

Regulatory Status of Irradiation of Meat and Poultry

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Abstract

The irradiation of pork was approved by the Food and Drug Administration (FDA) in 1985 and the USDA, Food Safety and Inspection Service (FSIS) in 1986 with a minimum and maximum dose of 0.3 and 1.0 kGy, respectively. The FDA authorized the use of gamma radiation from cobalt-60 or cesium-137, electrons with a maximum energy of 10 MeV, and X-rays with a maximum energy of 5 MeV for treatment of food in 1986. The FSIS petitioned the FDA to approve the irradiation of poultry in 1987. The FDA complied in 1990, allowing a maximum dose of 3.0 kGy. The FSIS amended the poultry products inspection regulations to allow poultry to be treated with ionizing radiation to control foodborne pathogens in 1992. Isomedix Inc., of Whippany, NJ, petitioned the FDA for approval of the irradiation of red meats in 1994. On Dec. 3, 1997, the FDA amended the food additive regulations to allow the use of ionizing radiation to treat refrigerated or frozen uncooked meat to control foodborne pathogens and to extend shelf-life. The FSIS is currently preparing its regulations to allow the actual use of the process.

Approval of red meat irradiation by the U.S. Food and Drug Administration (FDA) (Food and Drug Administration, 1997) prompted interest by industry and consumer groups in the U.S. In the rather brief time since that approval took place there have been several major conferences about the application of irradiation to meat and poultry. These have ranged from meetings sponsored by public interest groups to those sponsored by impacted industrial groups. As of April, when this paper was prepared, the U.S. Department of Agriculture (USDA), had not published regulations for irradiation of red meats. However, review of the regulatory actions that brought food irradiation to this point in the U.S. may be informative.

In response to a petition submitted in July 1984, by Radiation Technology, Inc., of Rockaway, New Jersey, the FDA on July 22, 1985, amended the food additive regula-

tions to permit gamma radiation treatment of pork to control *Trichinella spiralis* (Food and Drug Administration, 1985). The regulation approved the processing of pork carcasses or fresh, non-heat processed cuts of pork carcasses with a minimum absorbed dose of 0.3 kiloGray (kGy) and a maximum dose not to exceed 1 kGy to control *Trichinella spiralis*. The USDA Food Safety and Inspection Service (FSIS) amended the Federal meat inspection regulation on January 15, 1986, to permit the use of gamma radiation to control *T. spiralis* in fresh or previously frozen pork (Food Safety and Inspection Service, 1986). The authorization for the use of the following energy sources was published on April 18, 1986: 1) gamma rays from sealed units of the radionuclides cobalt-60 or cesium-137, 2) electrons generated from machine sources at energies not to exceed 10 million electron volts (10 MeV), and 3) X-rays generated from machine sources at energies not to exceed 5 MeV (Food and Drug Administration, 1986).

A food additive petition was filed by the USDA, FSIS on February 20, 1987, proposing that *Ionizing radiation for the treatment of food* (21 CFR 179.26) be amended to permit the safe use of sources of ionizing radiation to control food-borne pathogens by reducing the amount of microorganisms in poultry products. On May 2, 1990, the FDA amended the food additive regulations to permit the use of ionizing radiation for the treatment of fresh or frozen, uncooked poultry products at doses up to 3 kGy (Food and Drug Administration, 1990). The FSIS requested in their petition to the FDA that the poultry to be irradiated should be prepackaged in air-permeable packaging. The FDA did not require either a minimum dose or specific packaging requirements. However, the regulation does state that any packaging used shall not exclude oxygen.

FSIS amended the poultry products inspection regulations to permit use of ionizing radiation sources to treat fresh or frozen uncooked, packaged whole poultry carcasses or parts known as "ready to cook poultry" (Food Safety and Inspection Service, 1992). This includes fresh or frozen, uncooked ground, hand-boned, and skinless poultry and mechanically separated poultry. The treatment was for the purpose of controlling and reducing foodborne pathogens. The FSIS established a minimum dose of 1.5 kGy. A minimum dose of 1.5 kGy created significant problems for radiation processors because it meant that the maximum (3.0 kGy) to minimum (1.5 kGy) dose was a

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ratio of 2 to 1, which is difficult to achieve with standard pallet loads of poultry.

The regulation established several rules about labeling and about the actual irradiation process. The regulation specified that packages of poultry product irradiated in conformance with the regulation must bear the radura logo along with a statement such as, "Treated with radiation" or "Treated by irradiation." In addition, the logo must be placed prominently and conspicuously in conjunction with the required statement and must be colored green. The qualifying statement must be not less than one-third the size of the largest letter in the product name. The regulation also requires the establishment of an approved quality control system with records that will allow the USDA to monitor compliance. The system minimally must have proper licensing; adequate refrigeration storage during radiation processing of poultry; certification of training for operators of food irradiation facilities; and certification that the key facility quality control personnel are trained in quality control, food technology, irradiation processing, and radiation health and safety. Procedures must be established to ensure that each production lot of packaged poultry is accompanied by a certificate or traceable certificate that states that the food-contact packaging material is guaranteed by the supplier as complying with 21 CFR 179.45; and that the food-contact packaging material is air-permeable, but does exclude moisture and microorganisms from penetrating the package barrier. Procedures are required for the actual irradiation and dosimetry for the process, such as ensuring that the product is not reirradiated and that non-irradiated product is not commingled with irradiated product. (The American Society for Testing and Materials (ASTM) has recently published a guide for the irradiation of fresh and frozen red meats and poultry that anyone considering the establishment of a food irradiation facility should consult (American Society for Testing and Materials, 1996).

Isomedix Inc., of Whippany, NJ, submitted a petition on June 30, 1994, to the FDA to approve the treatment of fresh and frozen raw meat of all domesticated mammalian sources with ionizing radiation as an intervention step to control microbial pathogens and infectious parasites, and

to extend refrigerated shelf-life. Meat from bovine, porcine, ovine, and equine species were included in the petition, and maximum doses of 4.5 kGy and 7.0 kGy were requested for nonfrozen and hard-frozen meats, respectively. In response to the petition, on December 3, 1997, the FDA amended the food additive regulations to provide for the use of a source of radiation to treat refrigerated or frozen uncooked meat, meat by-products, and certain meat food products to control foodborne pathogens and extend shelf-life (Food and Drug Administration, 1997). No restrictions were established for packaging the meat.

FSIS Administrator Thomas Billy announced in March that the FSIS plans to propose a rule late this summer on how the agency should implement the irradiation of meat, including how the irradiated products should be labeled. Completion of the proposed rule has been slowed because the USDA is mandated to submit all major regulations for risk assessment by the Office of Risk Assessment and Cost Benefit Analysis (ORACBA). At this time the rule is under evaluation by ORACBA.

References

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