SJR

33

(7)

HOUSE COMMITTEE REPORT

Date referred: 3/11/88 FURTHER REFERRALS:

DATE: 3-31-88

The Health, Education and Social Services Committee has considered CSSSSJR 33(Res)

Relating to the labeling of irradiated food.

RECOMMENDS:

[x] replace with HCS CSSSSJR 33 (HESS) [x] the same title

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

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

ADOPTS: [ ] _____ letter of intent

ATTACHES NEW FISCAL NOTE(s):

- [ ] fiscal impact
- [ ] zero fiscal note
- [ ] zero with analysis
- [ ] same as previous fiscal note published _____
- [X] same as previous zero fiscal note published 2/9/88

SIGNING DO PASS:

SIGNING OTHER RECOMMENDATIONS:

Chairman's signature

90

- STATE OF ALASKA
1988 LEGISLATIVE SESSION

BILL VERSION: CS SS SJR 33 (Rules)
PUBLISH DATE: (SENATE) 2/9/88

FISCAL NOTE

REQUEST:

Revision Date: 2-4-88
Title: Labeling of irradiated food.

Sponsor: Kerttula
Requestor:

Agency Affected:
BRU:

Components:

EXPENDITURES/REVENUES: (Thousands of Dollars)

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

FUNDING: (Thousands of Dollars)

GENERAL FUND						
FEDERAL FUNDS						
OTHER						
TOTAL						

POSITIONS:

FULL-TIME						
PART-TIME						
TEMPORARY						

ANALYSIS: (Attach a separate page if necessary)

Prepared by: Senate Rules Committee
Phone: 465-4916
Division:
Date:

Approved by Chairman: Sen. Dick Eliason
Date: 2-4-88
Agency:

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

page ____ of ____

STATE OF ALASKA
THE LEGISLATURE

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May, 1988

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

Mary Van Nimwegen

HHESS 3-31-88 8:30 a.m.

February 10, 1988

Honorable Jalmar M. Kerttula
P.O. Box V (MS 3100)
Juneau, Alaska 99881

FEB 12 1988

Dear Senator Kerttula,

Thank you for sponsoring SB 355 and SJR 33.

Please consider additional measures to prevent the irradiation of food in Alaska. If possible, ban food irradiation facilities and/or resolve that the U of A Fairbanks end the feasibility study to build an irradiation facility until the Secretary of Health and Human Services initiates and concludes an inquiry into the wholesomeness and safety of irradiated food. (The Food Irradiation Safety and Labeling Requirements Act of 1987 [HR 956 & S 461] if enacted mandates an inquiry).

Enclosed is a copy of a letter sent to the UAF Board of Regents.

Sincerely,

William Thomas

Denny Thomas

Sylvia Thomas

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

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.

February 4, 1988

Board of Regents
Office of Regent Affairs, U of A
103 Bunnell
Fairbanks, Alaska 99775

Members of the Board of Regents,

Re: Alaskan Commodities Irradiation Project-An Options Anal,sis Study/ University of Alaska, Fairbanks

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."

Please end the feasibility study on building a food irradiation plant until the Federal government initiates and concludes an inquiry into the conflicting evidence of the wholesomeness and safety of irradiated food. (The Food Irradiation Safety and Labeling Requirement Act of 1987 [HR 956 & S461] if enacted mandates an inquiry).

We would appreciate a response.

Sincerely,

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

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.

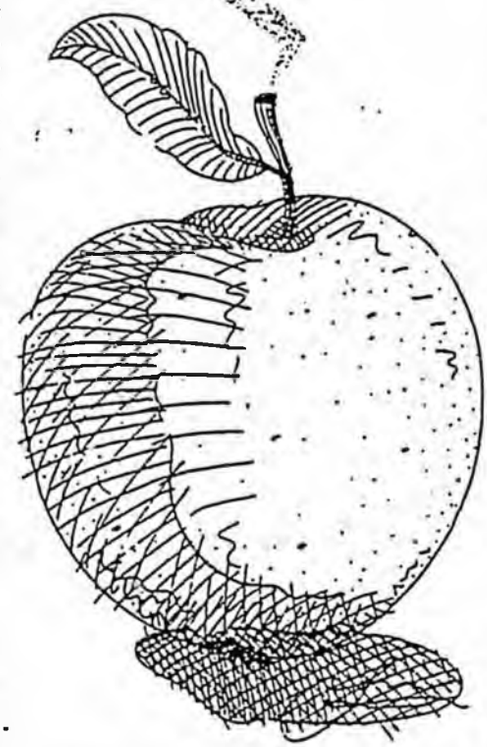
This is not the beginning of a science-fiction horror story. It is, in fact, a description of a method of food-processing designed to extend the shelf-life of commodities and kill insects infesting them. It has been used since 1963 on wheat but is a much more recent addition to other food items. Irradiation 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 is a student of osteopathic medicine at the University of New England, is the founder of Medical Students Against Food Irradiation.

Crackle,

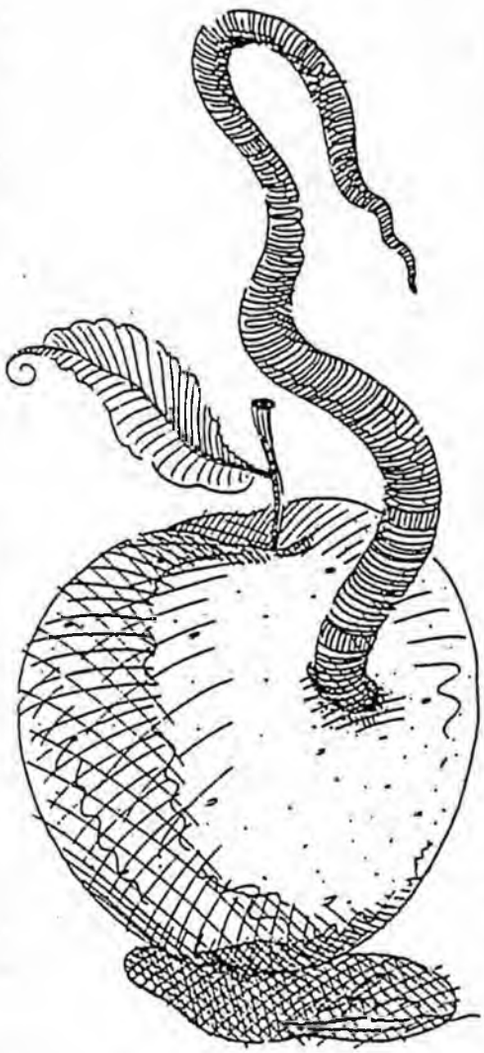
makes it imperative that the wholesomeness of irradiated food be very carefully assessed."

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 the 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 p[illegible]n, used in building nuclear weapon[illegible]ding to the coalition, Uncle Sam w[illegible] 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.

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

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

POSITION PAPER/Department of Health & Social Services

DRAFT

POSITION PAPER

SENATE JOINT RESOLUTION NO. 33

Senate Joint Resolution No. 33, relating to irradiated food, requests the U.S. Congress to place a moratorium on implementation of federal regulations regarding irradiation of food and requests an extensive study of the risks to human health posed by the irradiation of food. Reasons given include statements regarding serious and adverse effects on health, effects on food quality, and lack of labeling requirements to adequately inform the public.

The basis for this resolution appears to be founded on a number of inaccurate and misleading statements. The following comments are addressed to specific statements as follows:

Lines 7 and 8: "Whereas research on the consumption of irradiated food and food components contains examples of serious and adverse effects on health;"

Comment: There is no evidence provided by any scientifically conducted research meeting Food and Drug Administration Standards for toxicological studies which shows serious or adverse effects on health from the consumption of irradiated food. Some studies which have purported to show health effects have been rejected for failure to meet acceptable scientific standards involving controls, appropriate dose levels, and study design which allows for elimination of compounding factors. All available studies meeting acceptable scientific standards show that irradiated foods are safe for human consumption.

Presently, there are at least 25 countries using the radiation process routinely to irradiate a variety of food products. In this country, irradiation of wheat, wheat products, and potatoes has been approved since the mid 1960's. Irradiation of spices has been used extensively as well.

Lines 9 - 11: "Whereas the results of the research on the health effects of the consumption of irradiated food and food components are inconsistent, ambiguous, and therefore unreliable;"

Comment: The comments given above for lines 7 and 8 apply to this statement as well. After review of all available data, it is the judgement of such diverse groups as the World Health Organization, the Food and Agricultural Organization of the United Nations, the International Atomic Energy Agency, and the U.S. Food and Drug Administration that food irradiated within specified dose levels is wholesome and safe for human consumption. The results of research have been neither inconsistent or ambiguous when subjected to peer review.

Lines 12 - 14: "Whereas irradiation of food can affect vitamin content and nutrient profile and can create potentially harmful chemical compounds not found originally in the nonirradiated food;"

Comment: This statement is true, however very misleading since the implication is that these effects are unique to the radiation process. The statement applies to cooking and canning as well.

The issue of unique radiolytic products has received extensive consideration. Experiments have shown that few, if any, radiolytic products are unique to the irradiation process. At least 90% of the products are known to be natural components of food. The remaining 10% are known to be at least chemically similar, if not identical, to known natural food components. The concentrations of the products produced within the acceptable dose range approved by FDA are so low as to make it difficult for actual comparison because natural food components are not well characterized at the parts per million level.

Lines 17 and 18: "Whereas there is no federal requirement that irradiated food be labeled as irradiated;"

Comment: The federal government requires labeling of irradiated foods. Reference is made to 21 CFR Part 179.26 (c), Labeling. This section requires the labeling of irradiated food at the wholesale and retail level. The regulation requires that labels bear the words "TREATED WITH RADIATION" or "TREATED BY RADIATION" and that they be accompanied by the international symbol for food irradiation. Labeling is not required for food which merely contains an irradiated ingredient, such as a spice.

SJR 33 calls for an extensive study of the risk to human health posed by the consumption of irradiated food. This issue has been studied for many years. The U.S. Food and Drug Administration, after extensive review of all pertinent data, has not found any reason to be concerned about the safety of consuming food irradiated within the dose levels specified in 21 CFR Part 179. Without new evidence supporting the contention that irradiated food is harmful to health, it is unreasonable to call for another study.

Finally, SJR 33 would have serious ramifications for the Alaska Commodity Radiation Program, which is one of six state feasibility studies funded by the U.S. Department of Energy. The U.S. Congress has provided $5 million for fiscal year 1987 out of an anticipated $30 million ultimately needed to construct six commodity radiation facilities. The Alaska program will be administered by the University of Alaska and the Department of Transportation and Public Facilities. It has great potential impact on the Alaska seafood industry because of the extension of shelf life of seafood products by irradiation. The importance of this program to Alaska's overall economy could be great. Senate Joint Resolution 33 puts the state in opposition to this program as well as the scientific information which shows consumption of properly irradiated foods to be safe.

For the reasons stated above, the Deparment of Health and Social Services does not support Senate Joint Resolution 33.

Recommended By: Elizabeth Ward

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

Date: 4/3/87

Approved By: _____

Myra M. Munson
Director
Department of Health
and Social Services

Date: _____

March 9, 1987

Senator Jay Kertulla
Pouch V
Juneau, Alaska

MAR 12 1987

Dear Jay,

An issue that concerns me very deeply, along with making the Arctic and sub-Arctic nuclear free, is the irradiation of food to prolong shelf life. As you may know, spices have been irradiated and are sold to the unknowing public without any indication as to their radiated status. Now, permission has been given by the Department of Health and Human Services to irradiate fruits, vegetables, grains and other foodstuffs.

Past studies on animals fed irradiated foods show marked reduction in resistance to infectous diseases, significant reduction in growth rates and decline in fertility rate. Children fed irradiated foods developed blood abnormalities associated with leukemia. In spite of these facts, the FDA, military, and big business have pushed ahead with the irradiation of foods to use up excess nuclear waste.

I would like to see something done about this. A ban on irradiated foods, and certainly a ban on the importing of irradiated foods to Alaska would be desirable. We can also join California in their attempt to seek proper labeling and further investigation into the existing studies of irradiated foods and the health hazard they present, both to the consumer and to the personel working in radiation plants.

Enclosed is additional reading material in conjunction with this issue. Any action you would take to diminish the presence of irradiated foods in Alaska will be appreciated.

Sincerely,

Rocky

Lorraine "Rocky" Stone

Copies to:
Peter Goll
Niilo Koponen
Max Gruenberg
Mike Szymanski
Red Boucher
Bette Cato
Jay Kertulla
Ted Stevens
Frank Murkowski
Don Young

NCSFI

PRIORITY

National Coalition to Stop Food Irradiation

Phone: (415) 56N-CSFI P.O. Box 59-0488, San Francisco, CA 94159

MAKE COPIES OF THIS PAGE AND DISTRIBUTE TO OTHERS

BILL HR 4762, The Food Irradiation Safety and Labeling Requirement Act of 1986 has been introduced into the U.S. House of Representatives by California Congressman Douglas Bosco (D-Ca. 1st District). We need to familiarize U.S. Representatives throughout the country with HR 4762 and urge their support! 292 house votes will ensure its passage over a presidential veto. The present co-sponsors of HR 4762 can be found on page 1 under our list of Congressional Allies.

What you can do NOW!

1. If your local House member is not a co-sponsor, telephone him or her urging support for HR 4762, The Food Irradiation Safety and Labeling Requirement Act of 1986. The local and Washington D.C. telephone numbers and address can be obtained from your local library or Chamber of Commerce.
2. Make copies of this page and distribute to family, friends, co-workers, clientele, etc., encouraging them to telephone their congressional Representative and to clip and mail in the letter below urging support of HR 4762!
3. Mail in the letter below or write your own letter urging *support of* HR 4762.

ACT NOW. PROTECT YOUR FOOD FROM RADIATION!

..... CLIP HERE .....

Representative _____
U.S. House of Representatives
Washington, D.C. 20510

Dear Representative _____:

I urge you to support HR 4762, The Food Irradiation Safety and Labeling Act of 1986. This bill was introduced on May 7, 1986 by California Representative Douglas Bosco and 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. Safety of long-term consumption and the nutritional value of irradiated food.
   b. Contamination of foods from improper radiation.
   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 FDA to require labeling on a wholesale, retail, and restaurant level of *all* irradiated foods, both whole foods and food *ingredients*. 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.

The Department of Energy (DOE) envisions 1,000 facilities in local communities by the mid-1990s. With the recent Russion nuclear accident much information has surfaced about the existing dangers of nuclear plants and radioactive storehouses in this country. This is the time to stop and place strict limits on the expanded use of nuclear technology. It is irresponsible and dangerous to treat our food with radioactive nuclear materials, to have food irradiators in our communities, and to transport on our highways the large quantities of hazardous nuclear materials required for those facilities.

Please respond to this letter and let me hear your support for HR 4762.

Sincerely,

_____ _____
Signature Print Name

_____ _____
Street Address Date

_____
City State Zip

MAKE COPIES OF THIS PAGE AND DISTRIBUTE TO OTHERS

PRIORITY

National Coalition to Stop Food Irradiation

Phone: (415) 56N-CSFI P.O. Box 50-0408, San Francisco, CA 04150

CALIFORNIANS!!

TELL YOUR STATE ASSEMBLYMAN:

STOP FOOD IRRADIATION!

California's Joint Senate/House Resolution, SJR 50, passed the State Senate on July 10, 1986! Now we must pass it in the California Assembly. See the letter below for details on this far-sighted State resolution which seeks to put the brakes on food irradiation.

Let's flood our State Assemblymen's offices with letters, postcards, and telephone calls urging them to support SJR 50 and to oppose food irradiation!

YOU CAN OBTAIN THE NAME AND TELEPHONE NUMBERS OF YOUR CALIFORNIA ASSEMBLYMAN FROM YOUR TELEPHONE BOOK, LOCAL LIBRARY, MAYOR'S OFFICE, OR CHAMBER OF COMMERCE. THEIR SACRAMENTO ADDRESS IS BELOW.

CLIP AND MAIL the following letter or WRITE YOUR OWN letter or postcard. TELEPHONE your Assemblyman's local office, too! TELL THEM TO SUPPORT SJR 58 AND OPPOSE FOOD IRRADIATION!

CLIP HERE

Date_____

Assemblyman _____
State Capitol Building
Sacramento CA 95814

Dear Assemblyman _____:

I urge you to vote your support for California's Joint Senate/House Resolution, SJR 58, introduced by Senator Milton Marks and currently before the State Assembly. This resolution:

1. Requests the Secretary of Health and Human Services to arrange for an extensive study of the risk to human health and the environment of food irradiation.

2. Requests that no new regulations on food irradiation be propopsed until the U.S. Congress and the people have had an opportunity to review results of an extensive study of the potential dangers of irradiation of food and the development of a food irradiation industry.

3. Directs that copies of this resolution be transmitted to the President and Vice President of the United States, to the Secretary of Health and Human Services, to the Speaker of the House of Representatives, and to each Senator and Representative from California in the Congress of the U.S.

SJR 58 supports bill H.R. 4762, The Food Irradiation Safety and Labeling Requirement Act of 1986,, authored by California's Congressman Douglas Bosco and currently before the House of Representatives.

I urge you to vote for California's SJR 58 and oppose food irradiation!

Sincerely,

_____ _____
Signature Print Name

_____ _____
Street City State Zip

SECOND OPINION

HOT POTATO

How would you like to eat an 18-month-old potato?

Not a very appetizing thought, is it? The mind's eye pictures an 18-month-old potato as a rotted wad of mush with some greenish-brown tentacles sticking out of it. Actually, that picture is a fairly accurate one, unless the potato has been irradiated.

For those who are not familiar with food irradiation, it is the treatment of certain types of foods with radiation for the purpose of killing microbes that make food go stale. The outcome is expanded shelf life. That is why I asked how appealing an 18-month-old potato is to you. An 18-month-old potato, treated with radiation, looks the same as a new potato.

For the past decade there has been controversy over the concept and use of food irradiation. Proponents of the process (i.e., those in the irradiating business and many food distributors) claim that the process is a very useful method of dealing with food-related problems that we now use pesticides and other chemicals to control. They claim that these older processes are not as effective as irradiation. They also claim that there are no harmful side effects to the consumer of irradiated food.

Critics of the process contend that the studies conducted on possible side effects (or lack of them) to consumers who use irradiated food have been seriously flawed. They also contend that if the only advantage is to lengthen shelf life, why use this process when so many questions still remain.

The government does not seem to think there is a problem. For many years most of the dried herbs and spices you have used probably have been irradiated. Recently, under pressure from segments of the agribusiness industry, the Department of Health and Human Services approved regulations that expand the use of radiation to fruits, vegetables, grains and other foodstuffs.

The government also issued another set of regulations dealing with irradiated food. These dealt with labeling foods that have been treated with radiation so as to let consumers know what they were eating. In the original draft, these regulations did not call for "point-of-purchase" labeling. That means that you and I would not know we were buying an 18-month-old potato.

But there was a very strong reaction to those proposed regulations. Consumer groups and others flooded the Food and Drug Administration with calls for "point-of-purchase" labeling.

As a result, the Food and Drug Administration capitulated, but there are some hitches. In fact, in my opinion, the hitches are so significant that the victory is only partial, at best.

Here is what the FDA did: The regulations now require that any whole product treated with radiation must be labeled with a little flower-like symbol *and* must state that the food has been treated with radiation. This means that if your grocer has a potato that's been treated, there has to be a sign there displaying the symbol and the words of explanation.

But note that above I said "whole" product. Our government, in its scientific and consumer-protection wisdom, has decided that products having only some, but not all, of their ingredients treated with radiation do not have to be labeled as such. This means, for example, that potato salad that might have had 95 percent of its ingredients irradiated still will not be labeled. So you see, like it or not, you may be eating an 18-month old potato.

Further, there is no requirement to disclose to you that you are eating irradiated food in a restaurant or—and this is what really concerns PMS and its members—in a nursing home or a hospital.

As if all of this were not bad enough, here is the clincher. Two years from now the only way you will know that your whole food has been irradiated is by knowing what that little flower-like symbol means—because the regulations only require the words indicating a product has been irradiated to appear until approximately May, 1988. By then, supposedly, everyone will know the symbol.

Whether I am for or against food irradiation is not important. The issue is my right to know if the process is being used on foods I eat—and the foods I am, in effect, forced to eat in hospitals, nursing homes or other health-care facilities. I also should know if the ingredients of the food I eat have been treated. Then, at least, I'd have a choice. I could decide if I want an 18-month-old potato or a one-month-old spud.

This is called full disclosure, and it is something the People's Medical Society has been writing about since our founding. We should have a right to know what is in our food or what is being done to it. Similarly, we should have a right to know the side effects of medications, or the malpractice record of our doctor, or the mortality rates of a procedure at our hospital.

We are the only ones who are going to be able to change the system from one in which we "should" have the right to know to actually "having" the right to know.

Think about it. If the Food and Drug Administration is so confident that the process of food irradiation is so harmless, why are they letting the food industry drop the word-labeling requirement in two years? I think we all know why. The answer is that very few people are going to buy food that has a sign next to it that says it has been treated with radiation. But two years from now, when all we see is some cute little flower next to our produce, we won't know the difference.

So let's get our right to full disclosure made clear on this issue. Contact your federal lawmakers, and say you want them to introduce legislation that will require full-disclosure labeling of whole foods and foods whose ingredients have been treated with radiation, and especially in health-care institutional situations. And also tell them to make sure that they require the words "treated with radiation" to appear prominently on the product so long as the radiation process continues.

Let's take that radioactively hot potato and toss it into the laps of those we elected to protect our rights as consumers.

CHARLES B. INLANDER
President

People's Medical Society

Charles B. Inlander *President*

Lois Backus *Director of Policy Affairs*
Bill Bauman *Director of Membership Services*
Michael Rooney *Director of Projects*
Linda Svrank *Fulfillment Manager*

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Ed Weiner *Senior Editor*
Paper & Pencil Design Group *Art Direction*

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Off the Cuff

By Linda Copper
Consumers United for Food Safety

CUFFS thanks PCC for their continual support and their 1986 donation to help fund our activities. This money will help in our ongoing efforts to educate PCC members and others on the subject of food irradiation.

When several of PCC's members started investigating food irradiation in early 1984, I naively thought that this issue would probably die and disappear within a year. Now, two years later, Margaret Heckler, the lame duck head of Health and Human Services has approved for publication a FDA final rule to irradiate fruits and vegetables. They have consented to label such foods with the term "picowave."

CUFFS has submitted a bill to the Washington State Legislature which calls for clearer labeling, such as "treated with ionizing radiation." Bill #1096 has been assigned to Environmental Affairs Committee. Prime Sponsor is Ken Jacobsen. The Olympic Hotline telephone number is 1-800-562-6000. Our bill is modeled after a bill submitted in the state of Vermont. We will keep you informed on the bill's progress.

As this goes to press, we are working on a newsletter. Copies of this newsletter, also titled "Off the Cuff" will be in all PCC stores. Look for them.

Irradiated Fruits and Vegetables To Be Labeled "PICOWAVED"

By Connie Wheeler

Health and Human Services (HHS) has recently decided to allow low dose irradiation of fruits and vegetables and to label them "PICOWAVED."

If you saw the word "picowaved" and this symbol on a bin of papayas, would you know the papayas had been irradiated? Some consumers might confuse the word with "microwave."

When Congress put irradiated foods on the "additive" list it intended that irradiated foods be labeled: "treated with ionizing radiation" or "treated by gamma radiation" as HHS did when permitting the irradiation of pork.

The only reason irradiated fruits and vegetables will not be adequately labeled for the consumer is because of pressure from the irradiation industry which wants to avoid the word "radiation" because it accurately associates the treatment with nuclear wastes or X-rays.

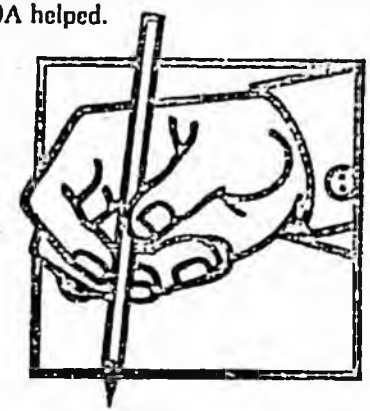
Martin A. Welt of Radiation Technology in a *New York Times* article (Sept. 8, 1985) threatened to challenge HHS in court if the word "radiation" was required on irradiated fruits and vegetables."

Neither the word "picowave" nor the word "pico" can be found in a dictionary. I had to go to the library to find out what it meant. According to the FDA press release, even the word "picowaved" may be omitted after two years and only the logo used.

Consumer groups have also objected to the lack of long term animal studies to measure health effects and the lack of environmental impact studies. Health and Human Services is supposed to assure the wholesomeness, safety and adequate labeling of our food supply.

You may feel that the labeling of irradiated foods is not an important issue for you, because you now know about "picowaved" and can avoid it if you wish. But even though you can avoid buying irradiated foods at the supermarket, it will be difficult to avoid irradiated foods entirely. If you eat at a restaurant, stay at a hospital, buy processed food or join the military you may be eating irradiated food whether you want to or not.

Now is the time to voice any objections—*before* irradiation facilities are built. Consumers have won a battle by securing at least some type of labeling on irradiated foods which was not included in the original FDA proposal. Over 5000 letters to the FDA helped.



Consumers wishing to object to obscure labeling can write:

Secretary Otis Bowen
Department of Health and Human Services
H.H.H. Building
200 Independence Avenue, S.W.
Washington, DC 20201

Cover-Up

Nuclear Greengrocers

Irradiation may be safe for food—but not for the environment

The nuclear firms that irradiate foods may not be the kind of people you want handling your potatoes.

The issue isn't just whether irradiated foods are safe to eat, though that debate continues. It's the irradiators themselves.

In December 1986, an executive of the California firm International Nutronics was convicted on a felony charge and put on two years' probation for concealing a 1982 spill in its Dover, NJ, plant. The sentencing judge also imposed on the firm the maximum fine that was possible: $36,000.

"This is not just a slap on the wrist," says appeals chief Samuel Moulthrop of the U.S. Department of Justice. "It is the first time an irradiation executive has been convicted on a criminal charge for violating Nuclear Regulatory Commission (NRC) regulations."

When water contaminated with cobalt-60 leaked from the plant, court records show, the company didn't notify the NRC, as required. Instead, to cover up—and fool inspectors—it put lead wool in walls and floors, and covered hot spots with telephone poles. Cleanup workers weren't given safety suits—just mops.

The company was also shown to be irradiating cocoa, a food not approved for the process. (So far, the FDA has sanctioned irradiation of wheat, potatoes, onions, spices and, more recently, a wide array of fresh produce.)

And while they *pretended* to be shut down, they were still irradiating liver meal for dog food, court records also showed.

Nor is International Nutronics' case unique. Radiation Technology, in New Jersey, hasn't been indicted for any wrongdoing, but it has been cited for 32 NRC violations between 1970 and 1984. In an investigation early in '86, the NRC found that the firm endangered workers by willfully circumventing a safety-lock system. Their license was suspended. Last summer, after the firm took several corrective actions, including barring the chairman (who had resigned) from any further involvement, the NRC restored the license. Meanwhile, the Justice Department has launched a criminal investigation. —*Janice Horowitz*

American Health
Feb 1987

The FOOD IRRADIATION ALERT!

The Newsletter of the National Coalition to Stop Food Irradiation

Volume 1, No. 5

OUR CONGRESSIONAL ALLIES

A sincere THANK YOU to those members of Congress opposed to the irradiation of food.

Douglas Bosco (D-CA 1st District) has reintroduced the Food Irradiation Safety and Labeling Requirement Act. The new number of this bill is HR 956.

He has been joined in the Senate by George J. Mitchell of Maine who has introduced a companion bill, Senate Bill (S) 461. Both bills have the same title — **The Food Irradiation and Safety Requirement Act of 1987.**

The following Congresspersons are currently sponsoring the House bill:

1. Ron Dellums (D-CA)	Oakland
2. Barbara Boxer (D-CA)	San Rafael
3. Fortney (Pete) Stark (D-CA)	Hayward
4. Leon Panetta (D-CA)	Monterey
5. Sala Burton (D-CA)	San Francisco
6. Augustus Hawkins (D-CA)	Los Angeles
7. Glenn Anderson (D-CA)	Long Beach
8. Anthony Beilenseon (D-CA)	Los Angeles
9. Esteban Torres (D-CA)	Norwalk
10. Howard Berman (D-CA)	Los Angeles
11. Peter De Fazio (D-OR)	Eugene
12. Michael Lowry (D-WA)	Seattle
13. Bill Richardson (D-NM)	Santa Fe
14. Robert Kastenmeier (D-WI)	Madison
15. John Conyers (D-MI)	Detroit
16. Frank Annunzio (D-IL)	Chicago
17. Charles Hayes (D-IL)	Chicago
18. William Lipinski (D-IL)	Chicago
19. Kenneth Gray (D-IL)	W. Frankfort
20. Andrew Jacobs (D-IN)	Indianapolis
21. Edward Feighan (D-OH)	Lakewood
22. James Traficant, Jr. (D-OH)	Youngstown
23. Don Sundquist (R-TN)	Memphis
24. Albert Bustamante (D-TX)	San Antonio
25. Olympia Snowe (R-ME)	Bangor
26. Edward Boland (D-MA)	Springfield
27. Nicholas Mavroules (D-MA)	Salem
28. Silvio Conte (R-MA)	Pittsfield
29. Steward McKinney (R-CT)	Stamford
30. Sam Gejdenson (D-CT)	Norwich
31. Claudine Schneider (R-RI)	Providence
32. Edolphous Towns (D-NY)	Brooklyn
33. Robert Mrazek (D-NY)	Huntington
34. Mayor Owens (D-NY)	Brooklyn
35. Robert Garcia (D-NY)	Bronx
36. Gary Ackerman (D-NY)	New York City
37. Benjamin Gilman (R-NY)	Middletown
38. Mano Biaggi (D-NY)	Bronx
39. Ted Weiss (D-NY)	Riverdale
40. Stephen Solarz (D-NY)	Brooklyn
41. Charles Schumer (D-NY)	Brooklyn
42. James Howard (D-NJ)	Middletown
43. Matthew Rinaldo (R-NJ)	Union
44. Dean Gallo (R-NJ)	Dover
45. Peter Rodino (D-NJ)	Newark
46. Frank Guarini (D-NJ)	Jersey City
47. James Florio (D-NJ)	Camden
48. Robert Roe, Jr. (D-NJ)	Newark
49. Christoper Smith (R-NJ)	Trenton
50. Peter Kostmayer (D-PA)	Doylestown
51. Robert Borski (D-PA)	Philadelphia
52. Joseph Kolter (D-PA)	Beaver Falls
53. Austin Murphy (D-PA)	Uniontown
54. Walter Fauntroy (D-DC)	Washington
55. Walter Jones (D-NC)	Farmville
56. George Darden (D-GA)	Marietta
57. Lawrence Smith (D-FL)	Hollywood
58. James Courter (R-NJ)	Morristown
59. Marge Roukema (R-NJ)	Ridgewood
60. Patricia Schroeder (D-CO)	Denver
61. Chester Atkins (D-MA)	Lowell

*See eulogy, this issue.

**Votes in committee, but not on the floor.

FAREWELL TO SALA BURTON

On Sunday, February 1, 1987, Representative Sala Burton died from complications of colon cancer. Sala Burton was an unfailing friend of people everywhere — the people of the Bay Area who elected her, the people of the United States and the people of the world. Sala was one of the earliest opponents of food irradiation, and a co-sponsor of the original Bosco Bill (HR 4762, now HR 956). In our hearts and memories we will continue to count Sala Burton among our dearest friends and staunchest allies, and remember her successful efforts to promote the well being of the people and our environment to her dying day. Thank you, Sala. We honor you, and your late husband, Philip.

Denis Mosgofian for NCSFI

SENATOR MITCHELL JOINS THE BATTLE

On Feb. 4, 1987 Senator George J. Mitchell (D-Me.) joined Rep. Bosco by introducing legislation prohibiting food irradiation. Senate Bill S 461 is the companion bill to HR 956, the "Food Irradiation Safety and Labeling Requirement Act of 1987."

Senator Mitchell's major concern is food safety. "Because I am not convinced that food irradiation has been sufficiently proven safe by the FDA, I'm pleased to join with Representative Bosco today in introducing legislation that would:

(1) prohibit either the Secretary of HHS or Agriculture from implementing regulations allowing the expanded use of irradiation;

(2) require all irradiated foods to be so labeled; and

(3) mandate a two-year study by the National Academy of Sciences of food irradiation, including the environmental and health issues associated with irradiation facilities.

Representative Bosco will touch upon the other troubling aspects of this technology including worker safety, adverse nutritional impacts, costs, effectiveness and environmental impacts associated with food irradiation.

I share his concern, but those concerns are all, I believe, secondary to the fundamental issue of safety."*

Welcome aboard, Senator Mitchell.

*press release, Feb. 4, 1987

VICTORY IN IRWINDALE

Irwindale, California is a small Mexican-American community of about 1000 residents bordering West Covina in the greater Los Angeles area. Primarily an industrial town close to the intersection of the San Bernardino Freeway and Route 210 it prospers from its industrial tax base. From the air Irwindale looks like a giant, rimless spoked wheel with the residential area at the hub and various industrial complexes as the spokes, separated by unincorporated areas.

One spoke, occupying about 24 acres is a facility of American Pharmaseal Corporation (APC). It is located directly across a small dry creek bed from the residential community of West Covina. The Irwindale facility is one of 22 APC plants nationwide specializing in the development, manufacture and marketing of plastic and latex disposable medical devices and other assorted healthcare equipment. It is the largest such facility on the West Coast. Currently this APC facility has about 750 employees, down from their high of 1250 employees seven years ago. Only 7 of these employees are residents of Irwindale.

A large percentage of APC's product is currently sterilized on-site using an ethelyne-oxide (ETO) sterilization process. In May, 1986 the company submitted an application to the Irwindale Planning Commission for a "Conditional Use Permit" to allow the construction and operation of a gamma energy (Cobalt 60) sterilization facility. This came as a surprise to the Planning Commission and the residents, several years earlier, when APC had originally informed the Planning Commission that they intended to expand their facility they had not mentioned that the source of sterilization would be Cobalt-60.

Shortly after the 1986 application for the Conditional Use Permit, the Los Angeles co-ordinator for NCSFI, Kathy Sundmark, was contacted by residents of Irwindale and West Covina. They wanted information and assistance in understanding the ramifications of a proposal to bring 4 million curies of Cobalt-60 into their community.

On June 6th, the Planning Commission voted 5 to 0 to reject the permit. This rejection came as a surprise to APC and its Cobalt-60 supplier, Atomic Energy Limited of Canada (AECL). APC/AECL were so certain of success APC had started construction on the facility without a permit. On June 10th the Planning Commission issued a stop work order.

APC began a campaign to reverse the Commission vote, organizing in the community and among their workers. They flew residents to their ongoing radiation facility in El Paso to show how

Continued on page 2

Continued from page 1

"safe" radiation facilities could be. They circulated petitions, rumors were spread that another rejection would force them to move the facility, and prepared a professional quality video to present their case. They then appealed the Planning Commission decision.

The second hearing took place on October 9th at the town hall. A citizens committee headed by Virginia Wilkerson invited Kathy Sundmark and other members of NCSFI to testify. Kathy was joined by Denis Moscofian and Brion Sprinsock, who had arrived at the last minute on separate flights from San Francisco and San Jose. At the hearing hall they found that APC had packed the hall with two busloads of its workers forcing virtually all community members to listen outside the small chamber.

Virginia Wilkerson, who lives next to the APC plant, presented a petition with 300 signatures opposing the facility. She claimed the firm failed to live up to the obligation of notifying residents near the plant of their intent. They had initially notified only five area residents.

Kathy Sundmark, a chiropractor, was introduced as a health professional. Her testimony centered on how ionizing radiation affects human health. Essentially exposure to radiation causes two general classes of problems – general body and organ damage called **somatic** damage and damage to hereditary cells or gonads called **genetic** damage.

Small doses over variable periods of time may cause immediate or delayed radiation effects. Whereas somatic effects harm only the person involved, genetic effects may not surface until the next generation. Birth defects and mental retardation are among the symptoms. **Genetic damage may be passed from generation to generation.**

Denis testified how ionizing radiation works, how it enters the body directly through the skin without us being aware of it. Radiation concentrates in those organs and tissues that normally use or deal with the chemical isotope that it derives from. It remains in the body bombarding surrounding tissues until it is no longer radioactive. In the case of Cobalt-60 it loses ½ its radioactivity every five years. After 50 years in the body it would become relatively stable but still capable of harm.

He quoted from a handbook written for radiation workers by Daniel Volz, an industrial hygenist:

"The prevailing scientific thought today is that any exposure to ionizing radiation is potentially harmful. This means there is a health risk at any level of exposure to ionizing radiation.

The experts can help define the magnitude of the risk at different exposure levels but the setting of acceptable limits are value judgements."

It was reported that a facility such as the one planned by APC/AECL would be permitted to emit 500 milirems of radiation per year, a figure given by the Nuclear Regulatory Commission (NRC) and said to be 20 times the amount of radiation that can legally be emitted from a nuclear power plant.

"On the walls of our irradiators, you can't even detect radiation," angrily disputed Franklin Frazier, an official of AECL. AECL had a great deal riding on the outcome of the hearing. They had expected to sign a long term contract to supply APC with Cobalt-60. In the first ten years, that contract would mean to AECL $11 million for the radioactive material itself. Shipping and container charges would be extra.

In one of the highlights of a long and stormy session, Frazier was to carry the dispute with Denis almost to the point of becoming physical.

A video prepared by APC/AECL stressed safety to the point of the absurd. It began with Victor Koch, a radiation supervisor filling a glass of water from a radiation storage pool and drinking it down. Later came a clip from a film made by the Department of Energy (DOE) in which a locomotive traveling 80 miles an hour slams into a nuclear fuel rod container. The fuel rod container housed in a lead-lined steel sleeve is propelled into the air. Later the same container is burned. The voice over announces no breech of the containment chamber.

Brion Sprinsock focused on the poor accident record of both the commercial radiation industry in general and AECL in particular. AECL has a history of appearing and testifying to the safety of their equipment before installation, and later this same equipment would fail and misfunction. He cited three specific cases, one of which caused the death of two people.

As Brion began to recite the litany of accidents – Radiation Technology, Inc.; International Nutronics, Inc.; etc., etc. – he was cut short by Elias Ornelas, Chairman of the Planning Commission. Disappointed and feeling that he had lost the vote of Commissioner Ornelas, he hurried through his testimony.

As Franklin Frazier testified on the safety record of commercial irradiating facilities, Commissioner Ornelas, looked up at him waving a paper. "If the facilities are so safe, how come there are so many accidents listed here?" Frazier angrily denied the fact of accidents.

Ornelas gazed down at the paper: "Do you mean all these accidents and dates are made up?" he queried.

Someone had provided Commissioner Ornelas with a copy of the "Irradiation Hall of Shame," a paper originally compiled by Brion Sprinsock of the 13 most significant accidents in the industrial radiation industry, accidents which occurred within the last 12 years to an industry not much more than 12 years old. It was the same paper Brion had been reading from when Commissioner Ornelas had cut him off.

APC went on to explain to the commission the benefits to Irwindale the new facility could bring. Besides the increase in tax revenue, they offered to give preferential treatment to community residents when hiring new workers, even offering on-the-job training for the unskilled. To further sweeten the pot, they offered a $5,000 annual scholarship to a resident of the city.

But as planning commissioner Mauro Martinez put it, "I'm a real estate broker and as such am required by law to reveal potential dangers to prospective buyers. A radiation facility will reduce the value of our property."

Martinez continued, "A lesson I learned when I worked as a machinist was that nothing ever works perfectly. There are always problems. If there is a facility there will always be fear, fear which will violate the sanctity of the home. We cannot allow that."

The 3 to 2 vote against granting the permit elicited an angry response from APC/AECL.

APC/AECL would not give up. Continuing their "Community Education" and free plane trips to the El Paso facility, they appealed the ruling over the heads of the Planning Commission to the City Council.

Rachel Duran, a local telephone lineperson, took up the flight initiated by Virginia Wilkerson. Returning from a trip to El Paso she was committed to keep the community from being the site of a large source of radioactive material. She said she "objected to the Irwindale plant primarily because it is located much closer to homes than the El Paso plant." The facility in Irwindale would be only 350 feet away from a residence as opposed to almost a mile in El Paso. With the intensity of radiation decreasing inversely by the square of the distance from a radioactive source, the danger of leakage would be considerably less the further away the facility. "Similarly, two gamma radiation plants in Orange County – one in Tustin and one in Irvine – are located in industrial areas away from homes."

Always concerned, but initially shy, Rachel and other locals from Irwindale and West Covina, assisted by Kathy Sundmark organized the community to respond to this second appeal.

After some initial indecision the City Council set a date for the appeal in November. But shortly before that date APC requested a postponement. Rachel, seeing this as an attempt to diffuse their momentum, successfully protested the postponement and forced APC into a showdown.

Under community pressure the hearing was held in a larger facility, the high school auditorium where over 300 residents and neighbors attended.

APC/AECL asked for and received permission for a 90-minute presentation, doubling the time of their last presentation. AECL brought with them a full line of top executives and a large group of high powered consultants. Their team of media people quickly assembled three video monitors and a top flight sound system. One monitor was for the City Council. The other two were at each end of the stage for the residents. APC/AECL's presentation focused on questioning the motives and expertise of NCSFI and others who would oppose irradiation.

As soon as their presentation concluded, APC/AECL's media crew packed up the equipment. NCSFI, however, improvised and was able to show a video of "Hot Streets" produced by PBS on a program called *Express*. "Hot Streets" contained the same DOE film clip as the APC presentation. However, the conclusion was far different, emphasizing an allegation that the type of casks shown in the video were not the same type casks used to transplant cobalt.

"Hot Streets" produced pictorial evidence of a driver who had transported radioactive waste from Southern California to a dump site in Nevada. The driver, violating regulations deviated from his prescribed route and passed through highly populated Los Angeles to pick up his girlfriend. Then getting back on Route 210 which passed close to Irwindale, he and his girlfriend meandered up to Nevada, stopping to spend a night in a casino motel. When they reached the Nevada site, the truck was found to be leaking radiation. In fact, it was so hot from leaked cobalt, they had to bury the cab.

With more time, NCSFI and community spokesmen covered in greater depth and intensity the issues of worker safety, dangers of ionizing radiation, transportation problems, and finally to "Malfunction 54," which refers to an AECL built linear accelerator radiation machine, that, as a result of software error, killed two people and maimed a third less than two months before the hearing.

Carl Trout, a former narcotics investigator who lived about 350 yards from the plant, said "Enough!" A veteran of the second World War, Mr. Trout was present during the atomic testing in the South Pacific.

The City Council gave both sides 102 minutes. However, after the NCSFI presentation, APC/AECL was given 30 minutes for rebuttal.

APC/AECL then called on Robert Jefferson, a former transportation expert with DOE, to counter NCSFI's comments on transportation hazards. Jefferson commented on the controversy surrounding the casks, as he had been in charge of the locomotive experiment. His comments were revealing, both for what he did and did not say. He did not refute the charge that the casks were not the same type as the ones that would be used by AECL. What he did reveal, however, was that the casks burned at 2200 degrees, not the 1500 degrees as the DOE has stated. He also disclosed that the impact blew 14 holes in the cask through which poured 3 inches of the protective lead shielding melted by the intense heat. Although the radioactive isotopes stayed inside the casks, there was a radiation release of 1½ millirems per hour. Radiation did leak out. The casks were vulnerable to accident and fire.

Two votes were taken that night. The first vote was to postpone a decision. That vote lost 3 to 2. Next the City Council voted 4 to 1 to uphold the original decision of the planning commission to deny the application of American Pharmaseal Corporation to build a radiation facility.

Perhaps the mood of the local residents is best summed up by Rev. Robert Beckstrom of Trinity Lutheran Church in Covina:

"I don't care what precautions they're going to take. They're still going to have problems. If this were an unpopulated area I'd say fine, but we've got children here."

AN UPDATE. .

It is our understanding that APC/AECL went shopping for a new home and were turned down by the City of Montclair.

SAFETY OF IRRADIATED WHEAT... (A Shell Game)

The game begins in 1973 when the Bharba Atomic Research Center (BARC) located in Bharba, India applied to the Indian Government for permission to irradiate wheat. The Indian government, in turn, requested the National Institute of Nutrition (NIN) to conduct research to determine if irradiated wheat is safe to eat.

During the course of their studies, NIN made several important observations:

1. Rats and mice fed diets containing *freshly* irradiated wheat (fed within 21 days after the wheat was irradiated at 80 Krads, considerably under the FDA recommended level of 100 Krads) showed elevated levels of polyploid cells in their bone marrow.

2. Normal monkeys and malnourished children fed diets of *freshly* irradiated wheat showed elevated levels of polyploidy in circulating lymphocytes. The irradiated wheat was immediately withdrawn from their diet. After several months the level of polypolidy returned to normal.

3. Mice fed freshly irradiated wheat based diets showed evidence of Dominant Level Mutation (DLM).

4. When wheat was stored for twelve weeks after radiation and then included in the diets, there was much less polypoidy and tests did not show DLM.

The meaning of increased polypolidy is not quite clear, though it is often found in association with malignancy. Whether it signifies precancerous or mutational changes is far from understood. The NIN researchers were, however, sufficiently alarmed to immediately discontinue the irradiated wheat.

The meaning of the positive DLM is obvious indicating undesirable changes in reproductive performance. Changes that would produce mutant offspring incapable of survival.

At the same time, Bharba Atomic Research Center was conducting its own irradiated food studies on rats and mice. They did not find any polyploidy or DLM from feeding irradiated wheat. Discussions between the two groups could not resolve the conflicting results.

The Indian Government then appointed a two-person committee to look into the dispute. According to NIN officials, these investigators "demonstrated an obvious bias against NIN". The report they wrote was highly critical of NIN and contained many assertions couched in impressive sounding technical language which were, in fact, untrue and scientifically unsound.

The government sent a copy of the report to NIN for their comments. In response NIN invited two of the foremost cytogeneticists of India to independently examine and evaluate their work. The findings of these two scientists along with NIN's reply were incorporated into a rebuttal of the charges by the original committee. After reviewing both confidential reports the government of India refused to permit the irradiation of wheat for more than 10 years.

The International Joint Expert Committee on wholesomeness of Irradiated Food (IECIF), a committee created by the International Atomic Energy Agency (IAEA) met in the fall of 1976 and discussed the safety of irradiated wheat. This meeting was chaired by Dr. Herbert Blumenthal of the Food and Drug Administration (FDA), a U.S. Agency. They acknowledged the points raised by the NIN studies and recommended further research be done. During that meeting, K. Vas, head of the Food Preservation section of the (IAEA) objected to NIN concerns, but avoided specifying his reasons. Nine days after the meeting had adjourned, Vas sent a leaked copy of the confidential report criticizing NIN studies to Dr. Blumenthal at the FDA in Washington. In his cover letter, Vas *did not mention the confidentiality of the report or that NIN had issued a response.* Dr. Blumenthal turned this report over to the FDA.

In their 1986 Final Rule authorizing irradiation of fruits and vegetables, FDA rejected concerns about the NIN studies basing their rejection on this leaked report by Vas. In their documentation for the Final Rule, they listed the report as "presented to the Joint Expert Committee in 1976".

A recent article by Food and Chemical News quotes from a letter by Dr. George Pauli, of FDA's Center For Food Safety and Applied Nutrition, to Dr. S.G. Srikantia under whose leadership the study had been conducted. "We agree that it was incorrect to cite the report as having been submitted to the FAO/IAEA/WHO Joint Committee on the Wholesomeness of Irradiated Food, 1976." Pauli added that the report's recipient, Dr. Herbert Blumenthal, the Center's Director of the Division of Toxicology, "agreed that he received the report after the expert committee had met."

Pauli went on to state that Vas had made no request that the report be kept confidential and Blumenthal interpreted the letter as authorizing him to use the report "as he saw fit". Despite the FDA admission, the Final Ruling still stands.

Some nagging questions persist:

Why has so much energy gone into discrediting the NIN study?

Why has much of this energy and subterfuge come from organizations which have a stake in promoting atomic energy?

Why has the FDA gone to great pains to ignore studies that show the negative effects of food irradiation?

It is important to point out that the NIN study is not isolated nor does it stand alone. The Institute of Bio-Chemistry, Federal Research Center, Federal Republic of Germany, reported in 1977 "that Chinese hamsters fed a freshly irradiated diet showed increased levels of polyploidy in their

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 Seed
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.

IRRADIATED WHEAT contd.

bone marrow and that such an increase did not occur when the same diets were stored and then fed." This study was done at higher levels of radiation than those used by NIN but what we feel is significant is that the phenomenon of increased polyploidy was present.

The Toxicology Laboratory of The Imperial Chemical Industries, U.K., reported in 1981, "that of four diets which they tested to determine if freshly irradiated diets led to mutagenic responses as expressed by dominant lethal mutations two were positive and the other two not." (Diets were fed within ten days of irradiation.

The studies by NIN are recognized by the independent scientific community and the journals in which they were originally published. It is our hope that the staff which produced these studies will soon be acknowledged for their major contribution to world health and food irradiation will be acknowledged for what it is: An idea without merit that causes more problems than it solves.

CHINA... (The Shell Game Continues)

A report on human feeding studies conducted in Shanghai China was presented at the Research and Development Associates in Boston on September 30, 1986. The report was given by Dr. Ari Brynjolfsson, a faculty lecturer in the Department of Applied Biological Sciences at M.I.T.

In this report Brynjolfsson states, *"Following extensive chemical analysis and animal experimentation, which have shown that irradiated foods are safe*, the Chinese researchers have carried out 8 *well-designed* experiments involving human volunteers consuming irradiated foods for 7 to 15 week periods. There were 17 to 70 test subjects in each experiment, and the total number of subjects was 439. Each clinical test in all the experiments failed to discern any significant difference between the control groups and test groups consuming irradiated foods." (Emphasis ours.)

Dr. Brynjolfsson continued with his description of the tests and statistical analysis of the results. Then later in his presentation, Brynjolfsson proceeded to tear into the Indian feeding study (see... SAFETY OF IRRADIATED WHEAT, this issue). His thesis is that the Chinese study finally puts to rest the controversy by invalidating the results of feeding irradiated wheat to malnourished Indian children.

However, George L. Tritsch, Ph.D., a cancer research scientist at Rosewell Park Memorial Institute, disagrees. In responding to a similar attack on the Indian study by Edward G. Remmers, Associate Director of the industry-sponsored American Council on Science and Health, ACSH), he responds, "I am not suggesting that this study be repeated in children, but since *malnourished children could well be the recipients of irradiated wheat, this study (referring to the Indian study) is particularly important.* I have not seen the data from the Chinese study, but I believe this study dealt with medical students: **young children do not have fully developed DNA repair systems and for this reason may be more susceptible to mutagenesis than adults.** I have not seen that Indians or anyone else have published data to suggest that their studies were invalid. In fact, they look particularly good to me as they were done in three species, were statistically significant even though only small numbers were involved, and polyploidy was directly related to feeding and stopped when feeding had ended. *Had the data been in fact flawed this would have appeared in print by this time in at least one of the journals concerned."* (Emphasis added.)

Dr. Tritsch further feels that in all the feeding studies known to him the amount of irradiated food and the length of the study have been arbitrary. He states "One needs to show that maximum exposure to any potential toxin is not harmful."

What the Chinese study does is to show that young adults in good health who eat irradiated food over a fifteen-week period do not display immediate ill effects that can be measured.

What the Chinese study does not do is invalidate the NIN study.

A PLAN FOR SUCCESS... THE CALIFORNIA CAMPAIGN

Californians against the irradiation for food are seeking to muster their US Representatives, and US Senators in support of National Legislation.

Last year Douglas Bosco, U.S. Representative from California, introduced HR 4762, the Food Irradiation Safety and Labeling Requirement Act of 1986. Fifty-two members of the House joined Congressperson Bosco as co-sponsors. Among these were 13 of the 14 Representatives from New Jersey. Seven of California's 45 Representatives co-sponsored the bill.

Wednesday, February 4th, Congressperson Bosco reintroduced his bill to the 100th Congress: its new number HR 956, The Food Irradiation Safety and Labeling Requirement Act of 1987, has 50 original co-sponsors. Coordinating with Representative Bosco, Senator George J. Mitchell of Maine introduced a companion bill to the Senate. The Senate Bill S 461 is identical to and has the same title as the House bill. In support of these bills a state campaign will be mounted based on a program developed by People for Responsible Management (PRM), the NCSFI affiliate that spearheaded the New Jersey campaign. PRM distributed their campaign literature through a network of New Jersey health food retail stores. Co-ordinating supporters of the movement against food irradiation PRM succeeded in flooding their Representatives with letters from constituents followed by phone calls to enlist co-sponsorship.

Our elected representatives can and will act on behalf of our interests, but only if we do our jobs as citizens and let them know what we want.

..... The California Plan .....

1. The state organizing team selected target Congressional districts, and got a list of all health food stores in each district, organized by zip code.

2. State team coordinator located a captain for each congressional district. Captains established close working relationship with a responsible contact person in each store.

3. Literature with attached perforated form letters to US Senators and Representatives were preprinted, 2,000 per district.

4. District captains delivered 500 pieces of literature (with the attached form letters) to the store contacts. The literature included instructions for signing and mailing.

5. District captains collect and deliver or mail letters to the US Representative or Senator, and follow up by telephone with the aides in the Representative/Senator offices.

Continued on page 6

WHAT YOU CAN DO

1. Join a local chapter/affiliate.
2. Send NCSFI a contribution.
3. Write your U.S. Representative/Senator (a hand-written letter is preferable). See model below.
4. Put a bumper sticker where it can be seen.

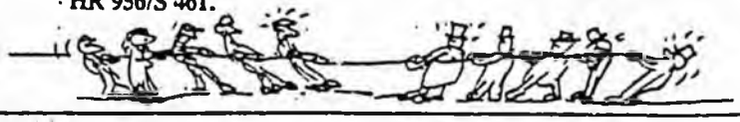
Bill HR 956, The Food Irradiation Safety and Labeling Requirement Act of 1987 has been introduced into the U.S. House of Representatives by California Congressman Douglas Bosco (D-Ca. 1st District). A companion bill S 461, also titled The Food Irradiation and Labeling Requirement Act of 1987, has been introduced into the Senate by Senator George J. Mitchell (D-Me.) We need to familiarize U.S. Representatives and Senators throughout the country with HR 956/S 461 and urge their support! We need sufficient votes to ensure it's passage over a Presidential veto. The present co-sponsors of HR 956 are listed page 1 under our list of Congressional Allies. Senator Mitchell submitted a single sponsor bill, planning to solicit support after submission.

What You Can Do NOW!

1. If your local House/Senate member is not a co-sponsor or supporter, telephone him or her urging support for HR 956/S 461, The Food Irradiation Safety and Labeling Requirement Act of 1986. The local and Washington, D.C. telephone number and address can be obtained from your phonebook, local library or Chamber of Commerce.

2. Make copies of this page and distribute to family, friends, co-workers, clientele, etc., encouraging them to telephone their congressional Representative and to clip and mail in the letter below urging support of HR 956/S 461!

3. Mail in the letter below or write your own letter urging support of HR 956/S 461.



Be sure to insert proper heading in letter.

Representative's name... OR *Senator's name...*
U.S. House of Representatives — Senate Office Bldg.
Washington, D.C. 20515 — Washington, DC 20510

ACT NOW!
PROTECT *YOUR* FOOD FROM RADIATION!

.....CLIP HERE.....

DATE _____

_____

_____

Washington, D.C. _____

Dear _____

I urge you to support The Food Irradiation Safety and Labeling Act of 1987. This bill 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 the 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 FDA to require labeling on a wholesale, retail, and restaurant level of *all* irradiated foods, both whole foods and food *ingredients*, 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.

The Department of Energy (DOE) envisions 1,000 facilities in local communities by the mid 1990s. With the recent Russian nuclear accident, much information has surfaced about the existing dangers of nuclear plants and radioactive storehouses in this country. This is the time to stop and place strict limits on the expanded use of nuclear technology. It is irresponsible and dangerous to treat our food with radioactive nuclear materials, to have food irradiators in our communities, and to transport on our highways the large quantities of hazardous nuclear materials required for those facilities.

Please respond to this letter and let me hear your support for The Food Irradiation Safety and Labeling Act of 1987.

Sincerely,

_____ _____
Signature — Print Name

_____ _____
Street Address — Date

_____
City — State — Zip

ARE "FOOD CRISES" SETTING THE SCENE FOR IRRADIATION?

From 1983-1986 United States Department of Agriculture (USDA) promoted food irradiation as a solution to the trichina "crisis" in pork, despite the claims of the National Pork Producers Countil (NPPC) that there is no trichina problem. At worst, only one out of every thousand U.S. hogs may be infected.

The state of Illinois, the country's second largest hog producer, has virtually eliminated trichina in its hogs. Illinois has adopted a simple blood sampling test for identifying infected swine. Tracing the identified herd back to the source farm, the infected hogs is eliminated, appropriate sanitation measures are taken, and the farmer indemnified. Iowa, the nation's number one producer, is following the Illinois lead.

The National Pork Producers council has decided not to use irradiation to control trichina. The blood sampling method is cheaper, more effective and safer than irradiation. For consumers, proper cooking controls trichina.

Another "crisis" is the Hawaiian fruit fly. Claiming to have been caught with their pants down when the Environmental Protection Agency banned EDB, the United States Department of Agriculture USDA sought a method to keep this pest from mainland shores. Working with the Hawaiian papaya industry they solved that problem, perfecting the "double dip," a disinfection technique which is non-toxic, cheap, safe and has been proven effective. This process involves submerging just-picked papayas in two baths of hot water. Hot in this case means thermometer hot, not gieger-counter hot. The Department of Energy, however, is pushing its own solution, the same solution they have for everything — irradiation. The DOE persists in its attempt to bring an irradiation facility to Hawaii.

The latest "food crisis" involves poultry. On November 19, 1986, the FDA filed an FSIS petition to irradiate poultry products giving as a reason the "reduction of some foodborne pathogens such as, but not limited to Salmonella, Campylobactor and Yersina. . ."

Salmonella is a general term applied to a group of about 2,000 closely related bacteria. A Salmonella infection can be caused by microbial contamination. In most cases Salmonella illness involves an unpleasant bout of gastrointestinal distress occurring between 6 to 72 hours after the bactena are ingested in contaminated food. There is a rare strain of Salmonella that causes typhoid fever. Only about 500 cases a year of the typhoid variety are reported in the U.S. and two-thirds of those are contracted abroad.

Salmonella, Campylobactor, and E. Colibacteria are among the pathogens found in the fecal matter of poultry. Modern poultry slaughterhouses are equipped with steel-fingered eviscerating machines. These gleaming metal contraptions scoop out the entrails from chickens through a cut below their breastbone. They can do this at a rate of up to 90 birds a minute.

In the last five years, these machines have been introduced into almost every butchering assembly line in the United States. For all their speed, they are not as precise as a pair of human hands. Often the machines tear the intestines and spill fecal matter onto the meat, contaminating the poultry. This is the cause of a recent rise in incidents of food poisoning in the United States.

United States Department of Agriculture (USDA) inspector Hobart Bartley, a critic of present meat inspection policies, cites three major reasons for this phenomenon:

1. The addition of high-speed, high volume technology to the assembly line, particularly the evisceration machines.
2. Repeated reductions in the food and safety inspection service which lost more than 400 of its inspectors to layoffs in February, 1986.
3. A shortcoming in federal meat inspection laws which do not require slaughterhouses to clean off "invisible" amounts of bacteria.

In an interview with over 80 consumer food writers recently, Dr. Donald L. Houston, Administrator of FSIS admitted that "The poultry industry is. . . highly mechanized. . . and some of the procedures that are in place do result in cross-contamination."

Later in the same interview he stated, "I think we have to retool this industry, which I don't think we can do politically or economically, because it would run into billions of dollars. . . , (or) we can find ways to essentially pasteurize those products before they leave that plant." (For pasteurize, read *irradiate.*)

By retool, does Dr. Houston mean the rehiring of FSIS inspectors along the production line, and the use of butchers for evisceration? With people instead of machines doing the work, there was not only precision in handling the poultry, but also an extra inspection of birds for possible fecal contamination.

Somehow high tech solutions always come back to haunt us. For some time now, farmers have been using antibiotics (primarily penicillin and tetracycline) in animal feed. Farmers who raise pigs, chickens or veal in closely packed "factory farm" pens claim that antibiotics promote rapid growth and keep disease down. The result is an antibiotic resistant strain of salmonella that has appeared in human populations and has been implicated in illness and even death.

In testimony before a House Agricultural Subcommittee, opponents of food irradiation outlined other methods for controlling contamination in the poultry industry. Some of these are: improving the maintenance of barnyards to prevent overcrowding and cross contamination; sterilizing the crates that carry chickens to packing houses; defeathering the chickens by steam scalding or some such method of "individualized" washing; introducing a poultry squeeze machine to squeeze out the intestines before evisceration, etc. And in the home, better than 85% of Salmonella bacteria can be destroyed by proper sanitation and handling. To educate the homemaker, the USDA has set up a toll-free meat and poultry hot line.* There is no limit to what the human imagination can come up with once freed from the magic bullet solution of irradiation as the cure-all for everything.

The new technology has caused some problems with poultry contamination, but the sharp increase in the reported number of Salmonella cases could be due to better reporting techniques, better diagnostic procedures, and more powerful computers dispensing available information more quickly.

Has the problem reached crisis proportion? In a telephone conversation this past fall, an FDA microbiologist told NCSFI that the FDA does not know if Salmonella is really the problem that it is touted to be. The reality is that there is no solid statistical evidence to prove any Salmonella increase. The studies that had been done prior to 1984 are not considered a valid cross-section of the nation. The 1984-1986 national study will be published late in the spring of 1987 and will serve as a reference base. In early 1987 another two-year study of similar proportions will begin: the results of this study will be measured against the 1984-1986 reference base. It will be 1989 before anything can be reported with any statistical certainty.

Why then the talk of this latest food crises?

Perhaps the following quotation may help illuminate the latest in this continuing series of "food crises."

"Should there be an increased concern on the part of consumers about chemical residues or the incidence of foodborne diseases caused by microbial contamination the prospects for food irradiation will be brighter."**

*(800-535-4555; in D.C. 447-3333)

**(Ron Krystnak in "Food Irradiation: An Economic Perspective." Food Market Commentary, Vol. 8.8, No. 3. A publication of Agriculture Canada, the Canadian equivalent of our own FDA.)

Continued from page 4

6. District captains' responsibilities include arranging a follow up meeting with the selected elected official for the purpose of educating that official or their aides on food irradiation, and requesting legislative support and co-sponsorship. Captains are also urged to make other contacts with stores, food co-ops, yoga organizations, environmentally active groups, senior clubs, chiropractors, etc.

It is a direct and basic approach. It will win in any state. If you want to help in the California campaign or start a campaign in your own state call me, Nora Cousens (707) 778-7244 or write PRM, c/o Roxbury Medical Group, Succassuna, NJ 07876.

WE STOP IT NOW OR EAT IT LATER!

WHO TO CONTACT

Your U.S. Representatives
House of Representatives
Washington, D.C. 20515

Your U.S. Senators
United States Senate
Washington, D.C. 20510

Secretary Otis Bowen
Department of Health and
Human Services (HSS)
Humphrey Building
200 Independence Avenue S.W.
Washington, D.C. 20201

Sanford A. Miller, PhD
Director, Center for Food Safety and
Applied Nutrition
Food and Drug Administration
HFF-1
5600 Fishers Lane
Rockville, MD 20857

Clyde Takeguchi, PhD
Pesticide Control Branch
Food and Drug Administration
HFF-334
200 C Street, S.W.
Washington, D.C. 20204

The Anti Food Irradiation Movement Is Growing:

Here is a the current list of NCSFI Chapters, Affiliates and Supporting Organizations. Welcome to new members (*)!

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

ACTIVIST ORGANIZATIONS

CHAPTERS

AUSTIN/CENTRAL TEXAS CHAPTER
Box 3714
Austin, TX 78764
(512) 443-3432
James M. Ebert, Ph.D.

BERKELEY, CALIFORNIA CHAPTER
2129 Oregon St.
Berkeley, CA 94705
(415) 848-4424
Elizabeth Rothschild

BOULDER, COLORADO CHAPTER
c/o Boulder Peace Consortium
1520 Euclid
Boulder, CO 80302
Steve Jones

BOSTON, MASS. CHAPTER
P.O. Box 616
Cambridge, MA 02140
(617) 776-4559
Kathleen Houlahan, Sheela Datz

BRAINERD, MINNESOTA CHAPTER
Sunberry Food Buying Club
8800 County Road 77 West
Brainerd, MN 56401
(218) 829-6811
Orla Payne

EAST HAWAII CHAPTER
P.O. Box 1559
Pahoa, HI 96778
Kathy Dorn
(808) 965-7140

GRAPHIC COMMUNICATIONS INTERNATIONAL UNION, LOCAL 583
2301 Ocean Avenue
San Francisco, CA 94127
(415) 239-7700

KONA, HAWAII CHAPTER
P.O. Box 792
Captain Cook, HI 96704
(808) 828-9296
Kara Riordan

LAWRENCE, KANSAS CHAPTER
P.O. Box 583
Lawrence, KS 66044
Josef Scales

LOS ANGELES, CALIFORNIA CHAPTER
P.O. Box 3294
So. Pasadena, CA 91030
(213) 682-2734
Kathleen Sundmark, D.C.

MID-PENINSULA, CALIFORNIA CHAPTER
Box 2384
Stanford, CA 94305
(415) 321-1620
Joel Hill

NAPA, CALIFORNIA CHAPTER
2411 Soda Canyon Road
Napa, CA 94558
(707) 252-8757
Marsha Tokareff

ORANGE COUNTY, CA CHAPTER
P.O. Box 9361
Newport Beach, CA 92658-9361
(714) 786-1940
Beverly Jerkunica

SAN DIEGO, CA CHAPTER
P.O. Box 21149
El Cajon, CA 92021
(619) 579-2552
Mitzi Narramore

SAN MATEO COUNTY, CALIFORNIA CHAPTER
Box 1211
Burlingame, CA 94011
(415) 344-9778
Alan Horn

SANTA CRUZ CHAPTER
See FOOD IRRADIATION RESPONSE

SONOMA COUNTY, CALIFORNIA CHAPTER
P.O. Box 524
Petaluma, CA 94953
(707) 578-6018
Nora Cousens

TWIN CITIES, MINNESOTA CHAPTER
1519 E. Franklin Avenue
Minneapolis, MN 55404
(612) 871-3993
Carolyn White

AFFILIATES

AMERICAN FRUITARIAN SOCIETY ORGANIC FOOD NETWORK
P.O. Box 17128
Austin, TX 78760
(512) 385-2841
Ann Abbott

ARROWHEAD MILLS
P.O. Box 2059
Hereford, TX 79045
(806) 364-0730

BURNABY, CANADA FOOD IRRADIATION ALERT
5338 Ewart Street
Burnaby, British Columbia, Canada V5J 2W4
(604) 435-0512

CITIZENS AGAINST A RADIOACTIVE DUBLIN (CARD)
6979 Portage
Dublin, CA 94568
(415) 828-5263
Lyn Duneli

CITIZENS AGAINST NUCLEAR TRASH (C.A.N.T.)
P.O Box 701
So. Casco, ME 04077
(207) 655-4661
Mark Knapp

COALITION FOR ALTERNATIVES IN NUTRITION AND HEALTHCARE (CANAH)
P.O. Box B-12
Richlandtown, PA 18955
Catherine Frompovich, PhD

COALITION TO LABEL IRRADIATED FOOD
P.O. Box 564
Creswell, OR 97426

COLORADO ALLIANCE TO PROTECT OUR FOOD
8332 Peakview #H-6
Ft. Collins, CO 80525
(303) 663-0811
Marty Campbell

CONSUMERS UNITED FOR FOOD SAFETY (CUFFS)
P.O. Box 22928
Seattle, WA 98122

DIE VERBRAUCHER INITIATIVE
Kolnstr. 198
Postfach 17 46
5300 Bonn 1
West Germany
(02 28) 65 90 44

DUBLIN AGAINST A RADIOACTIVE ENVIRONMENT (DARE)
6997 Dublin Blvd.
Dublin, CA 94568
(415) 828-8199
Sandra Sayles, D.C.

ENVIRONMENTAL POLICY INSTITUTE
218 D Street
Washington, D.C. 20003
Robert Alvarez
(202) 544-2600

FOOD IRRADIATION RESPONSE
Box 5183
Santa Cruz, CA 95063
(408) 426-CSFI
Brian Sprinsock / Kristine Albrecht

HEALTH AND ENERGY INSTITUTE
236 Massachusetts Ave. N.E. Suite 506
Washington, D.C. 2002
(202) 543-1070
Kathleen Tucker, Esq.

INTERNATIONAL ALLIANCE OF ATOMIC VETERANS
P.O. Box 32
Topoc, AZ 86436
(602) 768-7515

JAPAN PUBLIC CITIZEN
9th Floor, Central Building
1-1-5 Kyobashi, Chuo-Ku
Tokyo 104, Japan
(03) 272-3900
Mrs. Katsuko Nomura

NATIONAL HEALTH FEDERATION
5001 Seminary Road #1330
Alexandria, VA 22231
(703) 379-0589

THE NATIONAL NUTRITIONAL FOODS ASSOCIATION
125 E. Baker Avenue, Suite 230
Costa Mesa, CA 92626
(714) 966-6632

PEOPLE FOR RESPONSIBLE MANAGEMENT OF RADIOACTIVE WASTE (PRM)
c/o Roxbury Medical Group
Succassuna, NJ 07876
Walter Burnstein, M.D./Colleen McGrath
(718) 783-2146

* SACRAMENTO NATURAL FOODS CO-OP
2996 Freeport Blvd.
Sacramento, CA 95818
Carol Blackman
(916) 442-0380

SOUTHWESTERN REGIONAL COUNCIL OF UNITED FOOD AND COMMERCIAL WORKERS INTERNATIONAL UNION
3301 Watt Ave. #600
Sacramento, CA 95821
(916) 488-2300
Frank Kuberski

SPOKANE VITAMIN
West 1008 Rosewood
Spokane, WA 99208
(509) 326-5826
Glen Hamilton

VERMONT ALLIANCE TO PROTECT OUR FOOD
P.O. Box 237
Vergennes, VT 05491
(802) 877-3289
Ken Hannington

VERMONT PUBLIC INTEREST RESEARCH GROUP
43 State Street
Montpelier, VT 05602
(802) 223-5221

SUPPORTING ORGANIZATIONS

CONSUMERS COOPERATIVE OF BERKELEY
P.O. Box 4030
Richmond, CA 94804
(415) 526-0440

FAIRFAX GRASSROOTS PEACE AND ENVIRONMENTAL GROUP
152 Olema Road
Fairfax, CA 94930

INNER SUNSET COMMUNITY STORE
1515 Irving Street
San Francisco, CA 94122

MABEL'S COMMUNITY TABLE CO-OP
1156 East Commerce
San Antonio, TX 78205
George Gray, Coordinator
Day: (512) 925-7066
Eve: (512) 533-4774

THE NATIONAL INSTITUTE OF NUTRITIONAL EDUCATION
5600 S. Syracuse Circle, #205
Greenwood Village, CO 80111-2315

ORGANIC FARMS, INC.
10714 Hanna Street
Beltsville, MD 20705
(301) 595-5151

RAINBOW GROCERY
1899 Mission Street
San Francisco, CA 94103

SAN FRANCISCO VEGETARIAN SOCIETY
1450 Broadway
San Francisco, CA 94109

THOM'S NATURAL FOODS
843 Clement
San Francisco, CA 94118

VITAMIN EXPRESS
1425 Irving Street
San Francisco, CA 94122

WELLS CHIROPRACTIC GROUP
5363 Balboa St. #234
Encino, CA 91316
David Wells

WESTBRAE NATURAL FOODS
P.O. Box 8711
Emeryville, CA 94662
(415) 658-7518
Gretchen Gold

* WHOLE FOODS MARKET
8900 Shoal Creek Blvd., #111
Austin, Texas 78758
Margaret Wittenberg, Ed. Coordinator
(512) 451-6251

ON THE LEGISLATIVE FRONT

U.S.

February 4, 1987: Representative Douglas Bosco and Senator George Mitchell announced at a press conference in Washington, D.C. the introduction of their companion bills to impose a moratorium on food irradiation. (See our Congressional Allies article.) Be sure to act immediately and communicate your support for these bills to your own representative and senator. (See What You Can Do section.)

In March 1987, Representative Henry Waxman (D-Ca) will hold an informal Oversight Hearing to determine the propriety of the Food and Drug Administration (FDA) in approving the irradiation of food. This hearing, surely, will prove to be one of the highlights in Congress this spring. In line with this hearing, NCSFI is calling for public hearings on the FDA final rule authorizing commercial irradiation of food. NCSFI would like there to be hearings in important locations around the country so that all concerned citizens can have an opportunity to testify.

New Jersey

The N.J. Senate recently passed a bill introduced by Senator John H. Dorsey prohibiting the sale and distribution of irradiated (adulterated) foods in the state. The vote was 30 to 3 for passage.

A companion bill introduced in the assembly by Assemblymen Kelly and Loveys is yet to be voted on.

Hawaii

The battle between the people of Hawaii and the Department of Energy (DOE) is heating up. East Hawaii Coalition to Stop Food Irradiation (EHCSFI) organized an effective community response to CH2M Hill's pro papaya irradiation presentation in Hilo.

Before an audience of over 175 concerned citizens, CH2M Hill's Jacek Sivinski was given 90 minutes to present the first draft of an "independent" economic feasibility study commissioned by the Hawaiian State Legislature. Sivinski in his effort to whitewash the dangers of irradiation was met with a barrage of hard hitting questions from people armed with facts and determined to get straight answers.

Straight answers and an "independent" study of food irradiation might prove difficult for Sivinski and CH2M Hill. The DOE provides CH2M Hill cesium-137 for its own irradiation facility, the DOE has paid CH2M three million dollars from 1983 to the present to promote cesium irradiation, and the DOE has chosen CH2M Hill to build its food irradiation demonstration facility in Gainesville, Florida.

SIGN ME UP!

— Individual membership in NCSFI or local chapter. Includes a year's subscription to *Food Irradiation Alert!* ($15.00).

— Individual retail outlet/non-profit organization membership, including information manual, subscription, and bumper sticker selection ($50.00).

— For-profit organization membership, includes same material as for non-profit organizations, above ($100.00).

— Send me information on starting a **LOCAL CHAPTER.**

— Send me the Information **MANUAL** which is up-to-date, and consists of 190 pages of scientific studies, articles, fact sheets, media clips, etc., and cross-referenced in a 38 page summary, in a handy 3-ring binder ($20.00).

— Bumper stickers ($1.00/each).

— T-shirts ($10.00/each). Shirts are 100% cotton and will shrink!

Red __ Small __ Med __ Large __ X-Lrg
Blue __ Small __ Med __ Large __ X-Lrg

Name: _____

Address: _____

City: _____ State: _____

Zip: _____ Phone: _____

We pay postage on all orders.

Tell the world how you feel and support NCSFI!

Choice of the following:

1. _____ STOP FOOD IRRADIATION
2. _____ I'VE GOT NO TASTE FOR NUCLEAR WASTE— DON'T NUKE MY FOOD
3. _____ TELL YOUR GROCER—SAY NO TO IRRADIATED FOOD
4. _____ TELL THE FDA—DON'T NUKE MY FRUIT
5. _____ SAY NO TO FOOD IRRADIATION

1 - 10 $1.00 each plus 1 stamp for every 2 bumper stickers
Bulk prices on request.

I Will Put My Money Where My Interests Are!

Enclosed is my contribution to help NCSFI stop food irradiation. $ _____ .

RETURN ADDRESS:
NCSFI, P.O. Box 59-0488,
San Francisco, CA 94159

*Contributions should be made out to NCSFI.

WHAT IS FOOD IRRADIATION?

It is the proposal to use nuclear materials to treat food, supposedly to preserve it, prolong shelf life, and keep food insect free. In an irradiation facility food would be carried along a conveyor belt and exposed to gamma ionizing radiation. The process actually depletes nutrients and causes the formation of little-understood chemical compounds called "Unique Radiolytic Products" (URPS). Many reputable scientists believe the URPS are implicated in the development of cancer. Food irradiation facilities would need to be in large population centers and near agricultural areas, thus exposing a great number of people to the dangers of transportation and storage of radioactive material.

HAWAII ACTION ALERT!

Write a postcard today to:
Robert Souza, Mgr.,
Papaya Adm. Comm.
1100 Ward Ave., #860
Honolulu, HI 96814

and to:
Gov. John Waihee
State Capitol
Honolulu, HI 96813.

Tell them: No, I won't buy any irradiated papayas and I will boycott all irradiated food!.

NCSFI
National Coalition to Stop Food Irradiation
P. O. Box 59-0488
San Francisco, CA 94159

NCSFI's question is "To what question is 'Food Irradiation' an answer?"
The DOE's question is: "Where do we store Cesium-137"

BULK RATE
U.S. POSTAGE
PAID
PERMIT NO. 1195
SAN FRANCISCO, CA

The FOOD IRRADIATION ALERT!

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 INFORAMTION 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 49022, October 11, 1983; 49 FR 24968, June 18, 1984; 50 FR 15415, April 18, 1985) and in dry enzyme preparations (50 FR 24180, June 10, 1985). FDA also issued a final rule on July 22, 1985 (50 FR 29658) which amended 21 CFR 179.22(b) in response to a petition to provide for the safe use of gamma radiation at doses up to 1 kGy (100 krad) to control *Trichinella spiralis* in pork.

The act requires that a food additive, including a source of radiation used to process food, be shown to be safe under the proposed conditions of use before use of the food additive can be approved. That is, the agency must be assured with reasonable certainty that no harm will result from irradiation of food. A source of radiation is specifically defined as a food additive in section 201(s) of the act (21 U.S.C. 321(s)). The Senate report on the Food Additives Amendment of 1958 made clear that "[s]ources of radiation (including radioactive isotopes, particle accelerators and X-ray machines) intended for use in processing food are included in the term 'food additive' as defined in this legislation." S. Rept. 2422, 85th Cong., 2d Sess. 83 (1958).

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

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

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

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

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

chemically or pharmacologically related substance or substances in such diet.

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

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

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

II. Comments

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

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

A. Safety

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

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

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

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

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

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

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

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

In addition to studies available in the published literature, the U.S. Department of Agriculture (USDA) has made available through the National Technical Information Service (49 FR 40633; October 17, 1984) final reports of certain contracted animal toxicological studies of radiation-sterilized chicken and reports on chemical changes in food caused by irradiation. The agency has reviewed studies involving mice and dogs fed radiation-sterilized chicken meat and concludes that these studies do not show any treatment-related effects (Refs. 5 and 6). These studies are discussed in further detail in the responses to those comments which reference the USDA studies.

1. Radiolytic Products

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

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

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

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

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

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

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

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

FDA considered the potential carcinogenicity of hydrogen peroxide in its final rule permitting the use of hydrogen peroxide as an indirect food additive for sterilizing polyethylene food contact surfaces used for food packaging (46 FR 2541; January 8, 1981). The agency had specifically addressed a Japanese report of a bioassay of hydrogen peroxide performed with C57B mice in which the authors had indicated that the chemical may have caused duodenal cancer. Upon review and after consultation with the authors of the study, the agency stated that the evidence was insufficient to conclude that hydrogen peroxide is a carcinogen (46 FR 2341; January 9, 1981).

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

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

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

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

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

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

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

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

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

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

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

2. Spices

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

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

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

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

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

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

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

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

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

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

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

3. Other Minor Foods

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

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

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

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

4. Destruction of Nutrients

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

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

5. Selective Destruction of Microorganisms

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

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

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

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

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

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

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

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

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

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

6. Toxicological Studies

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

FDA agrees that its responsibility is to ensure that a food additive be demonstrated to be safe under the proposed conditions of use (21 U.S.C. 348(b)), but the agency does not believe that it was the intent of Congress, when formulating the act, that FDA ensure the consumer of absolute safety of all foods. Congress recognized that it would not be possible to determine with absolute certainty that no harm shall result from the intended use of a food additive. The Senate report stated: "Safety requires proof of a reasonable certainty that no harm will result from the proposed use of an additive. It does not—and cannot—require proof beyond any possible doubt that no harm will result under any conceivable circumstances." S. Rept. 2422, 85th Cong., 2d Sess. 6 (1958). As stated earlier, this is the standard of safety applied by FDA in its rulemaking for food additives.

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

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

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

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

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

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

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

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

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

among either macro- or micronutrients of the diet.

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

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

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

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

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

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

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

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

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

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

22. One comment stated that a in *Nature* magazine (Ref. 18) indi that eating sugars irradiated at d ranging from 0.05 to 2 Mrad can the same genetic changes in huma exposure to irradiation itself.

The agency has reviewed this and disagrees with the comment interpretation of what the study Indeed the authors clearly did no the conclusions attributed to them the comment. Furthermore, if hum animals were irradiated at doses 1,000 times lower than the levels this study, not only sterility but h would result within hours. On the hand, humans and animals have consumed food irradiated at up t Mrads (Refs. 27 through 32) with indication of adverse effects of a kind. The study the comment refe involved the effects of radiation carrot tissue in liquid culture irra at 20 kGy (2 Mrads). This study a others concerning the effects of irradiation on solutions of sugars discussed in the response to the previous comment.

The agency recognizes that irra sugar solutions have produced to in vitro. The agency concludes, h that irradiated sucrose solutions unsuitable models for predicting extrapolating toxicity of irradiate foods. Additionally, no evidence indicates that irradiated foods, in those containing sugars, will cau adverse toxic effects to animals o humans.

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

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

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

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

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

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

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

7. Alleged Adverse Effects

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

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

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

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

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

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

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

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

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

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

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

The agency agrees with the pathologist's statement and has attempted to evaluate the overall picture referred to by the pathologist. As stated earlier, 5 animal feeding studies (Refs. 20 and 33 through 36) concerning longevity and/or reproduction (out of 441 toxicological studies reviewed) were considered by agency reviewers to be well designed, properly conducted, and reported. The reports of these five studies indicate no adverse effects to test animals fed irradiated foods.

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

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

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

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

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

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

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

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

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

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

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

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

ich are structurally atypical of parent d molecules. Such URP's may be free ical coupling products of lipid and urts-derived radicals, dimers, and ss-linked products. However, ymatic hydrolysis of some of these mpounds by normal digestive ymes is expected to yield normal lecular subunits such as fatty acids, ino acids, monosaccharides, and mal metabolic products of these ounds which would be the same result from the normal digestion of the ginal parent molecules.
f exotic molecules of the extreme dicity implied by the comment were sent at any level of toxicological nificance in irradiated foods ingested test animals, some consistent dcological trends and patterns would manifest in the studies reviewed. cause it has seen no consistent trends patterns, the agency concludes that ds irradiated as prescribed by this gulation are safe.
12. One comment referenced a study bmitted to FDA by USDA on fruit flies osophila) fed irradiated chicken. This dy showed a dose-related decrease in spring (Ref. 50), and the comment ted that this effect is consistent with romosomal damage.
FDA notes that in the sex-linked cessive lethal study in Drosophila re was no evidence of mutagenicity. ditional data on fertility and undity were also included in the dy, and a dose-related decrease in spring was noted. Although there re fewer offspring in the groups sed on irradiated diets than in ncurrent controls, the agency ncluded that this effect could arise m a host of causes unrelated to productive toxicity, and is an reliable indicator of an adverse productive effect. Mammalian data on production are more relevant to mans, and these studies, as stated rlier, demonstrate no consistent tterns or trends indicative of a sitive reproductive effect.
13. One comment referenced a study bmitted to FDA by USDA and stated at mice fed radiation-sterilized icken meat showed a significant crease in testicular tumors, increased ath rate, increased kidney damage omerulonephropathy), and decreased rvival. In addition, the comment plied that male dogs fed radiation-rilized chicken had significantly lower dy weights throughout adulthood than gs fed a frozen control diet, and imed that this shows toxicity of the adiated chicken diet.
The agency disagrees with the mment that these studies demonstrate reatment-related increase in testicular tumors. The studies involving mice and dogs fed radiation-sterilized chicken were carried out at Raltech Scientific Services (Raltech). These studies were initiated under the sponsorship of the U.S. Army and completed under the sponsorship of USDA.

The report prepared by Raltech scientists suggested the possibility that chicken irradiated at approximately 9 megarads produced testicular tumors in CD-1 mice in lifetime feeding studies (Ref. 61). Agency scientists have independently examined the histopathology slides to determine whether testicular tumors were induced by ingestion of irradiated chicken. They concluded that the total histopathological evidence did not support a treatment-related induction of testicular tumors (Ref. 5).

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

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

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

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

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

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

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

FDA reviewed the kidney data in 11 chronic studies (Refs. 28, 33, 34, 55 through 62) in which rats were fed

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

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

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

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

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

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

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

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

B. Labeling Issues

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

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

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

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

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

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

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

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

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

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

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

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

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

FDA has historically required the disclosure of a food processing agent whenever it is material to the processing of foods. For example, flour is required to be modified by the term "bleached" if bleaching agents are used in processing and modified by the term "bromated" if potassium bromate is used in the processing of the flour. These requirements are part of the standard of identity for various flours (see 21 CFR 137.205).

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

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

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

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

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

The issue here is whether the irradiation of food is a material fact that must be disclosed to the consumer to prevent deception. As stated earlier, irradiation may change the characteristics of a food in a manner that is not obvious in the supermarket. Packaging materials and incidental additives such as processing aids that have no technical or functional effect in the food and thus do not ordinarily affect the characteristics of the food may be exempted under 21 CFR 101.100 from the normal labeling requirements under the act. Furthermore, Congress specifically exempted pesticide chemicals under section 403(1) of the act from a retail labeling requirement when the food has been removed from its shipping container.

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

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

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

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

The agency has also concluded, however, that the original labeling terminology required by existing 21 CFR 179.22 and 179.24 may be overly technical and that the type of radiation being used is not necessarily meaningful to consumers and that the retail label would be just as informative if the required retail statement were "treated with radiation." The regulation has been modified accordingly.

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

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

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

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

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

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

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

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

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

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

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

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

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

The agency agrees that irradiation causes certain changes in foods and that even small changes that pose no safety hazard can affect the flavor or texture of a food in a way that may be unacceptable to some consumers. Even those opposed to a retail labeling requirement agree that under certain conditions irradiation causes substantial changes in the organoleptic properties of some foods. Moreover, as discussed in the response to comment 36, irradiation may not change the food in any way that is visible to the consumer, so a label statement provides the only means of letting consumers know that a food has been irradiated. Thus, the absence of a label statement on retail foods may incorrectly suggest that an irradiated food is essentially unprocessed. Therefore, this regulation provides that the retail label contain a statement that the food has been irradiated.

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

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

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

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

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

45. Several comments suggested alternative language for the wholesale label statement based on the assumption that the agency would permit reirradiation of a food provided that the total absorbed dose did not exceed the permitted amount. These comments suggested statements such as "Ionization processed with a maximum of ——— kGy" or "processed with electromagnetic energy (or picowaves) or electron beam energy (as appropriate) in the range of 0.3 MeV to 10 MeV with a dose of ——— (blank to be filled in by processor)."

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

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

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

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

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

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

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

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

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

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

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

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

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

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

C. Current Good Manufacturing Practice

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

The agency has authority to conduct plant inspections for all food-processing plants. FDA did not intend to imply that compliance would be determined solely by inspection of records. FDA officials will inspect food irradiation plants and will copy and review required records to assure that the processor is complying with these regulations. The agency would like to clarify that it considers inspection of records to include copying of the records for further review, and is, therefore, adding the words "and copy" after "inspection" in new § 179.25(e) for the same reasons stated in the proposal for records inspection requirements (46 FR at 5719) based on sections 409, 703, and 704 of the act. Thus, if a food manufacturer chooses to engage in radiation processing of food, FDA will consider that processor to have waived any objections to the agency's requirement of inspecting and copying pertinent records with respect to irradiated foods.

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

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

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

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

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

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

(3) FDA is aware of the Codex Alimentarius standard concerning reirradiation of foods (Ref. 70). The Codex Alimentarius standard does not permit reirradiation of foods, except for foods with low moisture content (cereals, pulses, dehydrated foods, and other such commodities), irradiated for the purpose of controlling insect reinfestation. This same standard, however, states that a food is not considered to have been reirradiated when: (1) The food prepared from materials, which have been irradiated at low dose levels, is irradiated for another technological purpose; (ii) the food, containing less than 5 percent of an irradiated ingredient, is irradiated; or (iii) the full dose of ionizing radiation required to achieve the desired effect is applied to the food in more than one installment as part of processing for a specific technological purpose. In accordance with 21 CFR 130.6, FDA will review all food standards adopted by the Codex Alimentarius Commission. The agency is not required, however, to accept these standards.

Although the agency may, on its own initiative, propose adoption of a Codex standard under section 401 of the act (21 U.S.C. 341), any interested person may petition the agency to adopt a Codex standard (21 CFR 130.6). Because the agency has not proposed adoption of the Codex standard regarding reirradiation of foods as part of this rulemaking, this issue requires no further discussion at this time.

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

58. Some comments questioned the need for a 5 million electron volt limit for x-ray sources and stated that this energy limit should be increased to 10 million electron volts.

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

D. Other Technical Effects

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

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

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

The agency intended the term "f fruits and vegetables" to include mushrooms, which are fruiting bod fungi. The agency now believes the term "fresh foods" may more adeq describe foods such as fruits, vegetables, and mushrooms that a capable of additional growth and maturation but that may be treated ionizing radiation to inhibit those processes. FDA is revising the regu accordingly. In addition, the agenc agrees that the term "insect contro may be too restrictive. Therefore, t agency is substituting the term "arthropod pests" to include insec spiders, and mites, but to exclude such as bacteria, molds, mice, and

Although the agency believes th safety of food irradiation below 1 (100 krad) has been established, th agency proposed to limit the use o irradiation according to intended technical effect rather than simply dose. This was done both to avoid indiscriminate use of irradiation a aid enforcement of dose limits bec there would be no reason to exce permitted dose for the allowed tec effects. For example, overtreatme fruits and vegetables may adverse affect their marketability. Thus, exceeding the permitted dose wou result in a substandard product. In effect, compliance occurs due to a limiting factor.

In the specific case of papaya, t agency believes that an adequate commercial radiation facility can designed for papaya with the curr limitation. Alternatively, the agen review a petition to increase the maximum permitted dose for fresh foods.

The agency is aware that the permitted dose may also be some effective for other uses, such as decreasing the microbial burden i meat, fish, and poultry. FDA did n propose these uses, however, bec irradiating at such low doses wou be sufficiently effective for microb control to be self-limiting. The ag stated in the proposed rule that it consider other uses below 1 kGy (krad) if a petition supported by e that a specific technical effect ca

accomplished below 1 kGy (100 krad) and if an appropriate food additive regulation can be promulgated and can be enforced. The agency has received petitions for the use of irradiation to control trichinae in pork at doses below 1 kGy 100 krad). As discussed earlier in this preamble, the agency issued a final rule on July 22, 1985, in response to one petition to control *Trichinella spiralis* in pork (50 FR 29658). In this document, the agency is deleting § 179.22 and is incorporating that authorization for the irradiation of pork in new § 179.26(b).

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

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

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

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

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

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

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

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

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

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

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

E. Packaging

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

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

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

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

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

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

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

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

F. Public Education

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

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

G. Impact Analyses

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

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

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

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

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

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

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

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

The overall safety of transporting radioactive materials was evaluated in the NRC report entitled "Final Environmental Statement on the Transportation of Radioactive Material by Air and Other Modes" (NUREG-0170) (Ref. 75). The report concluded that the total risk from all transportation of such materials was acceptably low. NRC has considered, after review of the subject, that the regulations are adequate to protect the public against unreasonable risks from the transport of radioactive materials (46 FR 21619; April 13, 1981). NRC believes such shipments can be made safely because licensees shipping radioactive material for use in food irradiators are required to comply with an NRC regulatory program.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

III. Objections

Any person who will be adversely affected by this regulation may at any time on or before May 18, 1986 submit to the Dockets Management Branch (address above) written objections thereto and may make a written request for a public hearing on the stated objections. Each objection shall be separately numbered and each numbered objection shall specify with particularity the provision of the regulation to which objection is made. Each numbered objection on which a hearing is requested shall specifically so state; failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held; failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents shall be submitted and shall be identified with the docket number found in brackets in the heading of this regulation. Received objections may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

IV. References

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

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V. Agency Action

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

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

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

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

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

List of Subjects in 21 CFR Part 179

Food additives, Food packaging, Irradiation of foods.

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

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

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

Authority: Secs. 201(s), 409, 72 Stat. 1784–1788 as amended (21 U.S.C. 321(s), 348); 21 CFR 5.10; §§ 179.25 and 179.26 also are issued under secs. 402, 403, 701, 704, 52 Stat. 1046–1048 as amended, 1057, 67 Stat. 477 as amended (21 U.S.C. 342, 343, 371, 374); 21 CFR 5.10, 5.11.

§ 179.22 [Removed]

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

§ 179.24 [Removed]

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

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

§ 179.25 General provisions for food irradiation.

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

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

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

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

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

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

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

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

§ 179.26 Ionizing radiation for the treatment of food.

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

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

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

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

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

(b) *Limitations.*

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

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

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

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

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

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

Frank E. Young,
Commissioner of Food and Drugs.

Dated: March 29, 1986.

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

[FR Doc. 86-8584 Filed 4-15-86; 11:05 am]

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2-18-88
Vol. 53 No. 32
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federal register

Thursday
February 18, 1988

Briefings on How To Use the Federal Register—
For information on briefings in Tampa, FL, and Fort Lauderdale, FL, see announcement on the inside cover of this issue.

Proposed Rules

Federal Register
Vol. 53, No. 32
Thursday, February 18, 1988

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

NATIONAL CREDIT UNION ADMINISTRATION

12 CFR Part 761

Operational Procedures for Share Draft Programs; Federally-Insured State-Chartered Credit Unions

AGENCY: National Credit Union Administration (NCUA).

ACTION: Proposed rule; removal of part.

SUMMARY: The NCUA Board proposes to repeal Part 761 of its Rules and Regulations. Part 761 establishes principles for determining whether Federal or state law governs federally-insured state-chartered credit unions operating share draft programs under section 205(f) of the Federal Credit Union Act. It was an attempt, to the extent applicable state law did not conflict, to put federally-insured state-chartered credit unions under the same regulatory guidelines as Federal credit unions. As the NCUA has completely removed Federal credit union share draft guidelines, Part 761 no longer appears necessary.

DATE: Comments must be received on or before May 18, 1988.

ADDRESS: Send comments to Becky Baker, Secretary, NCUA Board, 1771 G Street, NW., Washington, DC 20456.

FOR FURTHER INFORMATION CONTACT: Hattie Ulan, Staff Attorney Office of General Counsel, at the above address, or telephone: (202) 357–1030.

SUPPLEMENTARY INFORMATION: Congress added section 205(f) to the Federal Credit Union Act (12 U.S.C. 1785(f)) in 1980 to authorize federally-insured credit unions (both federally-chartered and federally-insured state-chartered) to maintain share draft accounts. Section 205(f) states:

> Every insured credit union is authorized to maintain, and make loans with respect to, share draft accounts in accordance with rules and regulations prescribed by the Board * * *. [With certain exceptions,] an insured credit union may pay dividends on share draft accounts and may permit the owners of such share draft accounts to make withdrawals by negotiable or transferable instruments or other orders for the purpose of making transfers to third parties.

In November, 1980, the NCUA Board amended § 701.35 of the NCUA Rules and Regulations [45 FR 75169, November 14, 1980] to set forth numerous requirements for share draft accounts for Federal credit unions (FCU's"), including that each FCU board of directors provide for truncation, surety bond coverage, and written operational and program specifications.

Part 761 (which was promulgated together with the amendment of § 701.35) made those requirements applicable to federally-insured state-chartered credit unions ("FISCU's") to the extent doing so did not conflict with applicable state laws: "In the absence of state law authorizing share draft accounts, § 701.35 of ths chapter is applicable, to the extent it involves share draft accounts, except to the extent that any requirement set forth in § 701.35 conflicts with state law."

Section 701.35 has been modified several times since November, 1980. All of the requirements that appeared in the November, 1980, regulation that specifically addressed share draft accounts have been deleted from the regulation. Since § 701.35 no longer imposes specific requirements on share draft accounts, the NCUA Board believes that Part 761 s no longer needed.

The NCUA Board therefore proposes to delete Part 761 from its Regulations. FISCU's, as well as FCU's, are authorized to offer share draft accounts by section 205(f) of the FCU Act. No additional NCUA regulatory requirements are imposed. FISCU's may also be permitted to offer share draft accounts pursuant to state law. It has been NCUA's longstanding position that FISCU's offering share draft accounts pursuant to state law or section 205(f) of the FCU Act are subject to all other state regulatory requirements applicable to those accounts. The NCUA Board maintains this position in its proposed deletion of Part 761.

The NCUA Board requests comments on whether or not Part 761 should be deleted. FISCU's in particular, are invited to comment on whether NCUA regulation is necessary in connection with section 205(f). If commenters believe that the regulation should be retained, comment is requested on what changes, if any, should be made to the regulation.

By the National Credit Union Administration Board on February 10, 1988.

Becky Baker,

Secretary, NCUA Board.

[FR Doc. 88–3405 Filed 2–17–88; 8:45 am]

BILLING CODE 7535–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 179

[Docket No. 87N-0363]

Irradiation in the Production, Processing, and Handling of Food; Labeling

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend the regulations on the labeling of retail packages of irradiated food to extend for an additional 2 years the expiration date of the current wording requirement. This extension of the wording requirement will provide time to inform consumers about the meaning of the logo representing radiation. The proposed amendment will continue until April 18, 1990, the requirement that, in addition to the irradiation logo, the words "Treated with radiation" or Treated by irradiation" be placed prominently on labels, labeling, or other appropriate devices for all foods that have been irradiated.

DATE: Written comments by March 21, 1988.

ADDRESS: written comments 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 Takeguchi, Center for Food Safety and Applied Nutrition (HFF–330), Food and Drug Administration, 200 C Street, SW., Washington, DC 20204, 202–472–5740.

SUPPLEMENTARY INFORMATION: In the Federal Register of April 18, 1986 (51 FR 13376), FDA issued a final rule to amend the regulations on the use of irradiation

in the production, processing, and handling of food to, among other things, modify the requirements for labeling such foods. These regulations now require that the label and labeling of retail packages of foods that have been irradiated bear the appropriate international used logo, along with the words "Treated with radiation" or "Treated by irradiation" (21 CFR 179.26(c)(1)). For foods not in package form, the required logo and phrase are to be displayed with either the labeling of the bulk container or on a counter sign, card, or other appropriate device (21 CFR 179.26(c)(2)). The wording requirement expires on April 18, 1988, unless specifically extended by notice and comment rulemaking.

The required logo was developed in the Netherlands several years ago to identify a food that has been irradiated. In the final rule, FDA stated that this logo could provide identifying information in neutral form but acknowledged that its significance would not be recognized by most Americans until they had been fully informed about its meaning. Therefore, in its April 1986 rule, the agency required that both the specified wording and the logo be displayed on the label of retail foods.

The labeling requirement for irradiated foods, as the agency emphasized in the preamble to the final rule, "is not based on any concern about the safety of the uses of radiation that are allowed under this final rule" (51 FR 13375 at 13388; April 18, 1986). Rather, it was based on a decision by the agency, supported by numerous comments, to require labeling to avoid any confusion that may occur as to whether a product has been irradiated. Most food processing if ordinarily evident through labeling or direct observation. For example, canning and freezing are well-established processes that are readily apparent and therefore not generally declared on the label. Pasteurized milk, on the other hand, it not obviously pasteurized, but this fact is declared on the label. Similarly, there is no visual evidence that a food product has been irradiated; therefore, in the absence of any label information, "the implied representation to consumers is that the food has not been processed" (51 FR 13388; April 18, 1986). For these reasons, the agency concluded that consumers should be informed by means of a label statement and logo that the food has been irradiated.

Because it seemed likely that the meaning of the logo would be recognized after 2 years, FDA provided in the final rule that the wording requirement would expire on April 18, 1988. The agency stated, however, that it would assess the need for mandatory language to accompany the logo during this 2-year period.

For a number of reasons, very few consumers will have seen irradiated food with the required wording before this wording requirement expires. First, the small amounts of food irradiated in this country are primarily spices and seasonings used as ingredients in processed foods. The retail labels of such foods need not state that an ingredient was irradiated. Second, a major reason for irradiating fruits and vegetables is to prevent insects from being transported into areas where they are not endemic. The U.S. Department of Agriculture (USDA) establishes quarantine requirements for importing fresh fruits and vegetables. To date, however, irradiation has not been accepted as a quarantine treatment method for any food. USDA has proposed to permit irradiation as a quarantine treatment method for papaya from Hawaii transported to the rest of the United States or its territories (52 FR 292; January 5, 1987), but this rule is not yet final. Thus, the growth of commercial food irradiation has been slow.

Because most consumers have had no opportunity to associate the required information logo with irradiation treatment, FDA is proposing to amend § 179.26(c)(4) (21 CFR 179.26(c)(4)) by changing the expiration date from April 18, 1988, to April 18, 1990.

The agency has determined under 21 CFR 25.24(a)(11) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

In accordance with the Regulatory Flexibility Act, the agency has previously considered the potential effects of specifying the label and labeling requirements for retail packages of irradiated food on small entities, including small businesses. The agency had determined that these labeling requirements would not result in a significant impact. Because this proposal merely extends the expiration date for these labeling requirements for an additional 2 years, the agency has determined, in accordance with section 605(b) of the Regulatory Flexibility Act, that no significant impact on a substantial number of small entities would derive from this action. Further, in accordance with Executive Order 12291, the agency has determined that this rule will not be a major rule as defined by the Order.

Because of the short time before the current expiration date of April 18, 1988, FDA is allowing 30 days for comment rather than the customary 60 days.

Interested persons may, on or before March 21, 1988, submit to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 179

Food ingredients, Food packaging, Radiation protection. Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that Part 179 be amended as follows:

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

1. The authority citation for 21 CFR Part 179 continues to read as follows:

Authority: Secs. 201(s), 409, 72 Stat. 1784-1788 as amended (21 U.S.C. 321(s), 348); 21 CFR 5.10; §§ 179.25 and 179.26 also are issued under secs. 402, 403, 703, 704, 52 Stat. 1046-1048 as amended, 1057, 67 Stat. 477 as amended (21 U.S.C. 342, 343, 373, 374); 21 CFR 5.10, 5.11.

§ 179.26 [Amended]

2. Section 179.26 *Ionizing radiation for the treatment of food* is amended by changing the "April 18, 1988" expiration date in paragraph (c)(4) to "April 18, 1990."

Dated: December 24, 1987.

Frank E. Young,

Commissioner of Food and Drugs.

[FR Doc. 88-3435 Filed 2-17-88; 8:45 am]

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FOOD IRRADIATION
1987 INTRODUCED AND ENACTED LEGISLATION

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

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