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IRRADIATION OF FOODS— AN FDA PERSPECTIVE

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Abstract

Food irradiation has been a subject of controversy since its first use as a food process. This article reviews the legislative and regulatory history of food irradiation in the United States and the role of the U.S. Food and Drug Administration, then and now.

This article also discusses the status of FDA's regulations on food irradiation in the production, processing, and handling of food, as promulgated in the April 18, 1986, final rule, and reviews the safety, labeling, and current good manufacturing practice.

INTRODUCTION

Food irradiation is an inherently controversial issue, and the U.S. Food and Drug Administration (FDA) has long been in the middle of that controversy.

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Food is not only essential to support life but is also an important part of social, religious, and family traditions. Food has always been an important part of gatherings or rituals that encourage friendship, reinforce traditions, or celebrate good times. The popularity of ethnic restaurants is witness to the fact that food is an important way of expressing culture as well as a source of nourishment.

When most people think of culture, however, they do not think of science or new developments in technology. Food is to be enjoyed, not to be analyzed rationally; it is identified more with tradition than with new technology. It should not be surprising that the same people who seek the newest developments in medicine, even those not thoroughly tested, cherish the traditional arts of high cuisine and fear innovation in food technology.

To complicate matters further, the technology of radiation processing evokes an emotional response in many consumers that ranges from a disquieting uncertainty to intense fear. Consumers connect the concept of radiation not only with atomic bombs and nuclear power plants, but also with medical X-rays, to which they have learned unnecessary exposure is to be avoided. The combination of a technology (which elicits emotional responses ranging from uncertainty to fear) with food and its far different emotional values produces controversy.

Although some consumers may react so negatively to the mere thought of food irradiation that they will never find the process acceptable, we believe most will accept irradiated products if they are convinced that their fears are being addressed appropriately by responsible authorities. This requires that information be conveyed accurately to avoid the confusion and mistrust that results from contradictory messages.

Unfortunately, it has been our experience that information presented in the trade press, the popular press, and even professional meetings has not been very reliable. Rumors, secondhand stories, and opinions have often been presented as fact. Both opponents and proponents of food irradiation have been sources of misinformation or valid information presented in a misleading way. As staff members of the Food and Drug Administration, we have spent much time sorting fact from fiction and explaining that irradiation of food does not necessarily mean that a food will have an indefinite shelf life at room temperature.

In this paper, we will try to correct some of the misconceptions concerning FDA and food irradiation. We will try to explain FDA's current position, why it has developed, and how it evolved. We will not attempt to forecast the effects of economics and social values on future applications of this technology, because our experience as scientists and regulatory officials gives us no special expertise for such a task.

THE FOOD ADDITIVES AMENDMENT OF 1958

History

To understand the development of food irradiation in the United States, one must be aware of the impact of the Food Additives Amendment of 1958 to the Federal Food, Drug, and Cosmetic Act (the Act). Unfortunately, the conventional understanding of the philosophy behind this amendment and the requirements imposed for demonstrating safety are often based on total misunderstanding. Considerable energy has been spent discussing whether irradiation should be treated as a process or as a food additive. A reading of the legislative history of the 1958 Amendment makes clear that both Congress and the Administrative agencies were well aware that food irradiation is a process and never gave any indication otherwise. They did conclude, however, that this process should be demonstrated to be safe before it is used. They implemented this conclusion by defining sources of radiation (including radioactive isotopes, particle accelerators, and X-ray machines) intended for use in processing food as "food additives."

Although this definition may seem strange at first, it developed after years of debate and discussion and is consistent with the definition of other "indirect food additives" used in food processing. For example, a filter membrane is considered a food additive because its components might migrate to food under conditions of use. Yet there is no confusion in recognizing that filtering is a process and that the filter is an additive (albeit not an intentional additive or ingredient). In the same way, irradiation is considered a process, and a source of radiation is an additive because its use affects the characteristics of a food. Likewise, a source of radiation is obviously not an ingredient.

The Food Additives Amendment resulted from years of discussion concerning food safety. The nation was concerned with changes in the patterns of food production as a result of the population shift from rural to urban areas. This led to less home production of food and more consumption of processed food with a concomitant increase in the use of chemical additives and newly developed packaging materials. Congressional hearings in the early 1950s indicated that the existing food law was obsolete in that it required no testing of additives before marketing, but prohibited the use of any additive poisonous under certain conditions, even if it was safe under other conditions of use.

The first legislative result of this food law reform movement was the Pesticide Amendment of 1953 (often called the Miller Pesticides Amendment, for Congressman Miller of Nebraska). Congress then turned its attention to developing a "chemical additives" or "food additives" amendment.

At the same time, food irradiation research and development was growing and gaining publicity through the "Atoms for Peace" program. Commercial application of the technology appeared imminent. Thus it is not surprising that a bill submitted by Congressman Miller in January 1956 included the following definition:

> The term new food additive means any substance or treatment used, directly or indirectly, in or on food for the purpose of affecting the appearance, flavor, texture or storage property of such food, or for the purpose of otherwise altering any quantity or property of such food, which is not recognized among experts qualified by scientific training and experience to evaluate the safety of food, to be safe for use under the conditions of such use or intended use. The term does not include a pesticide chemical as defined in section 201(q) of this Act, or a food additive in use prior to January 1, 1956, which presents no reasonable probability of injury to health, or any substance approved for use in food by or under this Act. Each new food additive shall be deemed a food, for the purposes of this Act (1).

Congressman Miller noted special features of this bill in Congressional hearings as follows:

> The use of the word "treatment," and I use the word "treatment" where some of the other bills do not, in this definition is also significant. It was included so that the new and revolutionary treatment of food, the use of neutrons, ions, and so forth, that is being used in the treatment of meat, and things that may be used in the future, I think it ought to be included in the definition. If the ionic treatment, or the neutron treatment, or the isotope treatment of food shows that there is some need for investigation by the Department of Health, Education and Welfare it may be done (2).

Commissioner George Larrick of the Food and Drug Administration, testifying before Congress in February 1956, agreed that food irradiation should be regulated under any new law that might be enacted. He stated:

> Experiments in preservation of foods by ionizing radiation from x-ray, radioisotopes, and radiation from atomic piles have now advanced to a point where they offer a distinct possibility that the processes will be adapted to commercial use. These methods, as well as the use of radioisotopes as quality control measures, should not be permitted until it is shown that food products will be safe.
>
> We therefore recommend that the pretesting requirements and procedures of the legislation be made clearly applicable not only to radioactive substances that might be introduced into food, either deliberately or unavoidably, but also to any changes in food, or new substances formed in food, by subjecting it to radiation from internal or external sources.

> We would welcome committee consultation with representatives of the Atomic Energy Commission as well as our Department, in this connection. Staff members of the Department and of the Atomic Energy Commission are prepared to cooperate in working out an appropriate amendment for assuring the safety of food affected by radiation (3).

Several bills were introduced in the next two years as Congress attempted to sort out the specific requirements that would protect consumers, allow the food industry to operate efficiently, and give the government the enforcement powers to administer any law that might be adopted. Because very little discussion was given to the food irradiation process, one must seek indirect evidence as to what Congress had in mind regarding the regulation of the food irradiation industry.

Several bills introduced in 1957, including one supported by the FDA, discussed radioactive material intended as a source for irradiation of food in the definition of "food additive" (or "chemical additive" as it was often called). One noteworthy example was a new bill submitted by Congressman Miller. This bill attempted to distinguish between "intentional" food additives, such as ingredients, and "incidental" food additives, which are not intentionally added to food but that might unavoidably migrate to food from packaging material or processing equipment, or that might unintentionally affect the characteristics of the food. The proposed definition for an incidental additive reads as follows:

> The term "incidental food additive" means any substance intended for use in manufacturing, packing, processing, preparing, treating, packaging, or transporting food which foreseeably results, in the course of good manufacturing practice, in its getting into the food; including any radioactive material intended for such use or as a source for the irradiation of food (4).

Although the bill was substantially different from the bill eventually enacted, it provides evidence that at least one Congressman considered a source of radiation to be an incidental additive like other food processing equipment. The legislative history provides no evidence that other members of Congress or the Administration disagreed with this characterization of a source of radiation.

The definition of a food additive finally enacted in 1958 made no legal distinction between "intentional" and "incidental" additives. As discussed in the official report accompanying the legislation, both types of additives were encompassed by the definition and required premarket approval by regulation. Although the final law makes no distinction between types of additives, the fact that Congress was considering a source of radiation as an incidental additive is significant because it means that sources of radiation were to be

regulated like other food processing equipment, although the safety issues were unique because the radiation affected the characteristics of the food. This example illustrates that the common complaint that the Food Additives Amendment regulation of food irradiation is a mistake because irradiation is a process and not an additive is not based on fact. Congress considered a source of irradiation to be an incidental additive used for the process of irradiation, analogous to other incidental additives used in food processing equipment. Likewise, testimony from the FDA Commissioner shows that he was well aware that irradiation was a process, but that this technology must be regulated to assure its safety.

The Department of Health, Education and Welfare opposed Congressman Miller's bill that distinguished between two types of additives because it established two different procedures for demonstrating safety for the two types of additives. The Department believed that the same procedures and safety standards should be used regardless of whether an additive was intentionally introduced into food, caused changes in the food, or migrated to food.

The current definition of a food additive in the Food, Drug, and Cosmetic Act reads as follows:

> 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), if such substance is not generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures (or, in the case of a substance used in food prior to January 1, 1958, through either scientific procedures or experience based on common use in food) to be safe under the conditions of its intended use; except that such term does not include–
>
> (1) a pesticide chemical in or on a raw agricultural commodity; or
>
> (2) a pesticide chemical to the extent that it is intended for use or is used in the production, storage, or transportation of any raw agricultural commodity; or
>
> (3) a color additive; or
>
> (4) any substance used in accordance with a sanction or approval granted prior to the enactment of this paragraph pursuant to this Act, the Poultry Products Inspection Act (21 U.S.C. 451 and the following) or the Meat Inspection Act of March 4, 1907 (34 Stat. 1260), as amended and extended (21 U.S.C. 71 and the following); or
>
> (5) a new animal drug. (5)

Safety

Congress recognized that the word "safety" can convey different meanings to different people. At the time the Food Additives Amendment was being

considered, there was a consensus that the safety required of a food additive should be safety under conditions of use. In addition to the concern that food additives are properly tested for safety, there was agreement that the food law then in existence was obsolete in that it prohibited any added poisonous or deleterious substance to food, even if that substance was safe under conditions of use. However, several proposals were offered to clarify what was meant by "safety."

The concept of safety was explained in the Senate Report on the Food Additives Amendment of 1958:

> The concept of safety used in this legislation involves the question of whether a substance is hazardous to the health of man or animal. Safety requires proof of a reasonable certainty that no harm will result from the proposed use of any additive. It does not—and cannot—require proof beyond any possible doubt that no harm will result under any conceivable circumstance.
>
> This was emphasized particularly by the scientific panel which testified before the subcommittee. The scientists pointed out that it is impossible in the present state of scientific knowledge to establish with complete certainty the absolute harmlessness of any chemical substance. (6)

Congress also described, in the statute, some of the factors that should be considered in determining whether a substance is safe. Section 409(c)(5) of the Act reads as follows:

> In determining, for the purpose of this section, whether a proposed use of a food additive is safe, the Secretary shall consider among other relevant factors—(a) the probable consumption of the additive and of any substance formed in or on food because of the use of the additive;
>
> (b) the cumulative effect of such additive in the diet of man or animals, taking into account any chemically or pharmacologically related substance or substances in such diet; and
>
> (c) safety factors which, in the opinion of experts qualified by scientific training and experience to evaluate the safety of food additives, are generally recognized as appropriate for the use of animal experimentation data. (7)

Congress also considered whether specific testing procedures should be prescribed by law. Some thought that specific scientific procedures were necessary so that proponents of new food additives could be sure they were conducting the appropriate tests. However, both the Food and Drug Administration and members of a panel of scientists selected by the National Academy of Science advised against establishing specific procedures by statute. They emphasized that such procedures would be cumbersome and would prevent scientists from demonstrating safety in cheaper and more effective ways, primarily for two reasons. Available information on the use of some substances could

indicate that abbreviated testing was sufficient, while information on other substances might point to a need for specific tests that are not routinely needed. The legislation left the decision on what testing was necessary and sufficient to the discretion of scientists.

Procedures for Authorizing Use of an Additive

The burden of demonstrating that a source of radiation can be used safely to irradiate foods was, as for other additives, placed on proponents of its use. The principal procedure established for premarket approval of an additive's safe use is the filing of a food additive petition with data sufficient to demonstrate safety. Such a petition must provide a complete record on which to base a decision. An important feature of such petitions, however, is that once FDA decides that a petition is adequate to support a regulation prescribing safe conditions of use, the resulting regulation is applicable to everyone, not just the petitioner. The food industry argued strongly at hearings on the Food Additives Amendment that the Food and Drug Administration should not have authority to grant licenses to individual companies, and Congress agreed.

Although this procedure encourages competition in the marketplace for use of additives and processes shown to be safe, it probably also discourages an individual company from committing vast resources to demonstrate safety if a competitor gets equal advantages from that effort.

In a second procedure established to gain premarket approval, the government proposes a regulation establishing safe conditions of use. Such a proposal must meet the standard for demonstrating safety as a petition from industry. The public is allowed at least 30 days to comment on the proposal, and all substantive comments must be considered. This procedure is used far less frequently than a petition because a new regulation does not necessarily have high priority in the mission of a regulatory agency unless the regulation is deemed of clear benefit to public health or will allow the agency to operate more efficiently.

Enforcement of Regulatory Authority

The major purpose of the Food, Drug, and Cosmetic Act, with respect to foods, is to ensure safety and fair dealing. This is accomplished by a series of prohibitions regarding two types of actions: adulteration and misbranding.

1. *Adulteration.* The term "adulterated food" describes food that, for a variety of reasons, cannot be sold legally in the United States. It applies to food for both humans and animals.

The major provision concerning irradiated foods is section 402(a)(7), which states:

> A food shall be deemed to be adulterated . . . if it has been intentionally subjected to radiation, unless the use of radiation was in conformity with a regulation or exemption in effect pursuant to section 409 (the section concerning food additives). (8)

This provision is different from the adulteration provision for other food additives, which states that a food is adulterated if it is, or if it bears or contains, any unsafe food additive (i.e., a food additive not permitted for use by regulation). This distinction is necessary because an irradiated food would not contain the food additive, namely, the source of radiation.

A food that has been irradiated in conformance with the appropriate regulation still may be adulterated for other reasons. For example, a food containing filth or decomposed substances or a food held under insanitary conditions may be considered adulterated. Irradiation is not considered a substitute for good sanitation practices, and irradiated filth is still considered filth.

2. *Misbranding*. The misbranding provisions apply primarily to a label or labeling, both as to what is stated and what is not stated. The Food Additives Amendment of 1958 is relatively silent on the issue of labeling with a few minor exceptions.

(a) A petitioner, for use of an additive, is required to submit specimens of its proposed labeling [Section 409(b)(2)(B)]. This is usually not applicable to incidental additives, although labeling may be necessary to describe to a user how an additive is to be used in conformance with a regulation. For example, labeling on radiation sources used for inspection in food processing plants must give adequate directions for use, including the maximum dose to be applied. This provision is applicable primarily to the user of the source of radiation.

(b) A food additive regulation shall not be issued if its proposed use would promote deception of the consumer or otherwise result in misbranding as defined by the Act [Section 409(c)(3)(B)]. (9)

Thus, in determining retail labeling requirements for irradiated foods, one must review the general misbranding requirements of the Act. As indicated earlier, a source of radiation is not an ingredient; therefore, the provisions for ingredient listings are not generally applicable, except, perhaps, if irradiation of an ingredient changes it substantively so that the name given to the unirradiated ingredient is no longer valid or appropriate.

The primary provision concerning labeling is Section 201(n), which states:

> If an article is alleged to be misbranded because the labeling or advertising is misleading, then in determining whether the labeling or advertising is misleading there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, device, or any combination thereof, but also the extent to which the labeling or advertising fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the article to which the labeling or advertising relates under the conditions of use prescribed in the

labeling or advertising thereof or under such conditions of use as are customary or usual. (10)

Thus, an important consideration for labeling of irradiated foods is whether a consumer is likely to be misled if a label does not provide clear information that such foods have been so processed.

REGULATORY HISTORY

Background

Although the use of irradiation for preserving food was explored as early as 1936, food irradiation research in the United States started in earnest in the late 1940s. It was only a few years later, in the early 1950s, that the United States government became interested in this new processing method. At that time the United States Army conducted a feasibility study of irradiated food and, based on organoleptic and biological tests, concluded that food irradiation could provide a wholesome, good-tasting, economical, and shelf-stable product for field rations; reduce dependence on refrigeration; and greatly reduce food-handling costs for the military.

There was also substantial civilian interest in this new technology. As part of President Eisenhower's "Atoms for Peace" program, the Atomic Energy Commission (AEC) had an early interest in food irradiation, especially at low doses for insect control and shelf-life extension of fruits and vegetables as well as for control of microorganisms in food. Considering the widespread interest in food irradiation, it was not surprising that FDA was interested almost from the start.

FDA's involvement in the nutritional and toxicological aspects of irradiated foods began in the early 1950s, when in close cooperation with the military, the U.S. Department of Agriculture (USDA), and interested parties in the private sector, the Agency suggested wholesomeness testing for such irradiated products.

As discussed earlier, the passage of the Food Additives Amendment of 1958 required a premarket safety review prior to issuance of a regulation permitting use of irradiated foods. The agency has followed the same general procedures in the development of regulations for the use of sources of radiation as are followed in the development of regulations for other food additives. Under the Act, the agency's primary responsibility is to determine that use of the additive is safe under the proposed conditions. Since the 1960s when the first petition for the treatment of food with radiation sources was submitted, the agency has been confronted with the questions of what test procedures are appropriate to

establish a reasonable certainty of no harm for use of radiation sources in the treatment of food.

Traditionally, feeding studies are used to determine the safety of a typical food additive. Such testing requires a determination of the highest "no-effect level" for the tested substance and consideration of the amount of the substance likely to be consumed (11). (To allow for uncertainty in relating data gained from laboratory animals to humans, a 100-fold safety factor is typically applied, i.e., human consumption that is 1% of the highest consumption showing no effects in animals is considered safe.) (12)

For substances that may become a large percentage of the diet, a 100-fold safety factor is impossible and wholesomeness feeding studies are performed. "Wholesomeness" means a determination that the substance is microbiologically, nutritionally, and toxicologically safe. Wholesomeness feeding studies were attempted to assess the safety of many irradiated foods.

Initial efforts by FDA and industry to establish the safety of irradiated foods led to a scheme approximating traditional methods for evaluating substances added to the food supply. Because the radiation chemistry of foods was still largely unknown, and because irradiation produced many substances that were ill-defined, FDA required animal feeding studies to demonstrate that irradiated foods were safe. The initial philosophy of the FDA scientists was to develop a core of wholesomeness studies on different types of foods to provide a matrix from which the safety of other foods could be deduced.

Early Petitions

On February 15, 1963, FDA published its first regulation to provide for the safe use of gamma-radiation for the processing of foods (13). The regulation provided for the use of sealed sources of cobalt 60 for the radiation preservation of canned bacon at an absorbed dose of 45–65 kGy (4.5–5.6 Mrad). In addition, the regulation required that any coatings used on the inside of the can meet FDA specifications (presently regulated in 21 CFR 175.300, resinous and polymeric coatings) and that dosimetry records be retained for FDA inspection for a period of one year.

On August 21, 1963, FDA published a regulation to provide for the use of gamma-radiation sources, with maximum energy not to exceed 2.2 million electron volts (MeV), at an absorbed dose from 0.2 to 0.5 kGy (20 to 50 krad) for the irradiation of wheat and wheat products to control insect infestation (14).

On August 30, 1963, FDA published a regulation to provide for the safe use of electron beam radiation for the preservation of canned bacon at 45 to 56 kGy (4.5 to 5.6 Mrad) (15). The permitted radiation source was an electron accelerator producing a beam of electrons at energy levels not to exceed 5.0

MeV. The regulation required that the bacon be packed under vacuum or in an inert atmosphere. These first three actions led to three separate regulations, two for high-dose irradiation of bacon from the two types of sources and one for low-dose irradiation of wheat. It is interesting that the high-dose irradiation was described for "processing" of food, whereas low-dose irradiation was described for "treatment" of food. The regulations did not state why the different wording was used.

On February 6, 1964, FDA amended the regulation for gamma-radiation for the processing of canned bacon by 1) changing the heading of the regulation to read "gamma radiation for the processing and treatment of food"; 2) adding cesium 137 as a permitted source of gamma-radiation; and 3) requiring that the irradiation be conducted only "after packaging under vacuum or in an inert atmosphere" (16).

On July 8, 1964, FDA published an amendment to the irradiated wheat regulation to limit the sources of radiation to cobalt 60 and to permit irradiation of white potatoes to inhibit sprout development at an absorbed dose from 50 to 100 Gy (5 to 10 krad) (17).

On October 10, 1964, FDA amended the regulation permitting gamma-radiation for the treatment of wheat and potatoes by including sealed units of cesium 137 as another permitted gamma-radiation source (18).

On December 19, 1964, FDA published a new regulation for the use of X-radiation for the processing of food. The permitted radiation was a beam of X-rays produced by an electron beam from a particle accelerator striking a metal target (19). The accelerated electrons were restricted to energies no higher than 5 MeV. Other limitations were identical to those listed in the regulations permitting processing of canned bacon with gamma- and electron beam radiation.

On April 21, 1965, FDA amended the regulation permitting electron beam radiation for the processing of food to provide for conditions under which electrons with energies up to 10 MeV may be safely used on canned bacon and to limit the maximum thickness of food under irradiation to 3.2 cm with single beam irradiation or 7.0 cm with cross-firing beams (20).

The next day, April 22, 1965, the USDA issued a regulation requiring that an approved term, such as "Processed by Ionizing Radiation," appear on the labels of irradiated foods in conjunction with the product name (21). This was the first explicit labeling requirement.

On November 9, 1965, FDA amended the regulation permitting gamma-radiation for the treatment of wheat and potatoes by providing an increase in the upper limit for the dose that can be applied to potatoes from 100 Gy to 150 Gy (from 10 to 15 krad) (22).

On March 4, 1966, FDA published a notice of proposed rule making in the matter of various radiations regulated by the agency (23). For radiation used

in the disinfestation of wheat, the agency considered the term "wheat products" as too broad and indefinite and proposed restricting the use to "wheat and wheat flour from unirradiated wheat." The agency also proposed adding the term "high-dose" to the headings for gamma-radiation, electron beam radiation, and X-radiation for the processing of food and the term "low-dose" to the heading for gamma-radiation for the treatment of wheat and potatoes. In addition to proposing to limit the source of radiation, the conditions of use of the sources, and the specific food, the agency also concluded that food treated with radiation should have that fact declared on the label; where retreatment might cause the permitted maximum dose to be exceeded, a warning against retreatment should be included. Therefore, the agency proposed that for high dose irradiated food, "(To) assure safe use, the labeling of any food so processed shall bear, in addition to other information required by the Act, the statement: 'Processed by ionizing radiation.'" For low-dose irradiated food, "the label and labeling of any market package of food so treated shall bear, in addition to the other information required by the Act, the statement: 'Treated with ionizing radiation—do not treat again.' In the case of bulk shipment, the invoices or bills of lading shall bear such statement when the bulk commodity has been so treated" (23).

On July 13, 1966, FDA issued a regulation (24) resulting from the March 4 proposal and from a February 26, 1966, proposal. The new regulation provided for the use of electron beam radiation for wheat and wheat flour from unirradiated wheat with a specific thickness and flow limitation. In response to components on the labeling proposal, the agency rejected alternative labeling terms such as "ionizing energy" for "ionizing radiation," and the terms "sterilized" and "pasteurized" instead of "processed" and "treated." The final regulation required the following label statements for radiation treated food:

1. "Treated with ionizing radiation" on retail packages of low-dose treated foods
2. "Treated with ionizing radiation—do not irradiate again" on wholesale packages and on invoices or bills of lading of bulk shipments of low-dose treated foods
3. The statement "Processed by ionizing radiation" for high-dose gamma-radiation, electron beam radiation, and X-radiation treated food.

The agency denied a request for a hearing in a document published on January 7, 1967, because reasonable grounds were not stated for a hearing on the issue of relieving irradiated foods from the labeling requirements imposed or for staying the effectiveness of the order (25). In addition, the agency amended the labeling requirements to allow for optional wording to replace the term "ionizing radiation" on the labeling, such as "gamma-radiation," or "electron

radiation," or "X-radiation" (26). This amended labeling statement became effective on March 2, 1967, and remained in effect until April 18, 1986.

The use of materials satisfactory for holding and packaging food for irradiation led to § 179.45 *Packaging materials for use during the irradiation of prepackaged foods* (21 CFR 179.45). This regulation resulted from several food additive petitions to provide for packaging materials that may be safely subjected to the radiation treatment and processing of prepackaged foods. The first listing in this regulation was issued on March 12, 1965, in anticipation of irradiated food use and was subsequently amended several times (27–30).

In addition to the use of radiation to treat and process food, the agency has permitted the use of sealed sources of radiation for inspection of food and for controlling food processing (§179.21) since 1960. The maximum permitted dose allowed in §179.21 is 0.01 kGy (1 krad). This dose is so low that it does not significantly affect food. Applications of these devices or gauges include uses for checking fill of the container, for checking the presence (or absence) of foreign objects in food, and for measuring moisture content.

In addition to petitions resulting in the issuance of a regulation, many early petitions did not result in a regulation for a variety of reasons. Petitions for the use of radiation for microbial control on citrus (lemon and oranges) (31), strawberries (32), fish and fish products (33), and ham (34) were withdrawn without prejudice because of insufficient data to support the effectiveness or the safety of the process. FDA did not act on other petitions for irradiation of other foods because they were clearly incomplete.

FDA was concerned at that time that more than half of the petitions as originally presented did not provide necessary and persuasive evidence to support the requested regulations. On May 23, 1967, FDA's Bureau of Science conducted a seminar for government scientists and administrators interested in the processing and review of petitions involving irradiation of food. The seminar presentations were compiled into a report (35) that was used as an aid to those interested in submitting a well-designed petition and to facilitate agency evaluation. The report included sections from various scientific and administrative groups involved in the petition evaluation process at that time. In the introductory address, Robert S. Roe, then Associate Director for the Bureau of Science stated:

> The same general procedures are followed in the development of radiation regulations as are followed in the development of regulations for other types of food additives such as preservatives, emulsifiers, anticaking agents, etc. In the case of *any* food additive, FDA's primary responsibility is to determine that the additive or the process to be regulated is safe and that it does accomplish the intended effect. Therefore, proposals for regulations must be supported by data adequate to establish these facts. Much of this material will cover these necessary data.

> Food additive matters involving radiation require consideration as to what test procedures may be appropriate as compared with other food additive matters. The requirements, the procedures, and the protocol must be scientifically sound, and accurately and appropriately applied. As in all areas involving scientific advancements and technological improvement, procedures and even evaluations may be expected to change. Science is not static. New information appears frequently and often calls for reevaluation of test procedures and bases of interpretation. FDA always hopes to develop better methods of analysis, better test procedures, and less costly and more expeditious means of evaluating results, in this area and others. The questions to be answered cover a wide spectrum of scientific disciplines. What is the significance of radiation-induced mutations in microorganisms? What is a sound basis for extrapolation of data from one product to another, from one species to another, or from one level of exposure to another? What is the significance of the destruction of vitamins? In fact, what are appropriate safety tests? (36)

Thus, the 1967 seminar noted the need for more basic research in the various disciplines to improve safety evaluation. This set the stage for a future reevaluation as the data base grew.

Revocation of Bacon Regulations

FDA received a petition for radiation-sterilized ham that relied on many of the same reports originally submitted in the petition for radiation-sterilized bacon. FDA's growing concern that the quality of safety data submitted in irradiated food petitions was often not acceptable caused it to require submission of all relevant raw data on which the original reports were based. The results of that reevaluation sent shock waves through the food industry and discouraged interest in food irradiation. The agency concluded that adverse effects may have been seen in the studies, although the numbers of animals used were too small to be sure that such effects were caused by the irradiated food. In any case, evaluation of the complete data raised doubts that the safety of radiation-sterilized bacon had been demonstrated. Therefore, on August 24, 1968, FDA proposed to revoke the three regulations for high-dose gamma-, electron beam, and X-radiation processing of canned bacon (37). The revocation was issued as a final rule on October 17 of that year (38).

Agency Task Groups

Since 1968, scientists have learned much about the radiation chemistry of foods, providing a basis for estimating the quantity, identity, and toxicity of the radiolytic products formed by chemical changes caused by the absorbed radiation. New scientific information addressing the earlier questions and problems were becoming available.

In 1979, FDA established the Bureau of Foods Irradiated Food Committee (BFIFC) to review the existing agency policy and make recommendations regarding the establishment of those toxicologic testing requirements appropriate for assessing the safety of irradiated foods. BFIFC's recommendation focused on making the degree of testing compatible with the potential risk as indicated by the level of anticipated human exposure to radiolytic products formed. BFIFC recognized that safety assessments of irradiated food should be based on 1) projected levels of human exposure to the food; 2) estimates of the identity, amount, and potential toxicity of new chemical constituents generated in the food by the irradiation process; and 3) state-of-the-art, sensitive toxicological tests. BFIFC completed its review and submitted its final report in July 1980 (39).

BFIFC recognized that no single approach provided sufficient data to estimate that percentage of food consumption that might consist of irradiated food. Hence, in projecting human exposure to irradiated food, BFIFC used estimates of total food consumption, dietary items proposed for irradiation, and the percent of each dietary item which may be irradiated. Using a rough estimate based on these factors, BFIFC suggested that as much as 40% of the total diet could be irradiated, but anticipated that actual human exposure would not exceed 10% of the diet.

The first question confronting the Committee was: What should be tested? Or, more appropriately, what is the difference between an irradiated food and an unirradiated food? The Committee concluded that the only difference of toxicological relevance was the products formed during the process. The Committee then asked whether all production of radiolytic products should be of concern, or whether concern could be limited to some smaller portion of the radiolytic products. This led to a review of available studies that identified substances formed by treating various foods with radiation. The Committee used data from the United States Army's high protein food sterilization program. Army scientists had identified some 65 substances in the volatile fraction in the headspace of irradiated canned meats. Of these, 23 were also identified in thermally sterilized control meats, and 36 were identified as being present in volatile fractions of other foods. Thus, only six substances (or about 10%) could not be verified in the literature as being present in food, although these six were similar to natural food constituents.

Comparison of available data from model studies on volatile and nonvolatile products formed by irradiation and by heating showed that there were considerable similarities among the thermal and radiolytic products. Based on such considerations, the Committee judged that it was reasonable to conclude that the differences between the volatile components of irradiated and nonirradiated food could be taken to represent the relative differences caused by irradiation. Thus, based on analysis of the volatile fraction, the Committee

concluded that 10% of all radiolytic products may be unique to irradiated food, although not enough is known about components of nonirradiated foods at such low concentrations to prove that these 10% are indeed unique. That is to say, if we knew the exact composition of all processed foods, we might also be able to identify all the radiolytic products in nonirradiated foods.

Because it is impossible to prove that there are no unique products (one would need perfect knowledge), the Committee assumed that unique products are formed. They estimated that a 1-kGy absorbed dose would produce approximately 30 mg of radiolytic products per kg of food (this is much higher than seen in the volatile products discussed above). That means that for a 1-kg food substance, about 10% of the radiolytic products (or 3 mg) could be considered as possibly unique; or that a total of about 3 parts per million of that food substance could be unique. The 3 mg would be composed of several different products that could be formed. Recognizing that the identified products presumed to be unique were chemically similar to other food components, the Committee concluded that any single "unique" product of unusual toxicity that would be formed in significant amounts at doses below 1 kGy would be negligible.

This rationale was the basis for waiving the need for animal feeding tests because the test substances (the irradiated food) consisted of a small quantity of test material (the radiolytic products) diluted in a large amount of food. The Committee did not want to require expensive tests with hundreds or thousands of laboratory animals if such tests were incapable of providing useful information. Tests were recommended for foods irradiated above 1 kGy because of a perceived changes that, at such doses, the concentration of radiolytic products may be sufficient to allow a meaningful verification of the above safety analysis.

The Committee further concluded that a food (e.g., nutmeg) that comprises only a small fraction of the human diet (i.e., no more than 0.01% of the diet) and that is irradiated at doses up to 50 kGy (5 Mrad) would necessarily contribute far fewer radiolytic products to the daily diet–approximately 20 times less–than a food representing a significant fraction of the diet (e.g., 10%) irradiated at 1 kGy (100 rad). Consequently, BFIFC recommended that foods comprising no more than 0.01% of the daily diet and irradiated at 50 kGy (5 Mrad) or less also be considered safe for human consumption without toxicological testing. BFIFC based this recommendation on radiation chemistry and the anticipated low levels of human exposure to any possible unique radiolytic products generated in the irradiated minor ingredient.

The FDA agreed with BFIFC's scientific rationale and conclusion that an adequate margin of safety could be demonstrated for irradiated foods without the requirement of toxicological testing and adopted its recommendations concerning the safety of food irradiated at the proposed dosage levels (40).

Subsequently, in 1981, FDA's Bureau of Foods established a second team of scientists, the Irradiated Foods Task Group, to review all available toxicological data concerning foods treated by irradiation. The major objectives of this Task Group were to compile and summarize the toxicology data pertaining to irradiated foods, identify any consistencies with respect to adverse findings, look for patterns or trends in results among the studies, and to summarize the experimental results at the end of the review (41).

The data review proceeded in three phases. In phase I, all relevant toxicology studies were identified from FDA files and from the open literature. In phase II, 409 of these (all of the relevant available studies) were obtained in hard copy and summarized. These summaries categorized the studies as 1) "accepted" if on initial examination the study appeared to be reasonably complete; 2) "accepted with reservation" if the testing, on initial summary review, appeared acceptable but had some serious deficiencies interfering with interpretation of the data; or 3) "rejected" if there were inadequacies of the experimental design or data collection, or if dietary problems existed in the study that would prevent a valid evaluation. In phase III, 69 studies that either raised questions concerning the possibility of adverse effects or appeared to support a conclusion that the irradiated food studied was safe were examined in detail and reported (41).

Based on its examination of all the data, the Task Group concluded that studies with irradiated foods do not show adverse toxicological effects. However, the Task Group further concluded that traditional toxicological testing of food irradiated at doses below 1 kGy (100 krad) cannot be expected to provide meaningful answers to toxicity questions regarding such irradiated foods. The Task Group's reasons for this conclusion were: 1) nutritional imbalances created in the test animal fed high levels of irradiated or nonirradiated foods would tend to mask any potential toxicological manifestations; 2) the low concentration of any potentially toxic radiolytic products in the irradiated foods would prevent significant exaggeration of the amount of radiolytic products in a test diet; and 3) such toxicological testing is currently too insensitive to measure toxicity because the concentrations of unique radiolytic products potentially present in the irradiated foods tested are simply too low. Based on its review of all studies, including those which tested food irradiated at doses more than an order of magnitude higher than 1 Gy (100 krad), the Task Group agreed with BFIFC's conclusion that there was an adequate margin of safety for foods irradiated below 1 kGy (100 krad). Hence, the Task Group also agreed that toxicology tests on food irradiated at 1 kGy (100 krad) or below are not needed to support a conclusion that such foods are safe.

Agency-Initiated Rule Making

Under sections 409(b) and (d) of the Act, the Secretary may approve a food additive petition from an interested person or may propose the issuance of a food additive regulation upon the Secretary's own initiative. It is less common for FDA, acting as the Secretary's delegate, to propose and then establish a regulation itself, than to respond to a sponsor's petition. As discussed earlier, FDA had approved several food additive petitions for the use of various sources of radiation on certain foods and food-packaging materials prior to 1981.

On March 27, 1981, FDA published an advance notice of proposed rule making (ANPR) (40) that announced the availability of the BFIFC Report (39), which outlined a course of action for assuring the safety of irradiated foods and requested comments on the overall approach towards its food irradiation policy.

After evaluation of comments received on the ANPR, FDA published a proposed rule on February 14, 1984, that would 1) establish general provisions for food irradiation, 2) permit the use of food irradiation at doses not exceeding 1 kGy (100 krad) for inhibiting the growth and maturation of fruits and vegetables and for insect disinfestation of food, 3) allow irradiation to be used for microbial disinfection of certain dried spices and dried vegetable seasonings at a dose not to exceed 30 kGy (3 Mrad), 4) eliminate the current irradiated food labeling requirements for retail labeling, and 5) replace then current regulations dealing with the irradiation of food with new regulations (42).

Based on this proposal, on April 18, 1986, FDA published final regulations to permit additional uses of ionizing radiation for the treatment of food. These regulations 1) permit manufacturers to use irradiation at doses not to exceed 1 kGy to inhibit the growth and maturation of fresh foods and to disinfest food of arthropod pests, 2) permit manufacturers to use irradiation at doses not to exceed 30 kGy to disinfect dry or dehydrated aromatic vegetable substances (minor food ingredients such as spices and herbs) of microorganisms, 3) require that foods that are irradiated be labeled to show this fact, both at the wholesale and at the retail level, and 4) require that manufacturers maintain process records of irradiation for a specified period and make such records available for FDA inspection (41).

Apart from the ongoing rule making, FDA approved a number of food additive petitions to provide for the safe use of gamma-radiation at doses up to 10 kGy (1 Mrad) to control insect infestation and microbial contamination in dried herbs, spices, and vegetable seasonings (43–46) and in dry enzyme preparations (47). FDA also issued a final rule in response to a petition to provide

for the safe use of gamma-radiation at doses up to 1 kGy (100 krad) to control *Trichinella spiralis* in pork (48). These were incorporated into the April 18, 1986 final rule (41).

CURRENT STATUS

The April 18, 1986 final rule has significantly expanded permitted uses of food irradiation. FDA authorization for this process also affects other government agencies. In particular, the USDA's Food Safety and Inspection Service, with regulatory authority over meat and meat products, revised their regulations to permit irradiation of fresh pork on January 15, 1986 (49). Likewise, USDA's Animal and Plant Health Inspection Service has regulatory authority over quarantine restrictions for commodities that are imported, exported, and intended for domestic use. The purpose of such restrictions is to avoid the accidental introduction of exotic pests that are not found in the United States, or to avoid interstate movement of pests that have been introduced in certain areas of the country. USDA must recognize the efficacy of quarantine methods for specific commodities using chemical or physical treatment methods that are permitted in the U.S. before such treatment methods may be used to meet quarantine requirements. Food irradiation would allow another physical method as an alternative treatment.

Safety Testing

As discussed earlier, FDA concluded that an adequate margin of safety had been demonstrated for food irradiated at a dosage below 1 kGy without requiring animal feeding tests. In addition, the agency addressed all comments raising safety concerns in the April 18, 1986, final rule.

One common misperception was illustrated by a comment that had asserted that FDA's proposed regulation was illegal because it was not based on animal testing. Although recognizing that neither the Food Additives Amendment of 1958 nor its legislative history specifies the exact types of tests that must be conducted to establish safe conditions of use of an additive, the comment claimed that a recurrent theme in much of the legislative history is the need for testing in animals to establish the safety of a particular additive.

As discussed in the section on legislative history, there is no indication in the legislative history that Congress expected every additive, whether an ingredient, a source of irradiation, or an incidental additive, to be tested the same way; nor does the Act require such testing. Such a requirement would result in an unnecessary expenditure of resources. Consistent with this view, FDA has never required the same testing regimen for all types of additives.

FDA believes that the testing requirement envisioned by Congress was that there be sufficient testing to support the conclusion that there is a reasonable certainty of no harm from the expected use of the additive. The agency believes that any test that would not contribute to this conclusion should not be required. The agency has not required animal testing in the past under those situations where, by chemical or other testing and sound reasoning, it could conclude that the use of an additive was safe without animal testing. Animal testing is too insensitive to show an effect from irradiation of food at low doses and, thus, would not contribute additional information to the evaluation of the safety of such uses.

Nevertheless, as discussed in the section on Agency Task Groups, the agency reviewed all available animal studies to determine their adequacy and to evaluate the toxicological evidence. The agency reviewed 409 toxicity studies on irradiated foods (41). Forty-five of these studies dealt with subacute toxicity, 58 with subchronic toxicity, 126 with reproductive toxicity, 14 with teratology, 110 with chronic toxicity, and 102 with genetic toxicity of irradiated foods. Only five of the 409 studies reviewed (three chronic feeding studies (50–52), one reproduction study (53), and one combined chronic reproduction and teratology study (54–56) were considered by agency reviewers to be properly conducted and reported, fully adequate by 1980 toxicological standards, and able to stand alone in the support of safety. The reports of these five studies indicated no adverse effects from the irradiated foods fed to test animals.

Although most of the study reports were inadequate by present-day standards and could not stand alone to support safety, many contained individual experimental components which, when examined either in isolation or collectively, allowed the conclusion that consumption of foods treated with low levels of irradiation did not appear to cause adverse toxicological effects. Further, many of the studies were deemed useful for resolving certain questions. For example, if a potent toxic material were present at any level of toxicological significance in irradiated foods ingested by test animals, some consistent toxicological signs would be manifest in the studies reviewed. However, agency scientists saw no such effects that present consistent patterns or trends of adverse effects that might be attributable to exposure to food irradiated at low dose levels.

Labeling

The agency has required, since 1966, that all food treated with irradiation bear on the label a statement that such food has been treated with ionizing radiation. This includes required labeling of irradiated food for both retail and nonretail use.

For irradiated foods, FDA requires that the wholesale label bear either the statement "Treated with radiation, do not irradiate again," or the statement "Treated by irradiation, do not irradiate again," and that the retail label bear the following logo

along with either the statement "treated with radiation," or the statement "treated by irradiation."

In lieu of labeling individual items of unpackaged irradiated foods, FDA allows the required logo and label to be displayed to the purchaser as a point-of-purchase counter sign or card or on the labeling of the bulk container.

As with other processing methods, such as thermal pasteurization or sterilization, irradiation can alter the characteristics of food in ways that could be important to consumers. Changes in organoleptic properties (taste, color, smell, texture) may make the processed food more or less desirable to individual consumers. These changes may well be significant to prospective purchasers of irradiated food. Thus, knowing that a food has been processed by radiation may be important to many consumers. Unless the label indicates otherwise, these consumers would be likely to assume that the food has not been processed or has been processed by traditional means. It follows that the label of a food that has been irradiated but that does not state this fact is misleading, because the label fails to inform the consumers that the food has been processed, and that it has been processed in a nontraditional fashion. FDA believes that changes in food caused by the irradiation allowed under the proposed regulation, although of no safety concern, are sufficiently important that the consumer should know that this process has been used.

With industry uniformly using this logo in conjunction with the wording "treated with radiation" or "treated by irradiation" and an effort to educate consumers about the meaning of the logo, industry may use the logo without the accompanying terminology after April 18, 1988. FDA will assess the need for the mandatory language to accompany the logo during this two-year period.

Any extension of the wording requirement, if necessary, will be established through notice and comment rule making.

Let us review what is required on food labels. Food ingredients, including food additives that have a functional effect on food, are required to be disclosed on food labels. Therefore, the consumer is informed of the presence of these ingredients.

Conventional food-processing methods also affect the organoleptic properties of food in material ways, but in these cases the processing is either obvious to the consumer or conveyed to consumers through labeling or packaging. Shelf-stable canned foods have obviously been heat processed and frozen foods have obviously been frozen. Pasteurized milk is not obviously pasteurized, but this fact is declared on the label.

Canning, freezing, and pasteurization are, of course, well-established processes with which the consumer is familiar. Whether information is material under Section 201(n) of the Act depends not only on the abstract worth of the information but also on whether consumers view such information as important and whether the omission of label information may mislead a consumer. The large number of consumer comments submitted to FDA requesting retail labeling of foods treated with radiation attest to the significance placed on such labeling by consumers.

FDA has historically required the disclosure of a food-processing agent whenever it is material to the processing of foods. For example, the word flour in an ingredient statement or food name is required to be modified by the term "bleached" if a bleaching agent is used in processing, and modified by the term "bromated" if the flour has been bromated. These requirements are part of the standard of identity for various flours (see 21 CFR 137.205) (57).

There are many other instances where the fact of processing must be disclosed. Several standards of identity require label disclosure if the product has been enriched or fortified (see 21 CFR 137.305, enriched farina) (57). Several standards of identity for juices require that the label indicate when the product is made from a previously concentrated ingredient (see 21 CFR 146.145, orange juice from concentrate) (57). Orange juice must also be labeled "pasteurized" when pasteurization is part of the juice's processing (see 21 CFR 146.140, pasteurized orange juice) (57).

Foods made in semblance of a traditional food must disclose the processing difference. Potato chips made from dehydrated potatoes, onion rings made from minced onions, and fish sticks made from minced fish are all required to disclose the material differences in processing.

FDA believes the labeling of an irradiated ingredient in a multiple ingredient food is a different situation, however, because this ingredient has obviously been processed to become part of a new food, which is unlike any of its original ingredients. Consumers would not necessarily expect a multiple ingredient

food to have any of the characteristics of the processed ingredient, and particularly its holding qualities. Therefore, the retail labeling requirement applies only to food that has been directly irradiated (first-generation food), not to food that merely contains an irradiated ingredient (second-generation food).

Current Good Manufacturing Practice

FDA has issued general regulations regarding current good manufacturing practices (CGMP) (21 CFR Part 110) (57) as well as specific CGMP regulations for some types of food (21 CFR Part 113, 114, 118, 123, and 129) (57) or food additives (21 CFR 172.5, 174.5, 182.1, 184.1) (58). Such regulations are based on standard practices of responsible manufacturers in the industry.

CGMP regulations for irradiated food cannot be based solely on current radiation practices because of the lack of substantial experience with food irradiation. However, there has been extensive experience with other types of radiation processing (e.g., hospital supplies), and the industry has established standards in some cases. FDA considered both the experience and standard practices in the nonfood radiation processing industry and CGMP in the food industry in developing its regulation for irradiated food. FDA's regulation contains five general provisions for CGMP specific to irradiation to aid industry:

1. Any firm that treats food with ionizing radiation is no different from any other food processor. Therefore, such firms must comply with the umbrella CGMP regulations contained in Part 110 and any other regulations applicable to food handling. The provisions of Part 110 specify sanitation requirements and controls for the facilities, the equipment, the raw materials, and the process.

2. A food should be irradiated only at the dose reasonably required and under the conditions that would accomplish the intended technical effect, and not more than the maximum dose specified by the applicable regulation for that use.

3. Packaging materials subjected to irradiation, incidental to the radiation treatment and processing of prepackaged food, should be specifically authorized for use under such conditions.

4. Radiation treatment of food should conform to a scheduled process for food irradiation. A scheduled process is a written procedure that ensures that the radiation dose range selected by the food irradiation processor is adequate under commercial processing conditions for the irradiation to achieve its intended technical effect on a specific product and in a specific facility. Because this dose range may vary with the food irradiated and the radiation facility, FDA believes that each processor should develop and follow a scheduled process established by qualified persons having expert knowledge in radiation-processing requirements of food and specific for that food and for that irradiation processor's treatment facility.

5. A food irradiation processor should maintain records, as specified, for a period of time that exceeds the shelf life of the irradiated food product by one year, up to a maximum of three years. In addition, these records should be available for inspection and copying by FDA.

THE FUTURE

Industry Interest

Whether food irradiation will be a commercially practical alternative is difficult to predict because of the complexity of the issue. Many other factors, in addition to technical feasibility, are involved. A recent report prepared by staff at USDA's Economic Research Service (59) reviews in detail the technical, public health, and economic considerations applicable to food irradiation.

It is important to understand that FDA's responsibility in the evaluation of the process is limited to the determination of the safety of the process under specific conditions of use. FDA has no proper role as a promoter of a specific food additive or food process. The primary responsibility for such activities remains with industry.

Food irradiation is a technology developed, to date, primarily at government expense. In the U.S., this started with the United States Army and the Atomic Energy Commission granting monies for research. At present, the USDA is conducting some research, and the Department of Energy (formerly the AEC) is providing other funds.

The future of food irradiation will be determined by the actions of consumers and the food industry. Industry's role is to assess the feasibility of this technology and to determine its commercial potential. Food irradiation will never be a panacea to solve world food problems, but there are no doubt areas where this process is technically effective, economically feasible, and provides certain advantages to conventional processing. We have seen considerable interest in the use of radiation as an alternative to chemical fumigation of spices with ethylene oxide.

Consumer Interest

Consumer interest in this new food process is growing. As might be expected, the most active, organized consumer groups have been those opposed to the process. Consumer opposition has focused on labeling and the need for more safety information, as well as nonfood issues, such as environmental safeguards for the transportation and storage of radioactive material and worker safety.

Food irradiation is one of many useful technologies that may be important to maintain or even improve our food supply. It is now the role of industry to

demonstrate this to the consumer. Food irradiation is definitely a controversial technology and it is critical that the process and its potential are not oversold. Several recent consumer surveys (60–62) have studied opinions on issues of food irradiation. The surveys seem to indicate that, although there will be broad consumer acceptance for this new technology, there will always be a group that will not accept this technology for any reason. Consumer groups opposed to food irradiation believe that a vast majority of the consumers are unaware of this technology and will be opposed to its use even if they are informed. It seems that there will be no clear answer concerning final consumer opinions until such foods are test marketed. Accurate information presented in a credible manner, in conjunction with a high-quality food product, will be essential for success. Thus, the future of food irradiation now seems to be in the marketplace, where the focus will be on educational programs and test marketing.

Future Agency Action

At this time two considerations prevent the agency from proposing a general regulation allowing doses up to 10 kGy as recommended by the Codex Alimentarius Standard (63). First, doses above 1 kGy irradiation can significantly retard microbial spoilage without killing all spores of *Clostridium botulinum*. Under some conditions *C. botulinum* can grow and produce a toxin that constitutes a health hazard. Although this problem is not unique to food irradiation, techniques and regulations have been developed for other processing methods to ensure safety. Based on current knowledge, FDA is unable to prescribe safe conditions of irradiation at higher doses for foods to ensure that *C. botulinum* organisms would not develop and produce toxin without obvious spoilage.

Second, FDA reviewed a number of animal feeding studies to determine whether foods that are irradiated at doses above 1 kGy (100 krad) could be considered safe without additional toxicological studies. The agency found this data base, taken alone, to be inadequate to support a broad decision that all foods may be irradiated safely at higher doses up to 10 kGy (1 Mrad).

Therefore, FDA does not intend to initiate further rule making on food irradiation based on the information available at this time. The agency will, of course, continue to evaluate and respond on a case-by-case basis to all food-additive petitions involving irradiation.

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