International Regulatory Status and Harmonization of Food Irradiation

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ABSTRACT

U.S. regulatory officials and some consumer advocates, academicians, media, and industry representatives share the opinion that irradiation processing may be a solution to food safety and agricultural protection problems that now exist throughout the world. The status of existing regulations and new regulations being developed by U.S. regulatory agencies and being petitioned by industry groups is discussed and compared with regulations in other countries. Renewed interest on the part of the U.S. Army in using irradiated foods in many of their rations is reviewed. The status of demonstration irradiation facilities sponsored by the Department of Energy is outlined. Comments on harmonization of radiation process controls, dosimetry standards, and other practices that are important aspects of international trade in irradiated foods are provided.

Ionizing radiation has a long history of successful commercial use in the sterilization of medical devices and disposables, modification of polymers, and many environmental applications. However, the application of this technology to commercial food processing still presents a challenge to many authorities and other organizations. In this paper, I will concentrate on the activities of the Food and Drug Administration (FDA) of the Department of Health and Human Services, the Department of Agriculture, the U.S. Army, and the Department of Energy of the U.S. Government and the International Consultative Group on Food Irradiation (ICGFI), the Food and Agriculture Organization (FAO) of the United Nations, the World Health Organization (WHO), and the Codex Alimentarius Commission (CAC) in the international community as they relate to regulatory issues and commercial use of irradiation.

NEED FOR IRRADIATION

In a recent U.S. Senate hearing (23), a U.S. government official and a consumer advocate expressed the opinion, also shared by some academicians, industry, and media representatives, that radiation processing may be one solution to agricultural protection and food safety problems that exist throughout the world.

Currently, some countries protect agricultural products from harmful pest infestation by quarantine restrictions. Traditional quarantine treatments include chemical fumigation, physical treatments with vapor heat or cold temperature storage, and the establishment of pest-free zones. The availability of chemical fumigants, however, is changing. Ethylene dibromide, for example, is prohibited in Japan and the United States and the use of methyl bromide is being questioned. Physical treatments are not always effective, either. Irradiation provides an excellent alternative. It reduces processing delays by allowing for continuous treatment of product rather than batch treatment; it allows the quarantine treatment to occur after the product is packaged, preventing reinfeestation; and, most importantly, it helps reduce chemical emissions and residues that are of growing world concern.

In recent years, the public has become more aware of the threat of foodborne illness caused by pathogens. Pathogens such as *Escherichia coli*, *Campylobacter*, *Listeria*, *Salmonella*, and *Vibrio* species are widely distributed in the environment, and many of those pathogens normally inhabit the intestinal tract of healthy food animals. Their presence leads to medical costs, loss of worker productivity, and other less tangible costs of almost $5 billion in the United States alone (26). Also, researchers at Emory University and the U.S. Centers for Disease Control have estimated that over 6 million illnesses and 8,000 deaths are caused annually by bacteria in the U.S. food supply (26). Irradiation has been proven effective in virtually eliminating pathogens in products of animal origin (25,29,31).

U.S. REGULATORY AGENCIES INVOLVED IN FOOD IRRADIATION

In the United States, FDA sets the criteria for the safe use of food additives and processes. FDA’s involvement in food irradiation is mandated by the Federal Food, Drug, and Cosmetic Act (FFDCA) which specifically defines radiation sources as food additives (3). Food is adulterated if it is exposed to ionizing radiation unless the use conforms to regulations established under the FFDCA.

Some uses of ionizing radiation on specific types of foods are also regulated by U.S. Department of Agriculture (USDA) agencies. The Animal and Plant Health Inspection Service (APHIS) regulates uses of irradiation as a quarantine treatment for fruits to prevent infestation by exotic pests under the Plant Quarantine Act (2). The Food Safety and Inspection Service (FSIS) regulates the process in facilities under their inspection under provisions of the Federal Meat Inspection Act (I) and the Poultry Products Inspection Act (4) to ensure the safety and wholesomeness of irradiated meat and poultry products.

STATUS OF U.S. REGULATIONS

Regulations governing food uses of ionizing radiation in the United States were static for many years with only wheat, wheat
flour, and potatoes being approved for radiation processing. New regulations started to appear slowly in 1985 with FDA approval of irradiation to control trichina in pork. That FDA regulation, based on a petition from the radiation processing industry, allowed the use of ionizing radiation at absorbed doses between 0.3 and 1 kilogram (kGy) on fresh pork to destroy trichina (6). Absorbed dose is the energy imparted by ionizing radiation to the food as it is processed. FDA followed with another broader regulation in April 1986. That rule was proposed by FDA based on actions recommended by their Bureau of Foods Irradiated Foods Committee. It established new uses at absorbed doses up to 1 kGy to inhibit growth and maturation and control arthropod pests in fresh foods and extended the maximum absorbed dose for spices and dried vegetable seasonings to 30 kGy (8).

FDA’s most recent rule was published in May 1990 based on petitions submitted by FSIS and the radiation processing industry. It permits the use of irradiation on fresh or frozen poultry and poultry parts, including ground and mechanically separated poultry products, at absorbed doses of 1.5 to 3 kGy to control foodborne pathogens and other bacteria. Among the specific provisions is one stating that packaging for irradiated poultry may not exclude the passage of oxygen (12). That provision is intended to assure that the microflora are not altered by irradiation to allow pathogenic microorganisms to grow and produce toxins before microbial spoilage is evident.

In addition to the regulatory actions already finalized, FDA is currently considering six petitions to extend uses of radiation processing. Two petitions filed by industry request permission to use irradiation on seafood products; one is to extend shelf life and control microbial contamination in finfish and shellfish (14) and the other is to control pathogenic contamination in shellfish only (11). The National Aeronautic and Space Administration (NASA) has a petition pending to allow radiation sterilization of beefsteaks for use in the U.S. space program (10). NASA already has informal permission from FDA to radiation-sterilize beefsteaks for limited use by the astronauts, but they want to formalize the procedure to facilitate future applications. The last three petitions pending before FDA relate to irradiation of animal feed. Two submitted by animal feed manufacturers request permission to irradiate laboratory animal diets for the microbial disinfection of laboratory feed for various test animals (19,21). The most recent petition, submitted by a radiation processing firm, proposes radiation pasteurization of complete poultry feeds or feed ingredients (22). The FDA regulates animal feed and human food additives with the same set of requirements.

APHIS established a rule in January 1989 to permit radiation processing as a quarantine treatment on Hawaiian papayas moving from Hawaii to the U.S. mainland and certain U.S. territories. That regulation permits papaya to be irradiated to a minimum absorbed dose of 150 Gray to control the Oriental fruit fly, the Mediterranean fruit fly, and the melon fly. The regulation recognizes the maximum dose of one kGy established by FDA as applicable to this use. Papaya irradiation facilities must be approved by APHIS as being constructed to provide separation of irradiated and unirradiated fruit and must demonstrate the ability to deliver the required minimum dose to all parts of the fruit to be treated. The quarantine treatment is subject to monitoring by APHIS to include inspection of records and unannounced inspection visits. Cartons to hold the fruit must be approved by APHIS to assure that they provide no openings to allow entry of or oviposition by adult flies. Pallets must be overwrapped or strapped and be labeled with a radiation indicator at all times when in commerce. Also, each container must be labeled as treated by irradiation before it leaves the facility (9).

FSIS has two rules permitting irradiation in federally inspected facilities. The first, passed in January 1986, that permits the irradiation of pork to control trichina, is based on the earlier FDA rule that established the safety of that use. The two-phase rulemaking is required for irradiation of meat or poultry products because two different statutes support the activities of the two agencies. The FSIS regulation provides for gamma radiation to be used to treat pork carcasses and fresh or previously frozen cuts with an absorbed dose between 0.3 and 1 kGy to control trichina. At the permitted maximum dose, foodborne pathogens are not significantly reduced, so pork irradiated under this regulation would still require careful handling and thorough cooking to avoid foodborne illness. Machines generating electron beam or X-ray radiation are not permitted as sources because the petitioner did not provide data to support those sources in the petition. An additional petition would be required to expand the regulation to permit those sources. The rule further requires all irradiated pork to be labeled as such and carry the international “Radura” logo; it requires the treatment to be conducted using a quality control program having prior approval by FSIS (7).

The second FSIS regulation published in September 1992 is based on the May 1990 FDA regulation. It permits radiation processing of packaged, fresh, or frozen poultry and poultry products, including ground and mechanically separated poultry products, to an absorbed dose between 1.5 and 3 kGy to diminish the potential of foodborne illness by reducing foodborne pathogens in the poultry. There are some restrictions in the regulation: the 2:1 dose ratio is somewhat restrictive, requiring rather careful packaging and handling of the product; the packaging materials for poultry must be FDA approved materials that allow the passage of oxygen, but prevent the passage of moisture or microorganisms; and poultry products with added substances may not be irradiated unless all of the added substances are approved for irradiation by the FDA (20). The intent of this regulation is to provide the poultry industry with an opportunity to explore these basic applications of radiation processing and to determine if demand for the products warrants the additional research needed to expand the dose range or make other processing changes.

The U.S. rulemaking process includes a provision for public comment on all proposed regulations. Proposed rules are published in the Federal Register (FR), a daily publication of government actions. The FR announcement describes the proposed rulemaking action and identifies the prescribed comment period, usually 60 d. The recent poultry irradiation rule, proposed in May 1992, received over 1,000 comments. They were divided about 50:50 for and against the proposed action. There were large numbers of form letter responses received from both sides. Most supporting comments were from physicians; followed by consumers, then government agencies, academia, and scientific and trade organizations. Most opposing comments were from consumers, followed by consumer groups and labor organizations; only a few were from physicians. All comments were read, sorted, and analyzed, and the response to the comments was included with the regulatory decision in the September 1992 FR publication.

Once an FSIS final rule is published, there are several implementation steps to be followed. In the case of poultry irradiation, plants must request and be granted authority to irradiate poultry under FSIS inspection and operating procedures and must have prior approval of labels from FSIS. This implementation process is not unique to poultry irradiation; every new process is examined and controlled in the same way.

INTERNATIONAL REGULATORY STATUS

The regulatory status of food irradiation in other countries is both interesting and varied. Starting in the 1960’s, the International Atomic Energy Agency (IAEA), FAO, and WHO convened a Joint Expert Committee on Food Irradiation (JECFI) to review and evaluate accumulated safety data related to food irradiation. The last JECFI, convened in 1980, concluded that irradiation up
to a 10 kGy average absorbed dose, introduces no toxicological hazard in irradiated foods. Hence, toxicological testing is no longer needed. Also, they concluded that irradiation causes no special nutritional or microbiological problems. The JECFI conclusions were elaborated by CAC in two documents published in 1983: the Codex General Standard for Irradiated Foods and the Code of Practice for Operation of Radiation Facilities for Treatment of Foods (5). Those CAC standards, including provisions for strict control of process, labeling, and packaging, represent an international consensus on the safety of irradiated foods and provide a basis for the development of regulations by countries throughout the world.

ICGFI tracks the progress of clearances for irradiated foods in their Food Irradiation Newsletter (15). In the early 1980’s, several developed countries and many developing countries began to approve food products for irradiation following the Codex principles. The numbers of countries that approved food irradiation grew through the 1980’s from around 10 countries to over 30 by the end of the decade. Currently, 37 countries have approved more than 40 foods or food groups for irradiation (Fig. 1).

Figure 1. Trends in unconditional approval of one or more irradiated food items.

Two recent developments are significant in the international regulatory picture. The biggest change in the regulatory status was the food irradiation legislation passed by the United Kingdom in 1990 lifting the ban imposed in 1967. The Food (Control of Irradiation) Regulations 1990 permit the irradiation of eight food categories: fruits, vegetables, cereals, bulbs and tubers, spices and condiments, fish and shellfish, fresh meat, and poultry. Also, the regulations include requirements for process control, dosimetry, record keeping, packaging, microbiological testing, facility safety, and labeling to provide consumers with a choice of purchase. In addition, they require licensing for each separate facility and category of food to be irradiated. Imported foods must meet the same requirements as those processed in the United Kingdom (13). The Ministry of Agriculture, Fisheries, and Food issued the first license for irradiation of spices and condiments to a plant in Wilshire in June 1991.

The biggest regulatory surprise was a new law prepared by the Dutch Ministry of Public Health and Culture and passed in April 1992. The law stipulates that a maximum average absorbed dose of 10 kGy can be considered safe for treating commodities. However, food packaging materials, as well as foods, are governed by the maximum average absorbed dose (17). Irradiation cross-linking of polymers used in films or inks and the sterilization of empty food containers for subsequent aseptic filling require doses considerably higher than the legal limit of 10 kGy. If the law is administered as passed, the limitations may seriously affect the food packaging industry in The Netherlands.

**RENEWED U.S. ARMY INTEREST**

The U.S. Army has a long history of interest in radiation processing of food dating back to 1953 when their comprehensive program for development of the technology was initiated. A part of that program, sponsored by the Office of the Surgeon General, was the determination of the wholesomeness of irradiated foods. They conducted a number of feeding studies and several supplementary studies to address the wholesomeness of irradiated foods. The magnitude of the studies can best be described by the numbers of test animals used: over 15,000 mice; more than 10,000 rats; 300 dogs; and 37 monkeys were fed various diets of radiation sterilized foods for at least 2 years. In no case were any obviously toxic or carcinogenic substances found in the foods tested. The authors concluded that irradiated foods are as wholesome as nonirradiated foods (26). In the late 1950’s, limited human feeding studies were conducted. In the seven studies, each with 9 or 10 human volunteers, diets consisting of 35 to 100% irradiated foods were as acceptable and digestible as unirradiated diets. Extensive clinical tests did not reveal any untoward effects. In 1963 and 1964, the Army submitted the first petitions to the FDA that resulted in approval for irradiation of wheat, wheat flour, and potatoes. In the comprehensive research program in the 1960’s, the primary emphasis was on radiation-sterilized meats. The concept of “chemiclearance” was employed in determining the nature and extent of chemical changes in irradiated foods. Chemiclearance is an approach through which irradiated foods would be evaluated and approved based on chemical data. The underlying principle is that wholesomeness of food relates directly to the type and amount of chemicals formed by irradiation (i.e., radiolytic products) and that, in turn, those chemicals depend on food composition and irradiation conditions. If similar foods are irradiated under similar conditions, they will have a similar spectrum of radiolytic products and would be chemically and toxicologically equivalent (28).

In 1980, national and international interest in irradiation as an alternative to nitrite in cured meats prompted the transfer of the Army irradiated foods research program to the Agricultural Research Service of the USDA. Thus, Army irradiation activities were dormant until 1991 when food distribution problems associated with operations Desert Shield and Desert Storm rekindled the interest. In an October 1991 speech, General William Tuttle, Commander, U.S. Army Materiel Command, announced the Army’s renewed interest in the use of irradiation for two major applications: to extend the shelf life of refrigerated foods for field use and to produce shelf stable ration entrees. Gen. Tuttle explained that the Army’s interest is based on their concern for the quality of life for field troops as it affects performance. Field feeding is a crucial component of life’s quality and irradiation is one technology that can help simplify resupply and reduce dependence on frozen storage, control foodborne pathogens in fresh
foods, and at the same time enhance soldier morale. Currently, the Army’s program is limited to selection and economic evaluation of candidate items for field feeding and support for expansion of commercial applications of food irradiation (30). The U.S. Army Natick Research, Development and Engineering Center is working with USDA and FDA on petitions for extending radiation pasteurization to additional animal products, again based on the principle of chemiclearance.

DEPARTMENT OF ENERGY (DOE) ADVANCED RADIATION TECHNOLOGY (ART) PROGRAM

The ART program was established in 1985 when DOE was mandated by the U.S. Congress to develop and transfer nuclear technology for the irradiation of food and other agricultural commodities in cooperation with the states, other Federal agencies, and private organizations. DOE proceeded to negotiate cooperative regional projects in the states of Alaska, Florida, Hawaii, Iowa, Oklahoma, and Washington. In the ensuing years, a number of events occurred that produced significant impacts on the ART program and the food radiation processing industry in general. A small but highly vocal group of activists mounted a well-organized effort to stifle the radiation processing of foods; a radioactivity release in a commercial medical supply irradiation facility in Georgia resulted in the withdrawal of the DOE cesium sources; and, finally, the U.S. Congress failed to appropriate additional funds for the program after fiscal year 1988. The funding curtailment caused DOE to restructure their program to concentrate efforts on two projects in Florida and Iowa while, at the same time, devoting a small amount of funds to maintain interest in the other projects pending funding from other sources (24).

The Florida and Iowa projects are linear accelerator electron beam facilities with the capability of conversion to Bremsstrahlung. They also share the common objective to provide facilities for research on regional agricultural commodities. The Florida facility, sponsored by the Florida Department of Agriculture and Consumer Services, is located in Gainesville, Florida, adjacent to the University of Florida. They plan research on commodities of interest to their agricultural community including citrus fruit, strawberries, poultry, and seafood, and they also will use the facility to produce sterile fruit fly larvae in support of their fruit fly control program. Construction of the physical facility was completed early in 1991 and, although commissioning was several months away, they had a usable beam available in October 1992.

The Iowa facility is sponsored by Iowa State University and is located on campus in Ames, Iowa, adjacent to the meat export research center. The commodities of primary interest are pork and other meat products. Like the Florida facility, they experienced delays in start-up and commissioning. However, they, too, had a usable beam by October 1992 and expect to commission the facility early in 1993. In August 1992, the Iowa facility was the site for the ICGFI Workshop on the Use of Irradiation and Refrigeration to Ensure Hygienic Quality of Foods.

ISSUES REQUIRING INTERNATIONAL HARMONIZATION

International agreement on appropriate control and inspection procedures would eliminate unnecessary differences, improve mutual trust, and thus facilitate world trade in irradiated foods. To accomplish these goals, there are a number of vitally important issues that require harmonization early in the commercialization of food irradiation throughout the trading world.

An effective quality control program must be the primary control method for radiation processing of food. The program must be fully compatible with Good Manufacturing Practices or other systems to ensure general food safety; and, to be most effective, it should be based on the Hazard Analysis and Critical Control Point (HACCP) system. A control program for a food irradiation facility should address several major areas. Facility and licensing requirements must be documented, including licenses with nuclear regulatory authorities and registrations with occupational safety agencies and other agencies as appropriate. Documentation should also support the demonstrated ability to meet sanitation requirements established by regulators. Training is another important area to be addressed. Training provided to the radiation safety officer and relevant supervisory personnel should be documented in the quality control system. A third area relates to dose measurement procedures. Assurance that the absorbed dose limits for all foods are being met and procedures for controlling partial dose applications should be available. Handling, storage, and transportation encompass another area of control. If product is packaged before irradiation, there must be procedures to assure that all packages are intact. A record of temperature control is an important factor in irradiation of perishable foods. Prevention of cross-contamination, procedures for reirradiation, and separation of unirradiated and irradiated products are other important aspects of the control program. All records for the quality control system, exposure monitoring, and corrective actions taken should be maintained for a period of at least 2 years.

Labeling is an important issue related to harmonization. The best way to foster public acceptance of irradiated foods is full disclosure on retail and wholesale labels coupled with a sound public education program. U.S. regulations issued by the FDA and USDA require irradiated foods to carry the international irradiation logo (Fig. 2), along with a statement “Treated with radiation” or “Treated by irradiation” to appear on all irradiated food labels. In addition, statements are required on perishable foods indicating the handling requirements “Keep Refrigerated” or “Keep Frozen” as appropriate. Other factual claims describing the purpose of the treatment may also be added, e.g., “Irradiated to Control Foodborne Bacteria.”

Figure 2. International irradiation logo.

One advantage of irradiation is that the treatment occurs after packaging, thus avoiding recontamination. Packaging materials used to hold food during irradiation must comply with government requirements. Again, in the United States, materials are covered under a specific FDA regulation (18). It is the responsibility of the manufacturer to provide materials that comply with Federal regulations to their customers. Up-to-date packaging technology allows the use of combination processes, such as irradiation and modified atmosphere packaging, that provide more benefits than two processes could separately. Modern resins are available to create multi-ply, coextruded films and thermoformed trays to meet the most stringent needs of food suppliers. They provide moisture and gas barriers tailored to specific products that are needed for successful marketing of foods. However, most of the packaging materials approved to hold food during irradiation were developed before this new technology was available. Therefore, radiation processors should encourage packaging manufacturers to seek approval of new materials that comply with regulatory requirements and meet their current and future packaging needs. Also, in using new materials and combination processes
that provide benefits to packers and to consumers, radiation processors must be careful not to create conditions that may destroy spoilage bacteria and thus favor the growth of pathogens.

It is safe to say that there is disagreement about the importance of and need for methods to detect whether foods have been irradiated. The availability of validated detection methods should not be a prerequisite to approval of food uses of radiation processing. Detection is not a process control; there is no biological change that is solely dependent on the dose of ionizing radiation absorbed by a food. Still, detection is a good compliance tool to determine if a food has been treated. Methods currently available or those in the final stages of development will serve such a purpose. However, here too further collaborative testing and international agreement on suitable methods are needed to ensure the desired effect on international trade.

CONCLUSION

Much has already been done to harmonize regulations and facilitate trade in irradiated foods. The recent study by the WHO reaffirming the safety of radiation processing will reassure nations of the toxicological and microbiological safety and nutritional adequacy of irradiated foods (32). ICGFI has provided a variety of tools to assist in harmonization. They sponsor training courses for facility operators and food control officials, develop codes of good irradiation practice for major food commodities, and develop model regulations for control of the process. ICGFI Fact Sheets (16) on all major issues of consumer concern also serve as an excellent tool for consumer education. Still, there is much to be done before the potential for food irradiation is reached. International meetings such as the 1992 Annual Meeting of the International Association of Milk, Food, and Environmental Sanitarians provide an excellent forum for dialogue that will further enhance understanding and agreement. I appreciated the opportunity to participate in that significant effort.

REFERENCES


Derr. cont. from p. 886
