federal register

Wednesday
May 2, 1990

Part VI

Department of Health and Human Services

Food and Drug Administration

21 CFR Part 179

Irradiation in the Production, Processing, and Handling of Food; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 179

[Docket Nos. 86F-0507 and 86F-0509]

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 sources of ionizing radiation for the control of food-borne pathogens in poultry. This action is in response to petitions filed by Radiation Technology, Inc., and the U.S. Department of Agriculture, Food Safety and Inspection Service (FSIS).

DATES: Effective May 2, 1990; written objections and requests for a hearing by June 1, 1990.

ADDRESSES: Written objections may be sent to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Laura M. Tarantino, Center for Food Safety and Applied Nutrition (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-472-5740.

SUPPLEMENTARY INFORMATION:

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I. Introduction

In a notice published in the **Federal Register** of February 20, 1987 (52 FR 5343), FDA announced that a food additive petition (FAP 7M3974) had been filed by the U.S. Department of Agriculture, Food Safety and Inspection Service, Washington, DC 20250, proposing that § 179.26 *Ionizing radiation for the treatment of food* (21 CFR 179.26) be amended to provide for the safe use of sources of ionizing radiation (gamma radiation, electron radiation, and X-radiation) to control food-borne pathogens by reducing the amount of microorganisms, such as *Salmonella*, *Yersinia*, and *Campylobacter*, in poultry products.

In a notice published in the **Federal Register** of March 3, 1987 (52 FR 6391), FDA announced that a food additive petition (FAP 8M3422) had been filed by Radiation Technology, Inc., 108 Lake Denmark Rd., Rockaway, NJ 07866, proposing that § 179.26 be amended to provide for the safe use of a source of gamma radiation to irradiate poultry for the purpose of extending shelf-life and reducing the risk of salmonella poisoning.

In recent years, there has been a heightened awareness of the threat to public health from food-borne illnesses caused by pathogens, and in particular those caused by *Salmonella*, on chicken and other poultry. The subject petitions request that FDA amend the food additive regulations to provide for the use of ionizing radiation to treat fresh or frozen, uncooked poultry to reduce the number of illness-causing microorganisms on the food.

In this final rule, the agency is adding to the authorized uses of ionizing radiation the treatment 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). The poultry can be irradiated at doses of up to 3 kiloGray (300 kilorad) (one kiloGray (kGy) = 100 kilorad (krad)) for control of food-borne pathogens. The term "poultry," as used in this rule, is defined by FSIS in 9 CFR 381.1(b)(40) (i.e., any domesticated bird, including chickens, turkeys, ducks, geese, or guineas).

II. Determination of Safety

In 1958, Congress amended the Federal Food, Drug, and Cosmetic Act (the act) to prohibit the use of a new food additive until the sponsor establishes its safety, and FDA issues a regulation specifying conditions of safe use. A source of radiation was specifically defined as a food additive in section 201(s) of the act (21 U.S.C. 321(s)).

Under section 409(c)(3)(A) of the act (21 U.S.C. 348(c)(3)(A)), the so-called "general safety clause" of the statute, a food additive cannot be approved for a particular use unless a fair evaluation of the data available to FDA establishes that the additive is safe for that use. The concept of safety embodied in the Food Additives Amendment of 1958 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 an additive. It does not—and cannot—require proof beyond any possible doubt that no harm will result under any conceivable circumstances." (H. Rept. 2284, 85th Cong., 2d Sess. (1958).)

FDA has incorporated this concept of safety into its food additive regulations. Under 21 CFR 170.3(i), a food additive is "safe" is "there is a reasonable certainty in the minds of competent scientists that the substance is not harmful under the intended conditions of use." The agency reviewed the data and studies submitted in the petitions, as well as the entire record in its files relevant to the safety and wholesomeness of poultry treated with ionizing radiation. In addition, several letters were sent to FDA and FSIS in opposition to the FSIS petition. Most of these letters expressed opposition in general terms and urged FSIS to consider alternatives to reduce the levels of *Salmonella* in poultry. They provided no data or rationale, however, on which to deny these petitions. Those letters that addressed a specific issue are discussed below.

III. Data Summary and Evaluation

The agency evaluated: (1) Toxicity studies on irradiated chicken; (2) reports on the efficacy of the process and on the microbiological safety of the product; and (3) studies of the nutritional adequacy of the product.

A. Toxicity Data

1. Toxicity Studies Submitted in the Petition

The following reports of animal feeding studies with irradiated chicken were submitted in petiton FAP 8M3422 to demonstrate safety: An 80-week carcinogenicity study in mice carried out at Bio-Research Laboratories for Atomic Energy of Canada, Ltd., and a series of three feeding studies carried out at Centraal Instituut Voor Voedingsonderzoek (CIVO), The Netherlands. The latter studies consisted of: a multigeneration study in

rats; a chronic study in rats; and a 1-year toxicity study in beagle dogs.

a. *Carcinogenicity study in mice.* The mouse chronic feeding study conducted by Bio-Research Laboratories was reported in summary form. In this study, mice fed diets containing 50 percent by weight of chicken irradiated at 7 kGy (700 krad) or of nonirradiated chicken were compared to mice fed a standard commercial diet or a standard diet containing a known carcinogen. Each experimental group consisted of 100 male and 100 female mice. The authors of the study reported that a variety of internal neoplasms occurred in mice in the control and the experimental groups, but that the incidence and distribution of the tumors in all groups (except that in which the animals were fed a diet containing a known carcinogen) were comparable to values for spontaneously occurring mouse tumors as reported in the literature. The authors stated that "* * * there is nothing in the overall results that suggests a carcinogenetic effect in mice of irradiated chicken."

The agency found that interpretation of this study was confounded by high rates of mortality and autolysis. In addition, in the course of its initial review of this study, the agency noted a discrepancy in the numbers presented in two of the study report tables for the incidence of hepatomas in female mice fed irradiated chicken. Specifically, 11 tumors of this type were reported in one table, although data in a second table were consistent with the occurrence of just one such tumor in this group.

Because the data submitted on this mouse study consisted of a summary report without full detail, and because of the discrepancy concerning the incidence of hepatomas, the agency requested the original microslides and individual animal data from the laboratory where the study was conducted. After receiving this information, the agency found that the slides were no longer readable because the mounting medium had deteriorated, and that the testing laboratory had not conducted a complete histopathologic examination. The discrepancy regarding the number of hepatomas, however, was resolved by a letter from the Director General of the Food Directorate of Health and Welfare, Canada (Ref. 1), which stated that an examination of the raw data confirmed that the discrepancy was the result of a typographical error. The correct figure was verified as one hepatoma, a number not significantly different from the numbers noted for this tumor type in female mice fed the stock diet or non irriadated chicken. The agency finds that statistical analysis of the available data from this study does not raise a concern that irradiated chicken is carcinogenic in mice (Ref. 2). Because of deficiencies in the data, however, the agency is not relying on this study as a primary basis for evaluating the safety of irradiation of poultry.

b. *CIVO rat and dog studies.* The petitioner for FAP 8M3422 also submitted a series of three feeding studies carried out at CIVO.

i. *Multigeneration study in rats.* Rats were fed a control basal diet or a diet containing chicken that had been irradiated at 3 or 6 kGy (300 or 600 krad), or nonirradiated chicken, at a level of 35 percent of the diet. The investigators followed reproductive performance through three successive generations. The authors reported that there were no consistent differences between groups in measured reproduction parameters, such as fertility, number of young per litter, and mortality in utero. Feeding of irradiated chicken did not adversely affect body weight, growth rate, and mortality of offspring.

A 90-day subchronic feeding study was conducted with animals from the second litter of the third generation. The investigators measured body weight, hematologic parameters, and blood and urine chemistry. After sacrifice, gross and microscopic examinations of organs and tissues were carried out. The authors reported that no deaths occurred during the course of the study, and that growth rate, condition, and behavior of the animals were normal. There were no significant changes in blood or urine composition. The authors observed that body weights were increased in the test groups, and that the relative weights of liver and kidneys in male rats fed chicken irradiated at 3 kGy were slightly increased. However, the differences in organ weights were not accompanied by gross or microscopic abnormalities. The authors concluded that chicken irradiated at 3 and 6 kGy "* * * did not evoke any distinct deleterious effects when fed to rats at a dietary level of 35% during four generations."

ii. *Chronic rat study.* A second rat feeding study was conducted at CIVO. In this chronic 2-year study, rats were fed a standard diet or a diet containing nonirradiated or irradiated (3 or 6 kGy) chicken at a level of 35 percent dry matter. Each of the diets was fed to 60 male and 60 female rats. Observations were made of appearance, behavior, mortality, growth, hematologic parameters, and blood and urine chemistries. Extensive gross and microscopic pathological examinations were carried out.

The authors reported no differences among groups in appearance, behavior, mortality, or growth. Hematologic factors and blood and urine chemistries did not show distinct or consistent changes among groups. All abnormalities observed by gross and microscopic examination of tissues were those considered by the investigators to be related to normal aging of rats, and the type and incidence of the changes were comparable in test and control groups. There was no indication that the feeding or irradiated chicken induced neoplasms.

iii. *Beagle study.* In the third CIVO feeding study, beagle dogs were fed a standard diet or a diet containing 35 percent nonirradiated or irradiated (3 to 6 kGy) chicken for 1 year. Each group of dogs consisted of four males and four females. The authors reported that health, survival, appearance, behavior, and growth of the animals were not noticeably affected by inclusion of irradiated chicken in the diet. They found no evidence of abnormalities in hematologic factors, organ weights, or gross and microscopic appearance of organs and tissues and concluded that the feeding of irradiated chicken did not induce any deleterious effects in the dogs.

iv. *FDA's evaluation of the CIVO studies.* Upon evaluation of these feeding studies conducted at CIVO, agency scientists found that the studies appeared to be of high quality and that there was no evidence of adverse effects attributable to consumption of diets containing chicken irradiated at 3 or 6 kGy (Refs. 3 and 4). However, FDA examined the possibility that the addition of ethoxyquin, an antioxidant that was incorporated into the animals' food to inhibit rancidity, could have confounded the interpretation of this series of tests.

The laboratory investigators had noted that lipid peroxide values (a measure of rancidity) increased in chicken as a function of both storage time and irradiation. Thus, the investigators added ethoxyquin to the chicken to prevent development of rancidity in the chicken fat. Ethoxyquin was incorporated into both the control diets and the test diets to control for possible confounding effects. Nonetheless, the agency considered whether ethoxyquin could have decreased the ability of the studies to show a carcinogenic effect because dietary ethoxyquin and other antioxidants have been reported to inhibit the carcinogenic effects of

certain carcinogenic chemicals under some conditions (Ref. 5). The agency also considered the question of whether ethoxyquin might have altered the chemical changes that might occur during the irradiation process.[1]

The agency found that the level of ethoxyquin used in the study (35 parts per million (ppm) of diet) was much lower than the level shown to inhibit chemical carcinogenesis (around 10,000 ppm). Further, agency scientists concluded that ethoxyquin is unlikely to significantly alter the level and kind of radiolytic products because the ethoxyquin was not added to the chicken meat until after irradiation (for further discussion, see Ref. 4). Therefore, the agency concluded that the use of ethoxyquin did not confound the results of these studies.

To ensure that all available data relating to these three feeding studies had been evaluated, the agency requested and received necropsy and histopathology data on the individual animals. Review of these data supported the agency's finding (Refs. 3 and 4) that these studies were well-conducted, and that they provide no evidence of treatment-related adverse toxicological effects (Refs. 6 and 7).

2. Other Toxicity Studies in Agency Files

Even though the studies submitted in the petitions and discussed above were adequate to establish that the irradiation of poultry under the conditions specified in the regulation below does not present a toxicological hazard, the agency also evaluated the other available studies of irradiated chicken in its files.

a. *Raltech studies.* A series of U.S. Department of Agriculture-sponsored studies using chicken sterilized by irradiation was conducted by Raltech Scientific Services. The studies included a chronic feeding study in mice, a chronic feeding study in dogs, teratology studies in four species, a dominant lethal test in mice, a sex-linked recessive test in *Drosophila melanogaster*, and an Ames mutagenicity test. (Reports of these studies are available through the National Technical Information Service (see 49 FR 40623; October 17, 1984).) The Raltech studies were carried out with chicken that had been thermally processed to inactivate enzymes, cooled to approximately −40 °C, and irradiated in the frozen state in the absence of air at doses ranging from 45 to 59 kGy, some 15 to 20 times the maximum dose at issue in this rulemaking.

The agency discussed the findings of, and its conclusions regarding, the Raltech chronic feeding studies in mice and dogs, an incomplete study in rats, and the sex-linked recessive study in *Drosophila* in its recent decisions on irradiated foods on April 18, 1986 (51 FR 13376 at 13386), and December 30, 1988 (53 FR 53176 at 53188 through 53189). (See also Ref. 8.) Those discussions are incorporated herein.[2]

The teratology studies conducted at Raltech showed that feeding irradiated chicken to hamsters, rabbits, rats, and mice did not result in teratogenic effects in offspring. The agency's review found that the first three of these studies were of good quality. The agency stated that the study in mice, although negative, was of limited value because of procedural flaws in recording the data (Ref. 8).

The dominant lethal test in mice did not show adverse effects in animals fed irradiated chicken; however, FDA considered that study to be unsuitable for supporting safety because the positive control also produced negative results (Ref. 8). FDA found that the Ames mutagenicity test was well-conducted and provided no evidence of mutagenicity of irradiated chicken (Ref. 8).

The agency found no evidence in any of the Raltech studies of adverse effects that could be attributed to irradiation of chicken at doses of up to 59 kGy (Ref. 8). Because of differences in irradiation conditions, the radiation-sterilized chicken used in these studies does not model the changes that would be expected in chicken irradiated unfrozen and in the presence of air. Therefore, FDA is not relying on these studies as a primary basis for a safety evaluation. However, the agency finds that the lack of treatment-related adverse effects in the Raltech studies is consistent with the agency's conclusion that chicken irradiated at 3 kGy does not present a toxicological hazard.

b. *Genetic toxicity studies.* The agency also reviewed several in vitro and in vivo mutagenesis and genetic toxicity studies with irradiated chicken that were carried out at the Federal Research Centre for Nutrition, Karlsruhe, Federal Republic of Germany. These included: a reverse mutation test in *Salmonella typhimurium*; a sister chromatid exchange and hypoxanthine-guanine phosphoribosyl transferase mutation assay in cultured Chinese hamster ovary cells; and a micronucleus test, bone marrow sister chromatid exchange, and sister chromatid exchange in spermatogonia, all in rodents. The investigators reported that chicken irradiated at 7 kGy was not mutagenic in these tests.

The agency found that the tests in rodents (i.e., bone marrow micronucleus tests in rats, mice, and hamsters; sister chromatid exchange in bone marrow cells of mice and hamsters; and sister chromatid exchange in spermatogonia of mice) showed that animals fed irradiated chicken had numbers of micronuclei or sister chromatid exchanges in the tissues examined comparable to those fed nonirradiated chicken. The agency found that these studies demonstrate the lack of mutagenic effects from the irradiated chicken diet (Ref. 8).

Agency scientists noted that methodological deficiencies in the other

[1] In 1982, FDA reviewed all available toxicological studies with irradiated food. The agency concluded that the data were inadequate to support a decision that all foods may be irradiated safely at doses up to 10 kGy (see 51 FR 13378 at 13378 and 13384; April 18, 1986). Agency scientists concluded at that time that the reports of the CIVO studies were not completely acceptable for evaluating the safety of all foods irradiated at doses of up to 10 kGy because of a reservation about the use of ethoxyquin. The agency had not yet made its determination, which is set forth *infra*, about the significance of the use of this substance

[2] Briefly, the agency responded to comments and objections alleging that several of the Raltech studies showed adverse toxicological effects attributable to the feeding of radiation-sterilized chicken. Specifically, the comments and objections raised questions concerning the mutagenicity test in *Drosophila* and feeding studies in mice, dogs, and rats.

There was no evidence that radiation-sterilized chicken is mutagenic in the sex-linked recessive lethal study in *Drosophila*. The agency addressed an observation in this study of decreased numbers of offspring in groups raised on irradiated chicken meat. The agency noted that decreased numbers of offspring also occurred in those groups fed nonirradiated chicken, compared to those fed a control diet, and found that there was no evidence to show that radiation sterilization of chicken caused adverse reproductive effects in this test.

The agency also considered whether the Raltech feeding study in mice showed a treatment-related increase in testicular tumors. Agency scientists examined the histopathology slides from this study. The data were also referred to the National Toxicology Program's (NTP) Board of Scientific Counselors for peer review. FDA and NTP pathologists agreed that the evidence did not show a treatment-related induction of testicular tumors.

With regard to the Raltech dogs feeding study, the agency considered a comment that male dogs fed irradiated chicken had lower body weights than dogs fed frozen chicken. The agency noted, however, that the amount of food made available to the dogs was manipulated to obtain "ideal" body weights and concluded that any difference in body weights was not the result of radiation treatment.

Finally, the agency considered an objection that pointed to the fact that a chronic feeding study in rats was not completed. The rat feeding study was not completed because of lactation failure in parent females in all diet groups, including control groups. Thus, this study was not evaluated by the agency. The authors of the study reported that there was no evidence of toxicity from the test diets during the 9 months of the test.

studies limited their usefulness; however, these scientists found no evidence in any of these studies that indicated that irradiated chicken was mutagenic (Ref. 8).

3. Summary of Toxicological Findings

The agency has carefully reviewed the studies submitted with the petitions and the other available data and studies in its files on the toxicological effects of irradiated chicken. Adverse effects that were attributable to the consumption of irradiated chicken were not produced in any of these studies. While, as noted above, the agency found certain deficiencies in some of the studies, the agency concludes, based on all the evidence before it, that the irradiation of poultry at the petitioned level of up to 3 kGy does not present a toxicological hazard.[3]

B. Microbiological Considerations

1. Efficacy

The petitioners provided several reports and published papers describing the effectiveness of low-dose irradiation in reducing the number of microorganisms on poultry and other foods. For example, a number of reports submitted in the petitions point out that the radiation dose necessary to reduce the initial population of *Salmonella* by 90 percent (i.e., the D value) ranges from less than 0.5 kGy to approximately 1 kGy depending on such factors as the strain and the temperature at which irradiation is carried out (see, e.g., Ref. 10 for D values obtained under various conditions). Other microorganisms of potential public health significance, specifically *Yersinia* and *Campylobacter*, are even more radiation-sensitive than *Salmonella* (Refs. 11 and 12).

The agency has reviewed these as well as other published data and finds that irradiation at doses of up to 3 kGy (300 krad) is effective in lowering the burden of microorganisms in poultry. In particular, irradiation at these doses is effective in reducing the numbers of such food-borne pathogens as *Salmonella*, *Yersinia*, and *Campylobacter* (Ref. 13).

2. Selective Destruction of Microorganisms

The doses of radiation requested in these petitions do not sterilize the food. Thus, poultry treated in this way would require refrigeration and proper handling by the retailer and consumer to inhibit multiplication of surviving organisms. 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*. *C. botulinum*, however, does not ordinarily grow and produce toxin under the refrigeration conditions that should be used to store fresh poultry. Nevertheless, the agency considered whether *C. botulinum* could grow and produce toxin without the signs of spoilage familiar to the consumer if proper temperature control were not maintained.

FDA reviewed studies in which chicken skins were inoculated with large numbers of *C. botulinum*, irradiated, and stored at a temperature of 10 °C, to model poor refrigeration conditions, and 30 °C, to model a severe abuse temperature. These conditions were chosen to provide a worst-case scenario that would result in a much greater burden of toxin than would be expected under normal conditions.

In one series of studies (Refs. 14 to 16), chicken skins were inoculated with *C. botulinum* Type E, irradiated, incubated at 10 °C or 30 °C, and checked daily for off-odors indicative of spoilage and for toxin production.[4] The authors noted that irradiation appeared to injure spores of *C. botulinum* because spores on chicken skins irradiated at 3 kGy and held at 10 °C did not produce toxin at any time in the period studied, whereas toxin was produce on the nonirradiated chicken. After storage at 30 °C, toxin was produced on both irradiated and nonirradiated chicken. However, under all storage conditions, even those most favorable to toxin production, the natural flora surviving 3 kGy irradiation produced off-odors characteristic of spoilage before toxin was observed.

Another study examined the effect of 3 kGy irradiation on the growth of, and toxin production by, *C. botulinum* Types A and B on chicken skins (Ref. 17). The investigators reported that toxin was not formed from these varieties when the chicken was stored at 10 °C, whether irradiated or not. At the abuse temperature of 30 °C, toxin was formed in both irradiated and nonirradiated chicken, but toxin formation was delayed in the chicken subjected to irradiation. In this case also, the natural flora multiplied and produced an off-odor indicative of spoilage by the time samples became toxic.

Thus, these studies show that enough of the normal flora survives in poultry irradiated at 3 kGy (300 krad) that *C. botulinum*, if present, would not render the product toxic before the normal signs of spoilage became evident. Based on this evidence, the agency concludes that irradiation of poultry at 3 kGy does not result in any additional health hazard from *C. botulinum* (Ref. 13).

A letter to the agency contended that the irradiation process can accelerate the growth of *C. botulinum* at doses above 1 kGy (100 krad) and submitted copies of three reports on the irradiation of chicken skins inoculated with *C. botulinum* Type E.

The reports submitted with the comment were those discussed above (Refs. 14 to 16) that showed that no toxin was detected in the irradiated chicken before it spoiled. One of these reports (Ref. 16) described injury to *C. botulinum* spores caused by irradiation at doses of 1 to 4 kGy (100 to 400 krad), as well as repair of such injury. The other two reports (Refs. 14 and 15) concluded that: (1) No toxin was detected before spoilage occurred in chicken irradiated at a dose of 3 kGy, and (2) natural surviving microflora grew faster than *C. botulinum* spores. Thus, contrary to the assertion in the letter, these studies demonstrate that irradiation of chicken at a dose of 3 kGy or less will not result in any additional health hazard from *C. botulinum* Type E. As discussed above, comparable studies have also been conducted with *C. botulinum* Types A and B.

The FSIS petition requested that the packaging used for irradiated chicken be restricted to materials that are oxygen permeable. Packaging and storage of chicken under anaerobic conditions, such as vacuum or modified atmosphere packaging, can extend shelf-life by inhibiting outgrowth of aerobic spoilage

[3] In 1979, FDA established the Bureau of Foods Irradiated Food Committee (BFIFC) to review the existing agency policy concerning irradiation of foods (Ref. 9). BFIFC was charged to recommend "toxicologic [testing] requirements appropriate for assessing the safety of irradiated food * * *" BFIFC concluded that foods irradiated at doses above 1 kGy and comprising more than 0.01 percent of the diet warrant toxicologic evaluation. BFIFC recommended that foods irradiated at doses above 1 kGy be evaluated using a battery of mutagenicity tests, as well as 90-day feeding studies in two species (one rodent, one nonrodent), and that the rodent test include in utero exposure.

Among the studies of irradiated chicken that were evaluated by the agency were a battery of in vivo mutagenicity tests that FDA determined to be adequate to demonstrate safety. In addition, FDA reviewed a multigeneration study in rats (including a 90-day subchronic feeding study), a chronic carcinogenicity study in rats, and a 1 year feeding study in dogs and found them to be adequate to demonstrate the toxicological safety of the use of irradiation on poultry at the dose levels at issue in this regulation.

[4] Although *C. botulinum* Type E is associated primarily with marine products, its response to radiation was studied because chickens may be fed fish meal containing *C. botulinum* Type E, and thus it is conceivable that the intestinal tract of poultry may contain these organisms. Further, *C. botulinum* Type E will multiply and produce toxin at lower temperatures than other types of *C. botulinum*.

microorganisms, but it can also provide conditions conducive to growth of *C. botulinum*. The agency notes that the studies cited above examined *C. botulinum* toxin production and spoilage in chicken incubated both aerobically and anaerobically and found that spoilage preceded toxin production even in chicken incubated anaerobically. Use of air-permeable packaging materials does, however, provide an extra margin of safety. Because the petitioner requested that only air-permeable packaging be permitted, FDA is including a provision in the regulation that packaging used shall not exclude oxygen.

C. Nutritional Considerations

FDA reviewed data to determine whether irradiation of poultry would have an adverse effect on the nutritional value of the food. One study submitted in FAP 8M3422, carried out at CIVO, examined the composition and nutritive value of chicken irradiated at a dose of 3 or 6 kGy (300 or 600 krad), as compared to a nonirradiated control. Batches of irradiated and nonirradiated chicken were refrigerated for 3 to 7 days, cooked, and homogenized. Samples were then analyzed for general composition and content of nutrients, including vitamins. The investigators also performed bioassays of protein utilization and digestibility in weanling rats.

The authors reported that vitamin content showed considerable variation both between different batches of chicken and between different treatments of the same batch. They reported that there was, however, no distinct effect of irradiation on vitamin content, with the possible exception of a slight decrease in vitamin B_1 (thiamin) at a dose of 6 kGy (twice as high as the maximum does under consideration in this rulemaking). They also reported that determinations of the digestibility and of the utilization of the chicken protein for growth and synthesis of body protein revealed that irradiation did not decrease the nutritive value of protein in weanling rats.

The agency has also received reports of a study conducted at the U.S. Department of Agriculture on the effects of irradiation on nutrients in chicken and pork (Refs. 18 and 19). The authors reported that the levels of niacin and riboflavin did not change significantly with radiation doses of up to 7 kGy in samples of chicken that had been irradiated and then cooked, when compared to control samples that had only been cooked. The loss of thiamin in chicken irradiated in an air-permeable package at 0 °C at a dose of 3 kGy was 9 percent (Ref. 19). The authors of this study considered the effect on the dietary intake of thiamin if all chicken and turkey consumed were irradiated at 3 kGy and estimated that the maximal loss of thiamin in the diet would be 0.076 percent (Ref. 18).

After reviewing these reports and the studies submitted in the petitions in which irradiated chicken was fed to laboratory animals, FDA concludes that the data show that irradiation at the doses used does not have a deleterious effect on the levels or the bioavailability of the nutrients in chicken (Refs. 20 to 22).

One letter to the agency suggested that studies on vitamin losses in irradiated chicken should include comparisons of immediate losses, losses from storage, and losses from cooking.

The analysis of vitamins in the CIVO study discussed above was performed on chicken that had been stored in a refrigerator and cooked, and the USDA study (Ref. 18) explicitly considered the effect of irradiation on vitamin content in both raw and cooked chicken. Thus, FDA has considered the factors cited by the comment and has found no evidence of significant vitamin loss in chicken irradiated to a maximum dose of 3 kGy. The agency therefore concludes that irradiation of poultry at doses of up to 3 kGy will not have an adverse impact on the nutritional value of a person's diet.

IV. Current Good Manufacturing Practice Considerations

FDA has established general provisions defining current good manufacturing practice for the use of irradiation in the treatment of food in § 179.25 (21 CFR 179.25). This regulation discusses requirements such as recordkeeping and the need for a scheduled process for food irradiation. Section 179.25(b) states that: "Food treated with ionizing radiation shall receive the minimum radiation dose reasonably required to accomplish its intended effect * * *." Section 179.25(c) states that: "Packaging materials subjected to irradiation incidental to the radiation treatment and processing of prepackaged foods shall comply with § 179.45."

FSIS, in its petition, requested that FDA establish a minimum dose of 150 krad (1.5 kGy) for the irradiation of poultry and also requested that FDA require that poultry that is to be irradiated be prepackaged.

The minimum dose needed to control pathogenic organisms on poultry can vary with the particular microorganism and with the microbial burden on the food. The need for packaging before application of radiation also may vary with the intended effect of the treatment and the conditions of application. FSIS, based on its regulatory authority over operation of poultry processing plants, can establish specific packaging requirements and a minimum dose, consistent with current good manufacturing practice, for controlling pathogenic organisms in such plants. FDA concludes 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 comply with 21 CFR 179.25 and 179.26. Therefore, the regulation set forth below does not establish specific requirements for packaging or for a minimum dose.

V. Labeling

Food irradiated under the conditions of the regulation set forth below must be labeled as required by § 179.26(c) (21 CFR 179.26(c)). In addition, because poultry is also subject to regulation by FSIS, the labeling of poultry irradiated under the conditions of this regulation must comply with any requirements imposed by that agency under its authority to approve labeling of meat and poultry.

VI. Comment

The agency received a letter from two state legislators, dated February 22, 1988 (Ref. 23), asking FDA to deny these petitions and to rescind all regulations permitting sale of irradiated food. This request was based on the legislators' understanding: (1) That benzene is formed in all food when it is irradiated, and (2) that the Delaney Clause of the Federal Food, Drug, and Cosmetic Act prohibits the use of any food additive that is carcinogenic, regardless of the level at which it is present in food.

This letter did not provide any evidence that benzene is formed by irradiation of poultry at a dose of 3 kGy (300 krad) or less, or that if it is formed, it could be expected to be present in amounts that would pose a risk to consumers. FDA denied this request by a letter dated May 2, 1988 (Refs. 24 and 25), because there is no basis for concluding that benzene would be formed in irradiated poultry in toxicologically significant amounts, and because the Delaney Clause applies only to additives, not to impurities that may result in insignificant amounts from the use of additives. The request provided no evidence that increased concentrations of benzene have been, or could be, detected in poultry irradiated at a dose of 3 kGy or less. No further information was submitted to FDA after it denied this request. Therefore, the

request provided no basis for denying these petitions.

Moreover, FDA discussed the possible formation of benzene in its response to objections to FDA's earlier decisions to permit other applications of radiation in food (53 FR 53176 at 53197; December 30, 1988). In that document FDA discussed data demonstrating that very low concentrations of benzene (19 parts per billion) were produced by high dose (56 kGy) radiation sterilization of beef. FDA noted that an analysis by expert scientists found that such low concentrations were of trivial health concern, and that other foods irradiated at lower doses would present even less reason for concern (53 FR 53197).

VII. Conclusions

FDA has evaluated the information submitted in the petitions and other relevent material in its files. Based on these data, the agency concludes that the proposed use of ionizing radiation is safe, and that the regulations should be amended in 21 CFR 179.26(b) as set forth below. The agency is also making minor editorial changes in § 179.26(b) by numbering the entries and by spelling out in full the units of radiation dose.

In accordance with § 171.1(h) (21 CFR 171.1(h)), the petitions and the documents that FDA considered and relied upon in reaching its decision to approve the petitions are available for inspection at the Center for Food Safety and Applied Nutrition by appointment with the information contact person listed above. As provided in 21 CFR 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.

The agency has carefully considered the potential environmental effects of this action. FDA had 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. References

The following references 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.

1. Letter dated January 9, 1987, from S.W Gunner, Health and Welfare, Canada, to Sanford A. Miller, FDA.

2. Memorandum dated June 16, 1987, from J.A. Springer, FDA, to W. G. Flamm, FDA.

3. Memorandum dated August 7, 1985, from C. Kokoski, FDA, to C. Takeguchi, FDA.

4. Memorandum of meeting dated August 22, 1985, CFSAN Cancer Assessment Committee.

5. Wattenberg, L.W., "Inhibition of Chemical Carcinogenesis," *Journal of the National Cancer Institute*, 60:11, 1978.

6. Memorandum dated February 11, 1988, from H. Irausquin, FDA, to H. Blumenthal, FDA.

7. Memorandum dated July 14, 1986, from H. Irausquin, FDA, to C. Takeguchi, FDA.

8. Memorandum dated December 14, 1988, from H. Irausqui, FDA, to G. Pauli, FDA.

9. Brunetti, A.P. et al., "Recommendations for Evaluating the Safety of Irradiated Foods," final report prepared for the Director, Bureau of Foods, FDA, July 1980.

10. Mulder, R.W.A.W., "*Salmonella* Radicidation of Poultry Carcasses," Report 363, Spelderholt Institute for Poultry Research, Beekbergen, The Netherlands, 1982.

11. El-Zawahry, Y.A., and D.B. Rowley, "Radiation Resistance and Injury of *Yersinia enterocolitica*," *Applied and Environmental Microbiology*, 37:50, 1979.

12. Lambert, J.D., and R.B. Maxcy, "Effects of Gamma Radiation on *Campylobacter jejuni*," *Journal of Food Science*, 49:665, 1984.

13. Memorandum dated September 21, 1988, from D.A. Kautter, FDA, to C. Takeguchi, FDA.

14. 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 Science*, 47:887, 1982.

15. Firstenberg-Eden, R., D.B. Rowley, and G.E. Shattuck, "Competitive Growth of Chicken Skin Microflora and *Clostridium botulinum* Type E after an Irradiation Dose of 0.3 Mrad," *Journal of Food Protection*, 46:12, 1983.

16. Rowley, D.B., R. Firstenberg-Eden, and G.E. Shattuck, "Radiation-Injured *Clostridium botulinum* Type E Spores: Outgrowth and Repair," *Journal of Food Science*, 48:1829, 1983.

17. Dezfulian M., and J.G. Bartlett, "Effect of Irradiation on Growth and Toxigenicity of *Clostridium botulinum* Types A and B Inoculated onto Chicken Skins," *Applied and Environmental Microbiology*, 53:201, 1987

18. Fox, J.B., Jr., et al., "Effect of Gamma Irradiation on the B Vitamins of Pork Chops and Chicken Breasts" *International Journal of Radiation Biology*, 55:689, 1989.

19. Anonymous, "Status of Food Safety and Inspection Service Irradiation Activities," U.S. Department of Agriculture, Food Safety and Inspection Service, September 1988.

20. Memorandum dated April 2, 1979, from J.E. Vanderveen, FDA, to Petition Control Branch, FDA.

21 Memorandum dated May 17, 1988, from J.T. Tanner, FDA, to C. Takeguchi, FDA.

22. Memorandum dated February 16, 1989, from J.T. Tanner, FDA, to A. Dennis, FDA.

23. Letter dated February 22, 1988, from J.V Kelly, and J.H. Dorsey, New Jersey State Legislature, to Frank Young, FDA.

24. Letter dated May 2, 1988, from F Young, FDA, to J.V. Kelly, New Jersey State Legislature.

25. Letter dated May 2, 1988, from F. Young, FDA, to J.H. Dorsey, New Jersey State Legislature.

IX. Objections

Any person who will be adversely affected by this regulation may at any time on or before June 1, 1990, 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.

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: Secs. 201, 402, 403, 409, 703, 704 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 342, 343, 348, 373, 374).

2. Section 179.26 is amended by revising the table in paragraph (b) to read as follows:

§ 179.26 Ionizing radiation for the treatment of food.

* * * * *

(b) * * *

Use	Limitations
1 For control of *Trichinella spiralis* in pork carcasses or fresh, non-heat-processed cuts of pork carcasses.	Minimum dose 0.3 kiloGray (kGy) (30 kilorad (krad)); maximum dose not to exceed 1 kGy (100 krad).
2. For growth and maturation inhibition of fresh foods.	Not to exceed 1 kGy (100 krad).
3. For disinfestation of arthropod pests in food.	Do.
4. For microbial disinfection of dry or dehydrated enzyme preparations (including immobilized enzymes).	Not to exceed 10 kGy (1 megarad (Mrad)).
5. For microbial disinfection of the following dry or dehydrated aromatic vegetable substances when used as ingredients in small amounts solely for flavoring or aroma: culinary herbs, seeds, spices, vegetable seasonings that are used to impart flavor but that are not either represented as, or appear to be, a vegetable that is eaten for its own sake, and blends of these aromatic vegetable substances. Turmeric and paprika may also be irradiated when they are to be used as color additives. The blends may contain sodium chloride and minor amounts of dry food ingredients ordinarily used in such blends.	Not to exceed 30 kGy (3 Mrad).
6. For control of foodborne pathogens in 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).	Not to exceed 3 kGy (300 krad); any packaging used shall not exclude oxygen.

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Dated: April 3, 1990.

Alan L. Hoeting,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 90-10113 Filed 5-1-90; 8:45 am]

BILLING CODE 4160-07-M