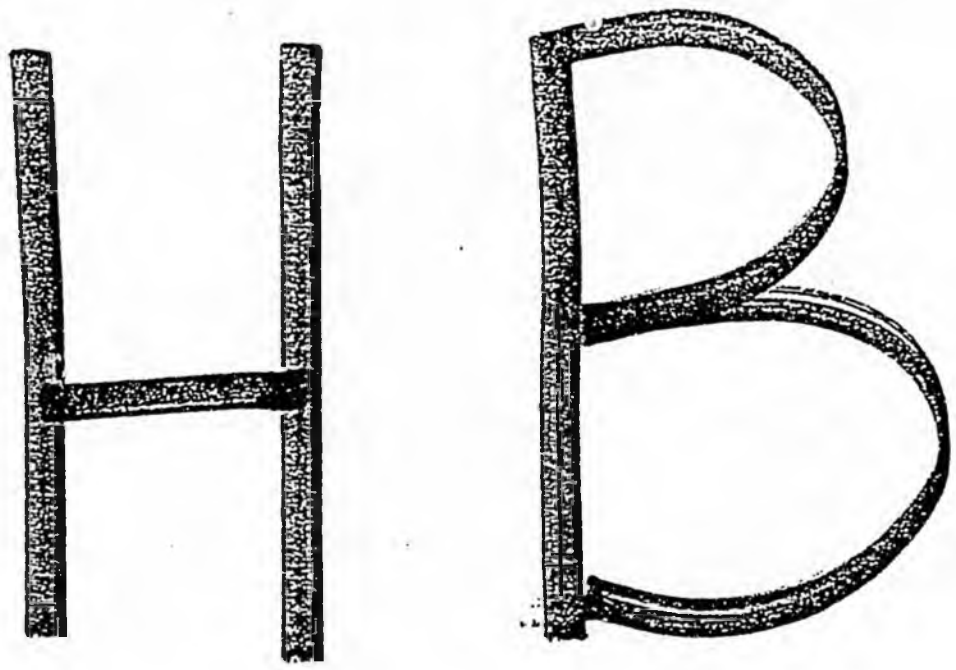

388

STATE OF ALASKA
THE LEGISLATURE

POUCH Y - STATE CAPITOL
JUNEAU, ALASKA 99811
907-465-3800

LEGISLATIVE AFFAIRS AGENCY

LEGISLATIVE REFERENCE LIBRARY

May, 1988

Copies of minutes listed below were originally included in this file. The minutes are available on the STAIRS database CMPR. In order to save space copies of minutes have not been left in the files.

Mary Van Nimwegen

House Judiciary:

3-9-88

3-11-88

Alaska State Legislature
House

Official Business

P.O. BOX V
State Capitol
Juneau, Alaska 99811

REPRESENTATIVE RANDY PHILLIPS
HOUSE DISTRICT 15
(907) 465-4949

MEMORANDUM

TO: House Judiciary Committee

FROM: Representative Randy Phillips R.E.P.

DATE: March 8, 1988

RE: Committee Substitute for House Bill 388 (HESS)
An Act relating to irradiated food

Committee Subsitute for House Bill 388 (HESS) would prohibit the sale of irradiated foods within the State of Alaska. As indicated by the attached sectional analysis (Attachment 1), this bill excludes irradiated spices from being considered as irradiated foods. Additionally advice from Ms. Banniser with regard to the original bill indicated that while this particular bill does not prohibit the manufacturing of irradiated food, AS 17.20.340 indicates that such manufacturing would also be prohibited (See Attachment 2). There were also some questions about the state's right to limit "interstate commerce" and I have attached another memorandum from Ms. Bannister concerning this question (See Attachment 3).

The provisions contained in Committee Substitute for House Bill 388 (HESS) would be added to the Alaska Food, Drug, and Cosmetic Act and this would mean that certain enforcement provisions included in that act would follow with the adoption of the language in this bill. Criminal penalties would be those as set out in AS 17.20.310 (See Attachment 4) and injunctive relief would be as provided in AS 17.20.280 (See Attachment 5). The bill does not include provisions for embargo and destruction of these items.

While the Food and Drug Administration was requested to participate in the teleconference hearing today, it declined for the reasons outlined in Attachment 6. Attachment 7 is a press release issued by the U.S. Department of Health and Human Services on December 12, 1985, concerning the "final rule to broaden the approved used of radiation. Attachment 8 is a copy of the statement that FDA Commissioner Young gave before the U. S. House Committee on Energy and Commerce, Subcommittee on Health and Environment concerning the current federal proposal on food irradiation. Attachment 9 is a copy of Congressman Bosco's statement before that same committee (Congressman Bosco is the prime sponsor of the measure on the House side).

The language in the original bill is based on a law adopted in Maine in 1987. Maine is the first state to ban the sale of irradiated foods.

In 1987 the New Jersey Legislature adopted a food irradiation ban; however, the Governor vetoed the bill. Vermont has enacted strict labeling requirements in the event the federal requirements are lifted. Legislation proposing a ban irradiated food has been reintroduced in New Jersey and is also being considered in Hew Hampshire, New York, Pennsylvania and Vermont. A list of the states considering food irradiation legislation is attached as Attachment 10. There is legislation also pending in the United States Congress regarding both the food irradiation and labeling issues (H.R. 956 and S. 461).

Food irradiation is being considered as a possible food preservation method. The actual process involves the use of cobalt-60 (an isotope that must be manufactured in nuclear reactors from nonradioactive cobalt-59) or cesium-137 (a water soluble byproduct of both nuclear weapons production and nuclear power generation). (See Attachment 11 for an article explaining this process and Attachment 12 for a history of food irradiation.) In 1958, Congress classified food irradiation as a food additive. This meant that before the process could be used, it had to be approved by the FDA under the Federal Food, Drug, and Cosmetic Act. While the FDA has approved food irradiation for five different uses [control of insects in wheat (1963), inhibit sprouts in potatoes (1964), control of trichinosis in pork (1985), slow growth and ripening and control pests in produce, and to kill insects and microorganisms in herbs and spices (1986)] the only use in the United States at the present time is in some spices and herbs. I have attached a list of spices and herbs that are being irradiated at the present time (See Attachment 13).

The greatest concerns I have with the food irradiation process are as follows:

1. Safety of the process and effect on humans ingesting irradiated foods.

2. Questions abcut the wholesomeness of irradiated foods (See Attachment 14).

3. Risks to the environment from the irradiator plants. There is danger both to the workers in an irradiation plant as well as residents of the surrounding area. I have attached a list of incidents that have occurred at some of the forty irradiation plants that current operated within the United States (See Attachment 15). Attachment 16 shows the location of the forty irradiation facilities in the U.S.

3. Possible creation during the process of mutuant and/or radiation resitant bacteria and the effect of the elimination of nonresitant bacteria making it easier for the mutuant bacteria to survive.

4. Possible creation during the process of potent carcinogens called aflatoxins.

5. Possible elimination of the organisms that produce signals and odors that alert people to food spoilage while the bacteria that causes food poisoning may be more resitant to radiation and therefore still present.

6. Radioactive food may occur if the process is not handled properly.

8. Transportation of radioactive materials. If Alaska were to have an irradiator plant, and this is one of the areas being researched by the University of Alaska at Fairbanks, the radioactive materials would have to be brought in from somewhere. To my knowledge, the nearest stockpile of cesium-137 is at Richland, Washington, near the Hanford plant and this would mean that such products would have to be trucked, barged or flown to Alaska. In addition, since cesium-137 is water soluble, if there were an accident enroute or at any such plant, the results could be devastating.

9. Safety questions exist concerning the storage of the radioactive material.

You might also be interested to know that irradiated food does get on the shelves. See the attached information regarding the Rice-A-Roni/Noodle-Roni matter. (See Attachment 17).

For your information, I have also attached a list of articles that I have available on this subject (See Attachment 18). If you wish to do further review on the matter, please do not hesitate to contact me.

I would appreciate your support of this legislation.

STATE OF ALASKA
THE LEGISLATURE

POUCH Y · STATE CAPITOL
JUNEAU, ALASKA 99811
907 465-3800

LEGISLATIVE AFFAIRS AGENCY

M E M O R A N D U M March 7, 1988

SUBJECT: Sectional analysis of CSHB 388 (HESS)

TO: Representative Randy Phillips

FROM: Theresa L. Bannister TB
Legislative Counsel

You have requested a sectional analysis of the above described bill.

As a preliminary matter, note that a sectional analysis or summary of a bill should not be considered an authoritative interpretation of the bill and the bill itself is the best statement of its contents.

Section 1 prohibits the knowing sale of irradiated food. Defines "irradiated" as having been treated with gamma radiation or other ionizing radiation. Excludes irradiated spices from being considered irradiated food, and excludes food from being considered irradiated food if the only irradiated ingredients are irradiated spices.

Section 2 indicates that the commissioner of environmental conservation (or the commissioner's designee) is responsible for enforcing the prohibition against the knowing sale of irradiated food.

TLB:bb
wkb3/079

ATTACHMENT 1

STATE OF ALASKA
THE LEGISLATURE

LEGISLATIVE AFFAIRS AGENCY

POUCH Y · STATE CAPITOL
JUNEAU, ALASKA 99811
907-465-3800

MEMORANDUM January 21, 1988

SUBJECT: Scope of irradiated food bill
(Work Order No. 5-1671)

TO: Representative Randy Phillips

FROM: Theresa L. Bannister TLB
Legislative Counsel

This memo accompanies the bill on irradiated food that you requested. Although sec. 1 of the bill does not prohibit the manufacturing of irradiated food, AS 17.20.340 indicates that the manufacturing would also be prohibited. AS 17.20.340 reads as follows:

> Sec. 17.20.340. SCOPE OF PROVISIONS DEALING WITH SALE. The provisions of this chapter regarding the sale of food, drugs, devices, or cosmetics include the manufacture, production, processing, packing, exposure, offer, possession, and holding of them for sale; the sale, dispensing, and giving of them, and the supplying or applying of them in the conduct of a food, drug, or cosmetic establishment.

Using the Alaska Food, Drug, and Cosmetic Act (AS 17.20) means that certain enforcement provisions in that Act, including criminal penalties (AS 17.20.310) and injunctive relief (AS 17.20.280), will apply to the enforcement of the irradiated food prohibition. Certain other provisions, including embargo and destruction of the items, would not apply to this prohibition as the bill is presently written; if you wish to have these provisions apply also, please advise.

If I may be of further assistance, please advise.

Attachment

TLB:gc
WKG1:036

STATE OF ALASKA
THE LEGISLATURE

LEGISLATIVE AFFAIRS AGENCY

POUCH Y · STATE CAPITOL
JUNEAU, ALASKA 99811
907-465-3800

MEMORANDUM February 1, 1988

SUBJECT: HB 388 and the Commerce Clause

TO: Representative Randy Phillips

FROM: Theresa L. Bannister
Legislative Counsel

You have requested a written opinion on whether the prohibition in HB 388 against selling irradiated food in the state violates the Commerce Clause of the U.S. Constitution. The prohibition applies only to food sold in the state, and it does not directly regulate or discriminate against interstate commerce. The state has a legitimate interest in protecting the health and welfare of its citizens, and the bill appears to be a reasonable exercise of this power. Although the prohibition will affect interstate commerce, I cannot think of an interstate commerce effect of this bill that would be considered to clearly exceed the protection of the physical health of the state's citizens. Since the benefits of this legislation are intangible and cannot be effectively measured against its effects on interstate commerce, and since the effects on interstate commerce do not clearly exceed the benefits of the bill, it is likely that a court would uphold the legislature's decision to exercise the state's police power in this manner. For the above reasons it is my opinion that HB 388 would not be held to violate the Commerce Clause of the U.S. Constitution.

If I may be of further assistance, please advise.

TLB:gc
WKG1:058

ATTACHMENT 3

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because it is misleading, in determining whether the labeling or advertisement is misleading, there shall be taken into account among other things representations made or suggested by statement, word, design, device, sound or combination of them, and the extent to which the labeling or advertisement fails to reveal facts material in the light of the representations or material with respect to consequences which may result from the use of the article to which the labeling or advertisement relates under the conditions of use prescribed in the labeling or advertisement or under customary or usual conditions of use. (§ 2(l) ch 129 SLA 1949)

Collateral references. — Products liability of manufacturer or seller for injury or death allegedly caused by failure to warn regarding danger in use of vaccine or prescription drug, 94 ALR3d 748.

Promotional efforts directed towards prescribing physician as affecting prescription drug manufacturer's liability for product-caused injury, 94 ALR3d 1080.

What constitutes "false advertising" of food products or cosmetics within §§ 5 and 12 of the Federal Trade Commission Act (15 USCS §§ 45, 52), 50 ALR Fed. 16.

Sec. 17.20.310. Penalties. A person who violates the provisions of AS 17.20.290, upon conviction, is punishable by imprisonment for not more than six months, or by a fine of not more than $500, or by both. If the violation is committed after a conviction under this section has become final, the person is punishable by imprisonment for not more than one year, or by a fine of not more than $500, or by both. (§ 5(a) ch 129 SLA 1949)

Sec. 17.20.320. Effect of written guaranty. A person is not subject to the penalties of AS 17.20.310 for having violated AS 17.20.290(1) or (3) if that person establishes a guaranty or undertaking signed by and containing the name and address of the person residing in the state from whom the article was received in good faith, to the effect that it is not adulterated or misbranded within the meaning of this chapter. (§ 5(b) ch 129 SLA 1949)

Sec. 17.20.330. Liability for dissemination of false advertising. No publisher, radio-broadcast licensee, or agency or medium for the dissemination of an advertisement, except the manufacturer, packer, distributor, or seller of the article to which a false advertisement relates, is liable under AS 17.20.310 for the dissemination of the false advertisement, unless the publisher, licensee, agency or medium has refused the request of the commissioner of health and social services to furnish the name and post office address of the manufacturer, packer, distributor, seller, or advertising agency, residing in the state who caused dissemination of the advertisement. (§ 5(c) ch 129 SLA 1949; am Executive Order No. 51, § 31 (1981))

any room, building, vehicle of transportation or other structure which is unsound, or contains filthy, decomposed, or putrid substance, or a substance that may be poisonous or deleterious to health or otherwise unsafe, is a nuisance. Whenever the commissioner of environmental conservation finds such an article, the commissioner shall immediately condemn or destroy it or in any other manner render it unsalable as human food. (§ 6(d) ch 129 SLA 1949; am Executive Order No. 51, § 28 (1981))

Effect of amendments. — The 1981 amendment added "of environmental conservation" following "the commissioner" in the second sentence.

Sec. 17.20.280. Injunction proceedings. The commissioner of environmental conservation and the commissioner of health and social services may apply to the superior court for, and the court has jurisdiction to grant, a temporary or permanent injunction restraining a person from violating their respective portions of AS 17.20.290. (§ 4 ch 129 SLA 1949; am Executive Order No. 51, § 29 (1981))

Effect of amendments. — The 1981 amendment added "of environmental conservation and the commissioner of health and social services" following "commissioner" and added "their respective portions of" following "person from violating."

Article 6. Prohibited Acts and Penalties.

Collateral references. — 25 Am. Jur. 2d, Drugs, Narcotics, and Poisons, § 40 et seq; 35 Am. Jur. 2d, Food, §§ 63 et seq., 74 et seq.

Sec. 17.20.290. Prohibited acts. (a) The following acts and the causing thereof are prohibited:

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

(2) the adulteration or misbranding of food, drug, device or cosmetic;

(3) the receipt in commerce of food, drug, device, or cosmetic that is adulterated or misbranded, and the delivery or proffered delivery of them for pay or otherwise;

(4) the sale, delivery for sale, holding for sale, or offering for sale of an article in violation of AS 17.20.050 — 17.20.070 and 17.20.100;

Alaska State Legislature
House

Official Business

REPRESENTATIVE RANDY PHILLIPS
HOUSE DISTRICT 15
(907) 465-4949

P.O. BOX V
State Capitol
Juneau, Alaska 99811

Memorandum

TO: Representative John Sund
Chairman, House Judiciary Committee

FROM: Representative Randy Phillips RP

DATE: March 7, 1988

RE: Food and Drug Administration
House Bill 388

At the request of Peggy Sepulveda of your office, my staff contacted the Food and Drug Administration with a request that it provide someone to testify at the upcoming hearing on CSHB 388 (HESS).

Carl Dasser of the Federal-State Relations Division of Food and Drug Administration has advised me that the FDA cannot testify on this matter. According to Mr. Dasser, the Code of Federal Regulations prohibits the FDA from testifying before state courts, administrative hearings, state legislative committees, etc. unless (1) there is an official request (preferably written) from the person or committee requesting such testimony and (2) agency has had a chance to approve the testimony that is to be given. The FDA has been requested by other states to provide testimony on the issue of food irradiation and has uniformly refused to testify; therefore, it is, at this time, refusing our request to present testimony.

Mr. Dasser indicated that if you had any questions about the testimony process that he would be happy to address your questions. His telephone number is (301) 443-6200. If you wish to present the FDA with a written request for testimony and questions that you would like answered, please address this to: Heinz Wilms, Director, Division of Federal-State Relations (HFC-151), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. If you or a member of your staff wishes to discuss the subject of food irradiation on an informal basis, please contact Mr. Dasser and he can make arrangements for someone from the Center of Food Safety to contact you.

Again, Mr. Dasser emphasized that since the FDA had turned down similar requests from other states, it felt it could not honor a request to participate in the hearing to be held this coming Wednesday.

ATTACHMENT 6

HHS NEWS

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

SENT TO YOU BY YOUR UNITED STATES SENATOR

Ted Stevens

ALASKA

P85-48
FOR IMMEDIATE RELEASE
December 12, 1985

Food and Drug Administration
James Greene (202) 245-1144
(Home) (202) 544-1581

H S Secretary Margaret M. Heckler today announced that she has approved for publication a Food and Drug Administration final rule to broaden the approved uses of radiation in foods.

"This process can lead to reduced use of pesticides on foods," Secretary Heckler said as she signed a final regulation allowing the use of picowaves (low-level ionizing energy) to kill insects in harvested fresh fruits and vegetables.

"I began work on this issue -- years ago -- as a member of Congress," Secretary Heckler said. "This regulation is an important step forward for consumers -- a proven, safe method to protect fresh fruits and vegetables from insects, and to inhibit spoilage and extend shelf life.

"Treatment of fruits and vegetables with picowaves may make some foods more available or less expensive. Unlike chemical pesticides--some of which are now under attack--irradiation leaves no residue in food. It does not make food radioactive, nor does it pose any radioactivity danger to the consumer."

Approval of the regulation will expand the uses of low-level radiation already allowed by the Food and Drug Administration. The process has been approved for use in the United States for two decades to kill insects in wheat and to slow the development of sprouts in potatoes. In addition, the use of radiation was approved in 1983 for herbs and spices, and in July 1985, for pork.

FDA Commissioner Frank E. Young, M.D., commented, "In all, the United States and 20 other countries allow the use of picowaves on foods."

-MORE-

ATTACHMENT 7

Secretary Heckler said that "30 years of research have shown this process to be safe." The secretary said that foods exposed at the picowave level allowed under the regulation (or at much higher levels, as well) do not become radioactive. Consumers are not exposed to radiation. Nutritional values are not significantly changed, she said.

The regulation will permit:

--fresh fruits and vegetables to be picowaved at up to one kiloGray* to kill arthropod pests (insects) and to inhibit spoilage;

--dry or dehydrated vegetable substances (herbs and spices) to receive up to 30 kiloGray to kill insects and bacteria. The limit for the use has been 10 kiloGray.

Under the regulation, manufacturers, food processors and food retailers must label fresh fruit and vegetables which have been exposed to picowaves. At the retail level, signs may be placed over bins, or on boxes if the items are displayed in the box, or items may be individually labeled.

All retail level labels will include the international logo first used in the Netherlands (see attached).

In addition, retail level labeling or displays must carry the statement "PICOWAVED," and may include the reason, such as: "PICOWAVED TO CONTROL SPOILAGE" or "PICOWAVED TO EXTEND SHELF LIFE."

After two years, FDA will consider whether the international logo is well enough known by the American public to be used without written labeling.

The regulation signed today will be published in the Federal Register following review by the Office of Management and Budget.

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*EDITORS NOTE: Gray (abbreviated Gy) is the international unit for expressing the amount of energy absorbed from irradiation. It replaced the older rad unit. One Gy equals 100 rad. Thus, one kiloGray is the same as 100 kilorads (used in earlier releases).

INTERNATIONAL LOGO

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

STATEMENT BY

FRANK E. YOUNG, M.D., PH.D.

COMMISSIONER

FOOD AND DRUG ADMINISTRATION

PUBLIC HEALTH SERVICE

DEPARTMENT OF HEALTH AND HUMAN SERVICES

BEFORE THE

SUBCOMMITTEE ON HEALTH AND THE ENVIRONMENT

COMMITTEE ON ENERGY AND COMMERCE

UNITED STATES HOUSE OF REPRESENTATIVES

June 19, 1987

SENT TO YOU BY YOUR
UNITED STATES SENATOR

Ted Stevens

ALASKA

FOR RELEASE ONLY UPON DELIVERY

ATTACHMENT 8

Mr. Chairman:

I welcome the opportunity to be here today to testify about the activities of the Food and Drug Administration (FDA) in the area of food irradiation.

Background

Our involvement with irradiation technology to preserve food goes back many years. The possibility that benefits could be derived from irradiated food was explored as early as the late 1930's. It was studied in earnest by the United States government in the 1950's as a potential preservative for military food rations as well as a means of eliminating microorganisms from food, controlling insects, and extending the shelf life of fruits and vegetables under the Atomic Energy Commission's "atoms for peace" program. Although FDA had not yet acquired the specific regulatory authority over the application of this new technology that the Agency possesses today, FDA became involved nonetheless by advocating that wholesomeness testing be conducted before any irradiated foods be marketed or otherwise routinely used.

FDA's involvement in the development of food irradiation became pivotal in 1958, when the Congress mandated in effect, that food irradiation be subject to Federal premarket approval. This involvement was accomplished through a change in the Federal Food, Drug, and Cosmetic Act to prohibit the use of a new food additive until its sponsor established the additive's safety and FDA issued a regulation

specifying its conditions of use. The definition of a food additive was drafted to specifically include sources of radiation intended for use in processing food because this use may affect the characteristics of food.

Since then, FDA has approved food irradiation for five different uses:

- o The first was to control insects in wheat and wheat flour in 1963.
- o The second, in 1964, was to inhibit sprout development in white potatoes.
- o In 1985 FDA approved a third use for food irradiation -- to control the organism that causes trichinosis in pork.
- o The most recent approvals, which occurred simultaneously in 1986, involved two uses. These were:
  - -- to slow growth and ripening and to control insects in fresh fruits and vegetables and
  - -- to kill insects and control microorganisms in dry or dehydrated herbs, spices, seeds, teas and vegetable seasonings.

As I will describe later in my testimony, FDA's principal focus in evaluating each of these uses was to ensure the safety of the irradiated food.

As these approvals indicate, many different technical effects can be accomplished by irradiating food. Irradiation can extend a

product's shelf life by inhibiting the growth and ripening of fresh produce, and by reducing the number of microorganisms that spoil food. Complete sterilization of food by irradiation results in a shelf-stable product similar to canned food. Pathogenic organisms, parasites, and insects found in food can be controlled by irradiation. Additionally, irradiation can change certain physical properties, such as decreasing the rehydration time of dehydrated vegetables, increasing the yield of fruit juice, and tenderizing meat. Other means available for accomplishing the same purposes as the permitted uses in our food irradiation regulations include cooking and chemical treatments.

When food is irradiated, most of the radiation passes through the food without being absorbed. It kills or sexually sterilizes any insects, and prevents fruits or vegetables from ripening too fast thereby extending shelf life. Irradiation leaves no residue in food. It does not make the food radioactive, nor does it pose any danger of radioactivity to consumers. Consumers are not exposed to radiation through handling or ingesting irradiated food.

The ionizing radiation used to accomplish food irradiation can come from various sources, including gamma rays, x-rays and electron beams derived from electron beam accelerators. While radioactive sources that produce gamma rays are currently the most commercially used sources in producing the desired energy levels, these other non-radioactive sources (i.e. electron beams and x-rays) can substitute for them quite well in many instances.

The amount of radiation necessary to treat foods varies depending upon the intended use. Multicell organisms are affected more readily than single cell organisms; growing organisms are affected more readily than dormant organisms. Thus, doses sufficient to slow the ripening process, inhibit sprouts and kill insects would not be enough to kill organisms such as the kind that cause trichinosis. In turn, microbes simpler than trichinella spiralis require a higher dose. Viruses, which are smaller than a biological cell, are very resistant to the effects of radiation.

With a few exceptions for minor dry ingredients, food irradiation permitted by FDA involves technologically low levels of radiation. For example, the amount of radiation necessary to sterilize food is approximately 50 times higher than the amount needed to control insects. It is true, of course, that food irradiation does require levels that are far too high to directly apply to humans, such as the levels used in chest x-rays, for example, but this fact has no bearing on the safety of food for human consumption that is treated with radiation.

A Spectrum of Concerns

Even so, the fact that this process exposes food to ionizing radiation understandably singles it out for more public attention and

concern than most food additives receive. And as with any controversial subject, there is a broad spectrum of views.

On one hand, we have heard expressions of frustration that, in the most technologically advanced country in the world, the full potential of food irradiation is not being met, especially compared with its use in other countries. Many of these concerns have been reflected in recent legislative efforts by Representative Morrison and others to facilitate research and development leading to commercial use as well as enhance public acceptance of food irradiation.

At the other end of the spectrum, some people have expressed the view that all of the safety issues related to food irradiation have not been resolved. These concerns are reflected in legislative efforts by Representative Bosco and others that would repeal some of FDA's approvals of food irradiation and require the National Academy of Sciences to study the risk to human health and the environment presented by the irradiation of food.

I can appreciate both points of view and welcome the opportunity to address these concerns today.

FDA's mission is to determine the safety of the process under specific conditions of use. In summary, I remain convinced that our actions in accomplishing this mission have been scientifically sound. I would characterize our approach over the years as fundamentally cautious and conservative.

We are, perhaps, situated even more toward the cautious end of the spectrum when compared with other nations. The Codex Alimentarius Commission, of the World Health Organization and Food and Agricultural Organization, based on a recommendation of its Joint FAO/IAEA/WHO Expert Committee has reviewed and assessed all data on the wholesomeness of irradiated foods, and has recommended that member nations permit the use of irradiation on food in doses up to 10 times higher than those that FDA has approved.

The Regulation of Food Additives

In carrying out its responsibilities, FDA has followed the same general procedures in the development of regulations for the use of sources of radiation that it follows in the development of regulations for other food additives. Congress' decision to include irradiated food in the food additive provisions of our statute clearly shows that it intended FDA to be responsible for regulating the use of irradiation by requiring a rigorous review of the potential hazards associated with this food treatment process.

As I stated earlier, the burden of demonstrating that a source of radiation can be used safely to irradiate foods was, as with other additives, placed on the proponents of its use. The principal procedure established for premarket approval of an additive's safe use

is the filing of a food additive petition. Such a petition must contain adequate data to demonstrate the safety of the use.

In addition, under the food additive provisions of the act, there is a second procedure by which food additive approvals may come about. The government may, on its own motion, propose to approve a particular set of conditions of use. The evidence supporting the safety of these conditions of use must meet the same standard for demonstrating safety as the evidence in a petition from industry. Generally speaking, the latter procedure is used far less frequently than the petition process. It is generally reserved for circumstances in which the Agency believes that proposing to approve a particular use will be of clear benefit to public health or will allow the Agency to operate more efficiently. In the case of food irradiation, both procedures have been utilized, for reasons that I will explain shortly.

The principal issue associated with the approval of an additive by either procedure is, of course, safety -- and the quality and quantity of scientific evidence needed to establish safety. As with any product or process, it is impossible to prove beyond any doubt that no harm will ever result under any conceivable circumstance. Congress recognized this fact in 1958. In the Committee reports from both Houses on the Food Additives Amendment, Congress said that safety requires proof of a reasonable certainty that no harm will result from the proposed use of any additive.

Food Irradiation and Safety Testing: Early Developments

Since the 1960's, when the first petition for the treatment of food with radiation sources was submitted, the Agency has been confronted with questions about what test procedures are appropriate to establish to a reasonable certainty that no harm will result from the use of radiation sources in the treatment of food.

Traditionally, high dose animal feeding studies are used to determine the safety of a food additive. Such testing requires a determination of the highest "no-effect level" for the tested substance and consideration of the amount of the substance likely to be consumed. To allow for uncertainty in relating data gained from laboratory animals to humans, a 100-fold safety factor is typically applied. In other words, the Agency will not approve human consumption at a level that is any higher than 1 percent of the highest level of consumption of which there was no adverse effect in animals.

Initial efforts by FDA and industry to establish the safety of irradiated foods relied on feeding irradiated food to laboratory animals. In effect, irradiated food was to be tested as if it were a discrete chemical entity similar to a "conventional" food additive. The initial philosophy of the FDA scientists was to develop a core of wholesomeness studies on different types of foods to provide a matrix from which the safety of other foods could be deduced. This approach yielded enough data to permit the Agency in the 1960's to approve

petitions for certain specified uses of ionizing radiation for inspecting food, controlling insect infestation in wheat and wheat flour, and inhibiting sprouting in white potatoes.

Other early petitions did not result in regulations for a variety of reasons. Petitions for the use of radiation for microbial control on citrus fruit, strawberries, fish and fish products, and ham were withdrawn without prejudice because they lacked sufficient data to support the effectiveness or the safety of the process. FDA did not act on other petitions for irradiation of other foods because they were clearly incomplete.

As scientists were discovering, evaluating the safety of irradiated foods by traditional testing methods was impractical for several reasons. The most significant problem was the inability to obtain the 100-fold safety factor. Because the irradiated food itself was considered the substance to be tested in these studies, it was impossible in most instances to feed the exaggerated amounts of food that are necessary for the purpose of traditional toxicological testing.

FDA found that more than half of the petitions that it was receiving on irradiation, as originally presented, did not provide necessary and persuasive evidence to support the requested regulations. As a result, the Agency's Bureau of Science conducted a seminar in 1967 for government scientists and administrators interested in the

processing and review of petitions involving irradiation of food. The seminar presentations were compiled into a report that was used as an aid to evaluation. The 1967 seminar noted the need for more basic research in various disciplines to improve safety evaluation.

Perhaps the low point for food irradiation occurred shortly thereafter, when in 1968 FDA revoked three regulations for irradiating bacon. This revocation reflected a culmination of FDA's concerns about the quality of the safety data being submitted in many irradiated food petitions. When FDA received a petition for irradiating ham that relied heavily on reports originally submitted with respect to bacon, the Agency chose to require submission of the relevant raw data on which the original reports were based. The Agency's reevaluation resulted in FDA concluding that the safety of radiation-preserved bacon had not been sufficiently demonstrated. This conclusion, and resulting revocations, discouraged interest in food irradiation for several years.

Food Irradiation and Safety Testing: An Evolution of Thought

Since 1968, however, scientists have learned much about radiation chemistry of foods, and new scientific data addressing the earlier questions and problems have become available. In the late 1970's, these developments resulted in a renewed interest in irradiation as a possible safe alternative to the use of chemicals in food -- which in turn led FDA to review of the complex issue of irradiated foods. An

internal FDA task force, the Bureau of Foods Irradiated Food Committee, was formed to evaluate the Agency's policy on irradiated foods in light of the then current knowledge in toxicology and radiation chemistry and to recommend criteria for safety evaluation.

The first question confronting the Committee was: what should be tested? Or, more appropriately, what is the difference between an irradiated food and an unirradiated food? The Committee concluded that the only difference of toxicological relevance was the products formed during the irradiation process.

The Committee then asked whether all such products should be of concern, or whether concern should be limited to some smaller portion of these products. Working with data from the U.S. Army's High Protein Food Sterilization Program, the Committee found that of 65 substances produced by irradiation that had been identified by Army scientists, most were also found in cooked meats and in other foods. Only six substances (or about 10 percent) could not be verified in the literature as being present in non-irradiated food, although these six were similar to natural food constituents. The Committee thus concluded that possibly up to 10 percent of all radiolytic products may be unique to irradiated food, although not enough is known about components of nonirradiated foods at such low concentrations to conclude that these 10 percent are indeed unique.

Nonetheless, the Committee decided to assume that unique radiolytic products (URP's) are formed during food irradiation. Based on a considerable body of data on radiation chemistry of foods the Committee then deduced that at an absorbed dose of 1 "kilogray" (kGy) of radiation, about 3 parts per million in a food substance could be unique to irradiated food. Because more than 10 different URP's are likely to be formed, the concentration of any one URP would thus be less than one part per million. The Committee concluded that the chances of a single URP of unusual toxicity being formed in significant amounts at doses below 1 kGy would be negligible, especially since the identified products presumed to be unique are chemically similar to other food components. The Committee also pointed out that its estimates probably overstated the total number of URP's.

The Committee concluded that food irradiated at a dose not exceeding 1 kGy is safe for human consumption and that below this dose, animal feeding tests are not necessary to establish safety. The Committee's finding of safety applied even to a diet where a substantial proportion of the food was irradiated at 1 kGy. Annual feeding and other toxicity tests were recommended, however, for foods irradiated above 1 kGy.

The Committee further concluded that a food that comprises only a small fraction of the human diet (e.g. nutmeg) and that is irradiated at doses up to 50 kGy would necessarily contribute far fewer radiolytic

products to the daily diet than a food representing a significant fraction of the diet irradiated at 1 kGy. Consequently the Committee also recommended that foods comprising no more than 0.01% of the daily diet and irradiated at 50 kGy or less also be considered safe for human consumption without toxicological testing.

As a check on the Committee's findings, FDA's Bureau of Foods established a second team of scientists, the Irradiated Foods Task Group, to review all available toxicological data concerning foods treated with irradiation. The major objectives of this Task Group were to compile and summarize the toxicology data pertaining to irradiated foods, identify any consistencies with respect to adverse findings, look for patterns or trends in results among the studies, and summarize the experimental results at the end of the review. They also tried to determine whether food irradiated at a dose above 1kGy could be considered safe without additional testing, as recommended by Codex Alimentarius. The review involved identifying from FDA files and from open literature all relevant toxicology studies (over 400). The Task Group examined all the studies, paying special consideration to those that appeared to raise questions about adverse effects. The Task Group concluded that studies with irradiated foods had not shown adverse toxicological effects and agreed with the previous Committee's conclusion that there was an adequate margin of safety for foods irradiated below 1 kGy. Hence, the Task Group agreed that toxicology tests on food irradiated at 1 kGy or below are not needed to support

a conclusion that such foods are safe. However, this data base was not adequate to support a broad decision that foods may be irradiated safely at higher doses.

Regulatory Efforts

In March of 1981, FDA announced in the Federal Register the availability of the first Committee's report and invited the public to comment on it. The Agency also stated that it was considering several options, including the possible issuance of regulations on the Commissioner's initiative to permit irradiation of food at doses not exceeding 1 kGy. Such an Agency-initiated regulation would be predicated on the view that since safety had been established at the 1 kGy level, a review of petition after petition for uses within that dose range would be an unnecessary burden and expense to the taxpayers.

Three years later, in February 1984, FDA published a proposal for its cornerstone regulation on food irradiation. Among other things, the Agency proposed to permit the use of irradiation at levels not to exceed 1 kGy for insect disinfestation of food and for the inhibition of growth and maturation of fresh fruits and vegetables. We designed our proposal to assure that no outstanding safety questions remained with regard to four important issues: radioactivity, radiolytic products, nutritional and microbiological concerns.

The Agency simultaneously proposed to permit the use of irradiation at higher doses as well -- 30 kGy -- for microbial disinfection of dried spices and dried vegetable seasonings. This higher dosage level was consistent with the recommendation of the Committee that foods comprising only a small fraction of the human diet could be safely irradiated at 50 kGy. Also, such foods are not sources of nutrients and, being dry, cannot support microbial growth.

In this case, as an additional safety factor, the Agency further noted that because spices are dry, irradiation would likely cause formation of fewer URP's than it would in a moist food. This is because most of the radiolytic products formed in food result from reactions of the hydroxyl radical with other food components -- and water is the primary source of hydroxyl radicals in food.

The Agency did lower the permitted dosage level for spices and seasonings in the proposal to 30 kGy from the 50 kGy that the Committee felt would be safe. FDA is obligated to set a limitation on the levels of use of any food additive substance so that the maximum levels are no higher than reasonably required to accomplish the intended technical effect. In this case, 30 kGy was considered sufficient from an effectiveness standpoint.

The final regulation for these uses was published two years later with only minor modifications. In the interim, FDA approved the use of irradiation not to exceed 1 kGy to kill trichinae in pork based on a petition that it received.

Lingering Misperceptions

Since then, we have discovered that two common misperceptions have developed about FDA's basis for approving these uses and I am happy to have this opportunity to address them. The first is that the regulations were deficient -- and even illegal -- because they were not based on animal testing, even though the law does not mandate any specific type of test.

We can all agree that there must be sufficient testing to support the conclusion that a reasonable certainty exists that no harm will result from the expected use of an additive. Logically, any test that would not contribute to this conclusion should not be required. FDA has not required animal testing in the past in those situations where, by chemical or other testing and sound reasoning, it could conclude that the use of an additive was safe without animal testing. We are satisfied that low doses and for minor uses of food irradiation, this is the case. Animal testing is simply too insensitive to show an effect from irradiation of food at low doses and, thus, would not contribute additional information to the evaluation of the safety of such uses.

As it turned out, our Task Force's review of the existing toxicological data led to the second misperception -- that the data to support the regulations were inadequate because only five of the 409 studies reviewed by FDA were considered by Agency scientists to be

properly conducted and reported. It is true that most of the reports were inadequate by present-day standards and could not stand alone to support safety. Nonetheless, many contained individual experimental components which, when examined either in isolation or collectively, allowed the conclusion that consumption of foods treated with low levels of irradiation did not appear to cause adverse toxicological effects.

Further, many of the studies were deemed useful for resolving certain questions. For example, if a potent toxic material were present at any level of toxicological significance in irradiated foods ingested by test animals, some consistent toxicological signs would be manifest in the studies reviewed. However, Agency scientists saw no consistent patterns or trends of adverse effects that might be attributable to exposure to food irradiated at low dose levels.

Thus, while the annual feeding studies were consistent with a finding that the process is safe, it should also be remembered that FDA did not rely on any of the reports of animal feeding studies as the basis for its regulations. Rather, we relied primarily on data we had on the effect of radiolytic products.

Conclusion

The future of food irradiation will be determined primarily by the actions of consumers and the food industry rather than by FDA. It is important to remember that FDA's responsibility in the evaluation of

food irradiation is limited to the determination of the safety of the process under specific conditions of use. FDA has no proper role as a promoter of a specific food additive or food process. The primary responsibility for such activities remains with industry and consumers who choose irradiated food. In addition, industry's role is to assess the feasibility of this technology and to determine its commercial potential.

Our present posture is to refrain from initiating any more across-the-board rulemaking at dosage levels higher than 1 kGy and to review any petitions that may be submitted to us on a case-by-case basis. At this time, two toxicity considerations prevent the Agency from proposing a general regulation allowing doses up to 10 kGy as recommended by the Codex Alimentarius Standard. First, doses sufficiently above 1 kGy irradiation may be able to retard microbial spoilage without killing all spores of Clostridium botulinum, the pathogen/bacterium that causes botulism. We must ensure that C. botulinum cannot grow and produce a toxin that constitutes a health hazard. If irradiation kills the bacteria that cause the symptoms of spoilage, such as a spoiled odor, but fails to kill all the botulinum spores, a particularly dangerous situation could result. Based on current knowledge, FDA is unable to prescribe generic conditions of irradiation for all foods at all feasible doses to ensure that C. botulinum would not develop and produce toxin without obvious spoilage.

At dosage levels not exceeding 1 kGy there is no such risk because food would spoil in the same manner as nonirradiated food. This is because a dose of 1 kGy or below helps extend shelf life by retarding ripening or sprouting, but is not enough to kill bacteria that cause spoilage.

Second, FDA reviewed a number of animal feeding studies to determine whether foods that are irradiated at doses above 1 kGy could be considered safe without additional toxicological studies. The Agency found this data base, taken alone, is not yet adequate to support a broad decision that all foods may be irradiated safely at higher doses.

Finally, as with any food processing, irradiation can reduce the level of nutrients somewhat, depending on the condition. Based on our earlier review, nutrient loss due to irradiation at doses below 1 kGy appear to be of no dietary significance. FDA has not yet permitted a food that is a good source of vitamins to be irradiated at higher doses. We believe that these should be evaluated on a case-by-case basis.

HISTORY OF FDA ACTIONS ON FOOD IRRADIATION

- February 1963: FDA approved gamma radiation preservation of canned bacon.

- August 1963: FDA approved gamma radiation for control of insect infestation of wheat and wheat products.

- August 1963: FDA approved electron beam radiation for the radiation preservation of canned bacon.

- October 1964: FDA approved gamma radiation for sprout inhibition of white potatoes.

- December 1964: FDA approved X-radiation for the radiation of preservation of canned bacon.

- July 1966: FDA approved electron beam radiation for the control of insect infestation of wheat and wheat products.

- July 1966: FDA approved labeling requirements for food treated by radiation.

- October 1968: FDA rescinded the bacon regulations.

- September 1979: Director, Bureau of Foods established the Irradiated Food Committee to provide a total reassessment of all relevant issues applicable to irradiated foods.

- March 1981: Advance Notice of Proposed Procedures for the Regulation of Irradiated Foods for Human Consumption (ANPR) published in the Federal Register.

- Autumn, 1981: FDA offered the opportunity for use of irradiation for insect disinfestation during the California Medfly situation based on certain conditions. However, no firm furnished evidence of meeting these conditions.

- July 1983: FDA approved gamma radiation for microbial decontamination of a specific list of spices and vegetable seasonings.

- February 1984: Proposed rule published in the Federal Register for the use of gamma radiation for sprout inhibition and shelf-life extension of fresh fruits and vegetables, for insect disinfestation of food, and for sterilization of spices.

- June 1984: FDA approved gamma radiation to control insect infestation in garlic powder, onion powder, and certain dried spices.

- April 1985: FDA expanded the specific list of dried spices and vegetable seasoning to include additional herbs, spices, and vegetable seasonings, and blends of these seasonings.

- June 1985: FDA approved gamma radiation to control insect and microbial infestation in certain dried enzyme preparations.

- July 1985: FDA approved gamma radiation treatment of pork to control Trichinella spiralis.

- April 1986: FDA issued final rule approving ionizing radiation for maturation inhibition of fresh food, insect disinfestation of food, and sterilization of spices. The final rule included labeling requirements for both retail and non-retail use, and Current Good Manufacturing Practice (CGMP) provisions. The Agency received objections to the final rule during the objection period.

- February 1987: FDA denied requests for a stay of the regulation for pork (1985) and for the general regulations (1986).

FOODS APPROVED BY FDA FOR IRRADIATION TREATMENT

Food	Purpose	Dose Limit	Date Approved
Fruits and vegetables	To slow growth and ripening and to control insects	Up to 1 kilogray (kGy)	April 18, 1986
Dry or dehydrated herbs, spices, seeds, teas, vegetable seasonings	To kill insects and control microorganisms	Up to 30 kGy	April 18, 1986
Pork	To control *Trichinella spiralis* (the parasite that causes trichinosis)	Minimum 0.3 kGy to maximum of 1 kGy	July 22, 1985
White potatoes	To inhibit sprout development	50 to 150 gray	Aug. 8, 1964
Wheat, wheat flour	To control insects	200 to 500 gray	Aug. 21, 1963

Kiki

Congressman Douglas H. Bosco before the
Committee on Energy & Commerce
Subcommittee on Health & the Environment
June 19, 1987

MR. CHAIRMAN.

When you take a bite out of an apple that's been exposed to nuclear radiation, in addition to the apple you'll be eating URPS. It's these URPS, or unique radiolytic products, that we'd like to focus on today. Why? Because the Food and Drug Administration has decided that URPs are safe for human consumption. Yet there is no proof that these chemical components are safe and there is growing concern in the scientific community and among the public as a whole that indeed they may cause serious health problems.

You will hear that treatment of food with nuclear radiation is no different than boiling or freezing. Yet Congress refuted that argument almost 30 years ago when it decided that because these unique radiolytic products, not otherwise known to food, are created by irradiation that the process results in a food additive. Freezing or boiling create no new compounds or additives in our food.

You will also hear that this subject has been studied to death, and that studies prove the irradiation process safe. Indeed there have been over 400 studies on the subject, yet in 1986 the FDA determined that only 69 of these studies were dependable. Believe it or not, of these 69, only 37 indicated irradiation was safe, and the remainder said it wasn't. In the final analysis, the FDA could only determine that five studies appeared to support safety. Hardly a convincing endorsement for safety. Yet the FDA was in such a hurry to approve irradiation that it took a scientific leap of faith. Unable to prove irradiation safe, the FDA simply decided to

allow only a relatively small dosage of radiation to be used on food under the assumption that less exposure would logically be more safe.

Mr. Chairman, if I had here beside me a pile of 100 rocks and started throwing them at you, it's likely you would feel greatly endangered. Yet if I had only ten rocks and started throwing them, would you sit back and feel safe? This is the very logic the FDA used in approving food irradiation, yet there are experts here today who will point to the serious flaws in this logic. Who will express their belief that exposure to even a single carcinogenic insult can cause serious health threats to the human body.

My legislation, HR 956, makes no judgment on food irradiation other than to require that it be proven safe before it can be used on our nation's food supply. Seventy-eight other members of the House have coauthored this legislation. Senator Mitchell has introduced this legislation in the Senate, with nine other sponsors.

I commend you, Mr. Chairman, for holding these hearings and ask that the balance of my remarks be included in the Committee record.

# # #

EXTENSION OF REMARKS of CONGRESSMAN DOUGLAS H. BOSCO
COMMITTEE ON ENERGY & COMMERCE
SUBCOMMITTEE ON HEALTH AND THE ENVIRONMENT
June 19, 1987

Food irradiation is a preservation method in which food is exposed to ionizing radiation in order to destroy insects and bacteria that can cause food spoilage and disease. Proponents of the process contend that the extended shelf life of radiation-treated foods may help boost exports, and that dependency on post harvest pesticides may be reduced. These supposed benefits are obvious. The question is, however, would public health and safety be jeopardized in the process? A growing number of scientists, consumers, and over 80 Members of Congress are concerned about the FDA's approvals of pork and produce irradiation on the grounds that proper safety studies have not been conducted. Therefore, until such time as reliable research indicates that this process is entirely safe, we believe that the FDA's approvals are, at best, premature.

In particular, I am concerned about: the safety and wholesomeness of human consumption of irradiated foods, environmental risks, the inability to control or supervise irradiation practices, and the apparent lack of an immediate need for irradiation.

To begin with, the long-term health effects of human consumption of irradiated foods are simply unknown. Although the federal government has studied this procedure for more than 40 years, attempts to evaluate its safety have proved rather elusive. In fact, when traditional means of testing the safety of irradiated foods proved inadequate, the FDA approved the irradiation of pork - in July of 1985 - and produce - in April of 1986 - based on theoretical calculations of radiation chemistry and on the anticipated low-level of human exposure to the unique chemical constituencies that occur in irradiated foods. In other words, because the FDA lacked tangible evidence to demonstrate the safety of irradiated foods, it concluded that, in theory, irradiated foods should be safe. In my view, American consumers deserve greater assurances about the safety of something as basic as their food supply.

Irradiation is also known to deplete essential vitamins, most notably B vitamins. Even though these nutritional losses may be similar to those that occur during cooking or canning, irradiated foods will be doubly inferior to an unirradiated food product if it is also cooked. Beyond vitamin degradation, many are concerned that certain irradiated foods may increase the risk to food poisoning caused by the botulism bacteria which is perversely resistant to radiation. It is feared that irradiation will remove the odorous bacteria that warn of food spoilage and leave dangerous levels of botulism intact.

Food irradiation is a potentially hazardous procedure. It

requires the use, transport, and disposal of large quantities of highly radioactive Cesium-137 or Cobalt-60. Many proponents point out that for many years Cobalt-60 has been safely used in radiation machines to treat cancer patients. However, these machines require far smaller quantities of the radioactive isotope than do food irradiation plants. In general, radiation machines utilize between 3,500 and 10,000 curies of Cobalt-60, while most food irradiation facilities are equipped to handle between one and ten million curies of Cobalt-60 or Cesium-137 at each plant. Moreover, if food irradiation is to revolutionize the way we eat, as some proponents of the technology envision, hundreds of food irradiation plants would be required to meet such an ambitious plan. My concern is that this tremendous increase in the amount of radioactive materials in and around our communities will likewise increase the risk of accidents where radiation is emitted. Unfortunately, the FDA did not conduct an environmental impact statement to examine whether existing regulations that would monitor the flow of these radioactive sources will be adequate to prevent radiation accidents.

These potential occupational and environmental risks are not unfounded. In 1977, a worker at a Rockaway, NJ irradiation plant accidentally walked into the radiation chamber and received a near lethal dose of radiation. In 1982, at a Dover, NJ irradiation plant, steel rods that encapsulate radioactive cobalt cracked open, contaminating the cooling water, which leaked throughout the plant. Later, a cleanup crew threw some of the contaminated water down shower drains into the public sewer.

I am also concerned about the FDA and other agencies' apparent inability to enforce labeling requirements and existing limitations on the permitted dosages of radiation that may be applied to foods, when no empirical test is available to detect irradiated foods. This lack of oversight ability raises the potential for abuse. Last year, a major British food company is alleged to have knowingly purchased contaminated shrimp, shipped it to the Netherlands for irradiation, and imported the shellfish into England in violation of the British ban on irradiated foods. In the United States, a North Carolina food irradiation plant came under investigation by the U.S. Department of Agriculture for allegedly irradiating pork and attempting to export it prior to the agency's approval for pork irradiation. Because inspectors do not have a test for irradiated foods, it is unclear to me how regulations governing food irradiation will be upheld.

Finally, the need for this particular industry remains a mystery to me. In this country we are fortunate to have a reasonably safe and abundant food supply. Even the commercial food industry has yet to take a stand on food irradiation or make any serious investments in the technology. In fact, you might be surprised to learn that the food industry did not petition the FDA to publish a rule permitting produce irradiation. Instead, FDA published the rule of its own initiative. In my view, this was an unusual move in that the agency was both the advocate for the use

of a food additive and the evaluator of its safety.

Mr. Chairman, the prospect of utilizing food irradiation alarms many scientists and consumers. In fact, the FDA received over 5,000 public comments in response to its rule to permit produce irradiation. In the absence of any Congressional action, many state and local governments have already taken steps to curb this industry's growth. For example, on May 29 Maine Governor John McKernan signed a bill into law banning the sale of irradiated foods in that state. Earlier this year, the New Jersey state Senate overwhelmingly approved a bill to ban the sale of irradiated foods in that state as well. Vermont has passed a labeling bill, and last year, the California state legislature passed a measure calling on the Department of Health and Human Services to require further safety studies, and requesting that no new regulations be promulgated broadening the uses of food irradiation. A similar resolution was passed by the Board of Supervisors in my own county of Sonoma.

Mr Chairman, I would also like to bring to the Subcommittee's attention recent action taken by the Canadian government on this issue. In May, a Canadian parliamentary committee unanimously endorsed a committee report which expressed deep reservations about the uses of food irradiation. The Standing Committee on Consumer and Corporate Affairs urged the government to resist the expansion of irradiated foods until further scientific studies indicate that irradiation poses no significant adverse health effects. The Committee also recommended that irradiated foods be fully labeled, and that wheat irradiation be banned until specific safety concerns are resolved. These recommendations are particularly noteworthy because Canada has been a leader in the development of food irradiation.

For all of these reasons, I believe a more prudent approach to formulating food irradiation policy is in order. Based on our limited understanding of the potential harmful implications of food irradiation, I believe Congress would do well to hold the program in abeyance until these unresolved safety concerns have been sufficiently addressed. The legislation that I have introduced, H.R. 956, would: prohibit pork and produce irradiation, require independent safety studies, and tighten labeling requirements for irradiated herbs and spices. I urge my colleagues to join with me in supporting this needed legislation.

Mr. Chairman, I appreciate the opportunity to testify before this Subcommittee on this subject and I would be happy to respond to any questions you may have.

FOOD IRRADIATION
1987 INTRODUCED AND ENACTED LEGISLATION

STATE BILL # OR CHAPTER # (1987 Laws/ Acts)	SUMMARY
AK SJR 33 (Intro 5/87)	Makes provisions relating to irradiated food.
HI SB 971 (Intro 3/87)	Makes an appropriation to promote consumer acceptance of irradiated agricultural products from Hawaii.
IL HB 212 (Intro 2/87)	Amends Food, Drug and Cosmetic Act. Requires labeling of irradiated foods sold at retail for off-premise consumption.
MA SB 47 z (Intro 5/87)	Provides for an investigation and study by the Department of Public Health relative to the potential health risks of food irradiation.
ME Chap. 174	Prohibits the knowing sale of irradiated food, with the exception of irradiated spices when those spices are only an ingredient in the food. Provides that irradiated spices are irradiated food and their knowing sale is prohibited.
NH HB 1082 (Intro 1/88)	Relates to irradiated food.
NJ AB 3150 (Intro 11/87)	Prohibits distribution and sale of irradiated food.
NJ SB 2571 (Intro 1/88)	Prohibits distribution and sale of irradiated food.
NJ SR 43z (Intro 2/87)	Memorializes Congress to rescind Food and Drug Administration's approval of food irradiation.
NY AB 4106 (Intro 5/87)	Defines "irradiated food"; makes it unlawful for any merchant, broker or processor to knowingly sell any irradiated food until studies of the effects on human health, on consumers, and on workers so exposed and impacts associated with transportation of radioactive materials used in processing are received and accepted by various state commissioners.
NY AB 5442 (Intro 6/87)	Defines food exposed to any process of irradiation as adulterated food.
PA HB 1632 (Intro 7/87)	Prohibits the sale of food products which have been exposed to or treated with radiation for preservative purposes or any other reason.
PA HB 1912 (Intro 10/87)	Defines adulterated food in relation to radiation under the Pure Food Law.
VT HB 635 (Intro 1/88)	Prohibits the sale of irradiated foods.

1/21/88 (Source: Information for Public Affairs, "State Net")

ATTACHMENT 10

Irradiating food growing preservation method

Most groups say irradiation is the safest way to keep food from spoiling and to kill bacteria

Recent federal initiatives are paving the way for a significant increase in the use of ir-done irradiation on foods in the United States.

New Dept. of Health and Human Services (HHS) regulations, if approved by the Office of Management and Budget (OMB), will permit irradiation of pork and fresh fruits and vegetables. Sweeping legislation now before Congress would further encourage irradiation of foods — a practice considered beneficial because it destroys insects, parasites, and microorganisms, including those that cause disease and promote spoilage.

In irradiation, food is exposed to ionizing energy from radioactive isotopes of cobalt or cesium or from devices that produce controlled amounts of beta rays or x-rays. For at least 20 years, some food and food products, including wheat and potatoes, have been irradiated abroad without adverse effects. At least 28 countries now irradiate some foods.

But the process has been little used in the United States. Although existing Food and Drug Administration (FDA) regulations now allow irradiation for insect disinfestation in wheat, sprout inhibition in white potatoes, and control of microorganisms and insects in herbs and spices, only the latter use has been widespread.

THIS MAY CHANGE, however, as the HHS reviews new uses and regulations for irradiation:

- In July, 1985, HHS gave the go-ahead for irradiation in the processing of pork, a process that is believed to eliminate the threat of trichinosis even if the pork is undercooked or eaten raw. These regulations — with comment from the U.S. Dept. of Agriculture (USDA), which regulates pork — are nearing OMB review completion.
- Just before leaving office, HHS Secretary Margaret Heckler signed off on regulations that would permit the irradiation of fresh fruits and vegetables to kill pests and prolong shelf life.
- HHS is considering extending the irradiation process to poultry, and studies of this application are now under way.

FOOD IRRADIATION ALSO has occupied the attention of federal legislators recently. Four House committees are considering H.R. 696, a food irradiation development and control bill that would allow irradiation of many foods at regulated doses (the lowest level to achieve effectiveness).

Under the proposed legislation, the FDA would retain general authority to regulate food irradiation. But the definition of irradiation in the Food, Drug, and Cosmetic Act would be changed so that it would be regulated as a process, like boiling or freezing, rather than a food additive.

The legislation would also require national uniformity in the regulation of food irradiation and would create a commission to coordinate and consolidate all food irradiation research, encourage investment by private sources in food irradiation, and promote a wider public understanding through educational programs.

A companion bill, S 288, with similar provisions, has not been debated.

THE CURRENT INTEREST in food irradiation springs from concern about the safety of pesticides, particularly when used in the post-harvest disinfestation of fruits and vegetables. Specifically, the discovery in 1984 that the post-harvest fumigant ethylene dibromide (EDB) leaves a toxic residue on food — followed by the banning of EDB by the Environmental Protection Agency — encouraged consideration of irradiation as an alternative to pesticide use.

The FDA, HHS, and USDA — as well as other proponents — all contend that irradiation in low doses actually has a wide variety of beneficial applications: It eliminates trichinae spirals in pork, the Medfly in citrus fruits, and the codling moth in apples; could destroy c. botulinum and salmonella in red meats, poultry, and fish; and extends the shelf life of fresh fruits, vegetables, and grains.

In November, 1985, the American Medical Association testified in favor of the proposed federal irradiation legislation before the House Agriculture Committee's subcommittee on Department Operations, Research, and Foreign Agriculture.

A. Harold Lubin, MD, director of AMA's Dept. of Foods, Nutrition, and Personal Health, testified that food irradiation produces no significant reduction in the nutritional quality of food and has a number of important beneficial effects, including killing the microorganisms that cause food spoilage.

JOSEPH A. LUIZZO, PHD, professor of food science at Louisiana State U. in Baton Rouge, praised the process as a food preservative.

"We've found that 90-95% of all bacteria are killed during the irradiation process," said Dr. Luizzo, who once worked under contract from the Atomic Energy Commission on food irradiation in the preservation of shrimp. "Food irradiation would allow the people in places like Iowa and Kansas to have fresh shrimp," he said, noting that his studies showed a 39-day shelf life for shrimp kept on ice after irradiation.

"There was no destruction of nutrients, either," he added.

THERE MAY BE drawbacks to the process. For example, research shows that some foods undergo color or texture changes when irradiated. Ironically, this may lead the public to assume that a food is not fresh when actually the shelf life has been extended.

In addition, some opponents to the process have suggested that food irradiation presents a hazard to the public and to plant workers.

Robert Alvarez, who is director of the Nuclear Weapons and Power Project of the Environmental Policy Institute, a public-interest group based in Washington, D.C., testified before Congress that the irradiation of food involves an ultrahazardous technology, which he said "poses several types of risks to the public and workers."

Food irradiation facilities would generate as much as 10 times more low-level radioactive wastes than all sources combined in the United States for the year 1981, he said, adding that existing irradiation facilities are poorly regulated. Alvarez also contended that irradiation intended to eliminate one food hazard may intensify another — for example, by producing radiation-resistant bacteria and viruses.

Other critics, such as the Health and Energy Institute of Washington, D.C., another public-interest group, claim that carcinogenic or genetic problems could arise from irradiating foods.

BUT THE MAJORITY of observers contend that irradiation is safe. HHS and FDA have both taken this position, as has the AMA.

"It is important to note that food irradiation does not make the irradiated food radioactive, since it is done at energy levels well below those required to induce radioactivity," the AMA's Dr. Lubin said in testimony before Congress. He added that, given widespread public interest in nutrition and health, physicians will need to be in a position to reassure patients who are concerned about the safety of the process.

A committee formed by the World Health Organization to study the subject of food irradiation in other countries in 1981 issued a report on "The Wholesomeness of Irradiated Food," which called the process safe and "free from toxicological hazard."

In a lengthy report on food irradiation, the American Council on Science and Health, a national association that is devoted to consumer education, states that the levels of radiation approved for treatment of foods "do not have enough energy to induce residual radioactivity in the food."

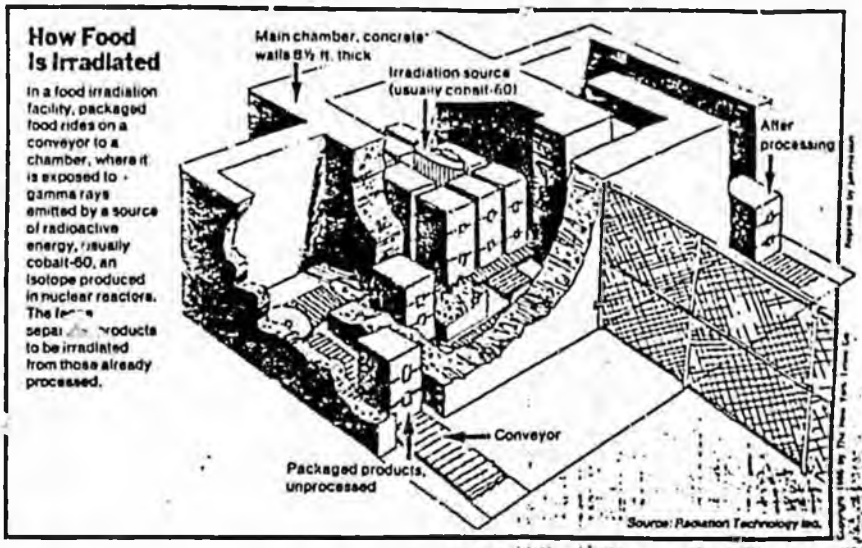
The council also said that workers who take proper precautions need not worry about adverse health risks. Irradiation facilities must comply with regulations issued by the Occupational Safety and Health Administration, the Nuclear Regulatory Commission, and the FDA, the council noted.

THE SAFETY ISSUE of food irradiation has been a problem for HHS, which has had difficulty finding a acceptable way to explain irradiation to the public. Reluctant to require the use of the word "radiation" for package labels because the word alone could arouse consumer fears and cause misunderstanding, HHS, against the advice of some in the FDA, ultimately substituted the word "pico-wave," meaning low-level ionizing energy, for "radiation."

Irradiated foods must now carry the word "picowaved" on their labels together with the international logo symbolizing irradiated foods. The circular symbol that holds a stylized rose with two petals was developed in the Netherlands several years ago and is used on many packaged irradiated foods abroad.

Most of the handful of irradiation firms in this country currently earn their money by sterilizing medical equipment and supplies and some food spices. They have stated in reports that public endorsement of the irradiation process by just one large, well-known food company would persuade consumers that the process is safe.

—Linda Bass



Irradiated foods must now carry the word 'picowaved' on their labels together with the international logo symbolizing irradiated foods.

ATTACHMENT 11

History of Food Irradiation

1898 - Bactericidal effects of x-rays first observed.

1905 - Patents for food irradiation process first issued in United States and Europe.

1920 - U.S. patent granted for irradiating beetles in tobacco with x rays.

1930 - French patent issued for preserving food by irradiation.

1943 - U.S. Army contracts with Massachusetts Institute of Technology to study feasibility of extending shelf life of food with irradiation.

1947 - MIT reports that shelf life of food can be extended through irradiation, offering a new method for assuring provisions for combat troops in remote battlefields.

1953 - U.S. Army Quartermaster Corps takes up food irradiation study at its laboratory in Natick, Mass., in conjunction with MIT, in federally funded study of irradiation of meat, fish, fruits, vegetables and dairy products.

1963 - U.S. Food and Drug Administration approves gamma irradiation to preserve canned bacon and for insect disinfestation of wheat and wheat products.

1964 - FDA approves irradiation for sprout inhibition of white potatoes.

1966 - FDA approves labeling requirements for irradiated foods.

1968 - FDA rescinds bacon irradiation rules after finding the studies on which original approval was made were based on poor laboratory quality controls.

Late 1960s - American astronauts and Russian cosmonauts begin eating radiation sterilized foods in space.

1969 - United Kingdom approves use of radiation sterilized foods in hospitals.

1975 - American astronauts and Russian cosmonauts share a meal of irradiated food in space aboard connection of Apollo-Soyuz capsules. Space explorers continue to dine on radiation sterilized food, as do others requiring such food in isolation, such as hospitalized bone marrow transplant patients.

1979 - FDA's Director of Bureau of Foods establishes the Irradiated Food Committee to provide a total reassessment of all relevant issues applicable to irradiated foods.

1981 - FDA publishes advanced notice of proposed rules on food irradiation in the *Federal Register.*

1981 - FDA offers to approve the use of irradiation for treating the California medfly crisis, provided certain conditions were met. Process not used because no person or organization applied for its use.

1983 - FDA approves irradiation of a specific list of spices and vegetable seasonings for microbial decontamination.

1984 (Feb. 14) - FDA publishes its proposed rule in *Federal Register* to allow irradiation of fresh produce for sprout inhibition, shelf-life extension and insect disinfestation of fresh produce and for sterilizing spices.

1984 (June 19) - FDA approves irradiation treatment to control insect infestation in garlic powder, onion powder and dried spices.

1985 (April) - FDA expands list of dried spices and vegetable seasonings that can be irradiated.

1985 (June) - FDA allows certain dried enzymes to be irradiated to control insect and microbial infestations.

1985 (July) - FDA approves low dose irradiation of pork and pork products to control trichinosis, the parasitic worm found in the muscles of some infected hogs.

1985 (December) - Canadian government announces it will allow food irradiation at up to 1,000 kilorads, 10 times the dose allowed in the United States, with only limited labeling requirements.

1986 (January) - The U.S. Department of Agriculture approves its own rules and guidelines for irradiating pork products.

1986 (April) - FDA publishes its final rule on post-harvest, low dose irradiation treatment of fresh fruits and vegetables and high dose irradiation of spices in the *Federal Register.*

1986 (June) - The British Advisory Committee on Irradiated and Novel Foods issues report recommending that food irradiation be legalized in the United Kingdom at doses up to 1,000 kilorads and that labeling be required.

1986 (June) - The People's Republic of China opens a commercial-size food irradiation plant in Shanghai and announces plans to build five regional food irradiation plants around the country.

1986 (July) - The U.S. Department of Energy announces it will build six regional food irradiation demonstration centers in the states of Alaska, Florida, Hawaii, Iowa, Oklahoma and Washington. A transportable cesium food irradiator is already operational unoer the DOE's Byproducts Utilization Program.

1986 (September) - Irradiated Puerto Rican mangoes go on sale in a one-time only test market in North Miami Beach, marking the first time in history that irradiated food is made commercially available in the U.S. The two tons of irradiated mangoes, at $1.49 a pound, are sold out within a week.

1986 (September) - Canadians announce plans to open food irradiation demonstration center in Montreal.

1987 (January) - USDA's Animal and Plant Health Inspection Service's rules for irradiating Hawaiian papaya are published in the *Federal Register.*

1987 (February) - USDA's petition for irradiation of chicken and poultry products to control salmonella is published by the FDA in the *Federal Register.*

1987 (March) - FDA rejects requests to put a hold on its new food irradiation rules adopted in April 1986, pending its decision on whether to hold requested public hearing on the new rules.

1987 (March) - FDA publishes petition from Radiation Technology, Inc., requesting irradiation treatment of poultry to control salmonella. Petition is similar to one published in February by the USDA.

Atomic Irdustrial Forum, Inc.
"Background Info", April 1987

FDA'S LIST OF FOODS AUTHORIZED FOR IRRADIATION

FOODS:

Fruits and Vegetables (April 18, 1986)
Pork (July 22, 1985)
Wheat, Wheat Flour
White Potatoes
Dried Enzyme Preparations

HERBS AND SPICES (Dried): (since July 1983)

Allspice	Cardamon	Cloves	Fenugreek	Marjoram	Oregano	Poppy Seed	Spearmint
Anise	Celery Seed	Coriander	Garlic Powder	Mustard Seed	Paprika	Rosemary	Star Anise Se
Basil	Chamomile	Cumin Seed	Ginger	Mustard Flour	Parsley	Saffron	Tarragon
Bay Leaves	Chervil	Dill Seed	Grains of Paradise	Nutmeg	Pepper, Black and White	Sage	Thyme
Caraway Seed	Chives	Dill Weed	Horseradish	Onion Powder	Red Pepper	Savory	Turmeric
Black Cumin	Cinnamon	Fennel Seed	Mace	Orange Petals	Peppermint	Sesame Seed	

* All the above listed foods are *authorized* for irradiation. That means they could legally be irradiated at any time. Presently we know of no whole foods that are routinely being irradiated and sold on a retail level with the following exceptions:
Puerto Rican mangoes were test marketed on a limited basis in Miami, Florida in Sept. 1986. (See Consumers Take Notice, Vol. 1, No. 4).
A small amount of spices being used in processed foods.
Although they are considering a request from Radiation Technology, Inc. the FSIS has not yet authorized any commercial irradiator to treat pork.

HOT NEWS

Cesium Salad

Brussels

Wild mushrooms in Belgium and Luxembourg have been found to contain dangerously high levels of radioactive cesium 16 months after the Chernobyl nuclear disaster in the Soviet Union, officials said yesterday.

A Luxembourg government official said it had banned the sale of one type of mushroom after tests showed cesium levels greater than recommended safety levels.

P.S.: Cesium never quits.

Home-Dumping

Radioactive Waste
Dump Plan Ratified

California has ratified a four-state compact that provides for the dumping of low-level radioactive waste in the state's eastern desert into the next century.

Legislation ratifying the pact was signed Thursday by Governor Deukmejian.

The bill by Assemblyman Steven Peace, D-Chula Vista, puts California into compliance with a 1980 federal law that requires the states to dispose of low-level radioactive wastes within their borders. If ratified by North and South Dakota and Arizona, it would be the first pact of its kind in the nation.

The waste — to be buried 40 feet underground in a dump site as large as three football fields — will consist of contaminated items, such as gloves, tools and other supplies used by hospitals, laboratories and nuclear plants. It will not include spent fuel from nuclear reactors.

CHERNOBYL'S LEGACY

It seems radiation, like guilt, keeps on giving. According to a study of the April 26, 1987 Soviet accident by the Lawrence Livermore National Laboratory in Livermore, California, the nuclear accident released as much long-term radiation into the world's air, topsoil and water as all the nuclear tests and bombs ever exploded. The report goes further to say this long-term radiation may contain 50% more cesium-137 than the total radiation produced by all atmospheric tests. Cesium 137 does not decay into harmless products for more than 600 years.

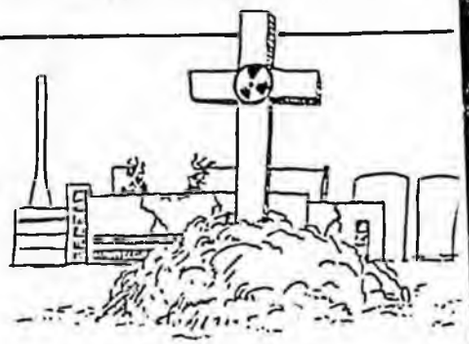
Using computer projections, Dr. John Gofman, Professor Emeritus of Medical Physics at the University of California (Berkeley), estimated that 1 million people, including over half a million outside the Soviet Union, will develop cancer as a result of the Chernobyl accident and half of these cancers would be fatal.

In a separate projection Ernest Sternglass, Ph.D., of the Radiology Department at The University of Pittsburgh, Pennsylvania, arrived at a similar estimate: 150,000-600,000 additional cancer deaths in Europe resulting from Chernobyl.

Both these estimates are derived from research by Dr. Abram Petkau, published in 1972 (the Journal of Health and Physics). Dr. Petkau's experiments showed that very low dose radiation over a prolonged period (protracted low dose exposure) produces unexpectedly large free radical damage compared to short exposures to medical x-rays or direct radiation from atomic fallout. This occurs, according to Petkau, because the free radical process becomes extremely efficient at low levels of radiation. Low dose radiation produces fewer free radicals which are statistically better able to do damage to the cell membrane. The insidious action of radiation on DNA in the cell produced mutations that lead to cancer, cancer is a free radical process. However, at high doses of radiation over a short period of time, the free radical process becomes very inefficient due to the extremely large number of free radicals generated per unit volume. These radicals are so reactive they smash into each other and literally wipe themselves out.

Dr. Petkau's observation seems to explain why less people died immediately after Chernobyl and Hiroshima than anticipated. Based on data from the Hiroshima experience, leukemia and other cancers are currently occuring among children and adults at 100-1000 times the predicted rate 40 years after the bomb.

You'd think we might have learned that radiation is unforgiving.



LOOKING FOR THE K.O.

In the August 21st issue of the Food and Drug newsletter, the editors of this industry bulletin analyzed the food irradiation controversy with some interesting insights.

"Food producers aren't enthusiastic about the process. They hesitate because of certain unproven aspects of the technology, high costs and popular rejection of irradiated foods as dangerous. Retailers share the anxiety about customer resistance."

In an interview with Sharon Bomer *ex-director* of The Coalition For Food Irradiation (CSFI), Bomer confesses "there were irradiation companies that tended to blow the issue out of proportion and to make fantastic claims." Bomer was talking about companies in the business of irradiating medical supplies and who wanted to move into food irradiation.

George Giddings, formerly of Isomedix, a company that irradiates medical supplies, feels that what hurt food irradiation was The Department of Energy (DOE).

"The DOE program is the single most controversy-raising aspect of food irradiation," said Giddings. "The strident anti-nuclear types see (it) as a ploy of DOE in favor of the nuclear power industry. They see a conspiracy to push food irradiation...If this program were eliminated and there was no hypothetical possibility of implementing this cesium plutonium scenario, I think much of the crazy food irradiation controversy would evaporate in no time."

Bomer blames the commercial irradiators and Giddings blames the DOE for the failure of food irradiation. Both of them seem to ignore the fact that the people in the anti-food irradiation movement have a deep commitment to safety of the food supply and the environment.

The Food & Drug newsletter editors conclude "If this debate were a boxing match [illegible]"

ATTACHMENT 13

Coalition for Alternatives in Nutrition and Healthcare
(C A N A H)

P.O. Box B-12
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Compilation of Bioassay Data on the Wholesomeness of Irradiated Food Items by Dr. J. Barna

Dr. Jozsef Barna of Budapest, Hungary published "A review of 1223 studies on the wholesomeness of some 278 different irradiated foods and feeds concerning the period from 1925 to date" [1979 when his report was published in Acta Alimentaria, Vol. 8 (3) pp. 205-315].

The following is an extrapolation of the information which indicates "adverse effects are indicated in italics":

Albumin - ovalbumin

anaphylactic reaction
increased serological activity
increased precipitation in serological test
loss of serological activity
reduced capacity to sensitization

Amino Acids in Medium

inhibition of bacterial growth on pH3

Apple Juice

inhibited growth of seeds
increased chromosome aberration in plant cells
cytotoxic in plant
antibacteric (bactericide and bacteriostatic)
radiomimetic effect

Apricot

retarded growth
reduced body weight
reduced weight gain

Aqua Destillata

cytotoxic in plant

Bacon

worse acceptance
retarded growth
reduced body weight
reduced weight gain
loss of body weight
disturbance in breeding performance
reduced number of progeny

Bacon (Cont'd.)

reduced viability of offspring
reduced RBC
reduced haemoglobin content
more frequent incidence of cataract
increased mortality
increased postnatal mortality
more frequent tumour incidence
increased malignity of tumour
more hypophysis tumour

Barley

increased chromosome aberration in plant cells

Bean

reduced biological value

Beef

reduced biological value
reduced food efficiency
reduced protein utilization
reduced food consumption
worse acceptance
disturbance in development
reduced growth
reduced body weight
reduced weight gain
reduced weight of testicle
increased relative weight of epididymis
increased liver weight
reduced reproductive performance
disturbance in breeding performance

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Beef (Cont'd.)

disorder in reproductivity
earlier manifestation of first oestrus
reduced fertility
fertility disorder
conceptual difficulties
reduced number of progeny
less parturition of pregnants
reduced number of pups per litter
increased haematocrit value
increased haemoglobin content
incidence of primary lymphocytic thyroiditis
extension of prothrombin time
lower prothrombin rate
hypoprothrombinaemia
glycosuria
disturbances in metabolism of fat and vitamins
increased phagocytosis due to antigen effect
increased liver cytochromoxidase activity
increased liver tributyrinase activity
increased far content in the liver
lower riboflavine excretion to urine
reduced serum vitamin E level
vitamin E deficiency
vitamin B_2 deficiency
vitamin K deficiency
insufficient coprophagia
reduced coprophagia
reduction of life span
increased mortality
increased mortality of progeny
haemorrhagic syndrome

Blood Serum/Plasma

inhibited growth of microorganism

Bread

lymphopenia
worse acceptance

Butter

disorder in reproductivity
reduced fertility
fertility disorder
conceptual difficulties
reduced total number of young born

Butter (Cont'd.)

reduced number of pups per litte
reduced number of young at weani
reduced vitamin E level in liver
increased mortality of progeny
reduced number of progeny

Cabbage

reduced SGPT activity
reduced AP activity in intestina mucosa
reduced GOT activity in tissues
increased esterase activity in tissues
reduced AP activity in tissues
reduced MAO activity in tissues
increased alanin-beta-aminopeptidase in tissues
reduced amino-oxidase activity in tissues
changed condition of pelage and skin

Cakes

worse acceptance

Carbohydrate Solution

increased chromosome aberration in microorganisms
inhibited growth of microorganis
antibacteric (bactericide, bacteriostatic) effect
growth inhibition in cell cultu
mutagen effect

Carrot

reduced food efficiency
reduced growth rate
retarded growth
reduction of body weight
reduced weight gain
reduced vitamin A level in live
increased malignity
formation of toxic substances radiotoxins

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Casein

reduced biological value
reduced digestibility
reduced growth
increased kidney weight
influenced moving activity
increased mortality
inhibited growth of microorganisms
late effect on microorganisms
lower number of emerging insect
longer duration of larval development

Cauliflower

worse acceptance

Celery

formation of toxic substances, radiotoxins

Cereal (Grain)

more frequent diseases
chronic nephritis
peritonitis

Chicken (cooked, stewed)

reduced nutritive value of lipid
reduced biological value
retarded growth
reduced intensity of growth
increased liver weight
increased kidney weight
conceptual difficulties
reduced nubmer of pups per litter
glycosuria
increased haematocrit value
increased haemoglobin content
increased SGOT activity
reduced SGPT activity
reduced AP activity in intestinal mucosa
reduced GOT activity in tissues
increased GOT activity in tissues
increased esterase activity in tissues
reduced AP in tissues
reduced MAO activity in tissues
increased alanin-beta-aminopeptidase in tissues

Chicken (Cont'd.)

reduced amino-oxidase activity in tissues
incidence of primary lymphocytic thyroiditis
increased phagocytisos due to antigen effect
reduced ascorbic acid content of adrenal
increased mortality of progeny
inhibited growth of microorganisms
antibacteric (bactericide, bacteriostatic) effec

Clam

affected liver weight
affected kidney weight
affected spleen weight
increased kidney weight
reduced testis weight
increased BUN level
reduced body weight
reduced measure of testis
reduced fertility
reduced viability of embryos
reduced hatchability

Coconut

extended chronaxy time

Coconut Milk

decreased gain in plant tissue weight
antimitotic effect (retardation or inhibition of mitosis in animal cells

Codfish

reduced biological value
reduced organ weights
reduced weight of liver in female
reduced uterus weight
reduced weight of caecum in female
increased weight of spleen in femal

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Codfish (Cont'd.)

increased spleen weight
increased kidney weight
reduced testes weight
disorder in reproductivity
inhibition of spermiogenesis
reduced resistance of spermatozoa
reduced activity of spermatozoa
reduced osmotic resistance of spermoa oids
lengthening of the oestrus cycle
higher globulin alfa-fraction value
reduced serum A/G quotient
increased SGOT activity
reduced SBChE
elevated SAP
increased serum aminotransferase
lower serum cholesterol level
reduced GPT activity in liver
increased liver aminotransferase
decreased liver BChE
decreased liver succinate dehydrogenase
decreased liver alanin aminotransferase
reduced aminotransferase in liver
reduced liver succino-dehydrogenase activity
reduced GPT activity in kidney
reduced succino-dehydrogenase activity in kidney
reduced ascorbic acid content of adrenal
more frequent intercurrent diseases
increased mortality of progency
more frequent pituitary adenoma
more frequent atrophy of genital tract
degeneration (atrophy) of testicles
degeneration of ovary

Compote (Fruit)

increased weight of spleen
reduced number of pups per litter
more frequent incidence of cataract
more frequent tumour incidence
hypophysis tumour
increased postnatal mortality
increased growth

Corn (Maize)

reduced digestibility
reduced weight gain
reduc d weight of offspring
lower weight of progeny at birt
oestrus disorder
longer reproductive cycle
reduced fertility
more frequent epithelioma
increased frequency of lympho-blastoma in liver, thymus lung, spleen, kidney

Corn Meal

longer duration of development of the larvae of Tribo

Crackers

worse acceptance

Cranberry

reduced growth

Dessert Powder (gelatine, vanilia

worse acceptance
reduced growth rate

Diet (complete)

reduced food consumption
reduced palatability
reduced nutritional quality
reduced growth
reduced growth rate
reduction of weight or weight
reduced weight gain in female
slower growth of females
reduced body weight
increased kidney weight
disturbance in reproduction
disturbance in breeding performance
reduced fertility

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Compilation of Bioassay Data (Cont'd.)

Diet (complete - cont'd.)

fertility disorder
sterility
higher male and female sterility
elevated number of dead implantation
reduced number of pups per litter
reduced number of progeny
lower live-birth percentage
reduced litter number at weaning
reduced lactation performance
lymphopenia
shift from lymphocytes towards neutrophilic cells
leucopenia
leucocyte degeneration
reduced concentration capacity of kidney in female
increased cytochrome oxidase activity in liver
reduced serum transaminase
reduced SGPT activity
reduced SAP
reduced vitamin A level in liver
vitamin A deficiency
vitamin K deficiency
reduced transketolase in erythrocytes
changed condition of pelage and skin
more frequent intercurrent diseases
rachitis
increased mortality
elevated mortality
increased neonatal mortality
increased perinatal mortality
increased mortality of progeny
haemorrhagic syndrome
rupture, dilatation of heart auricle
testicular atrophy
histological laesio in testes, spleen lymph node and liver
inhibited growth of microorganisms
increased polyploidia
increased backmutation frequency
mutagen by DNA repair
mutagen effect by HMA

Diet (test)

reduced food consumption
reduced nutritive value
reduced protein quality
reduced digestibility of starch
reduced body weight
reduced growth
reduced growth rate
delayed appearance of pelage
delayed opening of eyes
reduced thymic involution
increased thymus weight
affected sexual function
disturbed reproductive function
disturbed reproductive performance
reduced fertility of male
extended mating period
longer time for producing
prolonged gestation length
reduced number of viable offspring
reduced viability of offspring
reduced litter number at weaning
more frequent cannibalism
reduced lactation performance
lymphopenia
reduced leucocyte count
higher number of neutrophilic leucocytes
increased serum nucleic acids (RNA, DNA) content
hypoproteinaemia
reduced serum A/G quotient
increased blood AChE activity
increased serum aldolase activity
reduced serum BChE
reduced serum tributyrinase
increased cytochromoxidase activity in liver
reduced activity of transketolase in erythrocytes
antifolic acid effect
vitamin E deficiency
ascorbic acid deficiency
folic acid deficiency
more frequent intercurrent diseases

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Diet (test - cpnt'd.)

- increased preimplantation resorption
- increased mortality of progeny
- slower rate of thymus involution
- increased number of cell in thymus
- increased incidence of mamma fibroadenoma
- increased chromosome aberration in animal cells

Diet Extract

- increased backmutation frequency

Diet (synthetic, semi-synthetic, purified)

- reduced lipid digestibility
- reduced starch digestibility
- reduced growth
- reduced growth rate
- reduction of weight or weight gain
- loss of body weight
- increased liver weight
- decreased weight of spleen
- reduced weight of pups at weaning
- inferior reproductive performance
- reduced lactation index
- decreased peroxidation rate in endoplasmatic reticulum
- vitamin K deficiency
- increased mortality
- dilated coecum

Diet for farm animals

- reduced biological value
- reduced net protein digestibility
- reduced food efficiency
- reduced palatability
- reduced growth rate
- slower growth rate
- reduced body weight
- reduced egg production
- delayed age at which the first egg was laid
- delayed maximuzation of hatchability
- increased mortality

Diet for humans (MEAL kitchen ready etc., for cosmonauts, volunteer consumers)

- reduced growth

Egg (powder, dried whole)

- reduced growth
- reduced lactation index
- absence of maternal instinct
- more frequent cannibalism
- increased postnatal mortality
- increased mortality of progeny

European Plaice Fish (Pleuronectes plate

- less quick growth of females on irradiated diet
- relative reduction in liver weight

Fat

- reduced biological value
- reduced digestibility
- reduced reproductive capacity
- disturbance in breeding performance
- reduced sexual function in females
- influenced motility of gastronintestina tract
- extended chronaxy time
- increased mortality of progeny

Fat (animal)

Beef fatty tissue
- reduced growth
- reduced fertility
- reduced survival of offspring
- vitamin A deficiency
- reduction of life span
- encephalomalacia

Butter fat
- reduced growth
- reproductive disturbance
- increased mortality of offspring

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Fat (animal - cont'd.)

Lard
- absorption disturbances
- distrubed fat absorption
- disturbed digestion
- increased mortality
- more frequent tumour incidence
- changes in fatty acid composition of endoplasmic retic. of liver
- decreased hydrolysation activity of lipase in tissues
- low lipid peroxidation rate

Pork fatty tissue
- reduced growth
- vitamin A deficiency
- encephalomalacia

Fish (canned cooked, culinary fishery products, preserves, pasta)
- reduced biological value
- reduced nutritive value of lipid
- reduced protein utilization
- reduced growth rate
- reduced weight of testicle
- increased weight of spleen
- disturbance in breeding performance
- reduced activity of spermatozoids
- extended oestrus cycle
- more frequent cannibalism
- increased SGOT activity
- reduced SGOT activity
- increased SGPT activity
- reduced ascorbic acid content of adrenal
- more frequent intercurrent diseases
- higher blood sugar level at starving
- increased mortality of progeny
- increased excitability
- inhibited growth of microorganisms

Flounder (yellow tailed Fish (Limanda ferruginea)
- reduced protein utilization
- elevated SAP in female
- more pronounced enlargement of the salivary gland

Flour
- increased weight of spleen
- physiopathological injuries in fertility
- reduced number of viable offspring
- increased preimplantation loss
- physiopathological changes in longevity
- increased mortality of progeny
- thyroiditis
- more frequent tumour incidence
- increased meiotic chromosome aberration

Food (unidentified)
- reduced biological value
- reduced protein quality
- worse acceptance
- retarded growth
- reduction of weight
- reduced weight gain
- reduced reproductive capacity
- disturbance in breeding performance
- reduced fertility
- sterility
- reduced sexual function in females
- reduced RBC
- increased RBC
- decreased lipid digestion
- changes in immunological reactivity
- formation of toxic substances, radiotoxin
- increased cytochromoxidase activity in tissues
- toxic effect
- risk in irradiated food consumption
- few anomalies require further research
- more frequent incidence of cataract
- more frequent incidence of blind individuals
- increased mortality
- increased mortality of progeny
- thyroiditis
- rupture and dilatation of heart auricle
- haemorrhagic diathesis
- more frequent tumour incidence
- reduced fecundity of insects
- functional disorder in the thyreoid gland
- cytotoxic effect in animal cells
- mutagen effect on animals

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Food Product of Plant Origin

reduced biological value
reduced fertility
reduction of life span
teratogen effect
cytotoxic effect in animal cells
carcinogen effect
mutagen effect on animals

Fructose

inhibited growth of plants or plant tissues
decreased gain in plant tissue weight
cytotoxic effect in animal cells
inhibited growth of normal animal cells
inhibition of microbial growth
impaired respiration and oxidative phosphorylation
inhibition of the labelling of protein and DNA by radioactive precursors

Gelatine

reduced nutritive value
reduced growth rate
cytotoxix effect

Glycine

increased chlorophyll mutant rate

Glucose

leucopenia
lymphopenia
disorder of haematopoiesis
decreased gain in plant tissue weight
lower number of emerging insect
longer duration of larval development
increased chromosome aberrations in animal cells
increased chromosome aberration in plant cells
inhibited growth of rhizoma tissue
inhibited growth
inhibition of microbial growth

Glucose (Cont'd.)

impaired respiration and oxidative phosphorylation
inhibition of the labelling of protein and DNA by radioactive precursors
inhibited reproduction of microorganisms
cytotoxic effect in animal cells
inhibited growth of normal animal cells
antibacteric (bactericide, bacteriostatic effect
reduced rate of respiration
cytogenetic abnormalities
increased rate of chlorophyll mutants
increased dominant lethalita in Drosophi
Increased sex linked lethal mutation in Drosophila
increased autosomal recessive lethal mutation in Drosophila
increased forms of phenotypic alteration in Drosophila
Mutagen effect by HMA
mutagen by in vitro microbial test

Gluten

reduced protein value
reduced growth rate
reduced number of eggs laid
reduced hatchability of eggs

Grape

inhibited physiological activity of Saccharomyces

Green Bean

reduced intensity of growth
increased spleen weight
fertility disorder

Ham

retarded growth
reduction of weight
reduced weight gain
reduced number of pups per litter
reduced RBC
reduction of life span

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Herring (marinated)
- extended chronaxy time
- increased excitability of CNS

Histidine
- inhibited growth of microorganisms

Indian Mackerel Fish (Rastrelliger kanagurta)
- anaemia

Jelly Powder
- reduced growth

Lima Bean
- reduced biological value

Lipid
- reduced digestibility

Macaroni
- worse acceptance

Marinades
- hypothermia of central origin
- extended chronaxy time

Meat (culinary, preprepared, etc.)
- reduced fertility
- disturbance in metabolism of fat and vitamins
- change in allergen
- vitamin E deficiency
- vitamin B_2 deficiency
- internal bleeding
- increased mortality of progeny
- haemorrhagic syndrome
- inhibited growth of microorganisms
- late effect on microorganisms

Meat (organs)
- reduced body weight of youngs

Meat Product (culinary)
- vitamin B_1 deficiency
- vitamin B_2 deficiency

Medium
- inhibited growth of seeds
- inhibited growth of root tip per meristem
- inhibited growth of insect
- inhibited growth of plant or plants tissue
- supression of root hair formation
- lower number of emerging insects
- reduced emergence rate of adults insect
- increased chromosome aberration in animal cells
- increased chromosome aberration in plant cells
- increased chromosome aberration in microorganisms
- increased chromosome aberration in Drosophila
- increased mutation if Drosophila
- increased number of polyploid animal cell
- chromatid aberrations in plants
- cytotoxic
- cytotoxic effect in animal cells
- cytotoxic effect in plant
- cytotoxic effect in Drosophila
- antimitotic effect (retardation or inhibition of mitosis) in animal cells
- antimitotic effect
- micronucleus formations
- inhibited growth of normal animal cells
- inhibited growth of microorganisms
- inhibited RNA synthesis capacity of fibroblast
- inhibited DNA synthesis in bacerria
- reduced DNA synthesis
- antibacteric (bactericide, bacteriostatic) effect
- reduced number of microbe colony
- reduced number of viable microbes
- reduced physiological activity of microorganisms
- mutagen effect on microorganisms
- increased mutations in plant tissue

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Medium (Cont'd.)

increased mutation in Drosophila
increased sex-linked lethal mutation test in Drosophila
increased aberrant forms and phenotypic alteration in Drosophila
mutagen effect on animals

Milk (evaporated, powdered, whole)

reduced biological value
worse acceptance
reduced body weight
loss of body weight
changed anaphylactogenic activity
increased lethal shocking dose to allergenic response
reduced allergenic properties
reduced antigen-allergen activity
increased mortality
antibacteric (bactericide, bacteriostatic) effect

Mushroom

reduced food efficiency
reduced food consumption
reduced weight gain
reduced weight of liver in male
reduced weight of pituitary
reduced weight of uterus
reduced weight of kidney
disturbance in reproduction
(unreadable) of toxic substances, radiotoxins
toxic
increased postnatal mortality
inhibited growth of microorganisms

Oil

reduced reproductive capacity
disturbance in breeding performance
reduced sexual function in females
increased mortality of progeny

Oil (animal)

Fish oil
reduced food efficiency
reduced protein utilization
retarded growth
reduction of weight
reduced weight gain
positive BSP
disturbances in absorption
reduced total protein content
hypoproteinaemia
higher globulin gamma fraction valu
increased mortality
pigmentation of liver
pigmentation of spleen

Herring oil
reduced food consumption
reduced growth
less rate of exidative drug metabolism in the endoplasmic reti
greater induction of the oxidation metabolism of drugs
reduced rate of oxidative demethyla of aminopyrine
increased oxidative demethylation o aminopyrine
reduced hydroxylation of aniline
lower hydroxylation of biphenyls
reduced rate of metabolism of benzp
decreased peroxide concentration of endoplasmic retic
inhibited rate of lipid peroxidatio
high lipid peroxidation
greatly increased resistance to per xidation
increased antioxidante titer
changes in fatty acid composition o endoplasmic retic. of liver

Oil (plant)

Cereal oil
incidence of encephalomalatia

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Oil (plant - cont'd.)

Corn oil
- reduced digestibility
- reduced food consumption
- reduced growth
- increased liver weight
- increased fat content in liver
- changes in fatty acid composition of endoplasmic retic. of liver
- less rate of oxidative drug metabolism in the endoplasmic retic.
- reduced rate of oxidative demethylation of aminopyrine
- reduced hydroxylation of aniline
- reduced rate of metabolism of benzpyrene
- greater induction of the oxidation metabolism of drugs
- decreased peroxide content ration of endoplasmic retic.
- inhibited rate of lipid peroxidation

Cotton seed oil
- reduced growth
- lymphocyte infiltration

Soyabean oil
- reduced utilization of metabolizable energy
- reduced digestibility
- reduced food efficiency
- reduced protein utilization
- reduced food consumption
- disturbances in absorption
- decreased or disturbed fat absorption
- reduced growth
- retarded growth
- reduced body weight
- reduction of weight
- reduced weight gain
- increased liver weight
- more fragile RBC
- hypoproteinaemia
- reduced serum protein content
- increased serum gamma globulin level
- reduced serum lipid content
- reduced serum phospholipid content
- increased serum cholesterin level
- bradycardia

Oil (plant - cont'd.)

Soyabean oil (cont'd.)
- functional disorder of the liver
- positive BSP
- reduced thyroid function
- toxic effect
- decreased body temperature
- reduced oxigene uptake
- hypothermia of central origin
- diarrhoea
- incidence of encephalomalatia
- reduced excitability of CNS
- reduced life span
- increased mortality
- thyroid degeneration
- dilatation of small intestine, liver
- pigmentation in liver
- pigmentation in spleen
- testicular atrophy
- progressive transformation of adrena cortex

Oil (Wisson-oil)
- increased frequency of lymphoblastom in liver, thymus, lung, spleen, kidney

Onion
- increased spleen weight
- increased testicle weight
- increased liver weight
- reduced ovary weight
- reduced gonads weight
- reduced RBC
- reduced WBC
- leucopenia
- reduced haematocrit value
- fused rib cartilages
- more frequent skeletal abnormality
- higher incidence in abnormalities of trunk skeleton
- myeloid and RES hyperplasia
- leucocytosis in liver
- haemosyderosis
- pigmentation in liver
- pigmentation in spleen
- pigmentation in kidney

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Onion (Cont'd.)

osteodistrophia
deformation of testicles
degeneration of ovary

Orange

reduced growth rate
haemosyderosis
mucinous cerebral degeneration
inhibited growth of seeds
increased chromosome aberration in plant cells
cytotoxic effects in plant
radiomimetic effect in plants
reduced medullar hyperplasia of adrenal

Oranae Juice

antimitotic effects (retardation or inhibition of mitosis) in plant cells

Papaya

increased liver weight
aspermia
detrimental effect on offspring
aplasia of small intestine

Parsley

formation of toxic substances, radiotoxins

Peach

reduced growth
loss of body weight
reduced weight gain
reduced viability of offspring
toxic effect
more frequent tumour indicence

Peanut

increased frequency of lymphoblastoma in liver, thymus, lung, spleen, kidney

Peas

reduced biological value

Pepton in medium

cytotoxic effect

Pineapple

Jam
increased haemoglobin content
increased haematocrit value
incidence of primary lymphocytic throiditis
reduced fructose oxidation in heart
glycosuria

Juice
increased chromosome aberration in plant cells
cytotoxic effect in plant
radiomimetic effect in plant
depressed rate of mitosis
increased mutations in plant tissue

Plant

allergen reaction
formation of toxic substances, radiotoxins
increased chromosome abberation in plant cell
cytotoxic effects in plant
antimitotic effects (retardation or inhibition of mitosis) in animal cells
micronucleus formations
inhibited reproduction of microorganis
increased mutations in plant tissue

Plant Extracts (leaves, Vicia faba)

reduced growth
inhibited growth of seeds
inhibited development of seeds
inhibited growth of root
inhibited growth of plants or plants tissue

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Plant Extracts (Cont'd.)

increased chromosome aberration in plant cells
cytotoxic effects in plant
antimitotic effects (retardation or inhibition of mitosis) in animal cells
antimitotic effects (retardation or inhibition of mitosis) in plant cells
micronucleus formations
inhibited growth of normal animal cells
inhibited growth of malignant tissue
inhibited growth of microorganisms
reduced germ cell survival
inhibited DNA synthesis of plant
inhibited reproduction of micro-organisms
reduced number of microbe colony
mutagen effect on microorganisms
increased mutations in plant tissue

Pork (corned)

worse acceptance
decreased or disturbed fat absorption
reduced growth rate
retarded growth
reduction of weight
reduced weight gain
reduced weight of offspring
reduced weight of pups at weaning
conceptual difficulties
reduced number of progeny
reduced number of pups per litter
reduced number of young at weaning
increased phagocytosis due to antigen effect
reduced auto-oxidation rate
reduced fatty acid oxidation in kidney mitochondria
increased cytochromoxidase activity in liver
increased cytochromoxidase activity in kidney
increased cytochromoxidase activity in heart
reduced transketolase activity in erythrocytes

Pork (Cont'd.)

increased cytochromoxidase activity in tissues
vitamin B_6 deficiency
increased mortality
increased postnatal mortality
increased mortality of progeny
haemorrhagic syndrome
myocardial lesion
tyroid gland cancer
increased ATP-ase activity in tissues

Potato (white, cooked, raw)

reduced net energy
reduced biological value
reduced food consumption
reduced growth
retarded growth
reduction of weight
reduced weight gain
reduced weight of liver in females
affected ovary weight
reduced weight of ovary
reduced relative weight of spleen
reduction relative weight of lung
lowered weight of progeny
reduced weight of offspring
delayed opening of eyes
delayed opening of ear
delayed appearance of pelage
delayed coming out of teeth
reduced fertility
conceptual difficulties
increased resorption
altered measure of ovarium
extension of gestation period
reduced litter size
reduced number of progeny
influenced tolerance of galactose loading
toxic effect
more frequent diseases
more frequent respiratory diseases
more frequent incidence of cataract
increased embryonal resorption
increased embryo mortality
increased perinatal mortality
increased mortality of progeny

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Potato (Cont'd.)

- focal myocarditis
- coronary arteriosclerosis
- more frequent abscesses pneumonia
- bronchiectasia
- intestinal nephritis
- lesion in spleen, liver and lymph nodes
- testicle laesio
- more frequent tumour incidence
- spleen oedema
- reduced fecundity of insect females
- increased chromosome aberration in animal cells
- cytotoxic effect in animal cells
- micronucleus formations
- inhibited growth of microorganisms
- mutagen effect by DLT
- increased mutagen index

Potato Extract

- loss of body weight
- injured spermatozoon, early spermatid, developing spermatocytes
- increased postimplanation loss
- reduced WBC
- allergen reaction
- formation of toxic substances, radiotoxins
- toxic effect
- inhibited growth of seeds
- inhibited development of seeds
- increased chromosome aberration in animal cells
- increased chromosome aberration in plant cells
- cytotoxic effect in animal cells
- antimitotic effect (retardation or inhibition of mitosis) in animal cells
- antimitotic effects (retardation or inhibition of mitosis) in plant cells
- micronucleus formations
- inhibited growth of malignant tissue
- inhibited growth of microorganisms
- antibacteric (bactericide, bacteriostatic) effect

Potato Extract (Cont'd.)

- mutagen effect on microorganisms
- mutagen effect by DLT
- mutagen effect on animal

Potato in medium

- inhibited growth of seeds
- inhibited growth of root tip
- increased chromosome aberration in pla cells
- antimitotic effects (retardation or inhibition of mitosis) in plant cells
- micronucleus formations

Protein

- reduced biological value

Protein (animal)

- Milk protein
  - reduced biological value
  - change in antigenicity
  - increasing lethal shocking dose in gross anaphylaxis
  - slight diarrhoea
- Corn protein
  - reduced protein digestibility

Raisin

- reduced food efficiency
- reduced growth rate
- retarded growth
- reduction of weight
- reduced weight gain

Red Fish (Ocean Perch) (Sebastes marinus

- increased weight of spleen
- lower serum cholesterol level
- longer sleeping time from hexobarbital
- elevated SAP
- inhibited liver microsomal enzyme activity
- decreased liver aminopyrine N-demethylating and aniline-hydroxylating activity

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Ribose

inhibition of microbial growth
reduced rate of respiration
mutagen by in vitro microbial test
impaired respiration and oxidative phosphorylation
inhibition of the labelling of protein and DNA by radioactive precursors

Rice (polished too)

worse acceptance
reduced growth
increased neonatal mortality
increased perinatal mortality
lower free amino acid content in liver

Sausage

worse acceptance

Shrimp

worse acceptance
functional disorder of the thyroid

Soy Bean

extended chronaxy time

Spice Mixture
(allspice, black pepper, coriander, cumin, marjoram, nutmeg, paprika)

reduced growth rate
slightly reduced body weight
reduced weight gain
reduced liver GOT activity
reduced liver GPT activity
reduced depot fat

Starch

reduced digestibility
cytotoxic effect
reduced water intake
reduced body weight
reduced thymus weight in females
reduced kidney weight in male
increased WBC
reduced RBC

Starch (Cont'd.)

reduced haematocrit value
changed blood glucose level
increased BUN
reduced BUN
changed serum Na+ level
reduced serum P level
reduced SGOT
reduced SAP
increased male mortality
increased postnatal mortality
hyperplasia of stomach mucosa
changes in renal tubules
incidence of kidney cyst
cytotoxic
altered generating time of S. cerevisiae

Sterol (beef, egg, pork, yeast)

hepatoma

Strawberry

reduced food consumption
worse acceptance
reduced growth
retarded growth
reduction of weight
reduced weight gain
increased weight of testicles
increased pituitary gland weight
reduced prostate weight
increased rel. thyroid weight
increased rel. adrenal weight
increased rel. kidney weight
reduced liver weight in female
reduced liver weight in male
reduced heart weight in female
reduced spleen weight in female
reduced weight of offspring
first hatch chickens of F_1 performed poorly
greater incidence of head abnormalities in semen
decline in RBC
decline in haemoglobin content
periodical drop in egg production
increased mortality
increased embryo mortality

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Strawberry (Cont'd.)

increased mortality of progeny
incidence of liver fatty infiltration
increase in kidney concretions
incidence of cystic kidney
incidence of chronic nephritis
more frequent tumour incidence
trend to higher incidence of tumours
chromatid aberrations in animals
increased aberrant anaphase in plant cells

Sucrose (saccharose)

growth inhibition
inhibited lipid synthesis
inhibited protein synthesis
inhibited DNA synthesis
inhibited liver mitochondrial oxidative phosphorylation
improved oxidative phosphorylation in liver mitochondria
inhibited growth of seeds
inhibited growth of root tip per meristem
inhibited growth of plants tissue per cell
decreased gain in plant tissue weight
increased chromosome aberration in animal cells
increased chromosome aberration in plant cells
chromatid aberrations in animals
chromatid aberrations in plants
increased meiotic chromosome aberration
increased aberrant anaphase in plant cells
cytotoxic effect in animal cells
antimitotic effects (retardation or inhibition of mitosis) in animal cells
aberrant mitosis in animal cells
impaired respiration and oxidative phosphorylation
inhibition of the labelling of protein and DNA by radioactive precursors
inhibited growth of normal animals cells per tissue
inhibited growth of malignant tissue
inhibited growth of microorganisms
inhibited growth of pollen
reduced rate of respiration

Sucrose (Cont'd.)

increased mutations in plant tissue
increased mutation in Drosophila
increased dominant lethality in Drosophila
increased sex linked lethal mutation in Drosophila
increased autosomal recessive lethal mutation in Drosophila
increased aberrant forms of phenotypic alteration in Drosophila
mutagen by in vitro microbial test

Sugar

chromosome aberrations
cytotoxic effect
mutagen by in vitro microbial test

Sweet Cherry Juice

antibacteric (bactericide, bacteriostatic) effect

Thiamin in medium

cytotoxic effects in plant

Tomato

permeability changes in tissue hematomembrane of different organs

Tunafish (Thunnus thynnus)

conceptual difficulties
reduced number of pups per litter
increased mortality of progeny

Turkey

reduced growth
reduced weight gain

Vitamin Solution

increased mortality

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Wheat

reduced protein value
loss of body weight
increased liver weight
changed female liver weight
increased testicle weight
increased spleen weight
affected spleen weight
decreased spleen weight
changed male spleen weight
reduced reproduction of insect
reduced spermium number
reduced primary spermatocyte
affected spermatogonia
reduced spermatogonial A & B cells
reduced fertility
longer reproductive cycle
reduced germ cell count in testis
reduced RBC
decreased reticulocyte number
reduced number of neutrophilic leucocytes
changed serum albunim level
raised blood glucose
changed serum Ca level
formation of toxic substances, radio-toxins
lower serum inorganic phosphatase level
lower survival
increased mortality of progeny
pathological alteration in female liver
incidence of oedema in liver of females
periacinar infiltration in liver
tendency of steatosis
more frequent epithelioma
more frequent tumour incidence
more frequent incidence of lymphosarcoma
increased embryonal death
increased chromosome aberration in animal cells
more frequent incidence of polyploida at weaning
increased number of polyploidia in animal cells
increased meiotic chromosome aberration
increased number of aneuploid cells in tests

Wheat (Cont'd.)

aneuploidia
aberrations in chromatids and centromer
cytotoxic in animal cells
reduced germ cell survival
reduced viability of insect
mutagen by DLT
increased mutagenic index
increased chlorophyll mutants rate

Wheat Extract

increased incidence of chromosome abberation
inhibition of seed germination
mutagen effect

Wheat Flour (biscuit)

reduction of weight
reduced weight gain
increased weight of spleen
reduced prepubertal growth
fertility disorder
reduced litter number at weaning
reduced number of pups reared
reduction of life span
more frequent cannibalism
more frequent tumour incidence
more frequent mummary adenoma
increased number of non viable progeny
increased mortality of progeny
increased stillbirths
increased meiotic chromosome abberation in animal cells
increased cytogenetic abnormalities

Wheat Middling

reduced growth rate
reduced number of eggs laid
reduced hatchability of eggs

Wheat Product

increased number of polyploid animal cel

Xylose in medium

decreased gain in plant tissue weight

Yeast (dried)

inhibited growth of microorganisms

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"Storage time following irradiation can also alter the results of animal feeding studies or cytotoxicity, mutagenicity tests in such a way that changes disappear during storage or decrease gradually with it. In some cases detrimental results of feeding studies may be attributed to poor quality or improper preparation of food prior to irradiation or to inadequate storage conditions after irradiation. Adverse effects could be considerably reduced when irradiation was carried out in a nitrogen atmosphere or under buffered conditions at neutral pH."

"Often vitamin deficiencies were involved in the disorders, since supplementation of vitamins reduced or eliminated the adverse symptoms (growth retardation, fertility disturbances, increased mortality, etc.) of deficiencies. It is worth noting that supplementation of vitamin E did not necessarily reduce or eliminate the disorders in reproduction. Supplementation of other components of diets have also been observed to correct adverse effects in the parameters investigated. Thus addition of antioxidants reduced mortality and increased growth rate. Adverse effects in feeding studies have been eliminated by correcting amino acid imbalance."

"Among the biotechnical factors, adverse effects ascribed to ingestion of irradiated food may be derived from the test organisms used. Thus pathological effects observed during feeding test with irradiated food occurred spontaneously in animals fed on similar but non irradiated diet."

"The author is deeply indebted to the staff of the Biology Department of the Central Food Research Institute, Budapest, for their valuable technical assistance; he wishes also to thank Prof. K. Vas for his interest and help in this work."

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A Short History of Trouble

Irradiation Hall Of Shame

The industrial irradiation industry is relatively new. Created in the mid 1970's to sterilize medical supplies and packaging materials, this young industry has had a troublesome safety record. Problems have included radioactive leaks, spills, worker overexposures, failed or bypassed safety systems and failure to report to the Nuclear Regulatory Commission. The state of New Jersey hosts many of these problem plants. What follows is a summary of the 13 most significant incidents which have occurred in the last 12 years.

JUNE 16, 1974 Chief of radiation operations at the Isomedix irradiation plant in Parsippany, N.J. received an estimated 400 rem radiation dose, when he failed to take proper safety precautions. William McKim barely survived the one or two second overexposure to 147,000 curries of cobalt-60. Mr. McKim was in critical condition for one month before recovering.

1976-1980 In 1976 a double encapsulated cobalt-60 source was found leaking at the Isomedix irradiation plant in Parsippany, N.J. Following ion-exchange filtration, the source pool water was dumped down the plant's toilet. An extensive cleanup program followed which involved jackhammering concrete from the walls and floor of the source pool. During cleanup operation, Chem-Nuclear Corp. found the toilet and toilet pipe to be radioactive. Eventually, the toilet, tools, and parts of the source pool were shipped to a radioactive burial ground.

MARCH 14, 1977 The Nuclear Regulatory Commission fines Radiation Technology Inc. (RTI) $4050.00 following an October 1976 inspection which identified 10 violations of RTI's license. Violations incuded, failure to report a leaking cobalt-60 source, failure to adequately evaluate radiation doses to workers, disposing of radioactive material as normal trash and failure to provide required training to employees.

SEPTEMBER 23, 1977 An employee at the Radiation Technology Inc. (RTI) plant in Rockaway, N.J. entered the radiation cell for 10-20 seconds and received a whole body dose between 150-300 rems. The direct cause of the overexposure was a decision by RTI management to operate the facility with the safety interlock system inoperative.

SEPTEMBER 2, 1982 A service technician at the irradiation plant at the Institute for Energy Technolo Norway, was exposed briefly to the 650,000 curie cobalt-60 source. The plant worker received an estimated dose of 1,000 rems, and died on September 15, 1982 from radiation injury.

JUNE 11, 1986 Radiation Technology Inc., cited in 1986 as a source of ground water pollution, was ordered by the State of New Jersey to pay a $600,000 directive to study the problem. Volatile organics such as trichloroethylene, methylene chloride, and trichloroethane were found in test wells drilled on RTI's 15 acre site in Rockaway, N.J. The toxic products were stored in 100 bulging, rusty, leaky 55 gallon drums on the company's property.

JUNE 24, 1986 A federal grand jury indicts Eugene T. O'Sullivan, San Jose, Calif., and Bruce J. Thomas of Somerville, N.J., both employees of International Nutronics Inc. (INI) of Palo Alto, Calif. INI and the two employees are charged with conspiracy, mail fraud, wire fraud, and concealing a radiation spill from the Nuclear Regulatory Commission (NRC). In 1982, INI found a leaking cobalt-60 source in their source pool. A cleanup was begun which involved pumping the radioactive water through filters. During the filter operations, which were left running unattended overnight, a discharge line became detatched, spilling radioactive water onto the floor of the plant. INI employees were then instructed to dump the water down bathroom drains and into the public sewer system. INI then delayed an NRC inspection and attempted to hide radiation contamination from inspectors. (see detailed article in this issue)

JUNE 24, 1986 The Nuclear Regulatory Commission (NRC) revokes operating licenses for Radiation Technology Inc. (RTI) at their Rockaway, N.J. facilities. The license suspension comes after an NRC investigation into charges that RTI lied and deceived the NRC in regards to a March 3, 1986 shutdown. The March shutdown came after the NRC found RTI had bypassed safety equipment during plant operations, a repeated RTI failure, identical to the failure which lead to the worker overexposure in Sept. 1977. The NRC has turned this case over to the N.J. Justice Dept. for consideration.

SCIENCE BOX

COBALT-60 is a radioactive isotope of the metal cobalt. It is created by bombarding nonradioactive cobalt rods in a nuclear power reactor. Cobalt-60 gives off gamma rays and beta particles as it decays.

REMS are an arbitrary measure of radiation effects on living tissue. Like degrees or pounds, the number of rems increase as exposure to radiation increases. One chest X-ray, given to a 150 pound adult gives a dose of 5/100ths of one rem.

LIST OF THE 40 IRRADIATION FACILITIES IN THE U.S.

(not including those that can be found at hospitals of Universities)

This information was received by correspondence with the NRC (Nuclear Regulatory Commission)or the state licencer'swho is in charge of radioactive materials. Information on the specific irradiation companies was received by correspondence or through phone calls with the companies.

ALABAMA - None

ALASKA - None

ARIZONA - None

ARKANSAS - (1) PROCESSED TECHNOLOGY INC., P.O. BOX 256, West Memphis, AR, 72301. They irradiate: Food(on reaearch basis), medical products, cosmetics, and pharmaceutical products with Cobalt 60. P.T.I. is a subsidiary of Radiation Technology out of Rockaway, New Jersey.

CALIFORNIA - (3) INTERNATIONAL NUTRONICS INC., 1962 Barranca Rd.,Irvine, CA 92714 and INTERNATIONAL NUTRONICS INC., 1237 North San Antonio Rd., Palo Alto, CA 94303. They irradiate: Spices, Medical devices, medical products, electronic components, parts for nuclear reactors,gem stones, and cosmetics. Cobalt 60 is used.
RADIATION STERILIZERS,1401 Morgan Circle, Tustin, CA, 92680. They irradiate: Spices, medical devices, and "Bag in a Box"- a plastic bag that slips into a cardboard box that wine comes in. Cobalt 60 is used.

COLORADO - (2) COBE LABORATORIES, 1185 Oak Street, Lakewood, Colorado, 80215-4407 They irradiate: Medical devices and Gem stones. Cobalt 60
IOTECH INC., 11080 Irma Drive, Northglenn, CO, 80233. They irradiate: Medical products. Cesium 137 is used.

CONNETICUT - (1) BECTON DICKENSON, North Canaan, CT. Cobalt 60

DELAWARE - None

FLORIDA - (1) SHERWOOD MEDICAL, 2010 New Daytona Rd., Deland, Florida, 32720. They irradiate: Medical products. The Florida licensing office said they are aware of two other irradiation facilities both tentative as of Jan. 1987. One to be operated by a commercial firm out of Tampa and the other to be a joint facility by the D.O.E. and the Dept of Agriculture out of Gainsville. Construction by CH2M Hill. The commercial firm will irradiate strawberries and D.O.E. food.

GEORGIA - (1) RADIATION STERILIZERS INC., 2300 Mellon Court, Decatur, Georgia, 30035. They irradiate primarily medical supplies but also irradiate spices and "Bag in a Box." They use Cesium 137.

HAWAII - None

IDAHO -None

ILLINOIS - (3) ISOMEDIX INC.,7828 Nagle Ave., Morton Grove, ILL. 60053. They irradiate: Spices, disposable medical supplies, medical devices, nuclear device testing, cosmetic research and food research.

ILLINOIS - (cont.) ISOMEDIX INC., 1880 Industrial Dr., Liberty, Ill., 60048 They irradiate: Some spices, disposable medical supplies, medical devices, some nuclear device testing, cosmetic research and food research.
RADIATION STERILIZERS INC., 711 East Cooper Court, Schamberg, Ill. 60195. They irradiate: Spices, medical products, cosmetics, gem stones, and nuclear testing equipment.

INDIANA - (1) ELI LILLY AND COMPANY, Lilly Corporation Center, Indianapolis, Indiana, 46285. They irradiate: pharmaceutical products. (address: 307 East McCarty Street)

IOWA - None

KANSAS - None

KENTUCKY -None

LOUISIANA - None

MAINE -None

MARYLAND - (2) Both irradiators are NEUTRON PRODUCTS, 22301 Mount Ephraim Rd., Maryland, 20842. They irradiate: food stuffs (non-commercial), cosmetics, baby powder, hand lotion, cosmetics packing, gem stones, personal care products, nuclear reactors parts, polymers, and medical devices. One irradiator has one and a half million curies and the other 400 curies of Cobalt 60. Neutron Products is primarily involved in construction of Cobalt 60 rads.

MASSACHUSETTS - (1) ISOMEDIX, 435 Whitney Street, Northborough, MA., They irradiate: some spices, disposable medical supplies, medical devices, some nuclear device testing, cosmetic research and food research.

MICHIGAN - None

MINNESOTA - (1) 3M (Minnesota mining and Manufacturing Company), 220 -2E-02, 3M Center, St. Paul, MN, 55144-1000

MISSISSIPPI - (1) ISOMEDIX INC., Industrial Park South, Box 2044, Columbus, MS, 39704. They irradiate: Some spices, disposable medical supplies, medical devices, some nuclear device testing, cosmetic research, and food research.

MISSOURI - None

MONTANA _ None

NEBRASKA - (2) BECTON DICKINSON AND COMPANY, 150 South 1st, P.O. Box 686, Broken Bow, NE, 68822. They irradiate: Medical supplies only.
SHERWOOOD MEDICAL, P.O. BOX 1169, Norfolk, NE 68701. They irradiate: medical supplies.

NEVADA - None

NEW HAMPSHIRE - None

NEW JERSEY - (6) ISOMEDIX, 9 Apollo Drive, Whippany, NJ, 07981. They irradiate:

NEW JERSEY -(cont.) Isomedix- Some spices, disposable medical supplies, medical supplies, medical devices, some nuclear device testing, cosmetic research and food research.
ISOMEDIX,25 Eastmans Rd., Parsippany, NJ 07054, They irradiate: see above, Isomedix.
ETHICON, (Johnson and Johnson), Route 22, Sommerville, NJ, 08876 They irradiate: Medical Products
RADIATION TECHNOLOGY,108 Lake Denmark Rd., Rockaway, NJ 07866 They irradiate: Food(research and development), medical devices, cosmetics, Spices, electronic components, testing of nuclear devices, Gem stones, personal care products, and food packaging. They use Cobalt 60.
PRECISION MATERIALS CORPORATION, Replogle Ave., Mine Hill, NJ 07801.
PROCESSED TECHNOLOGY, Salem. NJ. (Subsidiary of Radiation Technology. They irradiate: Food on a research basis, medical products, cosmetics, and pharmaceutical products. Cobalt 60 is used.

NEW MEXICO - None

NEW YORK - None

NORTH CAROLINA -- (1) PROCESSED TECHNOLOGY INC., P.O. BOX 757, Haw river, NC, 27258. They irradiate: Food on a research basis, medical devices. cosmetics, and pharmaceutical products. (Subsidiary of Radiation Technology) Cobalt 60 is used with a 1.3 million curie source.

NORTH DAKOTA - None

OHIO - (2) ISOMEDIX, 4405 Marketing Place, Groaveport, Ohio, 43125, They irradiate: see Isomedix New Jersey.
RADIATION STERILIZERS, 305 Enterprise Drive, Westerville, Ohio, 43081. They irradiate: see Radiation Sterilizers, California. They use Cesium 137 for irradiation.

OKLAHOMA - None

OREGON - None

PENNSYLVANIA - (1) PERMAGRAIN PRODUCTS INC.,.115 Reactor Road, Karthaus, PA. 16845. They irradiate: Manufactured floor products.

RHODE ISLAND- None

SOUTH CAROLINA - (2) BECTON-DICKENSON AND COMPANY, Airport Rd., Sumter S.C., 29150. They irradiate: Medical Supplies.
ISOMEDIX, Highway 295, P.O. Box 3408, Spartanburg, SC, 29304 They irradiate: Some spices, d posable medical supplies, medical devices, some nuclear device testing, and food research.

SOUTH DAKOTA - (1) 3M, 601 22nd Ave., South, Brookings, SD 57006. They irradiate: Medical Products.

TENNESSEE -None

TEXAS - (6) RADIATION STERILIZERS INC., 3001 Wichita Ct., Ft Worth , TX, 76140. They irradiate : Spices, Food on a research basis, medical products, cosmetics, gem stones, and nuclear device testing.
SHERWOOD MEDICAL, 400 Maple Street. Commerce, TX. They irradiate:

TEXAS -(Cont.) Sherwood Medical: Medical Products.
AMERICAN PHARMASEAL COMPANY: one Butterfield Trail, El Paso, TX 79906. They irradiate: Medical Products. (Two unit facility.)
ETHICON INC., P.O. Box 511, San Angelo, TX 76902. They irradiate: Medical Products. (A Johnson and Johnson Company.)
SURGIKOS INC., P.O. Box 130, Arlington, TX 76010. They irradiate: Medical devices. (A Johnson and Johnson Company)
JOHNSON AND JOHNSON, U.S. Highway 75 South, Sherman TX 75090 They irradiate: Medical Products.

UTAH - (1) ISOMEDIX, 9120 South 150 East, Sandy ,Utah, 84070. They irradiate: disposable medical supplies, some spices, some nuclear devices, cosmetics research and food research.

VERMONT - NOne

VIRGINIA - (1) APPLIED RADIANT ENERGY CORPORATION, 2432 Lakeside Dr., Lynchburg, Virginia, 24501. They irradiate: Spices, Flour, Wheat, Medical devices, Pharmaceutical products, Electronic components, personal care products, douches (expermental to date) and marine samplers.

WASHINGTON- None, But two are in the conceptual phase. One will be a fixed location irradiator and the other a transportable unit for agricultural products.

WEST VIRGINIA -None

WISCONSIN - None

WYOMING - None

NEW YORK PUBLIC INTEREST RESEARCH GROUP, INC.
9 Murray Street • N.Y., N.Y. 10007 • (212) 349-6460
Offices in Albany, Binghamton, Buffalo, Cortland, Fredonia, Long Island, New Paltz, New York City, Syracuse, and Westchester.

NCSFI
NATIONAL COALITION TO STOP FOOD IRRADIATION
P.O. Box 59-0488, San Francisco, CA 94159 Phone: (415) 566-2734

NEWS RELEASE

FOR RELEASE:
December 17, 1987

FOR MORE INFORMATION CONTACT
Denis Mosgofian: (415) 566-2734
National Coalition to Stop Food Irradiation
John C. Savagian: (212) 349-6460
New York Public Interest Research Group, Inc.

ILLEGAL IRRADIATED INGREDIENT USED IN RICE-A-RONI & NOODLE-RONI MANUFACTURED BY SUBSIDIARY OF QUAKER OATS COMPANY OF CHICAGO

The New York Public Interest Research Group (NYPIRG) and the National Coalition to Stop Food Irradiation (NCSFI), today publicly announced that Quaker Oats Company, Chicago, Illinois, appears to be in direct violation of the Food and Drug Administration's April 18, 1986 Final Rule authorizing ionizing radiation treatment of certain approved foods. In a letter to NYPIRG, Quaker acknowledged that its subsidiary, Golden Grain Macaroni Company, has been using irradiated mushrooms in two of its products, CHICKEN & MUSHROOM RICE-A-RONI & CHICKEN AND MUSHROOM NOODLE-RONI.

Following receipt of the letter, a joint investigation by NYPIRG and NCSFI was conducted between October and December of this year. Their research revealed that Golden Grain was using mushrooms imported from Taiwan by Cade-Grayson Company, Vista, CA. Cade-Grayson says its irradiation is done in Taiwan and by Radiation Sterilizers Inc., Tustin, CA, and was formerly done by the defunct Precision Materials Corp., Mine Hill, New Jersey.

ATTACHMENT 17

Irradiated Mushrooms, cont....

In tracking down the use of the cobalt-60 irradiated mushrooms, NCSFI's Director, Denis Mosgofian learned in conversations with a source at Cade-Grayson that the mushrooms were currently being irradiated at an average absorbed dose of 1,000,000 rads, ten times the dose permitted for any food item (except spices, herbs and enzymes) sold in the United States. Imported food items, according to the FDA, must conform to FDA and USDA regulations for U.S. produced and processed foods. "Monitoring imports has always been our problem," said Dr. George Pauli of the FDA. Because the FDA has no test to determine if a food has been irradiated and at what dose, inspectors are helpless to stop illegal imports.

"This abuse of the irradiation approval illustrates our concern that the government was so eager to approve irradiation to accommodate the Department of Energy, that it simply ignored the consumer protection and inspection requirements for permitting nuclear food processing. It is because of this incident and a myriad of other health, environmental and worker exposure concerns that Congress must now demonstrate its concern for the American people and pass the Bosco/Mitchell bill, THE FOOD IRRADIATION SAFETY AND LABELING REQUIREMENT ACT OF 1987, HR 956 AND S 461. Congress must impose a moratorium on the use of irradiation. If Congress is waiting for a smoking gun, we have just found it!", said Mosgofian.

Further research revealed that the Food and Drug Administration has no capacity to either monitor or control food irradiation, and its regulation provides zero protection for consumers. FDA's regulation does not require user of irradiation to report to FDA either products being irradiated or the dose used. FDA's regulation fails to require irradiated ingredients be identified on labels, regardless of the item's importance or percentage of the final product. FDA has no test available to determine if a food has been irradiated, nor at what dose, or a test to determine if irradiation has been utilized to cover up contaminated or old food.

According to NYPIRG and NCSFI, Quaker Oats, in using irradiated mushrooms, violated the FDA April 1986 Final Rule. According to John C. Savagian, Coordinator of NYPIRG's Food Irradiation Project, the FDA ruling does not list the irradiation of dried vegetables as one of the food items allowed. "We find it disheartening that the minute we learn a company has begun to use irradiated foods, we also find immediate violations in their compliance with FDA guidelines," Savagian said.

NCSFI and NYPIRG have asked Quaker Oats Company as the parent company, to accept responsibility for the violations and recall the Golden Grain products. NCSFI and NYPIRG have

officially asked the Food and Drug Administration to request the same. The two organizations also have called on supermarkets nation-wide to withdraw the products from store shelves. NYPIRG and NCSFI have further asked FDA to investigate the promotion and sale of irradiated products by all dried vegetable distributors, and to request access to company records to determine if other illegally dried vegetables, fruits and possibly seafoods have been distributed to United States food processors. "These abuses may be the tip of the iceberg," said Mosgofian, "Our research verifies anti-food irradiation organizations' worst fears, that irradiation is nearly impossible to monitor and that consumers are without the slightest protection."

NYPIRG has alerted the Attorney General's Office of the State of Maine. Last May, Maine passed a law prohibiting the sale of irradiated foods. According to Savagian, the Attorney General's office has been in contact with Maine grocers, Quaker Oats and its subsidiary Golden Grain, and is now poised to get the affected Rice-A-Roni and Noodle-Roni off the shelves. Other state legislatures, such as New Jersey, are nearing completion of their own anti-irradiation bills. According to NCSFI's Mosgofian, citizens of Florida and Oregon are circulating petitions for ballot initiatives for November 1988 to ban food irradiation in their states, and the city and county of Santa Cruz, California, are preparing to enforce their local noticing ordinances which require grocers to post notices alerting consumers to irradiated foods.

"Having our national office in San Francisco, and being a proud native means that while Quaker continues to use irradiated ingredients in its Rice-A Roni products, we will never consider it a 'San Francisco Treat," said Mosgofian.

-30-

QUAKER

October 29, 1987

Mr. Phil J. West
New York Public Interest Research Group, Inc.
9 Murray Street
New York, New York 10007

Dear Mr. West:

We have received your letter regarding the use of the irradiation process in products manufactured by The Quaker Oats Company. Bev Kloehn has asked me to respond.

The Quaker Oats Company does not use this process in the manufacture of its products. However, as I'm sure you are aware, the Federal Food and Drug Administration has approved irradiation for certain food products to destroy potentially harmful organisms, as an alternative to chemical fumigants or pesticides.

We do make products which require us to purchase ingredients from outside suppliers. Recently, supplies of a variety of dried mushrooms needed in two Golden Grain products have been unavailable from sources who previously provided us with this ingredient. At this time, the only quantities available are from sources which utilize FDA approved irradiation technology in their processing. Dried mushrooms are a minor ingredient in Golden Grain Chicken & Mushroom Rice-A-Roni and Chicken & Mushroom Noodle Roni.

As to concerns with diminishing food qualities and costs, The Quaker Oats Company is committed to manufacturing and distributing wholesome products of the highest quality. All our products meet regulatory requirements and strive to meet consumer needs and expectations.

It has been brought to our attention that Stokely Van Camp was listed as a member of the Coalition for Food Irradiation. Stokely Van Camp has been owned by The Quaker Oats Company since 1983; during this time, neither has been a member of that organization.

I hope I have answered all your questions.

Sincerely,

Jan Guifarro
Supervisor
Consumer Response Group

JMG/0365J

WHY IRRADIATE DRIED MUSHROOMS?

The April 18th FDA ruling allows for the irradiation of fruits and vegetables for two reasons; to slow sprouting and to kill microbials or insects on or in the product.

According to Cade-Grayson, there are two methods for preserving mushrooms, freeze drying and air drying. Freeze drying cost around $18 a pound while air drying cost only $7 a pound. Air drying however, does not kill all the microbials that would cause problems if the mushrooms were allowed to sit around on the shelf (as is the case with processed foods like Rice-A-Roni). Irradiation is thus added to the air drying process at a cost of only an additional .30 per pound. We have recently learned that California Vegetable Concentrates also purchases mushrooms from Taiwan, but instead of using irradiation or ethylene-oxide, the mushrooms are sent to West Germany were they are heat treated, clearly an alternative to chemicals and radiation.

WHAT ARE THE REGULATORY PROBLEMS WITH QUAKER USING THESE PRODUCTS?

According to sources in the FDA, there are three problems with this process:

1. Dried vegetables are not approved by the FDA for irradiation (see enclosed copy of FDA final rule, Friday, April 18, 1986);

2. It is illegal to import a food which is not legal to produce and use in the United States;

3. The dose of a million rads is ten times the approved dose set by the FDA on April 18, 1986, which is 100,000 rads, or radiation absorbed dose.

BACKGROUND ON THE COMPANY, CADE-GRAYSON

The two large public interest organizations learned that the importer, Cade-Grayson Company of Vista, California, has branches in Santiago, Chile and Miaoli Hsien, Taiwan.

Despite the fact that the jury is still out on the safety of consuming irradiated food, the Cade-Grayson Company "sold" Golden Grain on using irradiated mushrooms by telling the Rice-A-Roni producer that they were Cade-Grayson's only customer buying air-dried mushrooms without using irradiation, and that Cade-Grayson might have to add an upcharge for continuing to supply nonirradiated mushrooms to Golden Grain, according to Tom Ackart, Golden Grain's Quality Assurance Director.

Golden Grain was also sent a letter pursuading the reader to infer that other companies, such as Campbells, Land O' Lakes, General Foods and McCormicks were using irradiated products from Cade-Grayson. NYPIRG and NCSFI attempts to learn what other irradiated ingredients were being used by these companies have not been successful. The Quality Assurance Director of General Foods, White Plains, New York, stated it was proprietary information, while Director of Consumer Response was uncertain and said she would let us know. Uncle Ben's referred researchers to their legal department. Campbells denies using any irradiated ingredients in their products.

HOW MUCH OF THIS HAS BEEN SUBSTANTIATED?

Presently, the only information that we have in writing is the original letter that Quaker Oats sent to NYPIRG that started our investigation. That letter (also enclosed) only admits to the use of irradiated mushrooms, it does not mention at what dose, who supplied them or where they came from. It is extremely difficult to get anything in writing, although we are still trying. Obviously, it will be more difficult once this information goes public.

WHAT DO THESE PROBLEMS MEAN FOR THE CURRENT FDA LABELING REQUIREMENT?

Opponents of the present FDA ruling on irradiation have always argued that it is difficult for the public to learn which products are being irradiated and at what dose. The FDA does not require these companies to inform them they are using this process, and it has been left up to organizations like NYPIRG and NCSFI to try and track down the information. NYPIRG and NCSFI have twice surveyed the organizations listed as members of the Coalition For Food Irradiation. Many companies denied or have since withdrawn their support from the Coalition, and until the Quaker letter, only McCormicks admitted using irradiation spices.

We applaud the Quaker Oats Company and its subsidiary Golden Grain for informing the public, but it is quite possible that other food companies have not been truthful in answering our questions regarding the use of irradiated foods. The FDA has made a bad situation worse when it passed a weak label law. Presently, foods which contain irradiated ingredients do not have to be labeled. All irradiated fruits and vegetables require the Radura symbol and the words "treated with radiation" or "treated by irradiation." This coming April, the FDA will decide whether to drop the wording altogether.

Unfortunately, once we have alerted the public to this fact, as we have done regarding Quaker's Rice-A-Roni product, it is unlikely that any other company will voluntarily come forward and tell the public that it is using irradiated ingredients. Thus we are faced with the possibility that companies will be less forthcoming about using irradiated products at the same time that the FDA will relax an already weak labeling law.

WHAT SHOULD BE DONE ABOUT THIS?

1. We demand the immediate withdrawal of these products from food stores;

2. The Quaker Oats Company should accept responsibility for the actions of its subsidiary and recall the Rice-A-Roni products;

3. The State of Maine law prohibiting irradiated foods must be enforced, as should any other state, county or city law which has restrictions on the sale of irradiated foods;

4. The Food and Drug Administration should immediately access the records of Cade-Grayson Golden Grain, and all distributors of dried vegetables to determine the actual dosage for these products and investigate the course of action which lead to the illegal irradiation and introduction of these products into the United States; the FDA should, if need be, call on Quaker to withdraw its products from the shelves.

Further information can be provided by
John C. Savagian: (212) 349-6460 and
Denis Mosgofian: (415) 566-2734.

Representative Randy Phillips
File on Food Irradiation
March 8, 1988

NOTE: *indicates a report attached to Karla Hart's 11/19/87 research
**indicates a report attached to Hart's 11/30/87 supplemental research

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March 8, 1988

William B. Walker
4428 Mountainside Drive
Juneau, Alaska 99801

Representative John Sund
House Judiciary Committee

Dear Chairman Sund:

Re: HB 388 - Response to testimony of Sid Heidersdorf before House HESS and AK Dept. of H&SS position paper.

Radioactive materials

Large sources in Alaska of gamma radiation were referred to - as large as thousands of curies. Food irradiators may be 3-10 million curies.

There have been, and will undoubtedly continue to be releases of radioactive materials from food irradiators. No technology is error free.

Labeling

It was stated that most of the spices sold in Alaska have been irradiated and could not be sold under the proposed law. This claim should be documented.

If it is true:

Where is the labeling?

How do we know irradiated spices are not adding to cancer rates or aggravating long term degenerative diseases?

According to the National Coalition to Stop Food Irradiation (NCSFI), under FDA's current regs, foods containing up to 90% irradiated ingredients do not have to be labeled. The effort seems to be to conceal rather than inform.

Food safety and FDA approval

NCSFI reports that by 1979, the FDA had failed to demonstrate safety through animal feeding studies. One of their prime contractors had been convicted in federal court for falsifying data in similar work. FDA took a new approach.

The agency created a theoretical estimate of numbers of new and largely unknown chemicals formed in irradiated foods, and from that estimates of amounts people would be likley to consume. Assumptions would then be needed about safe amounts of exposure. A highly theoretical approach - hardly proof. In its 1986 approval of irradiation for fruits and vegetables was the following statement: "FDA concludes that available animal test data are not necessary for determining...safety...[FDA] believes that the number of adequate chronic feeding studies on irradiated foods is irrelevant to its safety conclusion." (from Progressive magazine)

All but 5 of 441 studies they reviewed were claimed to be flawed. But of these 5 used to support irradiation, 2 were reviewed extensively by the Division of Biostatistics and Epidemiology, New Jersey Medical School and found to show differences between test and control groups, some significant, thus raising concerns rather than documenting safety.

Is it possible to prove with 5 studies, or 3, the safety of the wide range of foods approved for irradiation? Has the FDA even addressed the effects that may occur to people who are malnourished or ill? Has the burden of proof simply shifted to the consumer?

Enforcement

Recently Quaker Oats marketed Rice-a-Roni containing dried mushrooms irradiated in Taiwan. The mushrooms were irradiated at 10x the legal limit. They were illegally imported. Dried vegetables are not approved for irradiation by the FDA. The supplier had claimed to be selling the same mushrooms to other corporations--who won't say. At last word, the FDA has not yet recalled the products, or examined the records of the supplier. It is uncertain whether they will. No labeling is required for this product.

We have a right to a food supply which is proven to be safe, not just theorized to be so. We have a right to know what we eat. Currently we are being allowed neither.

I urge passage of HB 388.

Sincerely,

William B Walker

William B. Walker

Jan. 30, 1988

Representative John Sund
House of Representatives
P O Box V
Juneau, AK 99811
Mail Stop: 3100

Dear Representative Sund,

I am writing to you to express my concern about food irradiation. I urge you to co-sponsor House Bill 388 prohibiting the sale of irradiated food in Alaska. The University of Alaska-Fairbanks is presently conducting a feasibility study to determine the suitability of Alaska as a site for a food irradiation demonstration facility. I believe the process of irradiating food should also be prohibited because to operate a facility nuclear waste, specifically cesium-137, will be brought into Alaska and stored in cooling ponds. Cesium-137 is highly water-soluable, any error either human or mechanical will cause irreversible contamination to the cooling ponds and any ground-water accessible to the facility. We have many ground-water contamination problems now without adding a new one. The University's proposal states that the facility will be regulated by federal guidelines. I don't find that very reassuring. The nuclear industry has a dismal safety record. Why should I expect this to be different.

Food Irradiation is controversial at best. The Dept of Energy under its Byproducts Utilization Program is attempting to find "socially beneficial" uses for the large stockpile of nuclear waste it has on its hands. Consequently, it is promoting food irradiation. In this process food is treated with a radiation shower created by the gamma rays of decaying nuclear waste. The FDA has approved this process for fruits, vegetables, and pork at doses up to 100,000 rads, and spices up to 3 million rads. Approval is pending for chicken and fish. The FDA looked at 441 studies and rejected all but 5 due to improper procedures. The 5 studies were the basis for their approval. The University's proposal states that recent studies show no harmful or toxic effects caused by irradiation. This is simply untrue. There are many studies that show adverse effects, as well as studies addressing the harmful effects irradiation has on nutrition. Also there has been no evaluation of the effects of long-term consumption.

The proposal also equates irradiation to canning and freezing. It isn't the same, at least with canning and freezing I know what I am buying. Processed foods containing irradiated ingredients are not required to have disclosure labels. (The FDA said that labels would confuse the consumer) Whole food has to be labeled with only a symbol meaning irradiation after April 1988. Irradiated food and unirradiated food look identical. There is no way to tell and no test to determine if a food has been irradiated or how much irradiation has been used. Also irradiation makes it very easy for sub-standard food to be passed off as fresh.

The University's proposal earmarks fish as a likely choice for food irradiation in Alaska. I would like to point out that Japan has withdrawn all support for food irradiation and will not allow import of irradiated foods in their country. Between Jan. and Sept. we exported 331 million dollars worth of fresh and fresh frozen sockeye salmon to Japan. We will lose Japan as a market if we use this process. I don't believe that a program that will impact our lives in such dramatic ways should be approved so quickly. Please consider co-sponsoring House Bill 388. Maine has banned it, Oregon and New Jersey are considering it. I believe that the health risks are too important to accept this program at this time.

Sincerely,

Rebecca Janik

Rebecca Janik
President-Alaska Coalition to Stop Food Irradiation
1650 Thuja Ave
Anchorage, AK 99507

enclosure

February 8, 1988

Honorable John Sund
Judiciary Committee
P.O. Box V (MS 3100)
Juneau, Alaska 99811

FEB 1988

Dear Mr. Sund,

The Department of Energy provided a grant to the University of Alaska in Fairbanks to conduct a feasibility study on building a demonstration food irradiation facility in Alaska.

Irradiation creates toxic substances, radiolytic products (RPs), which:

- sterilize fruit flies and spoilage microorganisms such as trichina, salmonella and bacteria.
- kill enzymes that produce sprouts in potatoes and onions.
- disable microbes and bacteria necessary for the body's immune system.
- deplete essential vitamins, nutrients and amino acids.
- and as studies indicate cause cancer and genetic mutations.

The Food and Drug Administration (FDA) refutes claim of any ill-effects using theortical calculations backed by 5 studies out of 441 it reviewed. Many of the 436 studies that the FDA dismissed show maladies to animals and humans. (See enclosed articles)

John Gofman, M.D., Ph.D., and professor emeritus of medical physics at U. C. Berkeley who "from a lifetime of research in both heart disease and cancer" claims, "I know what sort of studies are required to ascertain the delayed affects and the cumulative affect on humans of biological agents.... The kind of epidemiologic study required to find out whether or not a diet of irradiated food will increase (or decrease) the frequency of cancer or genetic injuries among humans simply has not been done."

The cornerstone of FDA approval of irradiation is the final report of the FDA Bureau of Foods Irradiated Foods Committee (BFIFC) released in July 1980. The report states, "Calculations based on radiation chemistry clearly indicate that irradiation doses of 100 krad (maximum approved dosage) or less yield a concentration of total radiolytic products in food that is so limited that it would be difficult to detect and subsequently

measure potential toxicological properties. In addition, at this dose unique radiolytic products (URPs) (chemicals found only in irradiated food, toxicity unknown) will be on the order of 3 ppm (parts per million).... Hence because of the low level of total unique radiolytic products produced, it is concluded that food irradiated at doses not exceeding 100 krad is wholesome and safe for human consumption."

Dr. Gofman responds, "Our ignorance about these foreign compounds (RPs & URPs) makes it simply a fraud to tell the public that 'we know' irradiated foods would be safe to eat."

George Tritsch, Ph.D, cancer research scientist at Roswell Park Memoral Institute in Buffalo, New York responds, "I am opposed to consuming irradiated food because of the abundant and convincing evidence in the referred scientific literature, that the condensation of free radicals formed during irradiation (RPs & URPs) produce statistically significant increases in carcinogenesis, mutagenesis and cardiovascular disease in animals and man."

In recognition of the conflicting evidence of food irradiation safety, please support House Bill 388 which bans the sale of irradiated food in Alaska. In addition please ban food irradiation facilities and/or resolve that the U of A Fairbanks end the feasibility study until the Federal government initiates and concludes an inquiry into the wholesomeness and safety of irradiated food. (The Food Irradiation Safety and Labeling Requirement Act of 1987 [HR 956 & S 461] if enacted mandates an inquiry).

We would appreciate a response.

Sincerely,

William Thomas

Sylvia Thomas

William, Sylvia & Denny Thomas
9040 Emerald
Anchorage, Alaska 99502

Enclosures:
-Food Irradiation Safety and Labeling Requirement Act of 1987 (Summary)
-"Zap, Crackle, Pop" & "No Fried Food in New Jersey", Magazine Articles
-Food Irradiation Fact Sheet
-Food Irradiation Article, Anchorage Daily News
-Letter to Anchorage Daily News

FOOD IRRADIATION SAFETY AND LABELING REQUIREMENT ACT OF 1987 (SUMMARY)

The Food Irradiation Safety and Labeling Requirement Act of 1987 will:

1) Place a moratorium on the recent FDA and USDA approval of the irradiation of fresh fruits and vegetables, pork, and tripling of the amount of radiation allowed on dried herbs and spices.

2) Direct the Secretary of Health and Human Services (HHS) to review existing studies on the safety and wholesomeness of irradiated food and to conduct new studies to determine:
   a. The safety of long term consumption and nutritional value of irradiated food.
   b. Contamination of foods from improper irradiation.
   c. Environmental impact on communities with irradiation facilities.
   d. Health risks to workers in radiation facilities.
   e. Safety in the transporting of radioactive materials.
   f. Emergency medical and evacuation plans for radiation accidents and liability.

3) Direct the FDA to require labeling on a wholesale, retail, and restaurant level of all irradiated foods, both whole foods and food ingrediants, the labeling to include the words "treated with ionizing radiation".

4) Amend the Food, Drug and Cosmetic Act to require FDA to keep records on irradiated food production patterns, dispersement, and dosage. This provision does not require brand name disclosure.

5) Impose an export moratorium on irradiated foods not legal for irradiation and human consumption in the U.S.

Zap,

Irradiated foods aren't coming; they're here

BY GARY GIBBS

The vault has concrete walls twelve to twenty feet thick. A door in the vault opens, and food enters on a conveyor belt. The door closes behind it. A shutter opens, and rods of radioactive cobalt 60, the waste products from nuclear reactors, or rods of cesium 137, the waste products of atomic-bomb construction, rise out of a bed of water. The food is exposed to a radioactive dose of 100,000 rads.

The rods go back down into the water, and the shutter closes. The door opens, the food leaves. Now it is ready for you to eat.

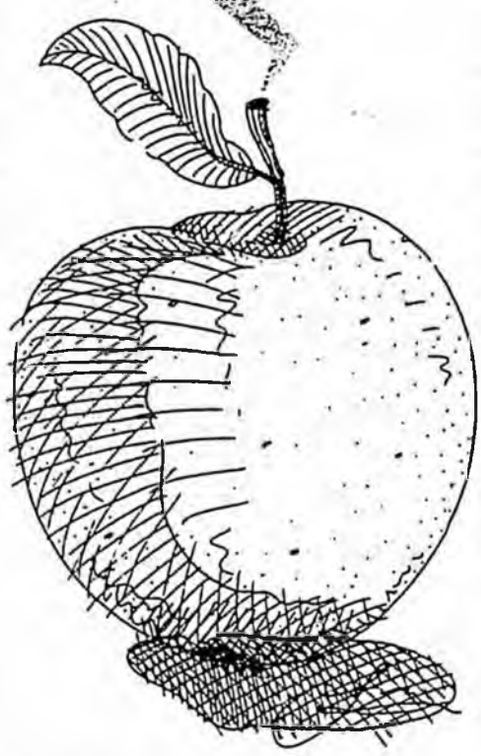
This is not the beginning of a science-fiction horror story. It is, in fact, a description of a method of food-processing designed to extend the shelf-life of commodities and kill insects infesting them. It has been used since 1963 on wheat but is a much more recent addition to other food items. Irradiation of herbs and spices was approved by the Food and Drug Administration (FDA) in 1983. Pork was added to the approved list in 1985. And the FDA gave irradiation the nod for fruits and vegetables in April 1986.

The U.S. Department of Health and Human Services (HHS) has predicted that 10 per cent, and possibly as much as 40 per cent, of our diet will be exposed to such radiation in the near future. Food irradiation is already a growth industry; if the HHS forecast proves true, it will soon be a multibillion-dollar one.

How much radiation are we talking about here? The FDA calls it "low-dose radiation." According to a basic physics textbook, 10,000 rads will destroy living tissue. One hundred thousand rads—the dosage the FDA allows for processing of fruits, vegetables, and pork—is 2.5 million times the exposure one gets in a typical chest x-ray. The FDA permits exposure of other foods to higher dosages, with the upper limit being three million rads.

The food does not become radioactive, but it does appear to become radiomimetic—that is, it produces effects similar to direct exposure to ionizing radiation.

Can this possibly be safe? The industry says yes and even claims it is a boon to humanity, a way to save the food lost to spoilage, estimated at perhaps one-fourth of the world's supply. The FDA says there are "no adverse effects." Health and Human Services Secretary Otis Bowen calls irradiation "a new technology that can produce benefits to consumers." His predecessor, Margaret Heckler, said, "Thirty years of research have proven this process to be safe."



But many scientists and consumer advocates disagree.

"Food irradiation is an extraordinarily dangerous experiment in public health," says Samuel S. Epstein, professor of environmental medicine at the University of Illinois Medical Center in Chicago. "I would strongly counsel any consumer under no circumstances to eat irradiated food." Eating such food, he says, "is like inviting someone to play Russian roulette and not telling him there's one bullet in the revolver."

The Food and Drug Administration itself raised disturbing questions in its *Final Report of the Recommendations for Evaluating the Safety of Foods*, issued prior to its authorization of food irradiation. In reviewing the scientific literature, the *Report* says that "chronic feeding studies in the recent past which have substituted up to 35 per cent of the normal [lab animal] diet with specific irradiated foods, e.g. beef, chicken, potatoes, onion, and papaya . . . had to be terminated before completion because of premature mortality and/or morbidity." In other words, the animals got sick or died.

The *Report* explains that it is difficult to feed human foods to animals since "the portion of the diet substituted, 35 per cent, did not provide the full complement of nutrients required." But if an unbalanced diet was the problem, why did the animals in the control groups live and remain healthy, while the animals eating identical diets of irradiated food died or became seriously diseased?

A more likely explanation than the unbalanced-diet theory, says nutritionist Jeff Reinhart of the Marin Clinic of Preventive Medicine and Health Education in San Rafael, California, is that irradiated food contains toxic byproducts caused by the radiation process and that crucial nutrients are depleted or destroyed.

One of the studies reviewed by the FDA involved human beings—fifteen Indian children. A research project by India's National Institute of Nutrition examined the effects of feeding irradiated wheat to the children. It found that 80 per cent of the children who ate irradiated wheat developed polyploid white blood cells in one month. Polyploidy is excessive genetic material which is associated with leukemia, senility, and direct exposure to radiation. In fact, the immune system, of which white blood cells are an integral part, is well known to be the most radiation-sensitive system of the body. The children who ate freshly irradiated wheat showed more polyploid cells than those who ate stored irradiated wheat. The control group, which ate an identical non-irradiated diet, showed no polyploid cells. The radiation dose was 75,000 rads, which is less than the 100,000-rad dose currently legal for wheat in the United States.

The researchers' conclusion: "Though the biological significance of polyploidy is not clear, its association with malignancy

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Gary Gibbs, a student of osteopathic medicine at the University of New England, is the founder of Medical Students Against Food Irradiation.

Crackle,

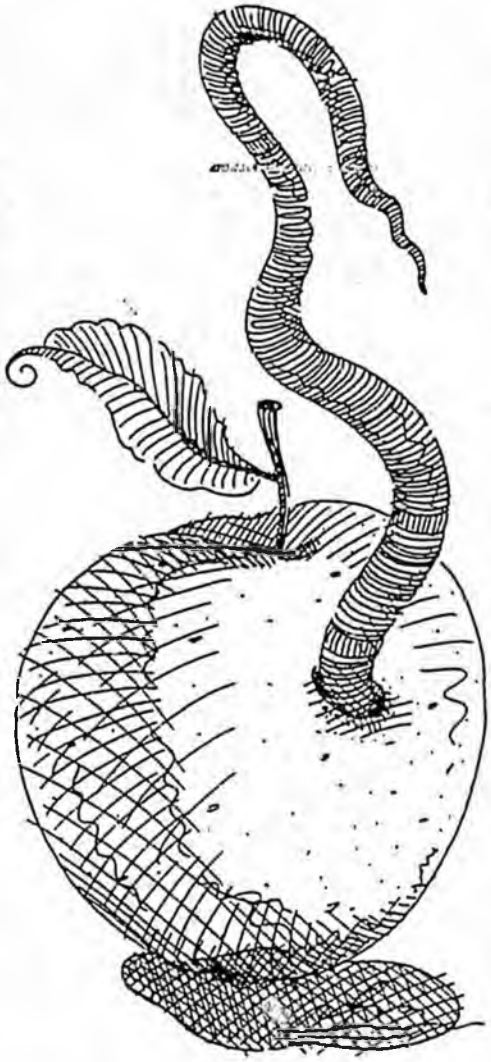
makes it imperative that the wholesomeness of irradiated food be very carefully assessed."

Because this study involved humans rather than animals, it has been in the forefront of the safety debates. Quick to condemn it is Martin Welt, former president of Radiation Technology, a major food-irradiation company. He says he has heard that "the Indian authorities at the Institute where the work was conducted have essentially refuted the concerns raised in the published study."

The FDA also criticized the study, referring to a report of the United Nations World Health Organization, which suggests the study is irrelevant because of the small number of children involved.

But the Indian scientists stand firm. Dr. B.S. Narasinga Rao, director of the National Institute of Nutrition in Hyderabad, adamantly rejects the criticisms. These "unjustified allegations," says Dr. Narasinga Rao, "almost amount to libel" of the Institute, "which is known world over for its important contributions in the field of nutrition."

As for the study, Dr. Narasinga Rao explained, "We did not anticipate any adverse effects of feeding irradiated wheat to these children. However, as soon as some abnormality was observed in these malnourished children, we terminated the study for ethical reasons. . . . We could not repeat such studies just for the sake of scientific curiosity since we knew that some abnormality would result."



So how did the FDA come to approve of food irradiation for American consumers? Its task force checked into 441 studies and accepted 266 for further review. Finally, however, it declared all but five studies to be "deficient." Considering the HHS prediction that up to 40 per cent of our food will be irradiated under the new guidelines, the FDA certainly seems to have made a hasty decision—basing it on only five studies, all of which supported the safety of the process, and ignoring the research in which laboratory animals died when 35 per cent of their diet was irradiated.

Some of the studies the FDA ignored are startling.

The effect of feeding irradiated food to fruit flies was tested by scientists who published their results in 1963 in *Science*, perhaps the most widely read scholarly scientific journal in the United States. The flies were fed food exposed to 150,000 rads; 12.6 per cent of their offspring had visible mutations. Some had only one wing, some had no wings. Others had curly wings, cut wings, bloated bodies, yellow bodies, rotated abdomens, and so forth. In the control group, less than 1 per cent exhibited such mutations.

"In view of the wide implications of the data," concluded the authors, "there is a need for more extensive and critical evaluation of the extent and pathways of indirect radiation effects."

The effects of feeding irradiated food to mice were studied at the University of Illinois College of Medicine and published in 1960. The mice ate a mixed diet of pork, chicken, milk, potatoes, and carrots. In one of two strains of mice studied, more than 17 per cent on the irradiated diet died or were killed because of rupture and/or expansion of the heart. No heart lesions were observed in the control group. When mice were fed a vitamin-supplemented diet of irradiated cooked milk, 83 per cent died or were killed because of heart lesions occurring within eighty-five days.

Twelve sets of experiments involving irradiated chicken meat were reviewed by the U.S. Department of Agriculture. Its 1984 report warned that mice that had eaten the meat in one study showed an increase in testicular tumors, cancer, and kidney disease.

But still the FDA chose to rely on its chosen five studies to prove safety. Its 1986 ruling approving the irradiation of fruits and vegetables included some remarks on the subject: "FDA concludes that available animal test data are not necessary for determining the safety of [these] uses of radiation. . . . [The FDA] believes that the number of adequate chronic feeding studies on irradiated foods is irrelevant to its safety conclusion."

Safety is not the only concern consumers need have. Irradiation has an adverse effect on the nutritional quality of food, in direct proportion to the amount of radiation involved. Vitamins A, C, E, and B are significantly depleted. At doses of 100,000 rads, for example, the vitamin content of apples is reduced to one-third its normal value. Essential amino acids, nucleic acids, and enzymes are also significantly depleted by irradiation, and unsaturated fatty acids are converted to toxic lipids.

What's worse, consumers may have no way of knowing whether they are buying irradiated food. Bowing to food-industry fears that consumers will reject irradiated foods, the FDA has ruled that they may remain unlabeled.

Irradiated canned peaches do not have to be labeled, nor do irradiated tomatoes in tomato soup or irradiated frozen peas—all examples cited by FDA spokeswoman Betty Campbell. She says, in fact, that she "cannot think of a case where a processed food would have to be labeled. The FDA does not consider irradiated processed food a *material fact*, as radiation does not change the food any more than any other types of processing." Asked to comment on the studies indicating possible dangers, Campbell says she has not read them.

Pop.

Labels are required only for unprocessed, whole foods, such as fresh fruits and vegetables. The irradiation label is accompanied by a symbol that looks like a flower. And after two years, the FDA plans to rule on whether the flower alone will be a sufficient label.

Some of these concerns are addressed by a bill pending in Congress. Sponsored by Representative Douglas Bosco, a California Democrat, it would require not only the labeling of irradiated food but also additional studies of the health and environmental impacts of treating food with radiation. The Senate sponsor of the measure is Democrat George Mitchell of Maine.

Studies do exist, of course, that indicate irradiated food may be safe. But one must ask who has done them and who has paid for them.

Many of the studies supporting safety were done by the Industrial Bio-Test Laboratories, Inc. (IBT). In 1983, IBT officials were found guilty of defrauding the Government in drug research; the charges included faulty record-keeping and suppression of unfavorable findings. Earlier, in 1977, the Army declared two out of three IBT animal-feeding studies in default. At the time, IBT had contracts totaling more than $8 million for animal feeding studies on beef, ham, and pork.

The Pentagon and the Department of Energy refuse to release their research on the effects of eating irradiated food, saying the results are classified in the interest of national security.

Who is pushing to expand food irradiation? One of the biggest promoters is the Department of Energy, the makers of nuclear weaponry and reactors.

"The DOE wants to play the fairy tale of Rumpelstiltskin with a new twist," says Kitty Tucker of the Health and Energy Institute in Washington, D.C. "Rumpelstiltskin turned straw into gold; the DOE wants to turn nuclear wastes into a saleable product by using them for food irradiation."

Another player is the Coalition for Food Irradiation, which consists of several major food processors. In Congressional testimony before the House Committee on Agriculture, the Coalition claimed in November 1985 that "the benefits of the process to the American public are many. Consumers will be able to buy products that stay fresher longer."

A third star member of the radiation team is the private radiation industry.

PATRICK JB FLYNN

"Food irradiation is just an adjunct to the use of radioactive materials," says Bruce Meyer of Radiation Sterilizers in Menlo Park, California. "Just like in medical radiation for cancer, you are selectively killing the micro-organisms that cause spoilage and insects."

That's not quite the way it works, though. Radiation doesn't just selectively kill; it goes entirely through the food, altering its molecular chemistry. When radiation hits the food, electrons are excited and begin a chain reaction resulting in destruction of DNA and thus a slowing down of the ripening process. Chemical bonds are broken and new chemicals are formed called "radiolytic products." These include the production of formaldehyde and benzene, known cancer-causing agents. In addition, new chemical products, called "unique radiolytic products," are formed, the effects of which are still unknown. Feeding studies are our best source of information, and, as we have seen, they are not reassuring.

Communities which will be, or are, the sites of radiation plants have reason to be concerned about the transportation of radioactive materials. By the mid-1990s, predicts Henry Mussman of the National Food Processors Association, 1,000 plants will be built. And the Nuclear Regulatory Commission allows plants a radiation-escape rate twenty times greater than it allows nuclear-power plants.

There are now, in the United States, more than forty industrial gamma irradiators with the potential ability to process food. Isomedix in Parsippany, New Jersey; International Nutronics, in Palo Alto, California, and Radiation Technology in Rockaway, New Jersey, are among those currently in the food-irradiation business, and many others are in the planning stages.

The hazards of having one in the neighborhood have already been documented. Radiation Technology has been cited by the NRC for dumping radioactive garbage with its regular trash, and state officials have charged the company with contaminating local water supplies with toxic chemicals.

International Nutronics had a plant in Dover, New Jersey. It was shut down by the NRC after water contaminated with radioactive materials was spilled on the floor, then flowed through a hairline crack between the wall and floor and down into the foundation.

Not just food is irradiated. Such items as blood agar and plasma, blankets and towels, bottles, cosmetics, needles, infant wear, peat moss, sanitary napkins and tampons, lubricating jelly, scalpel blades, and water also receive the treatment. The safety of irradiating these consumer goods is an open question.

Because we eat food, though, the safety of its irradiation is of primary concern. If the processing industry is as certain as it claims to be, why keep it so quiet? Why be afraid of labeling the food it treats? And if the FDA is as certain as *it* claims to be, why allow the secrecy?

The shroud covering the process has left most Americans in the dark, and that is the environment the food-irradiation industry requires for growth. ■

No Fried Food in New Jersey

When people get wind of plans to build a food-irradiation plant in their neighborhood, they won't stand for it. At least they didn't in Elizabeth, New Jersey.

In September 1985, Radiation Technology, Inc., (RTI) signed a twenty-one-year lease on a portion of a landfill sandwiched between Newark Airport and the Elizabeth seaport, a hub of East Coast shipping. The landlord was the Port Authority of New York and New Jersey, which had taken over the landfill—permeated with PCB-contaminated oil—from Elizabeth with a promise to turn it into an industrial park. The Port Authority was eager to find a tenant, and RTI was apparently less concerned than other prospects about the contamination. To sweeten the deal, the bi-state agency offered to advance the company $3.5 million for construction of the plant.

About six weeks after the signing of the lease, the Board of Freeholders of Union County, which includes Elizabeth, approved an ordinance declaring the county a nuclear-free zone. The nine-member board was unaware of RTI's plans when it agreed to ban the production, storage, use, and transportation of radioactive materials in the county (except for those used in hospitals and laboratories).

When some residents learned of the proposed plant, they were alarmed and urged the freeholders to block it with their infant ordinance. Amid a flurry of publicity, battle lines were quickly drawn. The Port Authority, Elizabeth Mayor Thomas Dunn, and the county counsel warned the freeholders not to intervene. Anti-irradiation activists, meanwhile, organized public forums; those who came voiced loud opposition to the RTI facility. They also provided the freeholders with information about RTI's record of environmental and safety violations at its plant in Rockaway, New Jersey.

In February 1986, after strenuous debate, the freeholders decided to enforce their nuclear-free-zone law against RTI.

A meeting held in Linden, New Jersey, had turned the tide. Organized by the town's chapter of the League of Women Voters with the help of Union County SANE, a peace group, the forum drew more than a hundred people, including elected officials. Three speakers on each side of the issue had their say, including Dr. Martin Welt, then the president of RTI.

The fou[illegible] of the company and a tireless, [illegible]tic supporter of food irradiat[illegible] did not hesitate to depict his critics as communists, dopers, or "cultists." At the Linden meeting, recalls organizer Georgene Granholm, his arrogance and contempt for the opinions of non-scientists helped turn the crowd against him.

"Welt was awful," she says. "He came off like a nut, like a mad scientist."

Granholm, mother of three children, was concerned about the health effects of eating irradiated food, which she believes have not been adequately studied. Like other local activists, though, she was even more worried about the danger of introducing a large quantity of radioactive material into the community.

"It's wrong," she says. "And I don't care who you are, if you're a citizen who lives around here, you're going to be bothered by it. People were annoyed by Dr. Welt coming into our territory and dictating to us that he was going to bring in nuclear wastes, simply because he had a deal with the Port Authority. I don't care if the PA had the authority or not, the deal was wrong from the start and should never have been considered for that spot, with such a dense population."

Shortly after Union County moved to stop the RTI plant, Welt sustained another rude jolt when safety violations at the company's Rockaway facility led the Nuclear Regulatory Commission to suspend RTI's license there. Although the license was soon restored, the episode heartened opponents of the Elizabeth plant and caused the Port Authority to think twice about its support for the project. In May 1986, the Authority told RTI not to proceed until it resolved its conflict with Union County. RTI responded by suing the county, challenging the constitutionality of the nuclear-free-zone statute.

While the suit was pending, the Nuclear Regulatory Commission suspended the company's Rockaway license, charging it with violating safety rules and lying to the Commission. The NRC said RTI had demonstrated "a pattern of wrongdoing so pervasive" that the agency couldn't guarantee the firm would follow NRC rules even with the supervision of outside auditors. Nevertheless, after RTI shuffled its top management and Welt resigned to become a consultant to the Department of Energy, the NRC restored the license.

Then RTI's opponents suffered a blow. In August 1986, Federal Judge John W. Bissell of Newark struck down the county's nuclear-free-zone law as an "unconstitutional burden on interstate commerce." He also ruled it was preempted by Federal regulations governing the use of radioactive materials. At that point, the Port Authority announced it would let RTI build the irradiation plant.

Though all seemed to be lost, popular pressure held fast. A bill to ban the sale of irradiated food was introduced in the New Jersey Legislature in October. That same month, the city councils of Newark and Elizabeth passed resolutions opposing the plant. And in February 1987, Mayor Dunn of Elizabeth reversed himself and demanded that the Port Authority stop the RTI project.

In June, the company officially shelved the project.

A combination of factors thwarted RTI. Financial problems definitely played a role: The New Jersey Department of Environmental Protection fined the company $600,000 for polluting the groundwater at its Rockaway site. RTI was fighting a product-liability suit. And, most important, it never received a cent of the $3.5 million promised by the Port Authority. Moreover, the New Jersey Senate's passage of the bill banning the sale of irradiated food—the Assembly is still considering it—dimmed the prospect of quick and easy profits from irradiation.

Alan Augustine, who chairs the Board of Freeholders, doesn't think the plant would have been dropped without public opposition. "We were a segment of a total attack that must have had some impact on RTI's turnaround," he says. By taking an early stand against the plant, he adds, the freeholders gave citizens' groups "the credibility of an elected body supporting their position."

The lesson of their struggle, area officials agree, is that local and state authorities should have more power to block commercial projects that threaten public health.

"In an area suc[illegible] as this," says Freeholder Brian Fahey, "I don't think it's adequate to have a policy that this type of industry is regulated by the Feds, and that the NRC can let it go anyplace it wants to go. Certainly the RTI plant had the potential of affecting the airport, the waterfront, Newark, Elizabeth, all the surrounding communities. It could have been a catastrophe for the whole region."

—Ken Terry

(Ken Terry is former chair of the Nuclear Free Zone Advisory Committee of Union County and an editor of Variety.)

Food Irradiation Facts

1. Food Irradiation in the U.S. is a technology designed to use radioactive WASTE PRODUCTS FROM WEAPONS MANUFACTURE to disinfest grains, produce, herbs, and spices, and control microorganisms in meat. It may use man-made Cobalt 60 or electron beam/x-ray machines.
2. Food irradiation is a way to privatize nuclear waste management. Cesium-137, the most radioactive waste material, is promoted by the Department of Energy for food irradiation.
3. The treatment exposes food to radiation for varying lengths of time, depending on the food, the purpose, and the size of the radiation source. Doses are 100,000 to 60,000,000 times that of a chest x-ray.
4. The food doesn't become radioactive unless it contains traces of silver, tin, strontium, or barium, or unless there is equipment or human error. However, electrons are knocked out of orbit, creating massive molecular rearrangement.
5. It is UNLIKE MICROWAVE, which doesn't possess enough energy to split molecules.
6. VITAMINS are depleted or destroyed. AMINO ACIDS tryptophan, cysteine, phenylalanine, and methionine break down. FATS turn rancid. CARBOHYDRATES form toxic chemicals. NUCLEIC ACIDS AND ENZYMES are adversely affected.
7. Damaging FREE RADICALS are formed, producing RADIOLYTIC PRODUCTS (RPs) not originally found in the food. These chemicals may be carcinogenic or mutagenic. Many RPs are unique, unknown, and untested.
8. AFLATOXIN, a carcinogen created by molds, is produced in greater quantities in irradiated food.
9. BOTULISM is not killed by currently approved doses, but its natural enemies are. Food may be contaminated without any warning smell.
10. WORLDWIDE STUDIES show adverse effects when animals eat irradiated food. Some are: cataracts, tumors, kidney damage, fewer offspring, higher mortality and chromosome breakage.
11. Irradiation can cause MUTATIONS of disease-producing organisms.
12. Irradiated food can become RECONTAMINATED, if not sealed properly, undermining its primary purpose.
13. Irradiation will NOT REDUCE THE USE OF CHEMICALS in food. It is done after harvest. Chemicals used in growing food will still be used. No one knows what will occur when RESIDUES ARE IRRADIATED. Other chemicals will be added to counteract changes in texture, odor and flavor caused by irradiation.
14. Hundreds or thousands of irradiation facilities will need to be built, many in populated areas. Permitted radioactive emissions are 20 TIMES HIGHER than nuclear power plants. These levels of radiation threaten workers and communities. Several serious accidents have already occurred. Emergency care evacuation plans are non-existent or inadequate.
15. Cesium-137 is stored in water-soluble form. A leak into the ground water would IRREVERSIBLY CONTAMINATE the environment and work its way up into the food chain.
16. There will be a great increase of RADIOACTIVITY ON THE HIGHWAYS. The Department of Transportation has less than 225 inspectors of hazardous cargo for the entire nation. Many accidents have already occurred.
17. For irradiation to work, agriculture will become more CENTRALIZED, to the detriment of the small farmer. Plant species will be hybridized to facilitate radiation tolerance, increasing crop vulnerabilities.
18. Irradiated food will NOT FEED THE STARVING. Hunger is political and economic, not technological.
19. Taxpayers financed most of the nuclear industry, including nearly $100 million for research and development of food irradiation. They will subsidize the sale of cesium-137, transportation, regulation, and clean-up of accidents. They may suffer health problems caused by a diet of irradiated food and increases in background levels of radiation. They will PAY MORE FOR IRRADIATED FOOD - estimated at 2 to 24 cents a pound.
20. There are SAFER, CHEAPER, VIABLE ALTERNATIVES. Some are: carbon dioxide fumigation, heat and cold treatments, and infrared.
21. Only "whole" irradiated foods like fruits and vegetables must be labeled, not irradiated ingredients of processed foods, which may comprise 80% of irradiated foods. There are NO PENALTIES in the FDA rule for failure to comply with labeling requirements. The FDA has no list of irradiators or irradiated foods.
22. There is NO WAY TO DETERMINE if food has been irradiated, the dosage, or number of times.

For more information, contact:

National Coalition to Stop Food Irradiation (N.C.S.F.I.)

P.O. Box 59-0488
San Francisco, CA 94159
(415) 566-2734

By KAY LEVINE
Daily News reporter

The University of Alaska is conducting a feasibility study on building a food irradiation plant in Alaska. The plant could be used to treat local products such as potatoes, reindeer meat and salmon.

"There is a potential there that it will open up some opportunities for producers in Alaska that don't currently exist," said John Zarling, director of the university's Institute of Northern Engineering in Fairbanks.

The Food and Drug Administration approved irradiation for wheat and potatoes more than 20 years ago, gradually adding other foods to the list. The growing popularity of the process has generated increased controversy over the safety and nutrition of the food products, possible mishaps involving radioactive materials, and cost.

Food being irradiated is passed through a lead-shielded concrete chamber where it's zapped with rays from radioactive cobalt 60 or cesium 137.

The process extends shelf life, kills insects and bacteria, and sometimes slows ripening. Some items may not need refrigeration if exposed to high-enough doses. Food does not become radioactive, however.

Zarling hastened to add he's not necessarily a proponent of food irradiation, but he thinks it's a good idea to find out if the process would be cost-effective and popular here.

Alaska's year-long project got under way

See Page E-3, IRRADIATION

Continued from Page E-1

Sept. 15 and is being financed by the Department of Energy, which provided a grant for $400,000.

The scope of the study was outlined in a proposal the university submitted to the department that says the university team will accomplish the following:

- Identify Alaska commodities suitable for irradiation.
- Identify the potential increase in commodity shelf-life and other improvements in quality attributable to irradiation.
- Analyze the economic feasibility of irradiating food in Alaska. This section would include studying possible location for irradiation plant sites.
- Find out if Alaskans will accept irradiated products and the facilities to produce them.

The study will not examine whether food irradiation is safe.

The proposal gives a long list of products that might be suitable for irradiation treatment. They include grains, lettuce, cabbage, berries, cut flowers, processed meats, dairy products, herring, halibut, crab, shrimp, clams, fish meal and surimi.

Zarling said no list exists of proposed sites. Team members will come up with one by considering the suitability of towns near food production points and transportation, he said. Candidate sites noted for problems like the number and intensity of earthquakes will be eliminated, Zarling said.

The proposal also mentioned the possibility of mobile irradiation units. The Department of Energy already has one mobile unit — it's basically a trailer — that has been used for demonstrations, Zarling said.

Many scientists, and organizations like the World Health Organization, see food irradiation as the answer to world food shortages: Less food will be lost to insects, and supplies won't be hurt by slow transportation.

Supporters also argue that gamma-ray exposure provides a safer alternative to pesticides, herbicides and traditional preservatives.

Critics note the process causes some structural changes in food that aren't fully understood. They suggest it creates cancer-causing substances like benzene and formaldehyde and others, called unique radiolytic products, that represent a question mark in scientific knowledge.

They say irradiation degrades the nutritional value of food and that consumers may worsen the problem by canning or freezing irradiated products.

The National Coalition to Stop Food Irradiation argues the federal government is trying to create consumer demand for irradiated food because it represents a way to get rid of spent fuel from commercial nuclear reactors and to create plutonium, used in building nuclear weapons. According to the coalition, Uncle Sam wants to set up 1,000 food irradiation plants across the country.

Indeed, five other states — Hawaii, Florida, Iowa, Oklahoma and Washington — are considering whether to build irradiation plants. Not all will conduct studies first.

Zarling acknowledged legitimate concerns exist about the safety of food irradiation plants, but he disagreed with the coalition's gloomy view.

"We talk about the government, but the government is us," he said. "I think it makes sense to see if we can find a use for (nuclear) byproducts."

In February, Sen. George Mitchell, D-Maine, and Rep. Douglas Bosco, D-Calif., introduced bills that would suspend FDA approvals of irradiation for everything except spices for two years. During that period, the National Academy of Sciences is expected to complete a study on the health and environmental effects of irradiation.

Although the House bill has 83 co-sponsors and the Senate bill has 10, neither bill is expected to move out of committee this year, said Kathleen Latimer, an aide to Rep. Bosco.

January 6, 1988

Letters From the People
Anchorage Daily News
P.O. Box 14-9001
Anchorage, Alaska 99514-9001

The Department of Energy (DOE) provided a grant to the University of Alaska in Fairbanks to conduct a feasibility study on building a food irradiation plant in Alaska. (Article Enclosed)

The Food and Drug Administration (FDA) approved irradiation based on theoretical calculations supported by 5 out of 441 studies reviewed. It dismissed evidence that irradiation decreases nutritional value and creates possible carcinogens.

Authorized by this approval the DOE plans to build demonstration irradiation facilities in six states including Alaska. We can avert these facilities (as public opposition has helped do in New Jersey, Florida, and California) by enacting the Food Irradiation Safety and Labeling Requirement Act of 1987. (HR 956 & S461) This bill will:

- Place a moratorium on FDA approval of irradiation of fresh fruits, vegetables, and pork.
- Mandate detailed studies on the impact of irradiation to our food and environment.
- Direct the FDA to require labeling of all irradiated food.
- Prohibit the export of irradiated foods not approved for consumption in the U.S.

Please contact Senators Ted Stevens and Frank Murkowski, US Senate, Washington D.C. 20510 and Representative Don Young, House of Representatives, Washington D. C. 20515 and ask them to support this bill. In addition to Congressional action contact state representatives to urge a state moratorium. For more information supporting accountability of food irradiation write the National Coalition to Stop Food Irradiation, P.O. Box 59-0488, San Francisco, California 94159.

William, Sylvia & Denny Thomas
9040 Emerald
Anchorage, Alaska 99502

CC: -Senator Ted Stevens (Alaska), U.S. Senate, Washington D.C. 20510
-Senator Frank Murkowski (Alaska), U.S. Senate, Washington D.C. 20510
-Congressman Don Young (Alaska), U.S. House of Representatives, Washington D.C. 20515
-Governor of Alaska, Steve Cowper, State Capitol Building, P.O. Box A, Juneau, Alaska 99811
-Senator Pat Rodey, 3111 C Street, Suite 510, Anchorage, Alaska 99503
-Senator Mitch Abood, 3111 C Street, Suite 535, Anchorage, Alaska 99503
-Representative Alyce Hanley, 3111 C Street, Suite 410, Anchorage, Alaska 99503
-Representative Drue Pearce, 3111 C Street, Suite 425, Anchorage, Alaska 99503
-Food and Drug Administration, Center for Food Safety and Applied Nutrition, Sanford Miller, Director, 200 C St., SW. Washington D.C. 20204
-Food and Drug Administration, Office of Consumer Affairs, R. Alexander Grant, Associate Commissioner, 5600 Fishers Lane, Rockville, Md. 20857
-Department of Energy, Byproducts Utilization Program, Richard Chitwood, Washington D.C. 20545
-Department of Energy, Consumer Affairs, Rose F. Bates, Director, 1000 Independence Ave, SW Washington D.C. 20585
-World Health Organization, Director-General Dr. Halfdan Mahler, CH-1211, Geneve 27, Switzerland
-World Health Organization, Regional Office for the Americas, Pan American Sanitary Bureau, 525 23rd St., NW Washington D.C. 20037
-Board of Regents, Office of Regent Affairs, University of Alaska, 103 Bunnell, Fairbanks, Alaska 99775
-President of the U of A, Donald O'Dowd, 101 Bunnell, Fairbanks, Alaska 99775
-Vice Chancellor for Research, U of A, Dr. Luis Proenza, 305 Signer's Hall, Fairbanks, Alaska 99775
-Director of the Institute of Northern Engineering, U of A, John Zarling, 123 Duckering, Fairbanks, Alaska 99775
-Senator George Mitchell (Maine), US Senate, Washington D.C. 20510
-Congressman Douglass Bosco (California), US House of Representatives, Washington D.C. 20515
-National Coalition to Stop Food Irradiation, Denis Mosgofian, Director, P.O. Box 59-0488, San Francisco, California 94159

539 Duckering Building
Fairbanks, Alaska 99775-1760

ENGINEERING

UNIVERSITY OF ALASKA FAIRBANKS
INSTITUTE OF NORTHERN ENGINEERING

February 26, 1988

John Sund, Chairman
Judiciary Committee
House of Representatives
P.O. Box V (MS 3100)
Juneau, AK 99811

Dear Representative Sund:

Enclosed are documents on food irradiation. We hope that this information is helpful in your deliberative process. Because this is such a large volume of material and we know you have many demands on your time, a brief summary statement about each document is included on the sheet entitled Summary Statements.

If specific questions arise, or if you need additional information, please call me. I will be happy to answer questions or provide additional materials.

Sincerely,

John P. Zarling

John P. Zarling, Director
Institute of Northern Engineering
and Principal Investigator
Phone: 907/474-7775

JPZ/jae

Enclosure

SUMMARY STATEMENTS

1. CAST report is based on a four year review of safety (wholesomeness) research studies conducted throughout the world by scientists representing various disciplines involved in food irradiation. CAST (Council Agricultural Science and Technology) has a current membership of 29 professional scientific societies. A summary statement is on page 1 and an overview of the safety of the process is found in pages 2-5.

2. FDA Final Rules and Regulations outlines the decision making process and the existing rules and regulations. Sections related to labeling have been highlighted.

3. Frank Young, FDA Commissioner's testimony before the U.S. Congress Subcommittee on Health and the Environment, June 19, 1987. His statement covers the misconceptions about the number of studies used in FDA's rule-making process (the rule-making was not based on only 5 of 441 studies as frequently reported in the consumer press) and the history of FDA's involvement in this issue. FDA approved foods are listed on the attached table. Young holds both a Ph.D. and a medical degree.

4. American Medical Association's (AMA) statement before U.S. Congress (Nov. 18, 1985) in support of the safety and use of the food irradiation process. An attached letter verifies that this continues to be the AMA's position.

5. World Health Organization's report on the wholesomeness of irradiated food. The United Nations continues to urge the adoption of this technology. This report created much of the current interest in this technology worldwide.

6. Consumer Papaya Test reports the results from a one-day market study in California. Despite reports in the popular press to the contrary, this market was approved for a one-day period only. Consumers purchased ten times more labeled "irradiated" papayas than conventionally processed papayas. In that test market, it was found that many consumers believed the choice was between irradiation and no treatment because they were unaware of conventional fresh produce processing. Food Technology is an official publication of the Institute of Food Technologists, a scientific society of food scientists and nutritionists.

7. Fact Sheet on the Alaskan feasibility study.

8. Fact Sheet on irradiated foods that very briefly summarizes the above and many other references on this topic. Potential implications for Alaska are briefly reviewed as are possible energy sources.

FOOD and WATER, INC.
3 Whitman Drive • Denville, NJ 07834 • (718) 783-2146 / (201) 625-3111

NEWS RELEASE

For Immediate Release:
February 18, 1988

BRITAIN RETAINS BAN ON FOOD IRRADIATION BUT MOVES TOWARD MORE STRINGENT REGULATION THAN U.S.

On February 4, 1988, the British Government postponed plans to permit the irradiation of food. In announcing the decision to retain its current ban, the government, in effect, conceded that food irradiation is a technology which is not now adequately regulated and that abuses have already occurred in the use of the technology.

The decision, announced by Junior Health Minister Edwina Currie, reflects the breadth of public opposition within the United Kingdom (UK) to the use of irradiation for purposes of food preservation. The decision represents a highly significant concession because it comes in the face of support from the nuclear industry to approve food irradiation and support of a British government Advisory Committee which favored use of the technology despite unanswered health and safety questions. In 1987, the British Medical Association also rescinded its approval of food irradiation and called for a continuation of the UK ban pending research and findings that clearly demonstrate the safety of the process.

In her statement announcing the extension of the UK ban, Mrs Currie stated that "The Government have therefore decided to maintain the present general prohibition on irradiated foods until they are satisfied that effective regulatory controls can be drawn up for the irradiation of specific foods in order to bring about good industrial and marketing practices and ensure informed consumer choice. Such controls should include assurances on the quality of the particular foods to be irradiated, requirements as to the maintenance of documentary records, the licensing of premises and inspection of operations. The availability of detection tests will be one of the factors to be taken into consideration and there would also be statutory provision for the labelling of irradiated foods and food ingredients." (emphasis added).

According to the London Food Commission, she did this despite her advisory committee's acknowledgement that:

1. Irradiation will require increased use of some chemical additives, notably anti-oxidants. Research by the London Food Commission (which provided much of the information contained in this release) has raised doubts about the safety of some anti-oxidants.

2. There may be problems with vitamin losses caused by irradiation for people at risk of dietary deficiencies, especially if they are pregnant or nursing mothers. The London Food Commission has shown that losses with irradiated food can be significant and occur in the very foods that current dietary guidelines (and Mrs. Currie herself) suggest should form part of a health conscious diet. There is widespread concern in Britain (and in the United States as well) that the diet of many people is already deficient.

3. There is insufficient scientific evidence to resolve some safety questions about irradiated foods, especially the effects of irradiation on additives, contaminants, pesticide residues and packaging materials. The London Food Commission has charged that the Committee report misrepresented the results of some scientific studies and did not resolve the concern about possible chromosomal damage from irradiated foods.

Food and Water is calling on the Food and Drug Administration (FDA) to pay similar heed to the concerns of American consumers and reconsider its approval of food irradiation until such time as the safety of this technology is adequately demonstrated in the refereed scientific literature.

We are calling on the FDA to acknowledge that theoretical assumptions of safety are insufficient when dealing with a technology as potentially hazardous and irreversible as food irradiation.

We are calling on the FDA to follow the lead of the British Government and rescind its approval until evidence more concrete than theory becomes available to support claims of safety.

Consumer safety requires that long-term feeding studies at elevated doses be performed prior to the approval of this technology. We are requesting that those studies be done before irradiated foods are sold to the public.

We are requesting that those studies which food irradiation's proponents so often cite as evidence of the technology's safety (e.g. the Chinese study that purported to show no chromosomal irregularities following a short test in which Chinese medical students were fed irradiated food) be submitted to respected professional journals for peer review by independent scientists. If such studies withstand peer review, they should then be published in the open scientific literature and exposed to public scrutiny -- a process not yet done.

Until those studies claimed as proof of food irradiation's safety are subjected to, and withstand, the traditional professional test of anonymous peer review, and until all outstanding environmental, health and regulatory concerns are satisfactorily addressed, food irradiation remains a questionable technology.

FOR FURTHER INFORMATION CONTACT:
MORDIE WEINTRAUB
718-783-2146
OR
DR. JUDITH JOHNSRUD
814-237-3900
OR
THE LONDON FOOD COMMISSION
88 OLD STREET
LONDON, ENGLAND EC1V9AR
TEL:01-253-9513

100TH CONGRESS
1ST SESSION

H. R. 956

To prohibit the implementation of certain regulations of the Secretary of Health and Human Services and the Secretary of Agriculture respecting irradiated foods, to amend the Federal Food, Drug, and Cosmetic Act to prescribe labels for irradiated food, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

FEBRUARY 4, 1987

Mr. BOSCO (for himself, Mr. RODINO, Mr. RINALDO, Mr. MRAZEK, Mr. ROE, Mr. FEIGHAN, Mr. FAUNTROY, Mr. BEILENSON, Mr. KASTENMEIER, Mr. ANNUNZIO, Mr. GILMAN, Mr. BIAGGI, Mr. DELLUMS, Mr. OWENS of New York, Mr. HOWARD, Mr. PANETTA, Mr. JACOBS, Mr. GUARINI, Mrs. BOXER, Mr. ACKERMAN, Ms. SNOWE, Mr. STARK, Mr. ANDERSON, Mr. KOSTMAYER, Mr. WEISS, Mr. LIPINSKI, Mr. CONYERS, Mr. SOLARZ, Mr. GEJDENSON, Mr. LOWRY of Washington, Mr. GALLO, Ms. KENNELLY, Mr. SCHUMER, Miss SCHNEIDER, Mr. SMITH of Florida, Mr. JONES of North Carolina, Mr. MURPHY, Mr. SUNDQUIST, Mr. HAYES of Illinois, Mr. BORSKI, Mr. RICHARDSON, Mr. BUSTAMANTE, Mr. TORRES, Mr. DEFAZIO, Mr. TOWNS, Mr. GARCIA, Mr. KOLTER, Mr. GRAY of Illinois, Mr. BOLAND, Mr. HAWKINS, and Mr. DARDEN) introduced the following bill; which was referred to the Committee on Energy and Commerce

---

A BILL

To prohibit the implementation of certain regulations of the Secretary of Health and Human Services and the Secretary of Agriculture respecting irradiated foods, to amend the Federal Food, Drug, and Cosmetic Act to prescribe labels for irradiated food, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "Food Irradiation Safety and Labeling Requirement Act of 1987".

SEC. 2. REGULATIONS.

(a) IRRADIATION OF PORK.—The Secretary of Agriculture may not implement the regulations relating to the irradiation of pork published in 51 Federal Register 1769 and may not issue any other regulation which would have the same legal effect as such regulations. The Secretary of Health and Human Services may not implement the regulations relating to the irradiation of pork published in 50 Federal Register 29658 and may not issue any other regulation which would have the same legal effect as such regulations.

(b) IRRADIATION OF OTHER FOODS.—The Secretary of Health and Human Services may not implement the regulations relating to the irradiation of food published in 51 Federal Register 13376. The Secretary may not issue any other regulation which would have the same legal effect as such regulations.

SEC. 3. STUDY.

(a) GENERAL RULE.—The Secretary of Health and Human Services shall arrange, in accordance with subsection (b), for a study of the risk to human health and the environment presented by the irradiation of food. The study shall include the following:

(1) A review of existing research on the safety and wholesomeness of consumption of irradiated food and the conduct of new studies of the consumption and nutritional value of irradiated food.

(2) A study of the contamination of food from improper radiation.

(3) A study of the risk to the health of individuals employed in facilities in which irradiation is conducted and an evaluation of the exposure to radiation, emergency medical plans for radiation accidents or emergencies, safety requirements in effect in such facilities, and employee training in safe irradiation procedures.

(4) A study of the risk to the health of residents of the area in which such facilities are located which may result from the accidental release from such facilities of the source of the food irradiation and an evaluation of the existing technology for cleaning such facilities when there has been an accidental release within the facility, methods for the evacuation of such areas in the case of such a release, emergency response systems, and an identification of persons responsible for cleaning facilities and personal liability for accidental releases.

(5) A study of the effect on the environment, on population centers of over 50,000, and rural areas of

transporting the sources of food irradiation and the protection of the drivers and the general public from injury from such transportation and an identification of the persons responsible for personal liability for accidents in transporting such sources.

(b) ARRANGEMENT.—The Secretary shall arrange with the National Academy of Sciences to conduct the study prescribed by subsection (a) or, if such an arrangement cannot be entered into, with another nonprofit private research entity with appropriate qualifications.

(c) REPORT.—The Secretary shall report the results of the study not later than 2 years after the date of the enactment of this Act.

SEC. 4. LABELING REQUIREMENT.

Section 403 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343) is amended by adding at the end the following:

"(q)(1)(A) If it is a food which has been treated with ionizing or gamma radiation unless the food is labeled or marked—

"(i) to provide notice that the food has received ionizing or gamma radiation or if it is composed of ingredients which have received such radiation, that the ingredients of the food have received such radiation, and

"(ii) to warn that the food should not be subject to further radiation.

"(B) The Secretary shall issue regulations respecting the labeling required by clause (A). Such regulations shall—

"(i) require that the labels appear in a conspicuous place on food retail and wholesale packages,

"(ii) in the case of non-packaged foods, require that the content of the label be placed in a notice displayed prominently where such food is held for sale, and

"(iii) require that the label statement appear in any invoice accompanying the food.

"(2) If it is a food which has been treated with ionizing or gamma radiation and which is offered for sale in a restaurant unless it has a mark placed beside it in the restaurant's menu with the explanation that the mark means that the food has been treated with ionizing or gamma radiation.

"(3) Any person engaged in the irradiation of food shall report semiannually to the Secretary—

"(A) a summary of all the foods that the person irradiated in the period reported on,

"(B) the categories of food irradiated and the total amount of food in each such category which was irradiated,

"(C) the persons for whom the irradiation was done and the types and amount of food irradiated for such persons,

"(D) the dosage levels of irradiation for each category of food irradiated and the method of calculating the dosage levels, and

"(E) assurances that its irradiation procedures are established by experts qualified in radiation processing of food.

The Secretary shall make such reports available to the public and may not destroy any such report.".

SEC. 5. EXPORTS.

Section 801(d)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381(d)(1)) is amended by striking out "and" at the end of subparagraph (C), by redesignating subparagraph (D) as subparagraph (E), and by inserting after subparagraph (C) the following:

"(D) is a food which has been treated with ionizing or gamma radiation and is labeled in accordance with section 403(q)(1) and does not bear or contain any food additive which is unsafe within the meaning of section 409, and".

SEC. 6. ENFORCEMENT.

Section 301 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331) is amended by adding at the end the following:

"(t) The failure to make the report required by section 403(q)(3).".

SEC. 7. EFFECTIVE DATE.

The amendments made by sections 4, 5, and 6 shall take effect upon the expiration of 180 days after the date of the enactment of this Act.

O

UNITED FISHERMEN OF ALASKA

211 4th Street, Suite 106
Juneau, AK 99801
907-586-2820

UNITED FISHERMEN OF ALASKA

Resolution 88-2

WHEREAS food irradiation destroys or depletes amino acids, nucleic acids, and vitamins A, B (thiamine), B2, B3, B6, B12, C, E, K and folic acid; and

WHEREAS foods high in polyunsaturated fatty acids (which are increasingly being valued for their contribution to health), when irradiated, form large molecules that cannot be degraded by the body, can partially obstruct blood vessels and increase blood pressure; and

WHEREAS food irradiation is known to produce unstable, chemically reactive free radicals which are highly toxic and increase carcinogenesis, mutogenesis and cardiovascular disease in animals and in man; and

WHEREAS reviews of the available literature on irradiated food overwhelmingly indicate adverse effects on animals including development of testicular tumors, kidney disease, shortened life spans, loss of weight, increased rate of infertility and death of offspring; and

WHEREAS the botulism bacterium, Clostridium botulism, is perversely resistant to gamma radiation (irradiation), while most of its natural competitors, including those that alert us to the decay of foods, are destroyed; and

WHEREAS resistant strains of Salmonellae have been developed by repeated irradiation under laboratory conditions; and

WHEREAS acceptable and effective methods of preserving food (freezing, canning, vacuum packing, etc.) already exist and irradiation does not eliminate the need for refrigeration, packaging and good food hygiene; and

WHEREAS several major markets for Alaska seafood, including Japan, Great Britain, the Scandinavian countries, West Germany, New Zealand and some states, have completely banned the sale of irradiated food for public consumption or halted further exploration of irradiated food due to consumer opposition; and

WHEREAS the price of irradiated food will be 2 to 24 cents per pound higher than non-irradiated food; and

WHEREAS the Department of Energy has provided $400,000 to the University of Alaska, Fairbanks, to help Alaska determine the feasibility of irradiating fresh and frozen fish, other seafood and agricultural products; and

WHEREAS the Department of Energy is the primary promoter of food irradiation as a means of inexpensively extracting weapons-grade plutonium from the reprocessing of nuclear waste; and

WHEREAS the specific use of radioactive cesium-137 or other radiocative waste products for food irradiation treatment in Alaska involves another whole range of concerns, including but not limited to worker and public safety (permitted radioactive emissions are 20 times higher than nuclear power plants); transportation of nuclear waste; construction of a radiation facility in a seismically inactive and tsunami-free area; and contamination of groundwater, the food chain and the environment by the highly water-soluble cesium-137 (half-life 600 years);

NOW THEREFORE BE IT RESOLVED that United Fishermen of Alaska strongly opposes the irradiation of seafood in the state of Alaska; and

BE IT FURTHER RESOLVED that United Fishermen of Alaska supports Senate Bill 355 and House Bill 388 which prohibit the sale of irradiated food in Alaska.

Jim Bacon
President

Date 3-1-88

(7)

HOUSE COMMITTEE REPORT

Date referred: 2/24/88 FURTHER REFERRALS:

DATE: March 11, 1988

The Judiciary Committee has considered HB 388

"An Act relating to irradiated food."

RECOMMENDS:

[✓] replace with CSHB 388 (HESS) [ ] the same title

[ ] attached amendment(s) [ ] a new title

- [ ] do pass
- [ ] do not pass
- [ ] no recommendation
- [ ] individual recommendations
- [ ] additional referral to the _____ Committee

ADOPTS: [ ] _____ letter of intent

ATTACHES NEW FISCAL NOTE(s):

- [ ] fiscal impact
- [ ] zero fiscal note
- [ ] zero with analysis
- [✓] same as previous fiscal note published 2/24/88
- [ ] same as previous zero fiscal note published _____

SIGNING DO PASS:

SIGNING OTHER RECOMMENDATIONS:

M A Gutierrez for No Rec

Chairman's signature

ALASKA STATE LEGISLATURE
HOUSE OF REPRESENTATIVES
RESEARCH AGENCY

P.O. Box Y, State Capitol
Juneau, Alaska 99811-3100
Mail Stop 3100
(907) 465-3991

June 13, 1988

MEMORANDUM

TO: Representative John Sund

FROM: David Teal, Director

RE: Food and Drug Administration--Objectivity and Reliability Relating to Food Irradiation
Research Request 88.202

I received a copy of a letter to you from Dr. Patrick A. Lynch, dated June 2, 1988, regarding memorandum 88.202, Food and Drug Administration--Objectivity and Reliability Relating to Food Irradiation. Dr. Lynch states that he feels the memorandum is slanted, and that an "erroneous conclusion [is] reached in the last paragraph wherein the FDA is accused as [sic] being an intermediary for the Department of Energy in a coordinated effort to shift the responsibility for by-products of nuclear weapon production elsewhere."

That portion of the memorandum which Dr. Lynch finds objectionable is not a conclusion reached by Ms. Brawley; it is the report of a criticism made by public interest groups. Because the criticism relates directly to the question posed and because it is consistently made by public interest groups, its omission would have been inappropriate. I would also point out that a major portion of the memorandum consists of direct quotations from the FDA's official document on the subject.

I edited the memo and believe the statement in question was clearly attributed to its sources. However, I apologize for any lack of clarity and assure you that neither bias nor obfuscation was intended by the analyst.

I've attached a more recent memorandum on food irradiation. We have additional information on this process in our files and would be happy to forward it to you if you wish.

Attachments:
Letter from Dr. Lynch
House Research Memoranda 88.202 and 88.251

cc: Dr. Patrick A. Lynch

ALASKA STATE LEGISLATURE
HOUSE OF REPRESENTATIVES
RESEARCH AGENCY

P.O. Box Y, State Capitol
Juneau, Alaska 99811-3100
Mail Stop 3100
(907) 465-3991

March 8, 1988

MEMORANDUM

TO: Representative John Sund

ATTN: Peggy Sepulveda

FROM: Patricia Brawley PB
Legislative Analyst

RE: Food and Drug Administration--Objectivity and Reliability Relating to Food Irradiation
Research Request 88.202

You asked this agency to provide information about the objectivity and reliability of the U.S. Food and Drug Administration (FDA) in relation to the question of food irradiation. Although confict of interest and/or unreliablity are accusations difficult to substantiate, and ultimate motivation is perhaps unknowable, it appears that the FDA's examination of food irradiation differs from normal testing procedures.

In responding to your request, I contacted public interest groups, including Public Citizen, the Center for Science in the Public Interest, and the National Coalition to Stop Food Irradiation. I have reviewed materials published by the FDA, the Library of Congress Congressional Research Service, the World Health Organization, and the University of Alaska Institute of Northern Engineering, as well as those published and disseminated by public interest groups. While public interest groups unanimously challenge the reliability and the objectivity of the FDA findings on food irradiation, I found no explicit accusations of conflict of interest; however, language in the FDA's "Irradiation in the Production, Processing, and Handling of Food; Final Rule" (Federal Register, April 18, 1986) clearly documents that the perceived mandate was not to test an hypothesis by a standard scientific model, but rather to "determine that the additive is safe under the proposed conditions of use" (p. 13377).

The 1986 FDA "Final Rule" recommendations are unusual in that they were "promulgated on the agency's initiative" (p. 13376), not on the petition of any member of the food industry, as is generally the case. In addition, the FDA consistently emphasizes findings and theories in support of food irradiation safety, and minimizes findings which challenge it. In its analysis of the subject, the FDA was concerned primarily with the consumption aspect of food irradiation, not with the safety of the process itself, nor with the transportation of the radioactive materials required to irradiate food.

While lack of reliability and objectivity is at the heart of the public outcry against FDA recommendations, a frequent criticism persists that the Department of Energy is behind FDA support of food irradiation. Food irradiation, agree public interest groups, is a technology looking for an application. The FDA is seen by many as an intermediary for the Department of Energy--which would like the responsibility for by-products of nuclear weapon production shifted elsewhere. Widespread use of nuclear waste materials for food irradiation would effectively disperse the product, eliminating the need for radioactive waste disposal sites, and would, in theory, create a seemingly altruistic raison d'etre for cesium-137, thus lifting the burden of responsibility for disposal from proponents of nuclear arms production.

Attachment

Federal Register

Friday
April 18, 1986

Part III

Department of Health and Human Services

Food and Drug Administration

21 CFR Part 179

Irradiation in the Production, Processing, and Handling of Food; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 179

[Docket No. 81N-0004]

Irradiation in the Production, Processing, and Handling of Food

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its regulations to permit additional uses of ionizing radiation for the treatment of food. These regulations: (1) Permit manufacturers to use irradiation at doses not to exceed 1 kiloGray (kGy) to inhibit the growth and maturation of fresh foods and to disinfect food of arthropod pests, (2) permit manufacturers to use irradiation at doses not to exceed 30 kGy to disinfect dry or dehydrated aromatic vegetable substances (such as spices and herbs) of microorganisms, (3) require that foods that are irradiated be labeled to show this fact both at the wholesale and at the retail level, and (4) require that manufacturers maintain process records of irradiation for a specified period and make such records available for FDA inspection. These regulations are promulgated on the agency's initiative and are necessary to permit the safe use of ionizing radiation. This document responds to comments on the February 14, 1984, proposed rule (49 FR 5714).

DATES: Effective April 18, 1986; objections by May 19, 1986.

ADDRESS: Written objections and request for a hearing to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Clyde A. Takeguchi, Center for Food Safety and Applied Nutrition (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-472-5740.

SUPPLEMENTARY INFORMATION:

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I. Introduction

Under section 409 (b) and (d) of the Federal Food, Drug, and Cosmetic Act (the act), the Secretary may approve a food additive petition from an interested person or may propose the issuance of a food additive regulation upon the Secretary's own initiative (21 U.S.C. 348 (b) and (d)). It is less common for FDA, acting as the Secretary's delegate, to propose and then establish a regulation itself, than to respond to a sponsor's petition. In the case of food irradiation, FDA had, before 1981, approved several food additive petitions for the use of various sources of radiation on certain foods and food-packaging materials (21 CFR Part 179). Subsequent to these approvals, an FDA committee evaluated testing criteria that would be necessary to support the safety of food irradiation for various uses.

In the Federal Register of March 27, 1981 (46 FR 18992), FDA published an advance notice of proposed rulemaking that announced the availability of the Bureau of Foods' (now the Center for Food Safety and Applied Nutrition) Irradiated Food Committee (BFIFC) Report (Ref. 1), which outlined a course of action for assuring the safety of irradiated foods, and requested comments on the overall approach.

In the Federal Register of February 14, 1984 (49 FR 5714), FDA published a proposed rule that would: (1) Establish general provisions for food irradiation, (2) permit the use of food irradiation at doses not exceeding 1 kiloGray (kGy) (100 kilorads: 100 krad) [1] for inhibiting the growth and maturation of fruits and vegetables and for insect disinfestation of food, (3) allow irradiation to be used for microbial disinfection of certain dried spices and dried vegetable seasonings at a dose not to exceed 30 kGy (3 Mrad), (4) eliminate the current irradiated food labeling requirements for retail labeling, and (5) replace the current sections (21 CFR 179.22 and 179.24) dealing with the irradiation of food with new §§ 179.25 and 179.26 (21 CFR 179.25 and 179.26). The proposal responded to comments on the advance notice of proposed rulemaking.

Apart from that ongoing rulemaking, FDA has approved a number of food additive petitions to provide for the safe use of gamma radiation at doses up to 10 kGy (1 Mrad) to control insect infestation and microbial contamination in dried herbs, spices, and vegetable seasonings (48 FR 30613, July 5, 1983; 48 FR 46022, October 11, 1983; 49 FR 24966, June 19, 1984; 50 FR 15415, April 18, 1985) and in dry enzyme preparations (50 FR 24190, June 10, 1985). FDA also issued a final rule on July 22, 1985 (50 FR 29658) which amended 21 CFR 179.22(b) in response to a petition to provide for the safe use of gamma radiation at doses up to 1 kGy (100 krad) to control *Trichinella spiralis* in pork.

The act requires that a food additive, including a source of radiation used to process food, be shown to be safe under the proposed conditions of use before use of the food additive can be approved. That is, the agency must be assured with reasonable certainty that no harm will result from irradiation of food. A source of radiation is specifically defined as a food additive in section 201(s) of the act (21 U.S.C. 321(s)). The Senate report on the Food Additives Amendment of 1958 made clear that "[s]ources of radiation (including radioactive isotopes, particle accelerators and X-ray machines) intended for use in processing food are included in the term 'food additive' as defined in this legislation." S. Rept. 2422, 85th Cong., 2d Sess. 63 (1958).

Section 409 of the act lists the criteria which must be considered by the agency before a food additive regulation is issued. The statute does not prescribe what safety tests should be performed but leaves that determination to the discretion of scientists. The definition of safety, as drawn from the legislative history of the Food Additives Amendment of 1958, has been codified in 21 CFR 170.3(i) as follows:

(i) "Safe" or "safety" means that there is a reasonable certainty in the minds of competent scientists that the substance is not harmful under the intended condition of use. It is impossible in the present state of scientific knowledge to establish with complete certainty the absolute harmlessness of the use of any substance. Safety may be determined by scientific procedures or by general recognition of safety. In determining safety, the following factors shall be considered:

(1) The probable consumption of the substance and of any substance formed in or on food because of its use.

(2) The cumulative effect of the substance in the diet, taking into account any

[1] The Systeme Internationale (SI) unit for expressing the amount of absorbed radiation dose is the Gray (joules/kilogram, abbreviated GY). An older unit commonly used is the rad. The equivalent value in rads (100 rad = 1 Gy) will be enclosed in parentheses when referring to the amount of absorbed radiation. The prefixes kilo (k) and mega (M) represent a thousandfold and a millionfold, respectively. Thus, kilorad means a thousand rads and a megarad means a million rads.

chemically or pharmacologically related substance or substances in such diet.

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

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

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

II. Comments

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

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

A. Safety

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

In the proposed rule, the agency stated "* * * that the safety of food irradiation below 1 kGy (100 krad) has been established * * * because: (1) Irradiation will not make the food radioactive, and thus cannot expose the consumer to radiation; (2) the chemical differences between irradiated foods processed at these doses and nonirradiated foods are too small to affect the safety of the foods; (3) food irradiated at doses up to 1 kGy (100 krad) will have the same nutritional value as similar foods that have not been irradiated; and (4) the balance between microbial spoilage organisms and pathogenic organisms is not adversely affected by radiation doses below 1 kGy (100 krad)" (49 FR 5716).

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

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

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

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

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

absorbed by the food. Based on data showing how much chemical change is likely to be caused by a given amount of radiation energy, BFIFC concluded that irradiation of food at 1 kGy (100 krad) would generate approximately 30 parts per million (ppm) of radiolytic products. Experiments have shown that very few of these radiolytic products are unique to irradiated foods; approximately 90 percent of the radiolytic products identified by BFIFC are known to be natural components of food (Ref. 1). BFIFC found the remaining 10 percent of the radiolytic products to be chemically similar to known natural food components. Because of this chemical similarity, those radiolytic products are likely to be toxicologically similar also. Because natural components of food are not well characterized at the parts per million level, some radiolytic products assumed by BFIFC to be unique may actually be natural components of foods. However, even if 10 percent of the radiolytic products are unique, their cumulative concentration in food irradiated at 1 kGy (100 krad) would be only 3 per million, one-tenth the concentration of 30 parts per million for all radiolytic products. Moreover, the concentration of any single URP will probably be less than 1 part per million for food irradiated at 1 kGy (100 krad). Because different portions of a food being irradiated will receive different doses, the average radiation dose absorbed by the food will necessarily be less than the maximum permitted dose. Therefore, the concentration of URP's generated in food from irradiation should be even lower than the upper bound estimate calculated by BFIFC.

BFIFC concluded that because of the extremely low potential concentration of individual URP's in foods irradiated at doses below 1 kGy (100 krad), and because any URP's are likely to be toxicologically similar to other food components, it would be virtually impossible to detect potential toxicological properties of these substances. The current state-of-the-art toxicity tests are not sensitive enough to detect the potential toxicity of URP's at these low levels unless the URP's are far more potent than experience in the radiation chemistry of foods and in toxicology would suggest.

Because the potential concentration of URP's in irradiated food is low, BFIFC concluded that food irradiated at doses not exceeding 1 kGy (10 krad) is wholesome and safe for human consumption, even where the food that is irradiated may constitute a substantial portion of the diet. Consequently, the committee recommended that foods irradiated at doses below 1 kGy (100 krad) be considered safe for human consumption without the requirement of toxicological testing. BFIFC based this recommendation on radiation chemistry and on the anticipated low levels of human exposure to any URP's generated in irradiated foods.

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

The agency agreed with the scientific rationale and conclusion reached by BFIFC that an adequate margin of safety could be demonstrated for irradiated foods without the requirement of toxicological testing and advised its recommendations concerning the safety of foods irradiated at the proposed dosage levels (March 27, 1981; 46 FR 18992).

Subsequently, in 1981, FDA's Bureau of Foods established the Irradiated Foods Task Group to review all available toxicological data concerning foods treated by irradiation. The major objectives of this Task Group were to compile and summarize the toxicology data pertaining to irradiated foods, identify any consistencies with respect to adverse findings, look for patterns or trends in response between studies, and to summarize the experimental results at the end of the review (Refs. 2 and 3).

The data review proceeded in three phases. In phase I, all relevant toxicology studies were identified from FDA files and from the open literature. In phase II, 441 of these studies were obtained in hard copy and summarized. These summaries categorized studies as: (1) "Accepted," if on initial examination the study appeared to be reasonably complete; (2) "accepted with reservation," if the testing, on initial summary review, appeared acceptable but had some serious deficiencies interfering with interpretation of the data; or (3) "rejected," if there were inadequacies of the experimental design or data collection, or if dietary problems existed in the study that would prevent a valid evaluation. In phase III, 99 studies that either raised questions concerning the possibility of adverse effects or that appeared to support a conclusion that the irradiated food studied is safe were examined in detail and reported (Ref. 4).

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

Based on the findings, rationale, and conclusions of BFIFC and the Task Group, FDA concludes that food irradiated at doses not exceeding 1 kGy (100 krad) is safe for human consumption. The agency further concludes that use of this level of irradiation should be exempt from requirements for toxicological testing because such testing would not be able to measure any toxicological properties of radiolytic products present in irradiated foods. In addition, the agency concludes that irradiation of dry or dehydrated aromatic vegetable substances is safe for human consumption at higher doses. The agency has determined that irradiation at doses no higher than 30 kGy (3 Mrad)

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

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

1. Radiolytic Products

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

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

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

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

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

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

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

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

FDA considered the potential carcinogenicity of hydrogen peroxide in its final rule permitting the use of hydrogen peroxide as an indirect food additive for sterilizing polyethylene food contact surfaces used for food packaging (46 FR 2341; January 9, 1981). The agency had specifically addressed a Japanese report of a bioassay of hydrogen peroxide performed with C57B mice in which the authors had indicated that the chemical may have caused duodenal cancer. Upon review and after consultation with the authors of the study, the agency stated that the evidence was insufficient to conclude that hydrogen peroxide is a carcinogen (46 FR 2341; January 9, 1981).

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

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

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

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

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

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

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

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

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

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

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

2. Spices

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

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

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

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

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

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

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

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

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

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

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

3. Other Minor Foods

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

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

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

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

4. Destruction of Nutrients

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

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

5. Selective Destruction of Microorganisms

13. One comment indicated that irradiation could contribute to increased aflatoxin contamination of foods. The comment cited a series of studies published in 1978 and 1979 by researchers from the National Institute of Nutrition of the Indian Council of Medical Research which reported that wheat irradiated at dose levels up to 250 kilorads showed a dose-dependent susceptibility to aflatoxin production (Refs. 11 and 12).

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

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

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

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

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

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

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

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

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

6. Toxicological Studies

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

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

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

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

The agency agrees that much of the testimony before enactment of the Food Additives Amendment of 1958 discussed animal testing of additives. This could be expected because most of the testimony about testing concerned direct food ingredients of unknown toxicity. Congress did not discuss how irradiation of food should be tested for safety. Furthermore, there is no indication in the legislative history that Congress expected every additive, whether an ingredient, a source of irradiation, or an incidental additive, to be tested the same way; nor does the act require such testing. Such a requirement would result in an unnecessary expenditure of resources. Consistent with this view, FDA has never required the same testing regimen for all types of additives.

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

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

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

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

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

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

among either macro- or micronutrients of the diet.

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

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

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

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

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

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

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

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

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

The agency therefore concludes that irradiated aqueous sugar solutions are unsuitable models for predicting and extrapolating toxicity of irradiated foods. Therefore, the effects observed in these types of studies are not considered by the agency to be a reason for concluding that the uses of irradiation set forth in this regulation are not safe. The agency also concludes that there is no evidence that radiolytic products from sugars present in irradiated foods cause toxic effects to animals or humans.

22. One comment stated that a report in *Nature* magazine (Ref. 16) indicates that eating sugars irradiated at doses ranging from 0.05 to 2 Mrad can produce the same genetic changes in humans as exposure to irradiation itself.

The agency has reviewed this study and disagrees with the comment's interpretation of what the study found. Indeed the authors clearly did not reach the conclusions attributed to them by the comment. Furthermore, if humans or animals were irradiated at doses even 1,000 times lower than the levels used in this study, not only sterility but lethality would result within hours. On the other hand, humans and animals have consumed food irradiated at up to 4 Mrads (Refs. 27 through 32) without any indication of adverse effects of any kind. The study the comment referred to involved the effects of radiation on carrot tissue in liquid culture irradiated at 20 kGy (2 Mrads). This study and others concerning the effects of irradiation on solutions of sugars were discussed in the response to the previous comment.

The agency recognizes that irradiated sugar solutions have produced toxicity in vitro. The agency concludes, however, that irradiated sucrose solutions are unsuitable models for predicting and extrapolating toxicity of irradiated foods. Additionally, no evidence indicates that irradiated foods, including those containing sugars, will cause adverse toxic effects to animals or humans.

23. A few comments stated that a study involving hundreds of thousands of humans over 20 or 30 years is necessary before FDA can say irradiated foods are safe.

The agency has never required such long-term testing in humans to approve the use of a food additive and disagrees that such a study is necessary or appropriate. The agency recognizes that it cannot say with absolute certainty that any food, irradiated or not, is absolutely safe for all people under all conditions. The agency believes that the differences between foods irradiated as prescribed by this regulation and nonirradiated foods are so small, particularly compared to normal variations in the diet, that no effect is expected to be observed. The agency

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

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

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

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

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

7. Alleged Adverse Effects

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

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

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

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

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

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

It is not entirely clear which studies the authors were referring to in the statement from their book. The agency acknowledges that Dr. Verrett was an FDA employee during which time she reviewed many of the early petitions on food irradiation. The agency has reevaluated her reviews of the studies contained in these petitions. Judging from the irradiated foods mentioned in the statement quoted from her book and in the memoranda in the petitions, it appears that she is referring to two studies in which rats were fed a diet of (1) irradiated bacon and fruit compote (mixtures) (Ref. 39) and (2) irradiated pork, peaches, jam, carrots, and flour (Ref. 41).

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

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

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

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

The agency agrees with the pathologist's statement and has attempted to evaluate the overall picture referred to by the pathologist. As stated earlier, 5 animal feeding studies (Refs. 20 and 33 through 36) concerning longevity and/or reproduction (out of 441 toxicological studies reviewed) were considered by agency reviewers to be well designed, properly conducted, and reported. The reports of these five studies indicate no adverse effects to test animals fed irradiated foods.

The agency review included reports of 44 chronic studies, 60 reproduction studies, and 68 combined chronic reproduction studies. Although most of these studies have been considered less than adequate for a variety of reasons, the agency has been able to conclude from them collectively that no treatment-related adverse effects on the longevity of test animals or their reproduction were evidenced by these studies.

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

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

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

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

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

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

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

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

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

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

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

which are structurally atypical of parent food molecules. Such URP's may be free radical coupling products of lipid and protein-derived radicals, dimers, and cross-linked products. However, enzymatic hydrolysis of some of these compounds by normal digestive enzymes is expected to yield normal molecular subunits such as fatty acids, amino acids, monosaccharides, and normal metabolic products of these subunits which would be the same result as from the normal digestion of the original parent molecules.

If exotic molecules of the extreme toxicity implied by the comment were present at any level of toxicological significance in irradiated foods ingested by test animals, some consistent toxicological trends and patterns would be manifest in the studies reviewed. Because it has seen no consistent trends or patterns, the agency concludes that foods irradiated as prescribed by this regulation are safe.

32. One comment referenced a study submitted to FDA by USDA on fruit flies (drosophila) fed irradiated chicken. This study showed a dose-related decrease in offspring (Ref. 50), and the comment stated that this effect is consistent with chromosmal damage.

FDA notes that in the sex-linked recessive lethal study in Drosophilc there was no evidence of mutagenicity. Additional data on fertility and fecundity were also included in the study, and a dose-related decrease in offspring was noted. Although there were fewer offspring in the groups raised on irradiated diets than in concurrent controls, the agency concluded that this effect could arise from a host of causes unrelated to reproductive toxicity, and is an unreliable indicator of an adverse reproductive effect. Mammalian data on reproduction are more relevant to humans, and these studies, as stated earlier, demonstrate no consistent patterns or trends indicative of a positive reproductive effect.

33. One comment referenced a study submitted to FDA by USDA and stated that mice fed radiation-sterilized chicken meat showed a significant increase in testicular tumors, increased death rate, increased kidney damage (glomerulonephropathy), and decreased survival. In addition, the comment implied that male dogs fed radiation-sterilized chicken had significantly lower body weights throughout adulthood than dogs fed a frozen control diet, and claimed that this shows toxicity of the irradiated chicken diet.

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

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

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

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

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

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

34. Several comments referenced two Russian reports (Refs. 52 and 53) that found damage to kidneys and testes in rats fed irradiated feed. The authors reported dose-dependent histopathological changes in the kidney and testes of rats fed irradiated lab-chow. The changes were claimed to be similar to those changes seen in human autoimmune disease involving these tissues.

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

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

FDA reviewed the kidney data in 11 chronic studies (Refs. 28, 33, 34, 55 through 62) in which rats were fed

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

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

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

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

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

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

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

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

B. Labeling Issues

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

The labeling provisions of this final rule differ from that in the proposed rule and from the current labeling regulations as follows: This regulation requires that the wholesale label bear either the statement "Treated with radiation, do not irradiate again," or the statement "Treated by irradiation, do not irradiate again," and that the retail label bear the following logo:

along with either the statement "treated with radiation," or the statement "treated by irradiation." Throughout the remaining discussion in the preamble about the labeling provisions, the agency has used the terms "treated with radiation—do not irradiate again," and "treated with radiation," to represent both alternatives that the manufacturer may use in its wholesale or retail labeling in order to simplify the discussion. In addition to the mandatory language, the manufacturer may also state on the wholesale or retail label the purpose of the treatment process or expand upon the kind of treatment used. That is, the manufacturer may include in the labeling any phrase, such as "treated with radiation to control spoilage," or "treated with radiation to extend shelf

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

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

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

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

In addition, the large number of consumer comments requesting retail labeling attest to the significance placed on such information by consumers. Moreover, several comments argued that irradiation of food altered the organoleptic properties of food, thereby reducing its nutritional value. These changes in the food, the comments asserted, make the irradiation of the food a material fact that must be disclosed under section 403(a) and 201(n) of the act. Because of these comments, FDA had decided to require that the label and labeling of food products bear the appropriate statements to inform consumers that the food has been irradiated. The agency emphasizes, however, that the labeling requirement is not based on any concern about the safety of the uses of radiation that are allowed under this final rule. Further responses to these comments are contained in paragraphs 38 through 49.

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

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

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

The agency agrees that conventional food-processing methods also affect the organoleptic properties of food in material ways but in these cases the processing is either obvious to the consumer or conveyed to consumers through labeling or packaging. Canned foods have obviously been canned and frozen foods have obviously been frozen. Pasteurized milk is not obviously pasteurized but this fact is declared on the label.

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

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

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

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

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

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

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

The issue here is whether the irradiation of food is a material fact that must be disclosed to the consumer to prevent deception. As stated earlier, irradiation may change the characteristics of a food in a manner that is not obvious in the supermarket. Packaging materials and incidental additives such as processing aids that have no technical or functional effect in the food and thus do not ordinarily affect the characteristics of the food may be exempted under 21 CFR 101.100 from the normal labeling requirements under the act. Furthermore, Congress specifically exempted pesticide chemicals under section 403(1) of the act from a retail labeling requirement when the food has been removed from its shipping container.

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

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

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

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

The agency has also concluded, however, that the original labeling terminology required by existing 21 CFR 179.22 and 179.24 may be overly technical and that the type of radiation being used is not necessarily meaningful to consumers and that the retail label would be just as informative if the required retail statement were "treated with radiation." The regulation has been modified accordingly.

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

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

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

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

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

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

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

Nor is there any statutory provision that exempts processes from being declared on a food label (49 FR 5718) and the agency must examine whether the failure to declare such processing is misleading to consumers. In this context it is not relevant whether irradiation is considered a process in determining whether retail labeling is appropriate.

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

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

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

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

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

The agency agrees that irradiation causes certain changes in foods and that even small changes that pose no safety hazard can affect the flavor or texture of a food in a way that may be unacceptable to some consumers. Even those opposed to a retail labeling requirement agree that under certain conditions irradiation causes substantial changes in the organoleptic properties of some foods. Moreover, as discussed in the response to comment 36, irradiation may not change the food in any way that is visible to the consumer, so a label statement provides the only means of letting consumers know that a food has been irradiated. Thus, the absence of a label statement on retail foods may incorrectly suggest that an irradiated food is essentially unprocessed. Therefore, this regulation provides that the retail label contain a statement that the food has been irradiated.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

C. Current Good Manufacturing Practice

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

The CGMP regulation for irradiated food could not be based solely on current radiation practices because of the lack of substantial experience with food irradiation. However, there has been extensive experience with other types of radiation processing (e.g., hospital supplies), and the industry has established standards in some cases. FDA considered both the experience and standard practices in the nonfood radiation processing industry and CGMP in the food industry in developing its proposed regulation for irradiated food and in evaluating comments.

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

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

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

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

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

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

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

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

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

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

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

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

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

The agency has authority to conduct plant inspections for all food-processing plants. FDA did not intend to imply that compliance would be determined solely by inspection of records. FDA officials will inspect food irradiation plants and will copy and review required records to assure that the processor is complying with these regulations. The agency would like to clarify that it considers inspection of records to include copying of the records for further review, and is, therefore, adding the words "and copy" after "inspection" in new § 179.25(e) for the same reasons stated in the proposal for records inspection requirements (48 FR at 5719) based on sections 409, 703, and 704 of the act. Thus, if a food manufacturer chooses to engage in radiation processing of food, FDA will consider that processor to have waived any objections to the agency's requirement of inspecting and copying pertinent records with respect to irradiated foods.

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

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

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

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

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

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

(3) FDA is aware of the Codex Alimentarius standard concerning reirradiation of foods (Ref. 70). The Codex Alimentarius standard does not permit reirradiation of foods, except for foods with low moisture content (cereals, pulses, dehydrated foods, and other such commodities), irradiated for the purpose of controlling insect reinfestation. This same standard, however, states that a food is not considered to have been reirradiated when: (1) The food prepared from materials, which have been irradiated at low dose levels, is irradiated for another technological purpose; (ii) the food, containing less than 5 percent of an irradiated ingredient, is irradiated; or (iii) the full dose of ionizing radiation required to achieve the desired effect is applied to the food in more than one installment as part of procesing for a specific technological purpose. In accordance with 21 CFR 130.6, FDA will review all food standards adopted by the Codex Alimentarius Commission. The agency is not required, however, to accept these standards.

Although the agency may, on its own initiative, propose adoption of a Codex standard under section 401 of the act (21 U.S.C. 341), any interested person may petition the agency to adopt a Codex standard (21 CFR 130.6). Because the agency has not proposed adoption of the Codex standard regarding reirradiation of foods as part of this rulemaking, this issue requires no further discussion at this time.

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

58. Some comments questioned the need for a 5 million electron volt limit for x-ray sources and stated that this energy limit should be increased to 10 million electron volts.

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

D. Other Technical Effects

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

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

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

The agency intended the term "fresh fruits and vegetables" to include mushrooms, which are fruiting bodies of fungi. The agency now believes that the term "fresh foods" may more adequately describe foods such as fruits, vegetables, and mushrooms that are capable of additional growth and maturation but that may be treated with ionizing radiation to inhibit those processes. FDA is revising the regulation accordingly. In addition, the agency agrees that the term "insect control" may be too restrictive. Therefore, the agency is substituting the term "arthropod pests" to include insects, spiders, and mites, but to exclude pests such as bacteria, molds, mice, and rats.

Although the agency believes that the safety of food irradiation below 1 kGy (100 krad) has been established, the agency proposed to limit the use of food irradiation according to intended technical effect rather than simply by dose. This was done both to avoid indiscriminate use of irradiation and to aid enforcement of dose limits because there would be no reason to exceed the permitted dose for the allowed technical effects. For example, overtreatment of fruits and vegetables may adversely affect their marketability. Thus, exceeding the permitted dose would result in a substandard product. In effect, compliance occurs due to a self-limiting factor.

In the specific case of papaya, the agency believes that an adequate commercial radiation facility can be designed for papaya with the current limitation. Alternatively, the agency will review a petition to increase the maximum permitted dose for fresh foods.

The agency is aware that the permitted dose may also be somewhat effective for other uses, such as decreasing the microbial burden in meat, fish, and poultry. FDA did not propose these uses, however, because irradiating at such low doses would not be sufficiently effective for microbial control to be self-limiting. The agency stated in the proposed rule that it would consider other uses below 1 kGy (100 krad) if a petition supported by evidence that a specific technical effect can be

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

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

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

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

Second, at the doses permitted in this regulation, the total amount of radiolytic products consumed is too small to be of concern, either because of low doses or because foods so treated are a minor part of the diet. Further, safety information from animal feeding studies is unnecessary under these circumstances. The proposal stated that FDA is reviewing a number of studies to determine whether foods that are irradiated at doses above 1 kGy (100 krad) can be considered safe without additional toxicological studies. As stated elsewhere in this document, the agency has reviewed these studies and found that five were acceptable by current standards. This data base is inadequate to support a broad decision that all foods may be irradiated safely at higher doses up to 10 kGy (1 Mrad).

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

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

The agency agrees that irradiation of animal feeds to control microbial contamination could be addressed, but not necessarily as part of this rulemaking. Ralston Purina Co. filed a food additive petition (FAP 2198) (December 18, 1984; 49 FR 49181) proposing that the regulations be amended to provide for microbial disinfection of laboratory diets for rats, mice, and hamsters by radiation treatment. The agency responded to this petition in the Federal Register of February 19, 1986 (51 FR 5992). Any interested person able to document the safe use of a source of radiation to treat animal feeds may submit an animal food additive petition for that use under the provisions of 21 CFR Part 571.

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

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

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

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

E. Packaging

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

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

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

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

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

and which may be subjected to incidental irradiation during the radiation treatment of prepackaged foods. This regulation was issued in response to petitions for packaging materials used with food during irradiation in anticipation of expanded uses of food irradiation in the 1960's. Therefore, the agency disagrees with the comment that § 179.45 is unnecessary.

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

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

F. Public Education

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

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

G. Impact Analyses

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

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

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

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

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

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

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

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

The overall safety of transporting radioactive materials was evaluated in the NRC report entitled "Final Environmental Statement on the Transportation of Radioactive Material by Air and Other Modes" (NUREG-0170) (Ref. 75). The report concluded that the total risk from all transportation of such materials was acceptably low. NRC has concluded, after review of the subject, that the regulations are adequate to protect the public against unreasonable risks from the transport of radioactive materials (46 FR 21619; April 13, 1981). NRC believes such shipments can be made safely because licensees shipping radioactive material for use in food irradiators are required to comply with an NRC regulatory program.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

III. Objections

Any person who will be adversely affected by this regulation may at any time on or before May 19, 1986 submit to the Dockets Management Branch (address above) written objections thereto and may make a written request for a public hearing on the stated objections. Each objection shall be separately numbered and each numbered objection shall specify with particularity the provision of the regulation to which objection is made. Each numbered objection on which a hearing is requested shall specifically so state; failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held; failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents shall be submitted and shall be identified with the docket number found in brackets in the heading of this regulation. Received objections may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

IV. References

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

1. *Brunetti, A.P., et al., "Recommendations for Evaluating the Safety of Irradiated

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2. "Food Additives Evaluation Branch. "Final Report for the Task Group for the Review of Toxicology Data on Irradiated Foods." Memorandum to W. Gary Flamm, April 9, 1982.

3. "Bibliography of reports evaluated by the Task Group.

4. "Evaluation forms for the referenced reports.

5. "Cancer Assessment Committee, Center for Food Safety and Applied Nutrition. Memorandum of Conference, October 1, 1984, and January 4, 1985.

6. "National Toxicology Program Board of Scientific Counselors. Final Summary Minutes for the "Peer Review of the Data from the Raltech Lifetime Feeding Study with Irradiated Chicken Meat in CD-1 Mice by the Technical Reports Review Subcommittee and Panel of Experts," held at Research Triangle Park, NC, March 28, 1985.

7. Beyers, M.L., et al., "Chemical Consequences of Irradiation of Subtropical Fruits," *in* "Recent Advances in Food Irradiation," P.S. Elias and A.J. Cohen, eds., Elsevier Biomedical Press, Amsterdam, pp. 171–188, 1983.

8. Basson, R.A. "Advances in Radiation Chemistry of Food and Food Components—An Overview," *in* "Recent Advances in Food Irradiation," P.S. Elias and A.J. Cohen, eds., Elsevier Biomedical Press, Amsterdam, pp. 7–25, 1983.

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10. Committee on Food Additives Survey Data, "1982 Foundage Update of Food Chemicals," Food and Nutrition Board, Commissioner on Life Sciences, National Research Council, National Academy Press, Washington, DC, 1984.

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12. Priyadarshini, E., and P.C. Tulpule, "Effect of Graded Doses of Gamma Radiation on Aflatoxin Production by *Aspergillus parasiticus* in Wheat," *Food and Cosmetics Toxicology*, 17:505–507, 1979.

13. "Board of the International Committee on Food Microbiology and Hygiene, "The Microbiological Safety of Irradiated Food," Report of a meeting with participation of WHO, FAO, and IAEA, Copenhagen, December 16, 1982, CX/FH 83/9, and references contained therein.

14. "Duval-Iflah, P., et al., "R-plasmid Transfer from *Serratia liquefaciens* to *Escherichia coli* in Vitro and in Vivo in the Digestive Tract of Gnotobiotic Mice Associated with Human Fecal Flora," *Infection and Immunity*, 961–990, June 1980, and references contained therein.

15. "Bradley, M.V., L.L. Hall, and S.J. Trebilcock, "Low pH of Irradiated Sucrose in Induction of Chromosome Aberrations," *Nature*, 217:1182–1183, 1968.

16. "Holsten, R.D., M. Sugii, and F.C. Steward, "Direct and Indirect Effects of Radiation on Plant Cells: Their Relation to Growth and Growth Induction," *Nature*, 208:850–856, 1965.

17. "Aiyar, A.S., and S. Rao, "Studies on Mutagenicity of Irradiated Sugar Solutions in *Salmonella typhimurium*," *Mutation Research*, 48:17–28, 1977.

18. Adams S., "Recent Advances in Radiation Chemistry of Carbohydrates," *in* "Recent Advances in Food Irradiation," P.S. Elias and A.J. Cohen, eds., Elsevier Biomedical Press, Amsterdam, pp. 149–170, 1983, and references contained therein.

19. "Diehl, J.F., et al., "Radiolysis of Carbohydrates and of Carbohydrate-containing Foodstuffs," *Journal of Agricultural and Food Chemistry*, 26:15–20, 1978.

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V. Agency Action

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

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

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

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

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

List of Subjects in 21 CFR Part 179

Food additives, Food packaging, Irradiation of foods.

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

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

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

Authority: Secs. 201(s), 409, 72 Stat. 1784–1788 as amended (21 U.S.C. 321(s), 348); 21 CFR 5.10; §§ 179.25 and 179.26 also are issued under secs. 402, 403, 703, 704, 52 Stat. 1046–1048 as amended, 1057, 67 Stat. 477 as amended (21 U.S.C. 342, 343, 373, 374); 21 CFR 5.10, 5.11.

§ 179.22 [Removed]

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

§ 179.24 [Removed]

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

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

§ 179.25 General provisions for food irradiation.

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

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

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

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

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

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

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

5. By adding new § 179.26, to read as follows:

§ 179.26 Ionizing radiation for the treatment of food.

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

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

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

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

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

(b) *Limitations.*

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

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

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

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

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

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

Frank E. Young,

Commissioner of Food and Drugs.

Dated: March 29, 1986.

Otis R. Bowen,

Secretary of Health and Human Services.

[FR Doc. 86-8684 Filed 4-15-86; 11:05 am]

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ALASKA STATE LEGISLATURE
HOUSE OF REPRESENTATIVES
RESEARCH AGENCY

P.O. Box Y, State Capitol
Juneau, Alaska 99811-3100
Mail Stop 3100
(907) 465-3991

May 6, 1988

MEMORANDUM

TO: Representative Randy Phillips

ATTN: Janet Seitz

FROM: Patricia Brawley
Legislative Analyst

RE: **Food Irradiation by Machine-Generated Electron Beams**
Research Request 88.251

You requested information about the machine-generated source of radiation recently recommended by the University of Alaska's Institute of Northern Engineering Food Irradiation Project. You specifically wished to know about the process of food irradiation by electron beams, and the type of fuel used in this process.

High energy electron beam machines are capable of producing, as sources of radiation, accelerated electrons (high energy electron beams) and X-rays. Like X-ray machines in hospitals and dental offices, they are powered by electricity. They contain no radioactive isotopes or materials, so the machines are harmless when the electricity is disconnected. Potential environmental and health risks involved in transportation, storage, and handling of radioactive isotopes (cesium 137 and cobalt 60) are thus eliminated. Problems involving facility maintenance, as well as possible damage from earthquakes, tsunamis, or other disasters are also eliminated. During use, as with X-ray machines, operators must be biologically shielded from the beams produced.

Unlike radioactive isotope sources, which constantly emit gamma rays, machine-generated sources work by a principle of kinetic energy: when objects are not in motion, energy is potential; when in motion, energy is kinetic. According to Dr. John Zarling, Director of the Institute of Northern Engineering and principal investigator of the food irradiation project,

> High energy electrons are produced when electrons emitted from a filament or cathode are accelerated by an electric field in a vacuum tube. This beam of electrons then passes through an alternating magnetic field where it is 'scanned' so it can emerge through a thin metallic window in a fan-shaped configuration.[1]

X-rays are created when high energy electrons hit a metal plate and are accelerated to a very high velocity. Electron beams do not penetrate as deeply as do X-rays, but they are more cost effective to use. High energy electron beams, like X-rays, can be directed or aimed, and thus are both more controllable and more efficient than gamma rays, which are emitted constantly and in all directions.

Hitting lead causes electrons to slow sufficiently for kinetic energy to be lost. Thus, according to Dr. Zarling, high energy electron beam irradiation facilities would require maze-like construction with thick walls of concrete and lead to contain and slow the beams until they return to a harmless state.

All sources recommended for food irradiation (accelerated electrons, X-rays, and gamma rays) produce similar results in foods. Ostensibly, the electron beam machine <u>as a process</u> is far less risky than other potential processes. Questions about the safety of the <u>product</u>--a separate but equally important issue--remain unchanged.

I hope this information is useful to you. If you have further questions, please call.

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[1]Quoted by Dr. Zarling from Morrison and Roberts, "Food Irradiation: New Perspectives on a Controversial Technology," U.S. Department of Agriculture, December 1985.

Patrick A. Lynch, M.D.
Radiologist
209 Moller Avenue
Sitka, AK 99835

June 2, 1988

Representative John Sund
Alaska State Legislature
House of Representatives
P. O. Box Y, State Capitol
Juneau, AK 99811-3100

Dear Representative Sund:

I have come across a copy of a memorandum directed to your attention for the attention of Peggy Sepulveda from Patricia Brawley, Legislative Analyst re the Food & Drug Administration--Objectivity and Reliability Relating to Food Irradiation, your Research Request 88.202.

In reading the response I have the very definite feeling that the analyst sensed a feeling of opposition to food irradiation for the analysis seems quite slanted.

I would, however, point out to you the erroneous conclusion reached in the last paragraph wherein the FDA is accused as being an intermediary for the Department of Energy in a coordinated effort to shift the responsibility for byproducts of nuclear weapon production elsewhere. May I strongly point out to you that this specifically refers to Radioactive Cesium 137 which has been encapsulated and stored at Hanford for many years without incident. Contrary to the opponents of food irradiation Radioactive Cesium 137 is the most ideal isotope for use in irradiation of food no matter what its origin may have been. It has a half-life of 30 years far exceeding that of man made radioactive cobalt. It has an ideal energy of 0.67 MEV thus requiring less protection and source shielding. It has not proven to be any more difficult to handle than any other isotope having been encapsulated safely for over 20 years and used in the Sandia Project.

I would hope that before any final conclusions are reached in your committee that the studies on the safety on radioactive isotopes,

specifically, radioactive Cesium 137 conducted by Dr. Garth Tingey, Batelle Northwest Laboratories of Richland, Washington, under commission from the United States government be available for part of your deliberations so that they may be conducted on the basis of fact and not on wide spread untruths as are promulgated in the last sentence of your analysts report.

Very Truly Yours,

Patrick A. Lynch, M.D.

Patrick A. Lynch, M.D.
Diplomate of the American
Board of Radiology

cc: Patricia Brawley
Peggy Sepulveda

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TESTIMONY BEFORE THE
SUBCOMMITTEE ON HEALTH AND THE ENVIRONMENT
OF THE
HOUSE COMMITTEE ON ENERGY AND COMMERCE
BY
RICHARD PICCIONI, PH.D.
SENIOR STAFF SCIENTIST
ACCORD RESEARCH AND EDUCATIONAL ASSOCIATES
JUNE 19, 1987

I am Dr. Richard Piccioni, Senior Staff Scientist with Accord Research and Educational Associates, a not-for-profit public health research group based in New York City. I hold a doctorate in biophysics from the Rockefeller University, conducted three years of postdoctoral research at the Rockefeller supported by grants from the National Science Foundation and the National Institutes of Health, and was an assistant professor of biological science at the City University of New York, where my research was funded by the US Department of Agriculture and the MacArthur Foundation.

Over the past twenty months a team of biologists, chemists, physicians, and statisticians in our organization have carried

out an in-depth examination of the technical basis of the Food and Drug Administration's recent approvals of food irradiation processing. We feel that there is no assurance in the scientific literature or the arguments of the FDA that the widespread irradiation of food will not be a significant, if silent, threat to the public health. In summary, we feel the FDA has adopted scientifically indefensible criteria for assessing, and in their view, demonstrating, the safety of irradiated foods.

The unique nature of food irradiation processing

Treatment of food with ionizing radiation presents issues of food safety qualitatively unlike those posed by any other food processing method or food additive. The large amount of energy contained in ionizing radiation provides the potential for exceedingly complex chemical transformation of food components, including the production of mutagenic or carcinogenic substances which were not present, or were present in far smaller amounts, before irradiation. This potential far exceeds that of ordinary heat processing, microwave radiation, etc., because the energy contained in each "quantum" of gamma radiation is so great. At the same time, because the production of these "radiolytic

products" takes place within the food itself, it is impossible to design a toxicological test in which animals are exposed to exaggerated doses of these products, the chemical identity of which remains largely unknown. Thus toxicologists are limited to biological testing which is thousands of times less sensitive than the testing typically required or other chemical additives or pesticide residues.

It should be clearly understood that without toxicological testing at exaggerated doses, the carcinogenic risk to large human populations ingesting any additive or residue is impossible to assess. Exposure of test animals to exaggerated doses is the most basic tool in use in estimating carcinogenic risk. In the case of food irradiation, this tool is simply not available.

At the same time, evidence from other types of experiments provides a strong indication that mutagens and/or carcinogens are indeed present in irradiated foods. What such experiments are unable to provide, however, is a quantitative estimate of the risk. In the absence of such a estimate, it is completely irresponsible to proceed with the sale and distribution of irradiated foods. Consequently, recent approvals by the FDA for food irradiation processing should be immediately rescinded.

Basis of FDA's approvals

To understand how this has come to pass, we must briefly review some recent history: In 1979, after years of controversy and false starts, radiation food processing was re-evaluated by a specially appointed FDA committee, the BFIFC (Bureau of Foods Irradiated Foods Committee). They acknowledged that feeding whole, irradiated foods to test animals, even over long periods of time, was completely inadequate to assess the carcinogenic potential of the radiolytic products present in those foods. As an alternative to direct biological testing, they proposed acceptance of a theoretical calculation of the maximum concentration of radiolytic products present in irradiated food and made the extraordinary leap of faith that parts-per-million residues of unknown substances pose no risk when ingested by millions of people over their entire lives.

Subsequently, an FDA task force reiterated the BFIFC recommendations, and reported the results of an elaborate "review" of the available literature on the toxicological testing of irradiated foods, testing which they, as well as the BFIFC, agreed was inherently incapable of providing definitive evidence of the safety of irradiated foods. The five studies which have been mentioned by others at this hearing provided, according to the FDA itself, only the assurance that irradiated food is not wildly mutagenic and/or carcinogenic. The task

force therefore justified its conditional approval of irradiation of fruits and vegetables with up to 100 kilorad, and spices with up to 3 million rad, on the same theoretical basis as proposed by BFIFC.

Positive evidence of carcinogenic risk

Proponents of food irradiation commonly claim there are no studies in the scientific literature showing mutagenic or carcinogenic activity in irradiated foods or food components. In fact, as our own literature survey has shown (Table I) dozens of such studies exist, observed in a variety of biological systems , published by a variety of authors in a variety of peer-reviewed scientific journals over a period of twenty years. Proponents of food irradiation commonly claim that the chemical changes occurring in irradiated foods are thoroughly understood, and that there have been no studies indicating the formation of known mutagens or carcinogens. In fact, a substantial number of studies can be found in the open scientific literature indicating the presence of known mutagens, carcinogens, or cytotoxic substances in food or food components which have been irradiated (Table 2). Furthermore, the radiation chemistry of foods is far from fully understood, as evidenced by a steady appearance in the literature of studies on new radiolytic products found in various irradiated foods (e.g., Simic and Jovanovic (1986), Akhlaq et al. (1987)). Many of

these radiolytic products have not been individually tested for mutagencity or carcinogenicity.

In short, the available scientific literature provides evidence to make a strong presumption of carcinogenicty in some if not all irradiated foods. The question is one of quantifying the risk.

Pesticide replacement

In the absence of a quantitative estimate of the carcinogenic risk posed by the consumption of irradiated foods, there is no basis to the further claim that food irradiation could replace carcinogenic pesticides with an improvement in the overall quality of the food supply. Recently, the National Academy of Sciences (1987) identified 23 pesticides which are responsible for the vast majority of the total carcinogenic risk posed by the presence of pesticide residues in the US food supply. Food irradiation would make essentially no contribution to the elimination of these pesticides since of the 23, several are herbicides or insecticides applied in the field to prevent pre-harvest losses (Chemical and Pharmaceutical Press, 1987), and the remainder are fungicides, whose replacement by irradiation is a highly dubious proposition (Sommer, 1966 and personal communication). In fact irradiation of fruits and vegetables may well increase, rather than decrease, the

requirement for post-harvest application of fungicides because irradiated products are more susceptible to infection by molds and fungi (Sommer, op. cit., and Niemand et al., 1985).

Radiation treatment of Salmonella-contaminated poultry

On the question of the use of ionizing radiation to inactivate Salmonella in poultry, it is important to understand two points::

1. Doses required for even partial "pasteurization" of poultry meat are far greater than the doses which have been deemed "safe" by any of the evidence or arguments provided by the FDA to date. The "massive" feeding studies of 5 megarad irradiated chicken are no more capable of assessing carcinogenic risk than are any of the other irradiated-food feeding studies the FDA has categorically dismissed before; all lack the dose-exaggeration factor essential to any valid toxicological test. All of the concerns of the presence of trace mutagens or carcinogens in foods irradiated at "low" doses of 100,000 rads are only greater at doses of one million rads, required for even partial Salmonella inactivation.

2. Major unresolved microbiological questions arise regarding the safety of gamma processing of

salmonella-contaminated poultry: much of the virulence of recent cases of salmonellosis has been attributed to the presence of antibiotic resistant strains of the pathogen, due in turn to the use of these antibiotics in the poultry industry (Cohen and Tauxe, 1986), the addition of a highly mutagenic processing procedure, namely, gamma irradiation, on poultry carcasses still containing low levels of antibiotics is an appalling scenario for the appearance in the irradiated food of new, antibiotic-resistant strains. This issue has received serious, but not adequate, attention in the scientific literature (Privet et al., 1971).

Enhancement of aflatoxin production

The FDA has also been quick to dismiss concerns that irradiation of Aspergillis flavus spores or the grains upon which this fungus can grow, can increase the production of the potent carcinogen aflatoxin (Federal Register, 4/18/86) citing and dismissing a single study on the subject. In fact (Table 3) there have been several studies showing serious aflatoxin--enhancement effects at or near the very doses proposed for the irradiation of grain.

Summary: rescind FDA approvals

In summary, the continuing research effort by our organization indicates clearly that recent and pending approvals of food irradiation processing by the FDA should be rescinded, and the same degree of caution now being expressed by several state and national agencies around the world be implemented on a federal level.

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Table 1 BIOASSAYS ON IRRADIATED ORGANIC MEDIA AND FOODS SHOWING POSITIVE MUTAGENICITY, CHROMOSOMAL DAMAGE, TERATOGENICITY, OR CYTOTOXICITY (page 1)

author(s)	date	irradiated material	observation	observed in
Kuzin & Kryukova	1961	plant leaves	chromosomal damage	plant embryos
Swaminathan et al.	1962	potato mash	chromosomal damage	barley embryos
Kuzin	1963	plant leaves	mutagenicity of extracts	plant cells
Swaminathan et al.	1963	culture medium	mutagenicity	drosophila
Chopra & Swaminathan	1964	potato mash	devel. abnormalities	barley embryos
Molin & Ehrenberg	1964	culture medium	cytotoxicity	bacteria
Berry et al.	1965	various sugars	cytotoxicity	human & mouse cells
Chopra	1965	culture medium	probable mutagenicity	bacteria
Holsten et al.	1965	coconut milk, sucrose	chromosomal damage	carrot explants
Parkash	1965	nucleic acids	mutagenicity	drosophila
Rinehart & Ratty	1965	culture medium	mutagenicity	drosophila
Frey & Pollard	1966	culture medium	mutagenicity	bacteria
Shaw & Hayes	1966	sucrose	chromosomal damage	human lymphocytes
Hills & Berry	1967	glucose	cytotoxcity	mouse fibroblasts
Hollowell & Littlefield	1967	plasma	chromosomal damage	human lymphocytes
Makinen et al.	1967	pineapple	chromosomal damage	onion roots
Parkash	1967	nucleic acids	mutagenicity	drosophila
Rinehart & Ratty	1967	nucleic acids	mutagenicity	drosophila
Rinehart & Ratty	1967	culture medium	mutagenicity	drosophila
Schubert et al.	1967	sucrose	cytotoxicity	bacteria
Steward et al.	1967	sucrose	cytotoxicity	carrot explants
Hollowell & Littlefield	1968	plasma	chromosomal damage	human leucocytes
Melette et al.	1968	wheat endosperm	mutagenicity	wheat
Ammirato & Steward	1969	sucrose	devel. abnormalities	plant root cells
Chopra	1969	culture medium	mutagenicity	bacteria
Moutschen-Dahmen et al.	1970	laboratory diet	preimplantation death	mouse
Schubert and Sanders	1971	various sugars	cytotoxicity	bacteria
Kopylov et al.	1972	potatoes	mutagenicity of extracts	mouse (sperm cells)
Kopylov et al.	1973	potatoes	mutagenicity	mouse
Bhaskaram & Sadasivian	1975	wheat	polyploidy	malnourished children
Vijayalaxmi & Sadasivan	1975	wheat	chromosomal damage	rat (bone marrow)
Vijayalaxmi	1975	wheat	polyploidy	rat (bone marrow)
Vijayalaxmi	1976	wheat	mutagenicity	mouse
Vijayalaxmi	1976	wheat	sperm count reduction	mouse
Vijayalaxmi	1976	wheat	polyploidy	mouse (bone marrow)
Vijayalaxmi	1976	wheat	aneuploidy	mouse (sperm cells)
Vijayalaxmi & Rao	1976	wheat	mutagenicity	rat
Vijayalaxmi & Rao	1976	wheat	sperm count reduction	rat

BIOASSAYS ON IRRADIATED ORGANIC MEDIA AND FOODS SHOWING POSITIVE MUTAGENICITY, CHROMOSOMAL DAMAGE, TERATOGENICITY, OR CYTOTOXICITY

author(s)	date	irradiated material	observation	observed in
Aiyar & Rao	1977	various sugars	mutagenicity	bacteria
FAO/IAEA/WHO	1977	potatoes	mutagenicity of extracts	mouse
Renner	1977	laboratory diet	polyploidy	hamster
Levina & Ivanov	1978	laboratory diet	autoimmune disease	rat
Vijayalaxmi	1978	wheat	low antibody levels	rat
Vijayalaxmi	1978	wheat	polyploidy, other effects	monkey
Wilmer et al.	1979	nucleic acids	mutagenicity	bacteria
Ivanov & Levina	1981	laboratory diet	testicular abnormalities	rat
Wilmer et al.	1981	nucleosides	mutagenicity	bacteria

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New York, NY (212)580-3889

able 2 IDENTIFICATION OF MUTAGENIC, CARCINOGENIC, OR CYTOTOXIC RADIOLYTIC PRODUCTS IN IRRADIATED ORGANIC MEDIA OR FOOD

uthor(s)	date	irradiated material	radiolytic product	comments
uzin	1965	plant matter, rat thymus, tyrosine	orthoquinones orthophenols	carcinogenic carcinogenic
erry et al.	1965	dextrose, fructose	glyoxal formaldehyde	mutagenic mutagenic
l Zeany	1980	buffalo meat	peroxides carbonyl compounds	mutagenic cytotoxic
ower & Wills	1986	benzpyrene, starch & oil mixtures	benzo(a)pyrenes quinones malonaldehyde lipid peroxides	carcinogenic carcinogenic mutagenic mutagenic
chubert et al.	1967	sucrose	hydroxyalkyl peroxides glyoxal	mutagenic mutagenic
chubert & Sanders	1971	D-glucose, D-fructose, D-mannose, D-rhamnose, D-galactose, D-fucose	alpha, beta-unsaturated carbonyl sugars	cytotoxic (toxicity increased upon heating irradiated solution)
teward et al.	1967	sucrose	formic acid	mutagenic
rey & Pollard	1966	minimal cell medium	hydrogen peroxide	mutagenic, generates secondary mutagens
hopra	1969	glucose	organic peroxides	mutagenic
uzin	1963	plant tissues	organic peroxides orthoquinones	mutagenic carcinogenic
ilmer et al.	1981	deoxy-D-ribose, D-ribose	hydrogen peroxide malonaldehyde carbonyl compounds	mutagenic mutagenic cytotoxic
rooks & Klamerth	1968	glucose	glyoxal malonyldialdehyde	mutagenic, binds to DNA mutagenic, binds to DNA

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Table 3 PUBLISHED STUDIES INDICATING INCREASED ~~ALFLATOXIN~~ AFLATOXIN PRODUCTION AFTER IRRADIATION

author	date	irradiated material	dose
Jemmali & Guilbot	1969	Aspergillis flavus spores	75 - 200 krad
Schindler & Noble	1970	Aspergillis flavus spores	20 - 500 krad
Priyadarshini & Tulpule	1976	wheat, potatoes, maize, sorghum, millet	10 - 75 krad
Priyadarshini & Tulpule	1979	wheat	50 - 250 krad
Schindler et al.	1980	Aspergillis flavus spores	75 - 450 krad

Accord Research and Educational Associates
New York, NY (212)580-3889
6/15/87

Alaska State Legislature
House

Official Business

REPRESENTATIVE RANDY PHILLIPS
HOUSE DISTRICT 15
(907) 465-4949

P.O. BOX V
State Capitol
Juneau, Alaska 99811

Memorandum

TO: Representative John Sund, Chairman
House Judiciary Committee

FROM: Representative Randy Phillips

DATE: March 10, 1988

RE: CSHB 388 (HESS)

Attached is a memorandum from Theresa L. Bannister, Legislative Counsel. This memorandum discusses the federal preemption clause, an issue raised by Representative Gruenberg at yesterday's committee meeting.

If you have any questions, please do not hesitate to contact me. Thank you for your assistance.

Attachment
cc: Rep. Fran Ulmer (w/attachment)
Rep. Sam Cotten (w/attachment)
Rep. Max Gruenberg (w/attachment)
Rep. Mike Navarre (w/attachment)
Rep. Ramona Barnes (w/attachment)
Rep. Robin Taylor (w/attachment)

STATE OF ALASKA
THE LEGISLATURE

LEGISLATIVE AFFAIRS AGENCY

POUCH Y STATE CAPITOL
JUNEAU ALASKA 99811
907 465 3800

M E M O R A N D U M March 10, 1988

SUBJECT: Federal preemption and CSHB 388(HESS)

TO: Representative Randy Phillips

FROM: Theresa L. Bannister
Legislative Counsel

You have requested an opinion whether the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) (herein FDCA) preempts the prohibition in CSHB 388(HESS) against the sale of irradiated food. Although I do not believe that the issue is strictly black and white, in my opinion the FDCA would not preempt this prohibition.

At the outset, there is no specific preemption provision in the FDCA for this area; the FDCA does not explicitly address state laws other than for margarine. Next, the proposed prohibition does not stand as an obstacle to the accomplishment and execution of the purposes and objectives of the FDCA, since the goal of the FDCA relevant to this inquiry is to protect the individual from unsafe food, and the goal of the proposed law is the same. Finally, the proposed law does not directly conflict with the FDCA. Although the FDCA allows the use of irradiation in certain foods, it does not mandate the sale of these foods, but merely prescribes the conditions under which such things as irradiation may be safely used in certain foods. (See 21 U.S.C. 348).

In addition, I believe that a court would hesitate to preempt this proposed law for two reasons. The first reason is that the prohibition of the sale of irradiated food in the state falls within the traditional police powers of the state to protect the health and welfare of its inhabitants. The second reason is that there is a growing reluctance of courts to infer federal preemption of state laws. 55 U. S. Law Week 2226.

In conclusion, I believe that it is unlikely that a court would hold that the prohibition proposed by CSHB 388(HESS) against the sale of irradiated food to be preempted by the Federal Food, Drug, and Cosmetic Act.

If I may be of further assistance, please advise.

TLB:gc
WKG2:45

Alaska Center for the Environment

700 H Street, Suite 4 • Anchorage, Alaska 99501 • (907) 274-3621

March 8, 1988

To House Judiciary Committee Members:

Alaska Center for the Environment is a nonprofit citizens organization interested in environmental protection. We support HB 388, relating to irradiated food.

We understand that the US Department of Energy has contracted with the University to construct a demonstration plant to irradiate fish. We are concerned about the possibility of having this type of facility in Alaska because of the risks involved. These risks include transportation accidents, releases through leaks or emissions or spills of radioactive materials. The Cesium-137 that is to be used would likely contaminate groundwater if spilled to the ground because of its solubility in water. Also, how would it be decided where to locate such a facility--will seismicity, flooding and environmentally unsuited areas be excluded from consideration?

We support passage of HB 388 as a step towards discouraging the development of the food irradiation industry in Alaska. There is too much that is unknown about the molecular changes in food resulting from irradiation and the production of unique radiolytic products to be assured that it is a safe process. In fact, of 413 available studies on food irradiation, the FDA found only 5 studies that appear to support safety (from Final Report Task Group Irradiated Food, U.S. Department of Health. April 1982).

Sincerely,

Kristine Benson

Kristine Benson
Hazardous Waste Specialist

(7)

HOUSE COMMITTEE REPORT

Date referred: 1/22/88 FURTHER REFERRALS: Judiciary

DATE: 2-23-88

The Health, Education and Social Services Committee has considered HB 388

"An Act relating to irradiated food."

RECOMMENDS:

[X] replace with CS HB 388 (HESS) [X] the same title

[ ] attached amendment(s) [ ] a new title

[X] do pass

[ ] do not pass

[ ] no recommendation

[ ] individual recommendations

[ ] additional referral to the _____ Committee

ADOPTS: [ ] _____ letter of intent

ATTACHES NEW FISCAL NOTE(s):

[X] fiscal impact

[ ] zero fiscal note

[ ] zero with analysis

[ ] same as previous fiscal note published _____

[ ] same as previous zero fiscal note published _____

SIGNING DO PASS:

SIGNING OTHER RECOMMENDATIONS:

M. E. Greenberg / No Rec

Chairman's signature

POSITION PAPER/Department of Health & Social Services

Position Paper

HB 388

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

HB 388 prohibits the sale of irradiated food including spices and food that contains an irradiated ingredient unless the only irradiated ingredient is a spice. While it appears passage of this bill would have economic impact due to the long established practice of irradiating spices, the scope of this position paper is limited to the health considerations of irradiated food.

Background

The health aspects of irradiated food have been studied for many years. The Food and Drug Administration (FDA) has conducted exhaustive reviews of all available studies and has determined that irradiated food is safe for human consumption. The FDA has concluded there is no scientific evidence meeting FDA standards for toxicological studies that shows adverse effects on health from the consumption of irradiated food. Results of studies used to support claims of harmful effects have been rejected due to lack of adequate scientific controls or design, including radiation doses far in excess of those considered acceptable for food processing. In its conservative approach, the FDA has approved the irradiation of certain foods only, and it has limited the radiation doses to one-tenth of those shown to be safe. This position is supported by such diverse groups as the Council for Agricultural Science and Technology, the World Health Organization, the Food and Agricultural Organization of the United Nations, the American Medical Association, and the International Atomic Energy Agency.

In addition to the FDA, numerous national and international organizations recognized in health, food technology, and radiation safety have closely examined claims of harmful effects presently being made by those opposed to food irradiation. In every case, these organizations have judged irradiated food to be safe for human consumption.

Position

Without acceptable scientific evidence showing that irradiation is harmful to health, the department believes it is inappropriate to forbid the sale of irradiated food in the state. Proper labeling of irradiated foods will allow those opposed to it to exercise their choice in the foods they purchase.

The Department of Health and Social Services opposes passage of HB 388.

POSITION PAPER/Department of Health & Social Services

Recommended by: Elizabeth Ward

Elizabeth Ward, M.N.
Director
Division of Public Health

Date: February 2, 1988

Approved by: Myra M. Munson

Myra M. Munson
Commissioner
Department of Health and Social Services

Date: Feb 2 1988

STATE OF ALASKA
1988 LEGISLATIVE SESSION

BILL VERSION: HB 388
PUBLISH DATE: _____

FISCAL NOTE

REQUEST:

Revision Date: 1/22/88
Title: An Act relating to irradiated food.
Sponsor: Phillips and Goll
Requestor: _____

Agency Affected: Health & Social Services
BRU: State Health Services
_____
Components: _____
_____

EXPENDITURES/REVENUES: (Thousands of Dollars)

OPERATING	FY 88	FY 89	FY 90	FY 91	FY 92	FY 93
PERSONAL SERVICES						
TRAVEL						
CONTRACTUAL						
SUPPLIES						
EQUIPMENT						
LAND & STRUCTURES						
GRANTS, CLAIMS						
MISCELLANEOUS						
TOTAL OPERATING	-0-	-0-	-0-	-0-	-0-	-0-
CAPITAL						
REVENUE						

FUNDING: (Thousands of Dollars)

GENERAL FUND						
FEDERAL FUNDS						
OTHER						
TOTAL	-0-	-0-	-0-	-0-	-0-	-0-

POSITIONS:

FULL-TIME						
PART-TIME						
TEMPORARY						

ANALYSIS: (Attach a separate page if necessary)

The enactment of HB 388 would have no direct fiscal impact on the Department of Health and Social Services.

Prepared by: Elizabeth Ward, Director Phone: 465-3090
Division: Public Health Date: 2-2-88

Approved by Commissioner: Mona M Munson Date: 2-2-88
Agency: Department of Health & Social Services

Distribution (by preparer):
Legislative Finance
Legislative Sponsor
Requestor
Office of Management and Budget
Impacted Agency(ies)

POSITION PAPER
DEPARTMENT OF ENVIRONMENTAL CONSERVATION

House Bill No. 388 February 2, 1988

"An act prohibiting the sale of irradiated food."

Department position:

The Department has not taken a position on this bill for the following reasons. The Department has no staff with training and experience in the irradiation of food. The Department's expertise regarding food products is inspecting the sanitary operations of food production facilities. There is a large amount of information and scientific data on this issue. Although review and analysis of the available data are beyond the Department's current capacity to effectively review and analyze, we are pleased to assist the committee in identifying useful information, including the following background.

FDA Requirements

The treatment of certain food products and spices with ionizing radiation is approved by the U.S. Food and Drug Administration (FDA). FDA has approved the following application dosages: for foods which can comprise more than 0.01% of the daily diet, the dosage cannot exceed 1 kilogray (KGy); for foods which can comprise less than 0.01% of the daily diet, dosage cannot exceed 50 KGy.

FDA Approved Sources of Irradiation

Approved irradiation sources include: radioactive isotopes (Cobalt-60 or Cesium-137) and machines (x-ray or electron beam).

FDA Foods Approved for Irradiation

FDA has approved the application of irradiation to the following foods: fruits/vegetables (slow growth and ripening and control insects); dried spices and herbs (kill insects and control microorganisms); pork (control trichinosis); white potatoes (growth and maturation inhibition); and wheat and wheat flour (control insects).

FDA Labeling Requirements

Labeling requirements have also been imposed by FDA to ensure that the consumer is aware that food they are consuming has been irradiated. Treated products contain a label statement that contains the international irradiation process logo (tulip) and

the statement "treated with radiation" or "treated by irradiation". On April 18, 1988 the requirement for the written warning is scheduled to be withdrawn. This action would leave only the international irradiation process logo on retail packages. FDA has informed DEC that this will probably not occur since the average consumer probably does not know what the logo symbolizes.

Enforcement

The department would enforce the provisions of this bill by inspecting food distributors, warehouses, and retail and wholesale outlets for food labeled with the federally required irradiation symbol and product statement. If irradiated food was found during the course of inspection, the department would embargo the product under the authority in 17.020.230 and require that it be destroyed or returned to an out-of-state distributor.

STATE OF ALASKA
1988 LEGISLATIVE SESSION

BILL VERSION : HB 388
PUBLISH DATE : 1/22/88

FISCAL NOTE

REQUEST:

Revision Date: -
Title : An Act relating to irradiated food.
Sponsor : Peter Goll and Randy Phillips
Requestor : Randy Phillips

Agency Affected : Environmental Conservation
BRU : Environmental Health
Components : Sanitation

EXPENDITURES/REVENUES: (Thousands of Dollars)

OPERATING	FY 88	FY 89	FY 90	FY 91	FY 92	FY 93
PERSONAL SERVICES	-	14.9	14.9	14.9	14.9	14.9
TRAVEL	-	-	-	-	-	-
CONTRACTUAL	-	2.0	2.0	2.0	2.0	2.0
SUPPLIES	-	1.0	1.0	1.0	1.0	1.0
EQUIPMENT	-	-	-	-	-	-
LAND & STRUCTURES	-	-	-	-	-	-
GRANTS, CLAIMS	-	-	-	-	-	-
MISCELLANEOUS	-	-	-	-	-	-
TOTAL OPERATING	0	17.9	17.9	17.9	17.9	17.9
CAPITAL	0	0	0	0	0	0
REVENUE	0	0	0	0	0	0

FUNDING: (Thousands of Dollars)

GENERAL FUND	0	17.9	17.9	17.9	17.9	17.9
FEDERAL FUNDS	0	0	0	0	0	0
OTHER	0	0	0	0	0	0
TOTAL	0	17.9	17.9	17.9	17.9	17.9

POSITIONS:

FULL-TIME	-	-	-	-	-	-
PART-TIME	-	1	1	1	1	1
TEMPORARY	-	-	-	-	-	-

ANALYSIS : (Attach a separate page if necessary)

Attached.

Prepared by : Douglas C. Donegan
Phone : 465-2609
Division : Environmental Health
Date : 2/2/88

Approved by Commissioner : Dennis D. Kelso
Date : February 2, 1988
Agency : Environmental Conservation

Distribution (by preparer) :
Legislative Finance
Legislative Sponsor
Requestor
Office of Management and Budget
Impacted Agency(ies)

STATE OF ALASKA

OFFICE OF THE GOVERNOR

BILL ANALYSIS

DEPARTMENT	DIVISION	BILL NUMBER	SPONSOR
Environmental Conservation	Environmental Health	HB 388	Peter Goll and Randy Phillips

SHORT TITLE OF BILL

"An Act relating to irradiated food"

DEPARTMENT POSITION: The passage of HB 388 would require that the Department expand it's inspection activities at approximately 500 retail markets to ensure that irradiated products were not being sold. The additional time per inspection is estimated to be approximately (Continued)

PREPARED BY	DATE	COMMISSIONER'S SIGNATURE	DATE
Douglas C. Donegan	2/2/88	Dennis D. Kelso	

SUMMARY

OTHER AGENCIES AFFECTED BY BILL	CONSTITUENT GROUP(S) AFFECTED BY BILL
ORGANIZATIONAL SUPPORT FOR BILL	**ORGANIZATIONAL OPPOSITION TO BILL**

FISCAL IMPACT: ☐ NONE ☐ FISCAL NOTE ATTACHED

BACKGROUND/LEGISLATIVE INTENT

ANALYSIS OF BILL/PROGRAM EFFECTS

AMENDMENTS PROPOSED

PLEASE ATTACH A SEPARATE SHEET FOR ADDITIONAL COMMENTS OR ANALYSIS.

01-009 (Rev. 12/83)

one (1) hour per inspection. These facilities are inspected once per year.

The Department would begin inspecting 51 retail markets in the Municipality of Anchorage, which are not currently inspected by the department. It is estimated that the inspection of these markets would be approximately 2 hours including travel time.

This inspection effort would amount to a total of 602 hours/year or about four months/year.

Position Title	No. of Positions	Range/Step	Barg. Unit
Environmental Sanitarian II	1	16/A	G

Time Status	Staff Months	Location	Election District
F	Four (4)	Anchorage, Ak.	7

Type of Expenditure		Amount
1	2	3
Salary	11.2	
Benefits	3.7	
Premium Pay	-	
Other	-	
Total Personal Services		14.9
Travel		-
Contractual		2.0
Commodities		1.0
Equipment		-
Other		-
Total Cost		17.9

Funding Source for Total Cost		
Federal Receipts	1002	-
G. F. Match	1003	-
General Fund	1004	17.9
GF Program Receipts	1005	-
Other		-

Justification

This position is required to support the implementation of HB 388 "An Act relating to irradiated food." Approximately 500 retail markets would be inspected to ensure that prohibited products were not being sold. All retail markets would be contacted and notified of the new law. It is estimated that the inspection of these facilities would require approximately 2 hours each, including travel time.

The additional inspection effort would amount to a total of 602 hours per year or about four months per year.

Request For New Position

Agency Environmental Conservation

BRU Environmental Health

Component Sanitation

Revised Date

FY 89