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IONIZING ENERGY IN FOOD PROCESSING AND PEST CONTROL:

I. Wholesomeness of Food Treated With Ionizing Energy

Council for Agricultural Science and Technology

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I. Wholesomeness of Food
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Council for Agricultural Science and Technology

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On the Cover

The international symbol for food treated with ionizing energy in accordance with approved methods

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Foreword

The decision to establish a task force to prepare a report on "Ionizing Energy in Food Preservation and Pest Control" was made by the CAST Board of Directors as a consequence of a Congressional request. Behind the requests received from individual members of Congress were concerns about the use of ionizing energy for food preservation as a commercial process and the use of ionizing energy as a substitute for chemicals employed to control pests in food products for export and domestic use.

Upon receipt of nominations from the member societies, a task force was developed by Board of Directors member James D. Kemp. The task force included expertise in agricultural engineering, dairy science, entomology, food science, horticulture, meat science, mechanical engineering, nematology, plant pathology, poultry science, sociology, toxicology, and weed science.

The task force chairman prepared an outline of subject matter in cooperation with several members of the task force, and this was used as a basis for developing topic assignments to be covered by individuals or groups of task force members. Several meetings were held among small groups of task force members while the basic manuscript was in preparation.

As the manuscript developed, it became apparent to the task force chairman and cochairman that the subject matter could be treated most advantageously in two reports, one dealing with the wholesomeness of food treated with ionizing energy and a second dealing with applications. The manuscript on wholesomeness was prepared first because this subject was considered fundamental to all uses of ionizing energy on food products.

Upon receipt by the CAST office in July 1985, the wholesomeness manuscript was reproduced and sent to all members of the task force, to members of the CAST Editorial Review Committee, and to an outside editor. Comments from all sources were incorporated into an edited draft, which was returned to task force members for further review and comment. A second edited draft was prepared and distributed as before. The third edited draft was typeset and returned to task force members and the CAST Executive Committee as a galley proof for final comments and approval. Editing of the report was done by Ralston J. Graham, Lincoln, Nebraska, with assistance from the CAST headquarters staff.

As the wholesomeness manuscript was moving through the editorial and review process, a number of comments were received from task force members about the most appropriate overall title for the two reports. As a consequence, the initial term "food preservation" was changed to "food processing" because some uses are not preservation. The term "pest control" was retained because, although pest control in food may be considered a part of processing, some applications of ionizing energy to be covered in the second report do not represent pest control in foods.

On behalf of CAST, we thank the task force members, who gave of their time and talents to prepare this report as a contribution of the scientific community to public understanding. We thank also the employers of the task force members, who made the time of the members available at no cost to CAST. The members of CAST deserve special recognition because the unrestricted contributions they have made in support of the work of CAST have financed the preparation and publication of this report.

This report is being distributed to certain members of Congress, the Food and Drug Administration, the Environmental Protection Agency, the U.S. Department of Agriculture, the Departments of Energy and Commerce, and the Agency for International Development; to media personnel who have asked to receive CAST publications; and to institutional members of CAST. Individual members may receive a copy upon request. The report may be republished or reproduced in its entirety without permission. If republished, credit to the authors and CAST would be appreciated.

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Summary

For treatment of food products, appropriate use of ionizing energy can extend the shelf life; reduce the requirement of chemicals for preservation and pest control; eliminate insects and parasites; free foods of pathogenic bacteria; decontaminate foods and food materials of bacteria, yeasts, and molds for purposes of hygienization; produce sterile products that can be stored without refrigeration; reduce the requirement of energy for refrigerated storage; reduce the cooking time; tenderize some foods; delay the ripening of fruits and vegetables; and limit the deterioration of quality of stored tuber and bulb crops by preventing postharvest sprouting.

The forms of ionizing energy used in food preservation and processing include gamma rays, x-rays, and accelerated electrons. Gamma rays and x-rays are part of the electromagnetic spectrum that includes radio waves, microwaves, infrared radiation, and visible light.

Ionizing energy receives its name from the fact that these forms of energy have the ability both to dislodge electrons from the molecules in the food to form fragments that are electrically charged, known as ions, and to excite the molecules in such a way that some cleave into smaller neutral fragments, known as free radicals. This ability makes ionizing energy useful, but it also has prompted more than 35 years of research to address concerns regarding the wholesomeness (safety for consumption) of treated food in which such chemical changes have occurred.

Ionizing energy now has been approved for extensive use in food preservation and processing in many countries, and several uses have been approved recently in the United States. The extensive research that has been done during the past 40 years provides the scientific background for the developments now occurring.

The presence of induced radioactivity in food treated with ionizing energy is a frequently cited concern regarding the wholesomeness of treated food. The energy levels of the gamma rays, accelerated electrons, and x-rays legally permitted for processing food, however, are so low that they do not induce measurable radioactivity.

The compounds formed in minute amounts when ionizing energy interacts with some of the food molecules have been studied at length. The types and amounts of compounds formed have not been found to impart toxic qualities to food. Similar compounds occur in unprocessed food and in food processed by well established conventional methods. In some instances, off-flavors develop with high doses of ionizing energy. These flavors generally can be avoided with proper control of the conditions of processing.

Numerous direct feeding studies have been conducted during the past 35 years to assess the wholesomeness of food processed with ionizing energy. Some have been large-scale experiments. Subjects tested have included humans and various animal species. Lifetime studies have been carried out with animals (including four generations of rodents). Assessments have been made of possible relationships between consumption of foods processed with ionizing energy, and the development of cancers, birth defects, and genetic changes. The results have provided no confirmed evidence that processing food with ionizing energy creates these or other toxicological hazards.

Tests to determine the utilization of nutrients in food treated with ionizing energy have disclosed no unfavorable effects in comparison with food processed by well established conventional means. No evidence has been found to indicate that antivitamin compounds are formed by treating food with ionizing energy.

No evidence has been found that treating food under the proposed technology with amounts of ionizing energy that do not eliminate all organisms would lead to development of radiation-resistant microorganisms, pathogens with increased virulence, unusual spoilage characteristics, or changes in physiological characteristics of the organisms that would make them difficult to identify.

It is 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 the fresh foods or with that of foods processed by well established conventional methods.

Overview

Food treated with ionizing energy is considered wholesome if harmful microorganisms and microbial toxins are absent, if the ionizing energy has produced no measurable toxic effects or radioactivity, and if the food presents no significant nutritional deficiency relative to the same food that has not been processed with ionizing energy or has been processed by well established conventional methods.

The only sources of ionizing energy used to preserve foods, eliminate pests and food-borne disease-causing organisms, and produce certain other beneficial effects are gamma rays from cobalt-60 and cesium-137, x-rays, and accelerated electrons (electron beams). Gamma rays and x-rays are part of the electromagnetic spectrum that includes radio waves, television waves, microwaves, infrared radiation, visible light, and ultraviolet radiation.

The microwaves employed for microwave heating and the infrared radiation used in broiling and baking have relatively long wavelengths and low energies. Gamma rays and x-rays have relatively short wavelengths and high energies. The units of energy (quanta) in gamma rays and x-rays are great enough to break chemical bonds in organic molecules in foods and this gives them their special value. When a sufficient number of certain critical bonds are split in the bacteria and other pests in food, the organisms are killed. Ionizing energy has some additional beneficial effects, for example, tenderizing some foods and preventing potatoes and certain other crops from sprouting in storage.

Ionizing energy now has been approved for extensive use in food preservation and processing in many countries, and several uses have been approved recently in the United States. The extensive research that has been done during the past 40 years provides the scientific background for the developments now occurring. The toxicological, nutritional, and microbiological aspects of food processing with ionizing energy as related to public health have received principal emphasis.

Toxicological Safety

Research on the toxicological safety of food processed with ionizing energy has included studies to determine whether ionizing energy induces the development of radioactivity and toxic compounds in food. In addition, many feeding studies have been done on the processed foods as such.

Humans are exposed continuously to ionizing energy from naturally occurring radioactive substances in the body and in the environment and are exposed intermittently to x-rays for medical and dental purposes. An important concern in earlier investigations of the wholesomeness of food exposed to ionizing energy was the possibility that the ionizing energy might induce radioactivity in the food. The amount of radioactivity induced in food treated with ionizing energy at legal energy levels (gamma rays from cobalt-60 or cesium-137, x-rays with energy less than 5 million electron volts, and accelerated electrons with energy less than 10 million electron volts) is so infinitesimal as to be beyond measurement.

Radiolytic products are molecular substances that are formed in minute amounts when ionizing energy interacts with some of the molecules in food. These compounds have been studied extensively to determine whether they impart toxic properties to food.

The standard toxicological approach to evaluating the toxicity of food treated with ionizing energy would be to add the food to the diet of test animals in quantities far greater than those to be used in practice, to find the maximum quantity that produces no observable adverse effect, and to divide this quantity by a safety factor (commonly 100) to obtain the quantity of the food to be allowed in human diets. This procedure is inappropriate for determining whether the radiolytic products are toxic and for evaluating their safety in human diets. Neither the food processed with ionizing energy nor the radiolytic products can be added in large excess, as is done in classical toxicological research. In toxicological research on a substance such as a food additive, the substance to be tested is added in a concentrated form. Even the large excess required for finding the no-effect level is such a small quantity that it has no substantial effect on the remainder of the diet. Radiolytic products, however, are present in such low concentrations that the needed excess for toxicological studies could not be supplied even if the diet were to consist wholly of a processed food. The radiolytic compounds, although present in small amounts and theoretically capable of addition in the excessive amounts needed to find the no-effect level, cannot be added like this in practice. They cannot be extracted quantitatively or added in the proportions in which they exist in food. Some of the radiolytic compounds have not as yet been identified. And food cannot be processed with great excesses of ionizing energy to produce a high concentration of radiolytic products without changing its character.

The difficulties just described may be offset in part by exposing several or all components of the test diet to practical doses of ionizing energy so that nutritional imbalances can be avoided. This approach is illustrated by several recent experiments in China. For up to 15 weeks, human volunteers were fed balanced diets of which 60 to 66% of the composition had been processed with ionizing energy. A broad spectrum of toxicologic tests revealed no adverse effects in the human subjects.

Many feeding experiments have been done in the United States and other countries in which food processed with ionizing energy has been used in diets in feasible quantities. The subjects have included humans and various animal species. Some experiments were conducted on a large scale. A number of the studies with animals involved lifetime feeding of the processed foods. There have also been studies of four generations of rodents. The kinds of harmful effects looked for have been the same as those looked for in the usual toxicological studies, namely, effects on mortality, body weight, food consumption, behavior, pathologic changes, blood count and hemoglobin, urine composition, reproductive performance, birth defects in offspring, and genetic changes. Additional studies have been made in which radiolytic compounds identified in processed food have been added in a mixture to the diets of test animals in amounts far exceeding those that would be consumed in the food. The results of these investigations, conducted over a period of some 35 years, have produced no confirmed evidence that consumption of foods processed with ionizing energy according to internationally approved procedures has adverse biological effects.

As a result of the findings in animal feeding tests and the accumulation of knowledge about the nature and predictability of radiolytic products, scientific thinking about procedures to investigate the toxicological safety of food processed with ionizing energy is gradually changing. Whereas the emphasis was once almost completely on animal feeding experiments, it now is gradually focusing on the radiolytic products.

Much research has been done on radiolytic products. As a result, it now is possible to predict the specific nature and approximate yields of many radiolytic products when different foods are processed with specific amounts of ionizing energy under specified conditions. Therefore, it has not been found necessary to examine each food to be processed and each condition of applying the ionizing energy as a separate case requiring complete independent studies. Although the occurrence of "unique" radiolytic products that might affect the safety of specific foods has been conjectured, no such compounds have ever been found.

A Joint Expert Committee on the Wholesomeness of Irradiated Food, representing the World Health Organization, the International Atomic Energy Agency, and the Food and Agriculture Organization of the United Nations, concluded in 1981 that no hazard is involved in processing any food with ionizing energy up to an average dose of 10 kilograys. The U.S. Food and Drug Administration (FDA) thus far has been more conservative, but it has issued a regulation allowing the use of as much as 30 kilograys for spices and dry condiments, which yield only small amounts of radiolytic products and constitute only a small portion of the total diet.

The Joint Expert Committee withheld judgment on the safety of doses of ionizing energy exceeding 10 kilograys, pending completion of comprehensive studies on chicken meat and ham that were then in progress. These studies now have been completed and evaluated, and no significant unfavorable effects were concluded to have resulted from the high doses used.

The use of relatively large amounts of ionizing energy to sterilize meat causes losses of certain vitamins and produces radiolytic products that impart a distasteful flavor and unpleasant aroma to the meat if the processing is done at room temperature in the presence of atmospheric oxygen. Although the compounds responsible for the flavor and odor are not hazardous, their formation can be avoided and the vitamin losses can be greatly reduced by freezing the meat and processing it while frozen in evacuated containers. When the processing with ionizing energy is done in this way, the loss of vitamins is often less than that encountered when meat is processed by other methods in standard use today.

Nutritional Quality

Experiments on the response of experimental animals and humans have been conducted to investigate the nutritional quality of food treated with ionizing energy under conditions that could be used commercially. Tests to determine the utilization of the nutrients and clinical tests of the subjects disclosed no unfavorable effects of foods processed with ionizing energy relative to comparable foods processed by conventional means.

When carbohydrates are treated with ionizing energy, there is some splitting of complex compounds, such as pectin and cellulose, to form smaller molecules. Pectic substances tend to lose their gelling power, an indication of the shortening of the molecular chains. Although ionizing energy may cause changes in the physical and chemical properties of high-carbohydrate foods, such as grains and some vegetables, these changes are not nutritionally significant. In experiments on the availability of complex carbohydrates to test animals and on the growth and reproduction of the animals, no significant effects of processing the carbohydrates with ionizing energy have been found. When certain foods high in sucrose (table sugar) were treated with high (sterilizing) doses of ionizing energy, however, the products resembled heat-caramelized sucrose in odor and appearance, and the growth of rats was decreased in feeding trials. The same was true of rats fed heat-caramelized sucrose.

The main reactions caused by ionizing energy in fats are oxidation, polymerization, decarboxylation, and dehydration. The chemical changes are reduced by processing the products when they are frozen and packaged in evacuated containers that exclude light and oxygen.

No effect on digestibility resulting from treating fat-containing foods with ionizing energy was found in experiments with humans, dogs, and rats. In one experiment with dogs, the absorption of lard processed with ionizing energy was slower than that of unprocessed lard, perhaps because the lard was processed in packages that did not exclude oxygen and, hence, did not prevent oxidation during processing.

The major changes in the protein fraction of foods as a result of processing with ionizing energy are the cleavage of large protein molecules into smaller protein molecules that upon digestion yield the same amino acids as the original proteins. No effects of major nutritional significance have been found.

Many experiments have been done on the effects of ionizing energy on vitamins. Some vitamins appear to be affected very little by ionizing energy. Vitamin K, for example, appears to be relatively stable. A significant proportion of the vitamin C may be changed to dehydroascorbic acid, but this compound has almost the same vitamin C value as ascorbic acid, which is vitamin C itself. Tocopherols, which are antioxidant compounds with vitamin E activity, seem to be especially sensitive to ionizing energy in the presence of oxygen, as would be expected from their antioxidant properties. Vitamins are sensitive also to processing by heat. Research on vitamin B_6 has shown less destruction of this vitamin in products sterilized by ionizing energy than by heat. Vitamin retention in food is greatest when the processing with ionizing energy is carried out at low temperatures in the absence of oxygen.

At one time, FDA hypothesized that ionizing energy might form antivitamin compounds in food. Although attempts have been made to detect the existence of such compounds in food treated with ionizing energy, no definite antivitamin effect has been discovered.

Microbiological Safety

Exposing food to ionizing energy delays spoilage and improves the hygienic quality by eliminating or reducing the numbers of organisms that cause disease or spoilage. When doses below 10 kilograys are used, not all the organisms are eliminated, and there has been some concern about potential adverse effects on safety. Among these concerns are (1) the microorganisms may become more resistant to ionizing energy through selection or mutation, (2) the pathogens may increase in virulence, (3) unusual spoilage characteristics may result because of changes in the normal flora, and (4) changes in physiological characteristics of the organisms may make it difficult to identify them. Research has not supplied evidence to indicate that any of these concerns are valid.

Substerilizing doses of ionizing energy do not provide assurance that growth of molds and production of aflatoxin and other mycotoxins will not occur in cereal products with moisture content exceeding 13% when they are stored at high relative humidity. However, no added hazards have arisen from alteration of molds during treatment with ionizing energy. In fact, there is evidence that preformed aflatoxin in food can be detoxified by using high doses of ionizing energy.

No known microbiological safety problems are produced when moist foods, such as fresh meats and poultry, are treated with amounts of ionizing energy less than 10 kilograys, provided that the foods are properly refrigerated. By proper selection of ionizing energy doses in the substerilizing range and use of refrigeration, not only can shelf life be extended, but also a major reduction or elimination of disease-causing organisms, such as salmonellae, shigellae, coliforms, staphylococci, trichinae, *Yersinia enterocolitica, Campylobacter jejuni,* and *Aeromonas hydrophila*, can be achieved. Fresh fish, however, must be kept refrigerated at a temperature below 38° F (3.3° C) to avoid the development of *Clostridium botulinum* Type E if ionizing energy exceeding 1 kilogray has been used to reduce the population of spoilage microflora.

In using high doses of ionizing energy, the principal objective is to sterilize the product. This is achieved by using heat and ionizing energy in turn. The food is brought to a temperature of 158 to 176° F (70 to 80° C) to inactivate autolytic enzymes. The time and temperature conditions used are sufficient to kill parasites and inactivate or sensitize to ionizing energy the known food-borne viruses and ionizing-energy-resistant microorganisms, such as *Moraxella-Acinetobacter* and *Micrococcus radiodurans.* The heat-treated food is then sealed under vacuum, frozen, and exposed to ionizing energy, using as a minimum the experimentally predetermined dose needed to reduce in numbers a theoretical population of one trillion viable spores of *Clostridium botulinum* Types A and B per can or package of food to a population of less than one spore per container. A population of one trillion spores per container far exceeds any natural population. Thus, with the low populations found in practice, the products would retain no viable spores. The dose of ionizing energy required to produce this effect provides as high a margin of microbiological safety for sterilization of foods as does the well-established thermal sterilization process.

Some Salient Points

1. Exposing foods to ionizing energy eliminates or reduces the numbers of organisms that can cause disease

or spoilage. As a result, the hygienic quality is improved, and the shelf life of the foods is increased. If enough ionizing energy is used, the foods are made sterile.

2. Dried vegetables respond well to sterilization with ionizing energy, but some fresh products are softened and discolored. Fresh fruits, vegetables, and meats must be blanched before sterilization with ionizing energy because they contain enzymes that continue to break down the molecules of these foods even after such sterilization if the foods are stored without refrigeration. Blanching inactivates these enzymes.

3. By breaking down certain proteins and carbohydrates into smaller molecular units, ionizing energy may enhance food quality in some instances by improving the texture, decreasing the cooking time, inhibiting the sprouting of stored tuber or bulb crops, and delaying the ripening of some fruits.

4. The amount of ionizing energy required to produce the desired effects in food processing and utilization is generally far less than the amount of heat energy expended in cooking.

5. Tests with animals and humans have disclosed no confirmed adverse toxicological or microbiological hazards from treating foods with the quantities of ionizing energy needed to control pests and microorganisms or to improve the quality.

6. No measurable radioactivity is produced in foods treated with ionizing energy at internationally approved energy levels.

7. Approximately 6 of each 10 million chemical bonds present in food are broken per kilogray of ionizing energy absorbed.

8. The radiolytic compounds produced by treating foods with ionizing energy are similar to those occurring in unprocessed foods and in foods processed by conventional methods.

9. Although compounds that cannot be found in unprocessed food may be identifiable in food that has been processed with ionizing energy, the compounds found have always been identifiable also in the same food that has been processed by other accepted methods (such as cooking), in other foods, or both. No compounds that are unique to food processed with ionizing energy have been found in 30 years of research.

10. No significant adverse effects on the nutritional quality have been found in foods processed with ionizing energy relative to foods processed by conventional means.

11. Ionizing energy has not been found to produce substances with antivitamin effects in foods.

12. There is a sharp distinction between producing nuclear energy in a nuclear reactor facility and exposing food to ionizing energy in a processing facility. In a reactor facility, the energy produced is based upon fission of uranium nuclei by neutrons. In a food processing facility, there is no uranium or other fissionable material and no source of neutrons to produce fission. The energy levels involved in processing food by ionizing energy are relatively low. They produce little heat, and the energy emanates from solid materials or from special apparatus that emits the energy only when it is turned on. There are no hot fluids or gases that could generate an explosion, no radioactive gases, liquids, or solids that could be widely disseminated in the surrounding environment, and no possibility for use of the sources to produce atomic bombs. The safety requirement is that of sufficient shielding of the sources to prevent undue exposure of the humans employed in the food processing facility. The technology of food processing by ionizing energy will be covered in some detail in a succeeding report. The facilities are similar to those in which ionizing energy is used to sterilize medical products, such as surgeons' gloves and sutures. There are almost 200 such plants in operation worldwide.

Introduction

The value of ionizing energy in food preservation and processing results primarily from its capability of splitting some of the molecules that are essential to life and reproduction of organisms. At proper doses, it can split enough of the molecules in food spoilage and disease bacteria and other living organisms in food so the organisms are completely nonfunctional and the food is sterile. At lesser doses, it can kill enough of these unwanted organisms so the shelf life of the food is extended. At still smaller doses, it can modify the properties of living foods in desired ways, for example, by inhibiting the deterioration of stored potatoes by preventing sprouting, and by delaying the ripening of some fruits, such as papayas, bananas, and mangoes. With some foods, there are other beneficial effects on quality that are not related to life processes.

The research on the use of ionizing energy in food preservation and processing that has been conducted in the United States and abroad for more than 40 years has attempted to provide answers to two questions. First, how can the desired objectives be accomplished without producing side effects of enough importance to affect adversely the apparent suitability of the food for human consumption? And second, is the treated food that appears superficially to be suitable for human consumption actually suitable in all significant respects?

The second of these questions has required the major effort because of the complexity of foods and their effects and because it is impossible to prove that no risk exists or no unfavorable effect will result from consumption of any food, whether or not it has been processed with ionizing energy. All that can be done is to investigate in detail the many possibilities and assess the results in a reasonable context.

The term commonly used to describe the suitability of food for human consumption is wholesomeness. As applied to food, the term wholesomeness means healthful. For food treated with ionizing energy, wholesomeness is generally understood to mean that harmful microorganisms and microbial toxins are absent, that the ionizing energy has not produced any measurable toxic effects or radioactivity, and that the food presents no significant nutritional deficiency relative to the same food that has not been treated with ionizing energy or has been processed by established methods. For foods that have absorbed only enough ionizing energy to extend their shelf life, the populations of some potentially harmful microorganisms may only be reduced. In some instances, of course, the treatment with ionizing energy does not assure wholesomeness, but merely alleviates the unfavorable condition in the original food.

This report reviews the scientific information available on wholesomeness of food processed with ionizing energy. A succeeding report will cover other important aspects of processing food by ionizing energy, including the technology, applications to different classes of food, ~~commercia~~lization, economics, and acceptance by consumers.

Three short CAST publications related to the wholesomeness of food processed by exposure to ionizing energy have been published recently under the titles, "Is Radiation a Food Additive?" (Coon and Josephson, 1984), "Are We Irrational About Irradiation?" (Coon et al., 1985a), and "Food Irradiation" (Coon et al., 1985b). These publications were produced in response to requests from several members of the U.S. Congress for information on the subject and the need of others for understanding about this technology for food processing.

Electromagnetic Radiation and Ionizing Energy

Electromagnetic radiation is a form of energy that moves through space at the speed of light with simultaneous variation of the electric and magnetic fields. Electromagnetic radiation in the visible spectrum provides the energy plants must have to grow and produce food products. Electromagnetic radiation in the infrared range has been used traditionally for broiling and baking. More recently, electromagnetic radiation in the microwave range has been utilized as a convenient source of radiant energy for cooking food quickly. Ultraviolet radiation is effective against the majority of bacteria and some molds and viruses; it is used in the food industry to kill airborne bacteria and bacteria on food surfaces.

Electromagnetic radiation occurs in a wide range of wavelengths. See Fig. 1. (The wavelength is the distance required for the electric and magnetic fields to go through one complete cycle and return to the original condition while travelling at the speed of light.) The various named regions of the spectrum range from radio waves, which have the longest wavelengths, through television, radar, microwave, and infrared radiation to light waves in the visible range, which have short wavelengths. From light waves, the spectrum continues through ultraviolet radiation, x-radiation, and gamma radiation in the very short wavelengths.

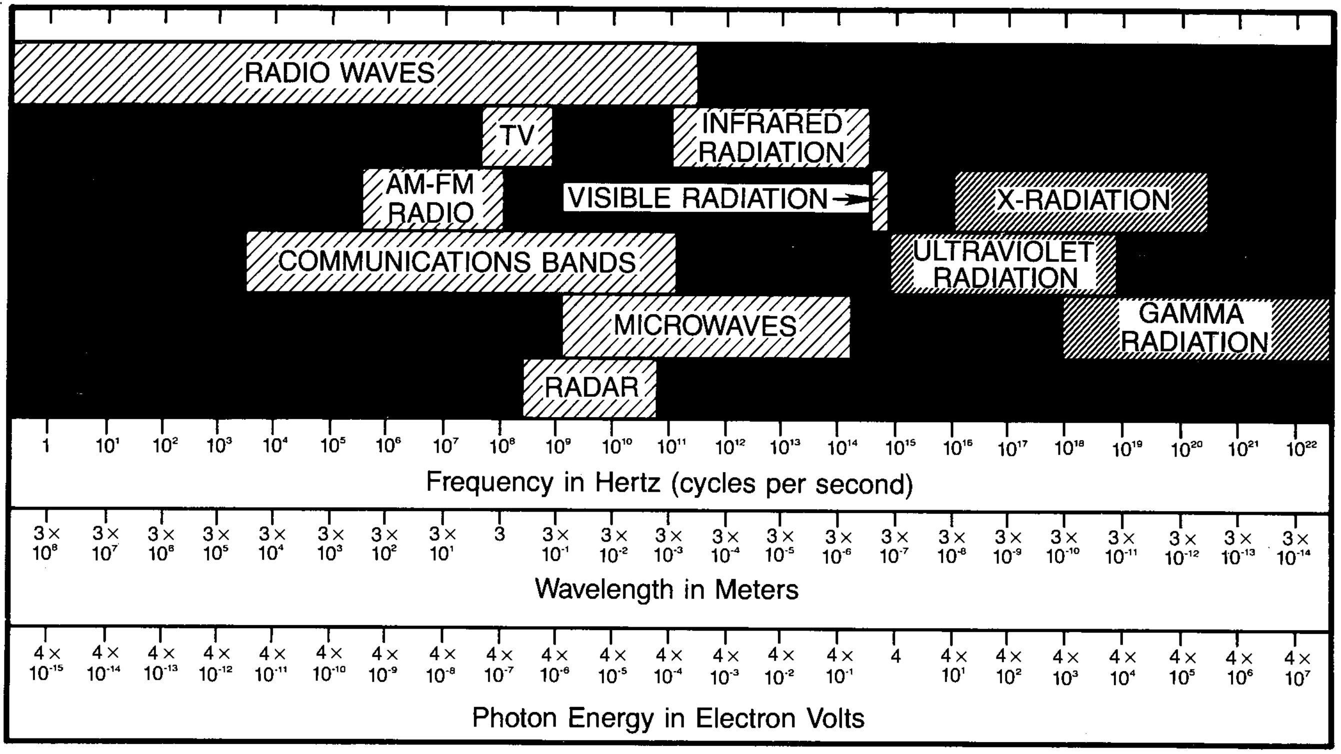

Fig. 1. The frequencies, wavelengths, and photon energies of the major part of the electromagnetic spectrum. The boundaries of the named segments are more or less arbitrary, and there is now some tendency to reduce the overlapping by defining the range between TV and infrared radiation as microwaves and the range between visible radiation and x-radiation as ultraviolet.

Electromagnetic radiation occurs in units called quanta or photons. The shorter the wavelength, the greater is the quantity of energy in one quantum or photon. When the quantity of energy in a quantum exceeds the energy that binds adjacent atoms in a molecule, the absorption of this energy by the molecule can break the chemical bond and cleave the molecule into smaller fragments that may be either electrically charged (ions) or neutral (free radicals). Visible light has this tendency to a small degree; it can break only the weakest bonds. Ultraviolet, x-ray, and gamma radiation are able to break the stronger bonds and even to expel electrons from atoms. They are known for this reason as ionizing radiation or ionizing energy.

The depth to which visible light and ultraviolet radiation penetrate in most solids is of the order of 1 micron or 0.00004 inch. X-rays and gamma rays penetrate deeply. Those with energies between about 0.15 and 4 million electron volts will penetrate about 30 centimeters (1 foot) of water. Fast charged particles, such as electrons, protons, and alpha particles, also have enough energy to cleave molecules as they penetrate foods. Accelerated electrons with an energy of 10 million electron volts will penetrate to a depth of about 4 centimeters (1.6 inches), but accelerated protons and alpha particles do not have enough penetrating power to be of practical value in food processing. Fast neutrons can cleave food molecules, but they are not permitted for food processing because they create radioactivity. (Cosmic radiation, received from outer space, consists of all these forms of radiation and many other fast particles.) A glossary of terms related to treatment of food with ionizing energy is found in Appendix I.

Ionizing Energy Level, Dose, and Effects

The energy level of individual energy units or photons, the dose or amount of ionizing energy absorbed by food, and the effects of the absorbed energy are all involved in the interaction of ionizing energy with food. The distinction must be appreciated to obtain a basic understanding of the subject.

The energy of individual photons is commonly expressed in electron volts. One electron volt is equivalent to 3.84 x 10^{-20} gram calorie or to 3.84 x 10^{-23} diet calorie of energy. Reference to the scale for photon energy in Fig. 1 will show that in moving from left to right the energy of one photon increases tenfold between succeeding scale marks. The amount of energy delivered by one photon increases as the wavelength decreases. Individual photons in the band of visible radiation have energy less than 3.1 electron volts, whereas the maximum energy of a single photon of gamma radiation from cobalt-60, one of the two standard sources for food processing, is 1.33 million electron volts. Therefore, the quantity of energy inherent in the most energetic photon of gamma radiation from cobalt-60 is more than 1,330,000/3.1 or 429,000 times as great as that in 1 photon of energy in the range of visible light.

In practice, many photons of energy are involved. The dose or amount of energy absorbed is given by the product of the energy of one photon and the number of photons absorbed.

In this report, the dose or amount of ionizing energy absorbed by food is expressed in grays. One gray is equivalent to 0.24 gram calorie or 0.00024 Calorie (diet calorie) per kilogram of food (0.00024 Calorie per kilogram is equivalent to 0.0001 Calorie per pound). One kilogray is 1,000 grays.

To obtain equal doses of energy from electromagnetic radiations differing in wavelength requires more photons of long-wavelength radiation than of short-wavelength radiation. Equal doses, however, will not have equal effects if the energy of the individual photons differs. Photons with low enough energy cannot rupture chemical bonds no matter how many are absorbed if the rate of absorption is low enough to permit dissipation of the heat energy.

Natural Background Radiation

In their normal environments, humans are exposed continuously to radiation from the stars and the sun and to radiation produced when atoms of naturally radioactive elements in the body and the environment decay with release of ionizing energy. The dose of ionizing energy absorbed by humans is measured in units of sieverts. One sievert is the dose of ionizing energy that produces the same biological effect on humans as a dose of one gray from gamma rays or fast electrons.

Cosmic Radiation

Cosmic radiation, received from outer space, contributes to the human body a radiation dose of about 0.00028 sievert per year on the average at sea level (see Appendix III, Table 1). The dose increases with altitude. It is about 0.0005 to 0.0006 sievert per year at an altitude of 2,000 meters (6,600 feet) and about 0.03 sievert per year at 12,000 meters (39,000 feet), the height of air travel. Cosmic radiation increases with magnetic latitude, especially at higher elevations.

Terrestrial Sources

Radiation from naturally radioactive elements in the soil, rocks, walls of buildings, and atmosphere contributes a dose of about 0.00026 sievert per year on the average (see Appendix III, Table 1). The dose of ionizing energy received from terrestrial sources is usually in the range from 0.00018 to 0.0007 sievert. In coastal areas of Kerala in India, however, the average dose is about 0.011 sievert per year. In Guarapari, Brazil, and in Ramsar, Iran, the dose may be as much as 0.017 sievert per year. In small places within these areas, it may be as high as 0.17 to 0.43 sievert per year (Anonymous, 1977).

Foods

All foods are slightly radioactive and contribute an internal dose of about 0.00027 sievert per year, or one-third of the natural background radiation absorbed in the human body. Usually the principal contributor to this dose is potassium-40. This naturally radioactive form of the element potassium emits electrons (beta rays) from the nucleus when it undergoes radioactive disintegration or decay. In the red bone marrow (often considered one of the most radiation-sensitive parts of the human body), the activity due to potassium-40 is about 130 disintegrations per second per kilogram; that is, about 130 potassium-40 atoms undergo radioactive decay per second, each with release of an electron, per kilogram of tissue.

Other naturally radioactive forms of elements that emit electrons from the nucleus include rubidium-87, carbon-14, sodium-22, and hydrogen-3 (tritium). In food, and especially in water, are also trace amounts of elements such as radon and polonium that undergo radioactive decay by emitting helium nuclei (alpha particles) from the nucleus. Radon gas produced in soil and rocks dissolves in groundwater and is released from the water into the air. The radon then may be inhaled. The radiation emitted by radon and other emitters of alpha particles contributes about 0.001 to 0.0045 sievert per year to the lungs (see Appendix III, Table 1).

Health Effects

The health effects of background radiation are not known from direct observation. Rather, the effects are inferred from observations of effects of much higher doses of radiation. The inferences usually are based upon linear extrapolations from observed effects with known relatively high doses to a zero effect at zero dose. Such extrapolations suggest that the total background radiation may be responsible for about 0.3% to 1% of the total cancers in humans.

Linear extrapolations generally are considered to provide conservative estimates; that is, they overestimate the true effects. The proper extrapolation procedure is not known, however, and some scientists are of the opinion that linear extrapolations underestimate the risk.

Although the contribution of background radiation to the total number of cancers appears to be small, attention by the news media has kept it in focus. The subject remains popular.

Induced Radioactivity

In addition to the ionizing energy released from naturally radioactive elements, humans nowadays are exposed to ionizing radiation resulting from human activities. The several sources are discussed in the following paragraphs.

The detrimental effects of excessive doses of ionizing energy on human health have been known for many years. Hence, the possible uses of ionizing energy for the benefits they may confer have long been subject to careful scrutiny.

Miscellaneous Sources

The major use of induced ionizing radiation is in x-rays for medical and dental diagnosis and treatment. The average human exposure from this source is equivalent to about 40% of the background radiation. Minor sources include the nuclear power industry, which results in a human radiation dose less than 0.4% of the natural background ionizing radiation. The dose from aviation is equivalent to about 0.4% of the natural background ionizing radiation, and the dose from the fossil fuel industry is equivalent to about 0.04%. (Aviation is a factor because radiation received from extraterrestrial sources increases with altitude as a result of the reduced thickness of the protective layer of air.)

The fallout of radioactive materials from nuclear explosions in the atmosphere peaked in 1963. At that time, the ionizing energy emitted from this source amounted to about 13% of the natural background in the United States. This contribution has steadily decreased since most of the testing in the atmosphere was stopped in 1962, and it is now less than 4% of the natural background (Anonymous, 1980).

Food Processing

A fundamental premise in the use of ionizing energy for food processing and pest control in foods is that it must contribute no measurable amount of radioactivity to the food treated. Radioactivity can be induced if the energy level is great enough. As a result of extensive research on this subject, the Joint Expert Committee on Irradiated Foods of the Food and Agriculture Organization of the United Nations (FAO), the International Atomic Energy Agency (IAEA), and the World Health Organization (WHO) (WHO, 1965, 1981b) recommended 10 million electron volts as the maximum permissible energy for electron generators and 5 million electron volts for x-rays. These maximum energy levels are accepted by health authorities in the United States (FDA, 1984) and by the international Codex Alimentarius Commission (CAC, 1984). According to the Joint (FAO-IAEA-WHO Expert Committee (WHO, 1965), these energy limits are conservative, and in special cases it may be reasonable to permit slightly higher limits. The FAO-IAEA-WHO Joint Expert Committee did not specify a maximum energy level for gamma rays because neither of the two approved sources (cobalt-60 and cesium-137) induces measurable radioactivity in food at any dose. The energy levels of the gamma rays from these sources are 1.33 million electron volts for cobalt-60 and 0.66 million electron volts for cesium-137.

Experimentally, no measurable radioactivity was induced in chicken meat products processed with electrons at energies of 10 million electron volts at doses as great as 68 kilograys in the U.S. Army-USDA wholesomeness studies listed in Appendix II. No measurable radioactivity was induced in beef sterilized with 71 kilograys of ionizing energy.

The sensitivity limit in the best direct measurements is usually about 1% of the natural radioactivity in the food; that is, the minimum increase in radioactivity that can be detected reliably in direct measurements is about 1% of the natural radioactivity. Estimates that provide far greater sensitivity have been made in special indirect ways. A summary representation of such data is shown in Fig. 2. A study of this figure indicates that the maximum level of ionizing energy recommended by the Joint FAO-IAEA-WHO Expert Committee (10 million electron volts) resulted in an estimated increase in radioactivity of a disintegration of one atom per week per kilogram of meat in comparison with a disintegration of more than 100 naturally radioactive atoms per second per kilogram of meat and compared with a disintegra-

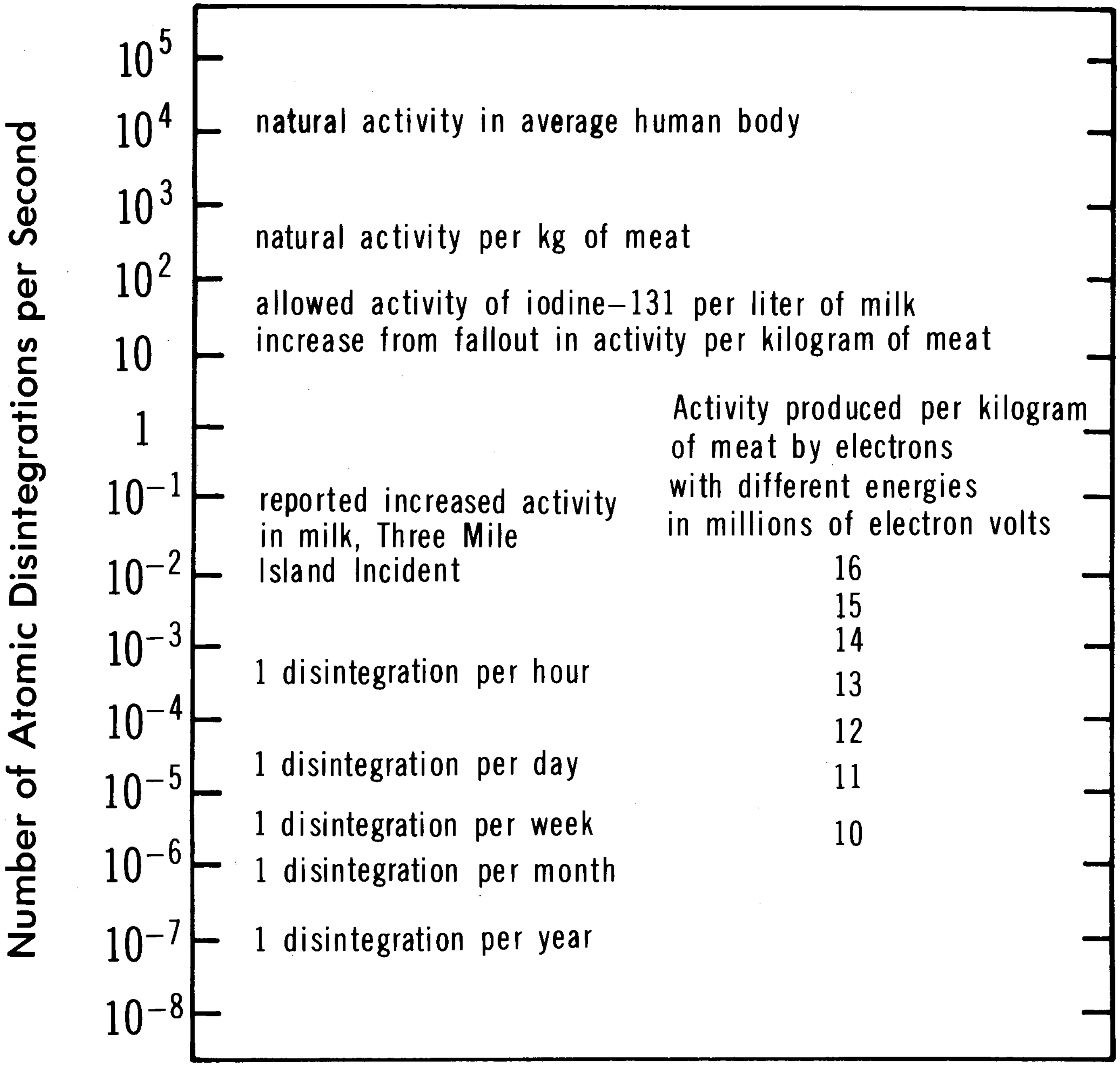

Fig. 2. Natural and induced radiation background from various sources, with values expressed in numbers of atomic disintegrations per second. The inset figures are for meat stored for 3 months after treatment with 32 kilograys of ionizing energy from electron beams at different energies (Becker, 1979).

tion of about 10,000 naturally radioactive atoms per second in the average human body weighing 70 kilograms (or more than 140 disintegrations per second per kilogram of human tissue). The estimated increase in radioactivity of meat resulting from radioactive fallout amounted to 10 atomic disintegrations per second per kilogram of meat.

The increased risk of cancer from the induced radioactivity caused by treating meat with accelerated electrons thus is negligible. If the same linear extrapolation that was used to obtain an estimate of an increase of 0.3 to 1% of the cancers from natural background ionizing energy is used to estimate the contribution of the induced radioactivity of food to human cancer, one finds that the contribution amounts to 0.000000003 to 0.00000001%. This assumes that all food has the same natural radioactivity as meat and that all food is processed with the maximum permissible energy at sterilizing doses.

Radiolytic Products

The terms "ionizing energy" and "ionizing radiation" have been used to describe the x-rays, gamma rays, and high-speed electrons that may be used in food processing because as these forms of energy enter and are absorbed by the living organisms in food, they dislodge electrons from some of the molecules, splitting the molecules and producing ions (electrically charged species) and other uncharged species that are highly reactive and soon react to form more stable molecules. This capacity of ionizing energy makes it useful for controlling the organisms that cause spoilage and destruction of food and the organisms that cause diseases or toxicoses in humans. When enough of their vital constituent molecules have been split, the organisms are no longer functional.

At the same time, the ionizing energy splits a few of the molecules of the food itself. The stable molecules thus produced are referred to as radiolytic products. Originally there was concern over whether some of these products might be different from products either found naturally in the food or formed upon processing food with other accepted means and whether these products would be detrimental in human diets.

Research on radiolytic products has been carried on for more than 30 years to discover their nature, the amounts formed, their relation to the nature of the food and the amount and form of ionizing energy absorbed, and the effect of conditions of processing. The scientific literature on this subject is extensive. The research has been conducted in various countries, and because of the potential importance of ionizing energy for food processing, the Food and Agriculture Organization of the United Nations, the International Atomic Energy Agency, and the World Health Organization all have been involved.

Low and Medium Doses of Ionizing Energy

By convention, treatments of food with amounts of ionizing energy up to 10 kilograys are considered low to medium doses. Much of the research on radiolytic products from doses in this range has been reviewed in the proceedings of symposia (Josephson and Merritt, 1972; Merritt, 1978) and books edited by Elias and Cohen (1977, 1983). From this research, several basic principles have emerged:

1. Roughly 1 molecule is changed per 100 electron volts of energy transferred to food[1].
2. The ionizing energy absorbed by a food is distributed among the various components in proportion to their weight fractions.
3. The radiolytic products of individual major food components, such as proteins, carbohydrates, and fats, are not affected by the other food components present.
4. A given major food component, such as a fat, produces the same kinds of radiolytic products independently of the food in which it occurs. (See Appendix III, Table 2, for a key to information on different food components.)
5. All of the known radiolytic products derived from major food components are found in unprocessed foods or in foods subjected to other accepted types of processing, such as cooking.

As a consequence of the foregoing principles, it is possible to predict the general nature and approximate yields of radiolytic products when different foods are treated with specific amounts of ionizing energy. Therefore, it is not necessary to examine each as a separate case.

The Joint Expert Committee on the Wholesomeness

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[1] The significance of this principle in terms of the degree of chemical change produced in food by ionizing energy may be appreciated from calculations indicating that for each kilogray of ionizing energy absorbed by 1 kilogram (2.2 pounds) of food, approximately 6 chemical bonds are broken in each 10 million chemical bonds present. This estimate is based upon (a) the fact that 1 kilogray is equivalent to 6.25×10^{21} electron volts of absorbed ionizing energy per kilogram (see Appendix I), (b) the approximation (FDA, 1980, 1986) that 1 chemical bond is broken per 100 electron volts of absorbed energy, and (c) the approximation that 1 kilogram of moist food contains 1×10^{26} chemical bonds.

of Irradiated Food, representing the World Health Organization, the International Atomic Energy Agency, and the Food and Agriculture Organization of the United Nations (WHO, 1981b), reviewed the available information from the standpoint of applicability to practice. The Committee's view was that the information on radiolytic compounds and toxicology of the products available at that time was ample to conclude that no hazard was involved in treating any food with ionizing energy up to an overall average dose of 10 kilograys and that further toxicological testing of foods so treated was no longer required. The Joint Expert Committee deferred its decision concerning foods treated with ionizing energy at doses exceeding 10 kilograys until the data from two comprehensive wholesomeness studies then in progress in the United States and the Netherlands were available.

The U.S. Food and Drug Administration (FDA) was more conservative (FDA, 1980, 1984; Brunetti et al., 1980). The FDA committee, which submitted its report in August 1980, 3 months before the meeting of the Joint Expert Committee, noted that doses of 1 kilogray or less yielded concentrations of radiolytic products so low that they were nearly impossible to detect. The FDA committee concluded that food treated with 1 kilogray of ionizing energy is safe for human consumption even if it constitutes a substantial portion of the diet.

Concurrently, the FDA committee concluded that a food such as a spice that comprises no more than 0.01% of the diet could be treated with ionizing energy up to 50 kilograys without any specific toxicological testing because such a food would contribute lesser amounts of radiolytic products to the diet than would a major dietary component receiving 1 kilogray of ionizing energy. The use of 30 kilograys for dried spices and vegetable seasonings has been approved recently (FDA, 1986).

High Doses of Ionizing Energy

Most applications of ionizing energy to food processing involve low to medium doses, conventionally those less than 10 kilograys. Higher doses are needed to assure sterilization, which involves inactivating the resistant spore forms of bacteria in addition to the more easily inactivated vegetative forms. Sterilization is required if moist food products are to be kept safely for extended periods of time without refrigeration.

Sterilization by ionizing energy is not feasible for fresh fruits and vegetables because it softens and discolors the tissues. Moreover, fresh fruits, vegetables, and meats contain enzymes that continue to act and break down the molecules in these foods even after sterilization with ionizing energy. Therefore, mild heat treatment (blanching) is necessary to inactivate these enzymes if such foods are to be preserved without refrigeration by sterilizing them with ionizing energy. Dried vegetables, such as soup mix ingredients, respond well to sterilizing doses of ionizing energy, as did the cooked vegetables tested in the Army's wholesomeness studies conducted between 1955 and 1965.

This section is concerned with the chemical consequences of using high doses of ionizing energy on meats. The reason for primary emphasis upon the chemical aspects is the shift in scientific thinking that has occurred in recent years regarding means of evaluating the safety of foods treated with ionizing energy. The standard approach to safety evaluation in the past has been feeding studies. Because of the limitations to be noted subsequently regarding the utility of feeding studies for safety evaluation, together with advances in means of identifying radiolytic products, measuring their yields, and predicting their occurrence, increasing emphasis now is being given to chemical evaluations.

According to FDA (1980), the total yield of radiolytic products is an important consideration in assessing the safety of foods processed with amounts of ionizing energy in excess of 10 kilograys. Determining the safety of treated foods involves in part verifying whether the products formed are safe and, if chemical evaluations are to be used, whether the products can be predicted. These matters are discussed in the following paragraphs.

Safety of Radiolytic Products

The safety of the radiolytic compounds formed is perhaps of first concern. Appendix III, Table 3, lists a number of different classes of volatile food compounds that are generally recognized as safe. Compounds in these same classes are formed from foods as radiolytic products. These radiolytic products thus may be inferred to be safe. Appendix III, Table 3, is derived from a comprehensive survey made by Josephson and Merritt (1972) and the Central Institute for Food and Nutrition Research in The Netherlands (TNO, 1977) in which the findings reported in more than 1,000 research papers were reviewed.

Among less volatile compounds, for example, the dioldiesters detected among radiolytic products in meats are found among plant lipids (Bergelson et al., 1964; Vaver et al., 1964). Similarly, long-chain hydrocarbons are commonly found in the waxy cuticles of fruits, such as apples, pears, and berries (Meigh, 1964). And complex fatty compounds that form in heated fats are present in concentrations greatly exceeding those formed from the reactions of molecular fragments, produced upon absorption of the ionizing energy, with each other and with other fat molecules in the food (Elias and Cohen, 1983; Nawar, 1983b). According to research by Nawar (1972, 1983a, 1983b), the extent to which fats decompose is less with relatively high doses of ionizing energy than with exposure to normal cooking or frying temperatures.

The Federation of American Societies for Experimental Biology appointed a committee that was asked to evaluate the safety of the known radiolytic compounds in beef. After studying the available information, the committee issued three reports (FASEB, 1977, 1979a, 1979b) in which the conclusion was as follows:

> The Committee has examined the available evidence on the possible health effects of the various volatile compounds identified in beef prepared by low-temperature irradiation preservation. In its opinion, the data do not demonstrate or suggest that the volatile compounds present any significant increment of hazard to the public from the normal consumption of beef prepared in this way.
>
> The Committee reaffirms its original conclusion that there is no evidence to suggest that the volatile radiolytic compounds found in beef irradiated in the described manner would constitute a hazard to the health of the consumer.

Predictability of Radiolytic Products

For the results of specific studies of radiolytic products produced from the components of a given food to be useful in predicting the nature and concentration of radiolytic products produced from these same components in other foods with various doses of ionizing energy, certain information is needed. The dose of ionizing energy, the proportions of the components in the various foods, and certain relationships must be known. And the physical and chemical conditions of irradiation, for example, the temperature and the availability of atmospheric oxygen, must be the same.

First, the relation between the dose of ionizing energy and the amounts of radiolytic products formed must be known (see Merritt, 1984). An example of experimental findings with various radiolytic products formed in beef with doses of ionizing energy ranging from 20 to more than 140 kilograys is shown in Appendix III, Fig. 1. The results indicate that, as with low doses, the amounts of radiolytic products increase linearly with the dose of ionizing energy absorbed.

Second, the relation between the proportions of individual food components in different lots of a given food and the quantities of radiolytic products formed from these components must be known. Merritt et al. (1978) processed different lots of beef of fat content ranging from 5 to 35% with 37 kilograys of ionizing energy at -13° F (-25° C) and made analyses for the same group of radiolytic products shown in Appendix III, Fig. 1. The yields of radiolytic products increased linearly with the fat content, producing results similar to those in Appendix III, Fig. 1.

Third, the relation between the proportions of individual food components in different kinds of foods and the quantities of radiolytic products formed from these components must be known (see Merritt et al., 1985). Appendix III, Fig. 2, shows, for example, that the quantities of hexane and hexene produced as a result of processing beef, chicken, ham, and pork with ionizing energy under identical conditions increased linearly with the content of fat in the various meats.

And fourth, the various radiolytic products from a given food component must be produced in similar ratios when different products are processed under given conditions. This requirement also is illustrated by Appendix III, Fig. 2.

The experimental findings included as examples in the preceding paragraphs indicate that prediction is feasible. Moreover, because of the linear relationships that exist, the prediction is relatively simple.

According to current understanding, radiolytic products result from precursors. Some of the products, such as hydrogen gas, may be almost completely nonspecific because all organic molecules in food except carbon dioxide contain hydrogen atoms. Some radiolytic products, however, are specific to a class of precursors, and some appear to be specific to the particular molecular structure of the precursor.

For example, hexane and hexene, analyses for which are shown in Appendix III, Fig. 2, are radiolytic products derived from a broad class of precursors — fats. Fats are chiefly the glyceryl esters of long-chain "fatty" acids. Analyses showed that palmitic, palmitoleic, stearic, oleic, and linoleic acids constituted 91 to 96% of the fatty acids in the fats of the ham, chicken, pork, and beef from which the data in Appendix III, Fig. 2, were derived. The hexane and hexene molecules are six-carbon chains that are shorter than those of all the fatty acids named and thus are derivable from all of them. This is part of the theoretical explanation for the observation in Appendix III, Fig. 2, that hexane and hexene were produced in small quantities in an approximately constant ratio as radiolytic products of the four meats studied and that the quantities produced depended upon the fat content of the meats.

An example of greater specificity is the radiolytic product heptadecadiene derivable from linoleic acid, a specific fatty acid found in combined form in certain fats. Heptadecadiene is produced from the linoleic acid component primarily by a series of steps involving the splitting-off of a 17-carbon fragment and the acquiring of a hydrogen atom to form the stable molecule. Hence, the more of the linoleic acid component is present in the fat, the more heptadecadiene will be formed. The specificity of linoleic acid for formation of heptadecadiene during processing with ionizing energy is indicated by the results of an investigation by Merritt et al. (1985) in which chicken and beef were processed under identical conditions. The chicken fat contained 26.1% linoleic acid among the fatty acid components, but beef fat contained only 3.8%. The results showed that five times as much heptadecadiene per kilogram of fat was found as a radiolytic product of chicken than of beef. Although this specific difference in precursors between chicken fat and beef fat had an important bearing on the production of heptadecadiene, the precursor is of widespread occurrence in oils produced by plants and is present in the grains used as a major component of poultry feeds. Poultry also may receive a blended animal-vegetable fat that contains much linoleic acid. Beef cattle, on the other hand, are fed mostly products other than grain. Moreover, part of the linoleic acid (an unsaturated fatty acid) in the diet is saturated during the first stage of digestion by the bacteria in the rumen, so that is is no longer linoleic acid when absorbed by the animals.

Thus, there is a commonality among the radiolytic products in foods of a given class owing to the common occurrence of the precursor molecules. The same radiolytic products are found, but the proportions vary with the proportions of the precursors.

A condition of processing that is of special importance where high levels of ionizing energy are used with meats is the presence or absence of oxygen in the atmosphere. A great deal of research has been stimulated by this effect, noted by Merritt (1966). This research has shown that some of the unstable neutral molecular fragments formed upon absorption of ionizing energy react readily with oxygen to produce stable molecular products. Although these products are generally alcohols and carbonyl compounds that are not hazardous, they impart a distasteful flavor and unpleasant aroma to the meat. As a consequence, current practice is to process the meat after it has been sealed in an evacuated container. In the absence of oxygen, the molecular fragments undergo other reactions to produce radiolytic products that do not impart adverse sensory properties.

The temperature of processing also is important. Meats, poultry, and fish are ordinarily processed in the frozen condition because the high doses of ionizing energy needed to achieve sterility have unfavorable effects on some vitamins (principally thiamine and vitamin E) and on the sensory qualities of these products if the processing is done at room temperature. The reason for the temperature effect is that the sphere of influence of the molecular fragments produced when a unit of energy is absorbed by a molecule is much smaller in a solid medium than in a semisolid or liquid medium. In a solid medium, some of the fragments recombine to form the original molecule. Processing temperatures of -4 to -40° F (-20 to -40° C) have been found to be the best compromise for producing a sterile product, while limiting the decrease in vitamin content, the development of undesirable odors and off-flavors, and the cost.

Predictions of the effects of dose of ionizing energy and composition of the substance processed are the most precise and the most useful. Because of the oxygen effect, processing preferably is done in the absence of free oxygen, and no attempt is made to predict the effect of different levels. Similarly, foods commonly are processed while unfrozen or frozen to specific temperatures as dictated by the dose of ionizing energy needed and the sensory qualities of the products, with little or no attempt to predict the effects of a range of temperatures.

A large amount of research has been conducted on the nature, mechanisms of formation, and predictability of radiolytic products. For further information on these subjects, see particularly the summary papers by Merritt and Taub (1983), Taub (1981, 1983, 1984), and Taub et al. (1976, 1979, 1980).

The validity of the mechanistic concepts developed in this research, as they pertain to the stepwise reaction of fragment ions and radicals, is illustrated by the results of an investigation of the radiolytic products produced when the fat known as tripalmitin, which contains three molecules of palmitic acid in combination with one molecule of glycerol, was treated with ionizing energy. Merritt and coworkers (reported by Merritt and Taub, 1983) showed that in addition to molecular hydrogen the major products predicted and found were, in descending order of amount, (a) palmitic acid, a common fatty acid, (b) pentadecane, a hydrocarbon, and (c) the combination product of an intact tripalmitin molecule with a molecular fragment resulting from the energy-induced loss of one molecule of palmitic acid from the original fat molecule. These stable products are a predictable consequence of the initial cleavage of the weakest or most susceptible bonds and of the eventual formation of the strongest or most preferred bonds. This investigation and others (e.g., Merritt et al., 1983) demonstrate that, despite the seeming potential for forming many different products, a small number of final products accounts for most of the chemical changes found.

FDA has recognized these principles governing the formation of radiolytic compounds, as evidenced by the conclusion that "Toxicological data obtained from a given irradiated food item may be applicable for another irradiated food in the same generic class" (that is, a food with similar chemical composition) (FDA, 1980). The FDA report noted further that "safety data collected from food irradiated at high doses are applicable to members of the same generic class receiving a lower dose."

"Unique" Radiolytic Products

The preceding paragraphs have reviewed the implications of the first of two factors that FDA (1980) postulated to be of prime importance in wholesomeness (safety) evaluation of foods treated with ionizing energy, namely, the probable total yield of radiolytic products. The discussion in the preceding paragraphs showed how the basic concepts relating to radiolytic products can be used in assessing the wholesomeness.

FDA (1980) was satisfied that food processed with 1 kilogray or less of ionizing energy was safe and that food produced with higher doses also was safe for most of the radiolytic products because the processing would "simply increase the amount of food constituents already present." On the other hand, concern was expressed about what were called "unique" radiolytic products, defined as "substances not found in the unirradiated food." On the basis of its definition, FDA estimated from some empirical data that "it is reasonable to assume that the URPs [unique radiolytic products] constitute 10 percent or less of the total radiolytic product yield." FDA (1986) later changed its definition of unique radiolytic products to "substances not known to be present in nonirradiated food." This definition is far broader than the original definition because it includes all foods, both with and without processing by means other than ionizing energy.

Scientists in the field use a somewhat similar but more conservative definition for unique radiolytic products. They take unique radiolytic products to be compounds that are formed by treating foods with ionizing energy, but are not found normally in any untreated foods and are not formed by other accepted methods of food processing. On the basis of this definition, no unique radiolytic compounds have been found in 30 years of research. Compounds produced in specific foods by ionizing energy have always been found in the same foods when processed by other accepted methods or in other foods. FDA (1980) recognized that this might be the situation and that what it defined as unique radiolytic compounds might in fact not be unique at all, stating that "It is quite possible that radiolytic compounds now classified as unique in irradiated foods also occur in foods which have been processed by conventional thermal methods."

Nonetheless, for safety's sake, FDA (1980) recommended additional nonmammalian tests and mammalian feeding tests for foods treated with doses of ionizing energy exceeding 1 kilogray as a basis for assuring the wholesomeness of foods thus processed for human consumption. The rationale for this recommendation was that although the amount of the unique radiolytic products (if any existed) would be negligible at doses of 1 kilogray or less because the total amount of radiolytic products was so small, this might not be true at high doses of ionizing energy.

The nonmammalian tests recommended included, as a minimum, tests for gene mutations in bacteria, gene mutations in cultured mammalian cells, DNA (deoxyribonucleic acid) repair in mammalian cells, and recessive lethal mutations in the fruit fly. The mammalian tests included 90-day feeding studies with a rodent species and a nonrodent species. The processed food would be considered acceptable if both sets of tests indicated that the processing had no unfavorable effect, but additional testing would be required if either or both showed an unfavorable effect.

The results of tests of the type called for by FDA are summarized in the following section. Some of these tests predated both research on the chemistry of radiolytic products and the FDA recommendations.

Feeding Studies of Toxicological Safety

In feeding studies of toxicological safety, such as would be done with a chemical food additive, the standard experimental approach is to add the proposed additive to a test diet in different quantities from zero to a large excess, which may produce readily measurable adverse effects in the experimental animals to which the test diet is fed. The magnitude of each measured response of the animals is plotted against the dose of the chemical to find a "no effect" level, which is the maximum dietary concentration that produces no measurable adverse effect. The no-effect level then is divided by an arbitrary safety factor, usually 100, to obtain the maximum concentration that will be allowed in food.

The standard toxicological approach does not work for food processed with ionizing energy. When food is treated with ionizing energy, many chemical substances are produced in low and varied concentrations. Some of the substances may be unknown. Although one or more specific radiolytic products might be identified and added in different concentrations (as in toxicological studies) to determine their effects, other factors remaining the same, the radiolytic products cannot be added collectively to unprocessed food in different total amounts to determine their effect. Treating a food processed with ionizing energy as a chemical food additive and adding different amounts to a test diet is feasible experimentally, but essentially useless as a toxicological study because it is generally impossible to add enough of such a food for a meaningful test. Even a diet consisting wholly of a food processed with ionizing energy would not provide enough of an excess to qualify as a toxicological test. Varying the concentration of radiolytic products by varying the dose of ionizing energy is feasible to a degree, but not to the extent required for toxicological work.

The kinds of harmful effects looked for in foods processed with ionizing energy — effects on mortality, body weight, food consumption, behavior, pathologic changes, blood count and hemoglobin, urine composition, reproductive performance, birth defects in offspring, and genetic changes — are the same as those looked for in toxicological studies of chemical food additives. These effects can be measured in subjects receiving foods with and without processing with ionizing energy, but the differences between the values obtained in measurements on the subjects cannot be attributed directly to anything but the difference in treatment of the foods. This is true not only because of the various radiolytic compounds resulting from food processing with ionizing energy, but also because the test animals respond to the overall effects of ionizing energy. These include the possible effects on toxicity of the food that may result from destruction or formation of toxic substances, the effects on nutritive value that may result from changes in concentration of nutritive substances and changes in digestibility of the various components of the food, and the effects of differences in populations of microbial and other pests. The overall effect thus is made up of many possible individual components, the individual contributions of which cannot be evaluated from the overall effect.

Evaluating the wholesomeness of foods processed by forms of radiation used commercially is complicated by the same kinds of problems. These forms include the infrared radiation used in broiling and baking and the microwave radiation used in microwave processing. Only a limited amount of scientific literature is available on the wholesomeness of foods prepared by these methods. Information is available on ultraviolet radiation as a cause of skin cancer, but there has been essentially no concern about the fact that plants and grazing animals are exposed to ultraviolet radiation before they are used as food. Ultraviolet radiation has shorter wavelengths than visible, infrared, or microwave radiation. Like x-radiation and gamma radiation, it supplies ionizing energy. In fact, the ultraviolet, x-ray, and gamma ray portions of the electromagnetic spectrum overlap (see Fig. 1).

In contrast, considerable information is available on the use of other forms of ionizing energy — x-radiation, gamma radiation, and high-speed electrons — for food processing. The knowledge that has been developed about the basic phenomena involved in the interaction of ionizing energy with matter has been useful in predicting possible changes in the naturally occurring chemicals in foods and in assessing the safety of the products. The attention that has been accorded ionizing energy from x-rays, gamma rays, and high-speed electrons is no doubt in part a consequence of the potential importance of ionizing energy for food preservation and processing. Important also are the negative context in which nuclear energy is commonly portrayed and the Food Additives Amendment of 1958, in which ionizing energy was classed with food additives on the basis that it may affect the characteristics of food. The American Medical Association (1984) and Coon et al. (1985a,b) have commented on this matter. In addition to projecting the erroneous implication that ionizing energy is a substance instead of energy that disappears when the source is removed, the legal classification of food irradiation as a substance rather than a process has created an important scientific and regulatory problem. The requirement that the safety of food processing by ionizing energy be assessed and its use regulated by the same standards as are chemicals used as food additives is impossible to meet. The consequence has been an attempt to substitute large amounts of other kinds of evidence. The description of experiments to follow provides an overview of the findings of the research in this area.

General Scientific Studies

Barna (1979) reviewed the results of 1221 studies conducted up to 1979 on the wholesomeness of 278 different foods and feeds treated with ionizing energy. The earliest references were to animal feeding studies carried out by Ludwig and Hopf (1925) and Narat (1927). He concluded that "neither stimulative nor adverse effects of the consumption of irradiated food are consistent, unambiguous and reproducible. Neither can specific effects be related to a given food, group or level of radiation dose." He also pointed out the technical inadequacies and emphasized the uncertainties of the evaluation and interpretation of the results of much of the early work.

In September 1950, Swift and Company began a three-generation rat-feeding study of raw ground beef that had been treated with accelerated electrons at a dose of 18.6 kilograys. The rats performed very well on both the test and control diets when fed over their life span (2 years) and through successive generations. Small and occasionally statistically significant decreases in growth, food efficiency, reproduction, adult body size, and survival were attributed to slightly decreased nutritional quality similar to that occurring during sterization by heat. These effects were eliminated by supplementing the diets with vitamins, and thus they were not considered to be an indication of toxic effects (Poling et al., 1955).

The U.S. Army's research on the wholesomeness of food treated with ionizing energy started in March 1948, when its Medical Nutrition Laboratory began tests of the effect of ionizing energy on the toxicity of its basal laboratory ration to rats. Beginning in 1953, the U.S. Army embarked upon a long-term comprehensive series of studies with the goal of commercial application for both military personnel and civilians. From the very beginning, one of the Army's major preoccupations was assurance that the treated food was wholesome. There were no statutes or precedents for assessing the wholesomeness of foods treated with ionizing energy or for controlling the process. The U.S. Army Medical Department, therefore, consulted with FDA, the National Research Council, and the Armed Forces Institute of Pathology on developing methods of testing foods for wholesomeness. These consultations continued throughout the decade of the 1950s and well into the 1960s.

The first phase of the Army's extensive wholesomeness assessment program was acute toxicity studies on the 46 foods listed in Appendix III, Table 4. These foods, treated with 0, 27.9, or 55.8 kilograys of ionizing energy, were tested in weanling rats for 8 weeks. During this feeding period, the animals were observed for signs of obvious toxicity. Upon conclusion of each study, gross pathological examinations were made. No toxic effects were observed from feeding the foods tested (Raica and Howie, 1966). Testing of three foods (gelatin dessert powder, raisins, and vanilla dessert powder) was complicated by their high sugar content, which resulted in products resembling heat-caramelized sugar in odor and appearance upon treatment with ionizing energy. The growth of rats was decreased in feeding trials with these products. Heat-caramelized sucrose had similar effects on growth of rats. Raica and Howie (1966) noted that the effect of sterilization of dry sugar preparations is not specific to ionizing energy because heat produces a comparably unacceptable product.

Encouraged by the results of the short-term studies, which showed no acute toxicity, the Army Medical Department undertook in 1955 seven 15-day tests with 41 young male human volunteers and a total of 54 foods (Appendix III, Table 5) supplying 32 to 100% of the dietary calorie intake. These studies, conducted between 1955 and 1958, showed no unfavorable effects of treating the foods with ionizing energy. The results are described in three reports published by the Army's Medical Nutrition Laboratory (Levy et al., 1957; Plough et al., 1957; Bierman et al., 1958). Brynjolfsson (1978) later summarized and appraised the results. The dose of ionizing energy for the foods tested was 23.25 to 37.2 kilograys except for white potatoes (0.093 to 0.186 kilogray), flour (0.66 to 0.74 kilogray), and oranges (1.3 kilograys).

In 1955, the Army Medical Department, with advice from the National Research Council and FDA on procedures, began long-term multigeneration animal feeding studies using the 21 foods shown in Appendix III, Table 6. These foods, chosen from the 46 foods in Appendix III, Table 4, were selected to represent typical members of all the classes of foods important in the diets of North Americans.

The foods were treated with 27.8 or 55.6 kilograys of ionizing energy and were supplied for 2 years or four generations in the diets of rats, mice, dogs, and monkeys at a rate of 35% of total dietary solids — quantities greater than normal consumption to increase the chances of revealing possible unfavorable effects. Vitamin supplementation was used as needed to assure nutritional adequacy of the diets and replace vitamin losses related to processing or storage conditions.

In this research, several anomalies appeared in the test animals (for example, hemorrhages, ruptured hearts, and vitamin deficiencies), but these were related to feeding the test animals foods they did not customarily eat, and not to treating the foods with ionizing energy. Several summaries have been published of the wholesomeness studies sponsored by the Army (Raica, 1963, 1965; Raica and Howie, 1966) and others (Reber et al., 1965).

The Army Surgeon General (1965) concluded from the results of this research and from other evidence reported in the literature that foods treated with up to 55.6 kilograys of ionizing energy from cobalt-60 or from electrons with energies up to 10 million electron volts had been found to be wholesome; i.e., safe, and nutritionally adequate.

As a result of these studies, petitions were submitted to FDA by the Army for approval of the use of ionizing energy for processing bacon and white potatoes, and by L. E. Brownell, T. Horne, and W. J. Kretlow of the University of Michigan (in cooperation with the Army) for approval of the use of ionizing energy to disinfest wheat and wheat products of insects. The petitions were approved in 1963 and 1964.

In 1966, the Army submitted a petition to FDA for approval to use ionizing energy for processing ham. No experimental wholesomeness data had been obtained directly on ham, but the argument submitted was that ham is a pork product intermediate between uncured pork and cured bacon, both of which had been found wholesome after treatment with ionizing energy in the studies begun by the Army in 1955. In the meantime, however, the standards for toxicity testing had changed, and FDA (Banes, 1968) recommended additional studies to investigate possible effects of the ionizing energy on reproduction, antinutrient factors, mortality, body weight gain, red blood count and hemoglobin, and risk of cataracts and tumors. The Army thereupon withdrew its petition for ham. FDA followed by rescinding its approval for use of ionizing energy on bacon because the evidence submitted previously to obtain that approval did not cover all the subjects on which information was desired according to the new criteria. When all the possible effects to which FDA called attention were investigated in subsequent research on beef and chicken rolls to be discussed later in this report, the conclusion was that there were no unfavorable effects.

Several publications have reported unfavorable effects of the use of ionizing energy on food. Reported effects ranged from toxicity of treated sugar solutions to carrot cells grown in tissue culture (Holsten et al., 1965), to effects on gonads, reproductive function, progeny, and diseases induced in albino rats fed fresh fish treated with ionizing energy (Shillinger and Osipova, 1970). At the request of the General Accounting Office of the U.S. Congress, Josephson (1978) reviewed the abstracts of 29 papers concerning possible adverse effects of foods preserved by ionizing energy. He noted no significant adverse findings that could not be explained or corrected by using the best technology, such as treatment at -40° F (-40° C) with exclusion of oxygen.

From the scientific standpoint, it is very important that negative findings be evaluated carefully because the new knowledge they generate, either directly or indirectly, may significantly advance the basic understanding of the process. Evaluation is important also from another standpoint, in that the controversy about treating food with ionizing energy is not conducted on a wholly scientific basis. Opponents often cite negative findings, scientifically valid or not, in support of their position. Moreover, when many experiments are conducted, an occasional statistically significant negative (and positive) outcome is to be expected even in the absence of any real effect. For such outcomes where the experimental design, scientific methods, and data interpretations are satisfactory, the only solution is to repeat the experiment to see if the results can be reproduced.

In September 1967, the International Society for Research on Nutrition and Vital Substances held its 13th International Convention on Vital Substances, Nutrition, and Civilization Diseases in Trier, West Germany, and Luxembourg City, Luxembourg. The subject for the Convention was "the dangers of nuclear irradiation." The announcement of the meeting indicated the intention to pass a resolution condemning the use of ionizing energy as a means of preserving foods. The resolution was to be based largely on a document by W. Herbst of the Radiological Institute, University of Freiburg. The document was published later (Herbst, 1968). The Herbst allegations and rebuttals by responsible scientists from the United States and West Germany are documented in the published Hearings Before the Subcommittee on Research, Development, and Radiation of the Joint Committee on Atomic Energy, Congress of the United States, July 18 and 30, 1968, Appendix 10, pp. 695-705. The U.S. Atomic Energy Commission concluded that the Herbst paper was "a masterpiece of half truths, innuendos, and statements taken out of context prepared to present only that picture which he wants to present."

Several other articles reporting unfavorable effects of foods treated with ionizing energy are discussed here. These include four Russian papers (Shillinger and Osipova, 1970; Kamaldinova, 1970; Levina and Ivanov, 1978; Ivanov and Levina, 1981) and five Indian publications (Bhaskaram and Sadasivan, 1976; Vijayalaxmi, 1975, 1978; Priyadarshini and Tulpule, 1976, 1979).

The papers by Kamaldinova (1970) and Shillinger and Osipova (1970) reported detrimental effects in rats fed food that had received 6 and 8 kilograys of ionizing energy. Shortly after these reports were published, the U.S. Army Laboratories at Natick, Massachusetts, asked knowledgeable scientists in the United States, Canada, the Federal Republic of Germany, India, and The Netherlands to review these reports. The reviewers found the experiments poorly designed and recommended that they be ignored.

In the experiments by Kamaldinova (1970), the basic diet did not meet modern standards, and the conclusions of the author were not supported by statistically significant data. The alleged changes in fat metabolism were claimed on the basis of tributyrinase measurements. An analysis of the data shows, however, that tributyrinase activity was identical in the parent test group and in the first-generation test and control groups. Only the parent control group showed slightly lower activity.

In the Shillinger and Osipova (1970) studies, the diets did not meet modern standards for calcium and for calcium/phosphorus ratio. Moreover, the fresh fish in the test diet had been treated with 6 kilograys of ionizing energy (not enough to produce a sterile product), but it was stored 2 months at temperatures between 30 and 45° F (-1 and +7° C) before feeding, whereas the control fish was stored frozen. Thus, there was opportunity for significant bacteriological and chemical changes in the treated fish that could have led to spoilage with unfavorable effects on the test animals. According to a personal communication to the chairman of the task force that produced this report for CAST from scientists responsible for the wholesomeness studies of foods treated with ionizing energy in the Soviet Union, the fish Shillinger and Osipova treated with ionizing energy was spoiled. When their experiment was repeated, no adverse effect of the treatment was found when the temperature of the product was kept below 50° F (10° C) during a short exposure to ionizing energy.

The publications by Levina and Ivanov (1978) and Ivanov and Levina (1981) reported harmful effects from feeding treated foods to rats for long periods. These experiments are considered to be faulty and the conclusions misleading for the following reasons.

Although the experiments were not described in sufficient detail so they could be repeated independently, the authors mentioned the "K-300 Gamma Ray Apparatus" of the "All-Union Food Conservation

Research Institute" as the source of the ionizing energy. By the time the foods were treated for the experiments, the strength of this source of ionizing energy had decreased so much that more than 10 hours would have been required to convey the dose of 56 kilograys reported (Metlitskii et al., 1968). Because the installation has no provision for controlling the temperature of the food during treatment, the temperature of the product could have risen enough during exposure to produce spoilage.

Additionally, the high doses of ionizing energy used by Levina and Ivanov were employed without exclusion of atmospheric oxygen. Treatment with ionizing energy under these conditions produces severe oxidative changes. Except for low-fat dry foods, the technology used since 1964 to obtain good-quality products with high doses involves carrying out the treatment on frozen, vacuum-packed foods at temperatures low enough so that at the end of the treatment the product temperature is -4° F (-20° C) or lower (Wierbicki, 1984).

In the paper by Levina and Ivanov (1978), reference was made to the concept of "radiotoxins" put forward by A. N. Kuzin. According to a personal communication from scientists of the Institute of Nutrition, USSR Academy of Medical Sciences, to the chairman of the task force that prepared this report for CAST, the Kuzin concept is no longer considered valid in the light of the results of subsequent experiments conducted on potatoes treated by ionizing energy by the International Food Irradiation Project and in the USSR.

Soviet authors, including Shillinger, Osipova, and Kamaldinova, have subsequently published papers that confirm the wholesomeness of foods treated with ionizing energy (Bronnikova and Okuneva, 1972; Kamaldinova, et al., 1977; Zaitsev and Osipova, 1981; Zaitsev and Maganova, 1981; Zaitsev et al., 1975).

The study in India by Bhaskaram and Sadasivan (1976) and two studies by Vijayalaxmi (1975, 1978) indicated abnormal white blood cells in children and monkeys fed wheat that had been treated with ionizing energy. Also from India, Priyadarshini and Tulpule (1976, 1979) and Behere et al. (1978) reported that the aflatoxin content in treated wheat, corn, sorghum, pearl millet, potatoes, and onions was greater than in their untreated counterparts.

The data reported by Bhaskaram and Sadasivan (1976) on possible chromosomal aberrations are meager and have large statistical fluctuations. Kesavan (1978), another Indian scientist who was the chairman of a committee that looked closely at the experiments, reported that the experiments were not designed well, and the results were imprecise. It was concluded that a mutagenic potential in wheat treated with ionizing energy had not been demonstrated. The 1.8% polyploidy in children on the diet containing treated wheat is in the normal range. The 0% polyploidy reported in children on the diet containing untreated wheat is abnormal and probably impossible.

Several studies to check for a mutagenic effect in wheat treated with ionizing energy did not confirm mutagenesis (George et al., 1976; Tesh et al., 1977; Reddi et al., 1977; Chauhan et al., 1977; Murthy, 1981a, 1981b; WHO, 1976). Elias, in his foreword to the paper by Tesh et al. (1977), stated that "The results of these studies showed that, in contrast to the Indian findings, neither the incidence of polyploidy nor the incidence of micronucleated cells were affected significantly by a diet containing flour prepared from irradiated wheat irrespective of the time of storage. Furthermore, the dominant lethal assay revealed no adverse effects on male germ cells in rats."

Priyadarshini and Tulpule (1976, 1979) heat-sterilized their foods before infecting them with the aflatoxin-producing fungi. In view of the findings by Sharma et al. (1978, 1979, 1981) that sterilization by heating destroys natural antifungal components in foods, it appears that the products being studied were not analogous to natural commodities that contain antifungal components. Whether the production of aflatoxin in such products is affected by treatment with ionizing energy remains to be determined. Other research to be mentioned subsequently indicates that ionizing energy in sufficient doses detoxifies aflatoxin (Temcharoen and Thilly, 1982).

During the 1960s, the U.S. Atomic Energy Commission (AEC) sponsored a series of animal feeding studies to assess the wholesomeness of fruits and vegetables that had been exposed to substerilizing doses of ionizing energy. Among the foods tested were bananas, strawberries, and papayas. The experimental results indicated that the treated fruits were wholesome.

Since the availability of some of the fruits tested was seasonal, AEC preserved the treated and untreated samples by freeze-drying for year-around feeding in the experiments. Critics pointed out the possibility that in experiments conducted in this way, some toxic volatile radiolytic products may have been lost along with the water in the drying process. The experiments have never been repeated to check this possibility, in part because AEC ceased work on this subject in 1969.

Although the momentum of U.S. research programs on ionizing energy for food processing was slowed as a result of the Army's withdrawal in 1968 of its petition for ham sterilized with ionizing energy, Canada completed 2-year animal feeding studies on fresh chicken and fish treated with low doses of ionizing energy. The Netherlands conducted wholesomeness tests on mushrooms, chicken, strawberries, and other foods treated with low doses of ionizing energy. These resulted in approvals of petitions for a long array of foods by the Netherlands Ministry of Health. Japan, too, completed its wholesomeness testing of white potatoes treated with ionizing energy to inhibit sprouting, and, since 1973, has been using ionizing energy for commercial processing of potatoes for the Tokyo market.

In 1969, the World Health Organization (WHO) sponsored the formation of a Joint Expert Committee on Wholesomeness of Irradiated Foods representing the Food and Agriculture Organization of the United Nations (FAO), the International Atomic Energy Agency (IAEA), and WHO. This Committee reviewed the wholesomeness data for the three foods (white potatoes, wheat and wheat flour, and onions) that had been approved for treatment with ionizing energy in two or more countries and recommended provisional approval worldwide for a 5-year period for treated potatoes and wheat and wheat flour. Because the nutrition data on these foods were based on the uncooked products, the 5-year period was to provide time to perform nutrition studies on these foods after they had been prepared for eating. The Committee made no recommendation on onions because of incomplete data owing to experimental difficulties in sustaining test animals in good health for 2 years or 4 generations on diets containing a high percentage of onions, whether or not they had been treated with ionizing energy.

The studies recommended by the Joint Expert Committee in 1969 were completed when WHO reconvened the Committee in September 1976. After reviewing the available wholesomeness data, the Committee recommended unrestricted approval of the use of ionizing energy on chicken (refrigerated shelf-life extension), potatoes (prevent sprouting), onions (prevent sprouting), wheat and wheat flour products (insect disinfestation), and two species of fish (shelf-life extension) (WHO, 1976, 1977).

The recommendations by the Joint Expert Committee were in turn adopted by the FAO/WHO-sponsored 117-country Codex Alimentarius Commission's Food Additives Committee and by the full Commission itself, which issued standards for the approved foods to facilitate their entering into international commerce (CAC, 1976).

In October-November 1980, the Joint Expert Committee again met in Geneva to review all the wholesomeness data worldwide on foods treated with ionizing energy. In the absence of any confirmed evidence of toxicity, the Committee recommended approval of all foods treated with doses up to an average of 10 kilograys without any further wholesomeness testing (WHO, 1981a, 1981b). The Joint Expert Committee deferred any recommendation on higher doses required for sterilization of foods until the wholesomeness studies in progress on sterilized ham in the Netherlands and chicken rolls in the United States (begun by RALTECH in May 1976) were completed (see Appendix II). Many of the wholesomeness data reviewed by the Joint Expert Committee were compiled by Elias and Cohen (1983).

Subsequently, the Codex Alimentarius Commission's Committee on Food Additives recommended to its parent Codex Alimentarius Commission the implementation of the recommendations of the Joint Expert Committee. In July 1983, the Codex Alimentarius Commission approved these recommendations (CAC, 1983a).

On March 27, 1981, following an in-house study (FDA, 1980), FDA (1981) published in the Federal Register its notice of intent to propose new regulations for foods treated with ionizing energy. On February 14, 1984, FDA (1984) published its proposed new regulations approving the use of doses up to 1 kilogray to disinfest fruits and vegetables of insects and up to 30 kilograys to decontaminate spices. On April 18, 1986, the final version of the regulation was published in the *Federal Register* (FDA, 1986) approving the use of doses of ionizing energy up to 1 kilogray to disinfest fruits and vegetables of insects and to delay ripening of fruits, and the use of 30 kilograys to decontaminate spices and dry condiments. Reconfirmed in the April 18, 1986, action was the prior approval to use 0.3 to 1 kilogray of ionizing energy to control trichina in pork (FDA, 1985b) and to use up to 10 kilograys to disinfect dry or dehydrated enzyme preparations (FDA, 1985a).

U.S. Government Wholesomeness Studies

In March 1971, the Army began a mammoth study to assess the wholesomeness of beef sterilized with ionizing energy in the dose range of 47 to 71 kilograys. The research on induced radioactivity, radiation chemistry, antivitamin effects, and some mutational evaluations was done in the Army's own laboratories. The principal mutagenesis testing was contracted to a university. The animal-feeding portion of the study was contracted to a company specializing in toxicity testing. Before completion of the contract, this company encountered legal difficulties unrelated to the contract that led to bankruptcy. In the process, the Army discovered that there were some procedural irregularities in the animal feeding tests. Although the quarterly reports submitted by the company had indicated no adverse effects of treating beef with ionizing energy, the decision was made at this point to reject all the results of the animal feeding work (see a report by the Comptroller General of the United States, 1978). Emphasis then would be placed upon the other portions of the study, as well as additional work on ham and pork performed in-house at the U.S. Army's laboratories at Natick, Massachusetts, and an extensive independent study then in progress with another contractor on chicken sterilized with ionizing energy. The aspects of wholesomeness represented by the research on induced radioactivity and radiolytic products done in the Army's laboratories were reviewed earlier in this report.

Mittler (1979) fed beef sterilized with 47 to 71 kilograys of ionizing energy and ham sterilized with 37 to 52 kilograys of ionizing energy to fruit flies to investigate possible mutagenic effects. These dosages were greater than any others reported in the literature in similar research. He reported that "no significant increases were induced in recessive sex-linked lethals, loss of chromosomes or non-disjunction" and that no stable mutagenic compounds were produced. Since the males had fed on the food treated with ionizing energy, both for their entire larval life and also as adults, the entire spectrum of spermatogenesis thus was sampled by the brooding technique. There was no induced significant increase in the genetic aberrations tested in any of the cells in spermatogenesis. In short, the experiments provided no evidence that genetic aberrations or mutagenicity resulted from consumption of beef and ham that had been sterilized with ionizing energy.

Gutherz and Fruin (1981) used the Ames *Salmonella/* mammalian microsome mutagenicity assay with several modifications to assess possible mutagenic effects of beef sterilized with ionizing energy. Their conclusion was that mutagenic potential was not induced in beef by ionizing energy in the form of gamma rays or accelerated electrons.

McGown et al. (1979a) investigated possible antithiamine properties in beef that had been sterilized by accelerated electrons at doses of 47 to 71 kilograys. They used 156 male and 156 female rats made thiamine-deficient by feeding a semipurified diet devoid of thiamine. Using repletion test diets containing beef and carefully controlled levels of thiamine, they monitored recovery rates by weight gain and measurements of the thiamine-dependent blood enzyme, erythrocyte transketolase. They found no evidence of antithiamine substances in beef sterilized by either gamma radiation or accelerated electrons.

In May 1976, the Army Medical Department awarded a contract to Raltech Scientific Services (RALTECH) to conduct the animal feeding, mutagenesis, and teratogenesis parts of a study of the wholesomeness of chicken meat processed with ionizing energy, which was to become the world's most comprehensive, expensive ($8 million), and lengthy (7 years) investigation of the wholesomeness of any food that had been treated with ionizing energy. The Army conducted in its own laboratories those portions of the study concerned with induced radioactivity, radiolytic products, and radiation-induced antivitamin activity. The chicken was exposed to an average dose of 58 kilograys of ionizing energy from cobalt-60 or accelerated electrons.

During the course of this study, RALTECH submitted nine reports to the Army and four reports to the Department of Agriculture. These and the supporting quarterly reports total approximately 35,000 pages (Appendix II). Eight reports by the Army, the Department of Agriculture, and the Federation of American Societies for Experimental Biology plus numerous other publications are also part of the study. Copies of most of the reports can be purchased from the National Technical Information Service (See Appendix II). Subjects treated in one or more of a total of 20 separate research projects include investigations of the possible effects of the use of ionizing energy for sterilizing chicken meat on the nutritional quality, teratogenicity (promotion of birth defects), toxicity, carcinogenicity (promotion of cancers), reproductive performance, and genetic toxicity (promotion of mutations) of the product.

Five diets were used in these studies (Wierbicki, 1984, 1985): a 100% rodent or dog chow diet as the negative or husbandry control (Diet N), which also served as the carrier for the chicken meat in the four diets; frozen chicken with no ionizing energy treatment (Diet F) and thermally sterilized canned chicken (Diet T) as positive controls; and chicken sterilized with ionizing energy in the forms of accelerated electrons and gamma rays (Diets E and G). Diets F, T, E, and G each contained 35% chicken meat and 65% Diet N.

More than 230,000 chilled, eviscerated broilers were used to produce the 134 metric tons of enzyme-inactivated (precooked) chicken meat needed for these studies (Wierbicki, 1984, 1985). Appendix III, Table 13, gives the quantities, and Table 14 gives the composition of the four groups of chicken meat produced for these studies. The packaging and appearance of the four groups of meat (marked FC, TP, GAM, and ELE, used for preparation of diets F, T, G, and E, respectively) are shown pictorially on the back cover of this report.

There were two aspects of the nutrition studies: (1) evaluation of protein efficiency ratios for the five diets using casein as the reference standard and (2) evaluation of the five diets for possible antivitamin B-1 and B-6 effects.

Ronning et al. (1979) reported that the protein efficiency ratios of diets containing chicken were higher than those for casein in both male and female rats. They concluded that the protein efficiency ratios were not affected adversely by any of the processing methods. (The protein efficiency ratio is the gain in weight per unit weight of protein consumed. The measurement usually is made with male rats under standard conditions of a 4-week assay period with diets containing 10% protein and adequate amounts of other nutrients.)

The results of studies on antithiamine effects in beef (McGown et al., 1979a) and chicken (McGown et al., 1979b) and antivitamin B-6 effects in chicken (McGown et al., 1981) are reported later in the nutritional quality section of this report. There was no evidence of antithiamine substances in beef that had been sterilized by ionizing energy at a maximum dose of 71 kilograys. There was no evidence of antithiamine activity in chicken sterilized with ionizing energy from gamma rays or accelerated electrons at a maximum dose of 68 kilograys. No antivitamin B-6 activity was observed in the electron-sterilized chicken. McGown et al. (1981) concluded that if an antivitamin B-6 factor is present in chicken sterilized with ionizing energy from gamma rays, "it is minimal, is detectable only under conditions of marginal vitamin B-6 status, and is overcome by added dietary pyridoxine."

Results of the genetic toxicity studies on the chicken that had been sterilized by ionizing energy or heat were reported by Kuzdaz et al. (1980), Sullivan et al. (1979), and Black et al. (1981a, 1981b). These studies were conducted to see if consumption of the chicken could bring about genetic changes (mutagenesis), partly because many mutagens are also carcinogens.

Four different genetic toxicity studies were done. One test was a modified Ames Test (modified because of the presence of histidine in chicken) using *Salmonella typhimurium* as the test organism. No mutagenesis was observed (Kuzdaz et al., 1980).

A second test used fruit flies *(Drosophia melanogaster)* to test for sex-linked recessive lethal mutations. There was no evidence that the chicken sterilized by ionizing energy caused such mutations, whereas the positive control (to validate the test), tris-(2,3-dibromopropyl)-phosphate, gave a significant positive response (Sullivan et al., 1979). As a side effect, the authors noted a dose-related reduction in numbers of progeny produced in cultures of the flies reared on chicken treated with ionizing energy in the form of gamma radiation. This effect was not considered important (Brynjolfsson, 1985; FDA, 1986). The fruit fly was the test organism for certain mutation studies, a use to which it has been put for many years, but it never has been considered a test organism to reflect possible adverse effects of foods on reproduction in humans. No impairment in reproduction attributable to sterilization of chicken with ionizing energy was observed in feeding trials with rats, mice, and dogs, which are mammalian species that would be expected to provide data more relevant to reproduction in humans.

The third test was for heritable translocation mutations in mice (chromosome damage). There was no evidence of chromosome damage from the chicken sterilized with ionizing energy (Black et al., 1981a).

The fourth test, a genetic toxicity study, was for dominant lethal mutations. There was no evidence of dominant lethal mutations in male mice exposed to the test diets and mated to virgin females (Black et al., 1981b).

These four studies provide evidence that chicken meat sterilized with ionizing energy from gamma rays and accelerated electrons is not mutagenic.

Tests were done with mice, hamsters, rats, and rabbits to see if eating the sterilized chicken would lead to birth defects (teratogenesis) (Dahlgren et al., 1977, 1978; Christopher et al., 1979; Israelson et al., 1982). The pregnant animals were exposed during the period of maximum organogenesis to the four test diets containing chicken that was either frozen or sterilized with heat or ionizing energy (from gamma rays or accelerated electrons) at 35% and 70% of the total diet. Positive controls (trans-retinoic acid for mice, hamsters, and rats and thalidomide for rabbits) induced significant incidences of resorbed embryos and congenital malformations in both soft and skeletal body tissue. But there was no evidence that the chicken diets produced significant maternal toxicity or congenital malformations. The authors concluded that there was no teratogenesis in the four different species of animals from eating any of the four chicken diets during the period of maximum organogenesis.

The long-term multigeneration, chronic toxicity, and carcinogenicity studies on chicken sterilized with gamma rays or accelerated electrons were conducted with rats, mice, and beagle dogs using previously described Diets N, T, F, G, and E. In these tests, the animals were exposed to their respective diets throughout their complete life span. Exposure prior to conception was accomplished by feeding all the parents their particular diet, followed by feeding the same diet to the mother during pregnancy and lactation through weaning. The nutrient content of the chicken used in Diets, T, F, G, and E and of all five diets (N, F, T, G, and E) was checked throughout the study. There were no significant differences in nutrient content among the four test meats and among the meat-containing diets.

The 2-year chronic toxicity, oncogenicity (tumor promotion), and four-generation study of rats on the five diets was terminated at the 39th week because of a lactation problem resulting in a high incidence of neonatal mortality not linked to any of the chicken diets. From analysis of the data from this study, Dahlgren et al. (1982) concluded that no adverse effects of feeding of chicken meat sterilized with ionizing energy were observed on body weight, food consumption, food consumption to weight gain conversion, reproductive performance, clinical signs, behavior, ophthalmoscopy, or the hematological or biochemical factors measured. They noted further that preweaning mortality resulting from lactation failure in the parent females was excessive among the F_{1b} progeny in all diet groups (the condition that led to early termination of the study). An investigation to determine the cause of the lactation failure was unsuccessful.

Besancenez et al. (1983) reported on the chronic toxicity and reproduction study with beagle dogs that were fed the five diets prenatally, during lactation and weaning, and then until death or for 36 months after weaning for females and 40 months after weaning for males. The investigators stated that no apparent signs of toxicity attributable to diet were observed in any of the groups in any generation. Male F_0 dogs fed the sterilized chicken diet (G) had significantly lower body weights through adulthood than dogs fed the frozen chicken control diet (F), but obesity in Group F males obscured the interpretation of this finding. The F_0 females in Group G produced more offspring in four successive pregnancies than did any other group. All diets supported reproduction and lactation adequately. Clinical pathology findings in general were unremarkable. From gross observations at necropsies and from tissues examined microscopically, no treatment-related abnormalities or changes were noted.

Ronning et al. (1984) described the 2-year chronic toxicity, oncology, and 3-generation reproduction studies using mice. The mice were fed Diets N, F, T, G, and E. Exposure of the F_0 and subsequent generations to the test and control diets began *in utero* and continued until death or scheduled termination. The chronic feeding study, which was continued for 24 months postweaning, was comprised of F_0 generation mice from which subgroups were also assembled for the reproduction phase.

According to Thayer and Wierbicki (1985), the only negative findings in the final report on the mouse study by Ronning et al. (1984) were (1) reduced survival of virgin female mice in the Diet G group and (2) increased incidence of benign interstitial Leydig cell neoplasms (benign slow-growing testicular tumors) in the Diet G and Diet E groups. Seifried et al. (1983) of Tracor Jitco, Inc., who made an independent review of the mouse data at the request of the U.S. Department of Agriculture, disagreed with both of these interpretations of the data.

FDA's Center for Food Safety and Applied Nutrition's Division of Pathology conducted its own independent review of the data on benign interstitial Leydig cell neoplasms in mice as well as the pathology slides from the RALTECH study. FDA concluded (Hart, 1985) that the chicken sterilized with ionizing energy did not cause the tumors for the following reasons:

"1. There was no increase in interstitial cell hyperplasia in the testes of these animals.

"2. There was no evidence of a progression of testicular lesion(s) from hyperplasia to neoplasia.

"3. There were no demonstrable toxic lesions (e.g., atrophy or necrosis) in the testes which could have contributed to the pathogenesis of neoplasia.

"4. All the testicular tumors were unilateral, i.e., none of the tumors was bilateral.

"5. Only one of the testicular tumors was interpreted as a malignant tumor." (The National Toxicology Program's Board of Scientific Counselors Peer Review Panel said it found no malignancy).

"6. A majority of the tumors were reported in animals at the time of terminal sacrifice (i.e., two years of age). Three of the animals with testicular tumors which died before the terminal sacrifice had other lesions also which may have contributed to their early mortality....

"7. Cystic vascular interstitial cell tumors mimic other tumors and the reported incidence of interstitial cell tumors is probably not represented fully in the historical control data."

A special peer review of the FDA study was conducted by the National Toxicology Program's (NTP) Technical Reports Review Subcommittee at the request of the director of FDA's Center for Food Safety and Applied Nutrition. The peer reviewers agreed with the seven reasons the Center's Division of Pathology gave for its original findings that the sterilized chicken did not cause the tumors. In the consensus conclusion, the NTP expert panel stated (Hart, 1985):

> The relatively low incidence rates for proliferative lesions of testicular interstitial cells and related gonadal stromal tissue in male CD-1 mice as well as other unidentified variables that may have entered into the generation of the presently available data do not allow the study to be categorized as demonstrating a carcinogenic response as a result of gamma or electron irradiation of the chicken meat fed to the mice.

FDA, in its final rule on use of ionizing energy for dry and dehydrated food enzymes (10 kilograys maximum) and *Trichinella spiralis* control in fresh pork (0.3 to 1 kilogray), officially confirmed the acceptance of this NTP panel conclusion (FDA, 1985a, 1985b). With the resolution in early 1985 of the last important issue that testicular tumors were not caused by feeding mice *in utero*, during lactation, and for periods as long as 2 years after weaning, with chicken that had been sterilized with ionizing energy, verification of the wholesomeness of this product was completed using the best scientific methods available at the time the experiments were conducted. The NTP announcement on March 28, 1985, was the denouement of more than 30 years of experiments, at a cost of many millions of dollars, to assess the wholesomeness of foods treated with ionizing energy. With that announcement, the known scientific barriers to approval of the use of ionizing energy up to a maximum dose of 68 kilograys on meats, poultry, fin fish, shell fish, and their products were removed.

International Studies

Barna (1979) compiled a list of more than 1200 publications on the wholesomeness of foods treated with ionizing energy, many of these publications from foreign countries. Only a brief summary of recent research is given here.

Extensive studies on the wholesomeness of foods treated with ionizing energy were conducted from 1970 to 1981 by the International Project in the Field of Food Irradiation located at the Institute for Nutrition in Karlsruhe, Federal Republic of Germany. The project was sponsored by the Food and Agriculture Organization of the United Nations, the International Atomic Energy Agency, and the Organization of Economic Cooperation and Development. The World Health Organization (WHO) served in an advisory capacity. Many countries participated by providing funds or other support to this project, which resulted in more than 60 technical reports (IPFFI, 1982). Most of these studies were on the toxicology and overall wholesomeness of foods treated with ionizing energy up to 10 kilograys. Experimental animals employed included dogs, mice, rats, and monkeys. Additional studies were done on the microbiological and nutritional properties of foods treated with ionizing energy, and on the possible teratogenic, mutagenic, genetic, and DNA effects of such foods. The foods investigated included chicken, teleost fish and fish products, onions, potatoes, wheat and wheat products, rice, cornstarch, cocoa beans, dates, strawberries, mangoes, papayas, mushrooms, spices, and condiments.

Extensive toxicological and reproduction studies were conducted in The Netherlands on chicken that had been treated with ionizing energy at doses of 3 or 6 kilograys. Research with rats was reported by deKnecht-van Eekelen et al., 1971, 1972); research with dogs was reported by Til et al. (1971). These studies led to the approval in The Netherlands of chicken pasteurized with ionizing energy, supported a similar successful petition in Canada in 1973, and provided the Joint Expert Committee on the Wholesomeness of Irradiated Food with the research data needed to recommend approval at its September 1976 meeting (WHO, 1976, 1977) of chicken pasteurized with ionizing energy.

In France, the wholesomeness of products that had received 3 or 6 kilograys of ionizing energy was investigated by feeding them for 24 months to rats and 18 months to mice. Additional toxicological studies were conducted on a mixture of nine compounds that had been identified in starch subjected to ionizing energy (formic acid, hydrogen peroxide, methyl alcohol, acetaldehyde, formaldehyde, glycoaldehyde, glyceraldehyde, malonaldehyde, and glyoxal) (Saint-Lèbe et al., 1973; Truhaut and Saint-Lèbe, 1978). The mixture (0.3 gram per kilogram of body weight) was fed daily to rats, corresponding to an amount of the radiolytic products 800 times greater than would be taken up by a baby consuming 30 grams (1.1 ounces) of the treated starch per day. No toxic effect was found (Truhaut and Saint-Lèbe, 1978).

In Germany, Reichelt et al. (1972) and Renner and Reichelt (1973) conducted a long-term feeding study especially designed to reveal possible effects of a diet containing a high concentration of free radicals. A diet containing 35% milk powder that had received 45 kilograys of ionizing energy and had a high content of long-lived free radicals, was tested in a 3-year multigeneration feeding study using 716 rats. Measurements were made in one or more generations on growth, food consumption, duration of pregnancy, litter size, litter weight, weaning ratio, blood picture (including hemoglobin and hematocrit), electrophoretic separation of serum protein fractions, total protein, serum enzyme activities, bone marrow smears, urine test, sleeping time after pentobarbitol anesthesia, teratogenicity, mutagenicity, organ weights (heart, liver, kidney, spleen), body weights, gross pathology, and histopathology of organ slices (liver, spleen, kidney, adrenals). In a related experiment, a diet containing 80% milk powder that had received 45 kilograys of ionizing energy was fed. The ionizing energy caused a considerable decrease in the concentrations of vitamins A, E, and B in the milk powder. With the exception of differences in body weights after a feeding period of 1 year, which showed up in some generations and disappeared when the diet was discontinued, no significant differences were observed between groups. When vitamin supplements were given, no differences in body weights were found. Diehl (1984) concluded that feeding rats the dry milk containing a high content of free radicals as a result of treatment with ionizing energy did not show any carcinogenic or chronic effect.

Renner et al. (1973) investigated the mutagenicity of the same dry milk powder in mice and rats. Two diets were used. One contained 35% whole milk powder treated with 45 kilograys of ionizing energy and 65% standard rat diet. The second diet was the same as the first except that the 65% standard rat diet also was treated with ionizing energy. In studies of one generation of mice and five generations of rats, no significant differences were observed in fertility, duration of pregnancy, litter size, weaning index, sex ratio, or number of fetal malformations. The fertility of male and female mice was also unaffected, and no embryotoxic or mutagenic effects were found. The high content of free radicals produced no observed harmful effects on any of the characteristics investigated.

Between 1974 and 1980, the International Atomic Energy Agency coordinated a research program on the wholesomeness of foods treated with ionizing energy. The main objectives of this program were to produce scientific data on the wholesomeness of the food items of special interest to developing countries and to facilitate public health clearance at national and international levels of the use of ionizing energy in food processing. Eight countries participated in this program. Among the foods assessed for wholesomeness were mackerel; shrimp; carp; black beans; corn; walnuts; prune-plums;

several varieties of fish native to the Philippines, Indonesia, and India; and actomyosin-lard mixtures (model systems) (WHO, 1976, 1981a). The Coordinated Research Program was activated to supplement results generated by the International Project in the Field of Food Irradiation, Karlsruhe, Federal Republic of Germany, which sponsored and coordinated activities in the field of wholesomeness testing of food in its 24 member countries, mainly developing ones (IPFFI, 1982; IAEA, 1981).

The wholesomeness of feed sterilized with ionizing energy for rats (van Logten et al., 1978) and swine (van Logten et al., 1980) and of ham sterilized with ionizing energy for rats (van Logten et al., 1983) was investigated in The Netherlands. The same products heat-sterilized by autoclaving were used for comparison. The results are summarized in the following paragraphs.

In the wholesomeness study on feed sterilized with 50 kilograys of ionizing energy, no clear effect was seen on fertility, average number of pups per litter, mean body weight of the pups, or number of infertile males or females. In one experiment, the weight gain of the female rats on the diet treated with ionizing energy was lower than that in the controls. This effect was not observed in the males. The authors reported that "no treatment related histopathological changes were observed" (van Logten et al., 1978).

In the study by van Logten et al. (1980) of the wholesomeness for swine of feed sterilized with 50 kilograys of ionizing energy or heat, the investigators concluded that "it was unlikely that changes in body weight gain, hematological parameters, organ weights, and histopathology were related to the treatment." Analyses of the diets before feeding began showed that sterilization by heat reduced the pepsin-available protein and the net protein utilization, whereas the diet sterilized by ionizing energy was hardly affected. The protein efficiency ratio was reduced in diets sterilized by both heat and ionizing energy, but the true digestibility, the percentage crude protein, and the amino-acid composition were not affected. Food intake by the animals receiving the heat-sterilized diet was lower than that of animals receiving the control diet or the diet sterilized by ionizing energy. At the end of the experiment, the general condition, weight gain, and quality of the carcasses of the groups receiving the control diet and the diet sterilized by ionizing energy were graded good, but those of the group receiving the heat-sterilized diet were below standard. Overall, no significant adverse effects related to sterilization by ionizing energy were observed.

Meat from the swine receiving the three diets described in the preceding paragraph was processed into ham for use in a subsequent study by van Logten et al. (1983) on the wholesomeness of ham for rats. Six diets involving ham were tested, with the variable factors being the diets fed the swine from which the ham was produced and the treatment of the ham: (1) control diet, no treatment of the ham; (2) control diet, ham sterilized by heat; (3) diet sterilized by heat, no treatment of the ham; (4) diet sterilized by ionizing energy, no treatment of the ham; (5) diet sterilized by ionizing energy, ham treated with 37 kilograys of ionizing energy; and (6) diet sterilized by ionizing energy, ham treated with 74 kilograys of ionizing energy.

The authors reported that no differences were found among rats receiving diets (2) through (6) in food intake, growth, or mortality. The only effect observed on organ weight was a lower thyroid weight with diet (1) than with diets (2) through (6).

Biochemical examination of the blood and urine revealed no treatment-related changes. Alterations in the white blood picture were found from time to time in different experimental groups, but these were not associated with the diets.

No gross or microscopic differences in the rats among diets were noted. The number of tumors and the length of the latency period did not differ among diets.

In an experiment conducted in the People's Republic of China (Anonymous, 1986), a group of 35 human volunteers received a diet containing 60% of grains, meat products, vegetables, and fruits that had been processed with ionizing energy (0.1 to 8 kilograys), and a second group of 35 human volunteers received a comparable diet without such processing. At the end of the experiment, which lasted 90 days, 23 different clinical, physiological, and biochemical tests were made on the subjects. No statistically significant differences were found between the results of the tests made on the two groups.

Another report from the People's Republic of China (Dai Yin, 1986) summarized the results of eight experiments on a total of 439 human volunteers. Six of these experiments involved daily consumption of rice, mushrooms, potatoes, and peanuts exposed to 0.2 to 1 kilogray and of sausage exposed to 5 to 8 kilograys of ionizing energy. Daily portions were 8.8 ounces (250 g) of mushrooms, potatoes, and sausage; 17.7 ounces (500 g) of rice; and 1.8 ounces (50 g) of peanuts. The two other experiments involved whole diets that included 60% or 66% of ingredients that had been exposed to ionizing energy at levels of 0.1 to 8 kilograys. During and after these experiments, lasting 7 to 15 weeks, there were no statistically significant differences between tests made on subjects receiving the food processed with ionizing energy and tests made on subjects receiving the food without such treatment.

Han Chi et al. (1986) reported the results of an additional Chinese experiment in which foods exposed to ionizing energy (rice at 0.37 kilogray, wheat at 0.4 kilogray, different meat products at 8 kilograys, chili at 1 kilogray, and 14 different vegetables at up to 3 kilograys) constituted 62 to 71% of the diets of human volunteers. Here again, no statistically significant differences in the standard clinical, physiological, and biochemical evaluations were detected between the subjects receiving the food processed with ionizing energy and those receiving comparable food without such processing.

International Summary Evaluations

At a meeting in 1980, a Joint Expert Committee on the Wholesomeness of Irradiated Food representing the Food and Agriculture Organization of the United Nations, the International Atomic Energy Agency, and the World Health Organization reviewed the data accumulated up to that time on the wholesomeness of food treated with ionizing energy (WHO, 1981a). The Committee concluded that treating any food commodity with amounts of ionizing energy up to an overall average dose of 10 kilograys introduces no nutritional or microbiological problems and presents no toxicological hazard; hence, toxicological testing of foods so treated is no longer required (WHO, 1981b). The Committee recommended the unconditional acceptance of all foods treated with any dose up to 10 kilograys. Full approval of this 1980 recommendation was granted in 1983 by the International Codex Alimentarius Commission after a review of the results of all available data on wholesomeness research carried out in many countries around the world. It was pointed out that at that time, 39 food items had been approved for treatment with ionizing energy on either an unconditional or provisional basis in 22 countries (CAC, 1983a).

The Joint Expert Committee drew no conclusions in its 1980 meeting about the wholesomeness of foods treated with ionizing energy at doses exceeding 10 kilograys. The Committee noted that information from the U.S. Army's comprehensive wholesomeness study then in progress on chicken meat receiving doses of ionizing energy up to 68 kilograys and the study then in progress in the Netherlands on ham receiving ionizing energy treatments of 37 and 74 kilograys were needed to permit scientific evaluation.

In November 1982, the International Project in the Field of Food Irradiation published its final annual issue of *Food Irradiation Information*, which for 12 years had reported the results of the studies from many different countries on treatment of food with ionizing energy. This publication was terminated because, to quote its Editorial Comment, "The wholesomeness question has largely been resolved and legislative aspects are now well on the road to final international acceptance...." This final issue of *Food Irradiation Information* reports the experience and progress in 19 of the 24 countries participating in the programs, including the United States (IPFFI, 1982).

Nutritional Quality

Only small effects upon the nutritional value of the macronutrients in foods are expected from the use of ionizing energy because of the small amounts of energy involved. Nonetheless, experimental investigation is necessary to determine the effects that actually do occur and especially to check the response of different classes of nutrients. A Joint Expert Committee representing the Food and Agriculture Organization of the United Nations, the International Atomic Energy Agency, and the World Health Organization (WHO, 1977) stressed the importance of examining possible changes in nutrients resulting from processing foods with ionizing energy, determining whether the availability of nutrients is altered, and determining whether any changes that do occur might have adverse nutritional consequences. The Joint Expert Committee noted also that small changes in the nutritional quality of foods eaten in small quantities would not have nearly as great an effect on the overall nutritional balance as would the same changes in foods that are consumed in considerable amounts in habitual diets. In some developing countries, large population groups depend upon a single food source, such as wheat, rice, or millet, for a very high proportion of several nutrients in their diets.

In this report, principal emphasis will be placed upon the nutritional aspects of foods exposed to ionizing energy under conditions being considered for application in commercial processing. Applying ionizing energy to isolated nutrients either as solids or in aqueous solutions does not always yield data that can be meaningfully extrapolated to intact foods (Raica et al., 1972). Bregvadze and Bokeriya (1971) and Metlitskii et al. (1968) stated that because of the protective qualities inherent in foods, the sensitivity of individual nutritional components to damage by ionizing energy is less than that of the same nutrients treated in pure form or in simple solutions and mixtures.

Composite Diets

Until recent studies from Mainland China were made public in April 1986, the only known study in which human subjects received a diet consisting of components treated with ionizing energy had been reported by Bierman et al. (1958). The foods were frozen, treated with the following amounts of ionizing energy, and stored 3 months at room temperature before use: potatoes, 0.09 kilogray; flour, 0.70 to 0.74 kilogray; orange juice, 23 kilograys; chicken, peaches, green beans, sweet potatoes, carrots, corn, coleslaw, and pineapple jam, 28 kilograys; and codfish, bacon, shrimp, tuna, and fruit compote, 37 kilograys. Also included among the dietary components was jelly, the composition and ionizing energy dosage of which were not specified. The control foods without ionizing energy treatment were similarly frozen, but were stored frozen. Oranges were processed with 1.4 kilograys of ionizing energy and stored at 34° F (1° C). Three different diets were tested, each with and without the ionizing energy treatment of the components enumerated, and these components were used in amounts to supply 80% of the total calories. The diets were fed to 13 male volunteers 20 to 23 years of age who had passed a careful medical examination. There were 15 days of control diets and 15 days of diets containing foods treated with ionizing energy.

No clinical abnormalities were noted in the human subjects. The ionizing energy treatment decreased the thiamine and ascorbic acid content and increased the "browning reaction" derivatives, fat-soluble carbonyl compounds, and thiobarbituric acid reactants. The authors concluded that the ionizing energy produced few changes in nutrient and caloric composition of the foods used in their study. They stated that in previous balance studies, the apparent digestibility of protein, carbohydrate, and fat was similar in the treated and control diets. The ability of the diets to maintain nitrogen balance was shown to be essentially unchanged. These investigators observed no unfavorable effects as a result of ingestion of the degradation products resulting from the treatments with ionizing energy.

There are a number of publications on the nutritive value of composite diets fed to animals. Kennedy (1965) observed little change in nutritive value of animal feeds treated with ionizing energy at doses of 5 and 10 kilograys. Ley (1972, 1975) maintained germ-free rat and mouse colonies with good results for 5 years on feed that had been sterilized by ionizing energy. Other investigators also have reported good nutritional results from feeding composite diets that had been treated with ionizing energy to sustain germ-free and specific-pathogen-free rats, mice, swine, and chickens (Sato, 1970; Schoen and Hiller, 1971; Udes et al., 1971; Ley et al., 1969; Coats et al., 1963). Raica and Howie (1966), Read et al. (1961), and Kraybill (1960) reported that the biological value of proteins and the metabolizable energy value of composite rodent diets were unaltered by sterilizing the diets with 56 kilograys of ionizing energy.

Carbohydrates

Some of the radiolytic products of carbohydrates in foods treated with ionizing energy (Thomas, 1986) are glucuronic, gluconic, and saccharic acids, glyoxal, arabinose, erythrose, formaldehyde, and dihydroxyacetone. Oligosaccharides yield monosaccharides and products similar to those obtained from simple sugars. Polysaccharides (starch, cellulose, or glycogen) yield smaller units, such as glucose, maltose, and dextrins, and the radiolytic products of these substances.

Josephson et al. (1974) summarized the main effects of ionizing energy upon carbohydrates as being those of hydrolysis and oxidative degradation. Polysaccharides are depolymerized, and cellulose is made more susceptible to enzyme hydrolysis. Pectin substances lose their gelling powers. In short, complex carbohydrates are converted into simpler compounds by ionizing energy. Although ionizing energy may cause changes in the physical and chemical properties of high-carbohydrate foods, such as grains and some vegetables, these have not been shown to be of nutritional significance.

Simic (1983) and Philips (1972) have reported on the radiation chemistry of carbohydrates in model systems. Philips (1972) and Diehl et al. (1978) point out that foods contain many substances, such as amino acids and proteins, that protect carbohydrates against damage from ionizing energy. Therefore, caution must be exercised in extrapolating findings with pure substances and model systems (Thomas, 1986).

Read et al. (1961) determined with rats that the availability of carbohydrates of several foods was unaffected by a sterilizing dose of 55.8 kilograys. Lang and Bässler (1966) fed rats a diet of which 72% was potatoes that had received either 0.1 or 1 kilogray of ionizing energy. No differences in utilization of starch calories were found between treated and control products.

Saint-Lèbe et al. (1973) treated dry cornstarch with either 3 or 6 kilograys of ionizing energy from cobalt-60 and then fed the starch raw or cooked as 62% of the diet to rats for 1 year. No significant differences in growth or reproduction were found to result from the treatments with ionizing energy.

In the section on feeding studies to assess the toxicological safety of foods treated with ionizing energy, mention was made of the finding by Raica and Howie (1966) that sterilizing doses of ionizing energy produced a change in appearance and odor of certain high-sucrose products (gelatin dessert powder, vanilla dessert powder, and raisins) resembling the change in sucrose when it is caramelized by heating. Growth of rats was decreased in feeding trials with the processed products. Caramelizing sucrose with heat had a similar effect on the growth of rats. The nutritional implication of this observation is that some foods and food products with high sucrose content will not respond well to high doses of ionizing energy in terms of palatability and nutritional quality.

Fats

The effects of ionizing energy upon fats are similar to changes resulting from heat or oxidative processes. The main reactions involve oxidation, polymerization, decarboxylation, and dehydration. These changes affect less than 0.2% of the total lipids at amounts of absorbed ionizing energy up to 50 kilograys and do not change the nutritional value of the foods.

Ionizing energy produces a large number of compounds from fats in foods, depending upon the fatty acid composition (Mitchell, 1957; Partmann, 1962; Chipault, 1962; Merritt, 1966; Nawar, 1972, 1983a, 1983b). Unsaturated fatty acids are more readily oxidized than are the saturated acids. The chemical changes are reduced by applying the ionizing energy when the products are frozen and in evacuated containers and by packaging the products to exclude light and oxygen (Gel'fand, 1970; Diehl, 1984; Wierbicki, 1984; Merritt et al., 1985).

Plough et al. (1957) reported that when human subjects were fed pork that had been exposed to 28 kilograys of ionizing energy and stored for 1 year at room temperature, the apparent digestibility of the fat was unaffected. Lard that had received 56 kilograys of ionizing energy was absorbed by dogs more slowly than untreated lard because of delayed emptying of the stomach contents (Schreiber and Nasset, 1959). (This observation has not been confirmed when the treatment was performed in the absence of oxygen, and is suspected to be a consequence of oxidation that resulted from treating the lard with ionizing energy in containers that did not exclude oxygen.) The overall digestibility was unaffected, however, indicating that the changes associated with absorption of the ionizing energy had not seriously affected the breakdown of the lipids and absorption of the end products during digestion. Moore (1961) fed rats corn oil that had received either 28 or 56 kilograys of ionizing energy and found that the treatment did not adversely affect the digestibility. Availability of the fat treated with ionizing energy was 95.8%, and availability of the fat in the untreated control was 94.8%.

Proteins and Amino Acids

Although doses of ionizing energy far in excess of the maximum dosage of 71 kilograys envisaged for use in commercial food processing have marked effects upon proteins and amino acids, doses in the usual range have little effect. As can be seen from Appendix III, Table 7, low doses of ionizing energy produced a small decrease in the protein content of clams and haddock fillets and tended to increase the content of amino acids as a percentage of the protein content, indicating some breakdown of the proteins into their constituent amino acids (Brooke et al., 1964, 1966). Ley et al. (1969) reported that in a feeding trial with rats, sterilizing the diet with ionizing energy had no significant effect on the amino acid composition of the diet (Appendix III, Table 9) or on the digestibility, biological value, and net utilization of the protein (Appendix III, Table 8). The protein was supplied in the form of soya, meat-and-bone, and fish meals.

de Groot et al. (1972) studied the nutritive value of chicken that had been pasteurized with ionizing energy. Data excerpted from their report (Appendix III, Table 10) show that a 6 kilogray dose of ionizing energy caused no significant changes in the amino acids in chicken stored at 41° F (5° C) for 6 days and subsequently cooked and homogenized. Their protein efficiency ratio data (Appendix III, Table 11), as well as other data from their report, led them to conclude that the nutritive value of the protein was not noticeably affected by treating the chicken meat with ionizing energy.

Frumkin et al. (1973) treated raw beef with 6 kilograys of ionizing energy and cooked meat (ready to be eaten) with 8 kilograys. They concluded that the ionizing energy did not reduce the nutritional value of the protein.

Thomas (1986) reported the results of a study by the U.S. Army Medical Department on the volatile compounds formed in beef sterilized with heat and with 56 kilograys of ionizing energy. The two treatments were selected to give equivalent lethality to microorganisms. It was concluded that ionizing energy caused no more degradation compounds than did steam heat sterilization (FASEB, 1977, 1979a, 1979b).

Vakil et al. (1973) found no significant changes in protein, fat, and mineral content of wheat treated with gamma rays (0.2 and 2 kilograys) for insect disinfestation. They found no change in total amino acid profiles and available lysine content as a result of treatment with ionizing energy. There was an 8% increase in free amino acids in wheat that received a dose of 10 kilograys. They concluded that the changes in physicochemical properties of the protein in wheat were of no major nutritional significance. These findings are in agreement with those of other investigators who reported the results of similar experiments on rice, buckwheat, wheat, corn, and kidney beans (Pape, 1973; Leonova and Sosedov, 1972; Doguchi, 1969; Metlitskii et al., 1968; Nair and Brownell, 1965; Metta and Johnson, 1959; WHO, 1976, 1981a).

Vitamins

A voluminous literature has accumulated during the past 40 years on the effect of ionizing energy on vitamins. Reviews of the scientific literature have been published by Thomas (1986), Murray (1983), Kraybill (1982), Josephson et al. (1975, 1978), Richardson et al. (1956), and Tobback (1977).

As pointed out earlier in this section, the effects of ionizing energy on individual vitamins in pure solutions or in the simpler model systems may be markedly different from those observed on the same vitamins in foods because of the protective effects of other food constituents. Basson (1983) recently reviewed the literature on the effects of ionizing energy on vitamins in pure form or in solution. Although the effects of ionizing energy on the vitamins in foods and the nutritional significance of these effects are emphasized in this report, attention is called to a study by Rao et al. (1978), reported in Basson's review, on the need to protect aqueous preparations of B-vitamins by adding glucose and treating them in the frozen state. As with chemical changes in the macronutrients in foods, the adverse effects of ionizing energy on vitamins can be reduced by excluding oxygen and light, treating the food at a low temperature, and using the lowest energy dose needed for processing the food.

Potatoes

Potatoes are an important dietary source of ascorbic acid (vitamin C). Murray (1983) reported a 28 to 56% reduction in the ascorbic acid content of potatoes treated with 0.1 to 0.15 kilogray of ionizing energy, a dosage in the upper part of the range required for sprout inhibition during storage. The reduction was attributed to a shift from ascorbic acid to dehydroascorbic acid, a change he concluded is "irrelevant from a nutritional point of view because dehydroascorbic acid has practically the same vitamin C activity as ascorbic acid." Thomas (1986) concluded that ascorbic acid losses during storage of potatoes treated with 0.05 to 0.15 kilogray of ionizing energy are very small.

Onions

Murray (1983) found that onions treated with 0.02 to 0.06 kilogray of ionizing energy for sprout inhibition in the presence of air resulted in some conversion of ascorbic acid to dehydroascorbic acid without significantly affecting the nutritional value.

Fruits

Ascorbic acid retention in oranges, tangerines, tomatoes, and papayas varies from 100% to 72% with ionizing energy doses from 0.4 to 3.0 kilograys (Josephson et al., 1978).

Meat

Thomas and Josephson (1970) reported that thiamine destruction in meat caused by exposure to ionizing energy could be reduced by excluding oxygen and treating the meat in the frozen state. Losses of thiamine, riboflavin, niacin, and pyridoxine were less when ham and pork were sterilized by 45 to 56 kilograys of ionizing energy at -112° F (-80° C) than when these products were sterilized with heat under normal commercial processing conditions.

Thomas et al. (1981) found that loss of thiamine from pork was less when it was sterilized with 60 kilograys of ionizing energy from accelerated electrons received in a short time than from gamma rays from cobalt-60 received over a longer time. A similar beneficial effect on thiamine retention was also noted in chicken and beef (Thomas, 1986). The products treated with accelerated electrons retained 2 to 2.5 times as much thiamine as those treated with gamma rays. Thomas et al. (1981) suggested that with the higher instantaneous concentration of molecular fragments resulting from the electron beam, the likelihood would increase that the fragments would react with each other instead of with thiamine.

Vitamin B_{12}, para-amino-benzoic acid, pantothenic acid, and folacin are sensitive to ionizing energy in aqueous solution, but not in food (Bregvadze and Bokeriya, 1971; Metlitskii et al., 1968). Treatment of ground pork with as much as 56 kilograys of ionizing energy resulted in less than 10% destruction of pantothenic acid and no destruction of folacin (Sheffner and Spector, 1957). Richardson (1955) found that treating diets for chickens with ionizing energy resulted in no significant decrease in folacin activity. Thomas and Josephson (1970) found that treating nonfrozen pork with 48 kilograys of ionizing energy resulted in a 68% loss of pantothenic acid.

Seafood

Liuzzo et al. (1966) found no appreciable losses of riboflavin, niacin, pantothenic acid, biotin, folacin, or vitamin B_{12} from chilled but unfrozen oysters treated with 2 kilograys of ionizing energy. There was considerable destruction of thiamine and pyridoxine.

Brooke et al. (1964) reported similar effects on B-vitamins in air-packed clams receiving 4.5 kilograys or vacuum-packed clams receiving 3.5 kilograys of ionizing energy after 30 days of storage in ice. Haddock fillets showed the same pattern after treatment at these doses and under the same storage conditions (Brooke et al., 1966). Kennedy and Ley (1971) obtained comparable results with cod fillets.

Niacin in mackerel was not affected by treating it with 1 to 45 kilograys of ionizing energy followed by filleting, grinding, and storing the product at -8° F (-22° C) in plastic bags (Murray, 1983). However, 3 kilograys induced 15% losses of thiamine and 26% losses of pyridoxine. Thiamine loss at high doses of ionizing energy can be reduced by applying the energy to a frozen, vacuum-packed product.

Cereals

Vakil et al. (1973) reported 90% retention of thiamine, riboflavin, and niacin in wheat exposed to 0.2 or 2 kilograys of ionizing energy from gamma rays. Josephson et al. (1977) reported no detrimental effect on the thiamine, riboflavin, niacin, or pyridoxine content of bleached, enriched, hard-wheat flour treated in the 0.3 to 0.5 kilogray range. In the same report, these investigators found no impairment of the nutritive value of bread baked with this flour.

Murray (1983) reported on an Iranian study with rice. He stated that "losses up to 22% in the thiamine as well as in riboflavin, niacin, and pyridoxine have been observed" as a result of treatments with ionizing energy.

Disinfestation of corn with 0.25 to 3 kilograys of ionizing energy followed by 4 years of storage had no effect on the protein quality or on the content of protein and vitamins according to Murray (1983). He reported also that treatment of sorghum and millet with 0.2 kilogray of ionizing energy for disinfestation produced no negative nutritional effects on amino acids, vitamins B_1 and B_2, niacin, and pantothenic acid.

Rolled oats packed under nitrogen and exposed to a 1 kilogray dose of ionizing energy showed only 5% loss of vitamin E, whereas exposure in the presence of air resulted in a 56% loss according to Diehl (1979b). Results similar to packaging under nitrogen were obtained with vacuum packaging during the first 3 months of storage after treatment. Packaging under carbon dioxide was not beneficial, however, presumably because of liberation of oxygen during the treatment with ionizing energy (Diehl, 1979c).

Vegetables

Murray (1983) reported that treatment of endives with 1 kilogray of ionizing energy affected the vitamin C content only slightly. Kidney beans treated with 0.15 kilogray of ionizing energy had a lower content of riboflavin immediately after treatment than did the controls, but the difference had disappeared by the time the beans had been stored for 5 months (Murray, 1983). The vitamin K levels in asparagus, cabbage, cauliflower, green beans, spinach, and broccoli treated with 28 or 56 kilograys of ionizing energy were as high as their nonirradiated frozen counterparts (Richardson, 1960). He found less destruction of vitamin B_6 in beef liver, cabbage, boned chicken, green beans, and sweet potatoes after sterilization with ionizing energy than with heat.

Dairy Products and Margarine

More than 30 years ago, Kung et al. (1953) reported that a dose of 4.4 kilograys at room temperature destroyed 40% of the carotenoids, 70% of the vitamin A, and 60% of the tocopherols in whole milk. Other studies with dairy products have shown losses of vitamin A ranging from 31% to 68%.

Destruction of vitamin A by ionizing energy is less in margarine than in butter, presumably because the vitamin A esters used to fortify margarine are less sensitive to ionizing energy than the natural vitamin A alcohol in butter (Sheffner and Spector, 1957). Post-treatment storage at 32° F (0° C) in the absence of air limited further losses of vitamin A in cream cheese and margarine. Treatment of cream cheese with 50 kilograys of ionizing energy at -112° F (-80° C) and subsequent storage without refrigeration resulted in only a 5% loss of vitamin A (Diehl, 1979a).

Ionizing energy generates unacceptable off-odors and flavors in dairy products. Until the technology can be improved, therefore, it is not likely that the effect of ionizing energy on the nutritional quality of dairy products will be of practical concern to consumers.

Oils

Vitamin D in salmon oil was not adversely affected by ionizing energy (Knapp and Tappel, 1961), presumably because the vitamin E in the oil provided protection (Thomas, 1986). When sunflower oil at 68° F (20° C) was exposed to a 30 kilogray dose of ionizing energy in the presence of air, followed by heating for 1 hour at 356° F (180° C), 98% of its alpha-tocopherol was lost; 65% was lost if the ionizing energy was applied at -22° F (-30° C) (Diehl, 1979b).

Antivitamins

Serious concern about the possibility that exposure to ionizing energy would result in forming antivitamins in food was nonexistent until Banes (1968) testified for FDA at a hearing by a committee of the United States Congress. At this hearing, FDA hypothesized that ionizing energy results in "apparent production of antinutrient factors" from its evaluation of the wholesomeness data in a petition from the U.S. Army to approve the sterilization of ham by ionizing energy.

Somogyi (1973) has defined an antivitamin "as a compound that diminishes or abolishes the effect of a vitamin in a specific way." This is an extension of an earlier characterization of an antivitamin as a compound that (1) has a chemical structure similar to that of the vitamin, (2) produces symptoms similar to those produced by lack of the vitamin, and (3) acts competitively with the vitamin.

When the U.S. Army drew up its procedures in the 1970s for assessing the wholesomeness of beef and chicken meat sterilized with ionizing energy, studies to detect the possible formation of antithiamine and antivitamin B-6 as a consequence of the treatment were included. The ability of beef and chicken preserved by ionizing energy, freezing, and heating to resupply vitamin B-6-deficient and thiamine-deficient rats with these vitamins was assessed experimentally. McGown et al. (1979a, 1979b) reported that in testing for possible antivitamin activity they found no differences among the animal groups in growth, erythrocyte transketolase activity, and pyrophosphate effect. These investigators concluded that beef and chicken sterilized with ionizing energy from accelerated electrons and gamma rays contained no antithiamine properties. In testing for possible antivitamin B-6 activity, McGown et al. (1981) reported no differences in terms of animal weight gain and similar responses of rats in their vitamin B-6 dependent blood-enzyme activities (plasma and red cell aspartate aminotransferase and alanine aminotransferase) when they were fed chicken that had been frozen or treated with ionizing energy. Responses of some of the enzymatic values, however, were slightly delayed in groups fed chicken that had been treated with ionizing energy at a marginal vitamin level. The authors concluded that if an antivitamin B-6 factor is present in chicken treated with ionizing energy from gamma rays, "it is minimal, is detectable only under conditions of marginal B-6 status, and is overcome by added dietary pyridoxine."

Minerals

Foods sterilized by heat may be expected to lose minerals more readily in cooked-out juices than are dry-packed foods sterilized by ionizing energy. A difference in nutrient value may be found also where iron is concerned, but for a chemical reason.

In red meats, the color results primarily from the iron-containing myoglobin in the muscle. During cooking, the meat changes color from red (characteristic of the reduced form containing ferrous iron) to grayish brown (characteristic of the oxidized form containing ferric iron) as a result of interaction of the pigment with atmospheric oxygen. The same process occurs to a lesser degree when red meat is treated with ionizing energy in the presence of atmospheric oxygen.

Dietary iron is absorbed best when it is present in the reduced (ferrous) state in a compound such as myoglobin. Thus, the availability of the iron decreases when red meat is cooked, and it decreases to a smaller degree when the meat is treated with ionizing energy in the presence of atmospheric oxygen.

If precooked meat is packaged under vacuum and sterilized with ionizing energy, the iron is reduced, and the grayish brown of the cooked meat changes to the purple red color of myoglobin (with attendant increase in availability of the iron). If the meat subsequently is exposed to light and air, the normal grayish brown color of cooked meat returns (Simic, 1983).

Summary Evaluation

When research on treatment of food with ionizing energy began in the United States shortly after World War II, the objective was to produce products similar in nutritional quality to that of comparable foods preserved by the well established methods used by food processors. Improvements in processing techniques in the ensuing 40 years have culminated in the attainment of this objective even at high doses of ionizing energy (Thomas, 1986; Josephson et al., 1978; Josephson et al., 1975). These technological advances include using improved energy sources and dosimetry methods, narrowing the maximum to minimum dose ratios, reducing atmospheric oxygen to the extent feasible in and around certain foods during and after treatment, treating at low and controlled temperatures those foods that can be frozen and thawed with little damage, and using improved packaging to serve as protection against losses of nutrients caused by moisture, light, and oxygen during storage after the treatment with ionizing energy (Wierbicki, 1984, 1985). An additional advance has been made in combining ionizing energy with other processes to reduce the required dose.

No significant impairment in the nutritional quality of protein, lipid, and carbohydrate conditions has been reported in foods exposed to ionizing energy under conditions proposed for processing on a commercial scale. Exposure of food to ionizing energy is somewhat destructive of vitamins, but no more so than are other food preservation methods used commercially. There is no evidence that beef and chicken sterilized with ionizing energy have antithiamine properties. Antivitamin B-6 properties in chicken, if any, are slight and can be overcome by adding dietary pyridoxine. Protection of nutrients is improved by holding the food at a low temperature during treatment and by reducing or excluding atmospheric oxygen.

Microbiological Safety

Foods that have been treated with quantities of ionizing energy up to 10 kilograys are not sterile, and dependence must be placed upon other methods of preservation to prevent multiplication of surviving microorganisms. Where there are surviving microorganisms, investigators have been concerned about the possibility of (1) development of resistance to ionizing energy in the surviving organisms, (2) increased virulence of pathogens, (3) unusual spoilage characteristics due to changes in the normal flora, and (4) changes in physiological characteristics that would make it difficult to identify the organisms. To date, however, there is no evidence to indicate that any of these possibilities are valid. As far as is known, therefore, none of these four possibilities present a risk to the consumer (Ingram and Farkas, 1977; Maxcy, 1983; WHO, 1976, 1981a).

No specific microbiological problems arise with dry food because the low moisture content prevents the organisms surviving the ionizing energy treatment from multiplying and spoiling the food. Cereal products with moisture content exceeding 13% and stored at high relative humidity, however, may allow growth and mycotoxin production by molds that survive the low levels of ionizing energy (0.25 to 1 kilogray) use for disinfestation of grain.

If malpractice in storage of dry cereal grain should occur, the growth of molds could produce a health hazard (WHO, 1977), but the available evidence indicates that treating grain with ionizing energy to control insects does not add to that hazard (Tsai et al., 1984). Preformed aflatoxin can be detoxified by high doses of ionizing energy. Temcharoen and Thilly (1982) found that after treatment with 50 to 100 kilograys of ionizing energy from gamma rays, peanut meal had lost its toxic and mutagenic properties attributed to the aflatoxin B_1 contaminant. Treatment with 1.0 to 10 kilograys removed 75% to 100% of the toxicity but not the mutagenicity.

Moist foods may contain a variety of microorganisms of public health significance. Some of these, such as *Salmonella, Bacillus cereus, Campylobacter jejuni, Clostridium perfringens, Escherichia coli, Vibrio cholerae, Vibrio parahaemolyticus, Yersinia enterocolitica, Clostridium botulinum* type E, and *Clostridium botulinum* types A and B, are well known. These differ in susceptibility to ionizing energy. According to the Codex Alimentarius Commission (CAC, 1983b), there are no microbiological safety problems with moist foods, such as fresh meats, poultry, and fish, that have been treated with medium doses (10 kilograys) of ionizing energy as long as these foods are stored and distributed near the temperatures of ice (36 to 41° F) (2 to 5° C) according to good manufacturing practice. As long as foods are refrigerated below 50° F (10° C), there is no microbiological safety problem for *Clostridium botulinum* types A and B. *Clostridium botulinum* type E, however, can grow and produce toxin when stored under refrigerated conditions of 37° F (3° C) or above. This toxigenic organism is of particular concern in fresh fish. According to studies by the Food and Agriculture Organization of the United Nations, the International Atomic Energy Agency, and the World Health Organization, fresh fish should be treated at doses between 1 and 2.2 kilograys; such doses are sufficient to extend the shelf life. In the United States, with good refrigeration systems and food manufacturing practices, a dose of 0.75 to 1.5 kilograys should be sufficient for the purpose. At doses below 2.2 kilograys (and particularly below 1.5 kilograys), a diverse and active spoilage population remains to avoid toxin production by *Clostridium botulinum* type E (Hobbs 1976; WHO, 1976, 1981b). Eklund (1982), however, cautioned that when ionizing energy exceeding 1 kilogray is used, avoiding the development of this organism, when present, requires that the fish be kept refrigerated at a temperature below 38° F (3.3° C).

In the unlikely occurrence of contamination of fresh poultry with *Clostridium botulinum* type E, the product would be safe at practical commercial dose treatments of about 3 kilograys. At 50° F (10° C), the surviving members of the natural microflora would be able to multiply and produce spoilage odors within 8 days, whereas the *Clostridium botulinum* type E survivors could not produce toxin within 14 days. At higher temperatures, even at 86° F (30° C), the other surviving microflora would grow and produce spoilage before botulinum type E toxin would be produced (Firstenberg-Eden et al., 1982), and this spoilage would be adequate to prevent use of the product.

Treating fresh red meats, poultry, and fish with 3 kilograys of ionizing energy destroys much of the microflora, thereby reducing public health hazards. For example, absorption of this amount of ionizing energy would greatly reduce or eliminate such organisms as salmonellae, staphylococci, *Yersinia enterocolitica, Campylobacter jejuni,* and *Aeromonas hydrophila* (El-Zawahry and Rowley, 1979; Lambert and Maxcy, 1984; Mossel, 1977; Tarkowski et al., 1984; Palumbo et al., 1986). The remaining flora would not be of public health significance (Maxcy, 1983).

Preservation by a Combination of Ionizing Energy and Freezing

Freezing foods and storing them in the frozen condition arrests bacterial growth, but treating them with ionizing energy while frozen reduces the populations of existing microflora and produces a concomitant reduction in public health hazards. Viruses, which might not be affected, can be reduced in numbers by precooking. The combination of ionizing energy and freezing is particularly suitable for eliminating *Salmonella* from such foods as frozen shrimp, frog legs, meats, and poultry.

Sterilization by Ionizing Energy

The currently recommended process for sterilizing meats by ionizing energy, sometimes called radappertization, is to heat the meat to an internal temperature of 158 to 171° F (70 to 77° C), vacuum-packaging the meat in airtight containers, reducing the temperature to

-40° F (-40° C), and following this with a high dose of ionizing energy while keeping the temperature of the meat between -40 and +14° F (-40 and -10° C). The preliminary heating inactivates the autolytic enzymes as well as meat-borne parasites and enhances the lethal effect of the ionizing energy on active microbial cells (Maxcy and Rowley, 1978). Many microorganisms that are relatively resistant to ionizing energy (for example, viruses, *Moraxella-Acinetobacter,* and *Micrococcus radiodurans*) are sensitive to heat and would be reduced in numbers or eliminated at 158 to 171° F (70 to 77° C).

The dose of ionizing energy is designed to reduce a population of 10^{12} (1 trillion) spores of the most resistant strain of *Clostridium botulinum* bacteria of types A and B per package of food to one viable spore, or a population of any less than 1 trillion to less than one viable spore per package (that is, to reduce the probability of survival of one viable spore of *Clostridium botulinum* to less than one package of food for each trillion packages processed). A population of 1 trillion spores of resistant *Clostridium botulinum* per package of product is many times greater than the worst cases of contamination. Thus, a great margin of safety exists.

Appendix III, Table 12, lists the minimum doses of ionizing energy required for sterilization of different foods under the concept described in the preceding paragraph. The values given were obtained by inoculating the various meats with 10 million spores of *Clostridium botulinum* per 40 to 45 grams. The minimum doses of ionizing energy given are at least 10 to 15 kilograys higher than the actual dose needed to inactivate the most resistant strains of *Clostridium botulinum* (Anellis et al., 1967, 1979). This extra dose is enough to assure the destruction of a spore population 1,000 to 10,000 times as great as the hypothetical maximum of 1 trillion per package. The population of *Clostridium botulinum* spores in poultry and meat is normally very low (Greenberg et al., 1966), and exposure to 10 kilograys of ionizing energy results in commercially sterile products when they are artificially contaminated with additional *Clostridium botulinum* spores, as has been demonstrated with ham (Anellis et al., 1967), bacon (Rowley et al., 1983), and chicken (Wierbicki, 1984). This is not to recommend that the safety factor for sterilizing food with ionizing energy be relaxed below the comparable safety factor for the well established canning process, but rather to point out that the process described for sterilizing food with ionizing energy has a large margin of microbiological safety.

The microbiological safety of food sterilized by ionizing energy on a commercial scale is assured by: (1) following established practices that include determining the dose requirements for the specific food and (2) incubating representative samples of the product for 10 days at 86° F (30° C) according to the USDA-Food Safety and Inspection Service incubation requirements for nonacid vacuum-packaged canned foods. The back cover of this report shows pictures of chicken meat that had been tested for sterility after sterilization by the method described in the first paragraph of this section.

Conclusion

On the basis of this review of all the pertinent worldwide data, both published and unpublished, that were available to the members of the writing group who prepared the first draft of this report, and their combined personal knowledge derived from involvement in research totaling about 175 years, it is concluded that foods processed with ionizing energy on a commercial scale are safe to eat. This conclusion confirms the statement made almost 21 years ago by the U.S. Army Surgeon General, who said to a Committee of the U.S. Congress that foods treated with ionizing energy are "wholesome; that is safe and nutritionally adequate" (Surgeon General, 1965).

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Appendix I: Glossary

Accelerator. In food irradiation, a device for producing beams of electrons with high speed and energy.

Alpha particle. A positively charged particle emitted from a nucleus and composed of two protons and two neutrons. It is identical in all measured properties with the nucleus of a helium atom.

Aqueous electron. The hydrated electron, a radiolytic product of water.

Becquerel. A unit of radioactivity. It is equal to one disintegration per second.

Beta particle. A charged particle emitted from the nucleus during radioactive decay and having a mass and charge equal in magnitude to those of the electron. A negatively charged beta particle is physically identical to the electron.

British thermal unit. The amount of heat required to raise the temperature of 1 lb of water 1° F at or near 39.2° F.

Carcinogen. A substance or agent producing or inciting cancer.

Cathode ray. A stream of electrons emitted by the cathode of a gas-discharge tube or by a hot filament in a vacuum tube. The electron beams used in food irradiation generated by accelerators are cathode rays.

Chemiclearance. Regulatory clearance of a particular use of ionizing energy on a particular food on the basis of knowledge of the radiolytic products produced and an evaluation of the effect of these products on the safety of the food for human consumption.

Curie. A basic unit used to describe the intensity of radioactivity of a radio-nuclide. 1 curie equals that quantity of radioactive material having 3.7×10^{10} disintegrations per second. This approximates the activity of 1 gram of radium. 1 curie is equivalent to 3.7×10^{10} bequerels.

Decimal reduction. The ionizing energy dose in grays needed to reduce a population (e.g., of bacteria) by a factor of 10, or one log cycle, leaving as survivors 10% of the original population.

Disinfestation. In food irradiation, the inactivation of food-borne insects or parasites.

Dose. The amount of ionizing energy absorbed by a material.

12D-dose. The dose sufficient to reduce the number of viable *Clostridium botulinum* spores by a factor of 10^{12}, required for sterilization of foods by ionizing energy (radappertization).

Dose-equivalent index. The index of biological effectiveness of different kinds of ionizing radiation relative to the effectiveness of x-rays with an energy of 200,000 electron volts. It replaces the previously used relative biological effectiveness.

Dose meter. A device for measuring dose.

Dosimetry. The process of measuring dose.

Electron. A negatively charged particle that is a constituent of all atoms.

Electron volt. The amount of kinetic energy gained by an electron accelerated through an electric potential difference of 1 volt. One electron volt equals 1.6×10^{-19} joule. One electron volt absorbed per gram is equivalent to a dose of 1.6×10^{-16} gray.

Free radical. A molecular entity with an unpaired electron in the outer orbit of an atom. A free radical is formed by the cleavage of a molecule upon reaction with another reactive chemical entity or upon absorption of a quantum of energy from either an energetic photon or a fast moving particle.

G value. Number of molecules changed per 100 electron volts of energy transferred to the system.

Gamma ray. A quantum or unit of short-wavelength electromagnetic radiation produced when an unstable atomic nucleus gains stability by release of energy.

Gray. A unit of absorbed dose of ionizing energy. It is equivalent to 1 joule, 10^7 ergs, 6.25×10^{18} electron volts, or 0.24 gram-calorie, all per kilogram. It replaces an older unit, the radiation absorbed dose (rad). One gray is equivalent to 100 radiation absorbed dose units.

Half life. The time required for a radioactive source to decay to one-half of its original radioactivity. The half-life of cobalt-60 is 5.27 years, and the half-life of cesium-137 is 30.3 years.

Hertz. The frequency or number of cycles of electromagnetic radiation per second.

High dose. In food irradiation, doses of 10 kilograys or more.

Induced radioactivity. Radioactivity resulting from exposure to ionizing energy.

Ion. An isolated electron or positron or an atom or group of atoms bearing an electrical charge, either positive or negative, caused by an excess or deficiency of electrons.

Ionization. Creation of ions by forming units of one or more atoms bearing positive or negative charges as a result of a deficiency or excess of electrons.

Ionizing energy. In food processing, high-speed electrons from machine sources or radiant energy from x-rays or gamma rays. The standard gamma ray sources are cobalt-60 and cesium-137.

Irradiation. The process of applying ionizing energy.

Irradiator efficiency. The percentage of the total radiation energy emitted by the irradiator source that is absorbed by the product being processed.

Isotopes. Atoms of a given chemical element having in the nucleus the same number of protons but different numbers of neutrons.

Joule. A unit of work or energy equivalent to 10^7 ergs or approximately 0.7375 foot-pound.

Low dose. In food processing, ionizing energy doses less than 1 kilogray. See also the definition for medium dose.

Medium dose. In food processing, ionizing energy doses of 1 up to 10 kilograys. In earlier literature, this dose range (substerilizing) was included in the low dose range. The recent division of the substerilizing dose range into low and medium is a result of FDA's notice in the *Federal Register* on March 27, 1981, of its proposed intent to approve without further wholesomeness testing all fruits, cereals, and vegetables exposed to doses up to 1 kilogray.

Mutagenicity. The capacity to induce mutations or heritable genetic changes.

Nitrosamines. Any of various neutral compounds characterized by the grouping NNO, some of which are powerful carcinogens.

Organoleptic. Affecting or employing one or more of the organs of special sense, e.g., taste and smell.

Photon. One unit or quantum of radiant energy.

Phytotoxicity. Poisonous to plants.

Positron. A positively charged particle having the same mass and magnitude of charge as the electron and constituting the antiparticle of the electron.

Protein efficiency ratio. The gain in weight per unit weight of protein consumed. The measurement usually is made with male rats under standard conditions of a 4-week assay period with diets containing 10% protein and adequate amounts of other nutrients. Casein (the milk protein), used as the reference, has an efficiency ratio of about 2.5.

Radappertization. Treatment of food with a dose of ionizing energy sufficient to prevent spoilage or toxicity of microbial origin no matter how long or under what conditions the food is stored after treatment, provided it is not recontaminated.

Radiation. Radiant energy. In food processing, the term is limited to gamma rays, x-rays, and electron beams.

Radiation absorbed dose (rad). An outdated term for absorbed dose. One radiation absorbed dose is equivalent to 100 ergs of absorbed energy per gram. One gray is equivalent to 100 rads.

Radicidation. Treatment of food with a dose of ionizing energy sufficient to reduce the number of viable specific nonsporeforming pathogenic bacteria to such a level that none is detectable in the treated food when it is examined by any recognized bacteriological testing method. Such treatment also inactivates foodborne parasites.

Radioactivity. The property possessed by some elements of spontaneously emitting ionizing energy from the nuclei of the atoms in the form of alpha particles, beta particles, or gamma rays.

Radiolytic. Related to chemical decomposition as a result of exposure to ionizing energy.

Radionuclide. An unstable form of an element that decays or disintegrates spontaneously, emitting radiation. Replaces the older term, radioisotope.

Radurization. Treatment of food with a dose of ionizing energy sufficient to enhance its keeping quality by causing a substantial reduction in the numbers of viable specific spoilage microorganisms.

Relative biological effectiveness. An obsolete term now replaced by the dose biological effectiveness equivalent index.

Ripening. To approach or come to full development and become usable as food.

Roentgen. The dose of gamma or x-radiation producing ion pairs carrying one electrostatic unit of charge per cubic centimeter of standard air surrounded by air. It is equivalent to 88 ergs per gram of air.

Roentgen equivalent man (rem). An obsolete unit of dose equivalence, now replaced by the sievert. One sievert is equivalent to 100 rems.

Senescence. The phase of plant growth from full maturity to death characterized by an accumulation of metabolic products, increase in respiratory rate, and a loss in dry weight, especially in fruit and leaves.

Sievert. The dose of ionizing energy that produces the same biological effect on humans as a dose of one gray from gamma rays or fast electrons. It replaces the older term, roentgen equivalent man (rem). One sievert is equivalent to 100 rem. For other forms of ionizing energy, the relationship between the sievert and the gray is not 1 to 1.

Teratogenicity. The ability to cause developmental malformations and monstrosities in the progeny of the exposed individual.

Unit prefixes. Pico (10^{-12}), nano (10^{-9}), micro (10^{-6}), milli (10^{-3}), kilo (10^3), mega (10^6).

X-ray. A short-wavelength electromagnetic radiation produced when high-energy charged particles (usually electrons) strike a metal target.

Wholesomeness. Foods processed with ionizing energy are generally considered wholesome when harmful microorganisms and microbial toxins are absent, when the ionizing energy has produced no measurable toxic effects or radioactivity, and when the food presents no significant nutritional deficiency relative to the same food that has not been processed with ionizing energy or has been processed by conventional methods.

Appendix II

1984 Toxicological Studies of Chicken Sterilized by Ionizing Energy — U.S. Army and Eastern Regional Research Center, U.S. Department of Agriculture[a]

Order Number	Title and Document Number	Form and Cost
PB84-186980	Wholesomeness Studies of Precooked (Enzyme Inactivated) Chicken Products in Vacuum Sealed Containers Exposed to Doses of Ionizing Radiation Sufficient to Achieve "Commercial Sterility" (Summary of Supporting Documents) ERRC-ARS Document No. 85 191 pages	Printed copy $ 17.50 Microfiche 4.50
PB84-186998	Animal Feeding Study Protocol Sterilized Test Foods; Packaging Materials for Use During the Ionizing Irradiation; Sterilized Chicken Products: Technology, Product Quality, Feasibility (Technical Report) ERRC-ARS Document Nos. 40, 82, and 84 (Protocol Grouping) 688 pages	Printed copy $ 51.50 Microfiche 7.50
PB84-187004	Animal Feeding Study of Irradiation Sterilized Chicken (Quarterly Reports) ERRC-ARS Documents Nos. 1 to 39 15,073 pages	Printed Copy $950.00 Microfiche 51.50
PB84-187012	Chronic Toxicity, Oncogenicity, and Multigeneration Reproductive Study Using CD-1 Mice to Evaluate Frozen, Thermally Sterilized, Cobalt-60 Irradiated, and 10 Mev Electron Irradiated Chicken Meat (Final Report) ERRC-ARS Document Nos. 41 to 54 10,328 pages	Printed Copy $690.00 Microfiche 40.50
PB84-187020	Irradiation Sterilized Chicken Meat: A Chronic Toxicity, and Reproductive Performance Study in Beagle Dogs. Volumes 1-9. 6,861 pages	Printed copy $475.00 Microfiche 31.50
PB84-187038	Irradiation Sterilized Chicken: Feeding Study in Rats ERRC-ARS Document No. 64 401 pages	Printed copy $ 34.50
PB84-187046	Hamster, Mouse, Rabbit, and Rat Teratology Studies of Irradiation Sterilized Chicken Products ERRC-ARS Document Nos. 65, 66, and 69 835 pages	Printed copy $ 70.00 Microfiche 7.50
PB84-187053	Genetic Studies: Dominant Lethal Study, Sex Linked, Recessive Lethal, Ames Mutagenicity, and Heritable Translocation Test of Thermal Processed, Frozen, Electron Irradiated, and Gamma Irradiated Chicken ERRC-ARS Document Nos. 68, 70, and 74 406 pages	Printed copy $ 37.50
PB84-187061	Protein Efficiency Ratio Determination of Irradiation Sterilized Chicken Products ERRC-ARS Document Nos. 71, 73 44 pages	Printed copy $ 9.50 Microfiche 4.50

PB84-187079	Antivitamin Studies of Irradiation Sterilized Beef and Chicken, Assessment of Mutagenic Activity of Irradiated Beef Using the Ames Salmonella/Mammalian Mutagenicity Assay	Printed copy Microfiche	$ 28.50 4.50
	ERRC-ARS Document Nos. 75, 76, 77 and 78 282 pages		
PB84-187087	Evaluation of the Health Aspects of Radiolytic Compounds Found in Irradiated Beef	Printed copy Microfiche	$ 23.50 4.50
	ERRC-ARS Document Nos. 79, 80, and 82 184 pages		
PB84-187095	Radiolysis Compounds in Bacon and Chicken	Printed copy Microfiche	$ 37.50 4.50
	ERRC-ARS Document No. 83 466 pages		

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[a] Documents available from the National Technical Information Service, 5285 Port Royal Road, Springfield, Virginia 22161.

Appendix III: Tables and Figures

Table 1. Average Dose-Equivalent Amounts of Radiation Received by Parts of the Human Body From Various Natural Sources of Radiation in the United States (Anonymous, 1980)

	Average Dose Equivalent Amounts in Millisieverts per Year[g]				
			Bone		G.I.
Radiation Sources	Gonads	Lung	Surfaces	Marrow	Tract
Cosmic radiation[a]	0.28	0.28	0.28	0.28	0.28
Cosmogenic radionuclides	0.007	0.007	0.008	0.007	0.007
External terrestrial[b]	0.26	0.26	0.26	0.26	0.26
Inhaled radionuclides[c]	—	1.0-4.5[d]	—	—	—
Radionuclides in body[e]	0.27	0.24	0.60	0.24	0.24[f]
Totals (rounded)	0.8	1.8-5.3	1.1	0.8	0.8

[a] Assuming 10% reduction to account for structural shielding.

[b] Assuming 20% reduction for shielding by housing and 20% reduction for shielding by body.

[c] Dose rates to organs other than lung included in "Radionuclides in body."

[d] Local dose-equivalent rate to segmental bronchi.

[e] Excluding cosmogenic contribution, which is shown separately.

[f] Excluding contribution from radionuclides in intestinal contents.

[g] The original units were millirems per year; 1 millisievert = 100 millirems.

Table 2. Reviews of the Radiation Chemistry of Basic Food Substances

Topic	Reference
Aqueous solutions - radiation chemistry principles	2, 3, 4
Amino acids and peptides	1, 2
Carbohydrates	1, 2, 3, 4
Fats	1, 2, 3, 4
Fruits	4
Meats	1, 2, 4
Nucleic acids	2
Nutritional aspects	1
Packaging materials	1
Proteins	3, 4
Seafoods	1
Vitamins	3

1 - Josephson and Merritt (1972).
2 - Merritt (1978).
3 - Elias and Cohen (1977).
4 - Elias and Cohen (1983).

Table 3. Distribution of Naturally Occurring Volatile Compounds Among Various Foods (Josephson and Merritt, 1972; TNO, 1977).

Alkanes	Alkenes and Alkadienes	Alcohols	Alkyl Benzenes	Carbonyl Compounds	Sulfur Compounds	Esters
Coffee	Coffee	Apples	Coffee	Apples	Strawberries	Apples
Cheese	Cheese	Pears	Cheese	Pears	Cabbage	Pears
Apples	Citrus fruits	Bananas	Fish	Bananas	Onions	Bananas
Grapes		Grapes	Berries	Grapes	Potato	Grapes
Citrus fruits		Berries	Tea	Berries	Celery	Peaches
		Tomatoes		Tomatoes	Peas	Berries
		Peaches		Onions	Rutabaga	Citrus fruits
		Coffee		Coffee	Coffee	Coffee
		Cocoa		Cocoa	Cocoa	Cocoa
		Tea		Tea	Tea	Wine
		Bread		Bread	Bread	Beer
		Wine		Wine	Beer	Cheese
		Beer		Beer	Milk	
		Cheese		Milk	Cheese	
		Meat		Cheese	Meat	
				Meat	Fish	
				Fish		
				Citrus fruits		

Table 4. Foods Fed to Rats for Eight Weeks After Treatment of the Foods With 0, 27.9, and 55.8 Kilograys of Ionizing Energy (Raica and Howie, 1966)

Meats

- Chicken
- Bacon
- Beef
- Beef, corned
- Frankfurters
- Ham
- Sausage
- Turkey

Fruits

- Apricots, dried
- Cherries, sour
- Melon
- Peaches
- Pears, dried
- Raisins
- Strawberries

Fish

- Haddock
- Salmon
- Shrimp
- Tuna

Vegetables

- Asparagus
- Beets
- Brussel sprouts
- Cabbage
- Carrots
- Cauliflower
- Celery
- Corn
- Cranberries
- Green beans
- Green peas
- Lima beans
- Mushrooms
- Potatoes
- Potatoes, sweet
- Spinach

Cereals

- Bread
- Cereal bar
- Crackers
- Macaroni
- Rice

Desserts and Other

- Dessert powder (vanilla)
- Gelatin dessert powder
- Nut roll
- Peanut butter
- Pound cake
- Whole dried milk

Table 6. Foods Used in Long-Term Feeding Studies to Investigate the Effect of Treating Foods With Ionizing Energy (Raica, 1963)

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

Table 5. Foods Fed to Human Volunteers in Short-Term Studies to Investigate the Effect of Treating the Foods With Ionizing Energy (Brynjolfsson, 1978)

11 meat items

- Bacon
- Corned beef
- Ground beef
- Beef steak
- Chicken
- Chicken stew
- Frankfurters
- Ground ham
- Ham steak
- Ground pork
- Sausage

5 fish items

- Cod
- Haddock
- Salmon
- Shrimp
- Tuna

9 fruit items

- Dried apricots
- Cherries
- Dried fruit compote
- Melon balls
- Oranges
- Orange juice
- Peaches
- Dried pears
- Strawberries

14 vegetable items

- Asparagus
- Green beans
- Lima beans
- Beets
- Brussels sprouts
- Cabbage
- Carrots
- Cauliflower
- Celery
- Coleslaw
- Mushrooms
- Peas
- Sweet potatoes
- White potatoes

9 cereal product items

- Bread
- Crackers
- Cereal bar
- Flour
- Macaroni
- Nut roll
- Pound cake
- Rice
- Corn

6 miscellaneous items

- Dessert powder
- Powdered whole milk
- Peanut butter
- Pineapple jam
- Strawberry jam
- Sugar

Table 7. Amino Acid and Protein Content of Clams and Haddock Irradiated With Different Amounts of Ionizing Energy and Treated in Different Ways (Brooke et al., 1964, 1966)

	Amino Acids As a Percentage of the Protein Content					
	Clams[a]			Haddock[b]		
Amino Acid	Non-irradiated[c]	4.5 Kilograys[d]	3.5 Kilograys[e]	Non-irradiated[c]	2.5 Kilograys[d]	1.5 Kilograys[e]
Tryptophan	1.10	1.24	1.15	1.27	1.18	1.18
Lysine	6.89	6.69	7.35	10.78	9.40	9.82
Histidine	1.31	1.74	1.35	2.26	1.75	2.22
Threonine	3.49	4.05	4.15	4.02	3.72	4.54
Valine	3.89	4.12	3.99	4.50	4.70	4.89
Methionine	2.18	2.30	2.12	3.00	3.11	3.31
Isoleucine	3.75	4.00	3.68	4.64	4.76	5.35
Leucine	6.27	6.50	5.89	5.32	7.54	8.47
Phenylalanine	2.88	3.43	2.68	3.32	3.40	4.15
½ Cystine	1.09	1.02	1.05	0.99	0.83	1.13
Ammonia	1.42	1.78	2.01	1.51	1.43	1.31
Arginine	6.24	6.79	6.93	6.66	6.07	5.13
Aspartic acid	7.46	7.60	7.75	9.30	9.78	11.05
Serine	3.47	4.08	3.81	3.91	3.79	4.97
Glutamic acid	11.35	12.11	12.41	13.33	11.12	15.75
Proline	2.85	3.24	3.14	2.97	3.14	3.57
Glycine	6.45	6.85	7.01	3.91	4.22	4.55
Alanine	7.62	7.76	7.97	5.41	5.73	6.08
Tyrosine	2.88	3.11	2.51	2.83	3.17	3.76
Protein (%)	10.75	8.97	10.05	19.00	17.49	17.63
Moisture (%)	85.50	88.28	86.30	79.56	81.14	79.10

[a] Stored 30 days at 32°F (0°C) after irradiation.
[b] Stored 30 days in ice.
[c] Fresh.
[d] Air packed.
[e] Vacuum packed.

Table 8. Protein Quality of Rat Diets After Treatment With Different Doses of Ionizing Energy (Ley et al., 1969)

Dose of Ionizing Energy, Kilograys	True Digestibility[a]	Biological Value[b]	Net Protein Utilization[c]
0	85.6	80.5	68.9
5	83.6	75.8	63.5
10	86.5	81.7	70.6
25	87.0	78.1	68.0
35	84.8	77.3	65.4
70	85.3	76.4	65.2

[a] True protein digestibility (PD) in percent is defined as

$$PD = \frac{[I - (F - F_k)]\,[100]}{I}$$

where I = nitrogen intake, F = fecal nitrogen output when the subject is on the test diet, and F_k = fecal nitrogen output when the subject is on a nonprotein diet.

[b] The biological value (BV) of a protein in percent is defined as

$$BV = \frac{\text{Retained Nitrogen} \times 100}{\text{Absorbed Nitrogen}}$$

or

$$BV = \frac{[I - (F - F_k) - (U - U_k)]\,[100]}{I - (F - F_k)}$$

where U = urinary nitrogen output with the test protein source, U_k = urinary nitrogen output with a protein-free diet, and the other terms have the same meanings as in footnote *a*. The protein to be tested is fed to the subject as the sole source of nitrogen in the diet at a level below that needed for maintenance.

[c] Net protein utilization (NPU) in percent is defined as

$$NPU = \frac{(R)\,(100)}{I}$$

where R = total retained nitrogen and I = nitrogen intake. The value of R somewhat exceeds the value of $I - (F - F_k) - (U - U_k)$ in the biological value in footnote *b* because some nitrogen is lost in digestion.

Table 9. Amino Acid Content of the Protein in a Rat Diet as Affected by Treatment With Ionizing Energy (Ley et al., 1969)

	Grams of Amino Acid per 16 Grams of Nitrogen	
Amino Acid	No Ionizing Energy Used	70 Kilograys of Ionizing Energy
Asparagine	8.85	8.38
Threonine	3.80	3.73
Serine	4.17	4.16
Glutamic acid	15.70	15.61
Glycine	5.82	5.79
Alanine	5.61	5.54
Valine	4.78	4.68
Isoleucine	3.99	3.99
Leucine	7.44	7.47
Tyrosine	3.28	3.38
Phenylalanine	4.12	4.28
Lysine	5.72	5.82
Histidine	2.29	2.37
Arginine	6.04	6.05
Methionine	2.33	2.11
Cystine	1.34	1.44
Tryptophan	1.16	1.32

Table 11. Nutritive value of Protein in Chicken Meat After Treatment With Different Doses of Ionizing Energy and Storage at 41°F (5°C) Four to Seven Days Before Cooking (de Groot et al., 1972)

Dose of Ionizing Energy, Kilograys	Protein Efficiency Ratio[a]
0	2.18
3	2.34
6	2.21

[a] Gain in weight per unit weight of protein eaten (usually measured with male rats under standard conditions of a 4-week assay period with diets containing 10% protein and adequate in all other essential nutrients).

Table 10. Amino Acid Content of Chicken Meat Treated With Different Doses of Ionizing Energy, Then Stored Six Days at 41°F (5°C) and Cooked (de Groot et al., 1972)

	Grams of Amino Acids per 16 Grams of Nitrogen With Indicated Doses of Ionizing Energy		
Amino Acid	None	3 Kilograys	6 Kilograys
Isoleucine	4.2	4.2	4.3
Leucine	6.7	6.7	6.8
Lysine	7.1	6.9	7.1
Methionine	2.3	2.3	2.35
Cystine	0.98	1.02	1.02
Phenylalanine	3.6	3.5	3.5
Tyrosine	2.9	2.8	3.0
Threonine	4.0	4.0	4.1
Tryptophan	0.98	0.93	0.96
Valine	4.8	4.8	4.9
Arginine	6.6	6.5	6.6
Histidine	3.4	3.3	3.3
Alanine	6.4	6.5	6.6
Aspartic acid	8.4	8.2	8.4
Glutamic acid	13.6	13.6	13.6
Glycine	8.5	8.8	9.0
Proline	5.5	5.6	5.7
Serine	4.1	4.1	4.2
Availability of lysine	94%	95%	96%
$\frac{\text{Amino acid N}}{\text{Kjeldahl N}} \times 100$	93	92	93

Table 12. Minimum Doses of Ionizing Energy for Sterilization of Different Foods (Wierbicki, 1984)[a]

	Temperature During Sterilization		Minimum Dose of Ionizing Energy, Kilograys	
Food	°C	°F	Range	Mean
Bacon	5 to 25	41 to 77	26.5-28.7	27.6
Beef	−30 ± 10	−22 ± 18	36.4-41.2	38.9
Beef	−80 ± 10	−112 ± 18	52.0-61.3	57.0
Ham	5 to 25	41 to 77	30.0-35.0	32.5
Ham	−30 ± 10	−22 ± 18	32.0-38.0	35.0
Codfish cake	−30 ± 10	−22 ± 18	30.4-32.4	31.7
Corned beef	−30 ± 10	−22 ± 18	24.4-25.7	25.1
Pork sausage	−30 ± 10	−22 ± 18	23.9-26.5	25.2
Shrimp	−30 ± 10	−22 ± 18	19.9-51.2	37.2
Pork	5 to 25	41 to 77	41.9-49.9	45.6
Pork	−30 ± 10	−22 ± 18	43.7-44.8	44.3
Chicken	−30 ± 10	−22 ± 18	43.4-46.2	44.8
Chicken[b]	−30 ± 10	−22 ± 18	42.7-47.8	43.9

[a] Summarized from published sources.

[b] Chicken meat with 0.75% sodium chloride and 0.3% sodium tripolyphosphate as additives.

Table 13. Quantities and Dates of Production of Enzyme-Inactivated Chicken Meat by Oscar Mayer and Company for Use in the RALTECH Studies on the Wholesomeness of Chicken Meat Processed by Ionizing Energy (Wierbicki, 1985)

			Quantities of Indicated Classes of Enzyme-Inactivated Chicken Meat Produced, kilograms[b]			
Contract No. NLABS[a]	Production No.	Production Dates	FC	TP	GAM	ELE
DAAG17-76-C-0042	1	April-May 1976	6,435	5,677	5,749	6,052
DAAK60-77-C-0024	2	Feb.-April 1977	10,459	9,652	10,196	9,778
DAAK60-78-C-0023	3	Feb.-April 1978	9,925	10,425	9,581	8,448
Modification						
DAAK60-78-C-0023	3A	April-May 1978	12,755	6,535	6,320	6,320
Total			39,574	32,289	31,846	30,598
Grand total			134,307			

[a] NLABS = U.S. Army Natick Research, Development and Engineering Center, Natick, Massachusetts.

[b] The class designations are codes used by RALTECH for the experimental diets containing 35% of the meat in the total diet and are defined as follows: *FC = Frozen Control Chicken* -- boneless, enzyme-inactivated (heated to an internal temperature of 163 to 176°F or 73 to 80°C), canned, and frozen. This corresponds to Diet F described in the text. *TP = Thermally Processed Chicken* -- boneless, enzyme-inactivated chicken, canned and thermally treated to produce commercial sterility. This corresponds to Diet T described in the text. *GAM = Chicken Processed With Ionizing Energy From Cobalt-60* -- boneless, enzyme-inactivated chicken, canned under vacuum, sterilized at -77°F ± 27° or -25°C ± 15° by 45 to 68 kilograys of gamma irradiation from cobalt-60, and stored without refrigeration. This corresponds to Diet G described in the text. *ELE = Chicken Processed With Ionizing Energy From Electrons* -- boneless, enzyme-inactivated chicken, vacuum packed in flexible pouches, sterilized at -77°F ± 27° or -25°C ± 15° with 45 to 68 kilograys of electrons with an energy of 10 million electron volts, and stored without refrigeration. This corresponds to Diet E described in the text.

Table 14. Chemical Composition of Enzyme-Inactivated Chicken Meat Prepared by Oscar Mayer and Company for Use in the RALTECH Studies on the Wholesomeness of Chicken Meat Processed by Ionizing Energy (Wierbicki, 1985)

Constituent or Measurement	No. of Samples	Frozen Control Chicken (FC)	Thermally Processed Chicken (TP)	Chicken Processed With Ionizing Energy From Cobalt-60 (GAM)	Chicken Processed With Ionizing Energy From Electrons (ELE)
Water, %	12	65.4	65.3	65.1	65.3
Protein, %	12	20.2	19.9	20.0	20.4
Fat, %	12	12.4	12.7	13.0	12.6
Ash, %	12	1.9	1.9	1.9	1.9
Sodium chloride, %	12	0.85	0.87	0.85	0.87
Phosphorus, %	12	0.265	0.263	0.260	0.266
Nonprotein nitrogen, %	8	0.36	0.35	0.38	0.38
pH	8	6.39	6.33	6.40	6.39

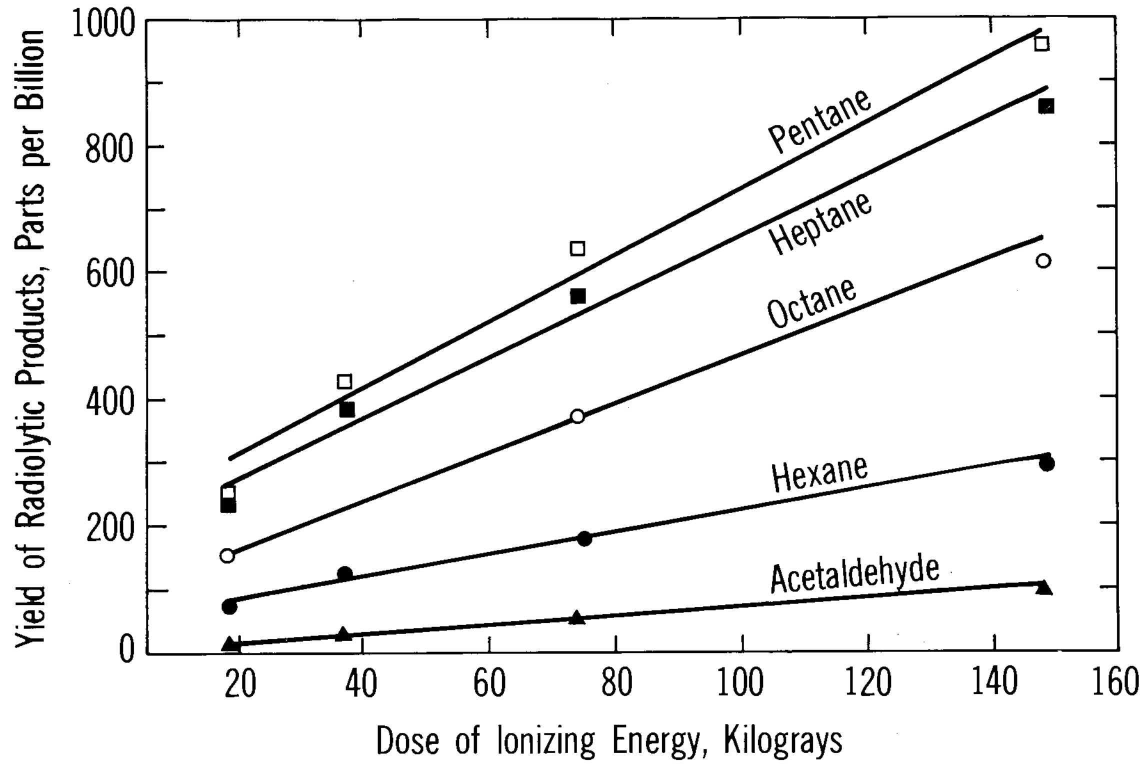


Fig. 1. Yields of five radiolytic products from beef with different doses of ionizing energy (Merritt et al., 1978).

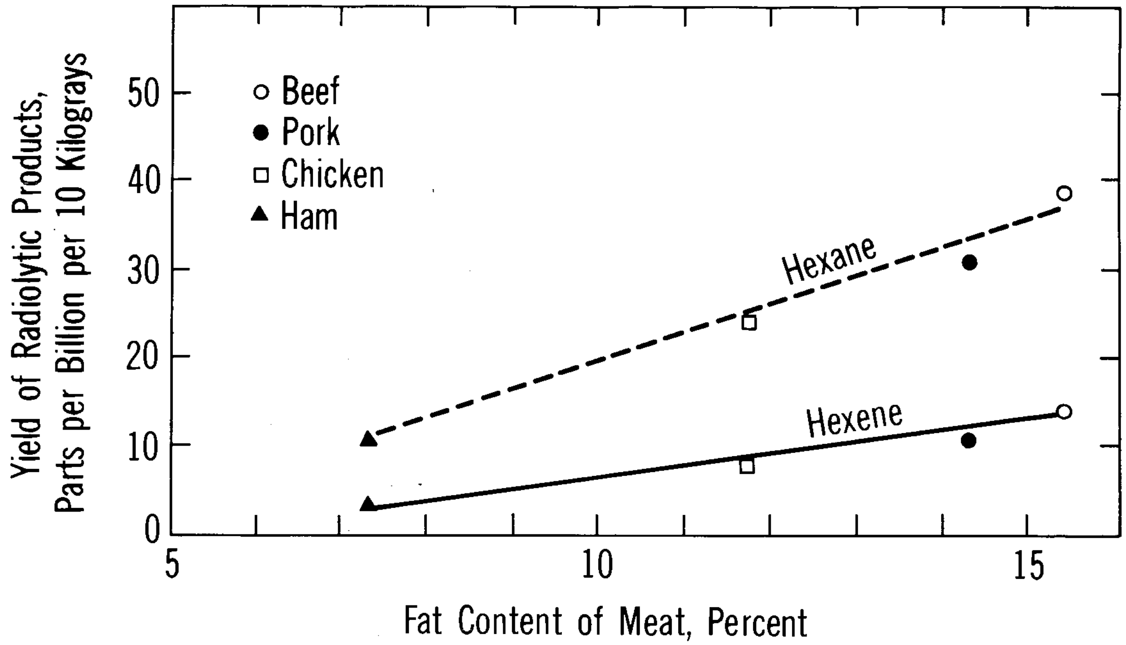
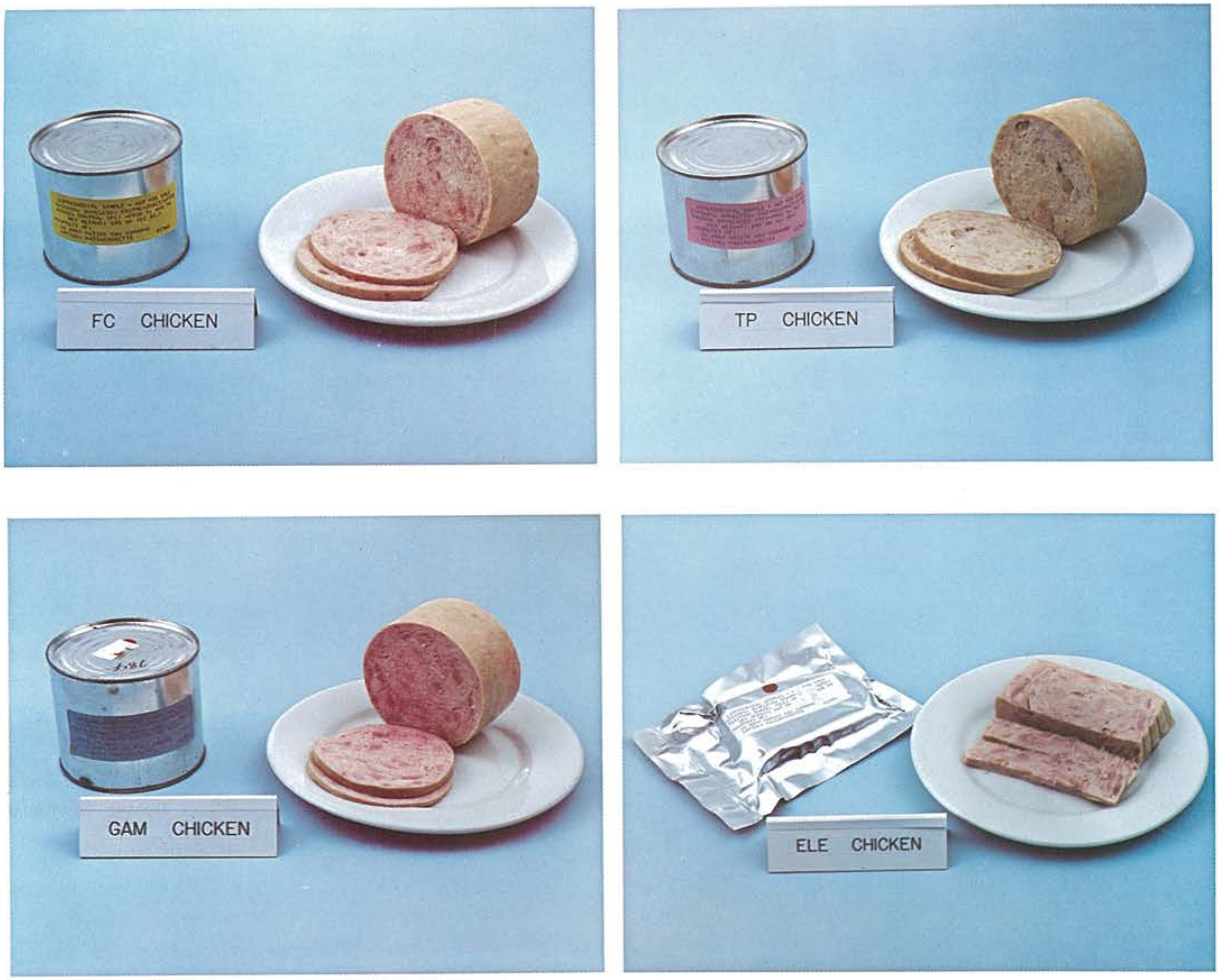


Fig. 2. Yields of two radiolytic products from ham, chicken, pork, and beef versus the fat content of the meats. Samples of each of the meats were treated with different doses of ionizing energy at -40° F (-40° C), and the results from the different doses were combined by calculating the yields of the two products shown per unit of ionizing energy absorbed (Merritt et al., 1985).



Products used in experimental work by the U.S. Army and the U.S. Department of Agriculture on the wholesomeness of chicken meat treated with ionizing energy. Upper left, frozen control. Upper right, thermally processed control. Lower left, processed with gamma rays from cobalt-60. Lower right, processed with accelerated electrons. From Wierbicki (1984).