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chemically or pharmacologically related substance or substances in such diet.

(3) Safety factors which, in the opinion of experts qualified by scientific training and experience to evaluate the safety of food and food ingredients, are generally recognized as appropriate.

In passing the Food Additives Amendment of 1958, Congress recognized that it is impossible to establish with complete certainty the absolute harmlessness of any chemical substance. The concept of safety used in the amendment involves reducing uncertainty about the safety of an additive to the point where the agency can reasonably conclude that no harm will result from its proposed use.

This objective can be achieved in a variety of ways. To determine whether consumption of a substance is safe, the agency considers the amount and identity of the substance ingested in light of what is already known regarding its toxicity. Ordinarily, animal feeding tests are essential for assessing toxicity of a substance. Not all situations require the same amount or type of testing, however, to determine whether use of an additive is safe. The degree of effort expended in reducing uncertainty about the safety of an additive must relate in some way to the likelihood that use of the additive poses a potential health risk to the public. Testing that is unlikely to provide information that would reduce uncertainty regarding safety should not be required. To do otherwise would waste scarce scientific resources that could be used for more productive purposes.

II. Comments

The agency received over 5,000 comments on the proposal. Many of the comments simply stated opinions for or against permitting food irradiation or requiring special labeling but identified no substantive issues to which the agency can respond. For example, some comments expressed concern that food might become radioactive, but none provided factual support. Other comments acknowledged that irradiation of food will not make the food radioactive. The agency believes that the proposal adequately addressed the issue of induced radioactivity in food (see 49 FR at 5716). Because no evidence has been submitted to contradict FDA's finding that the irradiation of food does not cause the food to become radioactive, no further discussion of this issue is necessary.

Many of the comments were concerned about the formation and the safety of radiolytic products, and the effect of irradiation on nutrients in food. A majority of those comments stated that more studies were needed because the long-term effects of these radiolytic products have not been ascertained with enough certainty to justify the conclusion that the use of irradiation is safe. The substantive comments and FDA's response to each are discussed below.

A. Safety

Before responding to the substantive comments relating to safety, the agency believes it would be useful to explain again its safety assessment of food irradiation and its conclusions concerning the safety of foods irradiated in compliance with this regulation. A summary of FDA's position on safety is set forth below.

In the proposed rule, the agency stated "* * * that the safety of food irradiation below 1 kGy (100 krad) has been established * * * because: (1) Irradiation will not make the food radioactive, and thus cannot expose the consumer to radiation; (2) the chemical differences between irradiated foods processed at these doses and nonirradiated foods are too small to affect the safety of the foods; (3) food irradiated at doses up to 1 kGy (100 krad) will have the same nutritional value as similar foods that have not been irradiated; and (4) the balance between microbial spoilage organisms and pathogenic organisms is not adversely affected by radiation doses below 1 kGy (100 krad)" (49 FR 5718).

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 the additive is safe under the proposed conditions of use. Since the 1960's when the first petition for the treatment of food with radiation sources was submitted, the agency has been confronted with the question of what test procedures are appropriate to establish reasonable certainty of no harm for use of radiation sources in the treatment of food. In the absence of adequate data on the chemical changes in food treated with radiation and information on the nutritional quality of such food, FDA concluded that petitioners should submit long-term animal feeding studies to demonstrate the "wholesomeness" of the irradiated food. In those instances where petitioners have provided adequate chemical and nutritional data to the agency, FDA has not required petitioners to submit long-term animal feeding studies. For example, FDA has issued regulations authorizing the use of x-rays for inspection of food, microwaves for heating food, and ultraviolet radiation for treating food based on chemical analyses (see 21 CFR 179.21, 179.30, and 179.39, respectively).

In 1978, FDA established its Bureau of Foods Irradiated Food Committee (BFIFC) to review the existing agency policy concerning the irradiation of foods. BFIFC's main task was to 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. 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 (Ref. 1).

BFIFC recognized that no single approach provided sufficient data to estimate the 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 percent of the total diet could be irradiated, but anticipated that actual human exposure would not exceed 10 percent of the diet.

Further, the committee considered those chemical constituents generated by irradiation, also known as radiolytic products. BFIFC assumed that some radiolytic products may be unique to irradiated foods and created the term "unique radiolytic products" (URP's) to mean substances not known to be present in nonirradiated food. However, BFIFC recognized that scientists do not know the extent to which these substances, although characterized as URP's, may actually be present as common constituents of the human diet.

BFIFC reviewed the available literature dealing with radiation chemistry, the identification and quantification of substances produced in foods as a result of irradiation, and found that the amount of radiolytic products generated is primarily dependent upon the amount of energy

will be adequate to accomplish the intended microbial disinfection of dry or dehydrated vegetable substances. The agency emphasizes that although toxicological data may sometimes be helpful in evaluating the safety of irradiated foods, such data are not scientifically necessary for determining the safety of radiation for the uses and doses encompassed by this regulation.

In addition to studies available in the published literature, the U.S. Department of Agriculture (USDA) has made available through the National Technical Information Service (49 FR 40823; October 17, 1984) final reports of certain contracted animal toxicological studies of radiation-sterilized chicken and reports on chemical changes in food caused by irradiation. The agency has reviewed studies involving mice and dogs fed radiation-sterilized chicken meat and concludes that these studies do not show any treatment-related effects (Refs. 5 and 6). These studies are discussed in further detail in the responses to those comments which reference the USDA studies.

1. Radiolytic Products

1. Many comments expressed the opinion that the radiolytic products produced during irradiation would made the food harmful. Some comments stated that the radiolytic products are free radicals and that ingestion of these free radicals would be harmful. Other comments stated that the free radicals may later form toxic substances.

The agency disagrees that free radicals or toxic substances will be produced in food at unsafe levels under the conditions prescribed by this rule. The issue is not whether free radicals, hypothetically, can later form toxic substances, but whether the formation of a toxic substance is sufficiently probable to raise questions about the safety of the irradiated food. Although the generation and subsequent reaction of free radicals comprise the major route by which radiolytic products are formed, such reactions are also common during conventional food processing and storage operations. As was discussed above, substances that are chemically similar to radiolytic products are often formed or are present in foods that are not irradiated.

The important issue the agency must consider with regard to radiolytic products is the probability that a toxic radiolytic end product may be formed and whether such a product would be present in sufficient amounts to make the food unsafe. The agency has no evidence to cause it to change its position that the chemical differences between foods irradiated at the doses allowed by this regulation and nonirradiated foods are too small to cause concern about the safety of the irradiated foods.

2. Some comments expressed the opinion that irradiated foods are unsafe because ingestion of irradiated foods may result directly in toxic free radical and peroxide formation within the body.

The agency disagrees. Although irradiation produces free radicals as reactive intermediates in the food itself, the high water content of all fresh food provides a medium for their rapid degradation after irradiation. Thus, they are not likely to persist or be present at all in food by the time that food reaches the consumer. However, irradiated dry spices and seasonings are examples of foods in which free radicals are known to persist for long periods of time. Nonetheless, the manner in which these foods are used—as ingredients in other foods that contain water—provides a means for rapid dissipation of the free radicals, thereby precluding their ingestion.

While peroxides are sometimes formed in irradiated foods, they are also formed in foods that are not irradiated. The agency has no evidence to suggest that irradiated foods would be metabolized differently from nonirradiated foods and thus form unique or toxic free radicals or peroxides within the body. Therefore, the agency believes that concerns about the safety of irradiated foods as expressed in these comments are unfounded.

3. One comment stated that "[a]ny preservation of foodstuffs by irradiation at any dose may be unwise," and that gaseous oxygen from air gives rise to free radicals, peroxides, and hydroperoxides. The comment also stated that increased concentration of hydrogen peroxide ordinarily results from irradiation. The comment noted that "[t]he addition of hydrogen peroxide to food as a preservative has been prohibited in a number of countries, notably Japan, as a contributor to carcinogenesis."

The formation of detectable quantities of hydrogen peroxide, organic peroxides, and hydroperoxides during irradiation of foods in the presence of oxygen is well documented, and food processors normally try to minimize contact of their products with air during processing and packaging. Peroxides result from free radical chemistry, as discussed earlier, between oxygen and the primary radiolytic products from the carbohydrates, fats and oils, and water present in food. The potential biological consequences of the thermal degradation of the intermediate peroxides and their reactions with the multitude of food components have been addressed by a number of researchers (Refs. 7, 8, and 9).

FDA considered the potential carcinogenicity of hydrogen peroxide in its final rule permitting the use of hydrogen peroxide as an indirect food additive for sterilizing polyethylene food contact surfaces used for food packaging (46 FR 2541; January 9, 1981). The agency had specifically addressed a Japanese report of a bioassay of hydrogen peroxide performed with C57B mice in which the authors had indicated that the chemical may have caused duodenal cancer. Upon review and after consultation with the authors of the study, the agency stated that the evidence was insufficient to conclude that hydrogen peroxide is a carcinogen (46 FR 2541; January 9, 1981).

In that document, the agency also considered the issue of human exposure to hydrogen peroxide in food and concluded that milk packaged in materials sterilized by hydrogen peroxide would contain hydrogen peroxide at a level no greater than 100 parts per billion at the time of packaging. Moreover, after 24 hours, the hydrogen peroxide concentration would fall to about 1 part per billion, i.e., more than 99.9 percent of the hydrogen peroxide will no longer be present in the food.

Similar considerations leads the agency to conclude that any hydrogen peroxide produced during irradiation of fruits and vegetables or meats in compliance with this final rule would rapidly degraded to negligible levels by natural enzymes and natural antioxidants in the food. Furthermore, any residual hydrogen peroxide, if present, would be considerably less than that encountered ordinarily in foods and environmental sources.

Organic hydroperoxides, formed by reaction of radicals resulting from reaction of oxygen with primary radiolysis products, are both thermally and chemically unstable and decompose to various aldehydes, ketones, alcohols and hydrocarbons which constitute the primary radiolytic end products also identified as components of both unprocessed and conventionally processed foods. The yields of these substances formed under the conditions of this regulation are sufficiently low to raise no concerns regarding safety.

Finally, microbiological studies that have reported toxic effects of irradiated aqueous sugar solutions in which peroxides and peroxo radicals are generated are discussed in paragraphs 21 and 22 of this preamble. The agency

has concluded that these studies are inappropriate models for assessing the safety of irradiated foods.

4. Some comments stated that no radiolytic products are unique and noted that the U.S. Army Natick Laboratory found no unique products in irradiated meats. These comments indicated that the term "unique" is misleading and should not be used.

The BFIFC report used the term unique radiolytic products (URP's) to describe substances produced in food during irradiation which have not been shown to be present in nonirradiated food. The BFIFC report recognized, however, that substances characterized as URP's may be normal minor constituents in the human diet that have simply not been detected through routine analysis of nonirradiated food.

As stated in the proposal, the agency agrees that some radiolytic products assumed to be unique may well be natural or common components undetected in nonirradiated food. However, it is impossible to demonstrate with absolute certainty that that will always be the case for all radiolytic products. Therefore, the agency cannot be certain that all radiolytic products are normal components of the human diet. To be prudent, the agency has assumed, for purposes of safety assessment, that some minor radiolytic products present may not be normal components of the human diet, and, thus, may be unique to the process. Based upon such conservative assumptions, the agency concludes that the amount of potential URP's would be so low as not to pose a safety problem.

5. One comment asked, "what happens to pesticide residues on produce when they undergo irradiation treatment? What are the health risks to humans?"

A pesticide chemical, like any other chemical component of food, will possess a certain level of sensitivity to ionizing radiation. The degree of sensitivity of a pesticide chemical to the primary ionizing energy and to chemical reaction with primary radiolytic products from other constituents of a food matrix will depend on the molecular structure of the pesticide. As is the case with other chemical components of a food, the total yield of radiolytic products from irradiation of any given pesticide will be a function of the amount of pesticide present, as well as its sensitivity to radiation.

The BFIFC estimated that the sum of all radiolytic products produced by irradiation at 1 kGy (100 krad) would be no more than 30 parts per million in food. This means the cumulative concentration of all radiolytic products from a pesticide residue would correspond to a concentration of less than 30,000 times smaller than the concentration of the pesticide residue itself. Because such low levels of pesticide residues are expected in food, the agency believes that the total amount of radiolytic products from a pesticide chemical that may be consumed from foods irradiated in compliance with this regulation at doses below 1 kGy (100 krad) will be virtually all. Therefore, the agency concludes that the potential toxicity of each radiolytic product from a pesticide chemical residue on foods that are irradiated would be negligible and that such pesticide residues do not pose a hazard to health.

2. Spices

6. One comment stated that foods such as spices comprise more than 0.01 percent of the daily diet and that the proposed rule was inconsistent with BFIFC's recommendation that irradiation of foods constituting less that 0.01 percent of the diet be considered safe up to 50 kGy (5 Mrad).

The agency agrees that spices, in total, may constitute more than 0.01 percent of the daily diet. The agency has estimated a probable intake of dried spices and culinary herbs of up to 3 grams per person per day. For the general population, this constitutes 0.1 percent of the total diet of 3 kilograms.

The comment was apparently confused by terminology in the BFIFC report recommending that a "food class" which contributes 0.01 percent or less to the daily diet be considered safe for irradiation at doses up to 50 kGy (5 Mrad). The 0.01 percent in the recommendation was intended to refer to the dietary contribution of an individual spice (e.g., nutmeg or turmeric) as a "food class," not all spices as a "food class." Because radiolytic products from different spices are likely to be different, there is no reason to add the amount of radiolytic products from one spice, such as nutmeg, to another spice, such as turmeric, when evaluating safety. The intent of BFIFC's recommendation was not to set a precise dietary percentage limit of 0.01 percent but rather to acknowledge that the amounts of radiolytic products that would potentially be consumed from irradiated dried spices and seasonings are so small that such irradiated foods can be considered safe as ordinarily used. Neither the proposal nor the final regulation permitting the irradiation of spices at 30 kGy (3 Mrad) is inconsistent with BFIFC's recommendation.

7. Some comments on the proposed rule expressed concern that large amounts of irradiated spices and seasonings used by certain ethnic groups in their food would exceed such consumption levels. The comments provided no information on which to base such a concern.

The agency recognizes that dietary patterns differ between groups of people and that certain groups consume more spices and seasonings than do other groups. Nevertheless, the agency has no reason to believe that any ethnic group will consume any irradiated spice or seasoning in amounts that would raise any safety concern, even considering dietary variations among ethnic groups. A single spice or seasoning would still be a minor ingredient in the diet. Moreover, as discussed in the previous response, the radiolytic products from one spice are different from those of another spice; therefore, their effects, if any, will not be cumulative.

8. The agency invited comments on the list of spices that is considered appropriate for irradiation. Comments recommended including those substances listed in § 182.10 *Spices and other natural seasonings and flavorings* (21 CFR 182.10), as well as other spices, seeds, and herbs commonly used as minor flavoring ingredients, and including teas and other vegetable seasonings. Some comments also stated that a specific list of spices was unnecessary and a phrase such as "herbs, seeds, and spices" should replace the individual listing of spices. One comment stated that to prohibit treating a spice mix because one minor ingredient is not on the list is not logical and suggested an alternative approach of granting overall approval to seasoning and flavoring substances currently considered generally recognized as safe because their safety would not be significantly changed by irradiation.

The agency disagrees that natural flavors should necessarily be included in the list and is not permitting the use of irradiation for natural flavors at this time. Natural flavors are components of food ingredients that have undergone some processing. Such flavors may be in solid or liquid form. The agency's conclusion that minor ingredients such as dried spices and seasonings may be irradiated safely was based on the fact that the amount of chemical change in the solid, dry state of a food is less than would occur when substantial portions of liquid are present and that dry ingredients would not support the growth of microorganisms that might survive irradiation. The agency has no

information from which to conclude that flavors in liquid form can be irradiated safely. Also, the agency has no information indicating that processed flavors require treatment for disinfection. Anyone interested in pursuing this matter further may do so by submitting an appropriate food additive petition.

The agency agrees that a specific list of spices and seasoning agents is unnecessary. Collective terms are used to describe different groups of these minor ingredients and such terms may be more appropriate than a detailed listing. Although herbs may be used for both culinary and medicinal purposes, a food additive regulation applies only to the irradiation of culinary herbs. Therefore, the agency is now modifying the regulation to permit irradiation of dry or dehydrated aromatic vegetable substances: culinary herbs, seeds, spices, teas, and vegetable seasonings.

2. Some comments apparently assumed that the proposed regulation would not permit irradiation of spice blends and requested modification of the regulation to permit such irradiation.

The issue is twofold: (1) Whether blends can be irradiated, and (2) whether the regulation authorizes the irradiation of enough ingredients to make the irradiation of commercial blends practical. The regulation does not preclude the irradiation of spice blends. The agency recognizes that the limited number of spices listed in the proposed rule would have prohibited blends containing other ingredients. As explained above, the agency agrees that the description of the substances that may be irradiated as dry or dehydrated aromatic vegetable substances should be more comprehensive than that listed in the proposed rule. In addition, salt and other adjuvants or minor ingredients (such as anticaking and free flow agents) may be used in a blend of seasoning substances. Under such limited conditions of use, the irradiation of these minor dry ingredients would pose no concern. Therefore, the agency is describing in this final rule the spices and seasonings in general terms and is explicitly authorizing the use of blends of aromatic vegetable substances, as well as salt and other dry foods ordinarily used as minor ingredients in such blends.

3. Other Minor Foods

10. One comment stated that color additives are important ingredients in the manufacture of processed foods, as well as drugs and cosmetics, and are used in minute amounts in the diet. This comment further stated that turmeric and paprika are color additives that are also included in the list of spices and vegetable seasonings that can be irradiated and suggested that the final regulation be expanded to include other listed color additives.

The agency does not agree that this regulation should include color additives. In preparing its proposed rule, the agency had not considered the ramifications of approving the irradiation of color additives. Such consideration would include whether specifications established for a color additive based on current manufacturing processes would still be adequate for the color additive after irradiation and what doses would be needed to accomplish the intended effects. Persons able to document the safe use of a source or radiation to irradiate color additives may submit a petition to the agency. The agency agrees that turmeric and paprika are both spices and color additives. However, their major use is as seasoning agents, and the agency sees no reason to preclude irradiation of these aromatic vegetable substances when they are also used as color additives (Ref. 10).

11. One comment stated that the rule should allow for the irradiation of dry enzyme preparations for microbial disinfection at a dosage up to 30 kGy (3.0 Mrad) because they are minor food ingredients.

The agency had not considered this specific use of irradiation in developing the proposed rule. However, the agency received a petition to treat dry enzyme preparations at doses up to 10 kGy (1 Mrad), and in the Federal Register of June 10, 1985 (50 FR 24190), the agency amended § 179.22 to permit this use. In this document, the agency is deleting § 179.22 and is incorporating that authorization for irradiation of dry enzyme preparations in new § 179.26(b). Persons able to document the safe use of a source of radiation at dosage levels higher than 10 kGy (1 Mrad) as authorized in new § 179.26(b) to control microbial contamination in dry enzyme preparations may submit a petition to the agency.

4. Destruction of Nutrients

12. Several comments stated that destruction of nutrients should be a concern in this rulemaking. The comments stated that many vitamins are light or heat sensitive, and that irradiation will destroy them. One comment stated that nutritional problems may develop for consumers because of nutrient loss when an entire class of foods is irradiated.

The proposal discussed this issue and explained that the available literature indicated that there are no nutritional differences between unirradiated beef and food irradiated at levels below 1 kGy (100 krad). The minor ingredients allowed to be irradiated at higher doses are not sources of nutrients. Therefore, the agency believes it is appropriate to conclude that destruction of nutrients is not an issue in this rulemaking. There have been no additional data submitted to change this conclusion.

5. Selective Destruction of Microorganisms

13. One comment indicated that irradiation could contribute to increased aflatoxin contamination of foods. The comment cited a series of studies published in 1978 and 1979 by researchers from the National Institute of Nutrition of the Indian Council of Medical Research which reported that wheat irradiated at dose levels up to 25 kilorads showed a dose-dependent susceptibility to aflatoxin production (Refs. 11 and 12).

The agency disagrees that irradiation would contribute to increased aflatoxin contamination of foods. The studies referenced do not replicate actual food-handling practices. In the studies, the wheat was irradiated, autoclaved, and then inoculated with an aflatoxin-producing organism. The agency has no evidence that would lead it to conclude that food irradiated and stored under normal handling practices would show increased aflatoxin production. FDA does not believe that the results cited justify a modification of this rule.

14. Several comments stated that irradiation intended to eliminate one food hazard may affect the microbial spoilage patterns of food, thereby creating a new hazard. These comments expressed concern that *C. botulinum* spores would survive irradiation and would produce botulinum toxin without typical signs of food spoilage.

The agency agrees that this is a legitimate concern in some situations, but it does not apply to irradiation of dry foods or foods irradiated below 1 kGy (100 krad). Irradiation of food below 1 kGy (100 krad) will destroy few spoilage bacteria and thus will not change normal spoilage patterns. Furthermore, irradiation of minor ingredients at high doses, as allowed in this rule, would pose no problems because these minor ingredients are dry and dry foods do not provide a growth medium for *C. botulinum* spores.

15. Some comments stated that food irradiation may create or produce potentially harmful radiation-resistant bacteria, new bacteria, or viral mutants. One comment raised the possibility that mutated deoxyribonucleic acid (DNA)

fragments might be incorporated by bacteria, viruses, or cells of the human digestive tracts to create other harmful mutants.

Mutants produced during the irradiation of food are essentially the same as those that occur naturally. The only real difference is in the rate at which mutations occur. Radiation may increase the frequency of mutations and thereby increase the rate of evolution in bacteria or viruses that would occur otherwise through natural evolutionary processes. However, there is no reason to expect that the resulting mutants would be different or more virulent than those created in nature (Ref. 13).

Because bacteria are highly evolved organisms, well adapted to their environment, the vast majority of mutations would tend to be detrimental for the organisms. Mutant organisms that are more radiation resistant than their parents may survive and be present in an environment exposed to frequent sublethal doses of radiation. Such radiation-resistant bacteria, however, would be a problem only if irradiation were essential to produce a safe food. This is not the case and not permitting the use of food irradiation would not prevent such a problem from occurring.

Furthermore, the agency does not believe that such radiation-resistant bacteria or viruses, if they were produced, would be more resistant to other antibacterial agents. Although it is possible that specific conditions and indiscriminate irradiation might produce mutants, the agency concludes that the possibility that such mutants would be more virulent or more harmful is remote (Ref. 13).

There are only a few reports of genetic exchange between bacteria in the mammalian gut (Ref. 14). A few theories state that host cells may incorporate prokaryotic DNA, but it is not clear whether such genetic information is expressed. The agency sees no reason to prevent irradiation of food because of such speculations.

a. Toxicological Studies

16. Many comments claimed that it is FDA's first responsibility to ensure the absolute safety of all food produced and consumed in this country, not simply to make the process of production easier and/or cheaper for producers.

FDA agrees that its responsibility is to ensure that a food additive be demonstrated to be safe under the proposed conditions of use (21 U.S.C. 348(b)), but the agency does not believe that it was the intent of Congress, when formulating the act, that FDA ensure the consumer of absolute safety of all foods. Congress recognized that it would not be possible to determine with absolute certainty that no harm shall result from the intended use of a food additive. The Senate report stated: "Safety requires proof of a reasonable certainty that no harm will result from the proposed use of an additive. It does not—and cannot—require proof beyond any possible doubt that no harm will result under any conceivable circumstances." S. Rept. 2422, 85th Cong., 2d Sess. 8 (1958). As stated earlier, this is the standard of safety applied by FDA in its rulemaking for food additives.

On the other hand, the legislative history makes clear that Congress did not intend FDA to make regulatory decisions on the use of an additive based on an arbitrary opinion as to whether the additive should be used. Thus, the agency, in approving the use of a food additive, considers whether the food additive is safe and effective and not whether such approval will be beneficial to the producer of the additive.

17. One comment asserted that FDA's proposed regulation was illegal because it was not based on animal testing. While 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.

The agency agrees that much of the testimony before enactment of the Food Additives Amendment of 1958 discussed animal testing of additives. This could be expected because most of the testimony about testing concerned direct food ingredients of unknown toxicity. Congress did not discuss how irradiation of food should be tested for safety. Furthermore, 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. Therefore, FDA concludes that available animal test data are not necessary for determining the safety of those uses of radiation encompassed by this document. Animal testing is too insensitive to show an effect from irradiation of food at the doses allowed and, thus, would not contribute additional information to the evaluation of the safety of such uses.

Nevertheless, the agency reviewed all available animal studies to determine their adequacy and to evaluate the toxicological evidence. FDA's evaluation of these studies confirms the agency's earlier conclusions that such data would not contribute further assurances of safety of foods irradiated in compliance with this rule.

18. One comment stated that food irradiation should be presumed dangerous until adequate scientific information is available for responsible decisionmaking and that FDA should make no decision until more information on hazards versus benefits of food irradiation is available.

For reasons discussed earlier in this section, the agency has determined that adequate information on radiation chemistry of foods is available to conclude that foods irradiated in compliance with this regulation are safe, and that the intended effects are achieved, thus complying with section 409 of the act.

19. One comment was concerned about the reliability of studies where animals were fed an abnormal diet and stated that results from these studies, positive or negative, may be misleading.

The agency agrees that standard toxicology tests where large percentages of the diet are composed of a single food, either irradiated or otherwise, may give results that could be misleading. The major difficulty in toxicological testing of irradiated foods has been to design tests that would provide useful and meaningful information regarding safety. It would be difficult to design a test that would exaggerate greatly the level of radiolytic products that will be ingested from irradiated food because, to accomplish this, the amount of irradiated food—the test substance that will be ingested—may also need to be increased. This increase in dietary intake may not be tolerated and may thereby become an added stress to the animal. A substantial change in diet may also create nutritional imbalances

among either macro- or micronutrients of the diet.

FDA believes, however, that useful information has been learned from those feeding studies where there has been some exaggeration of dose relative to that prescribed by this regulation. This information together with knowledge of the chemical changes that occur at low doses of irradiation is sufficient to establish the safety of food irradiated in accordance with this regulation.

20. One comment suggested that FDA should require animal feeding studies in which the animals are fed food irradiated at exaggerated doses to obtain an adequate safety factor.

FDA acknowledges that food additives have typically been tested in animals at levels that greatly exaggerate the proposed levels of use of the additive to establish an adequate margin of safety. This traditional method of establishing a margin of safety is inappropriate when the additive is a source of radiation. FDA has examined many early studies in which food fed to animals was irradiated at exaggerated doses to determine the effect of ingesting increasing amounts of radiolytic products. The agency noted that treatment of food with increasing doses of radiation can destroy essential components (e.g., nutrients) of the food or make the food unpalatable. These factors can confound experimental results.

Because these effects on food do not occur at the lower doses, exposure of the foods to exaggerated radiation doses would not in these instances represent a valid test for determining the safety of foods irradiated at the levels of use prescribed by this regulation. The agency has, therefore, concluded that exposing food to ever increasing doses of radiation as a means of increasing the amount of radiolytic products ingested is generally not appropriate.

21. A number of comments objected to approval of irradiation of any fruit or vegetable because of reports that irradiated sucrose solution caused toxic effects. The comments suggested that sucrose solutions would serve as good models for evaluating the safety of irradiated fruits and vegetables and that the reported toxic effects were reason to disapprove this use of irradiation.

The agency agrees that irradiated solutions of sugars have been shown to cause biological effects in vitro. Certain studies have shown: (1) Abnormal anaphase formation in bean root tips treated with sucrose solutions irradiated at 2 Mrads (Ref. 15), (2) decreased growth in carrot tissue cultures grown in sucrose solution irradiated at doses ranging from 0.05 to 2 Mrad (Ref. 16), and (3) increased revertants in *S. typhimurium* after incubation with irradiated solutions of sucrose and irradiated solutions of glucose and ribose (Refs. 7 and 17). (The agency points out that its use of the term "sugar" in this response is generic. Where appropriate, specific sugars are mentioned by name.)

The biologically active compounds formed during irradiation of sugar solutions in the presence of oxygen are predominantly dicarbonyl sugars produced by reaction of peroxy radicals with sugar molecules. These dicarbonyl sugars can then be converted to *alpha, beta*-unsaturated carbonyl sugars which are also present in nonirradiated foods. The yield of biologically active carbonyl sugars will be less in irradiated complex food matrices than in irradiated simple sugar solutions because of reactions with substances such as metal ions and oxygen present in foods (Ref. 9).

The authors of the study using bean root tips (Ref. 15) postulated that the increased amount of abnormal anaphase was due to a drop in the pH of the irradiated sucrose solution. In a subsequent experiment reported in the same paper, the authors concluded that the low pH caused by irradiation of the sucrose solution alone was the cause of the mutagenic effects.

In feeding studies where sugars are present in a typically complex food matrix there is no increase in mutagenicity after irradiation. For example, direct irradiation of mango pulp to 20 kGy (2 Mrad) produced no mutagenic effect (Ref. 7). This study demonstrated that when a food containing sugars is irradiated, the food does not produce the same toxic effects that occur when these sugars are irradiated in simple solution. There is ample evidence (Refs. 7, 18, and 19) that the types and quantities of radiolytic products from irradiation of sugar solutions are not only dose dependent but are also dependent on specific conditions such as oxygen concentration and metal ions present in foods but not present in simple sugar solutions. Other studies on irradiated foods such as strawberries, dates, and mangoes likewise show no evidence of toxic effects (Refs. 20 through 26). The other studies that the agency reviewed regarding the toxicity of irradiated sucrose were of such poor quality that the agency does not believe that the data can be evaluated in a meaningful way.

The agency therefore concludes that irradiated aqueous sugar solutions are unsuitable models for predicting and extrapolating toxicity of irradiated foods. Therefore, the effects obs these types of studies are not co by the agency to be a reason for concluding that the uses of irrad set forth in this regulation are s The agency also concludes that no evidence that radiolytic prod from sugars present in irradiate cause toxic effects to animals or

22. One comment stated that i in *Nature* magazine (Ref. 16) ind that eating sugars irradiated at ranging from 0.05 to 2 Mrad can the same genetic changes in hum exposure to irradiation itself.

The agency has reviewed this and disagrees with the commen interpretation of what the study Indeed the authors clearly did n the conclusions attributed to th the comment. Furthermore, if be animals were irradiated at dose 1,000 times lower than the level this study, not only sterility but would result within hours. On t hand, humans and animals hav consumed food irradiated at up Mrads (Refs. 27 through 32) wit indication of adverse effects of kind. The study the comment re involved the effects of radiation carrot tissue in liquid culture ir at 20 kGy (2 Mrads). This study others concerning the effects of irradiation on solutions of sugar discussed in the response to the previous comment.

The agency recognizes that ir sugar solutions have produced in vitro. The agency concludes that irradiated sucrose solution unsuitable models for predictin extrapolating toxicity of irradia foods. Additionally, no evidence indicates that irradiated foods those containing sugars, will ca adverse toxic effects to animals humans.

23. A few comments stated th study involving hundreds of tho of humans over 20 or 30 years u necessary before FDA can say irradiated foods are safe.

The agency has never require long-term testing in humans to the use of a food additive and c that such a study is necessary o appropriate. The agency recogn it cannot say with absolute cer that any food, irradiated or not, absolutely safe for all people u conditions. The agency believes differences between foods irrad prescribed by this regulation an nonirradiated foods are so sma particularly compared to norma variations in the diet, that no e expected to be observed. The a

believes that the substantial amount of available toxicological information supports the conclusion that the irradiation of food, as set forth below, is safe. Therefore, there is no basis for delaying for decades a decision to regulate food irradiation to conduct the type of study suggested by these comments.

24. Some comments also stated that many of the long-term toxicity studies on food irradiation were performed by Industrial Bio-Test Laboratories (IBT) and should, therefore, be considered invalid because much of the data generated by IBT had been falsified.

FDA agrees that studies containing falsified data performed by IBT should be rejected. All studies identified in the agency's review of available toxicological literature on food irradiation that had been performed by IBT were rejected. Much of the data compiled by IBT had been falsified or were proven invalid due to flaws in data collection, data reporting, and/or in experimental design. Thus the agency considers such data unacceptable to support safety.

25. Several comments stated that there are only a limited number of adequate chronic feeding studies on irradiated foods and that testing of the long-term health effects of consuming irradiated foods has been inadequate.

The agency has determined that because only minor chemical changes may result in food treated with low doses of radiation, animal feeding studies are not necessary to establish the safety of foods irradiated under conditions prescribed by this regulation. Therefore, it believes that the number of adequate chronic feeding studies on irradiated foods is irrelevant to its safety conclusion. The agency has evaluated those chronic studies that have been properly conducted and are considered to be adequate by current standards. None of those studies show adverse effects from the ingestion of irradiated food.

7. Alleged Adverse Effects

The agency reviewed 441 toxicity studies on irradiated foods (Refs. 2, 3, and 4). Forty-five of these studies dealt with subacute toxicity, 58 with subchronic toxicity, 128 with reproductive toxicity, 14 with teratology, 110 with chronic toxicity, and 102 with genetic toxicity or irradiated foods. Only 5 of the 441 studies reviewed (3 chronic feeding studies (Refs. 20, 33, and 34), 1 reproduction study (Ref. 35), and 1 combined chronic, reproduction, and teratology study (Refs. 36, 37, and 38) were considered by agency reviewers to be properly conducted, fully adequate by 1980 toxicological standards, and able to stand alone in the support of safety. The reports of these five studies indicate no adverse effects from the irradiated foods fed to test animals.

Although most of the studies were generally inadequate by present day standards and could not stand alone to support safety, many contained individual 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 have seen 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. The agency, therefore, concludes that irradiation of foods as prescribed by this regulation is safe.

26. One comment referenced a book, "Consumer Beware" by B. Hunter, which stated that rats fed irradiated bacon and irradiated bacon and fruit mixtures showed increased mortality and an increased incidence of tumors. The author stated that the tumor incidence was increased and longevity was decreased.

Summaries of these studies were submitted in an early petition for sterilization of bacon by irradiation. FDA originally issued a regulation based on this petition (28 FR 1465; February 15, 1963). However, following evaluation of the complete reports of this study, FDA concluded that the sponsor had not met its burden for demonstrating safety (33 FR 12055; August 24, 1968) and rescinded the bacon regulations (33 FR 15418; October 17, 1968). Although previous reviewers asserted that the irradiated bacon studies may have shown adverse effects, the agency, after extensive reexamination of the study, now concludes that the claimed adverse effects cannot be substantiated because: (1) The study was of poor quality, (2) the numbers of animals examined were too small (three rats per group per generation) to have any statistical significance concerning tumors or longevity, and (3) the "total" incidence was only slightly increased in the low-dose group with no apparent dose dependence. Most national and international scientific bodies do not consider an increase in total tumors appropriate criteria indicative of a carcinogenic response (Ref. 40). The important considerations for determining if there is a carcinogenic response is whether there is an increase in the number of tumors at a specific organ site. The Armed Forces Institute of Pathology report (Ref. 39) on this study maintained that the tumors "showed no predelection for any single organ." The numbers of animals at risk were too few to conclude that there was an effect on tumor incidence or longevity. If such effects had been caused by irradiated bacon, they should have been reproduced in the other irradiated feeding studies, including those the agency considers properly conducted (Refs. 20 and 33 through 38). However, such adverse effects were not observed.

27. One comment referenced a statement in the book "Eating May be Hazardous to Your Health," by J. Verrett and J. Carper that: "[i]rradiation at high levels has been shown not only to severely destroy vitamins and minerals in food, but also to cause reproductive problems, a shortening of the life span and other complications in laboratory animals. In some instances—for example, in irradiated jams and fruit compote—cancer is a suspected result." The comment also stated that Dr. Verrett was a biochemist and researcher with FDA for 15 years.

The agency agrees that irradiation at high dose levels has been shown to destroy vitamins and other nutrients in food. As discussed in paragraph 11 of this preamble, however, destruction of nutrients is not a public health problem under the conditions of use approved for sources of radiation by this regulation.

It is not entirely clear which studies the authors were referring to in the statement from their book. The agency acknowledges that Dr. Verrett was an FDA employee during which time she reviewed many of the early petitions on food irradiation. The agency has reevaluated her reviews of the studies contained in these petitions. Judging from the irradiated foods mentioned in the statement quoted from her book and in the memoranda in the petitions, it appears that she is referring to two studies in which rats were fed a diet of (1) irradiated bacon and fruit compote (mixtures) (Ref. 35) and (2) irradiated pork, peaches, jam, carrots, and flour (Ref. 41).

The longevity and tumor (cancer) questions referred to in study 1 are addressed in paragraph 26 of this preamble. The agency has stated that an increase in "total" tumors is not indicative of a carcinogenic response by modern criteria for judging

carcinogenicity and the numbers of animals at risk were too low to conclude that there was either a tumor or longevity concern.

During its evaluation of toxicology data in 1982, the Task Group listed reasons for difficulty in evaluating the reproduction data from this study. The reasons include: (1) Inconsistent reporting of the numbers of animals used in each replicate experiment in several summary tables. (2) stillborn animal data not reported for every generation. (3) number of pregnant females not reported for all generations. (4) number of litters cannibalized only reported for the parental generation. (5) no indication given as to how or from which litters subsequent generations were chosen, and (6) replicate experiments not consistently identified in the summary tables.

In the second study (Ref. 41), the authors stated that there was a higher growth rate in the 2d and 3d generation animals and inferior breeding performance. Dr. Verrett was also concerned with reproductive and longevity questions in this study. FDA's reevaluation of this study cannot support Dr. Verrett's claims because the study was of very poor quality. The study pathologist specifically detailed many of the study's shortcomings and stated in the final report that "any conclusions resulting from this work should be drawn from the overall picture rather than the detailed studies of isolated aspects or organs" (Ref. 41).

The agency agrees with the pathologist's statement and has attempted to evaluate the overall picture referred to by the pathologist. As stated earlier, 5 animal feeding studies (Refs. 30 and 33 through 38) concerning longevity and/or reproduction (out of 441 toxicological studies reviewed) were considered by agency reviewers to be well designed, properly conducted, and reported. The reports of these five studies indicate no adverse effects to test animals fed irradiated foods.

The agency review included reports of 44 chronic studies, 60 reproduction studies, and 66 combined chronic reproduction studies. Although most of these studies have been considered less than adequate for a variety of reasons, the agency has been able to conclude from them collectively that no treatment-related adverse effects on the longevity of test animals or their reproduction were evidenced by these studies.

28. One comment referenced the report of a study (Ref. 42) in which statistically significant changes in the weights of ovaries and testes were observed when irradiated onions were fed to mice.

FDA has evaluated the report of this multigeneration reproduction study and notes that it was only an abstract from the World Health Organization (WHO) and has never been published as a complete report. The effects reported were a decrease in ovarian weight significant when compared to both the normal control (no onion diet) and the onion control (unirradiated onion diet), and a decrease in testes weight significant as compared with the normal controls only. Histological examination did not reveal any particular changes in the ovary and testes of the group fed irradiated onions. No effects were observed on reproduction, fertility, or other parameters observed. In 1977, a WHO committee reviewed a draft of the manuscript and reported that because there were no observed abnormal histopathology changes or deleterious effects on reproduction, these organ weight changes, if real effects, were not regarded as being treatment related. Other reproduction, subchronic, or chronic studies on irradiated onions (Refs. 37 and 43 through 47) at comparable or higher doses of irradiated food administered to other animals did not report any changes in ovarian or testicular weights. These findings lead the agency to agree with the conclusions of the WHO committee.

29. One comment, citing a review paper (Ref. 48), stated that "when dogs have been fed irradiated egg solids, reproductive failure has occurred, and chicks and rats have died as the result of hemorrhage due to lack of vitamin K."

This statement has been taken out of context. The authors were actually referring to the nutritional imbalances seen in some of these irradiated food studies. The entire quote reads:

> Despite the fact that the experimental animals are provided with diets of known nutritional requirements for adequate growth and development, the high level of test food which is incorporated in the diets may present a completely unrealistic situation which can place a nutritional stress on the animals and result in nutritional imbalances. An example of this situation has been observed in feeding of high levels of irradiated egg solids to dogs where the interrelationship between biotin and avidin was found to exert a role in causing reproductive failure. A related example of difficulty which has been experienced in separating potential toxicity and nutritional adequacy of irradiated foods was the previously mentioned effect of radiation sterilization on vitamin K (antihemorrhagic factor) in certain foods, which resulted in hemorrhage and death in chicks and rats. Careful and detailed studies are necessary to elucidate the mechanisms involved in physiological abnormalities of this nature.

FDA agrees with the authors that nutritional imbalances resulting from feeding large amounts of a single food to animals confound the results of these studies.

30. One comment stated that polyploidy (chromosomal changes) has been shown as a toxic consequence in animals and humans fed irradiated wheat.

The agency does not believe that this is a correct statement. The agency is aware that in several experiments conducted by the National Institute of Nutrition (NIN), Indian Council of Medical Research, Hyderabad, India, the investigators claimed that polyploidy (chromosomal changes) was a toxic consequence in animals and humans fed irradiated wheat. A committee of Indian scientists critically examined the techniques, the appropriateness of experimental design, the data collected, and the interpretations of NIN scientists who claimed that ingestion of irradiated wheat caused polyploidy in rats, mice, and malnourished children. After careful deliberations, this committee concluded that the bulk of these data are not only mutually contradictory, but are also at variance with well-established facts of biology (Ref. 49). The committee was satisfied that once these data were corrected for biases which had given rise to these contradictions, no evidence of increased polyploidy could be associated with ingestion of irradiated wheat.

The agency agrees with the conclusions of the committee of Indian scientists that the studies with irradiated foods do not demonstrate that adverse effects would be caused by ingestion of irradiated foods.

31. One comment disagreed with FDA's conclusion that foods irradiated at doses below 1 kGy (100 krad) are safe and stated that there is little reassurance in the fact that unidentified radiolytic products are present in irradiated foods at low concentrations, particularly if single exotic molecules may be capable of causing carcinogenic chromosomal aberrations.

The agency recognizes that radiolytic products will be formed in irradiated food. Ionizing radiation results in the formation of unstable free radicals and other reactive chemical intermediates which normally undergo rapid reaction to form more stable molecules. Of the total radiolytic products formed, a small fraction may be assumed to be unique or "exotic." Radiolytic products and URP's have been defined both earlier in this section and in the BFIFC report (Ref. 1). Certainly some URP's will be formed

ich are structurally atypical of parent d molecules. Such URP's may be free ical coupling products of lipid and rbs-derived radicals, dimers, and ss-linked products. However, ymatic hydrolysis of some of these mpounds by normal digestive ymes is expected to yield normal lecular subunits such as fatty acids, ino acids, monosaccharides, and mal metabolic products of these mounts which would be the same result from the normal digestion of the ginal parent molecules.

r toxic molecules of the extreme icity implied by the comment were sent at any level of toxicological nificance in irradiated foods ingested test animals, some consistent icological trends and patterns would manifest in the studies reviewed. cause it has seen no consistent trends patterns, the agency concludes that ds irradiated as prescribed by this ulation are safe.

12. One comment referenced a study mitted to FDA by USDA on fruit flies osophila) fed irradiated chicken. This dy showed a dose-related decrease in spring (Ref. 50), and the comment ted that this effect is consistent with romosomal damage.

FDA notes that in the sex-linked cessive lethal study in Drosophila re was no evidence of mutagenicity. ditional data on fertility and undity were also included in the dy, and a dose-related decrease in spring was noted. Although there re fewer offspring in the groups sed on irradiated diets than in ncurrent controls, the agency ncluded that this effect could arise m a host of causes unrelated to productive toxicity, and is an reliable indicator of an adverse productive effect. Mammalian data on production are more relevant to mans, and these studies, as stated rlier, demonstrate no consistent tterns or trends indicative of a sitive reproductive effect.

13. One comment referenced a study bmitted to FDA by USDA and stated at mice fed radiation-sterilized icken meat showed a significant rease in testicular tumors, increased ath rate, increased kidney damage omerulonephropathy), and decreased rvival. In addition, the comment plied that male dogs fed radiation-rilized chicken had significantly lower dy weights throughout adulthood than gs fed a frozen control diet, and imed that this shows toxicity of the adiated chicken diet.

The agency disagrees with the mment that these studies demonstrate reatment-related increase in testicular tumors. The studies involving mice and dogs fed radiation-sterilized chicken were carried out at Raltech Scientific Services (Raltech). These studies were initiated under the sponsorship of the U.S. Army and completed under the sponsorship of USDA.

The report prepared by Raltech scientists suggested the possibility that chicken irradiated at approximately 6 megarads produced testicular tumors in CD-1 mice in lifetime feeding studies (Ref. 51). Agency scientists have independently examined the histopathology slides to determine whether testicular tumors were induced by ingestion of irradiated chicken. They concluded that the total histopathological evidence did not support a treatment-related induction of testicular tumors (Ref. 5).

These data were also referred to the National Toxicology Program's Board of Scientific Counselors for peer review. The Board concluded also that the data do not allow the study to be categorized as one demonstrating a carcinogenic response in mice fed chicken meat treated with gamma or electron beam radiation (Ref. 6).

All mice fed chicken meat diets (both nonirradiated frozen chicken meat control diets and irradiated chicken meat diets) showed signs of extensive mineralization and glomerulonephropathy and decreased survival compared to mice fed chow control diets. After careful examination of the studies and comparison of data between the mice fed chicken meat control diets and the mice fed chow control diets, the agency concludes that the effects were due to the high protein content of the chicken diets rather than to the fact that some diets were irradiated.

The agency noted decreased survival in the female mice of the group fed gamma-irradiated chicken. However, because the decreased survival occurred only in one sex group, and the result was only marginally significant ($p = 0.04$), the agency does not consider this effect to be treatment related.

With regard to the dog feeding study, the agency does not consider the body weight decrease to be of toxicological significance because of the nature of the protocol that was followed. The maximum quantity of diet provided for each dog was originally limited to 500 grams per day (approximately 300 grams dry matter per day). However, some dogs fed chicken meat diets (irradiated, frozen, or thermally processed) consistently consumed the entire daily ration and consequently had higher body weights than dogs fed chow control diets. This difference in body weights between the different diet groups is attributable to excessive caloric intake of the dogs fed chicken meat. Assuming that the dogs should maintain an "ideal" weight, the contract laboratory restricted the food intake for "selected" overweight dogs as required to initiate weight loss until acceptable body weights were obtained. The few dogs considered underweight were allowed to feed until their body weight increased to an acceptable level. Because the diet was manipulated in this way, the agency does not consider the changes in body weight to be treatment related.

14. Several comments referenced two Russian reports (Refs. 32 and 33) that found damage to kidneys and testes in rats fed irradiated feed. The authors reported dose-dependent histopathological changes in the kidney and testes of rats fed irradiated lab chow. The changes were claimed to be similar to those changes seen in human autoimmune disease involving these tissues.

FDA has found that information on critical details of the experimental design of the studies is either incomplete or missing. The reproductions of photomicrographs are unusable, and the numerical data are incomplete across dosage groups. There is no information on the survival rates of rats to the end of the experiment. The total number of rats actually examined for histopathologic observation is not stated nor is the scope of such observations. There is a general lack of incidence values and survival information that are critical for interpreting the findings in the kidneys and testes.

The agency notes that the authors had not published any previous studies in which rats were used as experimental models and, therefore, these authors may not have been familiar with common progressive nephrosis of the rat kidney. The qualitative description of the kidney changes reported is generally consistent with kidney disease commonly seen in aged laboratory rats. Many of the features of chronic progressive nephrosis (Ref. 54) common to aged rats are identical with the microscopic changes described in kidneys by the Russian authors. Without information on the comparative incidence and severity of the kidney lesions in all groups, the agency cannot verify that these reported effects are treatment-related, especially considering the inevitability of these types of kidney changes in rats as a result of old age.

FDA reviewed the kidney data in 11 chronic studies (Refs. 22, 33, 34, 53 through 62) in which rats were fed

various diets consisting of food or feed irradiated at various doses under a variety of conditions to see if it would be possible to confirm the findings of the Russian authors. An examination of these results revealed no findings or evidence of treatment-related kidney changes as were reported by the Russian authors. One of the 11 studies reviewed, which most closely resembled the Russian study (Ref. 28), had also investigated rats fed a diet consisting wholly of chow irradiated at both a lower (2 kGy, 0.2 Mrad) and higher (25 kGy, 2.5 Mrad) dose. The agency reviewed this study and found no evidence of treatment-related kidney changes as reported in the Russian study.

Further, the treatment-related kidney effects claimed by the Russian authors have not been reported in any other mammalian studies as an effect caused by ingestion of irradiated food. Also, data available on irradiation of animal feeds where the whole animal diet is irradiated have not shown comparable pathology (Ref. 27).

Based on the descriptions of the findings of testicular effects, FDA believes that such findings are probably not induced by radiolytic products in the irradiated diet. Extreme size and weight differences between right and left testes can arise from trauma (e.g., fighting) or may be present from birth. It is not clear whether some of the microscopic changes that are discussed affected both testes or were a feature of the smaller testes. FDA also reviewed 11 studies to verify the testicular lesions reported by Russian authors, and none of the studies reviewed revealed treatment-related testicular changes similar to those reported in the Russian reports. One of the 11 studies reviewed, which most closely resembled the Russian study (Ref. 28), found no evidence of treatment-associated testicular changes similar to those reported in the Russian study.

The agency concludes that, given the paucity of data from these two reports and the considerable, more substantial evidence from other studies, the results of these Russian reports do not raise valid questions concerning the safety of food irradiated under the conditions of this regulation.

35. One comment claimed that three reports showed dominant lethal effects of irradiated foods (Refs. 63, 64, and 65).

The agency has reviewed these studies, and two of these three studies have been addressed (Refs. 64 and 65) in the response to paragraph 30 of this preamble. The third study (Ref. 63) claimed to have demonstrated an increase in preimplantation deaths. In this study, mice were fed 50 percent of their standard chow diet irradiated at a dose of 50 kGy (5 Mrad). There was no increase in postimplantation losses. Postimplantation losses, determined by counting dead embryos, are believed to be the most reliable and sensitive indicator of dominant lethality. The authors found only preimplantation losses, which are much less sensitive than postimplantation losses and merely a measure of total implants dead or alive subtracted from the total number. In addition to the possibility that results of the study could be spurious, any number of factors other than dominant lethality may cause preimplantation losses, such as a decrease in the number of eggs ovulated.

If these effects were real, one would expect to see some effect on postimplantation losses at a lower dose because postimplantation losses are a much more sensitive indicator than preimplantation losses, as mentioned above.

Although the findings reported may be statistically significant, the authors were uncertain as to what to attribute these results. They concluded that the most probable mechanism by which these effects could be produced would be via chromosomal aberrations. The studies necessary to establish an association between these effects and chromosomal aberrations were not conducted. Additional treatment levels below that conducted as mentioned above to detect postimplantation losses or examination of the 24 to 48 hour fertilized eggs could have provided better evidence of causality; but these studies were not conducted. Thus, although preimplantation losses were observed, FDA concludes that there is no biological significance to this observation because it was not reproducible. In three comparable studies, two in mice and one in rats (Refs. 66, 67, and 68), where 100 percent of the chow diet was irradiated with 25 kGy (2.5 Mrad) giving comparable radiolytic products as those found in Ref. 63, no preimplantation losses were demonstrated.

B. Labeling Issues

Under current regulations (21 CFR 179.22 and 179.24), several specified foods are permitted to be irradiated provided that the label bears the following statements: (1) "Treated with ionizing (or gamma or electron) radiation" on retail packages, or (2) "Treated with ionizing (or gamma or electron) radiation—do not irradiate again" on wholesale packages and on invoices or bills of lading of bulk shipments. In the proposal, FDA stated that it was interested in receiving additional comments discussing: (1) Whether FDA should require any type of label statement on food that has been irradiated; (2) if so, whether the statement should be required only on labels of food that has been irradiated (first generation foods) or also on the label of finished foods which may contain irradiated ingredients (second generation foods); (3) whether any required label statement should remain the same as that provided under existing regulations (i.e., "treated with ionizing (or gamma or electron) radiation") or whether some other phrasing would be more appropriate (e.g., "processed with ionizing energy"); and (4) whether consumers would be more misled by the presence of some type of retail label statement or by the absence of such a statement.

The labeling provisions of this final rule differ from that in the proposed rule and from the current labeling regulations as follows: This regulation 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." Throughout the remaining discussion in the preamble about the labeling provisions, the agency has used the terms "treated with radiation—do not irradiate again," and "treated with radiation," to represent both alternatives that the manufacturer may use in its wholesale or retail labeling in order to simplify the discussion. In addition to the mandatory language, the manufacturer may also state on the wholesale or retail label the purpose of the treatment process or expand upon the kind of treatment used. That is, the manufacturer may include in the labeling any phrase, such as "treated with radiation to control spoilage," or "treated with radiation to extend shelf

life," or "treated with radiation to inhibit maturation" as long as the phrase truthfully describes the primary purpose of the treatment. Similarly, the manufacturer may choose to state more specifically the type of radiation used in the treatment, i.e., "treated with x-radiation," or "treated with ionizing radiation," or "treated with gamma radiation." If more specific description is indeed applicable.

The agency recognizes that, because this is a new technology, manufacturers may want to use additional labeling statements as part of a consumer education effort. For example, in addition to the required language, the firm may wish to state that "this treatment does not induce radioactivity." The agency will permit such educational statements if they are truthful and not misleading to consumers.

In lieu of labeling individual items of unpackaged irradiated foods, FDA is allowing 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.

Half the comments specifically addressed the retail labeling issue, and over 80 percent of those comments urged that retail labeling be "required to prevent consumer deception." The remaining comments opposed any retail labeling of irradiated foods. Most comments, however, were in favor of some sort of labeling for wholesale packages of foods still in processing to prevent reirradiation.

In addition, the large number of consumer comments requesting retail labeling attest to the significance placed on such information by consumers. Moreover, several comments argued that irradiation of food altered the organoleptic properties of food, thereby reducing its nutritional value. These changes in the food, the comments asserted, make the irradiation of the food a material fact that must be disclosed under section 403(a) and 201(n) of the act. Because of these comments, FDA had decided to require that the label and labeling of food products bear the appropriate statements to inform consumers that the food has been irradiated. The agency emphasizes, however, that the labeling requirement is not based on any concern about the safety of the uses of radiation that are allowed under this final rule. Further responses to these comments are contained in paragraphs 36 through 49.

36. One comment stated that FDA did not have the authority to require a retail label statement on foods that had been irradiated because such labeling was not a prerequisite for safe use under section 409(c)(1) and (d) of the act. This comment argued that where safety is not at issue, FDA's authority to require special labeling is much less expansive. This comment also stated that if the standard for misbranding under section 403(a)(1) of the act is whether an additive affects organoleptic properties of food (i.e., taste, color, smell, or texture of foods), the presence of many additives now commonly used in foods should be highlighted on current product labels because most additives affect these qualities to some degree. This comment also stated that conventional food-processing methods also affect the organoleptic properties of food.

The agency is of the opinion that there is adequate statutory authority under sections 403(a), 201(n), and 409 of the act to require a retail label statement on foods that have been irradiated even though there is no concern about the safety of such treatment at the doses provided by this final rule. Section 409(c)(3)(B) of the act prohibits the approval of a food additive if a fair evaluation of the data before the Secretary "shows that the proposed use of the additive would promote deception of the consumer in violation of this Act or would otherwise result in adulteration or in misbranding of food within the meaning of this Act." In this case, the standard for misbranding under sections 403(a) and 201(n) of the act is whether the changes brought about by the safe use of irradiation are material facts in light of the representations made, including the failure to reveal material facts, about such foods. Irradiation may not change the food visually so that in the absence of a statement that a food has been irradiated, the implied representation to consumers is that the food has not been processed.

Food ingredients, including food additives that have a functional effect in food, are required to be disclosed on food labels. Food additives such as aspartame that are present as ingredients in foods are required to be included on the ingredient labeling statement on the food's label. Therefore, the consumer is informed of the presence of these ingredients and the representation is not misleading.

The agency agrees that 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. Canned foods have obviously been canned 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 on the abstract worth of the information but 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 requesting retail labeling 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, flour is required to be modified by the term "bleached" if bleaching agents are used in processing and modified by the term "bromated" if potassium bromate is used in the processing of the flour. These requirements are part of the standard of identity for various flours (see 21 CFR 137.206).

There are many other examples where 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). 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). Orange juice must also be labeled pasteurized when pasteurization is part of the juice's processing (see 21 CFR 146.140, pasteurized orange juice).

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 these material differences in processing.

The agency concludes that requiring a retail label statement that a food has been irradiated is consistent with the agency's statutory authority and current labeling practice.

37. Several comments argued that a retail label requirement was inappropriate because irradiation was used in place of chemical fumigants and FDA does not require that these chemicals be identified on the retail label. One comment stated that "there is no more rational basis for labeling irradiated foods (at the retail level) than for labeling pesticide residues present in agricultural commodities, indirect additives from packaging, flour and bread from fumigated wheat, or the

current fumigated spices themselves." Another comment pointed out that FDA has long held the position that nonfunctional secondary additives need not be declared on the label and that the policy codified at 21 CFR 101.100 should apply to foods that have been irradiated.

The issue here is whether the irradiation of food is a material fact that must be disclosed to the consumer to prevent deception. As stated earlier, irradiation may change the characteristics of a food in a manner that is not obvious in the supermarket. Packaging materials and incidental additives such as processing aids that have no technical or functional effect in the food and thus do not ordinarily affect the characteristics of the food may be exempted under 21 CFR 101.100 from the normal labeling requirements under the act. Furthermore, Congress specifically exempted pesticide chemicals under section 403(i) of the act from a retail labeling requirement when the food has been removed from its shipping container.

As stated earlier, FDA believes that the irradiation of food is a material fact that must be disclosed. The agency recognizes, however, that the irradiation of one ingredient in a multiple-ingredient food is a different situation, because such a food has obviously been processed. Consumers would not expect it to look, smell, or taste the same as fresh or unprocessed food, or have the same holding qualities. Therefore, FDA advises that the retail labeling requirement applies only to food that has been irradiated when that food has been sold as such (first generation food), not to food that contains an irradiated ingredient (second generation food) but that has not itself been irradiated.

38. One comment stated that a retail label requirement would imply that there is a hazard involved in radiation processing and that such a statement would mislead the public about the safety of the process and have a negative impact on the development of this technology.

Although FDA recognizes the potential for consumer confusion, because there is no safety problem with food irradiated in accordance with this final rule, any confusion created by the presence of a retail label requirement can be corrected by proper consumer education programs, and the presence of a retail label statement should not deter the development of this technology. Consumer comments reflect a growing awareness of the process of food irradiation. Many consumer letters acknowledge that food irradiation, as prescribed by the proposed regulation, will not cause the food to become radioactive. The agency has also received comments stating that experiences in other countries, such as the Netherlands, demonstrate that consumers do not necessarily reject irradiated foods when they are properly labeled.

A recent Good Housekeeping Institute Survey seems to support this view (Ref. 69). In addition, elsewhere in this document the agency has made it clear that manufacturers have the option of providing additional labeling to describe the specific purpose of the treatment provided that such additional labeling is truthful and not misleading.

The agency has also concluded, however, that the original labeling terminology required by existing 21 CFR 179.22 and 179.26 may be overly technical and that the type of radiation being used is not necessarily meaningful to consumers and that the retail label would be just as informative if the required retail statement were "treated with radiation." The regulation has been modified accordingly.

39. Other comments suggested that the retail label statement be revised to state: "treated with ionizing radiation to prolong shelf life to ——— [insert date]."

As explained above, any confusion created by the terms "radiation" or "irradiation" required to appear as part of retail labeling can be corrected by appropriate consumer education programs. Recognizing that labeling itself is a valuable source of consumer education, FDA encourages optional statements to be included on the retail label that expand upon the kind of treatment used or the purpose of the treatment. Such additional explanatory language may be used whenever the additional language is applicable and not misleading.

For example, "treated with radiation to control insect infestation," "treated with radiation to inhibit maturation," and "treated with radiation to inhibit spoiling" are all examples of acceptable alternatives describing the purpose of the treatment if in fact the additional statements reflect the purpose of the treatment. "Treated with electron beam radiation" is an example of an acceptable expansion on the kind of treatment, if in fact an electron source was used. These optional statements would not only have an educational benefit, but would also avoid any possible mistaken inference by the public that the required labeling is a warning statement.

A manufacturer who wishes to label its product as "treated with radiation to extend the shelf life to ——— (*insert date*)" would, of course, be required to possess data substantiating that the radiation treatment would, in fact, extend shelf life until that date.

In addition, a manufacturer who finds that the terms "treated with radiation" or "treated by irradiation" are misinterpreted by a significant number of consumers may petition FDA for approval of alternative language, e.g., "freshness preserved by irradiation." However, the manufacturer would be required to provide adequate evidence demonstrating that the alternative language is both more readily accepted by the public and not misleading as to the nature of treatment as a form of radiation.

40. Several comments took the position that food irradiation is a food-preservation process and should be considered a process instead of a food additive, at least for labeling purposes. Those supporting this view stated that other food processes are not required to be revealed on the label and that food irradiation should be similarly exempt from label declaration. The comments also stated that a retail label statement is not justified on the basis of risk.

The agency agrees that irradiation uses permitted by this final rule are safe. The retail label requirements of existing 21 CFR Part 179 were based on misbranding considerations and not on food safety or health risk considerations. As has been explained before, section 201(s) of the act specifically includes a source of radiation as a food additive (21 U.S.C. 321(s)).

Nor is there any statutory provision that exempts processes from being declared on a food label (49 FR 5719) and the agency must examine whether the failure to declare such processing is misleading to consumers. In this context it is not relevant whether irradiation is considered a process in determining whether retail labeling is appropriate.

41. Most comments written in support of a retail label requirement for irradiated foods stated that the irradiation process has not been demonstrated to be safe, and that if irradiation treatment of food is permitted, the food label should inform consumers about which foods have been irradiated so that consumers can make informed decisions about the kinds of foods they buy.

As discussed elsewhere in this document, the agency has concluded that the irradiation of foods at a maximum dose of 1.0 kGy (100 krad) is safe when used to control arthropod pest infestation or to inhibit the growth and maturation of fresh foods. In view of this fact, the arguments in favor of a

retail label requirement based solely on the grounds that the irradiated food is not safe, must be discounted.

42. Several comments in favor of a retail label requirement argued that irradiation of food altered the organoleptic properties of food and reduced its nutritional value and that these changes are material facts requiring disclosure under sections 403(a) and 201(n) of the act. The comments stated that consumers have a right to know whether such processing has taken place.

A food is considered misbranded under section 403(a) of the act if its labeling is false or misleading in any particular. In determining whether labeling is misleading, the agency must take into account the extent to which the labeling fails to reveal material facts in light of representations made about the food or consequences that may result from the use of such food (section 201(n) of the act). Therefore, the agency must decide whether the changes in the organoleptic properties of irradiated foods constitute a material fact or whether the information that a food has been irradiated constitutes information that is material to a consumer even if the organoleptic changes were not significant.

The agency agrees that irradiation causes certain changes in foods and that even small changes that pose no safety hazard can affect the flavor or texture of a food in a way that may be unacceptable to some consumers. Even those opposed to a retail labeling requirement agree that under certain conditions irradiation causes substantial changes in the organoleptic properties of some foods. Moreover, as discussed in the response to comment 38, irradiation may not change the food in any way that is visible to the consumer, so a label statement provides the only means of letting consumers know that a food has been irradiated. Thus, the absence of a label statement on retail foods may incorrectly suggest that an irradiated food is essentially unprocessed. Therefore, this regulation provides that the retail label contain a statement that the food has been irradiated.

43. The agency has also reviewed comments that argue both for and against the substitution of the term "ionizing energy" for the term "ionizing radiation" in the proposed wholesale labeling requirement and in any retail labeling requirement that was contemplated but not proposed. Most of the arguments for the substitution stated that they favored use of the term "ionizing energy" to reduce the problem of confusing irradiation with radioactivity and argued that use of the term "ionizing energy" would be less likely to be misunderstood by consumers. Other comments argued that both terms are likely to be misunderstood by consumers.

In view of the fact that the term "energy" could be confused with its more ordinary meaning as applied to foods, namely, a capacity of the food to provide caloric energy, the agency does not agree that substitution of the term "ionizing energy" would be less likely to be misunderstood by consumers. Furthermore, none of the comments offered any substantive evidence that one term would more likely be understood than another, either at the wholesale or retail level.

The agency does recognize that some population groups may harbor a prejudice against anything treated with radiation but is of the opinion that with the labeling flexibilities provided in this regulation, manufacturers will be able to overcome these prejudices as consumers become more educated about the process and the advantages this technology has over alternatives existing in the industry.

44. One comment suggested that the agency use the term "picowave treatment" in order to parallel the term "microwave treatment" that is commonly used for another form of food processing.

The agency gave careful consideration to the use of this term but it finally concluded that it should reject this suggestion because the term "picowave treatment" is not in common use in the industry or in the scientific community and would be neither more informative to the consumers than the label statement "treated with radiation" nor more understood by those in the food-processing industry. In addition, the microwave terminology is associated with complete cooking of the food which in no way parallels irradiation treatment of food as permitted by this final rule.

45. Several comments suggested alternative language for the wholesale label statement based on the assumption that the agency would permit reirradiation of a food provided that the total absorbed dose did not exceed the permitted amount. These comments suggested statements such as "Ionization processed with a maximum of ——— kGy" or "processed with electromagnetic energy (or picowaves) or electron beam energy (as appropriate) in the range of 0.5 MeV to 10 MeV with a dose of ——— (blank to be filled in by processor)."

Elsewhere in this document the agency has addressed the issue of reirradiation and has concluded that multiple exposure of foods to radiation is inappropriate. Therefore, there is no need to discuss these comments.

46. A few comments suggested that the wholesale label statement be replaced by a code stamp that would reflect the pertinent information about the treatment similar to that now used for the place and date of production for canned foods.

The agency has rejected this approach because the purpose of requiring a wholesale label is to alert other food processors that a food has been irradiated. The code stamp currently used in the production of canned foods is informative only to the individual canner. Different firms use different codes for their own special tracking of food lots. For a code stamp to be useful at all, there would have to be a universal code used by all manufacturers. Even this approach, however, is unsatisfactory when compared to labeling because there is a greater chance for error in interpreting a code stamp than in reading a statement that the food has been irradiated.

47. A few comments suggested that the agency permit alternative language to be substituted for any required statement to reflect more accurately the type of processing involved. In place of the phrasing "treated with ionizing radiation," the comments suggested statements such as "treated with x-rays" or "treated with gamma radiation from cobalt-60" or "treated with electron beam energy."

In the Federal Register of January 7, 1987 (52 FR 140), the agency proposed that terms such as "processed (or treated) by x-radiation" and "processed (or treated) by gamma radiation" could be substituted for "processed (or treated) by ionizing radiation" at the option of the processor, whenever the more specific treatment was applicable.

The agency concludes that the option to describe the type of radiation should still be made available to food processors. The agency is of the opinion that it is in the public interest for labels to bear a statement that is as descriptive of the process as possible. Permitting these alternative labeling statements will also serve to educate the general public about the various types of treatment used by food processors.

48. Several comments recommended that FDA require a logo to represent "radiation" instead of a worded statement on the label of retail foods that have been irradiated. These comments pointed to the fact that there is a symbol used internationally to convey the fact that food has been irradiated. A comment from the U.S. Environmental Protection Agency (EPA),

although not opposed to the use of a logo to represent use of the irradiation process on food product labeling, expressed concern that the symbol that has been used internationally closely resembles EPA's official logo. EPA asserted that use of the symbol might cause consumer confusion about whether EPA had endorsed use of a product that carried such a logo.

The agency believes that the use of a logo in conjunction with a descriptive label of the process would serve to educate the general public that the logo and the label are synonymous. Thus, the agency is requiring that the label and labeling of retail packages of foods irradiated shall bear the following logo

along with the statement "treated with radiation." This logo derives from the symbol that has been used internationally to convey the fact that the food has been irradiated.

For irradiated foods not in package form, the required logo and phrase "treated with radiation" shall be displayed to the purchaser by other means as discussed elsewhere in this document. In addition, the label and labeling and invoices or bills of labeling shall bear the statement "treated with irradiation—do not irradiate again" when shipped for further processing, labeling, or packaging.

With industry uniformly using this logo in conjunction with the wording "treated with radiation" or "treated by irradiation" and an educational effort to inform consumers about the meaning of the logo, the agency has modified this rule to require 2 years after its publication only the use of the logo without the accompanying terminology. The agency will assess the need for the mandatory language to accompany the logo during this 2-year period. Any extension of the wording requirement will be established through notice and comment rulemaking.

49. Several comments argued that even if a retail label requirement were a part of the regulation that this requirement should not apply to fresh fruits and vegetables because such labeling was impracticable. Other comments simply asked how any retail label requirement would apply to fresh fruits and vegetables sold in bulk retail food stores.

The agency does not agree that retail labeling of fresh fruits and vegetables would be impractical. The final regulation as modified states that packaged fruits and vegetables include the logo and the statement "treated with radiation" on the label. For irradiated fruits and vegetables not in package form, the regulation provides three alternatives for meeting the labeling requirements. As an alternative, each item of irradiated food may be individually labeled. The agency has been informed that some companies plan to label each piece of irradiated food. The required information may be displayed to the purchaser with either: (1) The labeling of the bulk container plainly in view or (2) a counter sign, card, or other appropriate device bearing the logo and the term "treated with radiation" in order to inform the consumer that this product has been treated with radiation. This approach is consistent with the exemption provided in 21 CFR 101.22(e) for bulk fruits and vegetables that may have applied waxes or coatings and for processed foods sold in bulk without packaging.

C. Current Good Manufacturing Practice

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

The CGMP regulation for irradiated food could not 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 proposed regulation for irradiated food and in evaluating comments.

In general, comments were supportive of the proposed provisions in § 179.25, including the proposed requirement for a scheduled food irradiation process, to establish a standard operating procedure specific to each food and radiation facility. Many comments supported recordkeeping requirements and emphasized the need for personnel training and FDA inspection.

50. One comment on proposed § 179.25(c) was concerned about the training that would be required of the "qualified person with expert knowledge of radiation processing" and what Federal or State agency would license or otherwise certify a radiation processing specialist who is needed to establish scheduled processes. Another comment suggested that FDA convene a panel of experts to develop a protocol for the establishment of scheduled processes for food irradiation instead of leaving it to industry experts. The comment also suggested that the Codex Standards and the Code of Practice for irradiated food be incorporated or identified as a guideline for the establishment of a scheduled process (Ref. 70). [These documents were developed by the Codex Alimentarius Commission of the Food and Agriculture Organization of the United Nations, and the World Health Organization.]

The agency has no jurisdiction over the licensing or certification of radiation processing specialists. (However, see comments regarding the training of radiation safety personnel required by the Nuclear Regulatory Commission (NRC) in the section on environmental impact elsewhere in this document.) The manufacturer is responsible for choosing individuals who are qualified by appropriate scientific training and applied experience to ensure the integrity of the food irradiation process. FDA believes that there is sufficient incentive for food manufacturers to select qualified people and that FDA need not intervene. Therefore, each manufacturer is expected to select personnel having expertise and experience in the radiation processing of food and knowledge of the requirements of the particular facility. The specialist's work experience must be documented and must demonstrate training and experience in radiation processing of food. FDA believes that a background check for such personnel would be done in any case. FDA has no plans at this time to require the licensing of such individuals or to convene a panel of experts to develop a protocol for the establishment of scheduled processes. The agency agrees that the Codex Alimentarius Standard and Code of Practice is a useful guide but sees no need to require compliance with that code by regulation.

51. One comment on proposed § 179.25(d) asked if food processors wh

use irradiated ingredients in their retail products are subject to the recordkeeping requirements of this regulation.

The proposed rule and this regulation limit the maintenance of records to the food irradiation processor. Therefore, a food manufacturer who uses irradiated ingredients in foods designed for retail trade is not required to maintain records related to irradiation treatment.

52. One comment on proposed § 179.25(d) requested clarification about the length of time that records must be maintained. The comment stated that some dry foods, such as spices, may have a very long shelf life that cannot always be predicted by the processor. Another comment suggested that records be maintained only 3 years.

The proposed rule would have required the records to be kept for a period that exceeds the shelf life of the irradiated food by 1 year. FDA agrees that this requirement is not clear and is amending this regulation to require that the indicated records be retained for a period of time that exceeds the shelf life of the irradiated food by 1 year, or for 3 years, whichever period is shorter.

53. One comment stated that the allowed uses of irradiation should be specified in sufficient detail so that Federal and State officials may accurately determine whether a processor is complying with the regulations. The comment suggested that FDA consider specifying sampling procedures to monitor whether a processor is complying with the regulations.

As explained in this document, irradiation of food at the permitted safe levels does not produce amounts of unique radiolytic products sufficient to be detected using conventional food sampling and analysis techniques. Nonetheless, the agency agrees with the comment that specificity of procedures is essential to ensure that radiation processing has been properly carried out. That is why this final rule lists the permitted uses of irradiation and requires that a processor have a scheduled process for each food established by a qualified person with expert knowledge of radiation processing. The scheduled process must specify a dose range that will ensure that the absorbed dose will achieve its intended technical effect on the food being irradiated. The final rule also requires that records be kept that include, among other things, evidence of compliance with the scheduled process, source calibration, and dosimetry. Moreover, these records are to be made available for inspection by authorized employees of FDA. The agency believes that this is sufficient information to determine whether processors are complying with the regulation.

54. One comment stated that no mention is made in the regulation regarding the role of State officials. The comment expressed concern about possible questions regarding State activities in the area. The comment said that State officials might be called upon to assist FDA in enforcing the final regulation and wondered whether the final regulation ought to specify whether State activities involving food irradiation processing would be preempted under the regulation.

The act contains no specific provision preempting the field of food irradiation. The test of whether a State activity is preempted by Federal law and regulations is whether the State activity conflicts with and stands as an obstacle to the Federal program. The comment appeared to be concerned about whether State inspections or other actions in support of this final regulation would be preempted by this regulation. FDA notes that State officials routinely assist FDA in inspecting certain facilities that are within their State in order to conserve scarce agency resources. The agency has, for many years, worked closely with the States through cooperative work-sharing agreements affecting compliance with the act and its implementing regulations. These cooperative efforts would further the goal of this regulation and would not be precluded under any preemption doctrine.

55. Some comments stated that a regulation requiring access only to records is not adequate to ensure compliance, and that FDA should also propose strict monitoring or some degree of official inspection.

The agency has authority to conduct plant inspections for all food-processing plants. FDA did not intend to imply that compliance would be determined solely by inspection of records. FDA officials will inspect food irradiation plants and will copy and review required records to assure that the processor is complying with these regulations. The agency would like to clarify that it considers inspection of records to include copying of the records for further review, and is, therefore, adding the words "and copy" after "inspection" in new § 179.25(c) for the same reasons stated in the proposal for records inspection requirements (49 FR at 5719) based on sections 409, 703, and 704 of the act. Thus, if a food manufacturer chooses to engage in radiation processing of food, FDA will consider that processor to have waived any objections to the agency's requirement of inspecting and copying pertinent records with respect to irradiated foods.

56. One comment stated that testing of food irradiation dosage is limited by the accuracy of the testing dosimetry. The comment stated that the regulation must provide methods for determining the absorbed dose which can be directly related to standards of radiation maintained by the National Bureau of Standards.

The agency agrees that the accuracy of the testing dosimetry is important. Assuring accurate dosimetry is a part of developing a scheduled process. Nevertheless, optimum procedures for dosimetry may change, and FDA does not intend to limit dosimetry to any one specific system at this time. FDA would consider irradiation of food without adequate dosimetry to be a violation of the current good manufacturing practice regulations.

57. A few comments requested that the regulation permit multiple irradiations of food provided that the maximum dose limitation prescribed by regulation is not exceeded. The comments argued that there are conditions where a second radiation treatment would produce a useful effect without exceeding the maximum dose. One comment stated that the Codex Alimentarius standard for irradiated foods does permit reirradiation of foods under limited circumstances.

The agency disagrees that the regulation should permit the multiple irradiation of foods for the following reasons:

(1) An irradiated food that is properly packaged and stored should not require further irradiation to be marketable. Irradiation processing of food is not to be used as a substitute for good food sanitation practices.

(2) Where a food is irradiated more than once, the cumulative radiation dose cannot exceed the maximum allowable dose prescribed in the regulation. The determination of whether those foods that are irradiated more than once are in compliance with the regulation would be difficult and impractical, if not impossible. Inspection of irradiation records alone to determine compliance would be inadequate. Records maintained by different irradiation facilities with respect to the reirradiated food would not be available for inspection simultaneously. Moreover, if a food were irradiated in a foreign country and subsequently irradiated in the United States, the absence of records from the foreign radiation facility would make a determination of compliance with the regulation impossible.

(3) FDA is aware of the Codex Alimentarius standard concerning reirradiation of foods (Ref. 70). The Codex Alimentarius standard does not permit reirradiation of foods, except for foods with low moisture content (cereals, pulses, dehydrated foods, and other such commodities), irradiated for the purpose of controlling insect reinfestation. This same standard, however, states that a food is not considered to have been reirradiated when: (i) The food prepared from materials, which have been irradiated at low dose levels, is irradiated for another technological purpose; (ii) the food, containing less than 5 percent of an irradiated ingredient, is irradiated; or (iii) the full dose of ionizing radiation required to achieve the desired effect is applied to the food in more than one installment as part of processing for a specific technological purpose. In accordance with 21 CFR 130.6, FDA will review all food standards adopted by the Codex Alimentarius Commission. The agency is not required, however, to accept these standards.

Although the agency may, on its own initiative, propose adoption of a Codex standard under section 401 of the act (21 U.S.C. 341), any interested person may petition the agency to adopt a Codex standard (21 CFR 130.8). Because the agency has not proposed adoption of the Codex standard regarding reirradiation of foods as part of this rulemaking, this issue requires no further discussion at this time.

(4) The agency acknowledges that there could be certain circumstances where a useful effect could be produced by reirradiating a food without exceeding the maximum dose limitation prescribed by the regulation. However, as discussed earlier in this response, the agency believes that efforts to monitor compliance with this regulation through recordkeeping and records inspection would be difficult and impractical, and may even be impossible in certain instances. A further complication that would arise should reirradiation of foods be permitted involves the difficulty of complying with the labeling requirements prescribed by the regulation. Complex labeling at the wholesale level would be needed to ensure that the maximum cumulative dose absorbed by the food does not exceed the maximum dose limitation prescribed by the regulation. Wholesale labeling would also have to convey to what extent a previously irradiated food was treated. Furthermore, such cumulative doses would have to be the minimal radiation dose reasonably required to accomplish the intended technical effects. This minimal radiation dose would be very difficult to determine if it is administered in multiple doses. These complex issues would require careful consideration by the agency during a separate evaluation. For all of these reasons, the agency has concluded that reirradiation of food should not be permitted under this regulation.

58. Some comments questioned the need for a 5 million electron volt limit for x-ray sources and stated that this energy limit should be increased to 15 million electron volts.

The 5 million electron volt limitation for x-ray sources was based on data in an earlier petition and is consistent with recommendations of the Codex Alimentarius Commission. FDA has no data demonstrating the safety of sources operating at higher energy levels; accordingly, this regulation approves the use of x-ray sources of no more than 5 million electron volts. The agency will consider changing the limitation if data supporting the safe use of x-rays produced by machines using energy sources greater than 5 million electron volts are submitted in a food additive petition.

D. Other Technical Effects

59. Several comments were opposed to food irradiation because it can theoretically affect the metabolic processes of fresh foods, and thereby conceivably make them less resistant to spoilage by various fungal diseases.

The agency recognizes that irradiation affects the metabolic processes of fresh foods and may sometimes make them less resistant to spoilage. Irradiation, like other processes, will not solve all food-preservation problems and will sometimes be impractical. Food processors would probably not irradiate food if irradiation causes the food to spoil more quickly or to become less marketable. In such cases, irradiating food would be contrary to the processor's self-interest. Because the practicality of using food irradiation makes this process somewhat self-limiting, the agency concludes that it need not restrict the irradiation of fresh foods merely because some foods may be unsuited to such processing.

60. Many comments requested that FDA take a more general approach to permit irradiation up to a dose of 1 kGy on any food for any purpose consistent with current good manufacturing practice. One comment stated that the rule should be extended beyond fruits and vegetables to mushrooms and pork. Several comments asked that the safe dose be raised to 1.5 kGy (150 krad). The comments stated that 0.75 kGy (75 krad) is necessary for maximum shelf l extension of papaya, and the 1.5 safe dose would allow for some l in designing a commercial food irradiator. One comment stated t term "insect control" may be too restrictive and suggested "pest c Several comments stated that a maximum dose of 1 kGy is effect trichinae control and for microbi control in some foods.

The agency intended the term fruits and vegetables" to include mushrooms, which are fruiting b fungi. The agency now believes t term "fresh foods" may more ac describe foods such as fruits, vegetables, and mushrooms that capable of additional growth an maturation but that may be trea ionizing radiation to inhibit thos processes. FDA is revising the r accordingly. In addition, the age agrees that the term "insect con may be too restrictive. Therefor agency is substituting the term "arthropod pests" to include ins spiders, and mites, but to exclud such as bacteria, molds, mice, a

Although the agency believes safety of food irradiation below (100 krad) has been established, agency proposed to limit the use irradiation according to intende technical effect rather than simp dose. This was done both to av indiscriminate use of irradiation aid enforcement of dose limits b there would be no reason to exc permitted dose for the allowed effects. For example, overtreatm fruits and vegetables may adve affect their marketability. Thus exceeding the permitted dose w result in a substandard product effect, compliance occurs due to limiting factor.

In the specific case of papaya agency believes that an adequa commercial radiation facility ca designed for papaya with the c limitation. Alternatively, the ag review a petition to increase th maximum permitted dose for fr foods.

The agency is aware that the permitted dose may also be soc effective for other uses, such as decreasing the microbial burde meat, fish, and poultry. FDA di propose these uses, however, b irradiating at such low doses w be sufficiently effective for mic control to be self-limiting. The stated in the proposed rule tha consider other uses below 1 kG krad) if a petition supported by that a specific technical effect

accomplished below 1 kGy (100 krad) and if an appropriate food additive regulation can be promulgated and can be enforced. The agency has received petitions for the use of irradiation to control trichinae in pork at doses below 1 kGy 100 krad). As discussed earlier in this preamble, the agency issued a final rule on July 22, 1983, in response to one petition to control *Trichinella spiralis* in pork (50 FR 29658). In this document, the agency is deleting § 179.22 and is incorporating that authorization for the irradiation of pork in new § 179.26(b).

61. One comment stated that FDA's proposed rule would have relatively little impact on solving the overall problem of food spoilage and contended that FDA is apparently seeking to avoid, delay, or otherwise shelve indefinitely the approval of irradiation at higher dose levels. The comment stated there is no reason for FDA's reluctance to proceed on its own initiative to approve food irradiation at doses above 1 kGy, including radiation sterilization of chicken. Other comments stated that FDA should permit doses up to 10 kGy based on the Codex Alimentarius standard.

FDA's traditional approach to issuing a food additive regulation has been to respond to a properly documented petition. FDA initiated this rulemaking to permit food irradiation because it believed that an agency-initiated rulemaking would be more efficient for those uses where the agency needs no further safety data.

Two considerations prevent the agency, at this time, from proposing a general regulation allowing higher doses. First, at higher doses, irradiation can significantly retard microbial spoilage without killing all spores of *C. botulinum*. Under some conditions, *C. botulium* can grow and produce a toxin that constitutes a health hazard. Based on current information, the agency is unable to prescribe safe conditions of irradiation at higher doses for foods that would ensure *C. botulinum* organisms would not develop.

Second, at the doses permitted in this regulation, the total amount of radiolytic products consumed is too small to be of concern, either because of low doses or because foods so treated are a minor part of the diet. Further, safety information from animal feeding studies is unnecessary under these circumstances. The proposal stated that FDA is reviewing a number of studies to determine whether foods that are irradiated at doses above 1 kGy (100 krad) can be considered safe without additional toxicological studies. As stated elsewhere in this document, the agency has reviewed these studies and found that five were acceptable by current standards. This data base is 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 rulemaking on food irradiation based on the information before it 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.

62. Several comments discussed using irradiation to control microbial contamination of animal feeds. One comment stated that the agency should consider the use of irradiation to treat all animal feeds up to a maximum dose level of 25 kGy (2.5 Mrad).

The agency agrees that irradiation of animal feeds to control microbial contamination could be addressed, but not necessarily as part of this rulemaking. Ralston Purina Co. filed a food additive petition (FAP 2198) (December 18, 1984; 49 FR 49161) proposing that the regulations be amended to provide for microbial disinfection of laboratory diets for rats, mice, and hamsters by radiation treatment. The agency responded to this petition in the Federal Register of February 19, 1986 (51 FR 5992). Any interested person able to document the safe use of a source of radiation to treat animal feeds may submit an animal food additive petition for that use under the provisions of 21 CFR Part 571.

63. One comment stated that the agency should permit the use of radiation to sterilize meals to provide a more nutritious and palatable diet for persons who require sterile meals.

The agency is considering a separate rulemaking to permit the investigational use of unapproved food additives under section 409(i) of the act (21 U.S.C. 348(i)). That issue is not relevant to the uses of food irradiation permitted under this regulation.

64. Several comments stated that there were other alternatives to irradiation for insect control or for growth and maturation inhibition of fresh fruits and vegetables and that, therefore, there was no need to permit food irradiation.

The agency agrees that there are other methods both for insect control and to inhibit the growth and maturation of fresh fruits and vegetables. However, the existence of such methods is not a reason to prohibit equally safe alternatives, nor does the act authorize FDA to arbitrarily limit the safe alternatives that are to be allowed. The agency believes that the marketplace should determine which alternative treatment method is used when safety is not an issue.

E. Packaging

65. One comment stated that FDA should consider the possible migration of toxic substances from packaging materials to food during irradiation. Several comments noted that the proposed rule does not discuss packaging materials and that this omission may create confusion with respect to § 179.45. In addition, one comment asked specifically whether the irradiation of bulk packaging materials such as fiber drums and burlap bags is permitted even though they are not listed in § 179.45. The comment questioned the need for § 179.45 and suggested, as an alternative, granting approval for irradiation of all substances that are currently generally recognized as safe as packaging materials.

FDA points out that all packaging materials or components of packaging material that may reasonably be expected to migrate to food must comply with appropriate regulations authorizing their use. Components of packaging materials that have been irradiated may migrate to food to a different degree than components of an unirradiated material.

There are two aspects to this problem: (1) A packaging material that is irradiated before food contact may degrade or undergo crosslinking or some other change so that it is significantly different from the nonirradiated material and (2) packaging material irradiated while in direct food contact may produce low molecular weight materials that may migrate into the food.

In the first case, the irradiated material may be tested to see whether it is suitable for use in contact with food and complies with appropriate regulations. If the irradiated material is still suitable for use and complies with the applicable regulations, no additional regulations are required. If the irradiated material no longer complies with applicable regulations, interested persons may submit a food additive petition to amend the regulations accordingly.

In the second case, volatile materials migrating into prepackaged foods during irradiation would not have been considered in evaluating whether the packaging material was safe for its intended use, unless the packaging material had been specifically authorized under § 179.45. Section 179.45 lists packaging materials that may be formed into containers for holding or packaging food intended to be irradiated

and which may be subjected to incidental irradiation during the radiation treatment of prepackaged foods. This regulation was issued in response to petitions for packaging materials used with food during irradiation in anticipation of expanded uses of food irradiation in the 1980's. Therefore, the agency disagrees with the comment that § 179.45 is unnecessary.

Section 179.45, however, does not list packaging materials that are generally recognized as safe (e.g., glass, wood, natural fibers) but which may exhibit different characteristics of migration to food during irradiation. FDA knows of no information on such materials during irradiation by which they could be generally recognized as safe. Therefore, FDA does not consider such materials to be generally recognized as safe when used in packaging that is irradiated in contact with food. The agency invites petitions to amend § 179.45 to include generally recognized as safe packaging materials and other packaging materials not currently in § 179.45.

The agency agrees that the failure to address packaging in the proposal may cause confusion. Because of the possible confusion, FDA is adding a new paragraph in § 179.26 clarifying the intended requirement that packaging materials containing food during irradiation must comply with § 179.45.

F. Public Education

66. Many comments stated that a need exists for a public education campaign supported by the government and industry.

The agency agrees that there is a need for public education in this area. However, the agency is responsible for ensuring that food additives including a source of radiation are safe; FDA has no proper role as a promoter of a specific food additive or food process. The agency believes that the primary responsibility for such educational activities remains with industry in this instance.

G. Impact Analyses

The agency stated in the proposed rule that existing safeguards in regulations issued by the Occupational Safety and Health Administration (OSHA), the Nuclear Regulatory Commission (NRC), the Department of Transportation (DOT), and FDA are adequate to ensure that there will be no adverse environmental effect. However, many comments expressed concerns about the environmental impact of this regulation. These comments can be separated into three categories: (1) Radiation safety within the facility (worker safety), (2) waste storage and disposal, and (3) transportation. FDA requested a response to these comments from OSHA (Ref. 71), NRC (Ref. 72), and DOT (Ref. 73) and has summarized their responses below.

67. Several comments were concerned with worker exposure and with plant safety and claimed that current safety standards are inadequate to protect workers employed in industries handling radioactive materials.

A facility using radioactive material must first obtain a license from NRC or the corresponding agency in an agreement State. NRC has informed FDA that in order for a firm to be licensed to possess and use radioactive material in an irradiator, the firm must file an application with NRC or the corresponding State agency. The information that needs to be submitted includes the training and experience of individuals responsible for the radiation safety programs, the training provided to persons who will work under the supervision of the responsible individuals, a description of the facility, the safety systems designed to protect personnel from exposure to radiation, and the radiation protection program.

NRC states that the regulatory "Guide for the Preparation of Applications for Licenses for the Use of Panoramic Dry Source-Storage Irradiators, Self-contained [illegible] Source-Storage Irradiators, and Panoramic Wet Source-Storage Irradiators" (Ref. 74) provides guidance to potential applicants about specific details needed in an application for possession and use of radioactive material in an irradiator. The NRC staff reviews the application to determine that (1) the applicant's proposed equipment and facilities are adequate to protect health and minimize danger to life and property, (2) the applicant is qualified by training and experience to use the radioactive material for the purpose requested and in such a manner as to protect health and minimize danger to life and property, and (3) the program described will result in compliance with NRC's regulatory requirements. If the information provided in an application is satisfactory, a license is issued. After issuance, NRC conducts periodic inspections of irradiator facilities. In 1978 and 1979, NRC collected exposure data from all licensees. The average annual measurable dose for persons engaged in irradiation operations was 160 millirems. (The maximum permissible ionizing radiation dose for workers is 5,000 millirems per year.)

68. One comment stated that OSHA's ionizing radiation standard (29 CFR 1910.96) would apply to worker exposures from machine-produced radiations, but questioned the organization's ability to ensure worker safety.

In response to the comment, OSHA confirmed that its current ionizing radiation standard (29 CFR 1910.96) would apply to worker exposures to radiation from machine-produced sources. As in the past, OSHA will concentrate its inspectional resources on high priority problems, and will consider additional action should information develop indicating a need for concern.

69. Many comments were concerned about the safety of transporting radioactive materials in general, and also argued that implementation of this regulation would lead to increased amounts of radioactive materials being transported.

Both DOT and NRC have responded to this comment. They stated that the transportation of radioactive materials is an activity which is highly regulated by both the Federal and State governments. Both DOT and NRC have regulatory requirements that govern all aspects of transportation in detail, from quality assurance in packaging to requirements for posting information that is clearly visible on transporting vehicles.

The overall safety of transporting radioactive materials was evaluated in the NRC report entitled "Final Environmental Statement on the Transportation of Radioactive Material by Air and Other Modes" (NUREG-0170) (Ref. 75). The report concluded that the total risk from all transportation of such materials was acceptably low. NRC has concluded, after review of the subject, that the regulations are adequate to protect the public against unreasonable risks from the transport of radioactive materials (48 FR 21619; April 13, 1983). NRC believes such shipments can be made safely because licensees shipping radioactive material for use in food irradiators are required to comply with an NRC regulatory program.

Food irradiator sources are held in the form of welded sealed sources and are transported in accident-resistant packaging. There has never been a release of radioactive materials from one of these packages in the United States as a result of a transportation accident, even when transporting powders, liquids, or gases. The transportation of sealed sources would make a release even more unlikely.

70. One comment stated that DOT, NRC, and the States are ineffective in their regulation of transportation of radioactive materials.

DOT disagreed and stated in a letter to FDA that the approach being used by NRC, DOT, and the States has been effective in ensuring safety.

71. One comment stated that the absence of effective regulations for transporting radioactive materials has prompted over 200 local communities to impose bans or restrictions on nuclear cargo transportation in defiance of Federal preemption.

DOT advised FDA that this is a misleading statement. DOT has no evidence that the transportation of radioactive materials has caused any safety problem. DOT pointed out that there may be a myriad of reasons behind these local restrictions, many of which may be unrelated to safety. Finally, the existence of local restrictions against the transport of radioactive material provides no evidence that there is or has been a safety problem associated with such transportation.

72. One comment stated that the history of monitoring transportation of radioactive materials leaves much to be desired. The comment cited incidents reported over the past 2 years where (1) sources were simply "lost" or were found by children in public, unrestricted areas; (2) sources were accidentally mixed with scrap metal; or (3) offsite contamination from radiation byproduct facilities resulted in widespread contamination. The comment further questioned what would happen when millions of curies are added to the commercial sector, if the Federal government cannot keep track of the approximately 17,000 sources in the United States.

DOT advised FDA that the references made by the comment to lost sources are misleading. The incidents referred to did not involve sources as large as those to be used in a food irradiator. Sources that have been lost in transit in the United States have been those of very low activity or empty packages that pose relatively small risks. High activity sources such as those used for food irradiation are transported in large, heavy packages which are not likely to be easily lost. Additionally, DOT's regulations require that the shipper of such packages notify the consignee when a shipment is made so that the consignee expects it and can take prompt action if it is not delivered on time. The comment about radioactive material being mixed with scrap metal refers to an incident in which a radioactive source was incorporated into steel made from scrap metal. This incident involved international licensing authorities and had nothing to do with domestic transport.

The agency has determined that the existing controls over the transportation of radioactive materials are adequate to ensure safety even when the number of radiation sources increases, as might be expected as a result of this rule.

73. Many comments expressed concern that an increased use of radioactive materials will lead to a corresponding increase in problems regarding proper disposal of radioactive wastes and possible environmental contamination.

Under NRC's regulations, sealed sources used in an irradiator may be disposed of by transfer to an authorized recipient as specified in 10 CFR 20.301(a). An authorized recipient could be the original supplier of the sealed sources, another licensee which is authorized to possess the sealed sources, or a facility licensed to receive and dispose of radioactive wastes.

In practice, a cobalt-60 sealed source is usually returned to the original supplier at the end of its useful life. Disposal of the sealed sources could be accomplished by transfer to one of the existing facilities authorized to dispose of radioactive waste materials. In the United States, these facilities are located in the States of South Carolina, Nevada and Washington. With respect to the cesium-137 capsules which the Department of Energy (DOE) has available for use in irradiators, DOE will lease the capsules to licensees and the capsules will be returned to DOE at the end of their useful life.

The agency believes that these measures are adequate to safeguard against possible environmental contamination.

74. Many comments were concerned that food irradiation might cause the formation of mutant pathogens. One comment stated that an environmental impact statement must be filed for this reason by the agency before further action is taken.

The agency considered the potential environmental impact of permitting food irradiation and concluded that an environmental impact statement was not required, and submitted this finding of no significant impact and environmental assessment to the docket for public review, as noted in the proposal. No new information or comments have been received that would alter the agency's previous determination. A response to the comment that mutant pathogens may result during food irradiation has been provided earlier in this document.

75. Various comments on the economic impact of this process stated that this process would provide consumers with a greater variety and quantity of foods than that now available because of quarantine restrictions or limited shelf life. Other comments stated that the process is expensive and thus would increase the price of food. Comments from industry stated that the costs involved in commissioning a facility would require a broader range of uses to make the operation financially viable.

The agency believes that the marketplace will determine whether irradiation of food is economically feasible. No information was provided to suggest that issuance of this final rule would pose an unacceptable economic burden on society.

III. Objections

Any person who will be adversely affected by this regulation may at any time on or before May 18, 1988 submit to the Dockets Management Branch (address above) written objections thereto and may make a written request for a public hearing on the stated objections. Each objection shall be separately numbered and each numbered objection shall specify with particularity the provision of the regulation to which objection is made. Each numbered objection on which a hearing is requested shall specifically so state; failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held; failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents shall be submitted and shall be identified with the docket number found in brackets in the heading of this regulation. Received objections may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

IV. References

The following sources referred to in this document are listed below. Documents with an asterisk (*) have been placed on display in the Dockets Management Branch (address above), and may be seen between 9 a.m. and 4 p.m., Monday through Friday. All the references not on display are available as published articles, reports, and books.

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V. Agency Action

FDA has evaluated over 5,000 comments as well as information already in FDA's files and concludes that the proposed use of ionizing radiation is safe and that the regulations should be amended as set forth below.

The agency assessed the impact of the proposed rule on current and future uses of irradiation technology (February 14, 1984; 49 FR 5714). This assessment demonstrated that the proposed rule was not a major rule as defined by Executive Order 12291.

Further, it was determined that the rule would not have a significant impact on a substantial number of small entities under the Regulatory Flexibility Act. In order to accurately reflect changes in this final rule made in response to comments, FDA has prepared a revised threshold assessment of the economic effects of this rule. The findings of this assessment do not alter the agency's previous assessment. Therefore, the agency hereby finds that this is not a major rule as defined by that Order and certifies in accordance with section 605(b) of the Regulatory Flexibility Act that the rule will not have a significant economic impact on a substantial number of small entities.

The agency has previously considered the environmental effects of this rule as announced in the proposed rule (February 14, 1984; 49 FR 5714). No new information or comments have been received that would affect the agency's previous determination that there is no significant impact on the human environment and that an environmental impact statement is not required.

Section 179.25(e) of this final rule contains a collection of information requirement. FDA submitted a copy of the proposed rule containing the same requirement to the Office of Management and Budget (OMB). This collection of information requirement was approved for use through March 31, 1987 (OMB Control No. 0910–0186).

List of Subjects in 21 CFR Part 179

Food additives, Food packaging, Irradiation of foods.

Therefore, under the Federal Food, Drug, and Cosmetic Act, Part 179 is amended as follows:

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

1. The authority citation for 21 CFR Part 179 is revised to read as set forth below and the authority citations under 21 CFR 179.21 and 179.45 are removed.

Authority: Secs. 201(s), 409, 72 Stat. 1784–1788 as amended (21 U.S.C. 321(s), 348); 21 CFR 5.10; §§ 179.25 and 179.26 also are issued under secs. 402, 403, 701, 704, 52 Stat. 1046–1048 as amended, 1087, 67 Stat. 477 as amended (21 U.S.C. 342, 343, 371, 374); 21 CFR 5.10, 5.11.

§ 179.22 [Removed]

2. By removing § 179.22 *Gamma radiation for the treatment of food.*

§ 179.24 [Removed]

3. By removing § 179.24 *Low-dose electron beam radiation for the treatment of food.*

4. By adding new § 179.25, to read as follows:

§ 179.25 General provisions for food irradiation.

For the purposes of § 179.26, current good manufacturing practice is defined to include the following restrictions:

(a) Any firm that treats foods with ionizing radiation shall comply with the requirements of Part 110 of this chapter and other applicable regulations.

(b) Food treated with ionizing radiation shall receive the minimum radiation dose reasonably required to accomplish its intended technical effect and not more than the maximum dose specified by the applicable regulation for that use.

(c) Packaging materials subjected to irradiation incidental to the radiation treatment and processing of prepackaged foods shall comply with § 179.45.

(d) Radiation treatment of food shall conform to a scheduled process. A scheduled process for food irradiation is a written procedure that ensures that the radiation dose range selected by the food irradiation processor is adequate under commercial processing conditions (including atmosphere and temperature) for the radiation to achieve its intended effect on a specific product and in a specific facility. A food irradiation processor shall operate with 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.

(e) A food irradiation processor shall maintain records as specified in this section for a period of time that exceeds the shelf life of the irradiated food product by 1 year, up to a maximum of 3 years, whichever period is shorter, and shall make these records available for inspection and copy by authorized employees of the Food and Drug Administration. Such records shall include the food treatment, lot identification, scheduled process, evidence of compliance with the scheduled process, ionizing energy source, source calibration, dosimetry, dose distribution in the product, and the date of irradiation.

(Collection of information requirements approved by the Office of Management and Budget under control number 0910-0186)

3. By adding new § 179.26 to read as follows:

§ 179.26 Ionizing radiation for the treatment of food.

Ionizing radiation for treatment of foods may be safely used under the following conditions:

(a) *Energy sources.* Ionizing radiation is limited to:

(1) Gamma rays from sealed units of the radionuclides cobalt-60 or cesium-137.

(2) Electrons generated from machine sources at energies not to exceed 10 million electron volts.

(3) X-rays generated from machine sources at energies not to exceed 5 million electron volts.

(b) *Limitations.*

Use	Limitations
For control of *Trichinella spiralis* in pork carcasses or fresh, non-heat-processed cuts of pork carcasses.	Minimum dose 0.3 kGy (30 krad). Maximum dose not to exceed 1 kGy (100 krad).
For growth and maturation inhibition of fresh foods.	Not to exceed 1 kGy (100 krad).
For disinfestation of arthropod pests in food.	Do.
For microbial disinfection of dry or dehydrated enzyme preparations (including immobilized enzymes).	Not to exceed 10 kGy (1 Mrad).
For microbial disinfection of the following dry or dehydrated aromatic vegetable substances: culinary herbs, seeds, spices, teas, vegetable seasonings, and blends of these aromatic vegetable substances. Turmeric and paprika may also be irradiated when they are to be used as color additives.	Not to exceed 30 kGy (3 Mrad).
The blends may contain sodium chloride and minor amounts of dry food ingredients ordinarily used in such blends.	

(c) *Labeling.* (1) The label and labeling of retail packages of foods irradiated in conformance with paragraph (b) of this section shall bear the following logo

along with either the statement "Treated with radiation" or the statement "Treated by irradiation" in addition to information required by other regulations. The logo shall be placed prominently and conspicuously in conjunction with the required statement.

(2) For irradiated foods not in package form, the required logo and phrase "Treated with radiation" or "Treated by irradiation" shall be displayed to the purchaser with either (i) the labeling of the bulk container plainly in view or (ii) a counter sign, card, or other appropriate device bearing the information that the product has been treated with radiation. As an alternative, each item of food may be individually labeled. In either case, the information must be prominently and conspicuously displayed to purchasers. The labeling requirement applies only to a food that has been irradiated, not to a food that merely contains an irradiated ingredient but that has not itself been irradiated.

(3) For a food, any portion of which is irradiated in conformance with paragraph (b) of this section, the label and labeling and invoices or bills of lading shall bear either the statement "Treated with radiation—do not irradiate again" or the statement "Treated by irradiation—do not irradiate again" when shipped to a food manufacturer or processor for further processing, labeling, or packing.

(4) The wording requirements of paragraphs (c)(1) and (2) of this section pertaining to the label and labeling of retail packages of food shall expire April 18, 1988, unless extended by the Food and Drug Administration by publication for notice and comment in the Federal Register.

Frank E. Young,
Commissioner of Food and Drugs.

Dated: March 29, 1986.

Otis R. Bowen,
Secretary of Health and Human Services.

[FR Doc. 86-8584 Filed 4-15-86; 11:05 am]
BILLING CODE 4160-01-M

Statement of the American Medical Association

to the

Subcommittee on Department Operations,
Research and Foreign Agriculture
Committee on Agriculture
United States House of Representatives

Presented by

A. Harold Lubin, M.D.

Re: H.R. 696, the Federal Food Irradiation Development and Control Act of 1985

November 18, 1985

American Medical Association
535 N. Dearborn Street
Chicago, Illinois 60610

Department of Federal Legislation
Division of Legislative Activities
(312) 751-6741

retard the post-harvest ripening of food, and to improve the food's functional properties. The Food and Drug Administration would retain its authority to regulate food irradiation and no state or political subdivision would be allowed to establish any food irradiation requirement which is "in addition to or different from" any FDA requirements.

H.R. 696 also would create a Joint Operating Commission for Food Irradiation within the Department of Agriculture. The Commission would be composed of eight members including representatives of seven government agencies and one person representing the interests of the general public. The Commission would coordinate and review all federal research, development, and demonstration activities relating to food irradiation and collect and consolidate the data concerning food irradiation produced by federal agencies. In addition, the Commission would coordinate informational exchange and educational activities concerning food irradiation with appropriate federal agencies, states, private organizations and the general public. The Commission would also promote investment by private companies in the development and application of food irradiation and attempt to foster greater public understanding of the process of food irradiation. Finally, the Commission could petition the FDA to expand the scope of regulation allowing for commercial application of food irradiation.

The ADA supports H.R. 696. Many years of international experience have demonstrated that foods irradiated at levels of up to 10 kilograys (1,000 kilorads) are safe to eat. In fact, in 1980, the Joint Expert

Food irradiation may also be a viable alternative, in the post-harvest disinfestation of fruits and vegetables, to pesticides about which health concerns have been raised. Moreover, it may be effective in controlling trichinae in fresh pork and salmonella in red meats, poultry and fish.

In our view formal official reclassification of food irradiation is important in terms of public acceptance of the fact that food irradiation is a safe process, not a potentially hazardous food additive. It is important to note that food irradiation does not make the irradiated food radioactive since it is done at energy levels well below those required to induce radioactivity. We believe it is appropriate, however, that the bill would not eliminate the FDA's authority to regulate food irradiation. This would offer to the public assurance of continued protection.

The AMA supports the establishment of the Joint Operating Commission for Food Irradiation. The Commission would perform the vital function of coordinating research concerning food irradiation that currently is fragmented among many federal agencies. The Commission would also have the important function of promoting public understanding and acceptance of food irradiation. This would entail informing the public of the many potential benefits of food irradiation and addressing any unwarranted concerns regarding the process. Finally, we believe it is appropriate for the Commission to have the authority to petition the FDA if it believes that the commercial application of food irradiation should be expanded.

AMERICAN MEDICAL ASSOCIATION

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DIVISION OF LEGISLATIVE ACTIVITIES

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Legislative Attorney
(645-4769)

January 16, 1987

Martha E. Rhodes, Ph.D.
Assistant Commissioner
Florida Department of Agriculture
and Consumer Services
The Capitol
Tallahassee, FL 32301

Dear Ms. Rhodes:

I am writing in response to your letter of December 30, 1986, to the American Medical Association. In your letter you asked whether the 1985 testimony of Dr. Lubin to the Subcommittee on Department Operations, Research and Foreign Agriculture of the U.S. House of Representatives represents the current position of the AMA.

AMA policy concerning food irradiation has not changed since Dr. Lubin's testimony in 1985. In addition, we would have no objection to your utilizing a reprint of the AMA statement in informational packets for parties interested in irradiation.

Please feel free to call me if you have any questions concerning this letter.

Sincerely,

Thomas M. Wolff

TMW:bt

The World Health Organization is a specialized agency of the United Nations with primary responsibility for international health matters and public health. Through this organization, which was created in 1948, the health professions of more than 150 countries exchange their knowledge and experience with the aim of making possible the attainment by all citizens of the world by the year 2000 of a level of health that will permit them to lead a socially and economically productive life.

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Progress towards better health throughout the world also demands international cooperation in such matters as establishing international standards for biological substances, pesticides and pharmaceuticals; formulating environmental health criteria; recommending international nonproprietary names for drugs; administering the International Health Regulations; revising the International Classification of Diseases, Injuries, and Causes of Death; and collecting and disseminating health statistical information.

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Summaries of these reports and of all other WHO publications are included regularly in the *WHO Chronicle*, a monthly review of the Organization's activities, published in English, French, Russian and Spanish: annual subscription Sw. fr. 40.–.

This report contains the collective views of an international group of experts and does not necessarily represent the decisions or the stated policy of the Food and Agriculture Organization of the United Nations, the International Atomic Energy Agency, or the World Health Organization.

Wholesomeness of irradiated food

Report of a Joint FAO/IAEA/WHO Expert Committee

World Health Organization
Technical Report Series
659

World Health Organization, Geneva 1981

ISBN 92 4 120659 4

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PRINTED IN SWITZERLAND

81/4934 – Schuler SA – 8000

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JOINT FAO/IAEA/WHO EXPERT COMMITTEE ON THE WHOLESOMENESS OF IRRADIATED FOOD

Geneva, 27 October – 3 November 1980

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WHOLESOMENESS OF IRRADIATED FOOD

Report of a Joint FAO/IAEA/WHO Expert Committee

A Joint FAO/IAEA/WHO Expert Committee on the Wholesomeness of Irradiated Food met in Geneva from 27 October to 3 November 1980. The meeting was opened by Dr T. Fülop, Director of the Division of Health Manpower Development, on behalf of the Directors-General of the Food and Agriculture Organization of the United Nations, the International Atomic Energy Agency, and the World Health Organization. He mentioned that, as a result of recommendations from previous Joint Expert Committees and of the conclusions of other technical or legal expert consultations organized by these agencies, the FAO/WHO Codex Alimentarius Commission had adopted a general standard for irradiated foods as well as a code of practice relating to food irradiation facilities. Once the recommended general standard is accepted by Governments, foods evaluated by the Expert Committees would be permitted to be irradiated. These would include chickens, papaya, potatoes, strawberries, wheat and ground wheat products, cod and redfish, onions, rice, mangoes, dates, cocoa beans, spices, and pulses. A number of these products are of special interest to developing countries.

1. INTRODUCTION

The world's food requirements continue to grow, but in an environment of scarce resources and of limitations on methods of food production. In addition, the problems of food storage and processing make it necessary to search for effective alternative methods of food preservation, particularly where existing methods are costly because of the energy requirements and may be difficult to provide in some areas. Accordingly, it is reasonable to consider the use of ionizing radiation for food storage and preservation as one alternative, provided that it does not adversely affect the wholesomeness of food.

The need to consider the wholesomeness of food processed by irradiation was emphasized at an international level at a meeting sponsored by FAO, IAEA and WHO in Brussels in 1961 (*1*). The studies required to ascertain the wholesomeness of irradiated food were discussed by a Joint FAO/IAEA/WHO Expert Committee on Irradiated Food in Rome in 1964 (*2*). Taking as a premise that the

irradiation of food resulted in the production of radiolytic products in the food, the Committee adopted the view that these products represented additions to the food. It therefore concluded that the establishment of the safety of irradiated foods should follow procedures similar to those generally used for evaluating the safety of food additives and should be pursued on a food-by-food basis.

A subsequent Joint Expert Committee, which met in 1969 (*3*), had available for consideration the results of a number of toxicological studies carried out on three specific foods on the basis of the recommended procedures. It reviewed the comparative data on several varieties within a major crop, and accepted extrapolation of data from a major variety to all varieties of that crop. The Committee recommended temporary acceptance of irradiated wheat and potatoes as wholesome, and specified further studies on onions. The next Joint Expert Committee, convened in 1976 (*4*), reviewed a large number of animal studies on various irradiated foods. Unconditional or provisional acceptances were recommended for most of them. The Committee also reviewed the results of radiation chemistry studies on the major components of food; it noted that many of the radiolytic products identified were present in food treated by heat and other processes and considered that the health hazard from the concentrations found was probably negligible. It therefore encouraged further studies on the chemical changes in food components associated with irradiation.

A large number of data on irradiated foods and food components have since been generated. The present Committee was convened to evaluate the wholesomeness of the irradiated foods for which data were available. It was also asked to review the acceptability of irradiated food in general, in the light of all the toxicological data and the data from radiation chemistry studies, and to make suggestions for further studies where desirable.

2. GENERAL CONSIDERATIONS

2.1. Principles

The principles and guidelines set out in the reports of the 1964, 1969, and 1976 Joint FAO/IAEA/WHO Expert Committees formed the basis for the present Committee's approach to its consideration of the wholesomeness of irradiated food.

2.2. Reasons for the use of food irradiation

The Committee was aware that irradiation of food may be used to achieve a variety of desirable objectives including the following, which are classified according to the average radiation dose required to achieve the objectives in question:

Low-dose applications (up to about 1 kGy)
- Inhibition of sprouting
- Insect disinfestation
- Delay of ripening

Medium-dose applications (about 1–10 kGy)
- Reduction of microbial load
- Reduction in the number of non-sporing pathogenic microorganisms
- Improvement in technological properties of food

High-dose applications (about 10–50 kGy)
- Sterilization for commercial purposes
- Elimination of viruses

The sections that follow (3–7) summarize the evidence which enabled the Committee to assess the effect of the irradiation process on the wholesomeness of food and to arrive at conclusions on the acceptability of irradiated foods.

3. TECHNICAL ASPECTS

3.1 Radiation sources

The Committee stressed the importance of using appropriate radiation sources. From the point of view of safety, the energy level of the radiation applied to food is the most important characteristic that has to be regulated in order to prevent the possible formation of induced radioactivity in the irradiated material. In practice, this is only of importance when considering machine sources, since the most commonly used isotopic sources (^{60}Co and ^{137}Cs) emit radiation of a maximum energy ($\leqq$ 1.33 MeV) which is lower than that causing induced radioactivity. The Committee examined a recent unpublished report (*5*) showing that, with machine sources, induced activity is negligible and very short-lived below an energy level as high as 16 MeV. In this respect the Committee reconsidered and endorsed a

statement (in the report of a Joint FAO/IAEA Advisory Group on International Acceptance of Irradiated Foods (*6*)) that the radiation permitted for food irradiation should have a maximum energy level of (*a*) 10 MeV for electrons and (*b*) 5 MeV for gamma rays and X-rays. On the basis of that statement and the report of the Expert Committee that met in 1964, which indicated X-rays as a suitable type of radiation, the present Committee decided to recommend the inclusion of X-ray sources in the list of acceptable radiation sources.

3.2 Absorbed dose

The present Committee reiterated the view of the Expert Committee of 1976 (*4*) that, as a matter of principle, the applied dose of ionizing radiation should not be higher or lower than is needed to achieve the desired effect. Finding and applying the appropriate dose level is the key to the technologically and economically proper application of the irradiation process to food.

It was stressed that the application of the correct dose would be taken care of, wherever there was good irradiation practice. It was recognized that advice on the doses necessary for the treatment of specific food items and the procedures involved would assist those concerned. Such advice could be included in a code of technological practice.

The Committee noted that no new method for the determination of absorbed dose in the food itself, or indeed for the identification of irradiated food, had become available since 1976. It therefore upheld the view of the Expert Committee that met in 1976 (*4*) that effective dose control can only be exercised in the irradiation plant. The operation of irradiation facilities should be subject to supervision by the appropriate national authorities in order to ensure that proper dose control is exercised. In this respect it was noted that assistance in the calibration of dose control is offered by the IAEA through its programme on High- and Low-Dose standardization and inter-comparison for industrial radiation processing.

As regards setting an overall average dose[1] for the process of irradiation, it was considered that, contrary to the opinion expressed

[1] The overall average dose is the arithmetic mean value of all dosemeter readings in a given irradiation run. To determine this mean value, an adequate number of dosemeters must be randomly distributed in the food as it is exposed to the radiation. The number of dosemeters is considered adequate if it permits estimation of the dose distribution in each portion of the food material of different density and if the measurements are representative for all dose and density fluctuations during a usual run.

by the Expert Committee that met in 1976 (*4*), it is practical (for reasons such as the technical design of the irradiation facility) to stipulate an *average* value rather than to require that no part of the food shall receive less than a minimum, or more than a maximum, dose. Taking into account the ratio of maximum to minimum dose absorbed by the product (i.e., the "dose uniformity ratio") in pilot and currently used commercial facilities, the overall average dose may result in a small fraction of the food receiving a maximum absorbed dose up to 50% higher.

3.3 Processing conditions for irradiation

It is expected that, with wider application of food irradiation, processing conditions will be designed to meet specific technological requirements. Plant design should attempt to minimize the dose uniformity ratio to ensure appropriate dose rates and, where necessary, to permit temperature control during irradiation (e.g., for the treatment of frozen foods) and also control of the atmosphere. It is also necessary to minimize mechanical damage to the product during transportation, irradiation, and storage, as well as to ensure the maximum efficiency in the use of the irradiator. Where the food to be irradiated is subject to special standards for hygiene or temperature control, the facility must permit compliance with these standards.

3.4. Packaging of irradiated food

The packaging method and the packaging material used must be safe and appropriate to the food to be irradiated. Irradiation must not adversely affect the functional properties of the material chosen, nor must it render the material unsafe as determined by appropriate test methods of the kind applied to the unirradiated material.

3.5 Repeated irradiation

While adhering to the view that irradiation of food should normally be carried out once only in each case, the Committee agreed that in certain circumstances repeated irradiation might be justified. This is a departure from the statement in the report of the Expert Committee that met in 1976 that any repetition of irradiation is to be avoided. In deciding upon this change, the present Committee took account of the following findings: (*a*) the concentration of radiolytic products is

a linear function of dose; (*b*) there is a considerable and rapid reduction in the concentration of some of these radiolytic products following irradiation; and (*c*) an overall average dose based on toxicological and other considerations could now be established (see section 10). Consequently, a repetition of irradiation within this overall average dose would not be harmful, provided that no significant impairment of nutritional or technological properties occurred. The Committee agreed that, at the present stage of knowledge, the acceptability of repeated irradiation should be limited to the case of food commodities of low moisture content, in which reinfestation by insects could not be effectively prevented under practical conditions of storage and transport.

Two other types of repetition of the irradiation process were also considered acceptable: (*a*) when the food to be irradiated is a processed form of food that has already undergone low-dose treatment (for example, dried onion prepared from onions treated to inhibit sprouting); (*b*) when it includes irradiated minor ingredients (for example, meat products or dehydrated soup containing irradiated spices). In both cases, it was considered that the additional amounts of radiolytic compounds formed in the final products would be insignificant.

By analogy with tyndallization, fractionated irradiation (i.e., when the full dose has to be applied in two or more instalments) should not be considered as repeated irradiation.

3.6 Technological efficacy

The Committee stressed that, like other food processing techniques, food irradiation is justified only if it serves a useful purpose. Results of studies on the efficacy of the irradiation of the food items specifically examined by the present Committee clearly showed that the applications in question are technologically justified and effective.

3.7 Requirements of quality assurance and labelling

The use of sound raw materials and proper handling and processing techniques, as well as strict maintenance of the wholesomeness and other desirable qualities of foods are a necessity when irradiation or any other form of processing is applied. Furthermore, users and consumers are entitled to expect that the quality and safety of food is not adversely changed either by irradiation or by other currently accepted forms of treatment.

The Committee understood that irradiated foods would be subject to regulations covering foods generally, and to any specific food standards relating to individual foods. It was therefore not thought necessary on scientific grounds to envisage special requirements for the quality, wholesomeness, and labelling of irradiated foods.

4. ASPECTS OF RADIATION CHEMISTRY

4.1 Chemical analysis and wholesomeness evaluation

Treatment of foods with electrons (of energies up to 10 MeV) or gamma-rays and X-rays (of energies up to 5 MeV) does not produce radioactivity in the foods so treated. The need for toxicological evaluation of irradiated foodstuffs stems from the fact that the application of radiation energy results in chemical changes. The nature of the radiation-induced compounds depends primarily on the chemical composition of the food. The concentration of radiation-induced compounds generally increases with increasing radiation dose, but can be modified by factors during irradiation such as temperature, presence or absence of air, and the water content of the sample. The energy taken up by the irradiated food is much less than that taken up by heated foods. It is therefore not surprising that chemical changes caused by irradiation are quantitatively much smaller than those caused by heating. For instance, an absorbed dose of 10 kGy (1 Mrad) corresponds to a temperature rise of only 2.4 °C in a food having the heat capacity of water (4.184 J/°C; 1 cal_{th}/°C). This is about 3% of the energy needed for raising the temperature of water from about 20 °C to 100 °C.

The Expert Committee that met in 1976 concluded that the radiolytic products detected in the wide range of foods and individual food constituents that had been studied did not appear to pose any toxicological hazards in the concentrations at which they were detected. That Committee also accepted that, for doses below 10 kGy (1 Mrad), data may be extrapolated from one member of a food class to related members (p. 10 in that Committee's report (*4*)) and, furthermore, that if certain studies in radiation chemistry and toxicology were continued, a purely chemical approach to the wholesomeness evaluation of irradiated food may prove to be possible (p. 11 in the report (*4*)).

4.2 Recent studies

The above proposals stimulated a great deal of chemical research on irradiated foods and on model systems, which has confirmed the earlier assumptions and enabled more radiolytic products to be identified and quantitatively determined. Thus, the mechanisms of radiation chemical reactions in carbohydrates, lipids and proteins are now known in greater detail.

A study of the radiolytic products in beef, pork, ham and chicken has shown that formation of volatile hydrocarbons depends on the fat content of the meat, regardless of origin. The electron spin resonance spectra from the four types of meat irradiated at −40 °C were identical, indicating the production of common free radical intermediates (I. A. Taub & C. Merritt, unpublished observations).

Another study showed radiolytic products from various starches (derived from maize, amylomaize, waxy maize, wheat, manioc, potatoes, rice, and beans) to be qualitatively identical. Small quantitative differences were related to known properties of these starches, such as the ratio of amylose to amylopectin. These results were confirmed by electron spin resonance which showed that the nature of the radical intermediates is the same in all the irradiated starches (J. Raffi & L. Saint-Lèbe, unpublished observations).

A study of radiation-induced changes in a fruit model has shown that the extent to which these changes take place is in accord with well established kinetic laws. These changes may be calculated using digital computer methods to solve the differential equations which describe the reaction probabilities. Chemical analysis confirmed the prediction that the radiolytic products present in greatest yield in the irradiated fruit were derived from the major constituents of the fruit, i.e., from sugars. Yields of products derived from minor constituents such as protein, malic acid, phenolics, and nicotinamide were much lower (R. A. Basson and co-workers, unpublished observations).

The products of radiolysis in beef (irradiated with an average dose of 56 kGy (5.6 Mrad) at −30 °C ± 10 °C) have been studied in detail. Over 100 volatile compounds have been identified at concentrations varying from 1 to 700 μg/kg, with a total yield of 9 mg/kg. Most of the compounds are known to occur also in unirradiated foods. The Committee noted that this subject had been reviewed recently (*7*, *8*) and agreed that there were no grounds for suspecting these products of being a hazard to the consumer.

4.3 Conclusions

Since similar radiolytic reactions occur with the same constituents of different foods (protein, fat, carbohydrates, water, etc.), common radiolytic products are formed in roughly predictable yields when these foods are irradiated. Although only approximate predictions of product yields are possible at present, these are sufficiently accurate to enable estimates to be made of the upper limits of yields. Thus there is now considerable additional evidence to support the view that information obtained from toxicity tests on one irradiated food can be extrapolated to other foods of similar chemical composition, or to other processing conditions for the same food.

5. NUTRITIONAL ASPECTS

None of the evidence published since 1976 necessitates a change in the advice on the nutritional aspects of irradiated food given by the Joint Expert Committee that met in that year (*4*). The salient points are as follows:

Evidence from most studies suggests that in the low-dose range (up to 1 kGy) used for the irradiation of food, nutrient losses are insignificant. In the medium-dose range (1–10 kGy), losses of some vitamins may occur, if air is not excluded during irradiation and storage. In the high-dose range (10–50 kGy), the technology used to avoid effects on organoleptic quality (i.e., irradiation at temperatures below freezing and in the absence of air) also partially protects nutrients, so that losses may actually be lower than in the medium-dose range if such precautions have not been taken.

Conflicting results have been reported concerning the effect of radiation on vitamin C levels in foods. Some authors have determined only ascorbic acid, without taking into consideration that radiation converts some of this acid to dehydro-ascorbic acid, which is also biologically active. In future studies, both ascorbic and dehydro-ascorbic acid should therefore be determined.

The extent of losses of nutrients due to the irradiation of foods depends on many factors, such as the composition of the food, the radiation dose, the temperature, and the presence or absence of air during irradiation and storage.

Whether or not the loss of a nutrient in an irradiated food is of importance depends on circumstances, such as the contribution that

this food makes to the total diet. For instance, a partial loss of thiamine in fish would be of concern if that was the key source of thiamine to a particular population. Other relevant factors include the nutritional status and requirements of the population for which that food is intended. Some other areas of uncertainty (i.e., folic acid losses) require further investigation.

In 1976 the Joint Expert Committee suggested that the reduction of nutritional value produced by irradiation alone should be compared with that produced by other processes and during storage, and by combinations of irradiation with other processes (*4*). A considerable body of evidence is now available in this regard and the results give no cause for particular concern.

6. MICROBIOLOGICAL ASPECTS

The microbiological safety achieved by the food irradiation process is fully comparable with that of other currently accepted food treatments. No findings have been published during the past four years which would necessitate a reconsideration of the views expressed by the Joint Expert Committee in 1976 (*4*) regarding the microbiological implications of irradiation of food. The results of theoretical and practical work carried out since 1976 have not revealed any new microbiological problems besides those already reviewed.

The results of both field and "inoculated pack" studies have shown that the microbiological safety evaluation of a specific irradiated food can be based only on studies that have specifically been designed to reflect all the circumstances encountered in commercial irradiation. Furthermore, it is important that the hygienic aspects of each individual commodity should be examined separately and that the post-irradiation storage conditions should be carefully and adequately designed to control microbial growth.

6.1 Variations in radiation resistance

The natural radiation resistance of microorganisms and the consequences of their possible survival after irradiation have been reinvestigated with regard to some highly radiation-resistant microorganisms. No new health hazards arising from these organisms have been identified.

Additional experience has also been gained in the application of potentially useful and technologically acceptable combined treatments. For example, it has been demonstrated that the use of irradiation, in conjunction with heat and/or salt treatment, achieves a more efficient reduction in the number of organisms, especially the highly radiation-resistant organisms.

6.2 Radiation-induced genetic variations

Since 1976 there have been no reports to justify the concern, expressed before that time, about the development of irradiation-induced mutations under good operating conditions. As already stated in 1976 (*4*), the risk of inducing greater radiation resistance has only been shown under laboratory conditions.

Changes of taxonomically relevant characteristics, due to mutation, have not been observed under practical conditions of food irradiation and thus do not pose specific problems. Methods for the isolation and enumeration of damaged cells from heated or dried foods may be used for these purposes in the examination of irradiated food, but their applicability should be tested in each case.

No evidence has been reported of enhanced irradiation-induced pathogenicity of foodborne microorganisms, or of increased toxin formation, or induction of antibiotic resistance in irradiated bacteria. Accordingly, the Committee continues to hold the opinion expressed in 1976 that irradiation of food does not increase the pathogenicity of bacteria, yeasts and viruses.

Because of the intrinsic genetic variability of moulds, experimental results should be interpreted with caution. Laboratory experiments, carried out under conditions which differed greatly from those occurring in practice, have shown that mycotoxin production by moulds derived from irradiated spores may vary (in either direction) in comparison with the parent non-irradiated strain. Other laboratory experiments have shown increased mycotoxin production only if heavy inocula are incubated in irradiated, autoclaved moistened foods. These observations have no relevance to food irradiation under present conditions of practice, in which increased formation of mycotoxins has not been found (see section 8.3).

6.3 Microbiological aims of food irradiation

It has been demonstrated that irradiation can reduce the microbial load of a food, thereby increasing the useful life of a perishable food product. The efficacy of irradiation of spices for reducing microbial

load is well documented and this process may be a useful alternative to fumigation treatment. Laboratory animal diets have been irradiated successfully for a number of years on a large scale to render them commercially sterile. *Salmonella* occurs in livestock and is derived from feed and other sources. Since the incidence of such *Salmonella* can be reduced by irradiation of the feed, this process may afford a means of controlling *Salmonella* in poultry and some egg products and of dealing with this common public health problem in many parts of the world. The on-shore irradiation of fish and seafood has received much attention because, among other reasons, *Vibrio parahaemolyticus* is one of the most important foodborne disease agents in warmer climates.

In all, properly designed irradiation processes have been shown to be capable of achieving their intended microbiological objectives (e.g., commercial sterilization, destruction of pathogens). Problems of a microbiological nature that had before been thought might exist have not materialized. Nevertheless, in the case of irradiation, as in any other method of food processing, the gains in microbiological quality must be safeguarded by proper care of the product after processing.

7. TOXICOLOGICAL ASPECTS

7.1 Re-evaluation of provisional acceptances and new evaluations

The Committee reviewed data on fish, onions and rice for re-evaluation and on cocoa beans, dates, mangoes, pulses, and spices and condiments for evaluation. These data were developed in accordance with the guidelines set out in earlier reports of previous Joint Expert Committees. In making its evaluations the Committee used the principles and categories of acceptance, as set out in the previous report (*4*).

The Committee noted that, in the case of cocoa beans, onions, and spices, the presence of natural constituents exerted toxicologically significant effects when these commodities were fed at high levels in the test diet. These effects were found, whether or not the food had been irradiated. The information available on irradiated vegetables was insufficient to make an evaluation, using the principles previously established. The data on all these commodities were also used in considering the acceptance of irradiated food in general (see section 10).

7.2 Considerations arising from a review of data on irradiated laboratory animal diets and other diets

Concern was expressed by the 1976 Joint Expert Committee about the increasingly common practice of using irradiated prepared feeds for laboratory animals, because of the possible effect on control groups used in toxicological testing (*4*). Data requested on animal colonies reared on irradiated diets were made available to the present Committee, as summarized below.

Studies comparing diets (sterilized by autoclaving or irradiation at 25–44 kGy or treated to eliminate pathogens at 15 kGy) have been published by institutes in Austria, Denmark, France, Hungary, the Netherlands, and the United Kingdom. These included multigeneration studies in rats (*9–14*), mice (*15–17*), and pigs (*18*). In two of the studies (*10, 13*), some of the parent and F_1 generation animals were kept for the whole lifespan for information on carcinogenicity. The numbers of animals examined ranged from 5000 to 500 000.

The Committee concluded from these data that the rearing of test animals on laboratory diets sterilized by irradiation at doses of 15 to 45 kGy was unlikely to obscure any differences if a non-irradiated, hygienically acceptable feed had been used.

The Committee also reviewed information on the results of feeding commercial livestock on feedstuffs irradiated at doses of the order of 8 kGy to reduce organisms belonging to the Enterobacteriaceae, especially *Salmonella*. Breeding and performance studies in poultry (*19*), and pigs (*20, 21*) produced no evidence to show that feeding of irradiated diet to commercial livestock had any adverse effects.

The Committee was aware of the practice of using totally irradiated diets for maintaining patients on immunosuppressive therapy as the only practical means of supplying palatable food under these conditions. No published systematic investigations or accounts were available to the Committee for evaluation. The absence of reports of adverse effects suggests that this practice is not deleterious, and this fact was taken into account in the general assessment of the toxicological acceptability of irradiated food. The Committee recommended that if possible there should be a systematic collection and review of information relating to the use of radiation-sterilized human diets.

7.3 Toxicological evaluation of radiolytic products

The Committee reviewed a study in which the principal radiolytic products from irradiated polysaccharides were fed to rats for 6 months at 1700 times the concentration found after irradiation at 3 kGy. No toxic effects were noted (22). These data also support the conclusion set out in section 10 (See also section 4.2).

8. RE-EVALUATION OF FISH, ONION, AND RICE[1]

8.1 Teleost fish and fish products

Purpose of irradiation

(*a*) To control insect infestation of dried fish during storage and marketing.

(*b*) To reduce the microbial load of the packaged or unpackaged fish and fish products.

(*c*) To reduce the number of certain pathogenic microorganisms in packaged or unpackaged fish and fish products.

Average dose

For (*a*) up to 1 kGy, and for (*b*) and (*c*) up to 2.2 kGy.

Temperature requirement

During irradiation and storage the fish and fish products referred to in (*b*) and (*c*) should be kept at the temperature of melting ice.

Microbiological aspects

Vibrio parahaemolyticus is the agent, infectious for man, that is most typically associated with fish and other seafoods. However, infectious agents derived from the intestines of man or other warm-blooded animals may be present in fish because these agents were present in the water in which the fish grew or, as sometimes happens, because they were present in the only water that was available for cleaning fishing equipment (including holding compartments on the ship) or the catch. In addition to infectious agents, toxigenic, spore-forming bacteria such as *Clostridium botulinum* type E may well be present in the fish as caught.

No microbiological problems are likely to arise from irradiation for purpose (*a*). *V. parahaemolyticus* will be eliminated in the product by the doses recommended for purposes (*b*) and (*c*), while the levels of other pathogens and spoilage agents will at least be reduced. Irradiation that does not exceed 2.2 kGy (average dose) is expected to leave enough spoilage organisms to render the food unacceptable before cells derived from surviving *C. botulinum* spores can produce enough toxin to constitute a hazard. However, maintenance of the temperature of melting ice throughout the period of storage of the product has been specified as an additional safeguard against botulism; salting, drying, or other effective measures would have to be substituted if this temperature could not be maintained reliably.

Nutritional aspects

More recent studies have shown that after irradiation at 3 kGy, about 15% of thiamine and 25% of pyridoxine is lost, while riboflavin, niacin and vitamin B_{12} remain unaffected. Higher doses confirmed the particular sensitivity of thiamine and pyridoxine to destruction, the other B complex vitamins remaining practically unaffected. Further studies have confirmed the stability to irradiation of the amino-acid content, particularly of tryptophan. The protein quality of mackerel and hake remained unaltered even by doses of the order of 5 kGy.

The lipids extracted from salted dried irradiated mackerel showed no evidence of adverse nutritional effects at radiation doses of up to 8 kGy. Irradiation up to a dose of 2.2 kGy does not appreciably change the usefulness of fish as a good dietary source of protein, B vitamins, and iodine.

Toxicological aspects

The Committee noted that the results of the studies (ongoing in 1976) had now become available—i.e., short-term, long-term, reproduction, and dominant lethality studies in mice; a short-term study in

[1] Summaries of the data used in the evaluations and the references are given in a separate document entitled "Wholesomeness of irradiated food. Summaries of data considered by the Joint FAO/IAEA/WHO Expert Committee, Geneva, 27 October to 3 November 1980". Copies of this document are available, on request, from Division of Environmental Health, World Health Organization, 1211 Geneva 27, Switzerland.

rats, investigating changes in serum alkaline phosphatase levels when rats were fed on mixed eviscerated cod and redfish; and short-term and reproduction studies in rats fed on other fish varieties. These did not reveal any evidence suggesting that the feeding of irradiated fish to these animals caused any deleterious effects.

A large number of other feeding studies in which rats and mice were fed on other varieties of fish and fish products have also been reported since 1976. These consisted of short-term and long-term feeding studies and also reproduction, dominant lethality, and a number of mutagenicity studies. These new toxicological data, taken together with the results of previously evaluated studies on various types of irradiated fish, do not indicate any adverse effects arising from the administration of irradiated fish to test systems.

Evaluation

The previous provisional acceptance for cod and redfish is changed to unconditional acceptance for fish and fish products irradiated for the purpose of disinfestation, reducing the microbial load, and reducing the number of pathogenic organisms, at an average radiation dose of up to 2.2 kGy.

8.2 Onions

Purpose of irradiation

To inhibit sprouting during storage.

Average dose

Up to 0.15 kGy.

Microbiological aspects

No special microbiological problems of public health significance are known to be associated with irradiated onions.

Nutritional aspects

Recent studies have confirmed the previously reported lack of effect of irradiation, with doses of up to 0.15 kGy, on the ascorbic acid content of onions even after 10 months of storage. The content

of reducing sugars increased in irradiated onions to a smaller extent than in untreated onions. No changes occurred in the amino-acid composition.

Toxicological aspects

The requirement of the previous Committee for a multigeneration study in rats, at feeding levels below that causing biological changes due to the biologically active substances that were naturally present, has now been met. In addition, a number of short-term, reproduction, teratogenicity, and dominant lethality studies in rats have now been reported. None of these studies has shown any adverse effects when irradiated onions were incorporated at a 2% level in the diet of rats and mice. Additional corroborative evidence has been obtained from many mutagenicity studies on onions treated (for the prevention of sprouting) with doses of radiation of up to 0.15 kGy and from similar studies on dried onion powder treated with radiation doses of up to 15 kGy.

Evaluation

The previous provisional acceptance is changed to unconditional acceptance of onions irradiated, for the purpose of controlling sprouting, at an average dose of up to 0.15 kGy.

8.3 Rice

Purpose of irradiation

To control insect infestation in stored rice.

Average dose

Up to 1 kGy.

Prevention of reinfestation

Rice, whether prepackaged or handled in bulk, should be stored, as far as possible, under such conditions as will prevent reinfestation.

Microbiological aspects

If the moisture content of stored rice is too high, fungi such as *Aspergillus flavus,* which are sometimes toxigenic, may grow. Such moulds cannot grow in rice that is stored in a properly dry condition; however, there has been concern over some results that suggested that irradiation could enhance the toxigenic potential of the moulds. It has been shown that toxin-producing fungi are more susceptible than other fungi to irradiation; that a higher water activity is required for the growth of toxin-producing aspergilli than for that of other aspergilli; and that, even at a high water activity, non-toxin-producing strains of *Aspergillus* overgrow the toxin-producing strains and suppress their formation of toxin. Storage of rice at a sufficiently low level of moisture is critically important; the potential mycotoxin hazard is not enhanced by irradiation under practical conditions.

Nutritional aspects

The loss of thiamine on cooking, noted in the report of the 1976 Joint Expert Committee (*4*), may make any further losses due to irradiation relevant where rice is a staple item of the diet and a major source of thiamine. However, a recent study has shown that irradiation at dose levels up to 0.5 kGy did not alter the content of B vitamins or the amino acid composition.

Toxicological aspects

The Committee noted that the results of the long-term study in rats and the short-term study in monkeys, requested in 1976 (*4*), were now available. These showed that the ingestion of irradiated rice caused no adverse effects on the test animals. Another multigeneration study and a dominant lethality study in mice, as well as cytogenetic investigations of the bone marrow of mice and hamsters that had been fed irradiated rice in their diet, showed no adverse effects. These additional results, taken together with the results of the previously reviewed studies, do not indicate any adverse effects from the ingestion of irradiated rice.

Evaluation

The previous provisional acceptance is changed to unconditional acceptance of rice irradiated, for the purpose of controlling insect infestation, at an average dose of up to 1 kGy.

9. NEW EVALUATIONS[1]

9.1 Cocoa beans

Purpose of irradiation

(*a*) To control insect infestation in storage.

(*b*) To reduce the microbial load of fermented beans with or without heat treatment.

Average dose

For (*a*) up to 1 kGy, and for (*b*) up to 5 kGy.

Prevention of reinfestation

Cocoa beans, whether prepackaged or handled in bulk, should be stored, as far as possible, under conditions that will prevent reinfestation and microbial recontamination.

Microbiological aspects

Members of 11 genera of moulds, some of which are toxigenic, have been found to be natural contaminants of the cocoa bean embryo and are a major factor limiting the storage life of the product. Mould growth flourishes at moisture levels exceeding 8%. Irradiation with doses of 0.5 kGy eliminates moulds in young (under 2 months) beans, whereas a dose of 5 kGy eliminates moulds even in older beans. Pretreatment of cocoa beans with heat (100 °C for 10–15 minutes) enhances the radiosensitivity of the moulds they contain.

Nutritional aspects

Beans irradiated with doses in the range of 0.1 to 5 kGy showed no significant differences from unirradiated beans with regard to their content of reducing sugars, total amino acids, total fat, and protein. Analysis of cocoa fat in the irradiated material showed no detectable chemical difference from that in unirradiated material.

[1] See footnote 1 on page 20.

Toxicological aspects

The available results of the short-term and reproduction studies in rats do not indicate any adverse effect due to the irradiation treatment of the cocoa beans. Both irradiated and unirradiated cocoa beans depressed growth and reduced the food intake when incorporated at high levels in the diet of test animals. The observed toxic effects of the cocoa bean diet on fetal development and survival are related to the high theobromine content of the diet. This has been confirmed by cross-fostering experiments and specific studies using theobromine alone. A number of mutagenicity studies have shown the absence of any mutagenic potential in irradiated cocoa beans.

Evaluation

Unconditional acceptance of cocoa beans irradiated, for the purpose of controlling insect infestation or of reducing the microbial load, at an average radiation dose of up to 5 kGy.

9.2 Dates

Purpose of irradiation

To control insect infestation in stored dates.

Average dose

Up to 1 kGy.

Prevention of reinfestation

Prepackaged dried dates should be stored under conditions that will prevent reinfestation.

Microbiological aspects

No microbiological objectives are being pursued by irradiation of dried dates and no public health problems of a microbiological nature are envisaged.

Nutritional aspects

Irradiation of dried dates with doses in the range of 0.3 to 5 kGy had no effect on the reducing sugar content and on major carbohydrate components. No malonaldehyde was detected. No effect on the

protein content was discovered. Irradiation of dates with doses of up to 10 kGy induced no appreciable changes in the amino-acid composition.

Toxicological aspects

The available short-term study in rats revealed no adverse effects that could be related to ingestion of irradiated dates. The results of the reproduction study in rats and of many mutagenicity studies, including a study for induction of recessive lethals in *Drosophila*, revealed no adverse effects that could be ascribed to the irradiation treatment.

Evaluation

Unconditional acceptance of dates irradiated, for the purpose of controlling insect infestation, at an average dose of up to 1 kGy.

9.3 Mangoes

Purpose of irradiation

(*a*) To control insect infestation.
(*b*) To improve the keeping quality by delaying ripening.
(*c*) To reduce the microbial load by combining irradiation and heat treatment.

Average dose

Up to 1 kGy.

Microbiological aspects

Microbial species isolated from mangoes do not appear to be a threat to human health. Germination of naturally occurring or experimentally inoculated *Gloeosporium fusarium* and *G. singulata* is reduced by increasing the doses of irradiation, but complete inhibition requires a dose of 4 kGy, which is technologically unacceptable.

Nutritional aspects

Several studies have shown that irradiation at dose levels of up to 2 kGy caused only slight losses in ascorbic acid and carotene, compared with the effects of freezing or heat treatment. The contents of

riboflavin, niacin and thiamine are not affected. The levels of fat, protein, sugar, and minerals remain unaffected by irradiation.

Toxicological aspects

The available investigations included short-term, long-term, multigeneration, and teratogenicity studies in rats as well as a number of mutagenicity studies. The results indicated that the incorporation in the test diets or irradiated mangoes produced no adverse effects.

Evaluation

Unconditional acceptance of mangoes irradiated for the purpose of controlling insect infestation or for delaying ripening or reducing the microbial load at an average radiation dose of up to 1 kGy.

9.4 Pulses

Purpose of irradiation

To control insect infestation in stored pulses.

Average dose

Up to 1 kGy.

Prevention of reinfestation

Pulses, whether prepackaged or handled in bulk, should be stored, as far as possible, under conditions that will prevent reinfestation.

Microbiological aspects

No specific microbiological problems arise with pulses, whether irradiated or not.

Nutritional aspects

Pulses are a major source of dietary protein in certain parts of the world. Any deleterious effects of irradiation on the nutritional quality of these crops would therefore be of importance. Conflicting results

appear in studies of the protein efficiency ratio (PER)[1] and the effects on B-complex vitamins have not been well established for different pulses. These possible effects should receive consideration wherever irradiated pulses are used as staple items of the diet.

Toxicological aspects

The available short-term studies in mice and rats, as well as a reproduction study in rats, did not indicate any adverse effects due to irradiation of several varieties of dried beans and cowpeas. There was a reduction in the growth rate of rats after the ingestion of high dietary levels of both irradiated and unirradiated beans. A number of mutagenicity studies, including a dominant lethality study in mice, did not reveal any mutagenic potential in several varieties of irradiated dried beans.

Evaluation

Unconditional acceptance of pulses irradiated, for controlling insect infestation, at an average radiation dose of up to 1 kGy.

9.5 Spices and condiments[2]

Purpose of irradiation

(*a*) To control insect infestation.
(*b*) To reduce the microbial load.
(*c*) To reduce the number of pathogenic microorganisms.

Average dose

For (*a*) up to 1 kGy, and for (*b*) and (*c*) up to 10 kGy.

Microbiological aspects

Fungal contaminants, some of which are likely to be toxigenic, occur in untreated spices at an average level of 10^4/g. Other agents of possible concern to human health include the food-poisoning species

[1] The protein efficiency ratio is a rough measure of the nutritive value of proteins, obtained by dividing the gain in body mass by the mass of the protein consumed. It is usually measured in young rats, fed on a diet containing 10% protein under standard conditions.

[2] Inclusive of "dehydrated onion" and "onion powder".

Bacillus cereus and *Clostridium perfringens; Salmonella* and *Shigella* have been reported. Aerobic spore-formers and thermophilic bacteria at levels of up to 10^8/g must be dealt with by some means other than heat. Because the majority of the flora are radiosensitive, irradiation doses of 4–5 kGy reduce the total bacterial counts to less than 10^4/g. Commercial sterility can be achieved at doses of 15–20 kGy, depending on the initial microbial load. The flora that survive irradiation have a lower heat and salt tolerance, so that the subsequent heat treatment of products containing the irradiated spices can be reduced.

Nutritional aspects

Irradiation of paprika at temperatures in the range of 0 °C to 22 °C, with doses of 5–50 kGy, and subsequent storage for 6 months had practically no effect on the carotenoid content.

Radiation treatment with 5 and 15 kGy affected the relative concentrations of some fatty acids but not always in a dose-dependent manner. In some spices there is a small reduction in the proportion of some unsaturated fatty acids. Since spices do not contribute significantly to the nutritional quality of food, these changes are of no nutritional significance.

Toxicological aspects

The available reports of feeding studies in rats (including short-term, reproduction, and teratogenicity studies) are less comprehensive in the case of irradiated spices and condiments than for other irradiated foods. Some of the adverse effects observed in the test animals are related to the ingestion of high dietary levels of spices, both irradiated and unirradiated. No untoward effects, attributable to the irradiation treatment, were reported in these studies. The results of several mutagenicity tests revealed the absence of any mutagenic potential. In evaluating the safety of this commodity, the Committee took into consideration the low levels of spices used in the human diet.

Evaluation

Unconditional acceptance of spices irradiated for the purpose of controlling insect infestation, or of reducing the microbial load and the number of pathogenic microorganisms, at an average radiation dose of up to 10 kGy.

10. CONCLUSIONS ON THE ACCEPTABILITY OF IRRADIATED FOOD

10.1 Toxicological acceptability of irradiated food

The Committee, having reviewed new evidence, was able to formulate a recommendation on the acceptability of food irradiated up to an overall average dose of 10 kGy (see sections 2 and 3). This development follows logically from the approaches to the assessment of the wholesomeness of irradiated food adopted in the past by previous Joint Expert Committees, as described in the Introduction. The following considerations led to this development:

(*a*) All the toxicological studies carried out on a large number of individual foods (from almost every type of food commodity) have produced no evidence of adverse effects as a result of irradiation.

(*b*) Radiation chemistry studies have now shown that the radiolytic products of major food components are identical, regardless of the food from which they are derived. Moreover, for major food components, most of these radiolytic products have also been identified in foods subjected to other, accepted types of food processing. Knowledge of the nature and concentration of these radiolytic products indicates that there is no evidence of a toxicological hazard.

(*c*) Supporting evidence is provided by the absence of any adverse effects resulting from the feeding of irradiated diets to laboratory animals, the use of irradiated feeds in livestock production, and the practice of maintaining immunologically incompetent patients on irradiated diets.

The Committee therefore concluded that the irradiation of any food commodity up to an overall average dose of 10 kGy presents no toxicological hazard; hence, toxicological testing of foods so treated is no longer required.

10.2 Microbiological and nutritional acceptability of irradiated food

The Committee considered that the irradiation of food up to an overall average dose of 10 kGy introduces no special nutritional or microbiological problems. However, the Committee emphasized that attention should be given to the significance of any changes in relation to each particular irradiated food and to its role in the diet.

10.3 High-dose irradiation

The Committee recognized that higher doses of radiation were needed for the treatment of certain foods but did not consider the toxicological evaluation and wholesomeness assessment of foods so treated because the available data are insufficient for this purpose. Further studies in this area are therefore needed.

11. FUTURE RESEARCH

The Committee considered that future research is needed in the following areas in order to increase existing knowledge about the effects of irradiation on food and to facilitate future evaluations:

—The technological and economic feasibility of conducting food irradiation on a larger scale and with a wider variety of foods should be established (see section 3).
—Further studies in the area of wholesomeness assessment of certain foods irradiated at higher doses are desirable (see section 10.3).
—If possible, there should be a systematic collection and review of information on the effects of using irradiation-treated human diets (see section 7).
—The conflicting results published on the effect of radiation on the biological value of proteins and B complex vitamins in pulses should be clarified because of their importance as staple foods in many countries (see section 9.4).
—As there is little recent information on the effect of radiation on folic acid, future work should be carried out on representative folate-containing foods, since the diets in some parts of the world have a marginal folic acid content (see section 5).
—Further work on the effects of combination of irradiation with other processes on the nutritional value of foods so treated is desirable (see section 5).

12. RECOMMENDATIONS

The technological and economic feasibility of food irradiation on an industrial scale should be established. A wider variety of foods should also be studied with respect to their suitability for processing by irradiation. IAEA and FAO should facilitate such studies and collect data for the purpose of making recommendations.

The use of high-dose radiation for the treatment of certain foods has been recognized as being technologically feasible. To assess the safety of this process, further information is needed on its nutritional, microbiological and toxicological implications. Such information is being generated and should be brought together by FAO, IAEA and WHO for future evaluation.

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Food Irradiation:

What Is It? Where Is It Now? Where Is It Going?

by BERNARD S. SCHWEIGERT, Ph.D.

The question whether irradiation is an acceptable alternative method of food preservation has become a debatable scientific and environmental health issue of great public interest.

Dr. Schweigert, Professor and Chairman, Department of Food Science and Technology, University of California, Davis, received three degrees at the University of Wisconsin and has served on the faculty of Texas A and M, Michigan State and the University of Chicago. He has authored over 200 articles on nutrition, biochemistry and food science and has served as president of the Institute of Food Technology and on innumerable scientific advisory committees to government and industry.

Renewed interest in the potential for the use of irradiation in the preservation of foods has been evident since the issuance of regulations by the Food and Drug Administration in April of 1986, permitting the use of irradiation at low levels to control insects, to extend the shelf life of fruits and vegetables and to control parasites. Higher dosages were approved to control microbial contamination of spices, dehydrated onions and garlic. In an earlier article published in *Nutrition Today*, W. M. Urbain described this technology and its primary role in the killing of microorganisms and insects in our food supply. Irradiation of food has been extensively studied during the past 40 years. It is unique in that a temperature increase of only a few degrees occurs with the application of radiation to food systems. This has led to the term "cold sterilization" for foods so treated where the irradiation dose is sufficient to kill all microorganisms that are present. With appropriate packaging prior to irradiation, foods so treated are not susceptible to microbial spoilage when kept at room temperature. This led to some of us carrying a beef steak appropriately packaged and irradiated in our suit coat pockets as a demonstration item when talks on food irradiation were given!

WHAT IS IT?

Basically the process involves the exposure of foods to ionizing radiations developed either from radionuclide sources (cobalt-60 or cesium-137) or from electron accelerators (i.e., machine sources) which generate electron beams. The electron beam can be converted to x-rays which are comparable to the gamma rays that are emitted by cobalt-60 and cesium-137 sources. The program of research carried out

Irradiation involves the exposure of foods to ionizing radiations either from radionuclide sources or from electron accelerators.

Glossary

Irradiation: Exposure of foods to ionizing radiations from either radionuclide sources or from electron accelerators.

Radurization: Pasteurization of foods with treatment with 50,000 to 200,000 rads.

Radicidation: Treatment of food at a level to control food poisoning microorganisms (200,000 to 600,000 rads).

Radappertization: Sterilization to kill all microorganisms (1,000,000 to 4,000,000).

over the past 40 years was facilitated by the interest and support of the Atomic Energy Commission, impressed with the potential "peace time uses of atomic energy" in food preservation. Similarly the U.S. Army saw the potential application of radiation to the preservation of foods for the military. These sources of support have not been available in recent years and currently very little research is being carried out in the United States on the preservation of foods by irradiation. This topic, however, continues to be of major interest to scientists, to the food and allied industries and also to some consumer groups, who express concern relative to the application of this technology to our food supply. These concerns will be elaborated or in the subsequent discussion.

The amount of radiation absorbed by the food item is expressed in terms of rads, and more recently as Grays (100 rad = 1 Gray). We will be utilizing the term rads throughout this article, since it has been widely used, particularly in the earlier stages of the food irradiation studies. In general, the application of approximately 10,000 to 50,000 rad (100 to 500 Gray) is the effective dose range to control insects in our food supply, to inhibit the sprouting of potatoes and onions (Figure 1) and to control parasites in meat products. The "pasteurization level" called radurization is applicable for foods treated in the range of 50,000 to 200,000 rads (500 to 2,000 Gray), for example, for the control of *Salmonella* in poultry products. The application

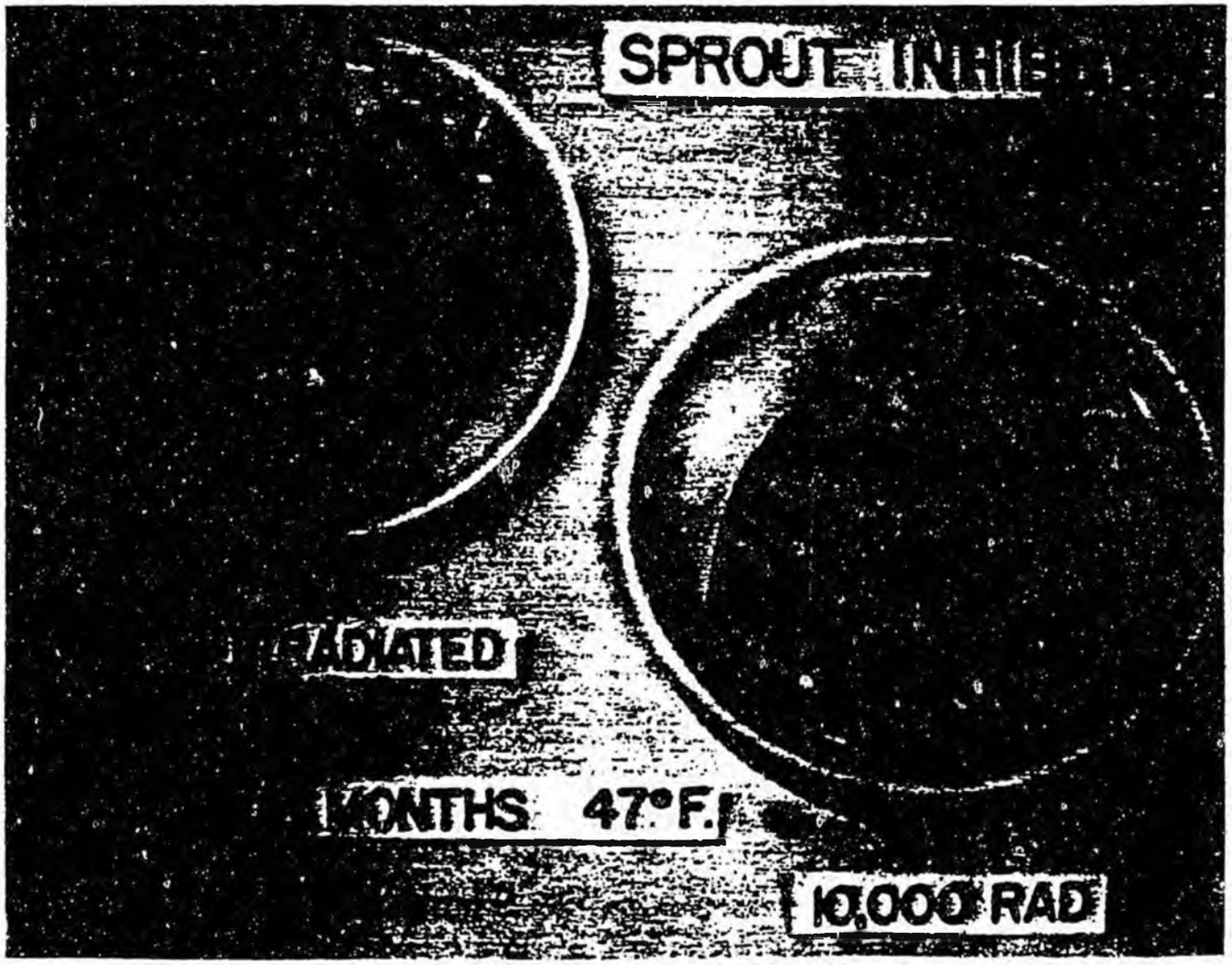

Figure 1. Photograph of nonirradiated and irradiated potatoes showing sprout inhibition after radiation.

of levels to provide control of food poisoning microorganisms (radicidation) is generally considered to be in the range of 200,000 to 600,000 rad and for sterilization to accomplish the killing of all microorganisms present 1,000,000 to 4,000,000 rad (radappertization) may be needed, depending upon the microorganism, the food and the technological circumstances used during the irradiation treatment. Each food system needs to be considered on a case-by-case basis to account for variables in the system (species or the nature of the source material—plant or animal for example, moisture content, temperature used during the irradiation treatment, fruit or vegetable variety, desired effect or effects to be achieved during the irradiation treatment, etc.). Some of these points will also be illustrated in the subsequent discussion.

Thus, we have available a technology that may have the potential to improve food products available to the consumer and to fill a need in the marketing system, which may have considerable potential for application in this, as well as other, countries. Many other countries also have governmental approvals for food irradiation, which are constantly under review.

It could well be asked why this technology has taken so long to be considered for application, or in fact, if it has a place in our food preservation system. Factors involved here are the decision of Congress, through the Delany Amendment, to require that the irradiation of foods be treated as a food additive. This, of course, requires 1) long-term feeding tests, etc., to assure wholesomeness of the process, 2) assurance of the safety of our foods, particularly when a new processing technology is being considered, 3) answers to questions raised during the course of the wholesomeness studies as to whether an adverse effect had occurred attributable to the irradiation treatment and 4) consideration of the uncertainties that would be associated with marketing such products with respect to consumer acceptance. Also, precise costs are unknown until we have actual commercial information available, assuming the process proceeds to that stage.

MECHANISM OF ACTION

The gamma and x-rays produced by radionuclides and machine sources interact with molecules in the food by transferring energy, forming free radicals. These free radicals may then react with the nuclear material of the cell (deoxyribonucleic acid—DNA), and thus prevent the microorganisms, parasites or insects present from reproducing. As noted above, the dosage required to achieve killing varies with the microorganism and insect involved. The free radicals formed may also react with other chemicals present in a food system. Of particular interest have been the changes, if any, in the sensory properties (primarily changes in flavor), in the nutritive value (primarily sensitive vitamins) and in any other substances that may affect the wholesomeness or safety of the irradiated food. This concern has evoked a great deal of research attention through the years. It is of interest that with the more conventional food processing methods (refrigeration and freezing; heat treatments such as canning and drying) in many circumstances we do not have comparable and as thorough information available. We do, of course, have the experience of consuming these foods over a period of years, which is an extremely important basis for assessing their safety.

Free radicals react with DNA to prevent microorganisms, parasites or insects present from reproducing.

WHERE WE ARE NOW

Low level applications of irradiation has been approved by the Food and Drug Administration in this country for inhibiting sprouting in potatoes and onions, for up to 3,000,000 rad controlling insects in grains, such as stored wheat, and parasites in pork products, for extending the shelf life of fresh fruits and vegetables and for controlling microbial contamination in spices and dehydrated onions and garlic. The only known commercial application in the United States is for controlling the microbial contamination of spices, dehydrated onions and garlic. Others are being explored, but are not as yet used commercially. Commercial applications in other countries include control of insects in grain (Russia), inhibition of sprouting in stored potatoes (Japan), and extending shelf life of certain fruits and vegetables being shipped from South Africa to Europe. Several other governmental approvals are available in various countries, although are not in full scale commercial practice at the present time.

With respect to the scientific information available, it is useful to review several kinds of data. In Table 1, we have documented from the work of W. M. Urbain the effect of dose level and storage times on the total plate count of microorganisms present in irradiated beef steak. This is a typical research finding in that the microbial load increases during storage at refrigeration temperature (4°C) at each of

Table 1
Effect of Various Doses of Gamma Radiation on the Total Plate Count (TPC) of Irradiated Beef Steaks*

Dose (rads)	TPC/g after Days Storage at 4°C			
	0	7	14	21
	1.6×10^4	1.0×10^7	5.6×10^7	7.0×10^8
50,000	1.8×10^4	6.2×10^4	7.7×10^8	3.0×10^7
100,000	8.0×10^3	3.3×10^5	3.0×10^6	9.0×10^6
250,000	1.0×10^3	2.8×10^2	8.6×10^3	9.8×10^3
500,000	60	1.0×10^2	2.0×10^2	2.2×10^2
1,000,000	<10	<10	<10	<10

* From Urbain WM. Food irradiation. *Adv Food Res* 1978;24:155–227.

Table 2
Effect of Irradiation* Temperature on Thiamin Content of Ham

Temperature of Irradiation (°C)	% Retention†
5	9
−20	53
−40	79
−60	87
−80	93

* Dose 3,000,000 to 4,000,000 rads.
† Initial content 3.67 mg/100 g.

Table 3
Threshold Dose for "Radiation Flavor"*

Meat	Dose
Pork	175,000
Beef	250,000
Chicken	250,000
Lamb	625,000

* Data from Thomas MH, Wierbicki E. Effect of irradiation dose and temperature on the thiamine content of ham. Technical Report 71-44-FL. Natick, MA: U.S. Army Natick Laboratories, 1971.

the irradiated dosages below a level that results in sterilization of the beef steaks (1,000 krad; 10kGray). Thus, we have scientific demonstration of the effect of irradiation on killing microorganisms in a major food product.

With respect to flavor changes, some differences have been observed with different meat products, as shown in Table 2. Obviously the detection of a "radiation flavor" may be sufficient to limit the marketing opportunities for products with this dosage. It should be noted that the effect on flavor is markedly sensitive to the temperature of the product when the irradiation is carried out. As noted earlier, each potential application of food irradiation is assessed on a case-by-case basis with full awareness of the variables in the process (temperature, packaging, nature of the food product, anticipated storage conditions after processing, etc.) that need to be considered.

NUTRITIVE VALUE, WHOLESOMENESS AND SAFETY OF IRRADIATED FOODS

It is of interest to note in Table 3 that irradiation reduces the thiamin content of ham and that the reduction is markedly influenced by the temperature in the food during irradiation. As expected, thiamin is much less sensitive to irradiation when the process is carried out at lower temperatures. It is of interest also that vitamins sensitive to the presence of oxygen, [namely vitamins A, C and E,] also show increased losses during irradiaton. Other vitamins are essentially stable. In addition, no significant change has been noted in the properties and nutritive value of carbohydrates, proteins, fats and minerals when the irradiation has been carried out at a range of dosages up to 4,000,000 rads. Some changes do occur that may be of interest. For example, fat oxidation occurs more rapidly with irradiation and some breakdown of complex carbohydrates occurs in plant tissues. This latter circumstance may lead to an interesting commercial application in that a 5% increase in juice yields has been obtained on the irradiation of citrus fruits.

On an overall basis, the changes in nutritive value approximate those associated with heat processing preservation methods. It is realized that some foods will be cooked, as well as irradiated, before consumption so there could well be some additive effects on the total nutritive value. These are not thought to be sufficiently major to be a serious deterrent to using food irradiation as a preservation method, assuming other aspects of the process are in the best interest of the consumer. No significant nutrient changes have been observed with the use of low levels of irradiation of foods.

The ability to assess the wholesomeness and safety of irradiated foods has been a major challenge to scientists in that every attempt was made to carry out parallel investigations to those used for food additives. This obviously was not possible with a food (i.e., to feed at levels of 100 times the intended usage level), and it was generally agreed that such feeding studies with at least two species of animals for each potential application would be carried out with the food providing 35% of the experimental diet as is noted in Table 4. Most of these studies were carried out using the rat and the dog for the 21 foods that were selected for these studies in the U.S. Army program. It will be noted that two fruits were included when the rat and the monkey were used. The reader will note that for certain of the foods it would be a heroic accomplishment for the experimental animal to consume with good acceptance this quantity of food in the daily diet! Other studies carried out with irradiated onions provided an even greater challenge in this respect! To this date we do not have ideal safety protocols for evaluating a process [such as irradiation] applied to foods.

Other studies to extract major constituents with various solvents supplement these studies. An effort was made to detect "unique radiolytic products" in these and other foods. From extensive gas chromatographic and other methods of analysis no new chemical products have been detected that are not present in our conventional food supply even though some increase or decrease in production of substances not normally found in a specific food product but in others were observed. From the extensive feeding studies carried out including those completed and reported recently with irradiated chicken no significant public health problem has been demonstrated with the feeding of irradiated foods to experimental animals. Some specific studies raised questions which led to additional research. It is recog-

Table 4
Foods Used in Long-Term Feeding Studies to Investigate the Effect of Treating Foods with Ionizing Energy

Food	Test Animal
Beef, ground	Rat, dog
Pork, loin	Rat, dog
Bacon	Rat, dog
Shrimp	Rat, dog
Codfish	Rat, dog
Chicken	Rat, dog
Tuna	Rat, dog
Beef stew	Rat, dog
Chicken stew	Rat, dog
Carrots	Rat, dog
Cole slaw	Rat, dog
Corn	Rat, dog
Beans, green	Rat, dog
Potatoes, white	Rat, dog
Potatoes, sweet	Rat, dog
Flour	Rat, dog
Fruit compote	Rat, dog
Evaporated milk	Rat, dog
Peaches	Rat, monkey
Oranges	Rat, monkey
Jam, pineapple	Rat, dog

nized that this is not a view held by every scientist in the world and we need to keep an open mind to any new studies that provide additional information.

CONSUMER ACCEPTANCE

This aspect has attracted considerable attention, particularly in the media, and has led to studies to ascertain the degree of potential acceptance or resistance to marketing of irradiated foods. On the one hand, we have inquiries asking, "Will the food glow in the dark?" when extensive studies have shown that the energy level of irradiation used does not result in any increase in induced radioactivity in the food product. Or, "I understand all the nutritive value is lost, and all of the body enzymes are destroyed when irradiated food is eaten!" Obviously, consumer education opportunities abound! On the other end of the range, we do have inquiries asking when we can use this unique process which will result in the ability to keep foods fresh longer, or to control food poisoning organisms, or to be an alternate to fumigants such as ethylenedibromide for treating and importing tropical fruits, such as papaya and mangos. It is of interest that two demonstration projects in the past year, one with the shipping of irradiated mangos from Puerto Rico to Florida, and the other for shipping irradiated papayas from Hawaii to California, resulted in apparent very good acceptance of the irradiated food products by consumers and they were judged superior in taste in the California study as compared to controls.

A number of groups have been formed around the United States equivalent to "coalitions against food irradiation," and have contacted congressmen, as well as state officials, to seek legislation to delay the application of the Food and Drug Administration approvals for food irradiation, or to ban the distribution of irradiated foods within the state. These are challenging times for food science and nutrition educators to provide the appropriate information to interested individuals, so that if and when irradiated foods are available for consumption, meaningful choices can be made by the consumer based on factual information.

Food scientists and nutrition educators are challenged to provide appropriate information to help consumers make meaningful choices.

Studies at the University of California at Davis, provided evidence that ecologically sensitive consumers, as well as younger and female consumers appear to have greater resistance to acceptance of irradiated foods than others in the population. They also showed that consumers were not well informed about irradiated foods. However, many of the conventional consumers had an open mind to the purchase of these food items, if they become available. They are currently studying another important aspect of consumer acceptance, namely how to appropriately label irradiated foods.

LABELING

Current Food and Drug Administration regulations provide for use of the international symbol for food irradiation (Figure 2) plus a written comment indicating the food has been irradiated. The Food and Drug Administration plans to review, in a 2-year period, how this system is working and if any modifications are merited. Even though we do not label foods processed by other methods with information on the method of processing, with this new and rather complex method of processing, information indicating food has been irradiated is appropriate. Considerable difference of opinion exists as to the best, simplest and most effective and accurate method to achieve this objective. It is of interest that secondary usage of irradiated ingredients (such as spices used in a formulated food does not require labeling that an ingredient has been irradiated. In this case, it is also of interest from a safety standpoint that the usage of an item such as irradiated spices in addition to being technologically

Figure 2. International symbol for irradiated foods.

Table 5
Promising Applications of Irradiation to Foods

1. Microbial control in spices and dried onions and garlic
2. Insect deinfestation of grain
3. Extending shelf life of fruits and vegetables
4. Controlling insects in imported fruits
5. Extending shelf life of marine food products
6. Inhibition of sprouting of potatoes

Table 6
Food Irradiation Issues

1. Safety
2. Nutritive value
3. Costs
4. Community acceptance
5. Consumer acceptance

suited, is also self-limiting as to the amount that a human would be consuming, in view of the flavor intensity of such products. However, some individuals feel that foods using irradiated spices, onions and garlic should also be so labeled.

PROMISING APPLICATIONS

As we look ahead, it would appear most likely that evolutionary, not revolutionary, changes to processing foods by irradiation will occur and these will be particularly selective in the United States where we are considered to have a good system of processing, storage and distribution of the food supply. As noted in Table 5, several promising

Evolutionary, not revolutionary, changes to processing foods by irradiation will occur.

applications of irradiated food are listed. The economic significance of these and the degree to which they meet consumer needs, are still somewhat uncertain. The most promising applications appear to be with the use of the machine sources of gamma irradiation, which can be turned on and off as needed and present far fewer difficulties in "community acceptance," which is associated with providing or transporting the radionuclide sources that constantly emit gamma rays. We have good systems for worker protection, shielding radioisotope sources during shipping, etc.; however, it is an aspect of high sensitivity to some members of a community to have the potential or actual presence of a radioactive source located in the community. In current work, design and cost estimates for the use of linear accelerators (machine sources) are being investigated.

WHERE ARE WE GOING?

As noted above, there continues to be interest in the issues about application of food irradiation in the scientific community, as well as in the consumer community (Table 6). Questions still occur relative to the safety of irradiated foods and we have limited human experience. These foods have been fed to astronauts and also in medical treatments where the reduced immune response of the patient requires feeding of sterilized food products.

The actual applications of irradiation to a specific food product will further identify any changes in nutritive value; however, this does not appear to be a major difficulty as compared to heat processing methods.

Until we have good pilot plant and commercial experience, costs will not be easy to define. From the engineering and economic literature, it would appear that on an overall basis, costs will be comparable to other processing methods and should not preclude further examination of the value of using this processing system for the preservation of foods.

The community and consumer acceptance issues will continue with considerable emotion. Answering the concerns with facts is essential and obtaining further research findings will be helpful in this connection. We also need to enhance consumer education activities, including providing information on the research findings obtained in many countries of the world where this food processing technique is being studied. It is of interest that the International Atomic Energy Agency in Vienna and the WHO/FAO organizations have indicated approval for the use of irradiation in the processing of foods up to and including the use of 1,000,000 rad. The International Atomic Energy Agency is also developing a 2-week training program for scientists from member countries to obtain a first-hand knowledge on procedures for operating a food irradiator to assure safety and appropriate application to individual food products.

The question has been asked if the federal funding of food irradiation by the Atomic Energy Commission and the U.S. Army can be justified in view of the very limited usage that has occurred on a commercial basis to date. The use of these funds to obtain valuable information on our conventional food processing and preservation methods (i.e., nutritional, sensory, microbiological, physical and chemical and toxicological characteristics) as controls have been very valuable. Also many undergraduate, graduate and postdoctoral students received financial support in their research studies, which has added significantly to the pool of educated scientists continuing to make important contributions to our knowledge of the properties of foods.

Members of the food science and nutrition scientific community will find it of interest to continue to follow developments and provide a leadership role with respect to this unique and potentially important method of food preservation.

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University of Alaska Fairbanks

Alaskan Commodities Irradiation Project:

An options analysis study

project objective

The overall goal of this feasibility study (which is being conducted for the State of Alaska) is to evaluate the potential social and economic benefits and risks that may be realized from the application of food irradiation technology to Alaska's seafood and agricultural products. Potential benefits include increased shelf life, allowing commodities to be shipped greater distances as fresh products without degradation of product quality, and decreased naturally occurring disease-carrying microorganisms that are of public health concern. Treatment of Alaska-produced food products may benefit the seafood and agricultural industries by opening new markets both in-state and worldwide for these value-added products. A potential added benefit to Alaskan consumers is a safer and more varied food supply.

project background and funding source

The U.S. Congress mandated a six-state research program with the ultimate objective of transferring irradiation technology to the private sector for commercialization if the net benefits are positive. Florida, Hawaii, Iowa, Oklahoma and Washington, as well as Alaska, are studying potential benefits of this technology. The funds appropriated by Congress have been transferred to the individual states by the U.S. Department of Energy. Alaska designated the Institute of Northern Engineering at the University of Alaska Fairbanks to conduct the feasibility study on behalf of the state.

research agency and project scope

The Institute of Northern Engineering is coordinating the efforts of an interdisciplinary team of researchers, including food scientists, economists, engineers and management specialists. This team is evaluating the technical (including safety), economic, financial, political and social feasibility of a food irradiation facility in Alaska. An advisory panel representing government, industry and the general public has been assembled to provide additional input and expertise.

final recommendations

At the conclusion of the feasibility study, which is expected by late summer 1988, the team, with input from the advisory panel, will make recommendations to the State of Alaska and the U.S. Department of Energy. The State of Alaska will make a final decision regarding the implementation of any recommendations.

University of Alaska Fairbanks

FACT SHEET: Irradiated Foods

the process

Irradiation is a physical process like canning, freezing, drying and pasteurizing. It is used to reduce levels of naturally occurring disease-carrying microorganisms of public health concern and to extend the shelf life of food. Shelf life of perishable foods such as fresh fish, poultry and meats can be extended two to three times.

During the irradiation process, foods are exposed to an ionizing radiation source. Ionizing radiation passing through the food breaks chemical bonds in undesirable microorganisms. It destroys bacteria, yeast and molds. Irradiation can kill or sterilize insects, and it can retard further ripening of fruits and vegetables. Because irradiation increases the temperature of the food only a few degrees, fresh foods retain their appearance, texture and flavor. However, because a few (six out of 10,000,000) chemical bonds are also broken in the food, some small quality changes occur. For example, irradiated dried vegetables cook faster, meat is tenderized and solanin, a naturally occurring toxin in potatoes, is not formed. Potatoes, strawberries, mangoes, frozen fishery products and grains are among the food products irradiated in foreign countries.

energy source

Machine-generated beams of electrons or X-rays, or gamma rays from isotopes such as cobalt-60 or cesium-137, can be used as the radiation source. Machine sources are attracting increased interest because they eliminate many environmental and safety concerns.

approved uses

In the United States, the Food and Drug Administration determines what foods can be irradiated, at what levels and for what purposes. Approval for wheat, wheat flour and potatoes dates from the 1960s. Irradiation of pork, dehydrated spices, herbs, teas, vegetable seasonings and fresh produce has been approved since 1984.

current uses

Some spices are disinfested using irradiation. In test markets, irradiated tropical fruits have sold well; appearance and quality of these fruits encouraged consumers to purchase them. Labeling is required so that informed consumers can select among available products.

American astronauts have been consuming irradiated food in space since the Apollo missions, and some American hospital patients, who cannot tolerate disease-carrying microorganisms, prefer irradiated foods over the alternatives.

-more-

food safety

Irradiated foods are not radioactive and the consumer is never exposed to radiation. The approved processing procedure has little effect on nutritional quality. Recent studies show no harmful effects from eating irradiated foods even when 100 percent of an individual's diet was irradiated food. Scientifically conducted animal studies also show no toxic effects.

The World Health Organization (WHO), the U.S. Food and Drug Administration (FDA) and the American Medical Association (AMA) have endorsed the process. More than 20 countries (including Canada, The Netherlands, Japan, France and Australia) have approved the process for foods intended for human consumption.

consumer protection

The food irradiation process is regulated under federal and state food safety and good manufacturing guidelines. Workers and training and safety procedures are governed by state and federal guidelines. International standards for the operation of food irradiation facilities have been established by the United Nations.

potential benefits and risks to Alaska

The irradiation process could increase the quality and selection of available food products, especially in rural Alaska. Reduction of pathogens of public health concern would improve the safety of foods available to all Alaskans.

Extended shelf life may allow fresh Alaskan products to be shipped into new in-state, national and international markets without degradation of quality. This could benefit the seafood industry by increasing Alaska's share of the premium fresh-fish market outside of the state and by increasing the availability of fresh fish in in-state markets. Marketing underutilized fish species with limited shelf life may also become feasible. It may also allow fresh Alaskan reindeer products to enter the growing national and international game meat markets. Increased shelf life could also provide more consistent market supplies and avoid spoilage.

Utilization of presently discarded by-products from the seafood and agricultural industries would eliminate some environmental concerns and increase total product value.

Selection of a radioactive isotope as an ionizing source for the process would cause some low-level risks associated with transporting and using this material. These risks could be mitigated by using an X-ray machine. Machines generate radiation only during periods of operation and can be turned off by simply flipping a switch. If a facility were to be built in Alaska, safety in design, construction and operation would be of primary importance.

University of Alaska Fairbanks

for more information call University Relations 474-7581

Food Irradiation and Alaska's Food Industries

By

Ruthann B. Swanson*, Carol E. Lewis**, Charlotte I. Hok***, and Deben K. Das****

Introduction

Canning, freezing, drying, and pasteurization are familiar food-preservation processes. Recently, another food-preservation process, irradiation, has gained attention in the American press. A study to evaluate the use of food irradiation is presently being conducted in Alaska by the Institute of Northern Engineering, University of Alaska Fairbanks. The purpose of this study is to determine the potential social and economic risks and benefits that may occur in Alaska from the application of food irradiation technology to Alaska's seafood and agricultural products.

This technology has been a subject of worldwide research and development for over 40 years. It is used to preserve various products in many countries. For example, potatoes are treated in Japan to inhibit sprouting, fresh strawberries are treated in the Netherlands to prevent molding, mangoes are treated in South Africa for insect disinfestation, and shrimp are irradiated in Australia to extend shelf life (VanKolj 1986). In the United States, it is primarily used to sterilize nonfood products, although selected food products have been approved for irradiation by the United States Food and Drug Adminstration (FDA).

Food Irradiation Project Background

The United States Congress in 1986 authorized research programs in six states, with the objective of transferring irradiation technology to the private sector for commercialization if net benefits prove to be positive. The states of Florida, Hawaii, Iowa, Oklahoma, and Washington as well as Alaska are evaluating the process. The funds appropriated by Congress were transferred to the individual states through the U.S. Department of Energy (DOE).

The Alaskan study team is an interdisciplinary group of researchers which includes food scientists, economists, engineers, and management specialists. An advisory panel representing government, industry, and the general public has been assembled to provide additional input and expertise. At the conclusion of the feasibility study, the team, with input from the advisory panel, will make recommendations to the state of Alaska and DOE. The Office of the Governor of the state of Alaska will make a final decision regarding the implementation of the recommendations.

The Irradiation Process

Food irradiation is a preservation process like canning, freezing, pasteurization, and heat sterilization, or chemical treatment that can be used to extend the shelf-life of food. Today, most food products, even when marketed fresh, have been processed to some extent. Chemical treatment of potatoes to inhibit sprouting, dipping of papayas in hot water to kill insects, and pasteurization of milk to kill naturally occurring disease-carrying and spoilage microorganisms are examples. In some cases, irradiation has the potential to replace existing processing techniques. In others, irradiation may be used in combination with these conventional processes. However, irradiation is not a panacea, and it cannot be used succesfully with all foods. Milk, for example, is unsuitable for irradiation processing.

Foods that are exposed to an ionizing radiation source are described as irradiated. During this process, radiation is passed through the food product (fig. 1). Bacteria, yeast, and molds are destroyed, and insects can be killed or sterilized. In addition, further ripening and sprouting of fruits

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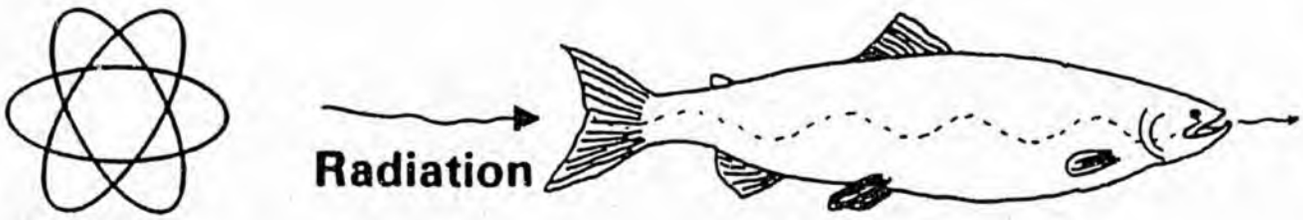

Figure 1. How irradiation works.

and vegetables can be retarded (fig. 2). Temperature of the food is raised only a few degrees during irradiation processing; fresh foods, therefore, retain their appearance, texture, and flavor. A few (6 out of 10,000,000) chemical bonds in the food are broken causing small quality changes in some foods. Irradiated dried peas and beans cook faster, irradiated meat is tenderized, and irradiated potatoes do not turn green after exposure to light, indicating that solanin, a naturally occurring toxin, is not formed (Loaharanu and Urbain 1982). Breaking bonds in the food also produces new compounds, known as radiolytic products, from the food's natural components. Some consumers fear that these compounds are unnatural or hazardous. In fact, most of these products have been found in the same or other foods that have not been processed using irradiation. Some radiolytic products are also produced when foods are cooked or processed traditionally (Josephson and Brynjolfsson 1987).

Irradiated foods are not radioactive, and the consumer is never exposed to radiation (Josephson and Brynjolfsson 1987). Recent studies show no harmful effects from eating irradiated foods even when 100 percent of the individual's diet was irradiated food (Brynjolfsson 1987). Scientifically conducted animal studies also show no toxic effects (CAST 1963). Under today's processing conditions, the irradiation process has little effect on the overall nutritive value of the

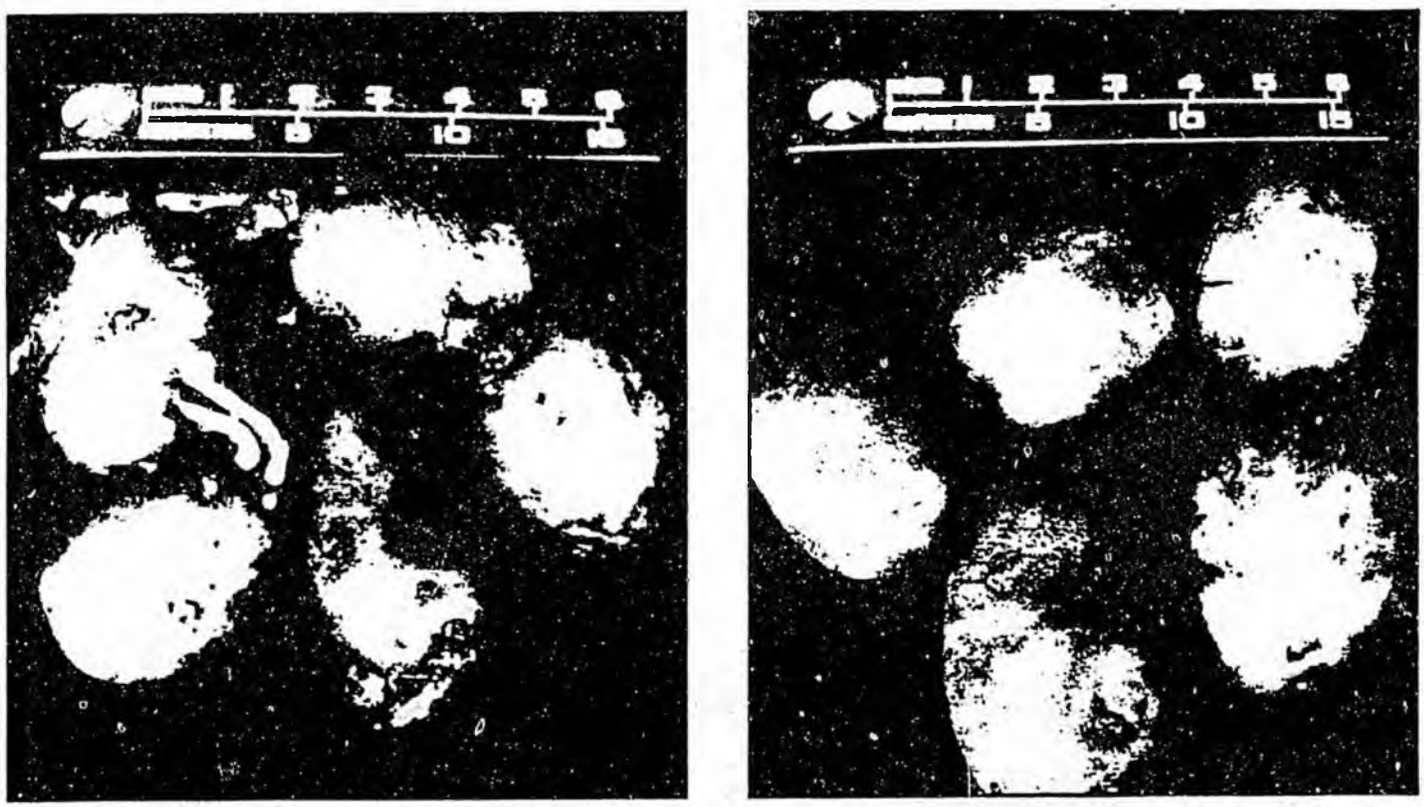

Figure 2. Effect of irradiation on conventionally processed supermarket potatoes after 1 month storage at room temperature; irradiated potatoes have not sprouted (Photographs courtesy of H. Farrar, IV and G. Subbararaman).

food, although the level of some vitamins may be lowered slightly. The irradiation effect is no greater (and may be less) than that found when other commercial processing methods are used (IFT 1986, Josephson et al. 1978).

There are two major benefits from using the irradiation process on food products. One benefit is increased shelf-life that will allow commodities to be shipped greater distances as fresh products without degradation of product quality. A second is decreased levels of naturally occurring, disease-carrying microorganisms that are of public-health concern, such as *Salmonella*, *Campylobactor*, and *Clostridium*.

Labeling

Foods treated with irradiation look like or, in some cases, look better (Bruhn and Noell 1987) than traditionally handled foods; therefore, labeling is required so that the consumer is aware that the food has been processed by irradiation (FDA 1986). The logo in Figure 3 is the international irradiation (radura) symbol used to identify irradiated foods. At the present time, the statements "treated with radiation" or "treated by irradiation" also must be used on the label. These labeling guidelines apply to all irradiated foods, including bulk foods, sold directly to consumers. When combination food products (cake mixes, salad dressings) contain irradiated ingredients, the product does not have to be labeled because such small quantities are involved and because it is obvious that the product has been processed (FDA 1986). Any product that is irradiated for wholesale distribution must also be labeled. The statement "treated with radiation, do not irradiate again" or "treated by irradiation, do not irradiate again" is required (FDA 1986).

Figure 3. International food irradiation logo (FDA, 1986).

Irradiated Food Products in the United States

The FDA has approved irradiation of a variety of food products for sale in the United States (Lecos 1986). This does not imply that these foods are currently available to retail consumers, nor that irradiated Alaskan commodities will be available for purchase in the near future.

Approved products in United States

The FDA determines which food products can be irradiated and at what levels and for what purposes in the United States (Lecos 1986). The agency has approved irradiation treatment of the food products listed in Table 1. Except for spices and dehydrated vegetables, the irradiation dose levels approved by the FDA are at pasteurization[1] levels. Therefore, although spoilage and disease-carrying microorganisms are reduced, the foods are not sterile. Proper handling and such storage as refrigeration and freezing remain very important in preventing the multiplication of surviving microorganisms. The USDA Food Safety and Inspection Service has requested that FDA approve the irradiation of poultry to kill *Salmonella*, a common source of foodborne illness (food poisoning), and other disease-carrying bacteria present (USDA-FSIS 1986). A similar petition to allow irradiation of fish for commercial sale is expected in the near future.

Current uses

American astronauts have been eating irradiated food in outer space since the Apollo missions (IFT 1983). In at least one American hospital, a variety of irradiated food products are served to some patients who cannot tolerate disease-carrying organisms. The patients prefer the irradiated foods over those not so treated (Aker 1984). However, the average

[1]defined as a process which reduces the number of naturally occurring microorganisms which cause spoilage and/or disease. The process does not sterilize, i.e., eliminate all such microorganisms.

Table 1. Foods approved for irradiation in United States.

Food	Year Approved	Purpose
Wheat, wheat flour	1963	Insect control
White potatoes	1964	Sprout inhibition
Pork	1985	Trichinella spiralis control; parasite causes trichnosis
Dehydrated herbs, spices, seeds, teas, vegetable seasonings	1986	Kill insects and control micro-organisms
Fresh fruit and vegetables	1986	insect control; Maturation inhibition

(Lecos 1986, FDA, 1986.)

American consumes little irradiated food, although irradiated spices and dehydrated vegetables are increasingly available. There is some speculation that irradiated fresh fruits and vegetables may soon reach American grocers' shelves. Despite its limited use with food products, many products that Americans use every day are irradiated. A few representative examples are listed in Table 2.

Labeled, irradiated, tropical fruits have been test-marketed in the United States (Bruhn and Noell 1987, Puzo 1986). Appearance and quality of the fruits encouraged consumers to buy the irradiated products (Bruhn and Noell 1987). Although response was positive in these market tests, extensive test-marketing has not been done in the United States.

Food Safety

Food safety is a major concern for the consumer and the food industry alike, and, for the past 40 years, food irradiation research has emphasized safety. The U.S. and British governments, like many consumers, have expressed concern about the safety of irradiated foods. As a result, the U. S. Congress and the British Ministry of Health requested independent reviews of food irradiation research. Foods treated with irradiation are considered safe to eat if: (1) no significant toxic effects or radioactivity are produced by processing, (2) nutritional quality is not significantly decreased when the irradiated food is compared to the fresh product or the same food processed using conventional methods such as canning and freezing, and (3) harmful microorganisms and microbial toxins are not present.

Researchers involved in the United States' review concluded:

> from all the available scientific evidence that foods exposed to ionizing energy under the conditions proposed for commercial application are wholesome, that is, safe to eat. Their nutritional adequacy compares favorably with that of fresh foods or with that of foods processed by well established conventional methods. (CAST 1986)

British scientists also concluded that irradiated foods are safe, wholesome, and nutritious (ACINF 1986).

The World Health Organization (WHO 1981), the U.S. Food and Drug Adminstration (FDA 1984, 1986), Canadian Government (1987), and the American Medical Association (AMA 1985) have also endorsed the process. Over 20 countries (including Canada, the Netherlands, Japan, France, and Australia) have approved the process for foods intended for human consumption. The food irradiation process is regulated in the United States under Federal food safety and good manufacturing guidelines (Engel 1987, FDA 1986). International standards for the operation of food irradiation facilities have been established by the United Nations (CAC 1984).

Table 2. Commonly used items that are irradiated in the United States.[1]

Baby bottle nipples	Nonstick cookware
Tampons	Baby powder
Water	Food packaging materials
Food containers	Cosmetics
First aid packs	Burn ointments

[1]40 irradiators are operating in the United States (Markovic 1985).

Irradiation Facilities

The use of radiation sources in Alaska is not new. At present, there are about 70 isotope sources, and licenses have been granted for approximately 1200 X-ray sources. These radiation sources are used for medical, industrial and research purposes (Heidersdorf, personal communication[1]). For example, Providence Hospital in Anchorage provides radiation therapy using a gamma isotope source. X-ray sources are used not only for medical purposes but also in airport security stations throughout the state.

The source

Three types of radiation sources are recommended for food processing: machine-generated 5 MeV X-rays and 10 MeV accelerated electrons and gamma rays from isotope sources (CAC 1984). Cobalt-60 and cesium-137 are the gamma isotope sources commonly used in the food-irradiation process. However, machine technologies are being improved and are beginning to compete with the use of traditional isotope sources.

Source transportation

Regulations and procedures for transporting gamma sources in Alaska are in place (Alaska Radiation Protection Regulations 1978) because these sources are currently used for medical, industrial, and research purposes. The regulations are as stringent as those for interstate transport (U.S. NRC 1984). Interstate transportation of all radioisotopes is governed by the U. S. Department of Transportation as well as by the Nuclear Regulatory Commission (NRC). When machine sources are employed, there is no transportation involved because there is no source to be transported (Rodrigues 1985). Thus, transportation concerns are moot.

Potential Benefits to Alaska

There are a number of potential benefits that could accrue to both the seafood and agricultural industries and to Alaskan consumers by extending the shelf-life of higher-

[1]Heidersdorf, S.D. 1987. State of Alaska Radiological Physicist. Spring 1987, Juneau AK.

valued products and increasing the value of now discarded by-products. Problems associated with small markets within the state, long distances to markets outside the state, and limited or expensive transportation networks, have hampered development of Alaska's food industries.

•The Alaskan consumer may benefit from an increase in the quality and selection of available foods. Reduction of pathogens of public health concern would also improve the safety of available foods. Not only are the numbers of spoilage microorganisms reduced by irradiation but the levels of naturally occurring disease-carrying microorganisms, such as *Salmonella* are also reduced (USDA-FSIS 1986).

•Extended shelf life may allow fresh Alskan products to be shipped into new in-state, national, and international markets without degradation of quality. This could benefit the seafood industry by increasing Alaska's share of the premium fresh-fish market outside of the state and by increasing the availability of fresh fish in in-state markets. Marketing of underutilized fish species with limited shelf-life may also become feasible (Kramer, personal communication[1]). It may also allow fresh Alaskan reindeer products to enter the growing national and international game meat markets (Drum, personal communication[2]).

•Increasing the shelf-life of fresh products could aid the Alaskan food industry by reducing market gluts, minimizing price fluctuations, providing more consistent supplies and reducing spoilage due to oversupplied markets. This should benefit both the seafood harvester (Nickerson et al. 1983) and the vegetable producer.

•Utilization of now-discarded by-products from the seafood and agricultural industries would eliminate some environmental concerns and increase total product value. Seafood processing "wastes" are dumped into the ocean in many Alaskan fishing communities (Monsen 1987), and slaughter plant by-products (Olson, personal communication[3]) are also discarded. Such by-products have extensive uses in the cosmetic, pharmaceutical, and animal feed industries (AECL 1987) outside of Alaska. A research and development project to identify the quality effects on Alaska-produced commodities could be the next phase in the evaluation of the irradiation process.

Request for Input

At the conclusion of the irradiation feasibility study, the research team will make a recommendation to the state of Alaska and the Department of Energy on the desirability of a research and demonstration irradiation facility in Alaska. Public comment is an important part of the study. Readers interested in making their views known to the study team should send written comments to:

Public Comment
Institute of Northern Engineering
539 Duckering
University of Alaska Fairbanks
Fairbanks, AK 99775.

[1]Kramer, D. 1987. Alaska Marine Advisory Program. June 1987, Fairbanks, Alaska.
[2]Drum, D. 1987. Indian Valley Meats, Inc., October 1987, Indian, Alaska.
[3]Olson, J. 1987. Mt. McKinley Meat and Sausage Co. October 1987, Palmer, Alaska.

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because of the research interest, collections were also made in stands near the edge of the species' ranges. One collection of white spruce was from the Firth River drainage on the Alaska-Yukon border. This stand was first described by **Dr. James V. Drew,** dean of the School of Agriculture and Land Resources Management of the University of Alaska Fairbanks, and a colleague when they visited the area as members of a soil survey team during the summer of 1958 when Dr. Drew was Assistant Professor of Agronomy at the University of Nebraska.

During 1987, a forest tree improvement cooperative was established in Alaska. The School of Agriculture and Land Resources Management is among the organizations providing the early direction for the cooperative. Dr. James V. Drew is a member of the executive committee. **Dr. Edmond C. Packee,** assistant professor of forest management, is a member of the technical committee. Tree improvement, the selection of the highest quality genetic stock and maintenance of the gene pool, is an important aspect of any reforestation program and has been quite profitable in the Nordic countries.

Dr. Leroy B. Bruce, assistant professor of animal science, AFES, Palmer Research Center has been appointed to the screening committee for research proposals submitted to the newly created Applied Agricultural Research Account. This is a fund held and administered by the Alaska Division of Agriculture to support applied agricultural research in Alaska. Producers in the agricultural industry, individuals in state and local agencies, and University of Alaska personnel may apply. These grants are to sponsor applied research to find practical solutions to agricultural problems. This type of grant fund is new to the state of Alaska and opens new doors to sponsoring agricultural research in the state.

Dr. Fredric M. Husby, associate professor of animal science, served in 1987 as chairman of the Western Regional Hatch Research Project W-166, "Characteristics and feed value of barley and western protein supplements for swine." Dr. Husby hosted the annual meeting of swine nutritionists in Fairbanks June 15-18, 1987. During this meeting, a five-year proposal for regional swine nutrition research was developed. Within the proposed study, two Alaskan barley varieties ('Otal' and 'Datal') will be produced at six locations in the Western region to determine the effect of production location on chemical composition. In addition, Alaskan fish meal and fish oil will be included in future studies as both protein and energy sources for weaner pig diets.

Dr. Glenn Juday assistant professor of plant ecology, has been on special leave from SALRM. He is writing a book entitled *Natural Areas in North America*. Research for the book has taken Dr. Juday through western Canada including Yukon, Alberta, Saskatchewan, Manitoba, and on to such locations in the U.S. as Indiana, Ohio, Illinois, and Kentucky. In Illinois, he chaired the Natural Areas Con-

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Introduced: 1/22/88
Referred: Health, Education &
Social Services and Judiciary

5-1671A

IN THE HOUSE BY PHILLIPS AND GOLL

HOUSE BILL NO. 388

IN THE LEGISLATURE OF THE STATE OF ALASKA

FIFTEENTH LEGISLATURE - SECOND SESSION

A BILL

For an Act entitled: "An Act relating to irradiated food."

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF ALASKA:

* Section 1. AS 17.20.290(a) is amended to read:

(a) The following acts and the causing <u>of the acts</u> [THEREOF] are prohibited:

(1) the manufacture, or sale, or delivery, holding, or offering of sale of <u>a</u> food, drug, device, or cosmetic that is adulterated or misbranded;

(2) the adulteration or misbranding of <u>a</u> food, drug, device or cosmetic;

(3) the receipt in commerce of <u>a</u> food, drug, device, or cosmetic that is adulterated or misbranded, and the delivery or proffered delivery of <u>the article</u> [THEM] for pay or otherwise;

(4) the sale, delivery for sale, holding for sale, or offering for sale of an article in violation of AS 17.20.050 - 17.20.-070 and 17.20.100;

(5) the dissemination of a false advertisement;

(6) the refusal to permit entry or inspection, or to permit the taking of a sample, as authorized by AS 17.20.200;

(7) the giving of a guaranty or undertaking <u>that</u> [WHICH] is false, except by a person who relied on a guaranty or undertaking to the same effect signed by and containing the name and address of the person residing in the state from whom the person who relied on the guarantee or undertaking received the food, drug, device, or cosmetic

in good faith;

(8) the removal or disposal of a detained or embargoed article in violation of AS 17.20.230 - 17.20.270;

(9) the alteration, mutilation, destruction, obliteration, or removal of the whole or part of the labeling of, or the doing of, another [ANY OTHER] act with respect to, a food, drug, device, or cosmetic, if the act is done while the article is held for sale and results in the article being misbranded;

(10) forging, counterfeiting, simulating, or falsely representing, or without proper authority using a mark, stamp, tag, label or other identification device authorized or required by regulations adopted under AS 17.20.230 - 17.20.270;

(11) the using, on the labeling of a drug or in an advertisement relating to a drug, of a representation or suggestion that an application with respect to the drug is effective under AS 17.20.110 or that the drug complies with the provisions of that section;

(12) the sale or offering for sale of frozen fish as fresh fish;

(13) the improper labeling and drug substitution by pharmacists under AS 17.20.105;

(14) the knowing sale of irradiated food; in this paragraph,

(A) "irradiated" means treated with gamma radiation or other ionizing radiation;

(B) "irradiated food" includes spices that have been irradiated, and food that contains an irradiated ingredient unless the only irradiated ingredient is a spice.

* Sec. 2. AS 17.20.290(b) is amended to read:

(b) The commissioner of environmental conservation or a designee

of the commissioner is responsible for enforcing the provisions of [PARAGRAPHS] (a)(1), (2), (3), (4), (6), (7), (8), (9), and (10) of this section, if the subject of the prohibited act involves food or cosmetics, and the provisions of [PARAGRAPH] (a)(12) and (a) (14) of this section. This subsection does not limit the authority of peace officers.