HB
25

SENATE COMMITTEE REPORT

No Action taken by SFC FURTHER

4/17/89 DATE TURNED INTO OFFICE_____

Mr. President:

Finance Committee considered CSHB 25 (Rules)

prohibiting under the Alaska Food, Drug, and Cosmetic Act the knowing sale of irradiated food; authorizing embargo and detention remedies in the case of a violation of the prohibition against the sale of irradiated food; etc

and recommended

[ ] replace with ___ CS_____ ___) [] same title
[ ] or adopt _____ CS_____ ___) [] new title
[] technical title change (HB only)

[ ] attached amendment(s) and

[ ] _____letter of intent adopted

[ ] do pass

[ ] do not pass

[ ] no recommendation

[ ] individual recommendations

[ ] further referral to _____

FISCAL NOTE(S) [ ] zero [ ] fiscal impact [ ] appropriation no FN
[ ] new [ ] updated [ ] previous
[ ] same as previous fiscal note(s) published _____

MEMBERS SIGNING DO PASS

OTHER RECOMMENDATIONS

_____ _____
_____ _____
_____ _____
_____ _____
_____ _____
_____ _____
_____ _____

_____
Chairman signature and recommendation

[ ] Committee Backup attached

Offered: 3/29/89
Referred: Rules

6-0222.J

Original sponsors: Phillips, Brown, Navarre and Taylor

IN THE HOUSE BY THE RULES COMMITTEE

CS FOR HOUSE BILL NO. 25 (Rules)

IN THE LEGISLATURE OF THE STATE OF ALASKA

SIXTEENTH LEGISLATURE - FIRST SESSION

A BILL

For an Act entitled: "An Act prohibiting under the Alaska Food, Drug, and Cosmetic Act the knowing sale of irradiated food; authorizing embargo and detention remedies in the case of a violation of the prohibition against the sale of irradiated food; and making the commissioner of environmental conservation responsible for enforcing the prohibition."

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

* Section 1. AS 17.20.230 is amended by adding a new subsection to read:

(c) If the commissioner of environmental conservation finds or has probable cause to believe that a person is violating AS 17.20.290(d), the commissioner may affix to the food that is the subject of the violation a tag or other appropriate marking that gives notice that the food may not be sold and warning all persons not to remove or dispose of the food until permission for removal or disposal is given by the commissioner or a court. A person may not remove or dispose of the detained or embargoed food without this permission.

* 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 (d) of this section. This subsection does not limit the authority of peace

H

officers.

* Sec. 3. AS 17.20.290 is amended by adding a new subsection to read:

(d) The knowing sale of irradiated food is prohibited.

* Sec. 4. AS 17.20.370 is amended by adding a new paragraph to read:

(14) "irradiated food" means food that has been treated with gamma radiation or other ionizing radiation; "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.

CC No. 1

STATE OF ALASKA
1989 LEGISLATIVE SESSION

BILL VERSION: HB 25
PUBLISH DATE: HOUSE 1/25/89

FISCAL NOTE

REQUEST:

Revision Date:
Title: An Act relating to irradiated food.
Sponsor: PHILLIPS AND BROWN
Requestor:

Agency Affected: Environmental Conservation
BRU: Environmental Health
Components: Sanitation.

EXPENDITURES/REVENUES: (Thousands of Dollars)

OPERATING	FY 89	FY 90	FY 91	FY 92	FY 93	FY 94
PERSONAL SERVICES	--	15.0	15.0	15.0	15.0	15.0
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	--	18.0	18.0	18.0	18.0	18.0
CAPITAL	--	--	--	--	--	--
REVENUE	--	--	--	--	--	--

FUNDING: (Thousands of Dollars)

GENERAL FUND	--	18.0	18.0	18.0	18.0	18.0
FEDERAL FUNDS	--	--	--	--	--	--
OTHER	--	--	--	--	--	--
TOTAL	--	18.0	18.0	18.0	18.0	18.0

POSITIONS:

FULL-TIME	--	--	--	--	--	--
PART-TIME	--	1	1	1	1	1
TEMPORARY	--	--	--	--	--	--

ANALYSIS: (Attach a separate page if necessary)

The passage of HB 25 would require that the Department expand its inspection activities at approximately 500 food distributors, warehouses and wholesale and retail outlets to ensure that irradiated products were not being sold. For facilities presently under inspection, the additional inspection time

(Continued)

Prepared by: Douglas C. Donegan DCD Phone: 465-2609
Division: Environmental Health Date: 1-19-89

Approved by Commissioner: Dennis D. Kelso Date: January 23 1989
Agency: Environmental Conservation

Distribution (by preparer):
Legislative Finance
Legislative Sponsor
Requestor
Office of Management and Budget
Impacted Agency(ies)

is estimated to be approximately one (1) hour per inspection.

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 two (2) hours including travel time.

This inspection effort would amount to a total of 602 hours/year or about four months/year.

Position Title	No. of Positions	Range/Step	Barg. Unit
Environmental Sanitarian II	1	16/A	G

Time Status	Staff Months	Location	Election District
F	Four (4)	Anchorage, Alaska	7

Type of Expenditure		Amount
1	2	3
Salary	10.8	
Benefits	4.2	
Premium Pay	0	
Other	0	
Total Personal Services		15.0
Travel		0
Contractual		2.0
Commodities		1.0
Equipment		0
Other		0
Total Cost		18.0

Funding Source for Total Cost	
Federal Receipts 1002	0
G. F. Match 1003	0
General Fund 1004	18.0
GF Program Receipts 1005	0
Other	0

Justification

This position is required to support the implementation of HB 25, "An Act relating to irradiated food." Approximately 500 food distributors, warehouses and wholesale and retail outlets would be inspected to ensure that prohibited products were not being sold. All facilities would be contacted and notified of the new law. The additional inspection time required for facilities presently inspected would be approximately (1) hour and for facilities not currently inspected would be approximately two (2) hours 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	of
Revised Date	

FY 90

STATE OF ALASKA
1989 LEGISLATIVE SESSION

BILL VERSION: CC HB 25 No. 2
PUBLISH DATE: HOUSE 1/25/89

FISCAL NOTE

REQUEST:

Revision Date: 1/20/89
Title: "An Act relating to irradiated foods."
Sponsor: Phillips & Brown
Requestor:

Agency Affected: Health & Social Services
BRU: State Health Services
Components: Laboratory Services

EXPENDITURES/REVENUES: (Thousands of Dollars)

OPERATING	FY 89	FY 90	FY 91	FY 92	FY 93	FY 94
PERSONAL SERVICES						
TRAVEL						
CONTRACTUAL						
SUPPLIES						
EQUIPMENT						
LAND & STRUCTURES						
GRANTS, CLAIMS						
MISCELLANEOUS						
TOTAL OPERATING	-0-	-0-	-0-	-0-	-0-	-0-
CAPITAL	-0-	-0-	-0-	-0-	-0-	-0-
REVENUE	-0-	-0-	-0-	-0-	-0-	-0-

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 25 would have no direct fiscal impact on the Department of Health and Social Services.

Prepared by: Elizabeth Ward, Director E. Ward Phone: 465-3090
Division: Public Health Date:

Approved by Commissioner: Myra M. Munson Date: 1/20/89
Agency: Health & Social Services

Distribution (by preparer):
Legislative Finance
Legislative Sponsor
Requestor
Office of Management and Budget
Impacted Agency(ies)

STATE OF ALASKA
1989 LEGISLATIVE SESSION

BILL VERSION: CSHB 25 (FIN)
PUBLISH DATE: HOUSE 2/10/89

FISCAL NOTE

REQUEST:

Revision Date:
Title: An Act relating to irradiated food.
Sponsor: Phillips/Brown
Requestor:

Agency Affected: Environmental Conservation
BRU: Environmental Health
Components: Sanitation

EXPENDITURES/REVENUES: (Thousands of Dollars)

OPERATING	FY 89	FY 90	FY 91	FY 92	FY 93	FY 94
PERSONAL SERVICES						
TRAVEL						
CONTRACTUAL						
SUPPLIES						
EQUIPMENT						
LAND & STRUCTURES						
GRANTS, CLAIMS						
MISCELLANEOUS						
TOTAL OPERATING	-0-	-0-	-0-	-0-	-0-	-0-
CAPITAL	-0-	-0-	-0-	-0-	-0-	-0-
REVENUE	-0-	-0-	-0-	-0-	-0-	-0-

FUNDING: (Thousands of Dollars)

GENERAL FUND	-0-	-0-	-0-	-0-	-0-	-0-
FEDERAL FUNDS						
OTHER						
TOTAL	-0-	-0-	-0-	-0-	-0-	-0-

POSITIONS:

FULL-TIME	-0-	-0-	-0-	-0-	-0-	-0-
PART-TIME						
TEMPORARY						

ANALYSIS: (Attach a separate page if necessary)

Prepared by: House Finance Committee
Division: Co-Chairman Ron Larson
Co-Chairman Lyman Hoffman
Phone: 465-3727
Date: 2/8/89

Approved by Commissioner:
Date:
Agency:

Distribution (by preparer):
Legislative Finance
Legislative Sponsor
Requestor
Office of Management and Budget
Impacted Agency(ies)

POSITION PAPER/Department of Health & Social Services

Position Paper

HB 25

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

HB 25 prohibits the sale of irradiated food including spices and food that contains an irradiated ingredient unless the only irradiated ingredient is a spice. 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 Word 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 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

The Department does not believe that sufficient evidence exists to show that irradiation of food is harmful to health. The Department believes that proper labeling of irradiated foods is necessary to allow those opposed to it to exercise their choice in the foods they purchase.

POSITION PAPER/Department of Health & Social Services

HB 25

Recommended by: Elizabeth Ward

Elizabeth Ward, M.N.
Director
Division of Public Health

Date: 1/20/89

Approved by: Myra M Munson

Myra M. Munson
Commissioner
Department of Health and
Social Services

Date: 1/20/89

STATE OF ALASKA
DEPT. OF ENVIRONMENTAL CONSERVATION
STEVE COWPER, GOVERNOR
(907) 465-2609

POSITION PAPER

House Bill No. 25 January 23, 1989

"An act relating to irradiated food."

Department Statement

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 is beyond the Department's current capacity, we are pleased to assist the committee in identifying useful information.

If the proposed law is to be enforceable, the Department recommends that 17.20.020(b) be amended to include irradiated foods. Without this addition, the Department's ability to embargo or detain irradiated food would be questionable.

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 food containing the irradiated label was found during the course of inspection, the department would embargo the product under the authority in AS 17.20.230 and require that it be destroyed or returned to an out-of-state distributor.

The Department is pleased to provide the following background information about irradiated foods.

Background Information

1. 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.

2. FDA-Approved Sources of Irradiation

Approved ionizing irradiation sources include: radioactive isotopes (Cobalt-60 or Cesium -137) and machines (x-ray or electron beam).

3. Foods Approved for Irradiation

FDA has approved the application of irradiation to the following foods: fruits/vegetables (to slow growth and ripening and control of insects); dried spices and herbs (to kill insects and control microorganisms); pork (to control trichinosis); white potatoes (to inhibit growth and maturation); and wheat and wheat flour (to control insects).

4. FDA Labeling Requirements

Labeling requirements have also been imposed by FDA. 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 was scheduled to be withdrawn. This action would have left only the international irradiation process logo on retail packages. FDA has extended the present labeling requirements to April 18, 1990.

Alaska State Legislature

Official Business

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

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

Memorandum

TO: Senate Finance Committee

FROM: Representative Randy Phillips R.E.P.

DATE: April 17, 1989

RE: CSHB 25 (Rules) - irradiated food

It is my understanding that George C. Giddings, Ph.D., has sent information to this committee for consideration. This information was accompanied by a cover sheet from Isomedix, Inc.

Dr. Giddings identified himself as a "consultant" on the transmittal sheet. When he appeared before the Subcommittee on Health and the Environment of the Committee on Energy and Commerce of the United States House of Representatives on June 19, 1987, he was identified as the director of Food Irradiation Services of Isomedix, Inc.

Isomedix, Inc. is a radiation sterilizing company that, as of January 1987, operated irradiation facilities as follows:

Illinois - One plant in Morton Grove.

One plant in Liberty.

Massachusetts - Plant at Northborough.

Mississippi - Plant at Columbus.

New Jersey - One plant at Whippany.

One plant at Parsippany.

Ohio - One plant at Groaveport.

South Carolina - One plant at Spartanburg.

Utah - One plant at Sandy.

Source: "List of the 40 Irradiation Facilities in the U.S. (not including those that can be found at hospitals of Universities" 1/87, NCSFI Information Manual, pp. 198-200.

Isomedix plants are involved in irradiating some spices, disposable medical supplies, medical devices, and are involved in nuclear device testing, cosmetic research, and food research.

Isomedix has had some problems with these plants as can be seen from the attached news articles. Kitty Tucker, President, Health & Energy Institute of Washington, D.C., during her testimony on February 3, 1988, before the House and Senate Economic Development Committees of the Hawaii State Legislature indicated the following regarding Isomedix:

> Isomedix, Inc. had a leaking cobalt-60 source in 1976, . . .
>
> Isomedix, the largest radiation sterilizing company in the U.S., has been cited by the NRC for 1) overexposing workers to radiation, 2) failing to post radiation areas, 3) allowing food and cigarettes in the same areas as radioactive materials, 4) operating the facility without authorized personnel physically present, and 5) failing to adequately monitor the water disposed into sanitary sewage systems. The last violation was discovered when former workers advised the NRC that Isomedix had conducted unsafe practices, such as disposing of contaminated water from the cobalt-60 pool by dumping it into a toilet connected to the public sewer system. The NRC verified that a pipe leading from a toilet was measurably contaminated in 1979. (p. 28, testimony of Kitty Tucker)
>
> A worker at Isomedix also entered the radiation chamber while the source was exposed, and he received a dose of about 4500 rads. Although he survived the exposure due to hospitalization and treatment, we do not know his current status. (p. 29, testimony of Kitty Tucker).

See attachments: "A Short History of Trouble. Irradiation Hall of Shame" and "Probe asked at irradiation plant".

Dr. Giddings' states in his cover transmittal that "Irradiated food is safe . . .". Again, quoting from Ms. Tucker's testimony before committees of the Hawaii State Legislature:

> On the other hand, independent experts warn of irradiation hazards and predict a far different outcome regarding consumer acceptance of food irradiation. Food irradiation has not been proven safe, for adverse effects have been demonstrated in study subjects ranging from fruit flies, to animals and to humans. A literature survey for the Hungarian Academy of Sciences found more than 1400 adverse effects of food irradiation cited in some 1200 studies reviewed. . . . (p. 2, Testimony of Kitty Tucker).

DANGERS TO CONSUMERS

There are sufficient hazards associated with food irradiation to warrant further research before this process is allowed in the United States or elsewhere. Several scientific studies have raised questions about the safety of eating irradiated foods:

**Malnourished children fed freshly irradiated wheat developed chromosomal abnormalities of the blood, which have been linked with cancer.
**Fruit flies fed gamma irradiated chicken had seven times fewer offspring than those fed heat-treated chicken.
**Chemicals called "radiolytic products" appear in foods after irradiation, and some of these chemicals are harmful to human health.
**Vitamins and nutrients are destroyed by food irradiation, reducing the nutritional quality of our foods.
**Aflatoxins, which are naturally occurring cancer causing agents, grow more readily on foods that have been irradiated.
**Some bacteria, such as the botulism organism, are very resistant to radiation and will grow rapidly on irradiated foods. (p. 6, Testimony of Kitty Tucker).

A paper prepared by Food and Water, Inc. in September of 1987, entitled "Food Irradiation: A Summary", on pages 1-3 further expands on the safety issues and references various source materials. This document is attached as Attachment 13 to the April 4, 1989, packet I delivered to the Senate Labor and Commerce Committee.

Dr. Giddings further states that "the worldwide trend is toward fact-based public acceptance in recognition of public health and other benefits, in the absence of significant risk."

Ms. Tucker stated in her Hawaii testimony that in Great Britain, West Germany and Australia food irradiation is illegal. A Canadian legislative committee has recommended rescinding approval to irradiate wheat and the European Parliament has indicated that on precautionary grounds they reject the "general authorization of irradiation as a method of conserving food."

Japan allows only irradiation of potatoes.

> However, Japanese food import regulations restrict imports of irradiated foods. A March, 1983, publication by the Japan Export Trade Organization (JETRO) states: 'The use of x-rays to sterilize foods is prohibited in Japan; its use is permitted only on potatoes.' Another JETRO publication (1979) states: "Food shall neither be irradiated nor contaminated with antibiotics,' and identifies potatoes as an exception. (Source: Feasibility of Irradiating Washington Fruits and Vegetables for Asian Export Markets, September 1986. Prepared by International Marking Program for Agriculture Commodities and Trade, Northwest Economic Associates, Pacific Northwest Laboratory (Operated for the U. S. Department of Energy by Battelle Memorial Institute), p. I-2)

For your further information, I am also attaching a copy of "Effects of feeding irradiated wheat to malnourished children" as published in The American Journal of Clinical Nutrition, February 1975.

I would like to thank the committee for its prompt consideration of this bill and I would appreciate your support of CSHB 25 (Rules).

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 McKimm barely survived the one or two second overexposure to 147,000 curries of cobalt-60. Mr. McKimm was in critical condition for one month before recovering.

1976-1980 In 1976 an 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 1981 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 detatched, spilling radioactive water onto the floor of the plant. INI employees were then instructed to dump the water down bathroom drains and into the public sewer system. INI then delayed an NRC inspection and attempted to hide radiation contamination from inspectors. (see detailed article in this issue)

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

SCIENCE BOX

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

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

Isomedix Decontamination Questioned

New Jersey Daily Record
MAY 3 1981

Probe Asked At Irradiation Plant

By CHRIS DUPIN
Business Writer

PARSIPPANY — Former workers at Isomedix Inc. are asking the U.S. Nuclear Regulatory Commission (NRC) to investigate the company's decontamination of several rooms at Isomedix's plant there between 1978 and 1980.

The employees — who left the company after a labor dispute last fall — are questioning how certain areas of the plant became contaminated with radiation after an accident at the plant at 25 Eastmans Road in 1978.

Isomedix is a firm that specializes in sterilizing medical products and treating other materials by exposing them to bombarding radiation from cobalt 60.

NRC spokesmen say they are aware of most of the incidents that the former workers want investigated, but say that as far as they can tell, the plant was cleaned up properly.

John Kinneman, the chief of Materials Radiological Protection Service at the NRC's office in King of Prussia, Pa., says the agency will review the complaints of the former workers when they make a regular inspection in the near future.

The NRC was not able last week to provide exact dates for many of the incidents that followed the 1978 accident, because officials did not have time to review the company's files.

John Deitz, the president of Isomedix, openly discussed the accident and cleanup but was reluctant to give some details because he was unsure of exact dates and because "I don't want to get into something that happened a long, long time ago."

Deitz added that the company "had gone to a lot of effort to do the cleanup right," spending "several hundreds of thousands of dollars, an amount comparable for a firm our size to what it's costing Jersey Central Power & Light to clean up Three Mile Island."

Isomedix's growth and position as a leader in the irradiation business is the subject of a feature article called "Gamma rays have a glowing future" in the current issue of Fortune magazine.

In 1978, company officials say a cobalt "pencil" — powdered radioactive cobalt encased in a double walled stainless steel rod — ruptured while it was inside a shielding pool — a deep concrete pit filled with water that absorbs the gamma rays the cobalt pencil gives off.

The company's president, George Deitz, says the firm is not absolutely certain what caused the rupture, but says it may have been caused by corrosion from fire extinguisher chemicals that got in the shielding pond when workers put out a small fire at the plant.

According Deitz and former workers, a welder was doing some work near the shielding pond when a lit some paper covering the pond and caught on fire.

Whatever the cause, after the ruptured pencil was discovered, Deitz said the cobalt pencils were withdrawn from the shielding pond and kept in a "hot cell" — a small concrete shielded room next to the pond.

George Bertos and Frank Brazitis — the two workers who are asking the NRC to look into the cleanup, are questioning whether the company promptly reported the ruptured pencil to the NRC.

Deitz said the company did, and Kinneman, while not having complete records to review, also believes the NRC was told of the leak promptly.

While storing the cobalt pencils in the hot cell — Kinneman says it was a safe place to keep them since they are manufactured in similar rooms — Isomedix moved to clean up the water in the shielding pond using ion-exchange resin filters.

Ion-exchange filters remove the cobalt molecules in the water and replace them with hydrogen.

When the water was cleaned to permissible levels, it was dumped down a toilet in the plant.

This is another area that concerns Bertos and Brazitis, because they say that when a more extensive cleanup that they worked on was done several years later, the toilet and its drain pipe were found to be radioactive and removed.

> "I don't want to get into something that happened a long, long time ago."
>
> — John Deitz, Isometrix

After the water in the pond was cleaned, lead plates were placed over the pond and the surrounding area was used only on a limited basis for the next few years.

Deitz said the company did not finish the cleanup job at that point because of a lack of funds, but in 1980 it decided to "decommission" the area and clean it up to the point where it could turned over to the owner of the building, the Electro-Protective Corp.

When the company began the cleanup, Deitz said Isomedix expected the job would take several weeks.

It hired Chem Nuclear Systems Inc., a Bellevue, Wash., company that specializes in cleanup work to supervise the job.

But instead of being able to wipe down the area and remove the radiation with brushes and various cleaning agents, the company was forced to use jack hammers to chip away large amounts of concrete.

In the shielding pool, up to six inches of concrete was stripped away from the wall and floor of the pool, and the floor surrounding the pool was also chipped away, according to Dietz and workers on the job.

It was during this job that the toilet and pipe were found to be radioactive and removed.

Kinneman says the toilet could have became radioactive from the earlier cleanup of water in the shielding pond in 1978.

He says iron plate is a particularly good absorber of cobalt and might show detectable levels of radiation after absorbing the small amounts of radiation that Isomedix was allowed to dump into the sewage system.

According to a Chem-Nuclear worker, at least some parts of the toilet showed radiation levels of 25 millirems.

Kinneman says 1 millirem is a level used by many firms as a permissible level of radiation to measure when a facility is acceptable for unrestricted use.

A Chem-Nuclear worker said his company became upset when after telling the company about the "hot" toilet, officials of the company tried to reduce radiation levels by washing it down with cleaning solutions that included hydrochloric acid.

He said Chem-Nuclear threatened to leave the job if the company didn't follow its advice to rip out the toilet and send it to a landfill.

Another potential problem that the workers are pointing to is several radioactive tools at the company's plant which they say were removed to another rented facility in West Orange.

Deitz says those tools were brought back to the plant and eventually shipped to a landfill, but the workers want to know if the West Orange plant was ever inspected for possible contamination.

Bertos and Brazitis were two of about a half-dozen workers who walked off their jobs last fall when some workers were barred from voting in an election that sought to have the Teamsters represent workers at the plant on Eastman's Road because the National Labor Relations Board classified them as supervisors.

Isomedix plant on Eastmans Road in Parsippany where radiation accident took place.

Nuclear panel finds company violated nine regulations

By LIV OBBY
Daily Record Staff Writer

DOVER — The Nuclear Regulatory Commission found nine violations of regulations governing radiation facilities at International Nuclonics Inc. here following a December 1982 leak.

Among the violations according to an NRC report just released was the failure of the Vault 66 company to report the radiation leak. But John Glenn of the NRC Region 1 Office, said yesterday an investigation to determine whether the company attempted to cover up the leak is not complete.

Maximum fines for each charge range up to $8,000, but Glenn said penalties have not yet been ordered.

"We're holding up the enforcement action because we're waiting to see how the progress with their cleanup of the facility," he said. "The cleanup is more important."

However, Glenn said the company which used Cobalt 60 to sterilize medical equipment will be cited a notice of violation sometime in the future.

He said the deadline for removal of all the contaminated materials is October, with the two Cobalt 60 pools used for sterilization to be removed by early September. The plant has not done any sterilizing since September 1982.

International Nuclonics officials were unavailable for comment.

Other violations include possession of unauthorized radioactive material, improper procedures during decontamination operations and no surveys of materials released from the plant. No significant evidence of ground water contamination was found, the report stated, and Glenn said the NRC concluded there is no real threat outside the building.

The report also noted that contaminated water was dumped into a shower stall at the site, allowing the liquid to escape into the sewer system. Contamination of the air and the food also was documented.

While Glenn said less than one minute's exposure to Cobalt 60 could be lethal, the facilities are constructed so that workers and people outside the plant are not exposed to hazardous levels.

There are no restrictions on locating radiation facilities near schools, as is the case with International Nuclonics which is across the street from Hamilton Field and the East Dover Elementary School, Glenn said. But he noted that the incident was "probably the worst" of its kind for such a facility.

Effects of feeding irradiated wheat to malnourished children[1]

C. Bhaskaram,[2] M.D., and G. Sadasivan,[3] M.Sc., M.B., B.S., M.Sc.

ABSTRACT Fifteen children suffering from severe protein calorie malnutrition were divided into three groups of five each and received diets containing either unirradiated, freshly irradiated, or stored irradiated wheat. All the children were hospitalized for a period of 6 weeks and leukocyte cultures were done initially and at intervals of 2 weeks. Children receiving freshly irradiated wheat developed polyploid cells and certain abnormal cells in increasing numbers as the duration of feeding increased and showed a gradual reversal to basal level of all after withdrawal of irradiated wheat. In marked contrast, none of the children fed unirradiated diet developed any abnormal cells while children fed stored irradiated wheat showed polyploid and abnormal cells in significantly decreased numbers. Though the biological significance of polyploidy is not clear, its association with malignancy makes it imperative that the wholesomeness of irradiated wheat for human consumption be very carefully assessed. *Am. J. Clin. Nutr.* 28: 130–135, 1975.

Irradiation has been recommended as a method to control insect infestation of stored grains, also to control sprouting in stored potatoes and onions. Irradiated foods have been screened for their wholesomeness and based on available evidence, a Joint FAO/IAEA/WHO Expert Committee that met in 1969 to discuss this question recommended that "temporary clearance" may be considered in the case of irradiated wheat (1). The Committee, however, specifically recommended that further studies for possible mutagenicity of irradiated foods should be undertaken, since in most studies done so far, tests for cytotoxicity of irradiated foods had not been employed.

While the wholesomeness of irradiated wheat has been studied extensively in experimental animals, similar studies in man are few and even these have been of short duration. Also, most studies have been carried out in well-nourished animals. In many developing countries, malnutrition is widely prevalent and there is evidence that malnutrition could adversely influence toxicity of many drugs. In such situations, the question of food irradiation thus acquires a new dimension.

In view of the large volume of literature generally supporting the absence of harmful effects of irradiated wheat in several mammalian species, it was thought that negative findings including cytotoxic studies in malnourished subjects fed irradiated wheat would add further support to the use of irradiation as a method of increasing food availability.

An investigation was, therefore, undertaken to determine the effects of feeding irradiated wheat to children suffering from protein-calorie malnutrition.

Materials and methods

Ten children aged between 2 and 5 years, suffering from kwashiorkor, were admitted to the hospital for investigation. All children had severe growth retardation, edema of the lower extremities, mental apathy and hypoalbuminemia – levels of serum albumin being below 2 g/100 ml. They conformed in all respects to descriptions of kwashiorkor given earlier from this Institute (2). All children were rehabilitated with diets which provided 4 g protein/kg body weight and 200 kcal/kg body weight daily. These levels of protein and calories have been found to bring about optimal responses (3). The diet contained 20 g wheat/kg body weight and provided about 2 g of protein/kg body weight. The diets of five children contained irradiated wheat, while that of the other five contained unirradiated wheat. Both groups of children were fed simultaneously. All the wheat used in these studies came from the same bulk supply. The rest of the protein in the diet came from dry skim milk. All children received these diets for a period of 6 weeks under supervision and it was ensured that food intake was complete. The details of the diet used in the study are presented in Table 1.

[1] National Institute of Nutrition, Indian Council of Medical Research, Hyderabad-500007, India.
[2] Research Officer. [3] Visiting Professor.

Method of irradiation

A local variety of wheat was obtained in bulk and irradiated pneumatically in aluminum containers (4 × 4 × 8 cm) in lots of 1.25 kg. The containers were kept at a distance of 12.5 cm from a cobalt-60 source which had a flux of 75,000 rads/hour. A total dose of 75,000 rads was given in four equally divided doses, exposing each side of the container at a time. Absorption of radiation was checked by standard ferrous sulfate dosimetry. The irradiated wheat was incorporated into the diets within 3 weeks after being irradiated.

The response of the children to these diets was evaluated using both clinical and biochemical parameters. Clinical response was assessed by the time taken for disappearance of edema and the gain in weight after edema had disappeared. The biochemical response was assessed by the rate of regeneration of serum albumin. Albumin levels were determined by the micro-Kjeldahl method. In addition, both before the institution of treatment and at intervals of 2 weeks thereafter, samples of peripheral blood were obtained to determine the extent and nature of chromosomal aberrations, using lymphocyte cultures.

Lymphocytes were cultured by a modified micro-method described by Atabakhsh and Sparkes (4) using phytohemagglutinin (PHA) as the mitogen. All cultures were terminated at 72 hours following a 2-hour period of exposure to 0.1 ml of 2.5 mg/100 ml colchicine. Chromosomal preparations were made by splashing on a wet slide, and stained with Giemsa stain. Twenty-five well-spread metaphases were analyzed for structural abnormalities like gaps, breaks, and deletions. During the course of the examination of these slides some cells with more than the normal complement of chromosomes were seen in some preparations. Therefore, in all preparations, 100 consecutive spreads were examined for the presence of polyploid cells.

As soon as it became evident that the feeding of irradiated wheat was associated with the appearance of polyploid cells, it was considered possible that this may have been due to the fact that the irradiated wheat was incorporated into the diets within 2–3 weeks after irradiation. The study was, therefore, repeated in five children, who received identical diets, but where the wheat after irradiation was stored for a period of 12 weeks before it was fed.

TABLE 1
Composition of the diet[a]

Ingredient	Amount, g/kg body weight	Protein, g/kg body weight	kcal/kg body weight
Skim milk powder	6	2	20
Wheat	20	2	70
Sugar	8		30
Clarified butter	8		70
Banana one per day			

[a] The diet provided 200 kcal and 4 g protein/kg per day.

Results

The results of the study are shown in Tables 2 and 3 and Figs. 1–4.

There were no differences between the three groups of children either in the clinical or the biochemical response. But in four of the five children who had received freshly irradiated wheat, varying numbers of polyploid cells were seen. They first appeared 4 weeks after the diets were started, the mean incidence at this

TABLE 2
Clinical and biochemical response to treatment

	Unirradiated wheat	Freshly irradiated wheat	Stored irradiated wheat
Initial weight, kg	7.8 ± 0.684	7.48 ± 0.674	6.68 ± 0.520
Gain in weight			
at the end of 4 weeks, kg	0.88 ± 0.162	0.92 ± 0.287	1.40 ± 0.179
at the end of 6 weeks, kg	1.44 ± 0.286	1.88 ± 0.314	1.88 ± 0.102
Serum albumin, g/100 ml			
initial	1.46 ± 0.085	1.19 ± 0.097	1.45 ± 0.261
gain at the end of 4 weeks	1.12 ± 0.188	1.46 ± 0.401	1.14 ± 2.102
gain at the end of 6 weeks	1.37 ± 0.227	1.96 ± 0.216	1.66 ± 0.129
Hemoglobin, g/100 ml			
initial	9.5 ± 0.95	10.5 ± 0.79	8.2 ± 0.77
at the end of 6 weeks	9.5 ± 0.82	10.9 ± 0.62	9.6 ± 0.86

All values are mean ± SE. There are no differences between the three groups in any of the parameters studied.

time being 0.8%. At 6 weeks it had increased to 1.8%. In addition to distinct polyploid cells, where the number of chromosomes could be easily counted, there were other abnormal cells, characterized by splitting of their centromeres with widely separated chromatids. When these cells were also considered, the mean incidence of total abnormal cells at 4 and 6 weeks of feeding were 1.2 and 3.8%, respectively. In marked contrast, not a single polyploid cell or any other type of abnormal cell was found in any of the children who received unirradiated wheat. In the two children who were followed up after withdrawal of the irradiated wheat, the number of polyploid and abnormal cells had decreased considerably at the end of 16 weeks and by the 24th week all abnormal cells had completely disappeared. In children who had received the stored irradiated wheat, the incidence of definite polyploid cells was 0% at 4

TABLE 3
Incidence of polyploid cells in children suffering from kwashiorkor treated with unirradiated and irradiated wheat diets

	Unirradiated wheat	Freshly irradiated wheat	Stored irradiated wheat[a]
Initial	0	0	0
2 weeks	0	0 (0.4)	0
4 weeks	0	0.8 (1.2)	0 (0.6)
6 weeks	0	1.8 (3.8)	0.6 (0.8)

Figures in parentheses indicate the percent of total abnormal cells, including polyploid cells. 100 consecutive cells from each child were examined at each time interval. Five children were studied in each group. [a]Wheat was stored for 12 weeks after irradiation prior to being fed.

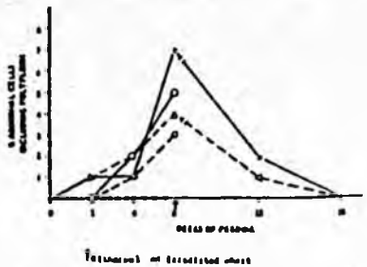

FIG. 1. Incidence of abnormal lymphocytes in five children fed freshly irradiated wheat

FIG. 3. Definite polyploid cell in a child fed irradiated wheat.

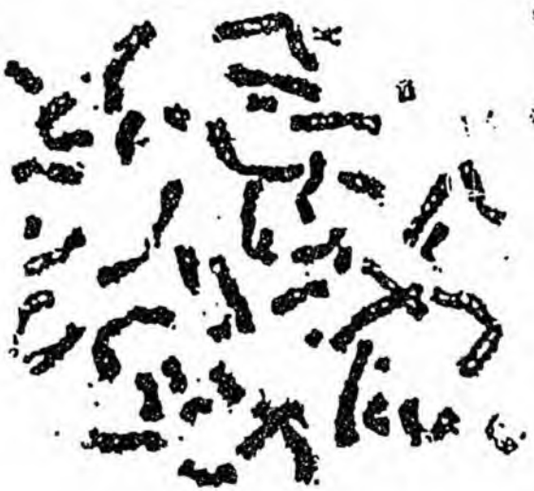

FIG. 2. Fuzzy chromosomal spread at the height of the disease.

FIG. 4. Abnormal spread in a child fed irradiated wheat.

weeks and only 0.6% at 6 weeks figures considerably lower than those seen in children fed freshly irradiated wheat. Even when the other types of abnormal cells were taken into consideration, at 4 weeks and 6 weeks, the figures were 0.6% and 0.8%. This reduction in the incidence was found to be statistically significant ($P < 0.01$). In none of the 15 children studied was there a single polyploid cell at the time of admission.

There were no differences between the three groups of children with regard to chromosomal aberrations like breaks, gaps, and deletions. The incidence of these aberrations at the height of the disease and after treatment were essentially similar. At the height of the disease in all children, the chromosomal spreads had a fuzzy appearance with indistinct borders. With the institution of treatment and improvement in nutritional status, the chromosomal outlines became sharper and the fuzziness tended to disappear.

Discussion

The most significant finding in this study is the appearance of a number of polyploid cells in children who had received freshly irradiated wheat, none in those who had received unirradiated wheat, and a considerably reduced number of polyploids in those who had received stored irradiated wheat. It must also be considered significant that the number of polyploid cells progressively increased with increasing duration of feeding irradiated wheat and that these cells gradually disappeared after irradiated wheat was withdrawn from the diet. These observations clearly indicate that the appearance of polyploid cells is due to the feeding of irradiated wheat. They further show that storage of wheat after irradiation greatly reduces the cytotoxicity induced by irradiation. Though the mechanism by which irradiated wheat induces polyploid cells is not known, these data suggest that a "colchicine-like" substance might have been formed in the wheat, as a result of irradiation, which tends to disappear with storage.

The precise biological significance of polyploidy is not known, but polyploid cells have been shown to occur in man in malignancy, after exposure to irradiation, during viral infections, and in senility (5).

The long-term health hazard significance of polyploidy seen in the children studied here who had received freshly irradiated wheat is not clear. On this will depend the answer to the question whether irradiated wheat is safe for human consumption. Though viral infections and administration of cytotoxic drugs may be associated with the presence of polyploid cells, its significance may perhaps not be the same as that of polyploid cells induced by the ingestion of irradiated wheat. While the former occur as isolated or as sporadic phenomena, wheat which is staple is consumed every day in large amounts and the consistent association of polyploidy with ingestion of such irradiated wheat has therefore to receive serious attention. The observation that polyploid cells were still present in circulation 16–20 weeks after irradiated wheat was withdrawn acquires importance in this context.

Very recently, it has been reported from this Institute (Vijayalaxmi and Sadasivan, to be published) that rats fed freshly irradiated wheat had increased numbers of polyploid cells in their bone marrows as compared with those fed unirradiated or stored irradiated wheat. A dominant lethal mutation effect, as well as reduced germ cell survival have also been reported in rats fed freshly irradiated wheat (6). In vitro cultures of human leukocytes in irradiated media have revealed significant chromosomal breakages (7). Viewed in the light of these observations, it is clear that a cautious approach has to be adopted to the whole question of the mutagenic potential of irradiated wheat.

The observation both in animals reported earlier from this Institute and in children reported here, that the cytotoxic effects of irradiated wheat were markedly reduced after it was stored for a period of 12 weeks must be considered important. They suggest that it is necessary to recommend that irradiated wheat be stored for periods beyond 12 weeks, before it can be considered safe for human consumption.

The authors are grateful to Dr. C. Gopalan, Director General, Indian Council of Medical Research, Dr. S. G. Srikantia, Deputy Director, Dr. B. S. Narasinga Rao and Dr. Vinodini Reddy, Assistant Directors, for their keen interest in this study and valuable guidance. They thank Dr. Sharat Chandra, Indian Institute of Science, Bangalore for his valuable suggestions. The authors also thank Mr. K. Visweswara Rao and Mr. A. Nadamuni Naidu for their help with statistical analysis and Mr. C. Nageswara Rao for his help in providing irradiated wheat.

References

1. World Health Organ. Tech. Rept. Ser. 451, 1970.
2. VENKATACHALAM, P. S., S. G. SRIKANTIA AND C. GOPALAN. Clinical features of nutritional oedema syndrome in children. Indian J. Med. Res. 42:555, 1954.
3. SRIKANTIA, S. G. Protein-calorie malnutrition in Indian children. Indian J. Med. Res. 57: Aug. Suppl. 36, 1969.
4. ARAKAKI, D. T., AND R. S. SPARKES. Microtechnique for culturing leucocytes from whole blood. Cytogenetics 2:57, 1963.
5. Editorial. Endoreduplication, polyploidy and leukaemia. Lancet ii, 511, 1964.
6. VIJAYALAXMI, C. Irradiated wheat induced dominant lethal mutation in rats. Mutation Res. In press.
7. SHAW, M. W., AND E. HAYES. Effects of irradiated sucrose on the chromosomes of human lymphocytes in vitro. Nature 211:1254, 1966.

ISOMEDIX

PLEASE DELIVER IMMEDIATELY TO:

Name: Senator Dick Eliason, Chairman
Labor & Commerce Committee

Telephone No. 907 465 4928

From: George G. Giddings, Ph.D., Consultant

Date: 12 April 1989

Time Transmission began: 4 Pm (Eastern daylite saving time)

Number of pages: 19
(including cover sheet)

We are transmitting from FAX NO. (201) 887-1476)

If you do not receive all of the pages,
please phone us at (201) 887-4700.

COMMENTS:

I just learned that your Committee will be hearing HB 25 to ban sale of so-called irradiated foods in Alaska. Last year I and professional colleagues sent out considerable documented information in opposition to predecessor legislation in the Alaska State Legislature. Given the closeness of the hearing on HB 25, and rather than replicate that which was sent out by me and others last year, I am faxing herewith the following more recent items: (1) consensis document from 12/1988 International U.N. Food Irradiation Conference at WHO HQ, Geneva, (2) list of U.S. delegation, (3) WHO position paper, (4) WHO new book announcement, (5) first two pages of USDA 35 page detailed denial of a petition for a hearing on its omnibus irradiated food approval regulation of 4/16/86. Irradiated food is safe and offers proven public health benefits, already being realized in a growing number of countries, in the absence of any proven risks! Anti-nuclear organizations mistakenly associate it with their real agenda because of the tiny, self-terminating and unneeded DOE demo-irradiation program that Alaska recently dropped out of (even though it was to be a linear accelerator like Florida and Iowa's). The "bottom line" is that States should not be preempting in advance their consumer's right of informed free choice with ill-advised, misguided legislation, born of confusion and misplaced anti-nuclear activism when the worldwide trend is toward fact-based public acceptance in recognition of public health and other benefits, in the absence of significant risk.

Respectfully,
G. G. Giddings
ISOMEDIX INC

DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOOD AND DRUG ADMINISTRATION

21 CFR Part 179

[Docket Nos. 81N-0004 and 84F-0230]

Irradiation in the Production, Processing, and Handling of Food

AGENCY: Food and Drug Administration.

ACTION: Final rule; denial of requests for hearing and response to objections.

SUMMARY: The Food and Drug Administration (FDA) is denying the requests that it has received for a hearing on the final rules that amended the food additive regulations to authorize the use of gamma radiation for the treatment of pork to control *Trichinella spiralis* and for the treatment of certain other foods. After reviewing the objections to the two final rules and the requests for a hearing, FDA has concluded that none of the objections has provided the information necessary to justify a hearing. FDA, however, is amending the language in the regulation that describes minor dry ingredients that may be radiation sterilized because objections and experience have shown that this language is ambiguous.

DATES: The amendment in 179.26(b) (21 CFR 179.26(b)) is effective December 30, 1988; written objections on the amendment and requests for a hearing on the amendment by January 30, 1989.

ADDRESS: Written objections on the amendment 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:

I. Background

In the Federal Register of July 22, 1985 (50 FR 29658), in response to a petition by Radiation Technology, Inc., FDA issued a final rule authorizing the irradiation of fresh pork to control *Trichinella spiralis*. FDA based its decision on data in the petition and in its files. The agency had published a notice announcing the filing of the petition (FAP 4M3789) in the Federal Register of July 23, 1984 (49 FR 29682).

In the Federal Register of April 18, 1988 (51 FR 13376), FDA issued a final rule, referred to herein as the "omnibus rule," that: (1) permitted manufacturers to use radiation at doses not to exceed 1 kilogray (kGy)(100 krad) to inhibit the growth and maturation of fresh foods and to disinfest food of arthropod pests; (2) permitted manufacturers to use radiation at doses not to exceed 30 kGy (3 Mrad) to disinfect dry or dehydrated aromatic vegetable substances (such as spices and herbs) of microorganisms; (3) required that foods that are irradiated be labeled to show this fact both at the wholesale and at the retail level; and (4) required that manufacturers maintain process records of irradiation for a specified period and make such records available for FDA inspection. FDA initiated this action by publishing a proposal in the Federal Register of February 14, 1984 (49 FR 5713).

A. Requests for hearing on final rules

Section 409(f) of the Federal Food, Drug, and Cosmetic Act (the act), 21 U.S.C. 348(f), provides that, within 30 days after publication of an order relating to a food additive regulation, any person adversely affected by such an order may file objections specifying with particularity the provisions of the order considered objectionable, stating reasonable grounds for the objections, and requesting a public hearing on such objections.

Under 21 CFR 171.110 of the food additive regulations, objections and requests for a hearing are governed by 21 CFR Part 12 of FDA's regulations. Under 21 CFR 12.22(a), (1) each objection must be submitted on or before the 30th day after the date of publication of the final rule; (2) each objection must be separately numbered; (3) each objection must specify with particularity the provision of the regulation or proposed order objected to; (4) each objection on which a hearing is requested must specifically so state; failure to request a hearing on an objection constitutes a waiver of the right to a hearing on that objection; and (5) each objection requesting a hearing must include a detailed description and analysis of the factual information to be presented in support of the objection. Failure to include a description and analysis for an objection constitutes a waiver of the right to a hearing on that objection.

FDA received 59 objections to the irradiated pork rule and 245 objections to the omnibus rule. Many of the objections expressed general opposition to food irradiation but identified no substantive question to which the agency can respond. Because these objections failed to raise any basis on which to question the validity of the final rules, the agency is denying them.

Seventeen objections to the irradiated pork rule and 53 objections to the omnibus rule pointed to a specific aspect of the rule but did not request a hearing. Twenty objections to the irradiated pork rule and 12 objections to the omnibus rule requested a hearing. These objections are addressed below.

Some of the objections requested a stay of the regulations. In the Federal Register of February 23, 1987 (52 FR 5450), FDA denied these requests because the public interest did not require a stay. FDA evaluated each of the contentions made in support of a stay and concluded that they failed to create significant doubts about the safety of the food irradiated under the conditions of either of the two regulations.

B. Standard for granting a hearing

The criteria for deciding whether to grant or deny a hearing are stated in 21 CFR 12.24(b). The regulation states that a hearing will be granted when the material submitted shows the following:

(1) There is a genuine and substantial issue of fact for resolution at a hearing. A hearing will not be granted on issues of policy or law.

(2) The factual issue can be resolved by available and specifically identified reliable evidence. A hearing will not be granted on the basis of mere allegations or denials or general descriptions of positions and contentions.

(3) The data and information submitted, if established at a hearing, would be adequate to justify resolution of the factual issue in the way sought by the person. A hearing will be denied if the Commissioner concludes that the data and information submitted are insufficient to justify the factual determination urged, even if accurate.

(4) Resolution of the factual issue in the way sought by the person is adequate to justify the action requested. A hearing will not be granted on factual issues that are not determinative with respect to the action requested, e.g., if the Commissioner concludes that the action would be the same even if the factual issue were resolved in the way sought, or if a request is made that a final regulation include a provision not reasonably encompassed by the proposal.

(5) The action requested is not inconsistent with any provision in the act or any regulation in this chapter particularizing statutory standards. The proper procedure in those circumstances is for the person requesting the hearing to petition for an amendment or waiver of the regulation involved.

(6) The requirements in other applicable regulations, e.g., 21 CFR 10.20, 12.21, 12.22, 314.200, 430.20(b), 514.200, and 601.7(a), and in the notice promulgating the final regulation or the notice of opportunity for hearing are met.

A party seeking a hearing is required to meet a "threshold burden of tendering evidence suggesting the need for a hearing." *Costle* v. *Pacific Legal Foundation*, 445 U.S. 198, 214–215 (1980), *reh. den.*, 445 U.S. 947 (1980), citing *Weinberger* v. *Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609, 620–621 (1973). An allegation that a hearing is necessary to "sharpen the issues" or to "fully develop the facts" does not meet this test. *Georgia Pacific Corp.* v. *U.S. E.P.A.*, 671 F.2d 1235, 1241 (9th Cir. 1982). If a hearing request fails to identify any evidence that would be the subject of a hearing, there is no point in holding one.

A hearing request must not only contain evidence, but that evidence must raise a material issue of fact concerning which a meaningful hearing might be held. *Pineapple Growers Ass'n* v. *FDA*, 673 F.2d 1083, 1085 (9th Cir. 1982). Where the issues raised in the objection are, even if true, legally insufficient to alter the decision, the agency need not grant a hearing. *Dyestuffs and Chemicals, Inc.* v. *Flemming*, 271 F.2d 281 (8th Cir. 1959), *cert. denied*, 362 U.S. 911 (1960). FDA need not grant a hearing in each case where an objector submits additional information or posits a novel interpretation of existing information. (See *United States* v. *Consolidated Mines & Smelting Co.*, 455 F.2d 432 (9th Cir. 1971)). Stated another way, a hearing is justified only if the objections are made in good faith, and if they "draw in question in a material way the underpinnings of the regulation at issue." *Pactra Industries* v. *CPSC*, 555 F.2d 677 (9th Cir. 1977). Finally, courts have uniformly recognized that a hearing need not be held to resolve questions of law or policy. (See *Citizens for Allegan County, Inc.* v. *FPC*, 414 F.2d 1125 (D.C. Cir. 1969); *Sun Oil Co.* v. *FPC*, 256 F.2d 233, 240 (5th Cir.), *cert. denied*, 358 U.S. 872 (1958)).

Even if the objections raise material issues of fact, FDA need not grant a hearing if those same issues were adequately raised and considered in an earlier proceeding. Once an issue has been so raised and considered, a party is estopped from raising that same issue in a later proceeding without new evidence. The various judicial doctrines dealing with finality are validly applied to the administrative process. In explaining why these principles "self-evidently" ought to apply to an agency proceeding, the D.C. Circuit wrote:

> The underlying concept is as simple as this: Justice requires that a party have a fair chance to present his position. But overall interests of administration do not require or generally contemplate that he will be given more than a fair opportunity.

Retail Clerks Union, Local 1401, R.C.I.A. v. *NLRB*, 463 F.2d 316, 322 (D.C. Cir. 1972). (See *Costle* v. *Pacific Legal Foundation, supra* at 1106. See also *Pacific Seafarers, Inc.* v. *Pacific Far East Line, Inc.*, 404 F.2d 804 (D.C. Cir. 1968)).

C. Objections to the pork regulation and the omnibus regulation

Six of the 20 objections to the irradiated pork rule that requested a hearing did not point to any specific aspect of the rule. Six of the 12 objections to the omnibus rule that requested a hearing were either form letters or objections that requested a hearing on the subject but that did not point to any specific aspect of the rule that they sought to challenge. Because no evidence was submitted in support of these objections, they raise no factual issue for resolution and, therefore, do not justify a hearing. The agency will not discuss them further.

One objection to the omnibus rule requested a hearing but was not submitted to FDA until after the close of the objection period. Hence, this objection failed to satisfy the requirements of 21 U.S.C. 348(f)(1) and need not be considered further by the agency. *ICMAD* v. *HEW*, 574 F.2d 553, 558 n.8 (D.C. Cir.), *cert. denied*, 439 U.S. 893 (1978). Issues raised in the tardy objection were also raised in other objections, however, and thus will be addressed in this document.

One of the objectors to the omnibus rule, the Health and Energy Institute, on behalf of itself and the Environmental Policy Institute (HEI), submitted numerous objections. However, HEI submitted very little evidence in support of these objections. HEI did promise, with respect to several of its objections, to submit evidence at any hearing that is held. FDA evaluated these objections. Most did not present enough information to draw the agency's action into question in a material way. These the agency proceeded to consider without further information from HEI. However, some of the objections did suggest the possible existence of a substantial issue of fact but did not identify enough evidence to determine whether these objections provided an appropriate basis for an evidentiary hearing. On February 2, 1987, the agency wrote to HEI and asked it to submit additional information on this latter group of objections to aid FDA in deciding whether any of them justified a hearing (Ref. 1). HEI provided additional information on March 6, 1987 (Ref. 2).

On May 5, 1987, the agency again wrote to HEI and requested two references that HEI had cited in its March 6, 1987, submission but that were not available in FDA's files (Ref. 3). FDA gave HEI 14 days to supply copies of these references. On May 21, 1987, HEI provided one of these references, an article cited by that reference, and two additional articles, but it was unable to obtain the second reference that FDA had requested (Ref. 4).

There was considerable overlap in the objections to the two rules on irradiation. Some objections raised in response to the pork rule are, in fact, more applicable to the omnibus rule. Therefore, FDA will deal with the objections to both rules together.

Because HEI provided the most detailed objections, its objections will be the focus of much of this document. Where other objections raised the same or a similar issue as one raised by HEI, FDA will incorporate these other objections in its descripnon of the issue. The agency has grouped together all objections that raise the same concern and has analyzed most of the objections according to the following four-part format: (1) A statement of a specific position or conclusion set forth by FDA in the final rule; (2) a summary of the challenge to that conclusion and of the basis for the request for a hearing, if one was made; (3) a discussion of whether the objection justified a hearing on that objection; and (4) where appropriate, a review of the evidence relevant to the objection.

II. Safety of Food Irradiation

In both the pork and omnibus final rules, FDA concluded that food irradiated under specified conditions is safe. FDA based its conclusion primarily on an analysis (49 FR 29682; 51 FR 13376 at 13378) that demonstrates that foods irradiated at doses permitted under these final rules undergo only minimal chemical change and are toxicologically indistinguishable from nonirradiated foods. The agency considered the sensitivity of a variety of state-of-the-art toxicology testing regimens, including extraction and concentration of radiolytic products, to determine the best way of evaluating the safety of irradiated foods (Ref. 5). The agency's analysis also included a review by the Bureau of Foods Irradiated Foods Task Group (Task Group) of all available

U.S. DELEGATION

INTERNATIONAL CONFERENCE ON THE ACCEPTANCE, CONTROL OF, AND TRADE IN IRRADIATED FOODS

HEAD

Kenneth A. Gilles, Ph.D., Assistant Secretary for Marketing and Inspection Services, U.S. Department of Agriculture, Washington, DC
elected Chairman of Conference

Delegates

James R. Brooker, Director, Utilization Research and Services Division, National Marine Fisheries Service, National Oceanic and Atmospheric Administration, U.S. Department of Commerce, Washington, DC

Donald D. Derr, Director, Food Ingredient Assessment Division, Science, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC

Ronald E. Engel, D.V.M., Ph.D., Assistant to the Administrator for International Scientific Liaison, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC

Harry Farrar IV, Ph.D., Manager, Applied Nuclear Research, Rocketdyne Division, Rockwell International, Canoga Park, California

→ George G. Giddings, Ph.D., Consultant, Council for Agricultural Science and Technology, Ames, Iowa

Richard A. Greenberg, Ph.D., Director, Office of Scientific Public Affairs, Institute of Food Technologists, Chicago, Illinois

George H. Pauli, Ph.D., Supervisor, Food Additives Policy Staff, Division of Food and Color Additives, Center for Food Safety and Applied Nutrition, Food and Drug Administration, U.S. Department of Health and Human Services, Washington, DC

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

Barbara H. Thomas, Office of Nuclear Nonproliferation Policy, International Affairs and Energy Emergencies, U.S. Department of Energy, Washington, DC

Document on Food Irradiation

Adopted on 16 December 1988 by the
FAO/IAEA/WHO/ITC-UNCTAD/GATT*
International Conference on the
Acceptance, Control of, and Trade in Irradiated Food
Geneva, 12-16 December 1988

The Conference, which brought together some 220 participants, was attended by official delegations from 57 countries, comprising government officials at the senior policy-making level, experts in law, health, energy, and food, and representatives of consumer unions, as well as by representatives from 13 international organizations.

Issued by the World Health Organization, on behalf of all sponsoring agencies, on 21 December 1988

*Food and Agriculture Organization of the United Nations, International Atomic Energy Agency, World Health Organization, and the International Trade Centre (a joint sub-organ of the United Nations Conference on Trade and Development and the General Agreement on Tariffs and Trade)

INTRODUCTION

1. All governments bear a responsibility to ensure sufficient supplies of safe, nutritious and acceptable food to meet the needs of their people. Such supplies should be of high quality and should comprise a wide variety of foodstuffs. Governments should also feel responsible towards contributing to the improvement of the global food supply.

2. In no country can these objectives be achieved without dependence on food processing and preservation technology to a greater or lesser degree. The problems of achievement are compounded by differing agro-climatic conditions, levels of technology, seasonality of production and the perishable nature of many crops. The application of food processing technology is therefore necessary for two important reasons. One is to prolong the availability of seasonally produced crops and to minimize food losses; the other is to reduce the incidence of illness caused by food-borne pathogens. Each country will have differing requirements in these two areas, but the overall trend towards increasing urbanization of the world's population results in an increasing need for processed food, and for the development of appropriate processing and preservation technologies.

3. In the case of certain food imports, additional specialized treatment may be applied to satisfy quarantine requirements necessary to exclude insect pests of economic or environmental significance from the importing country. Lack of acceptable quarantine treatments can result in the loss of foreign exchange earnings, which in turn could affect the ability of an exporting country to provide basic food supplies and socio-economic development for its own population. Irradiation, as a process to ensure that a pest is unable to become established in the importing country, can be an alternative to chemical fumigation and other physical methods.

4. No treatment of food can be employed in the long term unless it has the acceptance of the consumer. In many cases, acceptance can be expected because the palatability of the original food is maintained or because the choice is between the treated food and no food at all (because untreated food would be spoiled). Given the choice, many consumers would generally prefer that food should be unprocessed if at all possible, but such an ideal is not a practicable possibility in many cases, nor is it always desirable.

5. The foregoing requirements for treatment or preservation of food are currently being addressed by a variety of processes, some of which such as drying and salting are of considerable antiquity, while others such as fumigation, canning and freezing are of more recent origin. Treatment by ionizing radiation is now beginning to be used to supplement existing technologies for certain applications. One of these applications, which has potential for beneficial public health effects, is the reduction of pathogenic microorganisms in solid foods.

6. The Conference therefore devoted itself to a careful consideraton of the particular conditions under which food irradiation should be allowed to play a part in ensuring the supply of wholesome food in association with existing and already widely used food preservation and food quarantine treatments. In this context, the Conference recognized the Codex General Standard for Irradiated Foods and Recommended International Code of Practice for the Operation of Radiation Facilities Used for the Treatment of Foods. The Conference also considered consumer attitudes, inter-governmental and governmental activity, process control and trade.

CONSUMER ATTITUDES TO IRRADIATED FOOD

7. The potential for food irradiation to help maintain a safe and adequate food supply cannot be attained unless irradiated foods are accepted by consumers. On one level of acceptance, the final food product must be of satisfactory quality at a reasonable cost. On a deeper level, however, a consumer who is satisfied with the food currently available should not be expected to be enthusiastic about any change in the current food production system, especially if that change is perceived to be significant.

8. A consumer has a right to expect that food available in commerce is safe and wholesome; that is, the food promotes health because it is nutritionally adequate, microbiologically safe, and does not contribute to toxic effects due to chemicals either produced in the food during processing or added to food by some other means. The terminology used for food irradiation is sometimes confused with that used to describe radioactive contamination. This confusion can best be addressed by proper information. Consumers may also be concerned that introduction of ionizing radiation technology into food processing may lead to an increased probability of accidents leading to environmental contamination or worker hazards.

9. Although wholesomeness of the food is a necessity, it is difficult for a consumer to determine when the criterion of wholesomeness is met. Food is a complex mixture of components and its safety and nutritional adequacy cannot be judged outside the context of the diet of which it is a part. As with any other food processing technique, the matters of safety and nutrition related to food irradiation must continue to be monitored inter alia through further international cooperation and research. As new information becomes available, it should be considered by the authorities concerned.

10. Illness due to food-borne microorganisms is often difficult to trace to a particular food. Its usual incidence is often underestimated by consumers. If the facts on illness resulting from food-borne microorganisms are not understood by consumers, they may not be able to understand the potential impact of food irradiation and other methods for microbial control.

11. As part of the control of the irradiation process, consumers need to be convinced that the potential accomplishments of food irradiation are not negated by a misuse of technology. Although irradiation cannot reverse the effects of spoilage, consumers need reasons for confidence that irradiation will not be used to mask deficiencies of an inferior product. Such confidence can result from a better understanding of the capabilities and limitations of the various individual uses of irradiation and knowledge that irradiation is not being used as a substitute for otherwise achievable good manufacturing practices. Furthermore, like any other process, food irradiation must in no way be used to mislead consumers, and in this respect governments have a major role to play.

12. Information about irradiated food products and processing should be presented to consumers in an objective and clear manner on a continuous basis. The need for such information is particularly important at the time of introduction of irradiated food products when consumer interest and curiosity are expected to be greatest. If necessary, such information should include any special instructions on handling, storage and preparation of irradiated food at home.

13. In cases where irradiated foods are permitted, consumers should be able to make their own choice between irradiated and nonirradiated food. To enable them to make this choice, there must be clear and unambiguous labelling. It is for individual governments to meet this

need in their own countries. International standards for labelling are being developed by the Codex Alimentarius Commission*. Documentation must be sufficient to ensure transfer of information through international trade so that national labelling requirements can be met.

14. It is well known that the changes associated with food irradiation are difficult to detect. However, it is recognized that detection methods, if available, would augment standard regulatory procedures and would thereby help assure consumers that processors and distributors are adhering to government control procedures. Research on detection methodology should be continued.

15. Consumer confidence can be bolstered when there is clear evidence that the food irradiation process is being effectively controlled by a responsible industry and a governmental regulatory process. Because the factors needed to control the irradiation process effectively are the same everywhere, it is reasonable to expect substantial harmonization of national approaches.

INTER-GOVERNMENTAL AND GOVERNMENTAL ACTIVITY

16. In 1980, a Joint FAO/IAEA/WHO Expert Committee on the Wholesomeness of Irradiated Food declared that the irradiation of any food up to an overall average dose of 10 kGy causes no toxicological hazard and introduces no special nutritional or microbiologial problems.

17. Some concerns about the effects of irradiation on microorganisms in food had been raised earlier at a meeting of the Codex Committee on Food Hygiene in 1979. Therefore the microbiological safety of irradiated food was further considered at a meeting of the Board of the International Committee on Food Microbiology and Hygiene of the International Union of Microbiologial Societies in Copenhagen in December 1982 in order to provide a second opinion. In its conclusions, the Board was satisfied that there was no cause for concern. Food irradiation was said to be an important addition to the methods of control of food-borne pathogens and not to present any additional hazards to health.

18. Following these expert meetings, the Codex Alimentarius Commission, then representing 122 countries, in 1983 adopted the Codex General Standard for Irradiated Foods and the Recommended International Code of Practice for the Operation of Radiation Facilities Used for the Treatment of Foods. There was broad consensus among the representatives for this adoption, except for two countries which expressed their reservations.

19. The Codex General Standard for the Labelling of Prepackaged Food contains provisions on the labelling of irradiated foods (CODEX STAN. 1-1985, section 5.2). However, as many countries have not yet taken a final position as to how the fact of irradiation should be declared, this section remains under review until the next session of the Codex Committee on Food Labelling and of the Codex Alimentarius Commission in 1989.

20. At the request of over 60 Member States to continue a forum of international co-operation with emphasis on harmonization of national regulations based on the principles of the Codex General Standard for Irradiated Foods and its associated Code of Practice, an International Consultative Group on Food Irradiation (ICGFI) was established under the aegis of FAO, IAEA and WHO in May 1984. The main functions of the Group are to evaluate global developments, provide a focal point of advice and furnish information on food irradiation as required to Member States and the Organizations. The Group now has 28 member countries contributing either in cash or in kind to its activities, which include the maintenance of international inventories of food irradiation

*Codex General Standard for the Labelling of Prepackaged Food (CODEX STAN. 1-1985, Rev. 1-1991)

facilities, product clearances and national legislations and regulations, as well as the organization of workshops and task forces, and the preparation of technical guidelines for irradiation processing of various food groups. At its fifth meeting the Group noted that 20 countries are using irradiation for processing food and food ingredients; commercial and demonstration irradiators for treating food are being constructed or are in the advanced planning stages in fourteen countries. The Secretariat of the Group anticipated that some 25 countries will be applying the technology on a commercial scale by 1990.

21. The attitudes of governments towards irradiation of food range from those which have accepted and are applying the technology to those which are interested and exploring it, to those which have decided not to permit the technology at the present time, and to those which have no definite opinion. Some governments consider that there is no need for the technology in their countries. In general, however, countries which express reservations, such as potential misuse of the technology, have not disagreed in principle on the safety of food treated in accordance with adequate standards, such as the Codex General Standard for Irradiated Foods.

22. To a large extent the attitude of governments is influenced by consumer acceptance. If there is widespread opposition among consumers, this may be taken as a reason not to accept the method. Governments share the view that if the sale of irradiated foods is permitted in their countries, the foods would have to be labelled to inform consumers about the irradiation. Adequate regulatory control is generally regarded as the basic responsibility of governments to engender consumer confidence in the process.

23. Governments share the view that all food irradiation facilities should conform to internationally agreed standards of radiation protection, including worker and public safety, transport and disposal of source material and environmental protection.

PROCESS CONTROL

24. Facilities which are intended to carry out irradiation of food should meet appropriate standards of safety and good hygiene conditions for processing. Therefore, such facilities should be operated in accordance with the principles of the Codex General Standard for Irradiated Foods and associated Code of Practice; operational control of such facilities should be subject to inspection by competent authorities.

25. Facilities for irradiating food should be properly designed and constructed. Operation should be by appropriately trained personnel. It is necessary to have an infrastructure that includes support facilities and equipment, and a well-established regulatory system.

26. Food intended for treatment by irradiation should be of a quality acceptable for Good Manufacturing Practices (GMP). Hygienic practices which are needed in GMP for other processes are also necessary in the process of irradiation, but irradiation should not be used as a substitute for such practices. Wherever necessary, pre-treatment of food such as cooling, chilling and freezing should be carried out in such a manner as to achieve effective treatment. Suitable packaging materials are currently available for use when prepackaging is required to prevent recontamination after irradiation.

27. The effectiveness of the irradiation process depends on proper application of dose, and its measurement. Initial dose distribution measurements should be carried out to characterize the process for each product, and thereafter dosimeters should be used routinely to monitor correct execution of the process in accordance

with internationally accepted procedures. The dosimetry should be traceable to national or international standards and thus provide an independent control of the process.

28. Simple radiation indicators which can help the processor in identifying the food which is treated, applied to the product pack prior to treatment, are available for certain dose ranges.

29. As with all food processing, it is important to apply effective quality control, not only at the irradiation process level but also in production, storage, transport and retail sales. It is also necessary to identify critical control points and methods for monitoring by operators and regulatory authorities. The regulatory personnel and those responsible for food irradiation should be trained in quality control. The personnel responsible for controlling the plant should have proper training in operation of the facilities as well as in handling of the foods concerned. The quality control system would also include proper packaging suitable for the product and appropriate temperature control in storage and handling. Products which could become infested by insects or contaminated by microorganisms after treatment should be packed and stored in such a way that reinfestation or recontamination is prevented. Food should be handled, stored and transported according to GMP before, during and after irradiation.

TRADE

30. Control of food in trade by public authorities is essential, whether or not the food is treated by any process, to ensure that any treatment, if applied, is done in a safe and proper manner, and with adequate safeguards against abuse. Proper controls are particularly relevant to both national and international trade in irradiated food. Control should be exercised at all stages of handling up to the point of sale to consumers.

31. Because of the nature of the process, which makes it difficult at present to determine the circumstances of irradiation by examination of the food, control of irradiated food has to be established through legally-based administrative procedures. These procedures, whether the product is intended for domestic use or export, should include on the one hand a system of documentation allowing each batch of irradiated food to be identified with the irradiation facility and with the treatment given, and on the other hand a system of labelling. Other methods of control and compliance should be considered as technology progresses; therefore research on analytical methods for identification of radiation-processed food in trade should be encouraged.

32. The purpose of labelling need not merely be to inform the consumer of the fact of irradiation, but may also indicate the purpose for which treatment has been given (see also paragraph 19). The additional use of a logo to identify irradiated food should be encouraged.

33. The system of control should apply to both domestically produced and imported foods. Internationally recognized standards of control which allow adequate account to be taken of the needs and policies of individual countries would help to avoid the creation of unnecessary obstacles to trade.

34. The harmonization of Standards and Codes of Practice for regulating irradiated food and irradiation facilities by public authorities, and for the training of inspectors, plant operators and food control officials according to an internationally accepted and certified curriculum, would also help to achieve acceptance of irradiated foodstuffs by consumers in the importing country. The principles embodied in the Codex General Standard for Irradiated Foods and associated Code of Practice are considered to form a suitable basis for the harmonization of national procedures.

Food Irradiation

The position of the World Health Organization

Statements to the press issued on the occasion of the International Conference on the Acceptance, Control of, and Trade in Irradiated Food, 12-16 December 1988, Geneva

CONCLUSIONS

35. The Conference recognized that:

35.1 Food irradiation has the potential to reduce the incidence of food-borne diseases through the reduction of pathogen contamination in foods, especially in solid foods.

35.2 Food irradiation can reduce post-harvest food losses and make available a larger quantity and a wider variety of foodstuffs for consumers. It can also be an effective quarantine treatment for certain foods and thus contribute to international trade.

35.3 Regulatory control by competent authorities is a necessary prerequisite for introduction of the process in accordance with the principles of the Codex General Standard for Irradiated Foods and Recommended Code of Practice for the Operation of Radiation Facilities Used for the Treatment of Foods. Food irradiation is not to be used as a substitute for Good Manufacturing Practices.

35.4 International trade in irradiated foods would be facilitated by harmonization of national procedures based on internationally recognized standards for the control of food irradiation.

35.5 Acceptance of irradiated food by the consumer is a vital factor in the successful commercialization of the irradiation process, and information dissemination can contribute to this acceptance.

RECOMMENDATIONS

36. The Conference recommended that:

36.1 Consideration should be given to the application of food irradiation technology for public health benefits, especially for products where this process would seem advantageous.

36.2 Consideration should be given to the application of food irradiation technology where it can, in appropriate cases, reduce post-harvest losses of foods and serve as a quarantine treatment.

36.3 Governments should ensure that, as a prerequisite to any processing of food by irradiation or sale of irradiated food, regulatory procedures for control are introduced. Key principles which should be incorporated are the registration/licensing, regulation and inspection of food irradiation facilities, documentation and labelling of irradiated food, training of control officials, and employment of Good Manufacturing Practices.

36.4 Regulatory procedures for control of the food irradiation process should be consistent with internationally agreed principles as embodied in the Codex General Standard for Irradiated Foods and associated Code of Practice. Dosimetry traceable to national or international standards should be applied during the irradiation process, providing a means of independent verification.

36.5 Governments should encourage research into methods of detection of irradiated food so that administrative control of irradiated food once it leaves the facility can be supplemented by an additional means of enforcement, thus facilitating international trade and reinforcing consumer confidence in the overall control system.

36.6 Labelling of irradiated food for international trade should be in line with the provisions as adopted by the Codex Alimentarius Commission.

36.7 Governments should ensure that all phases of planning and operation of food irradiation facilities are subject to a regulatory structure consistent with relevant internationally accepted standards for human health, safety and environmental protection.

36.8 Governments, especially those that envisage authorization of food irradiation, are encouraged to provide clear and adequate information about food irradiation to the public. The active participation of all interested parties, including consumers, should be encouraged.

The contribution of food irradiation to public health

Food irradiation is a technology that can, under certain circumstances, be safely used to help control two of the most serious problems connected with food supplies: the huge avoidable losses of food through deterioration and the illness and death that result from the consumption of contaminated food.

Foodborne diseases

For WHO, the main interest in food irradiation comes from its capacity to destroy certain foodborne pathogens and thus to reduce the enormous public health problems caused by microbiologically contaminated foods. In 1983 a joint FAO/WHO Expert Committee on Food Safety concluded that foodborne disease, while not well documented, was one of the most widespread threats to human health and an important cause of reduced economic productivity.

A relatively high percentage of raw foods of animal origin are contaminated by pathogenic bacteria, and this results in high levels of foodborne illness in all countries for which statistics are available. Among the factors that appear to account for the increases in foodborne disease are explosive growth in the mass rearing of food animals, polluted environments, mass production of foods of plant origin, increasing international trade in food and animal feed, and the large-scale movement of people as guest workers, immigrants, and tourists.

Meat and meat products also play a major role in infections such as trichinosis and toxoplasmosis, caused by a parasitic nematode (or worm) and a protozoon-like microorganism respectively. It is conservatively estimated that the cost of medical care and lost productivity resulting from major diseases spread by contaminated meat and poultry amounts to at least US$ 1000 million a year in the United States of America alone.

Food irradiation is an important process which has the potential to reduce the incidence of foodborne disease. As with the treatment of liquids such as chlorination of drinking water and the pasteurization of milk, treatment with ionising radiation can significantly reduce pathogen contamination of solid foods.

Food losses

Food irradiation also has the capacity to kill insect pests and destroy the microorganisms that hasten the spoilage of food. WHO is interested in the nutritional improvements and economic savings that could be achieved through the use of irradiation to reduce avoidable food losses, particularly in countries where many desperately needed foods either rot before they reach consumers or, as is often the case with cereal grains, are ruined by insect pests during storage.

In countries with a warm climate, the estimated storage loss of cereal grains and legumes is at least 10%. With non-grain staples, vegetables, and fruits, the losses due to microbial contamination and spoilage are believed to be as high as 50%. In commodities such as dried fish, insect infestation is reported to result in the loss of 25% of the product, plus an additional 10% loss due to spoilage. With a rapidly expanding world population, any preventable loss of food is intolerable.

PAGE 1 — CONTINUED

Alternative to chemicals

Because of its capacity to destroy insect pests, food irradiation offers an important alternative to the use of chemicals as a means of meeting quarantine requirements for the insect disinfestation of food commodities in international trade. Interest in this particular application has increased following the recent banning, in several countries, of ethylene dibromide, a chemical that has been widely used to treat fresh fruits and vegetables in quarantine.

PAGE 2 — CONTINUED

The WHO position on consumer acceptance

Consumers have the right to know how the foods they eat have been processed and treated — whether by irradiation or by any other physical or chemical method of food preservation. Consumers also have the right to make their own food choices on the basis of this knowledge.

Public understanding of what irradiation can and cannot do is the only reliable path towards general acceptance and fuller use of food irradiation for the benefit of mankind.

The safety of irradiated food

One of the constitutional functions of WHO is to act as the world's directing and coordinating authority on questions of public health and to issue advice when controversies arise. In this capacity, WHO has convened meetings, dating back to 1961, of internationally respected experts asked to reach conclusions, based on a critical evaluation of available scientific data, concerning the wholesomeness of irradiated food. The conclusions reached are that foods irradiated up to an overall average dose of 10 kGy are nutritionally sound and safe for human consumption.

WHO is satisfied with these conclusions. The overall average dose of 10 kGy was used in view of the fact that most applications of food irradiation do not require higher doses. WHO does not mean to imply that food having been exposed to higher doses would automatically be rendered unsafe. Governments in some countries, such as the United States of America, have approved higher energy levels for specific applications. WHO is now in the process of preparing an international safety and wholesomeness evaluation of foods treated with energy levels higher than 10 kGy.

Labelling

WHO regards the clear labelling of irradiated foods as obligatory. This view is in line with the WHO position that consumers have the right to know what has been done to the foods they eat and to make their own choices. The facts that the irradiation technique is safe and effective and that irradiated foods are wholesome and pose no threat to health are not grounds for secrecy.

Consumer acceptance in individual countries

The international conference on food irradiation is an intergovernmental conference convened by the sponsoring agencies at the request of governments.

The role of WHO at the international level has been to secure the consensus of renowned experts that irradiated foods are safe and nutritious, to take the position that consumers have the right to know what has been done to the foods they eat, and to insist on the clear labelling of irradiated foods. WHO has no authority to advise individual governments on national questions of consumer acceptance.

PAGE 3 — CONTINUED

The controversial "Indian" studies

Background

A paper titled *Effects of Feeding Irradiated Wheat to Malnourished Children*, authored by Bhaskaram and Sadasivan and published in 1975, is frequently cited as providing scientific evidence that irradiated foods are unsafe for human consumption.

The study, which was conducted at the National Institute of Nutrition (India), involved the feeding of freshly irradiated wheat for 4-6 weeks to 5 malnourished Indian children aged from 2 to 5 years. The 5 children reportedly showed more chromosomal changes (polyploid cells) than children fed irradiated wheat that had been stored for 12 weeks prior to use. Earlier studies, involving experimental animals, had produced similar results.

The Bhaskaram and Sadasivan study was designed to assess how long irradiated wheat should be stored prior to consumption, and concluded with the recommendation that "irradiated wheat be stored for periods beyond 12 weeks, before it can be considered safe for human consumption." The study acknowledged that the "precise biological significance of polyploidy is unknown", and pointed out the need for further studies. The study also noted that other factors — such as the presence of viral infections (to which malnourished children are especially susceptible) and the administration of certain drugs — are known to produce polyploid cells.

The main question addressed in the study —namely, how long irradiated wheat should be stored prior to human consumption — has been resolved. Subsequent studies carried out by other investigators in the same country and elsewhere found no increase in chromosomal changes even when using wheat stored for only 24 hours after irradiation.

Questions concerning the reported link between chromosomal changes and the consumption of irradiated foods have also been submitted to scientific scrutiny through considerable additional research as well as through panels of experts convened by WHO and the governments of several countries.

The WHO reply

An FAO/IAEA/WHO Expert Committee examined the issue in 1976 and concluded that the significance of the reported chromosomal changes was not clear, since the natural frequency of such changes is highly variable. The director of the institute where the study was conducted was a member of the Expert Committee. The conclusions were as follows:

"The Committee noted the increase in frequency of polyploid cells reported in certain investigations on several species fed freshly irradiated wheat. However, no increase in polyploidy was seen when wheat stored for 12 weeks after irradiation was used. Since irradiated wheat is usually stored for longer than 12 weeks, no problems are likely to arise in practice. Furthermore, in studies carried out by other investigators, no increase in the frequency of polyploidy was observed even when using wheat stored for as short a period as 24 hours after irradiation .. Toxicological data do not indicate any health hazard resulting from the consumption of irradiated wheat and ground wheat products."

PAGE 4— CONTINUED

In its final evaluation, the Committee further recommended the "unconditional acceptance of wheat and ground wheat products irradiated for the purpose of disinfestation with a maximum radiation dose of 1 kGy (100 krad)."

Other evaluations

An independent investigative committee, appointed by the government of India, concluded in its report in 1976 that the data from the Bhaskaram and Sadasivan study failed to demonstrate any association between the consumption of irradiated wheat and chromosomal abnormalities.

Health agencies and expert committees in Denmark, the United Kingdom, and the United States of America concluded that the original Indian study did not demonstrate an adverse effect of irradiation.

When human volunteers in China consumed various irradiated foods for periods of 7-15 weeks, they showed no signs of any adverse health effects, including chromosomal changes.

WORLD HEALTH ORGANIZATION PUBLICATIONS

NEW BOOK ANNOUNCEMENT

Food Irradiation

A Technique for Preserving and Improving the Safety of Food

Published by the World Health Organization in collaboration with the Food and Agriculture Organization of the United Nations

1988, 84 pages (available in English; French and Spanish in preparation)
ISBN 92 4 154240 3
Sw.fr. 16.—US $12.80
Order no. 1150302

This book provides a factual, objective, and authoritative account of the role of food irradiation as a technique for improving food safety and reducing food losses. Written in non-technical language, the book attempts to give consumers, consumer protection groups, and government officials the facts they need to form an opinion about the acceptability of irradiated foods. To this end, chapters draw upon extensive scientific evidence, supported by practical experiences in more than 30 countries, to explain what the process is, how it works, and what it will and will not do. Throughout, information and explanations are guided by a genuine respect for the fears of consumers, particularly concerning questions of safety and quality.

The book opens with an explanation of conventional methods used to preserve food, including facts about how each method works and its comparative advantages and limitations. Against this background, readers are then given a view of the origins and development of food irradiation as a technique for preventing food spoilage and protecting consumers against foodborne disease. The critical questions of safety and quality form the focus of the third chapter, which summarizes the results of numerous scientific studies concerned with the effects of irradiation on the food itself, on the microorganisms and insects that may contaminate the food, and on the health and well-being of consumers.

Having summarized the scientific evidence, the book then reviews practical lessons gleaned from the use of food irradiation in some 34 countries. Readers learn which foodstuffs are suitable for radiation treatment, what actually happens to food and food contaminants when they are subjected to ionizing radiation, and what levels of radiation are used to preserve various kinds of food. The chapter also reviews the different sets of problems, faced in tropical and in developed countries, that need to be addressed in any consideration of the use of food irradiation. Safety issues are again considered in a chapter on legislation, which describes regulatory measures required to control the safe setting-up and operation of food irradiation facilities. The final chapter, concerned with the issue of consumer acceptance, provides concise factual answers to 16 questions about food irradiation that are frequently raised by consumers and consumer groups. The book concludes with a 10-page table showing which irradiated foods have been cleared for human consumption by governments in 34 countries, followed by presentation of an internationally-agreed standard and a code of practice recognized by regulatory authorities and industry.

Prepared by a group of 10 international experts, checked for technical accuracy by several food safety institutions, and backed by the authority of FAO and WHO, the book should do much to promote public understanding as the only reliable path towards general acceptance and fuller use of food irradiation for the benefit of mankind.

See reverse for more information

WHO • Distribution and Sales • 1211 Geneva 27 • Switzerland