HB

388

(11)

HOUSE COMMITTEE REPORT

Date referred: 3/14/88 FURTHER REFERRALS:

DATE: 4-22-88

The Finance 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

[ ] do pass

[ ] do not pass

[X] no recommendation

[ ] individual recommendations

[ ] additional referral to the ______ Committee

ADOPTS: [ ] ______ letter of intent

ATTACHES NEW FISCAL NOTE(s):

[ ] fiscal impact

[X] zero fiscal note

[ ] zero with analysis

[X] same as previous fiscal note published 2/24/88

[ ] same as previous zero fiscal note published ______

SIGNING DO PASS:

Pete Jones

Kay Wallis

Terry Brown

SIGNING OTHER RECOMMENDATIONS:

Al Adams - No Rec.

[illegible] No Rec

Ron Larson No Rec.

[illegible] No Rec

Mark Boyer No Rec.

Steve Frank No Recommendation

[illegible] No Rec.

Mike Davis No Rec

Al Adams

Chairman's signature

STATE OF ALASKA
1988 LEGISLATIVE SESSION

BILL VERSION: CSHB 388(HESS)
PUBLISH DATE: HOUSE 2/24/88

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. Lonegan
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)

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

Page 2 of 2

Revised Date

FY 89

No. 1

CSHB 388(HESS)
HOUSE 2/24/88

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 Elizabeth Ward Phone: 465-3090
Division: Public Health Date: 2-2-88

Approved by Commissioner: Myra 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)

RECEIVED
FEB 4 1988

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

Offered: 2/24/88
Referred: Judiciary

5-1671B

Original sponsors: Phillips, Goll and Taylor

IN THE HOUSE

BY THE HEALTH, EDUCATION AND SOCIAL SERVICES COMMITTEE

CS FOR HOUSE BILL NO. 388 (HESS)

IN THE LEGISLATURE OF THE STATE OF ALASKA

FIFTEENTH LEGISLATURE - SECOND SESSION

A BILL

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

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

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

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

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

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

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

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

(5) the dissemination of a false advertisement;

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

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

in good faith;

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

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

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

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

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

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

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

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

(B) "irradiated food" does not include spices that have been irradiated or food that contains spices that have been irradiated unless there are other irradiated ingredients in the food.

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

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

THE ROLE OF IRRADIATION IN FOOD PROCESSING:

CAN IT BENEFIT ALASKA?

by

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Circular 64

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INTRODUCTION

Processing food to preserve it for later use is a familiar technique. Canning, freezing, drying, pasteurization, sterilization, and chemical treatment of foods are commonly used and accepted processes. Methods of food processing are continuously being improved through research and development to bring high-quality, wholesome products into the marketplace.

Another preservation process, food ionization or irradiation, has been the subject of research and development for over 40 years. Although not as well known to consumers in the United States, it is used to preserve many different food products throughout the world. For example, potatoes are treated in Japan to inhibit sprouting, frozen fishery products are treated in the Netherlands to extend shelf life, and mangoes are treated in South Africa for insect disinfestation (Van Koij 1986).

The American consumer is not as likely to encounter food that has been irradiated as are consumers in other parts of the world. The United States Food and Drug Administration (FDA) is known internationally for its strict food safety program. Extensive testing is required before FDA will approve the preservation of food products using new methods. Once approved, newer methods often replace existing ones. Currently, there is speculation that the ionizing radiation technique may, in the future, replace chemical use in the processing of many foods, particularly fresh fruit (Loaharanu and Urbain 1982, USDA 1987), because it eliminates any possible chemical residue from post-harvest treatments. In food-related surveys, consumers have indicated that they prefer irradiated foods over foods preserved with chemicals (Sloan 1985). Use of irradiation to replace chemical treatment in food processing would parallel its adoption for the sterilization of medical products during the past 20 years. Indeed, the United States consumer is more likely to use irradiated food-packaging, pharmaceutical, and cosmetic products than irradiated food products (Markovic 1985).

Treatment of Alaska-produced food products by ionizing radiation may benefit the seafood and agricultural industries and the Alaskan consumer. A feasibility study to evaluate the potential social and economic benefits and risks as well as the costs of using the process in Alaska on Alaskan products is being coordinated by the Institute of Northern Engineering. A research and development project to determine effects on the quality of Alaskan products could be the next phase in the introduction of a new food-preservation technique to Alaska.

FOOD IRRADIATION PROCESS

Irradiation is used primarily to extend shelf life of food. The shelf life of perishable foods such as fresh fish, poultry, and meats can be extended two to three times. It may be used with other conventional processes or used alone as a single process replacing other techniques. Products are exposed to an ionizing radiation source that produces charged particles or ions. Because of this, the technique also is called ionizing energy preservation. Doses of radiation vary depending on the product, and the levels which can be used are regulated (Lecos 1986).

Irradiation can be used to preserve food (fig. 1) because ions passing through the food break chemical bonds in the microorganisms destroying them. Insects can be killed or sterilized. Further ripening and sprouting of fruits and vegetables also can be slowed as seen in Figure 2. The food does not become radioactive during the ionizing process any more than one's teeth become radioactive after a dental X ray. The irradiation process produces little, if any, change in the appearance of the food because the temperature of the food is raised only a few degrees (IFT 1983). There are small changes in the structural bonds that may alter the product slightly. For example, irradiated dried peas and beans cook faster than the conventionally dried product, and irradiated meat is tenderized. Potatoes do not turn green after exposure to light, indicating that solanin, a naturally occurring toxin, is not formed (Loaharanu and Urbain 1982).

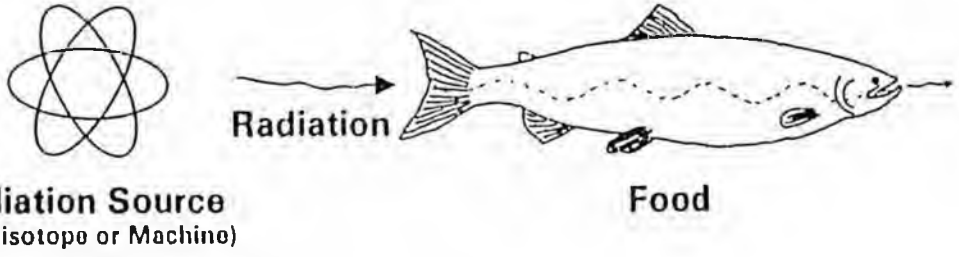

Figure 1. How food irradiation works.

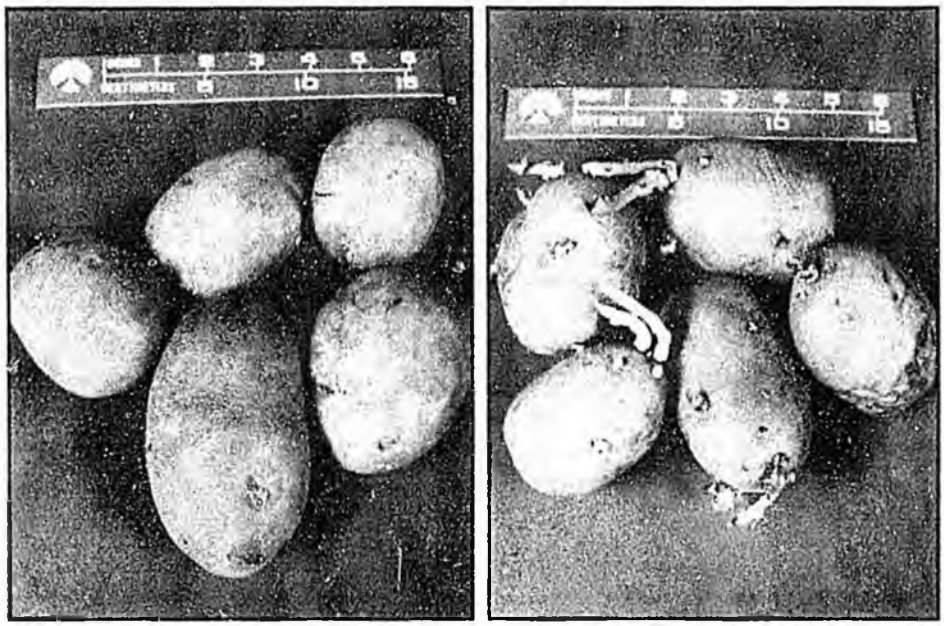

Figure 2. Sprout inhibition of supermarket potatoes stored at room temperature for one month. Control samples that received no additional treatment have sprouted after the one month storage period. Treated samples have not sprouted (Photographs courtesy of H. Farrar, IV, and G. Subbaraman).

LABELING

Foods treated with irradiation look like, or in some cases look better (Bruhn and Noell 1987) than, traditionally handled foods. Unlike foods preserved by some other processes, labeling is required in the United States so that the primary purchaser is aware that the food has been processed by ionization (FDA 1986). The logo in Figure 3 is the international radura (irradiation) symbol used for labeling.

There are labeling guidelines for all irradiated foods sold directly to consumers. At the present time, one of the following statements must accompany the radura logo: 1) "treated with radiation," or 2) "treated by irradiation." Such unpackaged products as potatoes or papayas must either be labeled individually, on the bin, or with a counter sign or card at the point of purchase (FDA 1986). When combination food products like cake mixes and salad dressings contain irradiated ingredients, such as spices, the package does not have to be labeled. Small quantities are involved, and it is considered obvious that the product has been processed in some way (FDA 1986).

Any product that is irradiated prior to wholesale distribution must also be labeled. This regulation is to prevent the reirradiation of foods during processing. The FDA allows a product to be irradiated only once, no matter how small the total dose would be. The statement "treated with radiation, do not irradiate again" or the statement "treated by irradiation, do not irradiate again" is required (FDA 1986).

Figure 3. Radura logo required for labeling (FDA 1986).

CURRENT USES OF IRRADIATED FOODS IN THE UNITED STATES

The FDA determines what food products can be treated with ionization and at what levels and for what purposes in the United States. The agency has approved ionization treatment of the food products in Table 1. Poultry and fish are not presently on the approved list. Because of the presence of Salmonella, a common source of food-borne illness (food poisoning), and increased awareness of the high levels of this and other disease-carrying bacteria present in products reaching retailers' shelves (Kampelmacher 1985), a petition has been filed to allow irradiation of poultry (Josephson and Brynjolfsson 1987, USDA-FSIS 1986). A petition to allow irradiation of fish for commercial sale is expected in the near future.

The FDA's approval for some food products dates from the 1960s, although the average American consumes little irradiated food. This is not true for American astronauts who began eating irradiated food in outer space during the Apollo missions (IFT 1983). In at least one United States hospital, patients who cannot tolerate disease-carrying organisms, consume irradiated foods. Foods eaten by these patients range from pastry and bread products to beverages and are preferred over the alternatives because they have normal appearance, taste, and texture (Aker 1984).

Table 1. Foods approved for irradiation in United States.

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

(Lecos, C.W. 1986, FDA 1986.)

Irradiated spices and dehydrated vegetables are the only food items that are likely to be consumed by the general public. There is some speculation that irradiated fresh fruits and vegetables may reach supermarket shelves in the near future. In test markets, southern California consumers purchased 13

pounds of conventionally processed papayas versus 150 pounds of labeled, irradiated papayas during a one-day sale period (Bruhn and Noell 1987). The papayas were displayed side by side in supermarkets, and consumers were encouraged to ask questions about the process and to taste the papayas. Labeled, irradiated mangoes also sold well in Florida (Puzo 1986). Appearance and quality of these tropical fruits encouraged consumer purchases in these markets. Although response was positive in these market tests, extensive market testing of irradiated food products has not been done in the United States. Despite its limited use with food products, many products that American consumers use every day are irradiated. A few representative examples are listed in Table 2.

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

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

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

FOOD WHOLESOMENESS

Food safety, or wholesomeness, is a major concern for the consumer and the food industry alike. For that reason, a major emphasis of food irradiation research and development during the last 40 years has been the safety issue. Foods treated with irradiation are considered safe to eat if: 1) no significant toxic effects or radioactivity are produced in the food product by processing, 2) nutritional quality is not significantly decreased when the irradiated food is compared to the fresh product or the same food processed using traditional methods, and 3) harmful microorganisms and microbial toxins are not present.

Toxicological Safety

Consumers frequently confuse irradiation with radiation and radioactivity, and fear that irradiated food is radioactive. However, exposing foods to low-dose ionizing energy will not make the food radioactive, and the consumer is never exposed to radiation (Josephson and Brynjolfsson 1987).

When foods are treated with ionizing energy to kill microorganisms or delay sprouting, a few (6 out of 10-million) chemical bonds are broken in the foods, producing new compounds. These compounds produced from the food's natural components are known as radiolytic products. Low doses of ionizing energy create very small amounts of these compounds. Some consumers fear that these compounds are unnatural or hazardous (Josephson and Brynjolfsson 1987). In fact, most of these radiolytic products, including free radicals, have been found in the same or other foods. Some of these products are produced when foods are cooked or processed using traditional methods. Trace amounts of other radiolytic products that are chemically similar to natural food compounds also may be formed (FDA 1986). Recent studies in which humans consumed irradiated foods revealed no need for concern (Brynjolfsson 1987). Similarly, no ill effects have been reported among individuals who have eaten irradiated foods as part of a daily diet.

Nutritional Quality

Under today's processing conditions, low-dose ionizing energy preservation has little effect on the overall nutritive value of the food. Carbohydrates and proteins retain their nutritional quality. Fats also are relatively stable, although a slight loss of unsaturated fatty acids may occur with storage. This loss is similar to that found after wheat is ground, and its effect on nutritional

quality is insignificant. Nutritional quality of iron, calcium, and other minerals is not affected by irradiation. Some vitamins such as riboflavin, niacin, and vitamin D also are very stable. However, levels of others, including thiamin, vitamin E, and vitamin A, may be reduced, but not any more so than by other commercial processing methods (IFT 1986, Josephson et al. 1978). In some cases, nutrient retention may be enhanced when ionizing energy preservation is used instead of other commercial processes (IFT 1986).

Microbiological Safety

Spoilage and disease-carrying microorganisms are reduced by ionizing energy preservation. Shelf-life is extended, lowering food losses when spoilage microorganisms are reduced (Loaharanu and Urbain 1982). Levels of disease-carrying microorganisms, such as *Salmonella*, *Campylobactor jejuni*, and *Clostridium perfringens* also are lowered, reducing potential health hazards and monetary losses due to illness (Josephson and Brynjolfsson 1987, Kampelmacher 1985, USDA-FSIS 1986). However, foods treated with low-dose ionizing energy are not sterile, so proper handling and storage continue to be very important to prevent multiplication of surviving microorganisms. The USDA is developing guidelines to ensure that irradiated meats and poultry are handled safely and properly during processing (Engel 1987). Other foods must be handled according to FDA's good manufacturing guidelines (FDA 1986).

International Opinions

The United States Congress, like many consumers, expressed concern about the safety of irradiated foods as interest in this process has been renewed in the last several years. As a result, that body requested a scientific review of research, both pro and con, conducted on food irradiation. Four years later, a report was issued which concluded that:

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

In addition, the FDA completed an extensive review prior to the recent approvals of additional foods for irradiation processing (FDA 1984, 1986). The American Medical Association has also endorsed the process for foods (AMA 1985).

Similar studies have been conducted worldwide. British scientists concluded that irradiated foods were safe, wholesome, and nutritious (ACINF 1986) in a study requested by the Ministry of Health. The Canadian government (1987) also concluded that "food irradiation is effective and does not pose a hazard to health." Earlier, the World Health Organization of the United Nations issued a report stating that food irradiation was safe at approved levels (WHO 1981).

The current international standards and a code for operation of food irradiation facilities were adopted in 1983 by the Codex Alimentarius Commission (CAC) (CAC 1984). The CAC is a United Nations body that sets international standards to protect consumers, facilitate international trade, and aid developing countries.

THE IRRADIATION FACILITY

The construction of a facility or facilities in Alaska to irradiate food products is a potential new use of a radiation source in the state. However, the use of radiation sources in Alaska is not new. There are numerous sources located at various sites throughout the state (Heidersdorf 1987). All facilities utilizing X rays whether in dentist offices or airport security stations employ radiation. This radiation energy is generated electromechanically. Gamma radiation sources are used by Providence Hospital in Anchorage to provide radiation therapy services and are also used for research and industrial purposes at various locations in-state. Many of the questions and concerns expressed about the location of a food-irradiation facility in Alaska center on the type of source that will be used, design of the facility, regulations regarding transportation of the radiation source, and geologic elements influencing location of a facility.

Ionization Source

Ionizing energy used in the irradiation of food can be generated by machine sources or gamma radiation sources. Machine sources include high-energy electron beams and X ray photons. Cobalt 60 and cesium 137 are potential gamma radiation sources. The technology using both types of sources is not really new, although more recently, gamma sources have been preferred for food irradiation. Only limited amounts of cesium 137 are available, and the production of more is unlikely. Adequate supplies of cobalt 60 are anticipated in the future (Sloan 1987). However, machine sources also are currently used in food irradiation facilities in several foreign countries. Electron beam accelerators and X ray photon machines also are routinely used for sterilization of medical products and food containers; crosslinking of plastic and rubber materials; and the curing of inks, coatings, and adhesives on a wide range of packaging materials, including those used for food.

There are both positive and negative aspects associated with each type of source. High-energy (10 MeV) electron beams do not have the penetrating capability of X rays or gamma sources, which may be a problem if conventional handling and packaging procedures are used. This problem may be overcome by using X rays rather than high energy electron beams. The penetration capability of X rays at levels used for food irradiation is slightly higher than that produced by the gamma source, cobalt 60. An in-line X ray converter may be used to increase the penetration of electron beams. However, the conversion

to X rays can drop the efficiency of high-energy electron beams by as much as 92 percent (Rodrigues 1985). The advantage of machine sources is their relative safety. Transportation concerns are moot because there is no isotope source to be transported and locational concerns such as geologic factors are minimized (Rodrigues 1985). If the safety of the machine is compromised it is turned off.

Photon emissions from a gamma radiation source are shielded by lowering the source into a pool of water or into a lead cask that acts as a shield (United Fresh Fruit and Vegetable Association 1986).

Transportation and Security of the Source

If machine-generated ionizing energy is used for food preservation, transportation safety is not a concern. However, consumers frequently express concern about transportation of gamma radiation sources. Regulations and procedures for transporting gamma sources in Alaska are in place (18 AAC 85.320) because these sources are currently used for medical, industrial, and research purposes in the state. The regulations regarding intrastate movement and storage must be as stringent as those for interstate transport (U.S. NRC 1984). Interstate transportation of all radioisotopes is governed by the United States Department of Transportation (DOT) as well as by the Nuclear Regulatory Commission (NRC).

Both cobalt 60 and cesium 137, the gamma radiation sources commonly used in food irradiation facilities, are transported to and from facilities in specially designed casks which have been rigorously field tested. Films of these tests show the cask intact after being dropped 2000 feet on its most vulnerable point. There were no leaks in the cask after a freight train that was transporting it was rammed against a barrier, nor after the truck trailer on which the cask had been placed melted in a fire.

Irradiation Facility Design

A typical design of a commodity irradiation facility is shown in Figure 4. This design is similar to a commercial potato irradiator that has been operating in Shihoro, Japan, since 1974 (Kameyama 1985). It uses cobalt 60 as a radiation source, although the basic design would not change if a machine source had been used. Among the 133 irradiation facilities operating worldwide, 71 use cobalt 60 as a source. Plants are operating in 41 countries ((Markovic 1985).

At the center of the irradiation chamber is the source (1). The source chamber is completely shielded by concrete walls, ceiling, and floor (2). Com-

modities to be irradiated are placed in containers and loaded onto the entrance conveyor (3) that carries them into the irradiation chamber, past by the source (4), and out of the chamber (5). This process irradiates one side of the commodities. A turntable (6) rotates the containers 180 degrees and the process is repeated. The containers are then removed at the exit point (7). All functions are performed by an operator from the control room (8) outside the irradiation chamber and can be viewed through a window (9).

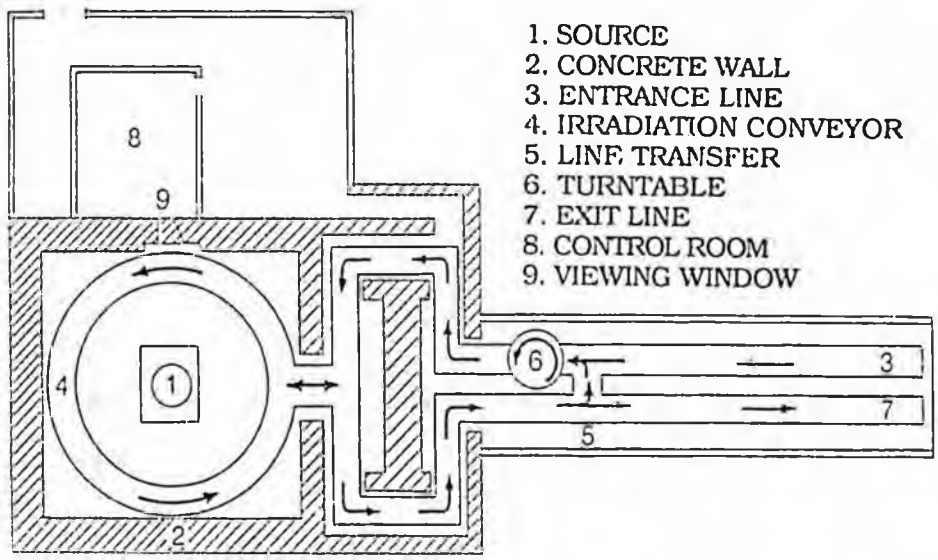

Figure 4. A typical food irradiation facility (Adapted from: Kumeyama 1985).

Facility Safety

There are three safety components within an irradiation facility: shielding, ventilation, and interlocking. Shielding must fully surround all ionizing areas. The amount of shielding (e.g., concrete or earth) necessary in a facility using a machine source is less than that necessary in a facility using a gamma radiation source. This is because the auxiliary equipment used to generate the radiation can be housed in a minimally shielded area outside the fully shielded irradiation chamber (Ramler 1982, Rodrigues 1985). Ventilation of the irradiation chamber disperses trace amounts of ozone and nitrogen oxides that are

produced during the irradiation process. Personnel entry is delayed until the dispersal is complete (Martin 1982, Ramler 1982). Interlocking is a key design factor in facility safety. Mechanical, electrical, and remote-radiation monitor interlocks are combined with complex mazes and visual/auditory warning signals to sense any mechanical or human violations. If violations occur, machine sources are automatically and immediately deactivated (Ramler 1982), and gamma radiation sources are lowered into the storage water pool or cask (Martin 1982).

When machine-generated X rays are used, the state of Alaska is responsible for the radiation facility. All radiation facilities in state that are not licensed by the NRC must be registered with the Alaska Department of Health and Social Services (Heidersdorf 1987). The NRC is the lead agency for the licensing of facilities using gamma sources. Rigid standards, regardless of source, are set for leak testing, radiation detection, personnel dose monitoring, waste disposal, operational procedures, training, emergency procedures, and a radiation safety program (Jarrett 1985).

Solid or liquid waste disposal is not a routine function in the irradiation process, regardless of source type. Spent gamma sources are returned to the seller for disposal (Martin 1982). If the cooling water in a plant using a gamma radiation source was accidently contaminated, it would first be contained and then cleaned up at the site or transferred to an authorized agent for cleanup and/or disposal after containment (U.S. NRC 1984).

Regardless of design, the safety of a facility depends on the human factor. Because of this, trained "health physicists" are in charge of on-site safety. These professionals have applied to and been examined by a national certification board that evaluates the candidate's training and qualifications (Martin 1982). Health physicists supervise and monitor all aspects of a facility, including personnel. Alaskan regulations covering general radiation safety and allowable exposure to workers and the public have been established (Heidersdorf 1987).

Environmental Factors Determining Plant Location

Many factors such as commodity production and harvesting areas, transportation networks, potential impact on local communities, and the projected major use of the facility will determine possible locations for an Alaskan irradiation facility. Final site selection and eventual construction will be influenced by environmental concerns. Seismic and volcanic activity, potential for groundwater contamination, and the presence of permafrost are considerations in the location of a facility employing a radiation source in Alaska. A detailed geotechnical exploration program would be conducted at a proposed site before final site approval.

Earthquakes are an important consideration because the state's southern coastline is part of the circum-Pacific seismic belt. The damage caused by the 1964 earthquake in Alaska has been widely documented (Eckel 1970, Hansen et al. 1966). Alaskan seismic shock zones are identified in the Uniform Building Code, the continually updated engineering criteria for safe building construction (International Conference of Building Officials 1976), and stringent design standards have been developed for facilities that employ radiation sources (ANSI 1984).

Most of Alaska's volcanoes are located along the Aleutian Chain and on the Alaska Peninsula, the location of many of the state's coastal fishing ports. This poses an obvious local hazard, but volcanoes can also have a distant effect because of falling ash, dispersion of gases, and the potential for tsunamis. Potential sites should be outside of potential distant hazard zones if possible (Davies 1987).

Although some tsunamis are generated by volcanic eruptions (Swanson and Kienle, in press), most are created along Alaskan coastlines by earthquakes. The Alaska State Division of Emergency Services has published a series of hazard maps outlining possible tsunami run-up for many coastal communities (Davies, 1987).

Groundwater maps have been developed for several Alaskan locales. The depth to the aquifer as well as soil conditions are factors in determining potential sites for an irradiation facility. Permafrost, or perennially frozen ground, is found in most parts of Alaska. It is continuous in the northern region, becoming discontinuous in interior Alaska and fragmented toward the southern boundary of the state. The coastal regions along the Gulf of Alaska are free from permafrost (Hartman and Johnson 1984). Although successful facility designs have been developed to erect structures on permafrost terrain (Permafrost, 1983), the best alternative is to avoid a site with permafrost.

IRRADIATION AND ALASKA'S FOOD INDUSTRY

Alaska's food-production industry may benefit from the location and use of an irradiation facility in the state. Both the seafood and agricultural industries must deal with problems unique to each. A list of Alaskan commodities that might benefit from irradiation is shown in Table 3. Of these, some may be eliminated because of the limits on the quantities that can be harvested in Alaska or because of the distance of production areas from a centrally located irradiation unit (Giddings 1984). Others could be eliminated because of the undesirable effects of irradiation on the quality of the Alaskan products (Molton 1987).

Table 3. Some Alaskan commodities that may benefit from irradiation processing.

Food industry	Commodity
Seafood	Halibut
	Other groundfish
	Salmon
	Crab
	Shrimp
	Defatted fish meal
Agriculture	Reindeer
	Domestic red meats
	Meat processing by-products
	Potatoes
	Cole crops
	Carrots
	Cut flowers
	Animal feeds

Seafood Industry

Alaska's seafood industry, the state's largest private industry employer, produces 25 percent of the entire value of fish and other seafood landed in the United States. Kodiak and Dutch Harbor are among the ten largest fishing ports in the country. Alaska's fishing industry continues to grow, pioneering new fishing grounds and developing new fisheries and product forms (Johnson

1986). Approximately 25 percent of the fish landed are canned, and most of the remaining fish are fresh-frozen. Only a small amount of Alaskan fish reach the premium fresh-fish market (Babbitt 1987).

The U.S. fresh-fish market has grown rapidly in recent years. Generally, Alaska's share of this premium market has been limited by transportation costs (Babbitt 1987). Because of the state's remote location, delivery of fresh fishery products means that, in most cases, air transportation is the only reliable transportation mode. Ironically, many of the same transportation problems limit the marketing of fresh Alaskan fishery products in-state. There are inadequate surface transportation links to inland areas from ports (Gray 1980). Thus, less than one percent of the Alaska seafood catch is marketed fresh in-state (Babbitt 1987). Several fish species, usually marketed fresh, have limited value because their short shelf-life limits their distribution through existing marketing systems (Kramer 1987).

Alaska's fisheries management programs have had an important role in increasing and maintaining fishing stocks, ensuring that a viable renewable-resource industry continues to flourish. However, these programs have also been responsible for establishing very short fishing seasons for some species. Halibut season, for example, typically lasts several hours to several days (Johnson 1986). Unlike most other Alaskan fish, about 50 percent of the halibut harvested is sold fresh (Babbitt 1987). These short harvesting seasons have resulted in gluts on the market, reducing price and quality of the product sold (Johnson 1986).

Much of the seafood processing is now done through joint ventures. In joint venture operations, United States fishermen harvesting fish in Alaskan waters supply foreign processors with their catch (Johnson 1986). The incomes accruing to Alaskans are limited to the ex-vessel value of the fish. A further reduction in the value of total fish products occurs in many Alaskan fishing communities, because the seafood processing "waste" is dumped into the ocean (Monsen 1987). This also creates potential environmental hazards and potentially reduces the value of the total fish landings (Lewis and Lewis 1982). These post-processing fish by-products can be important food sources in the animal feed (Brundage 1986) and animal health products industries (Tsuji 1983).

Agricultural Industry

Agricultural producers in Alaska market their products largely within the state. Milk, potatoes, cole crops, reindeer meat, and cut flowers are among them. The surface transportation system in Alaska has never been tailored to movement of agricultural products within the state or to markets outside the state (Lewis and Thomas 1982). Furthermore, the only land transportation network

is in the central area of the state and primarily serves Fairbanks and Anchorage, the largest population centers (Lewis et al. 1987). Shipment of fresh food to areas outside this network is always by air. Nonperishable, bulk items are transported to central collection points by coastal barges that operate seasonally. Freight is then shipped from these coastal ports inland on the river system (Lewis and Lewis 1982). The short production season for fresh-marketed crops limits the time for sales and the share of the annual market held by Alaskan products. (Lewis and Lewis 1980).

Products of the agricultural industry in Alaska that are not currently marketed are slaughter plant by-products. These by-products are presently discarded, thereby reducing the total value of slaughter plant output. In plants outside Alaska, by-products are used extensively in the pharmaceutical, cosmetic, and animal feed industries (AECL 1987). An exception is animal hides. Presently, small lots of cow hides are salt-cured and sold out of state. This practice is more common for reindeer hides but only because of their high value as a novelty item.

Benefits to Food Industries and Consumers

There are a number of potential benefits that could accrue to both the seafood and agricultural industries and to Alaskan consumers by extending the shelf-life of higher-valued products and increasing the value of currently discarded by-products. Products could be in transit to markets for longer periods of time, allowing known markets that cannot now be served economically to be reached. This could benefit the seafood industry specifically by increasing Alaska's share of the premium fresh-fish market outside of the state and by increasing the availability of fresh fish in Alaskan markets. It may also allow fresh Alaskan reindeer products to enter the growing national and international game meat markets.

Cost of transporting products to existing markets could be reduced if fresh products could be shipped over longer distances using surface rather than air transportation. This is a potential benefit to the seafood industry because of Alaska's remote location. The agricultural industry also could benefit because of the limited surface transportation system within the state. The Alaskan consumer, who currently pays high prices in the grocery store (University of Alaska Coop. Ext. Service 1987), should ultimately benefit from the lower transportation costs.

The quality and availability of foods in rural Alaska could be improved. Selection in these areas is frequently limited and costly (Nowak 1975, University of Alaska Coop. Ext. Service n.d.). Products shipped fresh, particularly vegetables, are handled at multiple points and are sometimes held for lengthy peri-

ods, thus reducing product quality and increasing costs, even when air transport is used. Other products are frozen prior to shipment and, unless care is taken, thawing and refreezing can occur (Lewis and Lewis 1980). Availability in rural markets with limited access also may be improved if less perishable products could be locally stored for longer periods of time. Lengthening the shelf-life of fresh products could thus benefit rural Alaskan consumers by improving product quality and providing an alternative to freezing as a preservation method.

Product safety for all Alaskan consumers may be improved. Ionization increases the shelf-life of foods by decreasing the numbers of spoilage microorganisms present. Simultaneously, levels of naturally occurring disease-carrying microorganisms are reduced. Reduction of these pathogenic microorganisms of public health concern would allow Alaskan consumers to enjoy a safer food supply.

Vegetable producers would be able to increase their acreage in production and their share of the fresh market if it were possible to hold products for longer periods of time. Similarly, increasing the storage period for fresh seafood could aid the seafood harvester by reducing market gluts, controlling price fluctuations, providing more consistent supplies, and reducing spoilage due to oversupplied markets. Market potential of underutilized but desirable fish species with a shelf-life too short to allow transporting to market may also be improved.

Marketing of underutilized or discarded by-products could increase the value of the product line now marketed by Alaskan food production industries, while improving environmental quality control. Irradiation of seafood and animal slaughter by-products would reduce naturally occurring disease-carrying organisms, potentially increasing the value of these products. When these by-products are used in in-state production of animal feeds (Brundage 1986), the Alaskan consumer may directly benefit from a safer (Van der Schaaf and Mossel 1963) and less costly food supply (Husby 1987, Husby and Wooding 1985). Alternatively, locally produced or imported animal feeds used in Alaska could be irradiated, reducing potential pathogens (Mossel et al. 1968). Animal hides other than reindeer could be marketed on a more frequent basis if quantities sufficient for economical shipment outside the state or for in-state use could be stockpiled. This cannot now be done because of the erratic nature and wide dispersion of the supply.

Process Cost

One important consideration is the cost of the irradiation process. How this cost compares to the cost of conventional preservation processes is an im-

portant factor determining its eventual use. In the case of fresh products, the cost will obviously be higher than doing nothing to the product. However, most commodities, even when marketed fresh, have been processed to some extent. Thus, improved product quality may warrant a price increase that would be acceptable to the consumer. It is possible that this potential processing cost increase may be offset by lower transportation costs. For example, if surface rather than air transportation can be used to reach markets that are currently only accessible by air, a substantial savings may result.

SUMMARY

Treatment of Alaska-produced food products by irradiation may benefit the seafood and agricultural industries by opening new markets both in Alaska and worldwide. One major use of this technology is to extend shelf-life so that products can be shipped greater distances as fresh products without degradation of product quality. Thus, food irradiation may allow Alaska to capitalize on existing strengths and overcome existing limitations. The Alaskan consumer's quality of life also may be improved if availability, safety, and quality of food products is improved by the irradiation process. In addition to extending shelf-life, ionization will also decrease microorganisms of public health concern, providing a direct benefit to the consumer.

This process has been reported by national and international organizations to be effective and safe. Regulations regarding its use have been established. Required labeling of irradiated food products will allow individual consumers to make informed choices among available products. Consumers in many countries are already eating irradiated foods and using irradiated medical, cosmetic, and household products everyday.

Can the food irradiation process benefit Alaska? Although there are potential benefits, much is unknown about the applicability of the process to Alaskan commodities and its acceptability by the Alaskan consumer. Potential social and economic benefits and risks as well as the costs of using the process in Alaska on Alaskan products will determine if this process is adopted.

FURTHER READING

For more detailed information about specific topics addressed in this publication, please consult the reference list. To aid the interested reader in finding this information, the references cited under major topics are listed below.

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PUBLIC OPINION MESSAGE

TO ALL MEMBERS OF THE STATE HOUSE AND SENATE

Sigma Xi strongly opposes HB 388 and SB 355. These bills are based on misinformation and emotional reactions, not scientific fact.

FDA labeling requirement will allow consumers to make informed choices.

We urge you to get accurate facts and vote responsibly.

Alaska Chapter, Sigma Xi Scientific Research Society

Submitted by:

William Mendenhall
Member, Advisory Committee
Office Phone 474-6125

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

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.

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 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

(YOU BY YOUR
U STATES SENATOR
Ted Stevens
ALASKA

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

P85-48
FOR IMMEDIATE RELEASE
December 12, 1985

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

HHS 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 he 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

Kit

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

S T A T E	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

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 McKinn barely survived the one or two second overexposure to 147,000 curries of cobalt-60. Mr. McKinn 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 Technology 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 1982 as a source of groundwater 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 datatched, 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.

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 low-dose irradiation on foods in the United States.

The Dept. of Health and Human Services (HHS) regulations it approved in 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:

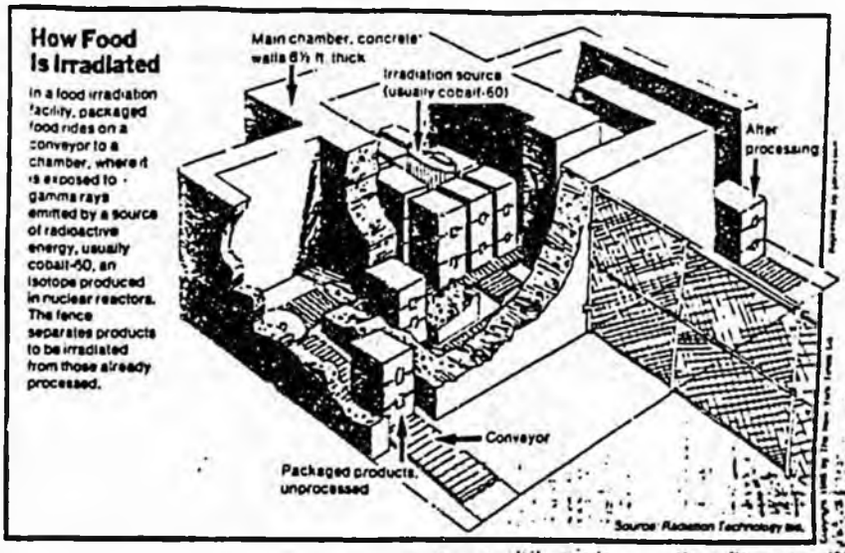
- In July, 1985, HHS gave the go-ahead for irradiation in the processing of pork, a process that is believed to eliminate the threat of trichinosis even if the pork is undercooked or eaten raw. These regulations — with comment from the U.S. Dept. of Agriculture (USDA), which regulates pork — are nearing 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.



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

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 spiralis 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 19-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 "picowave," 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

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 under 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 Industrial 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
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.

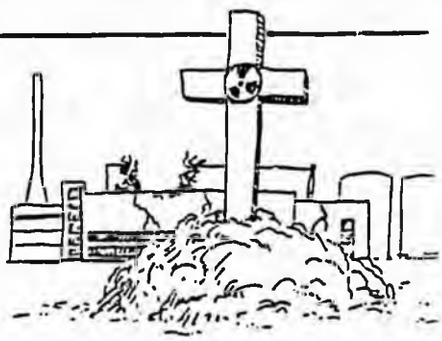
Using computer projections, Dr. John Gofman, Professor Emeritus of Medical Physics at the University of California (Berkeley), estimated that 1 million people, including over half a million outside the Soviet Union, will develop cancer as a result of the Chernobyl accident and half of these cancers would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

You'd think we might have learned t
radiation is unforgiving.



LOOKING FOR THE K.O.

In the August 21st issue of the Food and Dr newsletter, the editors of this industry bulle analyzed the food irradiation controversy with som interesting insights.

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

In an interview with Sharon Bomer *ex-director* o The Coalition For Food Irradiation (CSFI), Bome confesses "there were irradiation companies tha tended to blow the issue out of proportion and t make fantastic claims." Bomer was talking abou companies in the business of irradiating medica 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

ATTACHMENT 13

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

P.O. Box B-12
Richlandtown, PA 18955

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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Compilation of Bioassay Data (Cont'd.)

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 litt.
reduced number of young at wean
reduced vitamin E level in live
increased mortality of progeny
reduced number of progeny

Cabbage

reduced SGPT activity
reduced AP activity in intestin 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 tissue
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 microorgani
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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Compilation of Bioassay Data

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-exidase 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 spermoatoids
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
reduced weight of offspring
lower weight of progeny at birt
oestrus disorder
longer reproductive cycle
reduced fertility
more frequent epithelioma
increased frequency of lymphoblastoma in liver, thymus lung, spleen, kidney

Corn Meal

longer duration of development of the larvae of Trib

Crackers

worse acceptance

Cranberry

reduced growth

Dessert Powder (gelatine, vanilin

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

ON

ıdditive and the evaluator of its safety.

ıairman, the prospect of utilizing food irradiation
· scientists and consumers. In fact, the FDA received
public comments in response to its rule to permit
adiation. In the absence of any Congressional action,
and local governments have already taken steps to curb
ry's growth. For example, on May 29 Maine Governor
an signed a bill into law banning the sale of
foods in that state. Earlier this year, the New Jersey
e overwhelmingly approved a bill to ban the sale of
foods in that state as well. Vermont has passed a
ll, and last year, the California state legislature
ısure calling on the Department of Health and Human
require further safety studies, and requesting that no
ons be promulgated broadening the uses of food
A similar resolution was passed by the Board of
in my own county of Sonoma.

rman, I would also like to bring to the Subcommittee's
cent action taken by the Canadian government on this
ay, a Canadian parliamentary committee unanimously
ommittee report which expressed deep reservations
es of food irradiation. The Standing Committee on
Corporate Affairs urged the government to resist the
irradiated foods until further scientific studies
: irradiation poses no significant adverse health
: Committee also recommended that irradiated foods be
l, and that wheat irradiation be banned until specific
ns are resolved. These recommendations are
noteworthy because Canada has been a leader in the
f food irradiation.

of these reasons, I believe a more prudent approach
g food irradiation policy is in order. Based on our
standing of the potential harmful implications of
:on, I believe Congress would do well to hold the
:yance until these unresolved safety concerns have
ıtly addressed. The legislation that I have
.R. 956, would: prohibit pork and produce
:equire independent safety studies, and tighten
.rements for irradiated herbs and spices. I urge my
join with me in supporting this needed legislation.

man, I appreciate the opportunity to testify before
tee on this subject and I would be happy to respond
ns you may have.

.. ..

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Department of
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Drug Administration's

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ENT 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 low-dose irradiation on foods in the United States.

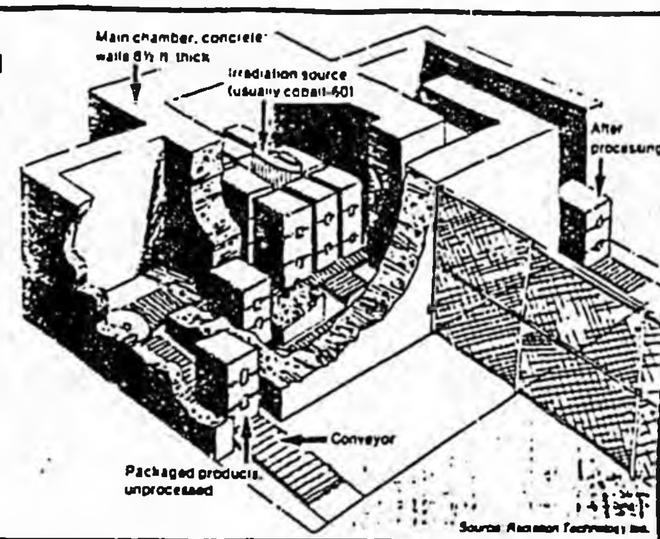
New Dept. of Health and Human Services (HHS) regulations, if approved by the Office of Management and Budget (OMB), will permit irradiation of pork and fresh fruits and vegetables. Sweeping legislation now before Congress would further encourage irradiation of foods — a practice considered beneficial 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.

How Food Is Irradiated

In a food irradiation facility, packaged food rides on a conveyor to a chamber, where it is exposed to gamma rays emitted by a source of radioactive energy, usually cobalt-60, an isotope produced in nuclear reactors. The fence separates products to be irradiated from those already processed.



Source: Radiation Technology Inc.

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.

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

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 "picowave," 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 Bosy

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 stenlizing 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.

19[illegible]6 (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 under 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 Industrial Forum, Inc.
"Background Info", April 1987

ATTACHMENT 12

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's who 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, disposable 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 protectio.'."

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-

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.

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

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 998
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

Accord Research and Educational Associates,

314 West 91st Street New York, N.Y. 10

Phone: (212) 580-3

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 of 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 an 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

Accord Research and Educational Associates
New York, NY (212)580-3889

Table 2 IDENTIFICATION OF MUTAGENIC, CARCINOGENIC, OR CYTOTOXIC RADIOLYTIC PRODUCTS IN IRRADIATED ORGANIC MEDIA OR FOOD

Author(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

Table 3 PUBLISHED STUDIES INDICATING INCREASED ~~AFLATOXIN~~ 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

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.

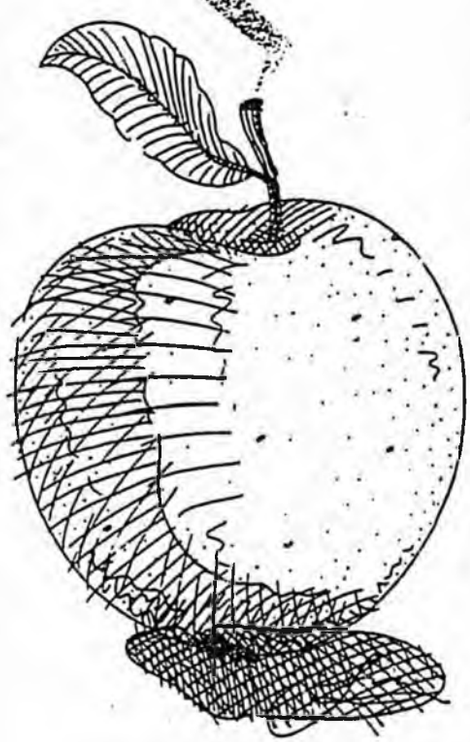
This is not the beginning of a science-fiction horror story. It is, in fact, a description of a method of food-processing designed to extend the shelf-life of commodities and kill insects infesting them. It has been used since 1963 on wheat but is a much more recent addition to other food items. Irradiation 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,

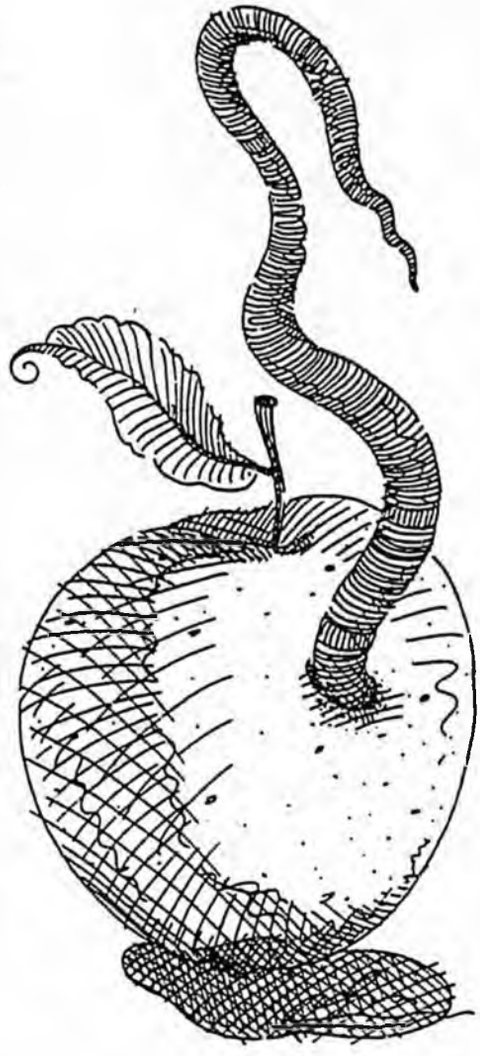
makes it imperative that the wholesomeness of irradiated food be very carefully assessed."

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 founder of the company and a tireless, enthusiastic supporter of food irradiation, Welt 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 such 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

530 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.

Editorial Opinion and Commentary

FAIRBANKS

Daily News-Miner

"Independent in All Things . . . Neutral in None"

Other opinions expressed on this page do not necessarily reflect those of the Daily News-Miner.

Monday, Feb 15, 1988 p. 4

Overreaction

A classic example of overreaction is the bill in the Legislature to ban the sale of irradiated foods.

The bill is aimed at new processes that use radiation to sterilize foods of bacteria, fungus and insects. Opponents say the process is dangerous and can cause changes in the food that may also be dangerous.

Scientists say the fears are groundless, that irradiation, in fact, offers exciting possibilities for food preservation.

The Legislature should not try to stand in the way of technology. If the public is concerned about buying irradiated food, a bill simply requiring that irradiated food be labeled would suffice.

The bill is also aimed at a proposed irradiation facility to be established at the university here. The university is one of six in the nation authorized by the U.S. Department of Energy to conduct a food irradiation feasibility study.

Scientists at the university are interested in using irradiation to extend the shelf-life of seafood products. It isn't hard to imagine the benefits that would occur if ways could be found to keep seafood fresher longer. The Legislature should try to encourage this project, not stand in its way.

Greater Fairbanks Chamber of Commerce
First National Center
709 Second Avenue
(907) 452-1105
P.O. Box 74446
Fairbanks, Alaska 99707

RESOLUTION #10-0388

RESOLUTION ON IRRADIATION

WHEREAS, the State of Alaska has requested the Institute of Northern Engineering at the University of Alaska Fairbanks to conduct a study on the potential social ar· economic benefits and conduct a study on the potential social and economic benefits and risks that may be realized from food irradiation technology; and

WHEREAS, the Institute of Northern Engineering will not complete the study until the fall of 1988; and

WHEREAS, both the House and Senate have bills before them that would ban the sale of irradiated products in Alaska, thus foreclosing any future window of opportunity; and

WHEREAS, the United States Congress through the Department of Energy has made available to Alaska a $5 million grant over a period of time for the purpose of conducting a range of studies regarding the feasibility of the process in Alaska; and

WHEREAS, the potential economic benefits to Alaska are in the areas of international trade and increased quality and selection of available food products, especially in rural Alaska; and

WHEREAS, economic development is a priority of the Governor for the State of Alaska and of the Greater Fairbanks Chamber of Commerce for the Interior and the state;

NOW THEREFORE BE IT RESOLVED, that the Greater Fairbanks Chamber of Commerce believes HB388 and SB355 should be postponed, or at least amended, pending the results from the study;

BE IT FURTHER RESOLVED that the Greater Fairbanks Chamber of Commerce urges the Governor and the state legislators to defer a decision on the proposed legislation until those results are available.

Dated this _____ day of _____, 1988.

By _____ By _____
Mike Kelly W.R. Cox

Guest Opinion
by
John P. Zarling
Director, Institute of Northern Engineering
at the
University of Alaska Fairbanks

The United States Department of Energy through congressional authorization has funded six feasibility studies on food irradiation; one is in Alaska. Feasibility of food irradiation is also being studied in Florida, Hawaii, Iowa, Washington and Oklahoma. The Institute of Northern Engineering at the University of Alaska Fairbanks was selected by the State of Alaska to carry out the study on behalf of the State. At the end of this summer, INE will produce a report on its findings which will be submitted to the State and DOE. The State of Alaska must then determine its future course of involvement, if any, in further assessment and/or development of this technology.

An interdisciplinary team composed of food scientists, engineers and economists at the University of Alaska Fairbanks is conducting the feasibility study. The study will evaluate the socioeconomic benefits and risks that may accrue from the application of irradiation technology to Alaska's seafood and agricultural products.

Wholesomeness of foods is important to all Alaskan consumers. Cooking, microwaving, chemically treating, freezing and drying are most of the techniques we presently

use for food preparation, processing or preservation. Exposing foods to proper doses of ionizing energy reduces or eliminates the numbers of disease causing organisms and thus offers an alternative to chemical treatment for preserving or disinfecting food products. An extension of shelf life is also possible if the food is properly packaged and stored. As a food preservation technique, the process might enhance Alaska's share of the global seafood market through shelf-life extension. For this to occur there must first be consumer acceptance and federal approval of the process for specific food products important to Alaskans.

Public interest in the issue of food irradiation as well as in the INE feasibility study exists. Letters to the editors have recently appeared in most major Alaskan newspapers addressing food irradiation. It has been the subject of radio talk shows and several bills/resolutions have been or are being introduced in Alaska's legislature. As a result, we all must evaluate for ourselves the potential benefits and risks of using ionizing energy for processing foods. Public concern generally centers on two main issues: (1) the safety of operating an irradiation facility and (2) the wholesomeness of irradiated foods.

The transportation and storage risks associated with using cobalt-60 or cesium-137 as the source of ionizing energy raise concern among some. The issues of whether irradiation creates harmful by-products in foods and whether

residual radiation remains in the products after processing are frequently misunderstood.

Ionizing energy required for the process can be in the form of gamma rays produced by radioactive isotopes such as cesium 137 or cobalt 60, or from x-rays or high energy electron beams produced by machines. If radioactive isotopes are used, there are some risks associated with the transportation and use of these materials. It is true that cesium 137 is contained in the by-product material from plutonium production. During the 1970s DOE separated and encapsulated cesium 137 from this by-product material. Presently DOE has less than half of its original production still in storage and no plans to process anymore. New commercial irradiators would not choose cesium 137 as a radiation source because it is unavailable. On the other hand, cobalt 60 is available from Canada as it can be produced in the CANDU nuclear power reactors. The Canadians sell this material for medical, research and industrial uses. Machines that produce x-rays or high energy electron beams are becoming cost competitive with radioactive isotopes and have the advantage of eliminating the risks associated with transporting and using radioactive materials. Machines are on only during the actual processing and when not in use can be turned off.

We in Alaska already have considerable experience with radioactive materials and radiation sources. About seventy

licenses have been issued by the State covering the use of radioactive isotopes for medical, industrial and research purposes. About 1200 x-ray machines are licensed for medical, dental and industrial use. If the State of Alaska decided to authorize building a food irradiation facility in Alaska, it would have to conform to all State of Alaska and U.S. rules and regulations governing such facilities.

The second concern centers on the wholesomeness of irradiated foods. The safety or wholesomeness issue of irradiating foods has been studied extensively for more than 30 years. Irradiation does not leave residual radiation in the food being processed nor does radioactive material ever come in contact with the food. Rather than cooking the product, gamma rays, x-rays or accelerated electrons are used to kill or sterilize potentially dangerous microorganisms, insects, parasites, molds and fungi which can lead to food spoilage or illness. Because the food's temperature is increased only slightly, the food appears virtually unchanged.

Based upon their review of the scientific data, the United States Food and Drug Administration has authorized the sale of irradiated fresh produce, pork, wheat and spices. Organizations such as the World Health Organization of the United Nations, the British Ministry of Health, the Canadian government and the American Medical Association have endorsed the process. The U.S. Department of

Agriculture has developed guidelines to ensure that irradiated foods are handled safely and properly during processing. All foods approved for irradiation processing must be processed according to FDA's good manufacturing guidelines, and irradiated foods must be labeled as such.

What specific benefits might irradiation technology offer to the seafood industry in Alaska? Irradiation can be used to extend the refrigerated shelf-life of certain fresh finfish and shellfish such as groundfish, flatfish fillets, scallop meat and shrimp. It can sanitize frozen products (such as blocks of shrimp, fillets and minced fish) and dehydrated products (such as fish meal and fish-protein isolate) to kill non-spore-forming pathogenic bacteria such as Salmonella. Irradiation can also destroy insect eggs and larvae that are sometimes associated with dried fish products. Irradiation preserved foods have been consumed by the astronauts since the Apollo missions.

Controversy does continue with respect to these approvals and the food safety issue. This concern has led to the establishment of a National Coalition to Stop Food Irradiation as well as an Alaska Coalition to Stop Food Irradiation. A paperback book on the same subject is being sold through several health food stores statewide. In response to the questions that have been raised, the Council for Agricultural Science and Technology, CAST, with 28 U.S. member scientific societies, has issued several publications

focusing on the safety of food processed with ionizing energy and providing answers to the questions raised. In its November 1987 publication CAST states, "The results of more than 30 years of research indicate that the risk is essentially zero in proceeding with the U.S. Department of Agriculture and Food and Drug Administration authorization for certain uses of ionizing energy in food processing."

In conclusion, the INE study will result in a set of recommendations for the State of Alaska and DOE. It is the State that will make a final decision on implementation of any of the recommendations.

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 30813, July 5, 1983; 48 FR 48022, October 13, 1983; 49 FR 24068, June 10, 1984; 50 FR 18413, April 18, 1985) and in dry enzyme preparations (50 FR 26180, June 10, 1985). FDA also issued a final rule on July 22, 1985 (50 FR 29668) 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 5718).

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

In 1978, FDA established its Bureau of Foods Irradiated Food Committee (BFIFC) to review the existing agency policy concerning the irradiation of foods. BFIFC's main task was to make recommendations regarding the establishment of those toxicologic testing requirements appropriate for assessing the safety of irradiated foods. BFIFC's recommendation focused on making the degree of testing compatible with the potential risk as indicated by the level of anticipated human exposure. BFIFC recognized that safety assessments of irradiated food should be based on: (1) Projected levels of human exposure to the food; (2) estimates of the identity, amount, and potential toxicity of new chemical constituents generated in the food by the irradiation process; and (3) state-of-the-art sensitive toxicological tests. BFIFC completed its review and submitted its final report in July 1980 (Ref. 1).

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

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

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

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

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

1. Radiolytic Products

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

2. Spices

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

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

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

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

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

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

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

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

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

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

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

3. Other Minor Foods

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

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

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

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

4. Destruction of Nutrients

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

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

5. Selective Destruction of Microorganisms

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

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

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

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

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

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

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

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

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

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

a. Toxicological Studies

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

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

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

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

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

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

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

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

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

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

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

among either macro- or micronutrients of the diet.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

7. Alleged Adverse Effects

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

B. Labeling Issues

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

The labeling provisions of this final rule differ from that in the proposed rule and from the current labeling regulations as follows: This regulation requires that the wholesale label bear either the statement "Treated with radiation, do not irradiate again," or the statement "Treated by irradiation, do not irradiate again," and that the retail label bear the following logo:

along with either the statement "treated with radiation," or the statement "treated by irradiation." Throughout the remaining discussion in the preamble about the labeling provisions, the agency has used the terms "treated with radiation—do not irradiate again," and "treated with radiation," to represent both alternatives that the manufacturer may use in its wholesale or retail labeling in order to simplify the discussion. In addition to the mandatory language, the manufacturer may also state on the wholesale or retail label the purpose of the treatment process or expand upon the kind of treatment used. That is, the manufacturer may include in the labeling any phrase, such as "treated with radiation to control spoilage," or "treated with radiation to extend shelf

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

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

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

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

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

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

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

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

The agency agrees that conventional food-processing methods also affect the organoleptic properties of food in material ways but in these cases the processing is either obvious to the consumer or conveyed to consumers through labeling or packaging. Canned foods have obviously been canned and frozen foods have obviously been frozen. Pasteurized milk is not obviously pasteurized but this fact is declared on the label.

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

FDA has historically required the disclosure of a food processing agent whenever it is material to the processing of foods. For example, flour is required to be modified by the term "bleached" if bleaching agents are used in processing and modified by the term "bromated" if potassium bromate is used in the processing of the flour. These requirements are part of the standard of identity for various flours (see 21 CFR 137.206).

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

C. Current Good Manufacturing Practice

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

The CGMP regulation for irradiated food could not be based solely on current radiation practices because of the lack of substantial experience with food irradiation. However, there has been extensive experience with other types of radiation processing (e.g., hospital supplies), and the industry has established standards in some cases. FDA considered both the experience and standard practices in the nonfood radiation processing industry and CGMP in the food industry in developing its proposed regulation for irradiated food and in evaluating comments.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

D. Other Technical Effects

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

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

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

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

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

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

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

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

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

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

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

Second, at the doses permitted in this regulation, the total amount of radiolytic products consumed is too small to be of concern, either because of low doses or because foods so treated are a minor part of the diet. Further, safety information from animal feeding studies is unnecessary under these circumstances. The proposal stated that FDA is reviewing a number of studies to determine whether foods that are irradiated at doses above 1 kGy (100 krad) can be considered safe without additional toxicological studies. As stated elsewhere in this document, the agency has reviewed these studies and found that five were acceptable by current standards. This data base is inadequate to support a broad decision that all foods may be irradiated safely at higher doses up to 10 kGy (1 Mrad).

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

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

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

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

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

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

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

E. Packaging

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

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

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

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

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

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

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

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

F. Public Education

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

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

G. Impact Analyses

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

III. Objections

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

IV. References

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

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V. Agency Action

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

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

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

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

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

List of Subjects in 21 CFR Part 179

Food additives, Food packaging, Irradiation of foods.

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

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

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

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

§ 179.22 [Removed]

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

§ 179.24 [Removed]

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

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

§ 179.25 General provisions for food irradiation.

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

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

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

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

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

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

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

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

§ 179.26 Ionizing radiation for the treatment of food.

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

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

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

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

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

(b) *Limitations.*

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

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

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

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

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

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

Frank E. Young,
Commissioner of Food and Drugs.

Dated: March 29, 1986.

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

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Statement of the American Medical Association

to the

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

Presented by

A. Harold Lubin, M.D.

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

November 18, 1985

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

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

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

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

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

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

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

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

AMERICAN MEDICAL ASSOCIATION

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DIVISION OF LEGISLATIVE ACTIVITIES

HARRY N. PETERSON, J.D.
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DEPARTMENT OF FEDERAL LEGISLATION

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Director

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(645-4769)

January 16, 1987

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

Dear Ms. Rhodes:

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

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

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

Sincerely,

Thomas M. Wolff

TMW:bt

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

By means of direct technical cooperation with its Member States, and by stimulating such cooperation among them, WHO promotes the development of comprehensive health services, the prevention and control of diseases, the improvement of environmental conditions, the development of health manpower, the coordination and development of biomedical and health services research, and the planning and implementation of health programmes.

These broad fields of endeavour encompass a wide variety of activities, such as developing systems of primary health care that reach the whole population of Member countries; promoting the health of mothers and children; combating malnutrition; controlling malaria and other communicable diseases, including tuberculosis and leprosy; having achieved the eradication of smallpox, promoting mass immunization campaigns against a number of other preventable diseases; improving mental health; providing safe water supplies; and training health personnel of all categories.

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

Further information on many aspects of WHO's work is presented in the Organization's publications.

The *WHO Technical Report Series* makes available the findings of various international groups of experts that provide WHO with the latest scientific and technical advice on a broad range of medical and public health subjects. Members of such expert groups serve without remuneration in their personal capacities rather than as representatives of governments or other bodies. An annual subscription to this series, comprising 15 to 20 such reports, costs Sw. fr. 80.–.

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

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

Wholesomeness of irradiated food

Report of a Joint FAO/IAEA/WHO Expert Committee

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Geneva, 27 October – 3 November 1980

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WHOLESOMENESS OF IRRADIATED FOOD

Report of a Joint FAO/IAEA/WHO Expert Committee

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

1. INTRODUCTION

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

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

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

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

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

2. GENERAL CONSIDERATIONS

2.1. Principles

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

2.2. Reasons for the use of food irradiation

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

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

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

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

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

3. TECHNICAL ASPECTS

3.1 Radiation sources

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

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

3.2 Absorbed dose

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

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

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

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

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

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

3.3 Processing conditions for irradiation

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

3.4. Packaging of irradiated food

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

3.5 Repeated irradiation

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

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

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

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

3.6 Technological efficacy

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

3.7 Requirements of quality assurance and labelling

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

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

4. ASPECTS OF RADIATION CHEMISTRY

4.1 Chemical analysis and wholesomeness evaluation

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

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

4.2 Recent studies

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

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

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

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

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

4.3 Conclusions

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

5. NUTRITIONAL ASPECTS

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

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

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

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

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

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

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

6. MICROBIOLOGICAL ASPECTS

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

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

6.1 Variations in radiation resistance

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

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

6.2 Radiation-induced genetic variations

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

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

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

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

6.3 Microbiological aims of food irradiation

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

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

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

7. TOXICOLOGICAL ASPECTS

7.1 Re-evaluation of provisional acceptances and new evaluations

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

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

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

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

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

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

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

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

7.3 Toxicological evaluation of radiolytic products

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

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

8.1 Teleost fish and fish products

Purpose of irradiation

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

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

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

Average dose

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

Temperature requirement

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

Microbiological aspects

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

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

Nutritional aspects

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

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

Toxicological aspects

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

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

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

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

Evaluation

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

8.2 Onions

Purpose of irradiation

To inhibit sprouting during storage.

Average dose

Up to 0.15 kGy.

Microbiological aspects

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

Nutritional aspects

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

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

Toxicological aspects

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

Evaluation

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

8.3 Rice

Purpose of irradiation

To control insect infestation in stored rice.

Average dose

Up to 1 kGy.

Prevention of reinfestation

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

Microbiological aspects

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

Nutritional aspects

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

Toxicological aspects

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

Evaluation

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

9. NEW EVALUATIONS[1]

9.1 Cocoa beans

Purpose of irradiation

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

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

Average dose

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

Prevention of reinfestation

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

Microbiological aspects

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

Nutritional aspects

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

[1] See footnote 1 on page 20.

Toxicological aspects

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

Evaluation

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

9.2 Dates

Purpose of irradiation

To control insect infestation in stored dates.

Average dose

Up to 1 kGy.

Prevention of reinfestation

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

Microbiological aspects

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

Nutritional aspects

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

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

Toxicological aspects

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

Evaluation

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

9.3 Mangoes

Purpose of irradiation

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

Average dose

Up to 1 kGy.

Microbiological aspects

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

Nutritional aspects

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

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

Toxicological aspects

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

Evaluation

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

9.4 Pulses

Purpose of irradiation

To control insect infestation in stored pulses.

Average dose

Up to 1 kGy.

Prevention of reinfestation

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

Microbiological aspects

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

Nutritional aspects

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

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

Toxicological aspects

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

Evaluation

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

9.5 Spices and condiments[2]

Purpose of irradiation

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

Average dose

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

Microbiological aspects

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

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

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

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

Nutritional aspects

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

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

Toxicological aspects

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

Evaluation

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

10. CONCLUSIONS ON THE ACCEPTABILITY OF IRRADIATED FOOD

10.1 Toxicological acceptability of irradiated food

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

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

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

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

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

10.2 Microbiological and nutritional acceptability of irradiated food

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

10.3 High-dose irradiation

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

11. FUTURE RESEARCH

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

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

12. RECOMMENDATIONS

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

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

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Food Irradiation:

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

by BERNARD S. SCHWEIGERT, Ph.D.

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

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

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

WHAT IS IT?

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

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

Glossary

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

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

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

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

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

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

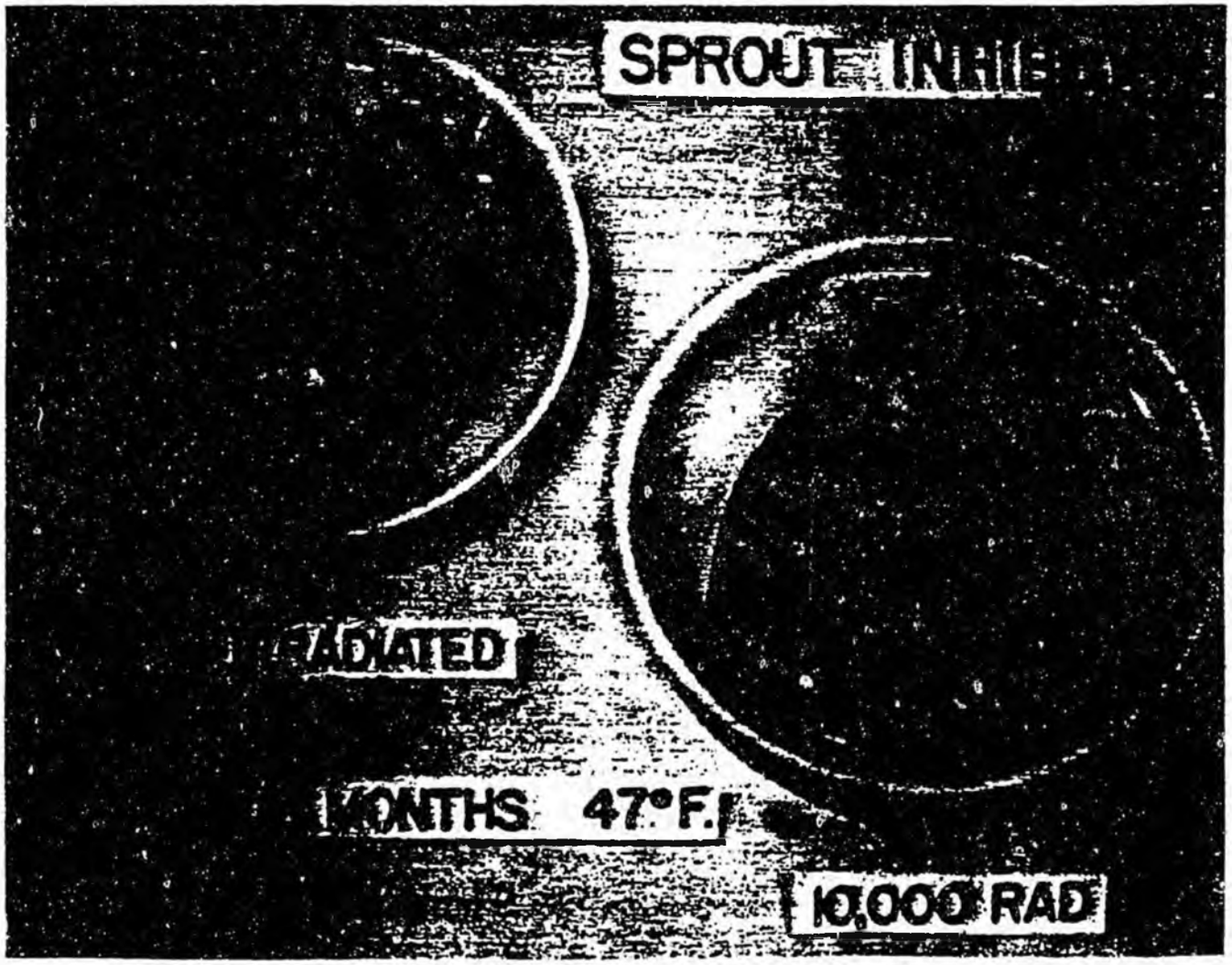

Figure 1. Photograph of nonirradiated and irradiated potatoes showing sprout inhibition after radiation.

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

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

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

MECHANISM OF ACTION

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

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

WHERE WE ARE NOW

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

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

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

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

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

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

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

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

Table 3
Threshold Dose for "Radiation Flavor"*

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

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

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

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

NUTRITIVE VALUE, WHOLESOMENESS AND SAFETY OF IRRADIATED FOODS

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

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

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

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

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

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

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

CONSUMER ACCEPTANCE

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

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

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

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

LABELING

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

Figure 2. International symbol for irradiated foods.

Table 5
Promising Applications of Irradiation to Foods

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

Table 6
Food Irradiation Issues

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

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

PROMISING APPLICATIONS

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

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

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

WHERE ARE WE GOING?

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

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

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

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

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

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

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University of Alaska Fairbanks

Alaskan Commodities Irradiation Project:

An options analysis study

project objective

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

project background and funding source

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

research agency and project scope

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

final recommendations

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

University of Alaska Fairbanks

FACT SHEET: Irradiated Foods

the process

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

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

energy source

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

approved uses

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

current uses

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

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

-more-

food safety

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

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

consumer protection

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

potential benefits and risks to Alaska

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

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

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

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

University of Alaska Fairbanks

for more information call University Relations 474-7581

Food Irradiation and Alaska's Food Industries

By

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

Introduction

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

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

Food Irradiation Project Background

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

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

The Irradiation Process

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

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

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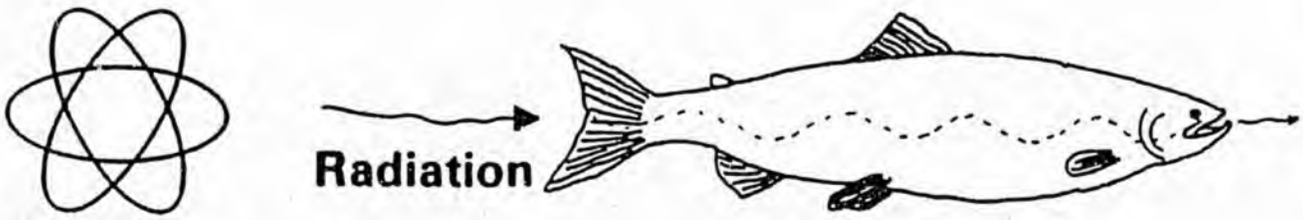

Figure 1. How irradiation works.

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

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

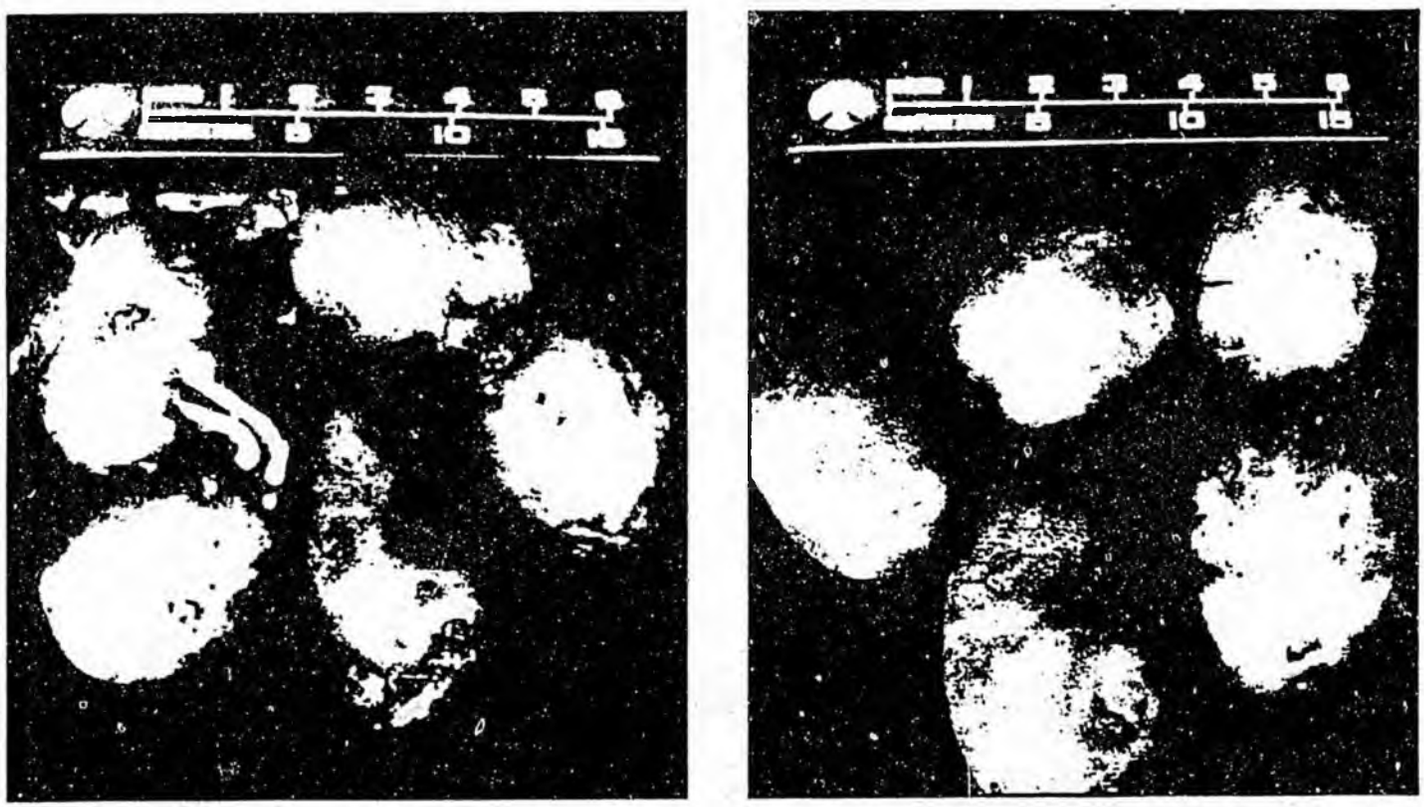

Figure 2. Effect of irradiation on conventionally processed supermarket potatoes after 1 month storage at room temperature; irradiated potatoes have not sprouted (Photographs courtesy of H. Farrar, IV and G. Subbararaman).

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

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

Labeling

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

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

Irradiated Food Products in the United States

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

Approved products in United States

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

Current uses

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

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

Table 1. Foods approved for irradiation in United States.

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

(Lecos 1986, FDA, 1986.)

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

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

Food Safety

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

Researchers involved in the United States' review concluded:

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

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

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

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

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

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

Irradiation Facilities

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

The source

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

Source transportation

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

Potential Benefits to Alaska

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

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

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

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

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

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

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

Request for Input

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

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

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

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

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

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

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

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

. . . Continued on page 41

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

5-1671A

IN THE HOUSE BY PHILLIPS AND GOLL

HOUSE BILL NO. 388

IN THE LEGISLATURE OF THE STATE OF ALASKA

FIFTEENTH LEGISLATURE - SECOND SESSION

A BILL

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

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

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

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

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

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

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

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

(5) the dissemination of a false advertisement;

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

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

in good faith;

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

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

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

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

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

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

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

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

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

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

(b) The commissioner of environmental conservation or a designee

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