users may call the Federal relay service toll-free at 1-800-877-8339 and ask to be connected to 202-326-4024.)

SUPPLEMENTARY INFORMATION: The Pension Benefit Guaranty Corporation (PBGC) administers the pension plan termination insurance program under Title IV of the Employee Retirement Income Security Act of 1974 (ERISA). PBGC's regulation on Allocation of Assets in Single-Employer Plans (29 CFR part 4044) sets forth (in subpart B) the methods for valuing plan benefits of terminating single-employer plans covered under Title IV. Guaranteed benefits and benefit liabilities under a