ALASKA LEGISLATURE COMMITTEE BILL FILES - 1987 - 1988 8879
HB 387 thru HB 388 353

HB
387

HOUSE COMMITTEE REPORT

(21)

Date referred: 2/24/88 FURTHER REFERRALS:

DATE: 3/11/88

The Finance Committee has considered HB 387

"An Act making a special appropriation to the Department of Public Safety for a reward program to promote the apprehension and conviction of persons who violate certain alcohol control laws; and providing for an effective date."

RECOMMENDS:

[X] replace with CS HB 387(Jud.) [ ] the same title

[X] a new title

[ ] attached amendment(s)

[X] do pass

[ ] do not pass

[ ] no recommendation

[ ] individual recommendations

[ ] additional referral to the ____________ Committee

ADOPTS: [ ] ________letter of intent

ATTACHES NEW FISCAL NOTE(s):

[ ] fiscal impact

[ ] zero fiscal note

[ ] zero with analysis

[ ] same as previous fiscal note published ____________

[ ] same as previous zero fiscal note published ____________

SIGNING DO PASS:

SIGNING OTHER RECOMMENDATIONS:

Chairman's signature

Offered: 2/24/88 5-1655B
Referred: Finance

Original sponsor: Hoffman

Funding Information
General Fund $250,000
Other Funds -0-
$250,000

IN THE HOUSE BY THE JUDICIARY COMMITTEE

CS FOR HOUSE BILL NO. 387 (Judiciary)

IN THE LEGISLATURE OF THE STATE OF ALASKA

FIFTEENTH LEGISLATURE - SECOND SESSION

A BILL

For an Act entitled: "An Act making a special appropriation to the Department of Public Safety for enforcement of alcoholic beverage control laws and for a reward program to promote the apprehension and conviction of persons who violate certain alcohol control laws; and providing for an effective date."

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

* Section 1. The sum of $250,000 is appropriated from the general fund to the Department of Public Safety for enforcement of alcoholic beverage control laws and for grants to municipalities and established villages for local programs to offer rewards for information leading to the apprehension and conviction of persons who violate AS 04.11.010 by selling, importing, or possessing alcoholic beverages in violation of an ordinance adopted by a municipality or established village under AS 04.11.490 - 04.11.500.

* Sec. 2. The unexpended and unobligated portion of the appropriation made by this Act lapses into the general fund June 30, 1989.

* Sec. 3. This Act takes effect on the effective date of an Act passed by the Fifteenth Alaska State Legislature relating to the enforcement of alcoholic beverage control laws and authorizing the Department of Public Safety to offer rewards and to provide grants to municipalities and established villages to offer rewards for information leading to the apprehension and conviction of persons who violate AS 04.11.010 by selling, importing, or possessing alcoholic beverages in violation of an ordinance adopted by a municipality or established village under AS 04.11.490 - 04.11.500.

STATE OF ALASKA
1988 LEGISLATIVE SESSION

BILL VERSION: CS HB 387 (Jud)
PUBLISH DATE:

FISCAL NOTE

REQUEST:

Revision Date: 03/02/88
Title:"An Act making a special approp. to the Department of Public Safety for enforcement of alcoholic beverage control laws and for a reward program to promote the apprehension and conviction of persons who violate certain alcohol control laws; prov. for effective date.
Sponsor: House Judiciary
Requestor: House Finance

Agency Affected: Revenue
BRU: ABC BOARD

Components:

EXPENDITURES/REVENUES: (Thousands of Dollars)

	FY 88	FY 89	FY 90	FY 91	FY 92	FY 93
OPERATING						
PERSONAL SERVICES	-	-	-	-	-	-
TRAVEL	-	-	-	-	-	-
CONTRACTUAL	-	-	-	-	-	-
SUPPLIES	-	-	-	-	-	-
EQUIPMENT	-	-	-	-	-	-
LANDS & STRUCTURES	-	-	-	-	-	-
GRANTS, CLAIMS	-	-	-	-	-	-
MISCELLANEOUS	-	-	-	-	-	-
TOTAL OPERATING	-	-	-	-	-	-
CAPITAL	-	-	-	-	-	-
REVENUE	-	-	-	-	-	-

FUNDING: (Thousands of Dollars)

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

POSITIONS:

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

ANALYSIS: (Attach a separate page if necessary)

Prepared By: Patrick L. Sharrock, Director
Division: Alcoholic Beverage Control Division
Phone: 277-8638
Date: 03/02/88

Approved by Commissioner: Hugh Malone
Agency: Department of Revenue
Date: 03/02/88

MAR 4 1988

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

Introduced: 1/22/88
Referred: Judiciary and Finance

5-1655A

Funding Information
General Fund $250,000
Other Funds -0-
$250,000

IN THE HOUSE BY HOFFMAN

HOUSE BILL NO. 387

IN THE LEGISLATURE OF THE STATE OF ALASKA

FIFTEENTH LEGISLATURE - SECOND SESSION

A BILL

For an Act entitled: "An Act making a special appropriation to the Department of Public Safety for a reward program to promote the apprehension and conviction of persons who violate certain alcohol control laws; and providing for an effective date."

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

* Section 1. The sum of $250,000 is appropriated from the general fund to the Department of Public Safety for a state program and for grants to municipalities and established villages for local programs to offer rewards for information leading to the apprehension and conviction of persons who violate AS 04.11.010 by selling, importing, or possessing alcoholic beverages in a community that has prohibited the sale, importation, or possession of alcoholic beverages under AS 04.11.490 - 04.11.500.

* Sec. 2. The unexpended and unobligated portion of the appropriation made by this Act lapses into the general fund June 30, 1989.

* Sec. 3. This Act takes effect on the effective date of an Act authorizing the Department of Public Safety to offer rewards and to provide grants to local governments to offer rewards for information leading to the apprehension and conviction of persons who violate AS 04.11.010 by selling, importing, or possessing alcoholic beverages in a community that has prohibited the sale, importation, or possession of alcoholic beverages under AS 04.11.490 - 04.11.500.

CSHB

387

SENATE COMMITTEE REPORT

FURTHER

DATE TURNED INTO OFFICE 5/7/88

4/27/88

Mr. President:

Finance Committee considered CSHB 387 (JUD)

making a special appropriation to the Department of Public Safety for enforcement of alcoholic beverage control laws and for a reward program to promote the apprehension and conviction of persons who violate certain and recommended alcohol control laws; efd

[✓] replace with ___ SCS CSHB 387 (FIN))[✓] same title
[ ] or adopt _____ CS _____)[ ] new title

[ ] attached amendment(s) and

[✓] do pass

[ ] do not pass

[ ] no recommendation

[ ] individual recommendations

[ ] further referral to _____

[ ] letter of intent adopted _____

Committee [ ] attached or [ ] adopted fiscal note(s)
[ ] new [ ] updated or [ ] previous
Approp. [ ] zero [ ] fiscal impact

MEMBERS SIGNING DO PASS

OTHER RECOMMENDATIONS

Rick Halford NO REC
Chairman signature and recommendation

[ ] Committee Backup attached

Offered: 2/24/88 5-1655B
Referred: Finance

Original sponsor: Hoffman

Funding Information
General Fund $250,000
Other Funds -0-
~~$250,000~~
245,000

IN THE HOUSE BY THE ~~JUDICIARY COMMITTEE~~ Senate

SCS - CS FOR HOUSE BILL NO. 387 (~~Judiciary~~ Finance)

IN THE LEGISLATURE OF THE STATE OF ALASKA

FIFTEENTH LEGISLATURE - SECOND SESSION

A BILL

For an Act entitled: "An Act making a special appropriation to the Department of Public Safety for enforcement of alcoholic beverage control laws and for a reward program to promote the apprehension and conviction of persons who violate certain alcohol control laws; and providing for an effective date."

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

* Section 1. The sum of ~~$250,000~~ 245,000 is appropriated from the general fund to the Department of Public Safety for enforcement of alcoholic beverage control laws and for grants to municipalities and established villages for local programs to offer rewards for information leading to the apprehension and conviction of persons who violate AS 04.11.010 by selling, importing, or possessing alcoholic beverages in violation of an ordinance adopted by a municipality or established village under AS 04.11.490 - 04.11.500.

* Sec. 2. The unexpended and unobligated portion of the appropriation made by this Act lapses into the general fund June 30, 1989.

* Sec. 3. This Act takes effect on the effective date of an Act passed by the Fifteenth Alaska State Legislature relating to the enforcement of alcoholic beverage control laws and authorizing the Department of Public Safety to offer rewards and to provide grants to municipalities and established villages to offer rewards for information leading to the apprehension and conviction of persons who violate AS 04.11.010 by selling, importing, or possessing alcoholic beverages in violation of an ordinance adopted by a municipality or established village under AS 04.11.490 - 04.11.500.

5-1655L

Original sponsors: Hoffman and Wallis

Funding Information	
General Fund	$245,000
Other Funds	-0-
	$245,000

IN THE HOUSE BY THE FINANCE COMMITTEE

SENATE CS FOR CS FOR HOUSE BILL NO. 387 (Finance)

IN THE LEGISLATURE OF THE STATE OF ALASKA

FIFTEENTH LEGISLATURE - SECOND SESSION

A BILL

For an Act entitled: "An Act making a special appropriation to the Department of Public Safety for enforcement of alcoholic beverage control laws and for a reward program to promote the apprehension and conviction of persons who violate certain alcohol control laws; and providing for an effective date."

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

* Section 1. The sum of $245,000 is appropriated from the general fund to the Department of Public Safety for enforcement of alcoholic beverage control laws and for grants to municipalities and established villages for local programs to offer rewards for information leading to the apprehension and conviction of persons who violate AS 04.11.010 by selling, importing, or possessing alcoholic beverages in violation of an ordinance adopted by a municipality or established village under AS 04.11.490 - 04.11.500.

* Sec. 2. The unexpended and unobligated portion of the appropriation made by this Act lapses into the general fund June 30, 1989.

* Sec. 3. This Act takes effect on the effective date of an Act passed by the Fifteenth Alaska State Legislature relating to the enforcement of alcoholic beverage control laws and authorizing the Department of Public Safety to offer rewards and to provide grants to municipalities and established villages to offer rewards for information leading to the apprehension and conviction of persons who violate AS 04.11.010 by selling, importing, or possessing alcoholic beverages in violation of an ordinance adopted by a municipality or established village under AS 04.11.490 - 04.11.500.

BILL NO: CSHB 386 (Jud) and CSHB 387 (Jud)

DATE: 2/25/88

TITLE: "An Act relating to enforcement of alcoholic beverage control laws..."

"An Act making a special appropriation for enforcement of alcoholic beverage control laws..."

CONTACT: Arthur English
Commissioner
465-4322

DEPARTMENT OF PUBLIC SAFETY

The Department of Public Safety strongly supports CSHB 386 (Jud), An Act relating to enforcement of alcoholic beverage control laws, and its companion bill CSHB 387 (Jud), An Act making a special appropriation to the Department of Public Safety for enforcement of alcoholic beverage control laws and for a reward program.

The illicit importation and sale of alcoholic beverages in communities which have adopted "local option" laws to restrict the sale or possession of alcoholic beverages is a major law enforcement and public safety concern in many parts of rural Alaska. The consumption of alcohol and illicit drugs is a contributing factor in a very high percentage of the crimes committed in rural Alaska, especially violent crimes. The consumption of "bootlegged liquor" has contributed in many cases to abuse and neglect of children, disruption of the family unit, suicide, fatal accidents, assaults, and murder.

CSHB 386 (Jud) would broaden the scope of the present Alaska State Trooper's statewide Drug Investigative Unit to include both drugs and alcoholic beverages. The bill also authorizes the Department to establish and administer, and provide grants to municipalities and villages to establish and administer, reward programs for persons who provide information leading to the arrest and conviction of bootleggers.

CSHB 387 (Jud) makes a special appropriation to the Department to carry out the investigative duties and reward program described in CSHB 386 (Jud). A detailed description of the combined Alcohol and Drug Investigative Unit, and the way in which the appropriation would be spent, is attached.

The Department believes that passage of CSHB 386 (Jud) and CSHB 387 (Jud) will provide the State Troopers with valuable tools that can be used to help curtail the destructive flow of bootleg liquor to rural Alaska.

Arthur English, Commissioner

SUMMARY ANALYSIS

CS HB 386 (Judiciary)

Section 1. Will include alcohol with drug enforcement. Will primarily focus on investigation, apprehension, and conviction of bootleggers in local option communities.
An annual detailed report will be delivered to the Legislature on the activities of drugs and alcohol enforcement.

Section 2. The establishment of a reward program, and grant system for villages for reward programs, leading to apprehension and conviction of bootleggers who violate local option laws.

Section 3. Effective date - July 1, 1988.

SUMMARY ANALYSIS

CS HB 387 (Judiciary)

Section 1. An appropriation of $250,000 from the general fund for enforcement of local option laws.

Section 2. Unused funds would lapse to general fund 6-30-89.

Section 3. This Act will take effect on the effective date of CS HB 386 (Judiciary).

SUMMARY ANALYSIS

CS HB 387 (Judiciary)

Section 1. An appropriation of $250,000 from the general fund for enforcement of local option laws.

Section 2. Unused funds would lapse to general fund 6-30-89.

Section 3. This Act will take effect on the effective date of CS HB 386 (Judiciary).

3/22 arm

SENATE COMMITTEE REPORT

FURTHER

FINANCE

DATE TURNED INTO OFFICE ______________

3/22/88

Mr. President:

JUDICIARY Committee considered CSHB 386 (JUD)
enforcement of alcoholic beverage control laws; efd

and recommended

[ ] replace with ___ CS ______________)[] same title
[ ] or adopt ______ CS ______________)[] new title

[ ] attached amendment(s) and

[X] do pass (Majority)

[ ] do not pass

[ ] no recommendation

[X] individual recommendations

[ ] further referral to ______________

[ ] letter of intent adopted ______________

Committee [X] attached or [ ] adopted fiscal note(s)
[ ] new [ ] updated or [X] previous
[X] zero [ ] fiscal impact

MEMBERS SIGNING DO PASS	OTHER RECOMMENDATIONS
Patrick Rodey	[signature]
[signature]	
[signature]	

[signature] Do pass
Chairman signature and recommendation

[ ] Committee Backup attached

HB

388

(11)

HOUSE COMMITTEE REPORT

Date referred: 3/14/88 FURTHER REFERRALS:

DATE: 4-22-88

The Finance Committee has considered HB 388

"An Act relating to irradiated food."

RECOMMENDS:

[X] replace with CS HB 388(HESS) [X] the same title

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

[ ] do pass

[ ] do not pass

[X] no recommendation

[ ] individual recommendations

[ ] additional referral to the ________ Committee

ADOPTS: [ ] ________ letter of intent

ATTACHES NEW FISCAL NOTE(s):

[ ] fiscal impact

[X] zero fiscal note

[ ] zero with analysis

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

[ ] same as previous zero fiscal note published ________

SIGNING DO PASS:

Pete Jones

Kay Wallis

Ray Brown

SIGNING OTHER RECOMMENDATIONS:

Al Adams - No Rec.

Kott Kaufl? no rec

Ron Larson No Rec.

[illegible] no rec

Mark Boyer NO REC.

Steve Rieger No Recommendation

[illegible] no rec.

Mike Davis No Rec

Al Adams

Chairman's signature

STATE OF ALASKA
1988 LEGISLATIVE SESSION

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

FISCAL NOTE

REQUEST:

Revision Date: -
Title: An Act relating to irradiated food.
Sponsor: Peter Goll and Randy Phillips
Requestor: Randy Phillips

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

EXPENDITURES/REVENUES: (Thousands of Dollars)

OPERATING	FY 88	FY 89	FY 90	FY 91	FY 92	FY 93
PERSONAL SERVICES	-	14.9	14.9	14.9	14.9	14.9
TRAVEL	-	-	-	-	-	-
CONTRACTUAL	-	2.0	2.0	2.0	2.0	2.0
SUPPLIES	-	1.0	1.0	1.0	1.0	1.0
EQUIPMENT	-	-	-	-	-	-
LAND & STRUCTURES	-	-	-	-	-	-
GRANTS, CLAIMS	-	-	-	-	-	-
MISCELLANEOUS	-	-	-	-	-	-
TOTAL OPERATING	0	17.9	17.9	17.9	17.9	17.9
CAPITAL	0	0	0	0	0	0
REVENUE	0	0	0	0	0	0

FUNDING: (Thousands of Dollars)

GENERAL FUND	0	17.9	17.9	17.9	17.9	17.9
FEDERAL FUNDS	0	0	0	0	0	0
OTHER	0	0	0	0	0	0
TOTAL	0	17.9	17.9	17.9	17.9	17.9

POSITIONS:

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

ANALYSIS: (Attach a separate page if necessary)

Attached.

Prepared by: Douglas C. Lonegan
Phone: 465-2609
Division: Environmental Health
Date: 2/2/88

Approved by Commissioner: Dennis D. Kelso
Date: February 2, 1988
Agency: Environmental Conservation

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

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

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

Type of Expenditure		Amount
1	2	3
Salary	11.2	
Benefits	3.7	
Premium Pay	-	
Other	-	
Total Personal Services		14.9
Travel		-
Contractual		2.0
Commodities		1.0
Equipment		-
Other		-
Total Cost		17.9

Funding Source for Total Cost	
Federal Receipts 1002	-
G. F. Match 1003	-
General Fund 1004	17.9
GF Program Receipts 1005	-
Other	-

Justification

This position is required to support the implementation of HB 388 "An Act relating to irradiated food." Approximately 500 retail markets would be inspected to ensure that prohibited products were not being sold. All retail markets would be contacted and notified of the new law. It is estimated that the inspection of these facilities would require approximately 2 hours each, including travel time.

The additional inspection effort would amount to a total of 602 hours per year or about four months per year.

Request For New Position

Agency Environmental Conservation

BRU Environmental Health

Component Sanitation

Page 2 of 2

Revised Date

FY 89

No. 1

CSHB 388(HESS)
HOUSE 2/24/88

STATE OF ALASKA
1988 LEGISLATIVE SESSION

BILL VERSION: HB 388
PUBLISH DATE: -

FISCAL NOTE

REQUEST:

Revision Date: 1/22/88
Title: An Act relating to irradiated food.
Sponsor: Phillips and Goll
Requestor:

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

EXPENDITURES/REVENUES: (Thousands of Dollars)

OPERATING	FY 88	FY 89	FY 90	FY 91	FY 92	FY 93
PERSONAL SERVICES						
TRAVEL						
CONTRACTUAL						
SUPPLIES						
EQUIPMENT						
LAND & STRUCTURES						
GRANTS, CLAIMS						
MISCELLANEOUS						
TOTAL OPERATING	-0-	-0-	-0-	-0-	-0-	-0-
CAPITAL						
REVENUE						

FUNDING: (Thousands of Dollars)

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

POSITIONS:

FULL-TIME						
PART-TIME						
TEMPORARY						

ANALYSIS: (Attach a separate page if necessary)

The enactment of HB 388 would have no direct fiscal impact on the Department of Health and Social Services.

Prepared by: Elizabeth Ward, Director Elizabeth Ward Phone: 465-3090
Division: Public Health Date: 2-2-88

Approved by Commissioner: Myra M Munson Date: 2-2-88
Agency: Department of Health & Social Services

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

RECEIVED
FEB 4 1988

POSITION PAPER/Department of Health & Social Services

Position Paper

HB 388

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

HB 388 prohibits the sale of irradiated food including spices and food that contains an irradiated ingredient unless the only irradiated ingredient is a spice. While it appears passage of this bill would have economic impact due to the long established practice of irradiating spices, the scope of this position paper is limited to the health considerations of irradiated food.

Background

The health aspects of irradiated food have been studied for many years. The Food and Drug Administration (FDA) has conducted exhaustive reviews of all available studies and has determined that irradiated food is safe for human consumption. The FDA has concluded there is no scientific evidence meeting FDA standards for toxicological studies that shows adverse effects on health from the consumption of irradiated food. Results of studies used to support claims of harmful effects have been rejected due to lack of adequate scientific controls or design, including radiation doses far in excess of those considered acceptable for food processing. In its conservative approach, the FDA has approved the irradiation of certain foods only, and it has limited the radiation doses to one-tenth of those shown to be safe. This position is supported by such diverse groups as the Council for Agricultural Science and Technology, the World Health Organization, the Food and Agricultural Organization of the United Nations, the American Medical Association, and the International Atomic Energy Agency.

In addition to the FDA, numerous national and international organizations recognized in health, food technology, and radiation safety have closely examined claims of harmful effects presently being made by those opposed to food irradiation. In every case, these organizations have judged irradiated food to be safe for human consumption.

Position

Without acceptable scientific evidence showing that irradiation is harmful to health, the department believes it is inappropriate to forbid the sale of irradiated food in the state. Proper labeling of irradiated foods will allow those opposed to it to exercise their choice in the foods they purchase.

The Department of Health and Social Services opposes passage of HB 388.

POSITION PAPER/Department of Health & Social Services

Recommended by: Elizabeth Ward

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

Date: February 2, 1988

Approved by: Myra M. Munson

Myra M. Munson
Commissioner
Department of Health and
Social Services

Date: Feb 2 1988

Offered: 2/24/88
Referred: Judiciary

5-1671B

Original sponsors: Phillips, Goll and Taylor

IN THE HOUSE

BY THE HEALTH, EDUCATION AND SOCIAL SERVICES COMMITTEE

CS FOR HOUSE BILL NO. 388 (HESS)

IN THE LEGISLATURE OF THE STATE OF ALASKA

FIFTEENTH LEGISLATURE - SECOND SESSION

A BILL

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

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

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

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

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

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

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

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

(5) the dissemination of a false advertisement;

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

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

in good faith;

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

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

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

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

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

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

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

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

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

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

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

THE ROLE OF IRRADIATION IN FOOD PROCESSING:

CAN IT BENEFIT ALASKA?

by

Ruthann B. Swanson
Assistant Professor of Food Science
Agricultural and Forestry Experiment Station

Carol E. Lewis
Associate Professor of Resource Management
Agricultural and Forestry Experiment Station

Charlotte I. Hok
Laboratory Assistant
Institute of Northern Engineering

Debendra K. Das
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John P. Zarling
Professor of Mechanical Engineering and Director
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William G. Workman
Associate Professor of Economics
Agricultural and Forestry Experiment Station

Robert R. Logan
Assistant Professor of Economics
Department of Economics

Agricultural and Forestry Experiment Station
School of Agriculture and Land Resources Management
University of Alaska Fairbanks

James V. Drew, Dean and Director

Circular 64

March 1988

INTRODUCTION

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

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

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

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

FOOD IRRADIATION PROCESS

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

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

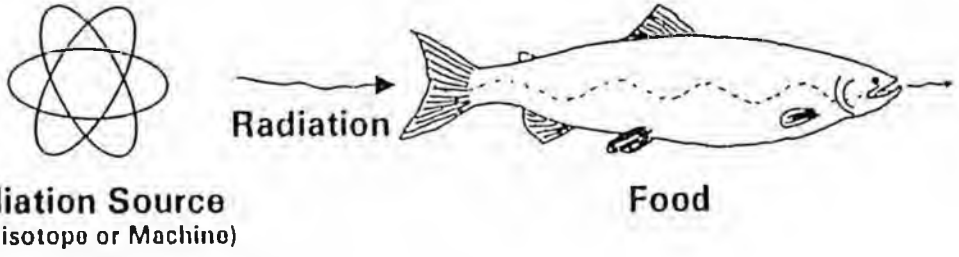

Figure 1. How food irradiation works.

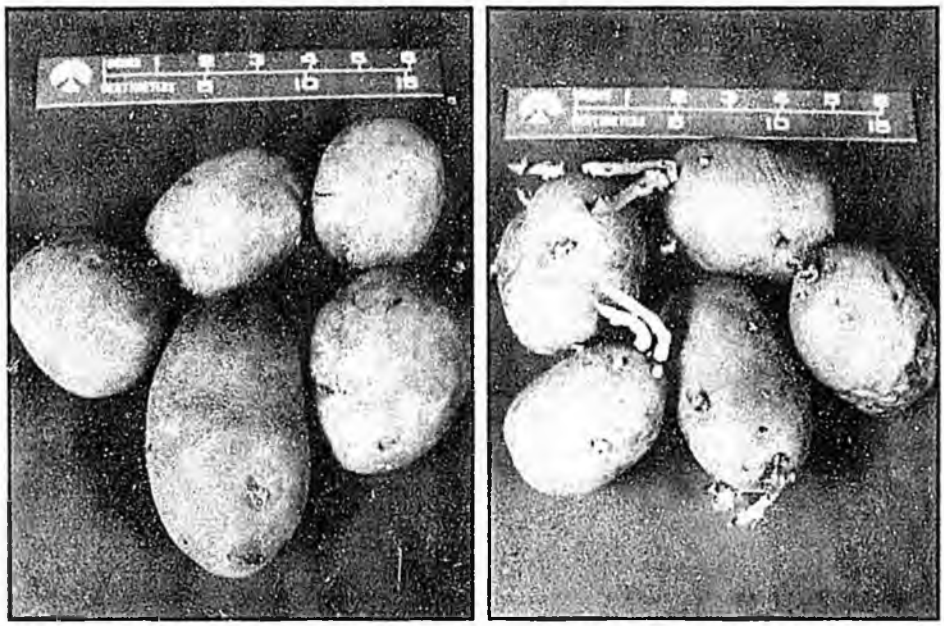

Figure 2. Sprout inhibition of supermarket potatoes stored at room temperature for one month. Control samples that received no additional treatment have sprouted after the one month storage period. Treated samples have not sprouted (Photographs courtesy of H. Farrar, IV, and G. Subbaraman).

LABELING

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

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

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

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

CURRENT USES OF IRRADIATED FOODS IN THE UNITED STATES

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

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

Table 1. Foods approved for irradiation in United States.

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

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

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

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

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

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

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

FOOD WHOLESOMENESS

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

Toxicological Safety

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

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

Nutritional Quality

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

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

Microbiological Safety

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

International Opinions

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

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

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

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

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

THE IRRADIATION FACILITY

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

Ionization Source

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

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

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

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

Transportation and Security of the Source

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

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

Irradiation Facility Design

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

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

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

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

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

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

Environmental Factors Determining Plant Location

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

CORRECTION

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HAS BEEN REPHOTOGRAPHED
TO ASSURE LEGIBILITY

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

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

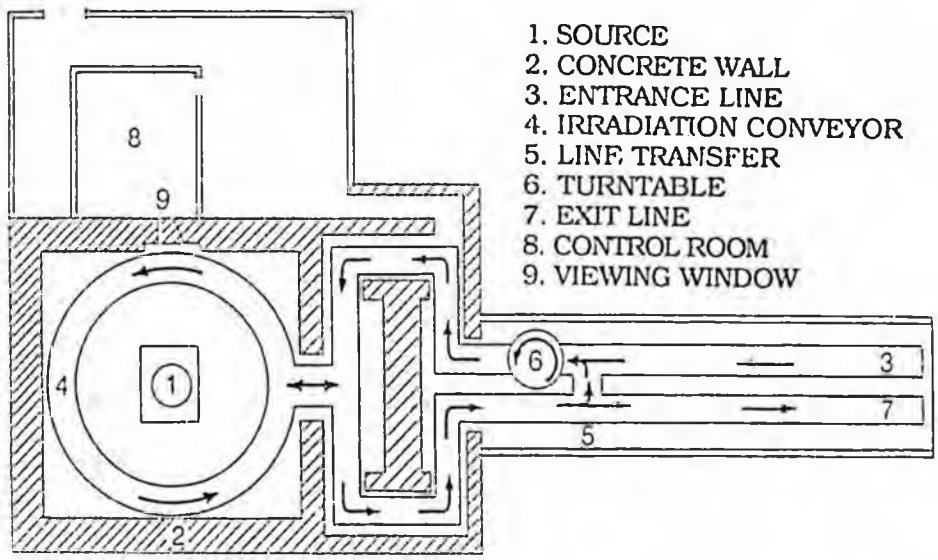

Figure 4. A typical food irradiation facility (Adapted from: Kumeyama 1985).

Facility Safety

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

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

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

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

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

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

IRRADIATION AND ALASKA'S FOOD INDUSTRY

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

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

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

Seafood Industry

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

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

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

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

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

Agricultural Industry

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

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

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

Benefits to Food Industries and Consumers

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

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

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

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

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

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

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

Process Cost

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

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

SUMMARY

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

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

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

FURTHER READING

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

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PUBLIC OPINION MESSAGE

TO ALL MEMBERS OF THE STATE HOUSE AND SENATE

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

FDA labeling requirement will allow consumers to make informed choices.

We urge you to get accurate facts and vote responsibly.

Alaska Chapter, Sigma Xi Scientific Research Society

Submitted by:

William Mendenhall
Member, Advisory Committee
Office Phone 474-6125

POSITION PAPER
DEPARTMENT OF ENVIRONMENTAL CONSERVATION

House Bill No. 388 February 2, 1988

"An act prohibiting the sale of irradiated food."

Department position:

The Department has not taken a position on this bill for the following reasons. The Department has no staff with training and experience in the irradiation of food. The Department's expertise regarding food products is inspecting the sanitary operations of food production facilities. There is a large amount of information and scientific data on this issue. Although review and analysis of the available data are beyond the Department's current capacity to effectively review and analyze, we are pleased to assist the committee in identifying useful information, including the following background.

FDA Requirements

The treatment of certain food products and spices with ionizing radiation is approved by the U.S. Food and Drug Administration (FDA). FDA has approved the following application dosages: for foods which can comprise more than 0.01% of the daily diet, the dosage cannot exceed 1 kilogray (KGy); for foods which can comprise less than 0.01% of the daily diet, dosage cannot exceed 50 KGy.

FDA Approved Sources of Irradiation

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

FDA Foods Approved for Irradiation

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

FDA Labeling Requirements

Labeling requirements have also been imposed by FDA to ensure that the consumer is aware that food they are consuming has been irradiated. Treated products contain a label statement that contains the international irradiation process logo (tulip) and

the statement "treated with radiation" or "treated by irradiation". On April 18, 1988 the requirement for the written warning is scheduled to be withdrawn. This action would leave only the international irradiation process logo on retail packages. FDA has informed DEC that this will probably not occur since the average consumer probably does not know what the logo symbolizes.

Enforcement

The department would enforce the provisions of this bill by inspecting food distributors, warehouses, and retail and wholesale outlets for food labeled with the federally required irradiation symbol and product statement. If irradiated food was found during the course of inspection, the department would embargo the product under the authority in 17.020.230 and require that it be destroyed or returned to an out-of-state distributor.

STATE OF ALASKA

OFFICE OF THE GOVERNOR

BILL ANALYSIS

DEPARTMENT	DIVISION	BILL NUMBER	SPONSOR
Environmental Conservation	Environmental Health	HB 388	Peter Goll and Randy Phillips

SHORT TITLE OF BILL

"An Act relating to irradiated food"

DEPARTMENT POSITION The passage of HB 388 would require that the Department expand it's inspection activities at approximately 500 retail markets to ensure that irradiated products were not being sold. The additional time per inspection is estimated to be approximately (Continued)

PREPARED BY	DATE	COMMISSIONER'S SIGNATURE	DATE
Douglas C. Donegan	2/2/88	Dennis D. Kelso	

SUMMARY

OTHER AGENCIES AFFECTED BY BILL	CONSTITUENT GROUP(S) AFFECTED BY BILL

ORGANIZATIONAL SUPPORT FOR BILL	ORGANIZATIONAL OPPOSITION TO BILL

FISCAL IMPACT: ☐ NONE ☐ FISCAL NOTE ATTACHED

BACKGROUND/LEGISLATIVE INTENT

ANALYSIS OF BILL/PROGRAM EFFECTS

AMENDMENTS PROPOSED

PLEASE ATTACH A SEPARATE SHEET FOR ADDITIONAL COMMENTS OR ANALYSIS

01-009 (Rev. 12/83)

one (1) hour per inspection. These facilities are inspected once per year.

The Department would begin inspecting 51 retail markets in the Municipality of Anchorage, which are not currently inspected by the department. It is estimated that the inspection of these markets would be approximately 2 hours including travel time.

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

Alaska State Legislature
House

Official Business

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

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

Memorandum

TO: Representative John Sund
Chairman, House Judiciary Committee

FROM: Representative Randy Phillips

DATE: March 7, 1988

RE: Food and Drug Administration
House Bill 388

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

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

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

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

ATTACHMENT 6

HHS NEWS

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

P85-48
FOR IMMEDIATE RELEASE
December 12, 1985

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

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

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

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

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

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

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

-MORE-

ATTACHMENT 7

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

The regulation will permit:

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

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

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

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

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

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

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

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

INTERNATIONAL LOGO

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

STATEMENT BY

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

COMMISSIONER

FOOD AND DRUG ADMINISTRATION

PUBLIC HEALTH SERVICE

DEPARTMENT OF HEALTH AND HUMAN SERVICES

BEFORE THE

SUBCOMMITTEE ON HEALTH AND THE ENVIRONMENT

COMMITTEE ON ENERGY AND COMMERCE

UNITED STATES HOUSE OF REPRESENTATIVES

June 19, 1987

SENT TO YOU BY YOUR
UNITED STATES SENATOR

Ted Stevens

ALASKA

FOR RELEASE ONLY UPON DELIVERY

ATTACHMENT 8

Mr. Chairman:

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

Background

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

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

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

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

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

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

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

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

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

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

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

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

A Spectrum of Concerns

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

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

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

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

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

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

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

The Regulation of Food Additives

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

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

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

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

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

Food Irradiation and Safety Testing: Early Developments

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

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

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

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

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

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

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

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

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

Food Irradiation and Safety Testing: An Evolution of Thought

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

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

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

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

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

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

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

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

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

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

Regulatory Efforts

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

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

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

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

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

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

Lingering Misperceptions

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

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

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

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

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

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

Conclusion

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

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

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

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

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

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

HISTORY OF FDA ACTIONS ON FOOD IRRADIATION

- February 1963: FDA approved gamma radiation preservation of canned bacon.
- August 1963: FDA approved gamma radiation for control of insect infestation of wheat and wheat products.
- August 1963: FDA approved electron beam radiation for the radiation preservation of canned bacon.
- October 1964: FDA approved gamma radiation for sprout inhibition of white potatoes.
- December 1964: FDA approved X-radiation for the radiation of preservation of canned bacon.
- July 1966: FDA approved electron beam radiation for the control of insect infestation of wheat and wheat products.
- July 1966: FDA approved labeling requirements for food treated by radiation.
- October 1968: FDA rescinded the bacon regulations.
- September 1979: Director, Bureau of Foods established the Irradiated Food Committee to provide a total reassessment of all relevant issues applicable to irradiated foods.
- March 1981: Advance Notice of Proposed Procedures for the Regulation of Irradiated Foods for Human Consumption (ANPR) published in the Federal Register.
- Autumn, 1981: FDA offered the opportunity for use of irradiation for insect disinfestation during the California Medfly situation based on certain conditions. However, no firm furnished evidence of meeting these conditions.
- July 1983: FDA approved gamma radiation for microbial decontamination of a specific list of spices and vegetable seasonings.
- February 1984: Proposed rule published in the Federal Register for the use of gamma radiation for sprout inhibition and shelf-life extension of fresh fruits and vegetables, for insect disinfestation of food, and for sterilization of spices.
- June 1984: FDA approved gamma radiation to control insect infestation in garlic powder, onion powder, and certain dried spices.