ALASKA LEGISLATURE COMMITTEE BILL FILES - 1987 - 1988 8879

HB 388 cont. Leg. Finance 354

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

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

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

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

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

# FOODS APPROVED BY FDA FOR IRRADIATION TREATMENT

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

Kit

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

MR. CHAIRMAN.

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

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

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

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

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

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

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

# # #

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

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

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

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

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

Food irradiation is a potentially hazardous procedure. It

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

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

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

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

of a food additive and the evaluator of its safety.

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

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

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

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

# FOOD IRRADIATION
# 1987 INTRODUCED AND ENACTED LEGISLATION

| S T A T E | BILL # OR CHAPTER # (1987 Laws/ Acts) | SUMMARY |
|---|---|---|
| AK | SJR 33 (Intro 5/87) | Makes provisions relating to irradiated food. |
| HI | SB 971 (Intro 3/87) | Makes an appropriation to promote consumer acceptance of irradiated agricultural products from Hawaii. |
| IL | HB 212 (Intro 2/87) | Amends Food, Drug and Cosmetic Act. Requires labeling of irradiated foods sold at retail for off-premise consumption. |
| MA | SB 47 z (Intro 5/87) | Provides for an investigation and study by the Department of Public Health relative to the potential health risks of food irradiation. |
| ME | Chap. 174 | Prohibits the knowing sale of irradiated food, with the exception of irradiated spices when those spices are only an ingredient in the food. Provides that irradiated spices are irradiated food and their knowing sale is prohibited. |
| NH | HB 1082 (Intro 1/88) | Relates to irradiated food. |
| NJ | AB 3150 (Intro 11/87) | Prohibits distribution and sale of irradiated food. |
| NJ | SB 2571 (Intro 1/88) | Prohibits distribution and sale of irradiated food. |
| NJ | SR 43z (Intro 2/87) | Memorializes Congress to rescind Food and Drug Administration's approval of food irradiation. |
| NY | AB 4106 (Intro 5/87) | Defines "irradiated food"; makes it unlawful for any merchant, broker or processor to knowingly sell any irradiated food until studies of the effects on human health, on consumers, and on workers so exposed and impacts associated with transportation of radioactive materials used in processing are received and accepted by various state commissioners. |
| NY | AB 5442 (Intro 6/87) | Defines food exposed to any process of irradiation as adulterated food. |
| PA | HB 1632 (Intro 7/87) | Prohibits the sale of food products which have been exposed to or treated with radiation for preservative purposes or any other reason. |
| PA | HB 1912 (Intro 10/87) | Defines adulterated food in relation to radiation under the Pure Food Law. |
| VT | HB 635 (Intro 1/88) | Prohibits the sale of irradiated foods. |

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

ATTACHMENT 10

# A Short History of Trouble

## Irradiation Hall Of Shame

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

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

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


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

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

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

JUNE 11, 1986 Radiation Technology Inc., cited in 1982 as a source of groundwater pollution, was ordered by the State of New Jersey to pay a $600,000 directive to study the problem. Volatile organics such as trichloroethylene, methylene chloride, and trichloroethane were found in test wells drilled on RTI's 15 acre site in Rockaway, N.J. The toxic products were stored in 100 bulging, rusty, leaky 55 gallon drums on the company's property.

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

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

## SCIENCE BOX

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

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

# Irradiating food growing preservation method

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

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

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

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

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

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

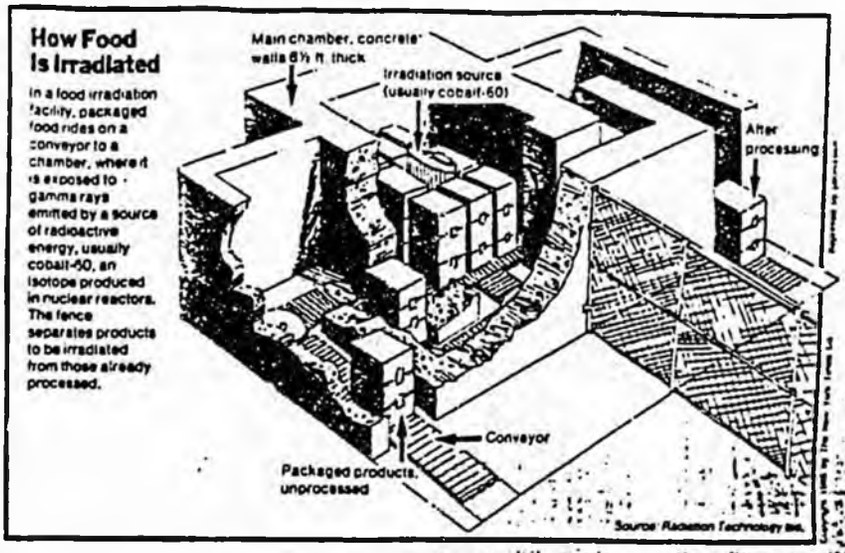
- In July, 1985, HHS gave the go-ahead for irradiation in the processing of pork, a process that is believed to eliminate the threat of trichinosis even if the pork is undercooked or eaten raw. These regulations — with comment from the U.S. Dept. of Agriculture (USDA), which regulates pork — are nearing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

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

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

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

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




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

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

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

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

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

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

"We've found that 90-95% of all bacteria are killed during the irradiation process," said Dr. Luizzo, who once worked under contract from the Atomic Energy Commission on food irradiation in the preservation of shrimp. "Food irradiation would allow the people in places like Iowa and Kansas to have fresh shrimp," he said, noting that his studies showed a 19-day shelf life for shrimp kept on ice after irradiation.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

—Linda Bass



ATTACHMENT 11

## History of Food Irradiation

**1898** - Bactericidal effects of x-rays first observed.

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

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

**1930** - French patent issued for preserving food by irradiation.

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

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

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

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

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

**1966** - FDA approves labeling requirements for irradiated foods.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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



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

# FDA'S LIST OF FOODS AUTHORIZED FOR IRRADIATION

## FOODS:

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

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

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

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

## HOT NEWS

### Cesium Salad

Brussels

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

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

P.S.: Cesium never quits.

### Home-Dumping

**Radioactive Waste Dump Plan Ratified**

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

Legislation ratifying the pact was signed Thursday by Governor Deukmejian.

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

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

## CHERNOBYL'S LEGACY

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

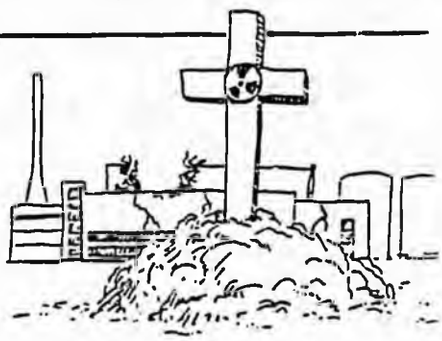
Using computer projections, Dr. John Gofman, Professor Emeritus of Medical Physics at the University of California (Berkeley), estimated that 1 million people, including over half a million outside the Soviet Union, will develop cancer as a result of the Chernobyl accident and half of these cancers would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

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

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

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

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



## LOOKING FOR THE K.O.

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

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

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

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

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

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

The Food & Drug newsletter editors conclude "If this debate were a boxing

ATTACHMENT 13

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

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


### Compilation of Bioassay Data on the Wholesomeness of Irradiated Food Items by Dr. J. Barna

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

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

Albumin - ovalbumin

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

Amino Acids in Medium

*inhibition of bacterial growth on pH3*

Apple Juice

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

Apricot

*retarded growth*
*reduced body weight*
*reduced weight gain*

Aqua Destillata

*cytotoxic in plant*

Bacon

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

Bacon (Cont'd.)

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

Barley

*increased chromosome aberration in plant cells*

Bean

*reduced biological value*

Beef

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

Coalition for Alternatives in Nutrition and Healthcare
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P.O. Box B-12
Richlandtown, PA 18955



Compilation of Bioassay Data (Cont'd.)

Beef (Cont'd.)

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

Blood Serum/Plasma

inhibited growth of microorganism

Bread

lymphopenia
worse acceptance

Butter

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

Butter (Cont'd.)

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

Cabbage

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

Cakes

worse acceptance

Carbohydrate Solution

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

Carrot

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

Coalition for Alternatives in Nutrition and Healthcare
(C A N A H)
P.O. Box B-12
Richlandtown, PA 18955

Compilation of Bioassay Data



Casein

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

Cauliflower

worse acceptance

Celery

formation of toxic substances, radiotoxins

Cereal (Grain)

more frequent diseases
chronic nephritis
peritonitis

Chicken (cooked, stewed)

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

Chicken (Cont'd.)

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

Clam

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

Coconut

extended chronaxy time

Coconut Milk

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

Codfish

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

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Codfish (Cont'd.)

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

Compote (Fruit)

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

Corn (Maize)

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

Corn Meal

longer duration of development of the larvae of Trib

Crackers

worse acceptance

Cranberry

reduced growth

Dessert Powder (gelatine, vanilin

worse acceptance
reduced growth rate

Diet (complete)

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

ON

ıdditive and the evaluator of its safety.

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

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

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

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

.. ..

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Department of
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Drug Administration's

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ENT 10

# Irradiating food growing preservation method

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

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

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

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

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

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

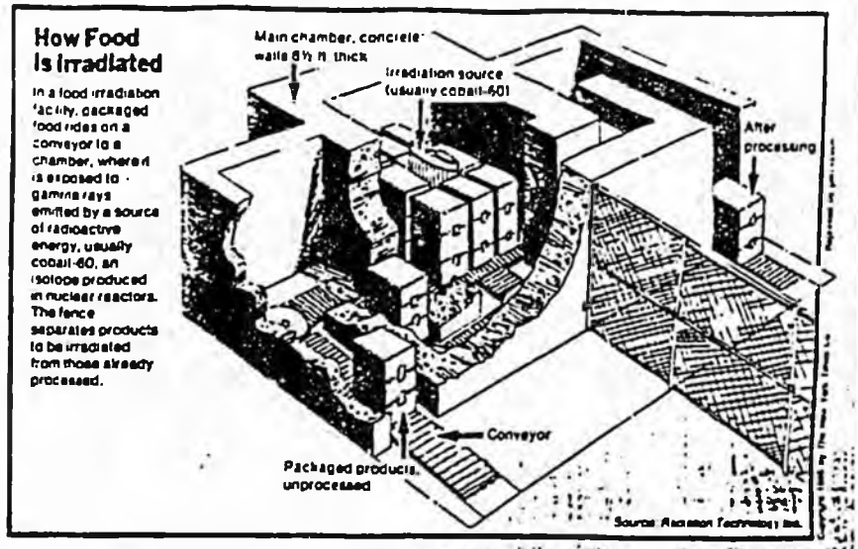
- In July, 1985, HHS gave the go-ahead for irradiation in the processing of pork, a process that is believed to eliminate the threat of trichinosis even if the pork is undercooked or eaten raw. These regulations — with comment from the U.S. Dept. of Agriculture (USDA), which regulates pork — are nearing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

**FOOD IRRADIATION ALSO** has occupied the attention of federal legislators recently. Four House committees are considering H.R. 695, a food irradiation development and control bill that would allow irradiation of many foods at regulated doses (the lowest level to achieve effectiveness).

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

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

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




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

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

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

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

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

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

"We've found that 90-95% of all bacteria are killed during the irradiation process," said Dr. Luizzo, who once worked under contract from the Atomic Energy Commission on food irradiation in the preservation of shrimp. "Food irradiation would allow the people in places like Iowa and Kansas to have fresh shrimp," he said, noting that his studies showed a 19-day shelf life for shrimp kept on ice after irradiation.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

—Linda Bass



ATTACHMENT 11

## History of Food Irradiation

**1898** - Bactericidal effects of x-rays first observed.

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

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

**1930** - French patent issued for preserving food by irradiation.

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

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

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

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

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

**1966** - FDA approves labeling requirements for irradiated foods.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

**19[illegible]6 (January)** - The U.S. Department of Agriculture approves its own rules and guidelines for irradiating pork products.

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

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

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

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

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

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

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

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

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

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



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

ATTACHMENT 12

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

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

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

ALABAMA - None

ALASKA - None

ARIZONA - None

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

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

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

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

DELAWARE - None

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

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

HAWAII - None

IDAHO -None

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

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

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

IOWA - None

KANSAS - None

KENTUCKY -None

LOUISIANA - None

MAINE -None

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

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

MICHIGAN - None

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

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

MISSOURI - None

MONTANA _ None

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

NEVADA - None

NEW HAMPSHIRE - None

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

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

NEW MEXICO - None

NEW YORK - None

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

NORTH DAKOTA - None

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

OKLAHOMA - None

OREGON - None

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

RHODE ISLAND- None

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

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

TENNESSEE -None

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

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

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

VERMONT - NOne

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

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

WEST VIRGINIA -None

WISCONSIN - None

WYOMING - None

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

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

# NEWS RELEASE

FOR RELEASE:
December 17, 1987

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

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

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

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

ATTACHMENT 17

Irradiated Mushrooms, cont....

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

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

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

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

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

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

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

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

-30-


October 29, 1987

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

Dear Mr. West:

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

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

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

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

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

I hope I have answered all your questions.

Sincerely,

Jan Guifarro
Supervisor
Consumer Response Group

JMG/0365J

## WHY IRRADIATE DRIED MUSHROOMS?

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

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

## WHAT ARE THE REGULATORY PROBLEMS WITH QUAKER USING THESE PRODUCTS?

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

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

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

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

## BACKGROUND ON THE COMPANY, CADE-GRAYSON

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

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

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

## HOW MUCH OF THIS HAS BEEN SUBSTANTIATED?

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

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

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

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

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

WHAT SHOULD BE DONE ABOUT THIS?

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

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

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

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

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

# UNITED FISHERMEN OF ALASKA

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

UNITED FISHERMEN OF ALASKA

Resolution 88-2

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Jim Bacon
President

Date 3-1-88

# Alaska State Legislature
## House

Official Business

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

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

Memorandum

TO: Representative John Sund, Chairman
House Judiciary Committee

FROM: Representative Randy Phillips

DATE: March 10, 1988

RE: CSHB 388 (HESS)

Attached is a memorandum from Theresa L. Bannister, Legislative Counsel. This memorandum discusses the federal preemption clause, an issue raised by Representative Gruenberg at yesterday's committee meeting.

If you have any questions, please do not hesitate to contact me. Thank you for your assistance.

Attachment
cc: Rep. Fran Ulmer (w/attachment)
Rep. Sam Cotten (w/attachment)
Rep. Max Gruenberg (w/attachment)
Rep. Mike Navarre (w/attachment)
Rep. Ramona Barnes (w/attachment)
Rep. Robin Taylor (w/attachment)

# STATE OF ALASKA
# THE LEGISLATURE

## LEGISLATIVE AFFAIRS AGENCY

POUCH Y STATE CAPITOL
JUNEAU ALASKA 998
907 465 3800

M E M O R A N D U M March 10, 1988

SUBJECT: Federal preemption and CSHB 388(HESS)

TO: Representative Randy Phillips

FROM: Theresa L. Bannister
Legislative Counsel

You have requested an opinion whether the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) (herein FDCA) preempts the prohibition in CSHB 388(HESS) against the sale of irradiated food. Although I do not believe that the issue is strictly black and white, in my opinion the FDCA would not preempt this prohibition.

At the outset, there is no specific preemption provision in the FDCA for this area; the FDCA does not explicitly address state laws other than for margarine. Next, the proposed prohibition does not stand as an obstacle to the accomplishment and execution of the purposes and objectives of the FDCA, since the goal of the FDCA relevant to this inquiry is to protect the individual from unsafe food, and the goal of the proposed law is the same. Finally, the proposed law does not directly conflict with the FDCA. Although the FDCA allows the use of irradiation in certain foods, it does not mandate the sale of these foods, but merely prescribes the conditions under which such things as irradiation may be safely used in certain foods. (See 21 U.S.C. 348).

In addition, I believe that a court would hesitate to preempt this proposed law for two reasons. The first reason is that the prohibition of the sale of irradiated food in the state falls within the traditional police powers of the state to protect the health and welfare of its inhabitants. The second reason is that there is a growing reluctance of courts to infer federal preemption of state laws. 55 U. S. Law Week 2226.

In conclusion, I believe that it is unlikely that a court would hold that the prohibition proposed by CSHB 388(HESS) against the sale of irradiated food to be preempted by the Federal Food, Drug, and Cosmetic Act.

If I may be of further assistance, please advise.

TLB:gc
WKG2:45

# Alaska Center for the Environment

700 H Street, Suite 4 • Anchorage, Alaska 99501 • (907) 274-3621


March 8, 1988

To House Judiciary Committee Members:

Alaska Center for the Environment is a nonprofit citizens organization interested in environmental protection. We support HB 388, relating to irradiated food.

We understand that the US Department of Energy has contracted with the University to construct a demonstration plant to irradiate fish. We are concerned about the possibility of having this type of facility in Alaska because of the risks involved. These risks include transportation accidents, releases through leaks or emissions or spills of radioactive materials. The Cesium-137 that is to be used would likely contaminate groundwater if spilled to the ground because of its solubility in water. Also, how would it be decided where to locate such a facility--will seismicity, flooding and environmentally unsuited areas be excluded from consideration?

We support passage of HB 388 as a step towards discouraging the development of the food irradiation industry in Alaska. There is too much that is unknown about the molecular changes in food resulting from irradiation and the production of unique radiolytic products to be assured that it is a safe process. In fact, of 413 available studies on food irradiation, the FDA found only 5 studies that appear to support safety (from Final Report Task Group Irradiated Food, U.S. Department of Health. April 1982).

Sincerely,

Kristine Benson

Kristine Benson
Hazardous Waste Specialist

Accord Research and Educational Associates,

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

Phone: (212) 580-3

TESTIMONY BEFORE THE
SUBCOMMITTEE ON HEALTH AND THE ENVIRONMENT
OF THE
HOUSE COMMITTEE ON ENERGY AND COMMERCE
BY
RICHARD PICCIONI, PH.D.
SENIOR STAFF SCIENTIST
ACCORD RESEARCH AND EDUCATIONAL ASSOCIATES
JUNE 19, 1987

I am Dr. Richard Piccioni, Senior Staff Scientist with Accord Research and Educational Associates, a not-for-profit public health research group based in New York City. I hold a doctorate in biophysics from the Rockefeller University, conducted three years of postdoctoral research at the Rockefeller supported by grants from the National Science Foundation and the National Institutes of Health, and was an assistant professor of biological science at the City University of New York, where my research was funded by the US Department of Agriculture and the MacArthur Foundation.

Over the past twenty months a team of biologists, chemists, physicians, and statisticians in our organization have carried

out an in-depth examination of the technical basis of the Food and Drug Administration's recent approvals of food irradiation processing. We feel that there is no assurance in the scientific literature or the arguments of the FDA that the widespread irradiation of food will not be a significant, if silent, threat to the public health. In summary, we feel the FDA has adopted scientifically indefensible criteria for assessing, and in their view, demonstrating, the safety of irradiated foods.

The unique nature of food irradiation processing

Treatment of food with ionizing radiation presents issues of food safety qualitatively unlike those posed by any other food processing method or food additive. The large amount of energy contained in ionizing radiation provides the potential for exceedingly complex chemical transformation of food components, including the production of mutagenic or carcinogenic substances which were not present, or were present in far smaller amounts, before irradiation. This potential far exceeds that of ordinary heat processing, microwave radiation, etc., because the energy contained in each "quantum" of gamma radiation is so great. At the same time, because the production of these "radiolytic

products" takes place within the food itself, it is impossible to design a toxicological test in which animals are exposed to exaggerated doses of these products, the chemical identity of which remains largely unknown. Thus toxicologists are limited to biological testing which is thousands of times less sensitive than the testing typically required of other chemical additives or pesticide residues.

It should be clearly understood that without toxicological testing at exaggerated doses, the carcinogenic risk to large human populations ingesting any additive or residue is impossible to assess. Exposure of test animals to exaggerated doses is the most basic tool in use in estimating carcinogenic risk. In the case of food irradiation, this tool is simply not available.

At the same time, evidence from other types of experiments provides a strong indication that mutagens and/or carcinogens are indeed present in irradiated foods. What such experiments are unable to provide, however, is a quantitative estimate of the risk. In the absence of such an estimate, it is completely irresponsible to proceed with the sale and distribution of irradiated foods. Consequently, recent approvals by the FDA for food irradiation processing should be immediately rescinded.

Basis of FDA's approvals

To understand how this has come to pass, we must briefly review some recent history: In 1979, after years of controversy and false starts, radiation food processing was re-evaluated by a specially appointed FDA committee, the BFIFC (Bureau of Foods Irradiated Foods Committee). They acknowledged that feeding whole, irradiated foods to test animals, even over long periods of time, was completely inadequate to assess the carcinogenic potential of the radiolytic products present in those foods. As an alternative to direct biological testing, they proposed acceptance of a theoretical calculation of the maximum concentration of radiolytic products present in irradiated food and made the extraordinary leap of faith that parts-per-million residues of unknown substances pose no risk when ingested by millions of people over their entire lives.

Subsequently, an FDA task force reiterated the BFIFC recommendations, and reported the results of an elaborate "review" of the available literature on the toxicological testing of irradiated foods, testing which they, as well as the BFIFC, agreed was inherently incapable of providing definitive evidence of the safety of irradiated foods. The five studies which have been mentioned by others at this hearing provided, according to the FDA itself, only the assurance that irradiated food is not wildly mutagenic and/or carcinogenic. The task

force therefore justified its conditional approval of irradiation of fruits and vegetables with up to 100 kilorad, and spices with up to 3 million rad, on the same theoretical basis as proposed by BFIFC.

Positive evidence of carcinogenic risk

Proponents of food irradiation commonly claim there are no studies in the scientific literature showing mutagenic or carcinogenic activity in irradiated foods or food components. In fact, as our own literature survey has shown (Table I) dozens of such studies exist, observed in a variety of biological systems , published by a variety of authors in a variety of peer-reviewed scientific journals over a period of twenty years. Proponents of food irradiation commonly claim that the chemical changes occurring in irradiated foods are thoroughly understood, and that there have been no studies indicating the formation of known mutagens or carcinogens. In fact, a substantial number of studies can be found in the open scientific literature indicating the presence of known mutagens, carcinogens, or cytotoxic substances in food or food components which have been irradiated (Table 2). Furthermore, the radiation chemistry of foods is far from fully understood, as evidenced by a steady appearance in the literature of studies on new radiolytic products found in various irradiated foods (e.g., Simic and Jovanovic (1986), Akhlaq et al. (1987)). Many of

these radiolytic products have not been individually tested for mutagencity or carcinogenicity.

In short, the available scientific literature provides evidence to make a strong presumption of carcinogenicty in some if not all irradiated foods. The question is one of quantifying the risk.

Pesticide replacement

In the absence of a quantitative estimate of the carcinogenic risk posed by the consumption of irradiated foods, there is no basis to the further claim that food irradiation could replace carcinogenic pesticides with an improvement in the overall quality of the food supply. Recently, the National Academy of Sciences (1987) identified 23 pesticides which are responsible for the vast majority of the total carcinogenic risk posed by the presence of pesticide residues in the US food supply. Food irradiation would make essentially no contribution to the elimination of these pesticides since of the 23, several are herbicides or insecticides applied in the field to prevent pre-harvest losses (Chemical and Pharmaceutical Press, 1987), and the remainder are fungicides, whose replacement by irradiation is a highly dubious proposition (Sommer, 1966 and personal communication). In fact irradiation of fruits and vegetables may well increase, rather than decrease, the

requirement for post-harvest application of fungicides because irradiated products are more susceptible to infection by molds and fungi (Sommer, op. cit., and Niemand et al., 1985).

Radiation treatment of Salmonella-contaminated poultry

On the question of the use of ionizing radiation to inactivate Salmonella in poultry, it is important to understand two points::

1. Doses required for even partial "pasteurization" of poultry meat are far greater than the doses which have been deemed "safe" by any of the evidence or arguments provided by the FDA to date. The "massive" feeding studies of 5 megarad irradiated chicken are no more capable of assessing carcinogenic risk than are any of the other irradiated-food feeding studies the FDA has categorically dismissed before; all lack the dose-exaggeration factor essential to any valid toxicological test. All of the concerns of the presence of trace mutagens or carcinogens in foods irradiated at "low" doses of 100,000 rads are only greater at doses of one million rads, required for even partial Salmonella inactivation.

2. Major unresolved microbiological questions arise regarding the safety of gamma processing of

salmonella-contaminated poultry: much of the virulence of recent cases of salmonellosis has been attributed to the presence of antibiotic resistant strains of the pathogen, due in turn to the use of these antibiotics in the poultry industry (Cohen and Tauxe, 1986), the addition of a highly mutagenic processing procedure, namely, gamma irradiation, on poultry carcasses still containing low levels of antibiotics is an appalling scenario for the appearance in the irradiated food of new, antibiotic-resistant strains. This issue has received serious, but not adequate, attention in the scientific literature (Privet et al., 1971).

Enhancement of aflatoxin production

The FDA has also been quick to dismiss concerns that irradiation of Aspergillis flavus spores or the grains upon which this fungus can grow, can increase the production of the potent carcinogen aflatoxin (Federal Register, 4/18/86) citing and dismissing a single study on the subject. In fact (Table 3) there have been several studies showing serious aflatoxin-enhancement effects at or near the very doses proposed for the irradiation of grain.

Summary: rescind FDA approvals

In summary, the continuing research effort by our organization indicates clearly that recent and pending approvals of food irradiation processing by the FDA should be rescinded, and the same degree of caution now being expressed by several state and national agencies around the world be implemented on a federal level.

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Table 1 BIOASSAYS ON IRRADIATED ORGANIC MEDIA AND FOODS SHOWING POSITIVE MUTAGENICITY, CHROMOSOMAL DAMAGE, TERATOGENICITY, OR CYTOTOXICITY (page 1)

| author(s) | date | irradiated material | observation | observed in |
|---|---|---|---|---|
| Kuzin & Kryukova | 1961 | plant leaves | chromosomal damage | plant embryos |
| Swaminathan et al. | 1962 | potato mash | chromosomal damage | barley embryos |
| Kuzin | 1963 | plant leaves | mutagenicity of extracts | plant cells |
| Swaminathan et al. | 1963 | culture medium | mutagenicity | drosophila |
| Chopra & Swaminathan | 1964 | potato mash | devel. abnormalities | barley embryos |
| Molin & Ehrenberg | 1964 | culture medium | cytotoxicity | bacteria |
| Berry et al. | 1965 | various sugars | cytotoxicity | human & mouse cells |
| Chopra | 1965 | culture medium | probable mutagenicity | bacteria |
| Holsten et al. | 1965 | coconut milk, sucrose | chromosomal damage | carrot explants |
| Parkash | 1965 | nucleic acids | mutagenicity | drosophila |
| Rinehart & Ratty | 1965 | culture medium | mutagenicity | drosophila |
| Frey & Pollard | 1966 | culture medium | mutagenicity | bacteria |
| Shaw & Hayes | 1966 | sucrose | chromosomal damage | human lymphocytes |
| Hills & Berry | 1967 | glucose | cytotoxcity | mouse fibroblasts |
| Hollowell & Littlefield | 1967 | plasma | chromosomal damage | human lymphocytes |
| Makinen et al. | 1967 | pineapple | chromosomal damage | onion roots |
| Parkash | 1967 | nucleic acids | mutagenicity | drosophila |
| Rinehart & Ratty | 1967 | nucleic acids | mutagenicity | drosophila |
| Rinehart & Ratty | 1967 | culture medium | mutagenicity | drosophila |
| Schubert et al. | 1967 | sucrose | cytotoxicity | bacteria |
| Steward et al. | 1967 | sucrose | cytotoxicity | carrot explants |
| Hollowell & Littlefield | 1968 | plasma | chromosomal damage | human leucocytes |
| Melette et al. | 1968 | wheat endosperm | mutagenicity | wheat |
| Ammirato & Steward | 1969 | sucrose | devel. abnormalities | plant root cells |
| Chopra | 1969 | culture medium | mutagenicity | bacteria |
| Moutschen-Dahmen et al. | 1970 | laboratory diet | preimplantation death | mouse |
| Schubert and Sanders | 1971 | various sugars | cytotoxicity | bacteria |
| Kopylov et al. | 1972 | potatoes | mutagenicity of extracts | mouse (sperm cells) |
| Kopylov et al. | 1973 | potatoes | mutagenicity | mouse |
| Bhaskaram & Sadasivian | 1975 | wheat | polyploidy | malnourished children |
| Vijayalaxmi & Sadasivan | 1975 | wheat | chromosomal damage | rat (bone marrow) |
| Vijayalaxmi | 1975 | wheat | polyploidy | rat (bone marrow) |
| Vijayalaxmi | 1976 | wheat | mutagenicity | mouse |
| Vijayalaxmi | 1976 | wheat | sperm count reduction | mouse |
| Vijayalaxmi | 1976 | wheat | polyploidy | mouse (bone marrow) |
| Vijayalaxmi | 1976 | wheat | aneuploidy | mouse (sperm cells) |
| Vijayalaxmi & Rao | 1976 | wheat | mutagenicity | rat |
| Vijayalaxmi & Rao | 1976 | wheat | sperm count reduction | rat |

BIOASSAYS ON IRRADIATED ORGANIC MEDIA AND FOODS SHOWING POSITIVE MUTAGENICITY, CHROMOSOMAL DAMAGE, TERATOGENICITY, OR CYTOTOXICITY



| author(s) | date | irradiated material | observation | observed in |
|---|---|---|---|---|
| Aiyar & Rao | 1977 | various sugars | mutagenicity | bacteria |
| FAO/IAEA/WHO | 1977 | potatoes | mutagenicity of extracts | mouse |
| Renner | 1977 | laboratory diet | polyploidy | hamster |
| Levina & Ivanov | 1978 | laboratory diet | autoimmune disease | rat |
| Vijayalaxmi | 1978 | wheat | low antibody levels | rat |
| Vijayalaxmi | 1978 | wheat | polyploidy, other effects | monkey |
| Wilmer et al. | 1979 | nucleic acids | mutagenicity | bacteria |
| Ivanov & Levina | 1981 | laboratory diet | testicular abnormalities | rat |
| Wilmer et al. | 1981 | nucleosides | mutagenicity | bacteria |

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

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

| Author(s) | date | irradiated material | radiolytic product | comments |
|---|---|---|---|---|
| uzin | 1965 | plant matter, rat thymus, tyrosine | orthoquinones<br>orthophenols | carcinogenic<br>carcinogenic |
| erry et al. | 1965 | dextrose, fructose | glyoxal<br>formaldehyde | mutagenic<br>mutagenic |
| l Zeany | 1980 | buffalo meat | peroxides<br>carbonyl compounds | mutagenic<br>cytotoxic |
| ower & Wills | 1986 | benzpyrene, starch & oil mixtures | benzo(a)pyrenes<br>quinones<br>malonaldehyde<br>lipid peroxides | carcinogenic<br>carcinogenic<br>mutagenic<br>mutagenic |
| chubert et al. | 1967 | sucrose | hydroxyalkyl peroxides<br>glyoxal | mutagenic<br>mutagenic |
| chubert & Sanders | 1971 | D-glucose, D-fructose, D-mannose, D-rhamnose, D-galactose, D-fucose | alpha, beta-unsaturated carbonyl sugars | cytotoxic (toxicity increased upon heating irradiated solution) |
| teward et al. | 1967 | sucrose | formic acid | mutagenic |
| rey & Pollard | 1966 | minimal cell medium | hydrogen peroxide | mutagenic, generates secondary mutagens |
| hopra | 1969 | glucose | organic peroxides | mutagenic |
| uzin | 1963 | plant tissues | organic peroxides<br>orthoquinones | mutagenic<br>carcinogenic |
| ilmer et al. | 1981 | deoxy-D-ribose, D-ribose | hydrogen peroxide<br>malonaldehyde<br>carbonyl compounds | mutagenic<br>mutagenic<br>cytotoxic |
| rooks & Klamerth | 1968 | glucose | glyoxal<br>malonyldialdehyde | mutagenic, binds to DNA<br>mutagenic, binds to DNA |

Table 3 PUBLISHED STUDIES INDICATING INCREASED ~~AFLATOXIN~~ AFLATOXIN PRODUCTION AFTER IRRADIATION

| author | date | irradiated material | dose |
|---|---|---|---|
| Jemmali & Guilbot | 1969 | Aspergillis flavus spores | 75 - 200 krad |
| Schindler & Noble | 1970 | Aspergillis flavus spores | 20 - 500 krad |
| Priyadarshini & Tulpule | 1976 | wheat, potatoes, maize, sorghum, millet | 10 - 75 krad |
| Priyadarshini & Tulpule | 1979 | wheat | 50 - 250 krad |
| Schindler et al. | 1980 | Aspergillis flavus spores | 75 - 450 krad |

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6/15/87

March 8, 1988

William B. Walker
4428 Mountainside Drive
Juneau, Alaska 99801

Representative John Sund
House Judiciary Committee

Dear Chairman Sund:

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

Radioactive materials

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

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

Labeling

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

If it is true:

Where is the labeling?

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

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

Food safety and FDA approval

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

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

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

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

Enforcement

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

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

I urge passage of HB 388.

Sincerely,

William B Walker

William B. Walker

Jan. 30, 1988

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

Dear Representative Sund,

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

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

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

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

Sincerely,

Rebecca Janik

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

enclosure

February 8, 1988

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

FEB 338

Dear Mr. Sund,

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

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

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

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

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

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

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

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

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

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

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

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

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

# Zap,

## Irradiated foods aren't coming; they're here

BY GARY GIBBS

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

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

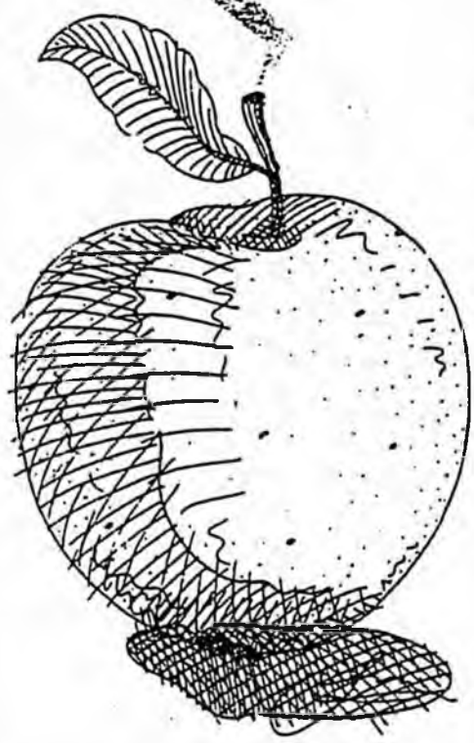
This is not the beginning of a science-fiction horror story. It is, in fact, a description of a method of food-processing designed to extend the shelf-life of commodities and kill insects infesting them. It has been used since 1963 on wheat but is a much more recent addition to other food items. Irradiation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

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

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

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

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



But many scientists and consumer advocates disagree.

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

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

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

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

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

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

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

# CORRECTION

THIS DOCUMENT
HAS BEEN REPHOTOGRAPHED
TO ASSURE LEGIBILITY

February 8, 1988

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

FEB 1988

Dear Mr. Sund,

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

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

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

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

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

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

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

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

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

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

We would appreciate a response.

Sincerely,

William Thomas

Sylvia Thomas

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

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

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

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

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

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

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

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

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

# Zap,

## Irradiated foods aren't coming; they're here

BY GARY GIBBS

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

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

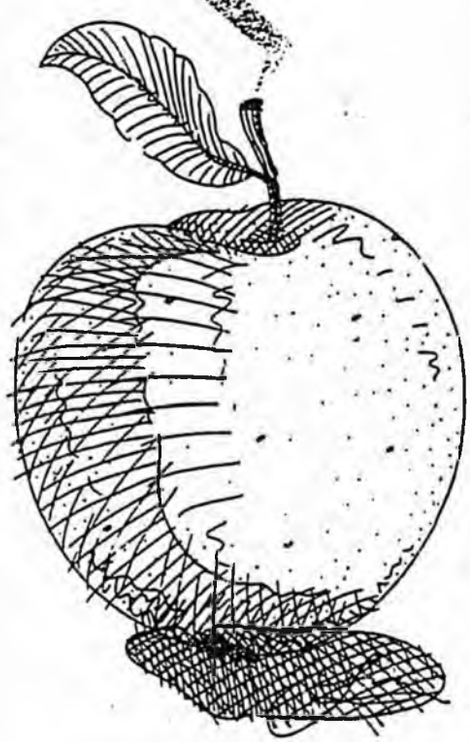
This is not the beginning of a science-fiction horror story. It is, in fact, a description of a method of food-processing designed to extend the shelf-life of commodities and kill insects infesting them. It has been used since 1963 on wheat but is a much more recent addition to other food items. Irradiation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

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

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

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

Can this possibly be safe? The industry says yes and even claims it is a boon to humanity, a way to save the food lost to spoilage, estimated at perhaps one-fourth of the world's supply. The FDA says there



are "no adverse effects." Health and Human Services Secretary Otis Bowen calls irradiation "a new technology that can produce benefits to consumers." His predecessor, Margaret Heckler, said, "Thirty years of research have proven this process to be safe."

But many scientists and consumer advocates disagree.

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

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

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

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

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

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

# Crackle,

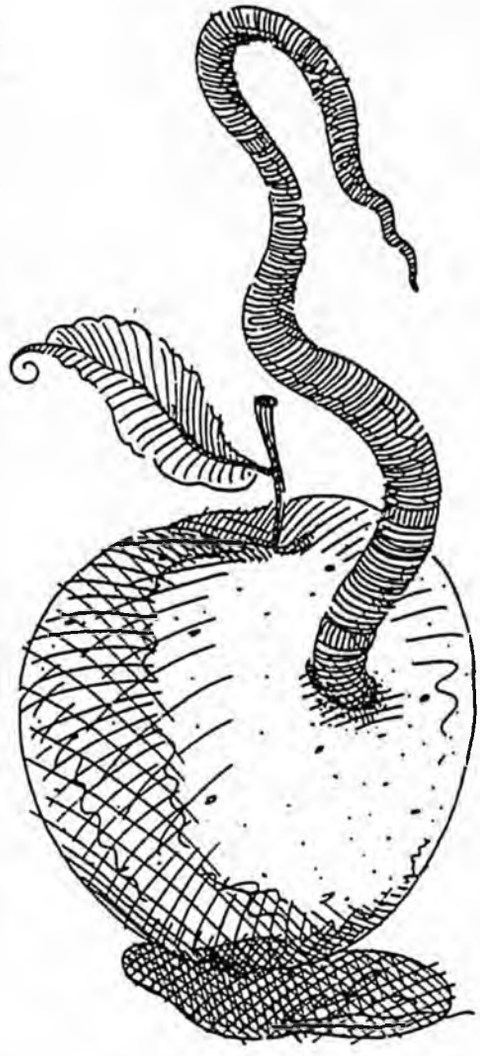
makes it imperative that the wholesomeness of irradiated food be very carefully assessed."

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

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

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

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



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

Some of the studies the FDA ignored are startling.

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

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

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

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

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

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

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

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

# Pop.

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

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

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

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

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

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

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

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

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

PATRICK JB FLYNN

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

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

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

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

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

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

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

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

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

# No Fried Food in New Jersey

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

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

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

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

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

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

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

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

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

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

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

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

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

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

In June, the company officially shelved the project.

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

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

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

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

—KEN TERRY

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

# Food Irradiation Facts

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

*For more information, contact:*

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

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

By KAY LEVINE
Daily News reporter

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

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

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

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

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

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

Alaska's year-long project got under way

See Page E-3, IRRADIATION

Continued from Page E-1

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

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

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

The study will not examine whether food irradiation is safe.

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

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

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

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

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

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

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

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

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

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

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

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

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

January 6, 1988

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

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

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

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

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

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

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

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

530 Duckering Building
Fairbanks, Alaska 99775-1760

ENGINEERING

# UNIVERSITY OF ALASKA FAIRBANKS
## INSTITUTE OF NORTHERN ENGINEERING

February 26, 1988

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

Dear Representative Sund:

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

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

Sincerely,

John P. Zarling

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

JPZ/jae

Enclosure

# SUMMARY STATEMENTS

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

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

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

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

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

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

7. Fact Sheet on the Alaskan feasibility study.

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

Editorial Opinion and Commentary

FAIRBANKS

**Daily News-Miner**

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

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

Monday, Feb 15, 1988 p. 4

## Overreaction

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

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

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

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

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

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

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

RESOLUTION #10-0388

RESOLUTION ON IRRADIATION

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

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

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

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

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

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

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

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

Dated this _____ day of _____, 1988.

By _____ By _____
Mike Kelly W.R. Cox

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

federal register

Friday
April 18, 1998

Part III

# Department of Health and Human Services

Food and Drug Administration

21 CFR Part 179

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

chemically or pharmacologically related substance or substances in such diet.

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

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

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

## II. Comments

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

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

### A. Safety

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

In the proposed rule, the agency stated "* * * that the safety of food irradiation below 1 kGy (100 krad) has been established * * * because: (1) Irradiation will not make the food radioactive, and thus cannot expose the consumer to radiation; (2) the chemical differences between irradiated foods processed at these doses and nonirradiated foods are too small to affect the safety of the foods; (3) food irradiated at doses up to 1 kGy (100 krad) will have the same nutritional value as similar foods that have not been irradiated; and (4) the balance between microbial spoilage organisms and pathogenic organisms is not adversely affected by radiation doses below 1 kGy (100 krad)" (49 FR 5718).

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

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

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

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

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

# CORRECTION

THIS DOCUMENT
HAS BEEN REPHOTOGRAPHED
TO ASSURE LEGIBILITY

federal register

Friday
April 18, 1986

Part III

# Department of Health and Human Services

## Food and Drug Administration

21 CFR Part 179

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 179

[Docket No. 81N-0004]

# Irradiation in the Production, Processing, and Handling of Food

AGENCY: Food and Drug Administration.

ACTION: Final rule.

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

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

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

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

SUPPLEMENTARY INFORMATION:

Table of Contents



## I. Introduction

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

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

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

Apart from that ongoing rulemaking, FDA has approved a number of food additive petitions to provide for the safe use of gamma radiation at doses up to 10 kGy (1 Mrad) to control insect infestation and microbial contamination in dried herbs, spices, and vegetable seasonings (48 FR 30813, July 5, 1983; 48 FR 48022, October 13, 1983; 49 FR 24068, June 10, 1984; 50 FR 18413, April 18, 1985) and in dry enzyme preparations (50 FR 26180, June 10, 1985). FDA also issued a final rule on July 22, 1985 (50 FR 29668) which amended 21 CFR 179.22(b) in response to a petition to provide for the safe use of gamma radiation at doses up to 1 kGy (100 krad) to control *Trichinella spiralis* in pork.

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

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

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

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

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

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