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" or "we") is amending the food additive regulations to provide for the safe use of ionizing radiation for control of food-borne pathogens in crustaceans at a maximum absorbed dose of 6.0 kiloGray (kGy). This action is in response to a petition filed by the National Fisheries Institute, 1901 North Fort Myer Dr., Arlington, VA 22209 (petitioner). The petition proposed that the food additive regulations in part 179, "Irradiation in the Production, Processing and Handling of Food" (21 CFR part 179), be amended to provide for the safe use of approved sources of ionizing radiation for control of food-borne pathogens in raw, frozen, cooked, partially cooked, shelled, or dried crustaceans or cooked or ready-to-cook crustaceans processed with batter, breading, spices, or small amounts of other food ingredients. In a letter dated July 16, 2009, the petitioner requested a maximum absorbed dose of 0.85 or below (Ref. 1).

DATES: This rule is effective April 14, 2014. See section VII of this document for information on the filing of objections. Submit either electronic or written objections and requests for a hearing by May 14, 2014.

ADDRESSES: You may submit either electronic or written objections and requests for a hearing identified by Docket No. FDA–2001–F–0049, 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:

• Mail/Hand delivery/Courier (for paper submissions): Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Instructions: All submissions must include the Agency name and Docket No. FDA–2001–F–0049 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.

Docket: For access to the docket to read background documents or objections received, go to http://www.regulations.gov and insert the docket number(s), 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.


SUPPLEMENTARY INFORMATION:

I. Background

In a notice published in the Federal Register of February 6, 2001 (66 FR 9086), we announced that a food additive petition (FAP 1M4727) had been filed by the National Fisheries Institute, 1901 North Fort Myer Dr., Arlington, VA 22209 (petitioner). The petition proposed that the food additive regulations in part 179, "Irradiation in the Production, Processing and Handling of Food" (21 CFR part 179), be amended to provide for the safe use of approved sources of ionizing radiation for control of food-borne pathogens in raw, frozen, cooked, partially cooked, shelled, or dried crustaceans or cooked or ready-to-cook crustaceans processed with batter, breading, spices, or small amounts of other food ingredients. In a letter dated July 16, 2009, the petitioner requested FDA to modify the scope of the petition to exclude consideration of breaded and battered crustaceans. Subsequently, we published an amended notice of filing for the petition of February 6, 2001, in the Federal Register (74 FR 47592; September 16, 2009), indicating that the petition proposed to amend the regulations in part 179 to provide for the use of ionizing radiation for the control of food-borne pathogens in raw, frozen, cooked, partially cooked, shelled, or dried crustaceans, or cooked or ready-to-cook crustaceans processed with spices or small amounts of other food ingredients. On August 31, 2012, at our request the petitioner clarified the scope of its amended petition from 2009 by providing us with a list of the particular "other food ingredients" that would be added to the crustaceans prior to being irradiated (Ref. 2).

The petitioner requested a maximum absorbed dose of 6.0 kGy to achieve a 6-log reduction of Listeria monocytogenes.

II. Evaluation of Safety

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 defined as a food additive. While the source of radiation is not literally added to the food, the radiation is used to process or treat food, such that, analogous to other food processing technologies, its use can affect the characteristics of the food. In the subject petition, the intended technical effect is to reduce the microbial load on and prolong the shelf life of crustaceans.

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 for that use. Safe or safety in the context of food additives "means that there is a reasonable certainty in the minds of competent scientists that the substance is not harmful under the intended conditions of use. It is impossible in the present state of scientific knowledge to establish with complete certainty the absolute harmlessness of the use of any substance." 3

The FD&C Act does not prescribe the safety tests to be performed and 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.

Specifically, in evaluating the safety of a source of radiation to treat food intended for human consumption, we 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 this regard, the following three areas of possible concern need to be addressed: (1) Potential toxicity, (2) nutritional adequacy, and (3) potential microbiological risk from the treated food. Each of these areas is discussed in detail in this document. We have considered the data and studies submitted in the subject petition as well as additional data and information in our possession relevant to safety. This includes our previous evaluations of the safety of the irradiation of other foods, including the irradiation of poultry ("poultry rule") (55 FR 18538; May 2, 1990), the irradiation of meat ("meat rule") (62 FR 64107; December 3, 1997), the irradiation of molluscan shellfish

2 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) (21 U.S.C. 321(s)).

3 21 CFR 170.3(f).
(“molluscan shellfish rule”) (70 FR 48057; August 16, 2005), and the irradiation of fresh iceberg lettuce and fresh spinach (“fresh iceberg lettuce and fresh spinach rule”) (73 FR 49593; August 22, 2008).

A. Radiation Chemistry

“Radiation chemistry” refers to the chemical reactions that occur as a result of the absorption of ionizing radiation. Numerous studies regarding the chemical effects of ionizing radiation on different foods under varied conditions have led to a sound understanding of the fundamental principles of radiation chemistry. The knowledge gained through these studies provided us with a knowledge base from which general conclusions about irradiated foods can be drawn by extrapolating from data on particular foods irradiated under specific conditions to similar types of foods irradiated under different, yet related, conditions. Overall, the data show that the type and amount of products generated by the radiation-induced chemical reactions (“radiolysis products”) are dependent upon the chemical constituents of the food and the specific conditions under which the food has been irradiated. The principles of radiation chemistry also govern the extent of change, if any, in the nutrient level and the microbial load of irradiated foods.

We have reviewed the pertinent data and information concerning radiation chemistry as it applies specifically to crustaceans irradiated at a maximum absorbed dose of 6.0 K Gy. As described in the review memoranda, our safety review of the conditions of use generally focused on the effects of irradiation on the provision that individuals are most likely to consume, i.e., the meat or flesh of crustaceans.

1. Factors Affecting the Radiation Chemistry of Foods

Along with the chemical composition of the food, the specific conditions of irradiation are essential to assessing the radiation chemistry of a given food. The specific conditions include radiation dose, physical state of the food (e.g., solid or frozen versus liquid or non-frozen state, dried versus hydrated state), and ambient atmosphere (e.g., air, reduced oxygen, or vacuum). The radiation dose directly affects the levels of radiolysis products generated in a particular food; therefore, we can extrapolate from data obtained at higher radiation doses to draw conclusions about the amounts of radiolysis products expected to be generated at lower doses. Generally, the types of radiolysis products resulting from irradiation are similar to those produced by alternative food processing methods, such as canning and cooking (Refs. 3 and 4).

The extent of chemical change that occurs when food is irradiated is also determined by the physical state of the food. When the food is in a frozen state, the initial radiolysis products have a greater tendency to recombine rather than diffuse throughout the food and react with other food components. Provided all conditions are the same, including dose and ambient atmosphere, the extent of chemical change that occurs in a specific food will be lower if the food is in a frozen state than a non-frozen state because the radiolysis products are less mobile in frozen conditions. Likewise, the extent of change in the dehydrated state is less than the change that occurs in the fully hydrated state.

Furthermore, the atmosphere can affect the formation of radiolytic products in a given food, thus having the potential to affect the chemical composition of the food. Irradiation in oxygenated environments facilitates the formation of additional oxidation-reduction (redox) agents as a result of the interaction between oxygen and the radiolysis products of water (e.g., hydrogen radical, hydroxide radical, and solvated electrons (a free electron in a solution)). Because all foods have components that are susceptible to redox reactions, an atmosphere with high oxygen content increases the likelihood of such occurrences and therefore, leads to the formation of a greater number and variety of radiolysis products when compared to an atmosphere with low oxygen content (Refs. 3 and 5). 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 radiolysis products generated by irradiation are similar to those produced by other food processing methods (Refs. 3 and 4).

Radiation-induced chemical changes, if sufficiently large, may cause changes in the organoleptic or sensory 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 food. Thus, in most cases, the dosage selected will be the lowest dose required to achieve the desired effect, and the irradiation will be conducted under reduced oxygen levels and/or on food held at low temperatures or in the frozen state.5

2. Radiation Chemistry of the Major Components of Crustaceans

The major components of crustaceans are water, proteins, and lipids. Irradiation of water produces reactive hydroxyl and hydrogen radicals. These radicals are likely to recombine forming water, hydrogen gas, or hydrogen peroxide; however, they can react with other components of the irradiated food, in this instance, crustaceans, forming secondary radiolysis products. While the most significant effects of irradiation on the protein and lipid components of crustaceans result from chemical reactions induced by radicals generated from the radiolysis of water, additional radiolysis products can result directly from the absorbed radiation. These products form in very small amounts and are the same as or similar to compounds found in food that have not been irradiated (Ref. 4).

Because meat is high in protein, lipids, and water, the radiation chemistry of proteins, lipids, and water (in both liquid and frozen states) was extensively discussed in the preamble to the meat rule (62 FR 64107 at 64110 to 64111). The radiation chemistry of proteins and lipids discussed in the meat rule is also relevant to other flesh foods, including foods such as poultry and fish, that may be referred to as “meat” in common usage, but that do not conform to the definition of meat in 9 CFR 301.2.

Crustaceans are similar to other flesh foods in that they consist predominately of protein (up to 21 percent), lipid (approximately 1 to 2 percent), and water (74 to 84 percent). However, they differ from other flesh food in that they contain lower levels of fat and slightly higher levels of carbohydrate (up to 2.5 percent) by weight of the raw edible portion (Ref. 6). While the carbohydrate level in crustaceans is slightly higher than in other flesh foods, the overall level remains relatively low.

a. Proteins: We have previously provided a detailed discussion of

---

4 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 J.F. Diehl, “Chemical Effects of Ionizing Radiation,” Chapter 3 in “Safety of Irradiated Foods,” Marcel Dekker, New York, 1995.

5 In the case of crustaceans, irradiation would occur under either chilled or frozen conditions. This temperature requirement is not necessary for dried crustaceans because they are shelf stable due to their low water activity.
The term “spice” refers to dried or dehydrated aromatic vegetable substances that are used in small amounts solely for flavoring or aroma (e.g., black pepper, red pepper, and bay leaves). This term is consistent with the currently regulated uses of “spice” in § 179.26(b)(5) (21 CFR 179.26(b)(5)).

This regulation addresses the irradiation of these “other food ingredients” to the extent that their use in crustaceans is authorized. The use of other ingredients in crustaceans prior to irradiation must be consistent with existing food additive regulations, generally recognized as safe determinations, and prior sanctions. For example, calcium disodium EDTA is approved for use under the conditions specified in 21 CFR 172.120 in cooked canned shrimp and cooked canned crabmeat and is not approved for use in other types of shrimp or crabmeat or in other crustaceans.
oxidation reactions and have concluded that these products are not harmful. Moreover, the addition of these specific organic compounds to crustaceans prior to irradiation results in the formation of these radiolysis products at such low levels that irradiation of crustaceans with the proposed additional food ingredients will not meaningfully increase exposure to radiolysis products (ibid.).

Overall, we concluded that the irradiation of all proposed ingredients will not increase the exposure to radiolysis products when used on crustaceans at levels consistent with good manufacturing practices (GMP) and in accordance with other applicable laws and regulations.

4. Consideration of Furan as a Radiolysis Product

During our review of the chemical effects of irradiation, as a part of the evaluation of this and other irradiation petitions, we became aware of a report that suggested irradiating apple juice (“apple juice report”) may produce furan (Ref. 23). Studies have demonstrated that furan can cause tumors in laboratory animals. This prompted us to initiate research on whether the apple juice report was accurate and whether furan was a common radiolysis product in food. We confirmed that certain foods form furan in low quantities when irradiated. Our studies also show that some foods form furan when heated and other foods form furan during storage at refrigeration temperatures (Ref. 24). Testing of irradiated raw shrimp and cooked crab meat show that if furan is formed when these foods are irradiated, it is formed at levels that are below the limit of detection of the available analytical methods, or below the background levels of natural furan formation during storage (Ref. 25). Therefore, because all crustaceans have similar composition, we concluded that the consumption of irradiated crustaceans will not increase the amount of furan in the diet.

5. Consideration of 2-Alkylcyclobutanones as Radiolysis Products

A class of radiolysis products derived from lipids, identified as 2-alkylcyclobutanones (2–ACBs), has been reported to form in small quantities when fats are exposed to ionizing radiation. These compounds were once considered to be unique products, formed in small quantities during the irradiation process; however, a recent report has demonstrated that 2–ACBs also can be detected in non-irradiated food (Ref. 26). The type of 2–ACBs formed depends on the fatty acid composition of the food. For example, 2-dodecylcyclobutanone (2–DCB) is a radiation by-product of triglycerides with esterified palmitic acid. Researchers have reported that 2–DCB is formed in small amounts (less than 1 microgram per gram lipid per kGy) in irradiated chicken (Ref. 27) and in even smaller amounts in irradiated ground beef (Ref. 28). Both of these foods are of relatively high total fat and palmitic acid content (Ref. 6).

In the molluscan shellfish rule, we provided a detailed discussion of the significance of the formation of 2–DCB to the safety evaluation of irradiated molluscan shellfish, a food which, like chicken, ground beef, and crustaceans, contains significant amounts of triglycerides with esterified palmitic acid (70 FR 48057 at 48065 to 48067). We concluded that no issues were raised that had not been previously considered in the meat and poultry final rules (70 FR 48057 at 48060 and 48065 to 48067). In our assessment in the meat rule, we considered all of the available data and information, including the results of genotoxicity studies and previously reviewed studies in which animals were fed diets containing irradiated meat, poultry, and fish (62 FR 64107 at 64113). While 2–DCB and other alkylcyclobutanones would be expected to be present in these irradiated foods, we found no evidence of toxicity attributable to the consumption of these substances. The macronutrient composition of crustaceans (protein, lipid, carbohydrate) is comparable to other flesh foods (Ref. 6). Due to the similar lipid levels, the formation of 2–ACBs in crustaceans is expected to be similar to the levels of 2–ACBs produced in other flesh foods. Therefore, considering all available data and information, the formation of 2–ACBs from irradiating crustaceans under the conditions proposed in this petition is not a safety concern.

B. Toxicological Considerations

To adequately evaluate the safety of irradiated food products, we assessed all available toxicological data from the relevant toxicology studies of which we are aware. For the toxicological evaluation of irradiated crustaceans, the relevant studies are those studies examining flesh-based foods, including studies on fish high in PUFAs. These include 24 long-term feeding studies, 10 reproduction/teratology studies, and 15 genotoxicity studies with flesh-based foods irradiated at doses from 6 to 74 kGy. No toxicologically significant adverse effects attributable to irradiated flesh foods were observed in any of the studies, all of which were discussed in detail in the meat rule (62 FR 641107 at 641112 to 641114). The dose of irradiation used in the relevant studies was similar to, or considerably higher than, the maximum absorbed dose requested in this petition (6.0 kGy). Therefore, these data demonstrate that crustaceans irradiated at levels up to 6.0 kGy will not present a toxicological hazard (Ref. 7).

In evaluating the safety of irradiated crustaceans, we also relied upon the integrated toxicological database derived from the extensive body of work reviewed by us (Ref. 29) and by WHO relevant to the assessment of the potential toxicity of irradiated foods. Although these studies are not all of equal quality or rigor, we concluded that the quantity and breadth of testing, as well as the number and significance of endpoints assessed would have identified any real or meaningful harm. The overwhelming majority of studies showed no evidence of toxicity. In those few instances where adverse effects were reported, we found that those effects have not been consistently reproduced in related studies conducted at higher doses or for longer durations, as would be expected if the effects were attributable to irradiation (62 FR 64107 at 641112 to 641114).

Similarly, during the early 1980s, a joint Food and Agriculture Organization/International Atomic Energy Agency, World Health Organization (FAO/IAEA/WHO) Expert Committee evaluated toxicological and microbiological safety and nutritional adequacy of irradiated foods. The Expert Committee concluded that irradiation of any food commodity at an average dose of up to 10 kGy presents no toxicological hazard (Ref. 30). In the 1990s, at the request of one of its member states, FAO/IAEA/WHO conducted a new review and analysis of the safety of data on irradiated foods. This more recent review included all studies in our files that we considered as reasonably complete, as well as those studies that appeared to be acceptable but had deficiencies interfering with the interpretation of the data (62 FR 64107 at 641112). The FAO/IAEA/WHO review also included data from the U.S.

\*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 in only brief summary form. While many of these studies cannot individually establish safety for the previously cited reasons, they still provide important information that, evaluated collectively, supports a conclusion that there is no reason to believe that the irradiation of flesh foods presents a toxicological hazard.
Department of Agriculture (USDA) and from the German Federal Research Centre for Nutrition at Karlsruhe, Germany. FAO/IAEA/WHO concluded 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. 31).

Therefore, based on the totality of evidence, we conclude that irradiation of crustaceans under the conditions proposed in this petition does not present a toxicological hazard.

C. Nutritional Considerations

It has been well established that the nutritional value of the macronutrients (proteins, fats, and carbohydrates) in the diet are not significantly altered by irradiation at the petitioned doses (Refs. 32 to 34). PUFA's, particularly long-chain, omega-3 fatty acids, are generally considered to be nutritionally important components of seafood. As noted in section II.A.2.c., PUFA levels were not reduced significantly by ionizing radiation. Thus, we conclude that, as with molluscan shellfish (70 FR 48057 at 48060), potential losses of PUFA's from irradiation of crustaceans would be expected to be minimal and have no nutritional significance.

We have carefully reviewed the data and information submitted in the petition, as well as additional information available in the scientific literature, to determine the potential impact of irradiation at a maximum absorbed dose of 6.0 kGy on the nutritional value of crustaceans (Ref. 32). In this review, FDA considered all nutrients known to be present in crustaceans, but focused primarily on those vitamins having an established sensitivity to radiation and those vitamins for which at least one of these foods may be identified, under our labeling regulations, as either a "good source" or an "excellent source," for contributing more than a trivial amount to the total dietary intake of that vitamin (i.e., more than 1 to 2 percent). Irradiation of any food, regardless of the dose, has no effect on the levels of minerals that are present in trace amounts (Ref. 3). Levels of certain vitamins, on the other hand, may be reduced as a result of irradiation. The extent to which a reduction in the level of a specific vitamin occurs as a result of food irradiation depends on the specific vitamin, the type of food, and the conditions of irradiation. Not all vitamin loss is nutritionally significant; however, and the extent to which a 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.

Crustaceans, as a group, show some variation in vitamin content, but all crustaceans are excellent sources of vitamin B12, and certain crustaceans may be identified as good sources of folate, niacin, riboflavin, pyridoxine, pantothenic acid, and vitamin C. Certain crustaceans (i.e., shrimp and blue crab) contain vitamin E at levels greater than 10 percent of the current Reference Daily Allowance per reference amount customarily consumed (RACC). Of these vitamins present in crustaceans, only vitamin C, thiamine, vitamin E, and, to a lesser extent pyridoxine, are considered to be sensitive to irradiation (Ref. 32). Although thiamin is present in other types of flesh food, crustaceans are not considered a good source of thiamin (ibid.). Despite the presence of vitamin C, pyridoxine, and vitamin E in crustaceans, they make up a negligible amount of the dietary intake of these vitamins in the United States. Based on data from the USDA Continuing Survey of Food Intakes of Individuals (Ref. 35), the entire food category of "fish/shellfish (excluding canned tuna)" contributes to less than 1 percent of the vitamin C intake of the U.S. diet and less than 2 percent of the vitamin E and pyridoxine intakes of the U.S. diet. Furthermore, because crustaceans account for only 40 percent of the entire category of "fish/shellfish (excluding canned tuna)," the impact of these vitamin levels from consuming crustaceans will be of even less significance (Ref. 32). Potential losses of vitamin C, thiamine, vitamin E, and pyridoxine, as a result of irradiation of crustaceans at a maximum absorbed dose of 6.0 kGy, are of minimal to no consequence to the overall U.S. diet.

Other vitamins present in crustaceans (i.e., niacin, pantothenic acid, vitamin B12, and folate) are relatively insensitive to irradiation, particularly at the doses requested by this petition. Of these vitamins, only vitamin B12 is provided in meaningful amounts to the U.S. diet from the intake of crustaceans. The stability of vitamin B12 to irradiation has been demonstrated in numerous studies and was previously discussed in the molluscan shellfish rule (70 FR 48057 at 48062). Molluscan shellfish contain the highest amounts of vitamin B12 among foods considered to be fish/shellfish; therefore, our evaluation and discussion in the molluscan shellfish rule are relevant to this petition. Further, in its review of this petition, we considered potential B12 losses in crustaceans in addition to other irradiated foods containing vitamin B12 (ibid.). We conclude that any potential losses of radiation-insensitive vitamins in foods, irradiated under the conditions described in this petition, would be minor and the resulting impact on nutrient intake in the U.S. diet would be negligible (ibid.).

We also analyzed the contribution of crustaceans to vitamin D intake and found that only 0.30 percent of dietary vitamin D for U.S. adults (18 years and older) comes from the consumption of crustaceans (Ref. 37). Due to this small contribution of vitamin D from crustaceans to the overall U.S. dietary intake, the potential losses of this vitamin from crustaceans irradiated under the conditions described in this regulation would be minor and the resulting health impact would be negligible.

Based on review of the available data and information, we conclude that irradiation of crustaceans with a maximum absorbed dose of 6.0 kGy will not adversely impact the nutritional adequacy of the diet.

D. Microbiological Considerations

Irradiation at the requested doses will reduce, but not entirely eliminate, the number of viable pathogenic (illness causing) microorganisms in or on crustaceans. Furthermore, as discussed in this document, irradiation of crustaceans is expected to extend the shelf-life of the treated product by reducing the number of non-pathogenic food spoilage microorganisms.

The predominant non-pathogenic bacterial flora of freshly caught fish or shellfish are from the Pseudomonas group, with Acinetobacter and Moraxella, generally present. As crustaceans begin to spoil, the bacteria from the Pseudomonas group can increase to as much as 90 percent of the
microorganisms and pathogenic foodborne microorganisms. Generally, the common spoilage organisms such as pseudomonas and the pathogens of concern are quite sensitive to the effects of ionizing radiation. Chen et al. investigated the microbial quality of irradiated crab meat products, including white lump meat, claw, and crab fingers (Ref. 42). The $D_{10}$ values for spoilage bacteria ranged from less than 0.40 to 0.46 kGy. Further, it was determined that the shelf-life of food products derived from the claw and finger of crabs were extended approximately 3 days beyond the unirradiated samples (ibid.). Following irradiation fresh, peeled, and deveined tropical shrimps stored at 10–12 degrees Celsius were found to have an increase in shelf-life to 10–14 days when irradiated at 1.5 kGy and 18–21 days when irradiated at 2.5 kGy as compared to the unirradiated control samples, which spoiled within 4 days (Ref. 43). In a study performed by Scholz et al., irradiation at 5 kGy extended the shelf-life of Pacific shrimp (Pandalus jordani) to 5 weeks when stored at 3 degrees Celsius (Ref. 44).

Information regarding doses needed for control of pathogenic organisms in the petition and other information in our files show that $D_{10}$ values for vibrios can range from less than 0.10 up to 0.75 kGy depending on the crustacean, its physical state, temperature, and other factors (Refs. 39, 42, 45, and 46). In frozen, unpeeled, and uncooked shrimp, the $D_{10}$ values for L. monocytogenes ranged from 0.7 kGy to 0.86 kGy (Refs. 39 and 47) and for crab meat, the $D_{10}$ value cited in the literature was 0.59 kGy (Ref. 42). The $D_{10}$ values cited in the published literature for several Salmonella serotypes in grass prawns and shrimp homogenate ranged from 0.30 to 0.59 kGy (Refs. 45, 49, and 50). Thus, irradiation of crustaceans at a maximum absorbed dose of 6.0 kGy would be effective at controlling pertinent pathogens (Ref. 40).

In evaluating the subject petition, we have carefully considered whether irradiation of crustaceans under the conditions proposed in the petition could result in significantly altered microbial growth patterns such that these foods would present a greater microbiological hazard than comparable food that had not been irradiated. In considering this issue, we focused on whether the proposed irradiation conditions would increase the probability of significantly increased growth of, and subsequent toxin production by, C. botulinum because this organism is relatively resistant to radiation in comparison to non-spore forming bacteria. We have concluded that the possibility of increased microbiological risk from C. botulinum is extremely remote because: (1) The conditions of refrigerated storage necessary to maintain the quality of crustaceans are not amenable to the outgrowth and production of toxin by C. botulinum and (2) sufficient numbers of spoilage organisms will survive such that spoilage will occur before outgrowth and toxin production by C. botulinum (Refs. 40 and 51).

Based on the available data and information, we conclude that irradiation of crustaceans conducted in accordance with current GMP under 21 CFR 172.5 will reduce bacterial populations without increased microbial risk from pathogens that may survive the irradiation process.

### III. Comments

We have received numerous comments, primarily form letters, from individuals stating their opinions regarding the potential dangers and unacceptability of irradiating food. We have also received several comments from individuals or organizations stating their opinions regarding the potential benefits of irradiating food and urging us to approve the petition. None of these letters contain any substantive information relevant to a safety evaluation of irradiated crustaceans. Additionally, we received several comments from Public Citizen (PC) and the Center for Food Safety (CFS) requesting the denial of this and other food irradiation petitions, as well as joint comments from CFS and Food and Water Watch (FWW).

Overall, the comments were of a general nature and not specific to the requests in the individual petitions. These comments raised a number of topics, including studies reviewed in the 1999 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 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; our purported failure to meet 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 food-borne disease. The topics raised in the FWW/CFS comments included issues with ACBs, our purported failure to define a list of foods covered by the petition; general issues with toxicity data; purported microbiological resistance; and purported negative effects on organoleptic properties.

Many of the comments from PC and CFS were also submitted to the dockets for the rulemakings on the irradiation of molluscan shellfish (Docket No. 1999F–4372, FAP 9M4682) and on the irradiation of fresh iceberg lettuce and fresh spinach (Docket No. FDA–1999–F–2405, FAP 9M4697). For a detailed discussion of our responses to the previously mentioned general comments, we refer to the molluscan shellfish rule (70 FR 48057 at 48062 to 48071). For a detailed discussion of our response to the FWW/CFS comments, we refer to our fresh iceberg lettuce and fresh spinach rule (73 FR 49593 at 49600–49601).

Accordingly, because these comments do not raise issues specific to irradiated crustaceans and because we have already responded to these comments elsewhere, we are not further addressing these comments in this document. There were no additional comments submitted to this docket.

IV. Conclusions

Based on the data and studies submitted in the petition and other information in our files, we conclude that the proposed use of irradiation to treat chilled or frozen raw, cooked, or partially cooked crustaceans, or dried crustaceans, with or without spices, minerals, inorganic salts, citrates, citric acid, and/or calcium disodium EDTA used in accordance with applicable laws and regulations, is safe, providing that the absorbed dose does not exceed 6.0 kGy. Therefore, we are amending § 171.26 as set forth in this document. In accordance with § 171.1(h) (21 CFR 171.1(h)), the petition and the documents that we considered and relied upon in reaching our decision to approve the petition are available for public disclosure (see FOR FURTHER INFORMATION CONTACT). As provided in § 171.1(h), we will delete from the documents any materials that are not available for public disclosure.

V. Environmental Impact

We have previously considered the environmental effects of this rule as announced in the notice of filing for FAP 1M4727 (66 FR 9086). No new information or comments have been received that would affect our previous determination that there is no significant impact on the human environment and that an environmental impact statement is not required.

VI. Paperwork Reduction Act of 1995

This final rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

VII. Objections

If you will be adversely affected by one or more provisions of this regulation, you may file with the Division of Dockets Management (see ADDRESSES) either electronic or written objections. You must separately number each objection, and within each numbered objection you must specify with particularity the provision(s) to which you object and the grounds for your objection. Within each numbered objection, you must specifically state whether you are requesting a hearing on the particular provision that you specify in that numbered objection. If you do not request a hearing for any particular objection, you waive the right to a hearing on that objection. If you request a hearing, your objection must include a detailed description and analysis of the specific factual information you intend to present in support of the objection in the event that a hearing is held. If you do not include such a description and analysis for any particular objection, you waive 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, and will be posted to the docket at http://www.regulations.gov.

VIII. Section 301(ll) 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(ll) of the FD&C Act (21 U.S.C. 331(ll)). Section 301(ll) 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(ll)(1) to (4) of the FD&C Act applies. In its review of this petition, FDA did not consider whether section 301(ll) of the FD&C Act or any of its exemptions apply to irradiated crustaceans. Accordingly, this final rule should not be construed to be a statement that irradiated crustaceans, 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.

IX. 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. References without asterisks are not on display; they are available as published articles and books.


2. L. Weddig, National Fisheries Institute, email message to T. Croce, FDA, August 31, 2012.


32. Memorandum for FAP 1M4727 from A. Edwards, FDA, to T. Croce, FDA, April 4, 2011.


40. Memorandum for FAP 1M4727 from R. Merker, FDA, to T. Croce, FDA, April 11, 2011.


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

§ 179.26 Ionizing radiation for the treatment of food.

Use Limitations

14. For control of food-borne pathogens in, and extension of the shelf-life of, chilled or frozen raw, cooked, or partially cooked crustaceans, Not to exceed 6.0 kGy. cooked or dried crustaceans (water activity less than 0.85), with or without spices, inorganic salts, citrates, citric acid, and/or calcium disodium EDTA.


Leslie Kux,
Assistant Commissioner for Policy.
[FR Doc. 2014–07926 Filed 4–11–14; 8:45 am]