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DATE INTO FDA: 02/14/01

TO: BERNARD A SCHWETZ HF-1

FROM: WENONAH HAUTER, PUBLIC CITIZEN

SYNOPSIS: MEETING REQUEST FOR THE ACTING PRINCIPAL DEPUTY COMMISSIONER AND APPROPRIATE STAFF TO DISCUSS THE ISSUE OF FOOD IRRADIATION. ALSO URGES FDA TO DENY SEVERAL PENDING PETITIONS ON IRRADIATED FOOD.

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HFS-1 *CESIAN*

COORDINATION: HF-40 ANNE B CRAWFORD
HF-40 WANDA G RUSS

SIGNATURE REQUIRED:

REFERRALS FROM HF-40

1050
N. 7
D. 1

ASSIGNED TO	ACTION	DUE DATE
HF-40 CRAWFORA REMARKS: WRUSS WILL ADVISE.	PREPARE RESPONSE FOR SIGNATURE	
HF-1 CRIMC REMARKS: PLEASE ADVISE WRUSS OF DECISION.	NECESSARY ACTION	

1050
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Public Citizen



Buyers Up • Congress Watch • Critical Mass • Global Trade Watch • Health Research Group • Litigation Group
Joan Claybrook, President

Feb. 12, 2001

Dr. Bernard Schwetz
U.S. Food and Drug Administration
14-71 Parklawn Building
5600 Fishers Lane
Rockville, MD 20857

Dear Dr. Schwetz,

We are writing to urge you to deny several petitions pending before the FDA related to irradiated food. In particular, a pending petition to irradiate “ready-to-eat” foods — which comprise an estimated 37 percent of the typical American’s diet — should be denied until a comprehensive battery of experiments based on modern testing protocols is conducted.

Public Citizen has been closely monitoring food irradiation for more than 15 years. In October, we released a report showing how the FDA failed to adequately screen the safety of irradiated food before approving it for human consumption. (The Executive Summary is enclosed.)

Among the many findings of our report, we learned that the FDA did not comply with two of the agency’s most critical operating guidelines regarding food additives: (1) The FDA did not determine a 100-fold safety factor for irradiated food (21 CFR §170.22); and (2) The FDA did not review studies that met the protocols established by the National Academy of Sciences / National Research Council (21 CFR §170.20).

Additionally, in the course of legalizing the irradiation of numerous classes of food over a 14-year span, the FDA relied on dozens of studies declared “deficient” by agency toxicologists.

To date, the FDA has legalized the irradiation of spices (1983), pork (1985), fruit and vegetables (1986), poultry (1990), red meat (1997), eggs (2000), sprouting seeds (2000) and juice (2000). These classes of food comprise more than half of the U.S. food supply. If the FDA approves the pending “ready-to-eat” petition, an estimated 80-90 percent of the U.S. food supply would be eligible for irradiation.

For several reasons, this is an alarming scenario. Most importantly, the FDA based its nutritional and toxicology models on the assumption that only 10 percent of the food supply would likely be irradiated. In July 1980, the FDA’s Irradiated Foods Committee reported that “from a practical point of view, it is anticipated that the actual human exposure will probably not exceed 10 percent of the diet in the near future.” (Enclosed.)

- over -

Ralph Nader, Founder

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01-778

Based on this assumption, the Committee prescribed a battery of experiments to assess the potential toxicity and mutagenicity of irradiated food. Unfortunately, not only did these experiments fall far short of those battery prescribed by the FDA's Red Book, but the FDA not comply with the *abbreviated* battery of experiments before legalizing the irradiation of pork, fruit and vegetables, poultry, red meat, eggs, sprouting seeds and juice.

Moreover, the Irradiated Foods Committee cautioned that, even if 10 percent of the food supply were irradiated: "When irradiation results in the significant loss of important micronutrients, enrichment may be considered appropriate." (Enclosed.) To date, however, no analysis has been done of the nutritional deficiencies that would be created among the populace should 80-90 percent of the food supply be irradiated.

In addition to the "ready-to-eat" petition (Docket No. 99F-5522), several other petitions and rules related to irradiated food are pending before the FDA:

- A petition to legalize the irradiation of fresh or frozen molluscan shellfish (Docket No. 99F-4372);
- A petition to legalize the irradiation of raw, frozen, cooked, partially cooked, shelled, dried, or ready-to-cook crustaceans (Docket No. 01F-0047);
- A petition to legalize the irradiation of unrefrigerated meat and meat products (Docket No. 99F-5321);
- A petition to increase the maximum dose for the irradiation of poultry products (Docket No. 99F-5322); and
- A proposed rule to amend food irradiation labeling requirements (Docket No. 98N-1038).

This last proposal is of particular concern. The FDA is considering "alternative" labeling language such as "cold pasteurized" and "electronically pasteurized, despite receiving comments from more than 20,000 Americans urging the agency to maintain the current labeling rules.

Public Citizen and our 150,000 members are greatly concerned about curbing food-borne illnesses while maintaining the integrity of our food supply. Though irradiation may provide some solutions to the first problem, the process presents significant nutritional and toxicological hazards that have yet to be adequately addressed.

We would greatly appreciate an opportunity to discuss the issue of food irradiation with you and your staff at your earliest convenience.

Sincerely,



Wenonah Hauter
Director, Critical Mass Energy and Environment Program

Enclosures

A Broken Record

How the FDA Legalized –
and Continues to Legalize –
Food Irradiation Without
Testing It for Safety

A special report by

Public Citizen's

Critical Mass Energy and Environment Program

The Cancer Prevention Coalition

and

Global Resource Action Center for the Environment

October 2000

Executive Summary

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“Since irradiated food and its unknown components will be added to the ever-growing pool of chemicals in the human environment, the possibilities of toxic effects, already formidable, become even more so.”

– FDA toxicologist Jacqueline Verrett,
May 1967

*speaking at an FDA Bureau of Science
staff seminar on food irradiation*

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and Continues to Legalize –
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The complete *Broken Record* report can be viewed or downloaded at www.citizen.org/cmep.

Or contact Public Citizen at:
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Public Citizen, founded by Ralph Nader, is a non-profit research, lobbying and litigation organization based in Washington, D.C. Public Citizen advocates for consumer protection and for government and corporate accountability, and is supported by over 150,000 members throughout the United States.

“Our knowledge 8 or 10 years ago about the teratogenic effect of drugs—for example, Thalidomide and its effects on the embryo—was sketchy. In fact, it was practically nonexistent. I submit, sir, that the same situation obtains with respect to irradiated food.”

– Associate FDA Commissioner Daniel Banes,
July 1968

*testifying to Congress regarding the lack of understanding
about the subtle, harmful effects that chemical
compounds can have on the human body*

A Broken Record

How the FDA Legalized –
and Continues to Legalize –
Food Irradiation Without
Testing It for Safety

by

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“We were guinea pigs.”

– Rep. Melvin Price,
July 1968

*speaking during a congressional hearing
(held five years after the U.S. Army
began irradiating bacon)
on the discovery of Army documents
revealing that lab animals fed irradiated food
suffered premature death and cancer*

Executive Summary

This past May—almost 45 years to the day after a U.S. Army general proudly showed members of Congress a picture of a beef tenderloin that had undergone “radiation sterilization”—irradiated meat went on public sale in the United States.

Today, somewhere in Iowa or Florida or North Dakota, someone is biting into a hamburger that has been irradiated with the equivalent of 150 million chest x-rays—and maybe sprinkling it with spices that have been “treated” with the equivalent of 1 *billion* chest x-rays.

Has the U.S. Food and Drug Administration done its job to ensure that this food—food that has been exposed to deadly radioactive material or electrons fired nearly to the speed of light—is safe for human consumption?

Unfortunately, for the American consumer, the answer is ‘No.’

In the most in-depth investigation ever conducted into the FDA’s oversight of food irradiation, these disturbing facts have come to light:

- Since 1983, FDA agency officials have knowingly and systematically ignored federal regulations and their own testing protocols that must be followed before irradiated food can legally be approved for human consumption.

- Since 1986, FDA officials have legalized irradiation for several major classes of food while relying on nearly 80 scientific studies that the agency’s own expert scientists had dismissed as “deficient.” (The FDA legalized the irradiation of eggs in July, for instance, based on three “deficient” studies, one of which was conducted in 1959.)

- None of the seven key scientific studies that FDA officials used to legitimize their first major approval of food irradiation in 1986 met modern standards. (One of them had actually been declared “deficient” by FDA toxicologists; three others had never been translated into English.)

- FDA officials have systematically dismissed evidence suggesting that irradiated food can be toxic and induce genetic damage. Much of this evidence resulted from government-funded research submitted to the FDA and members of Congress as early as 1968.

- Officials of the FDA, U.S. Army and other federal agencies have consistently misled Congress about the potential hazards of food irradiation, and about the reasons that past research initiatives have failed to demonstrate that irradiated food is safe for human consumption.

In short, the FDA has legalized high-dose radiation “treatments” of fruit, vegetables, beef, pork, lamb, eggs and spices—all without certifying that any of the scientific studies they used to justify these decisions met modern standards.

In this report, we attempt to answer the questions “Who?” “What?” “Where?” and “How?” One question remains: “Why?”

Food Irradiation: Roots and Reasons

From efforts by the Atomic Energy Commission to fulfill the promise of President Eisenhower's "Atoms for Peace" program, to efforts by the Energy Department to find markets for radioactive waste generated by nuclear bomb facilities and power plants... From efforts by the food industry to rid their products of pathogens and extend their global reach by increasing shelf-life, to efforts by the weapons industry to find new applications for "Star Wars" technology...

The history of food irradiation is a long one and, like the technology itself, there is far more to it than meets the eye.

In the mid-1960s, after more than a decade of research, the U.S. Army sent a few thousand pounds of irradiated bacon to military personnel in Vietnam. In 1968, however, the Food and Drug Administration (FDA) revoked the Army's irradiation permit after reviewing previously unreleased Army records indicating that lab animals fed irradiated food suffered premature death, cancer, reproductive dysfunction and other problems.¹

A Congress member remarked after learning of the previously hidden Army documents, "We were guinea pigs."²

Meanwhile, international interest in the technology had grown enough to prevent food irradiation from joining atomic locomotives and airplanes, nuclear-powered pacemakers and wristwatches, and plutonium-heated long johns in the ash bin of history. During a meeting in Rome in 1964, officials from the United Nations and International Atomic Energy Agency resolved to "influence legislation in various countries" and "facilitate international acceptance of the process."³

During the 1970s, pressure mounted on DOE officials to solve their radioactive waste problems at two nuclear bomb factories—Hanford in Washington and Savannah River in South Carolina. Food irradiation rose to the top of the list of solutions. "I frankly would like to see us use everything," a DOE official told a congressional committee in 1983, "including the squeal, if you want to refer to pork, we possibly can."⁴

In 1979 FDA toxicology director Hubert Blumenthal—while serving on the international committee that sought to "influence" national legislation—called for the creation of the FDA's Irradiated Food Committee (IFC). Based on a theoretical calculation of how many new chemicals are formed in irradiated food, the panel recommended no further testing for food irradiated at low levels and for food comprising a small percentage of the typical American's diet.⁵ The panel recommended animal testing for high-level irradiation,⁶ but the battery of tests was far less comprehensive than the battery normally used by the FDA.⁷

Two years later, a second FDA panel reviewed 409 toxicology studies on irradiated food and labeled all but five of them "deficient."⁸ Though none of the five studies met FDA stan-

dards, they formed the foundation of FDA rulings to legalize the irradiation of spices in 1983;⁹ pork in 1985;¹⁰ fruit, vegetables and spices in 1986;¹¹ poultry in 1990;¹² beef and lamb in 1997;¹³ and eggs this past July.¹⁴

(See "Food Irradiation Timeline," Appendix I.)

New Chemicals Never Studied

Before legalizing a food additive for human consumption, the FDA is required by federal regulations to establish at least a 100-fold safety factor for humans. This is achieved by determining the highest level at which laboratory animals are unharmed by a proposed additive—the "highest no-adverse effect level"—and then dividing that level by 100.¹⁵

In the case of irradiated food, the "additive" is comprised of new chemical compounds called unique radiolytic products (URPs) formed in food when it is exposed to radiation.

In 1977 the first in-depth analysis of the radiolytic products formed in irradiated food was released. Working under an Army contract, the Federation of American Societies of Experimental Biology (FASEB) of Bethesda, Md., measured the concentrations of 65 chemical compounds in irradiated beef and found that 55 either did not occur naturally in beef, did not occur naturally in any food, or increased in concentration when exposed to radiation. FASEB scientists, for example, measured a 650 percent increase in the concentration of benzene—a "known human carcinogen" according to the U.S. Environmental Protection Agency.¹⁶ (See Chart 2.)

FASEB scientists became among the first to publicly acknowledge the unlikelihood of identifying every new chemical formed in irradiated food: "The possible presence of undetected substances can never be excluded."¹⁷

Despite these uncertainties, the FDA's Irradiated Food Committee did not recommend further experiments for foods irradiated at low levels or for foods that comprise a very small portion of the typical American's diet. The IFC also stated, without presenting specific evidence, that any URPs formed in irradiated food likely would not cause health problems in humans because the chemicals likely would be similar to chemicals in non-irradiated food.

The IFC also did not discuss the formation of radiolytic products (unique or otherwise) in poultry, pork, fruit, vegetables, eggs and other classes of food for which the FDA subsequently legalized irradiation.

Furthermore, the IFC report included little or no discussion about establishing a 100-fold safety factor for humans by determining the highest no-adverse effect level for lab animals; how—or even whether—researchers should identify or quantify radiolytic products; or whether the testing of radiolytic products generated in one class of food could be used to demonstrate the safety of other classes of irradiated food.

Most significantly, the IFC prescribed a series of experiments far more limited than those detailed in the FDA's published guidelines, which required five short-term mutagenicity studies, two-year carcinogenicity tests on two rodent species, one-year toxicity tests on one rodent and one non-rodent species, and a multigeneration reproduction/teratology test on rodents.¹⁸

A review of FDA documents reveals that the agency neither fulfilled its own testing requirements, nor determined the highest no-adverse effect level for lab animals or 100-fold safety factor for humans when the agency legalized the irradiation of pork in 1985; fruit, vegetables and spices in 1986; poultry in 1990; red meat in 1997; and fresh shell eggs in July of this year.

Additionally, the agency failed to fulfill the specific IFC requirement that foods irradiated at doses above 100,000 rads and comprising more than 0.01% of the typical American's diet be used in tests in which "the concentration of radiolytic products is maximized." (emphasis in original).¹⁹ The agency, in fact, has failed to specifically address the issue of radiolytic products in its three most recent food irradiation rulings—poultry in 1990, beef in 1997, and eggs this past July.

Flaws in the FDA's Key Studies

On April 18, 1986, the FDA approved what would become known as the "Omnibus Rule," which legalized the irradiation of fruit and vegetables, and tripled the maximum irradiation dose for spices.²⁰

Then-FDA Commissioner Frank Young wrote in the *Federal Register* that five studies endorsed by the agency's blue-ribbon Irradiated Foods Task Group (IFTG) "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... studies indicate no adverse effects from the irradiated foods fed to test animals."²¹

Listed in the *Federal Register's* footnotes, however, were *seven* studies—including a 1972 German study that the IFTG had actually declared "deficient" four years earlier. Internal FDA documents that perhaps could explain this discrepancy were either missing from agency files during a recent inspection, or have yet to be produced by FDA officials in response to a formal request under the U.S. Freedom of Information Act.

Beyond this as yet unexplained discrepancy, an analysis of the seven studies reveals numerous flaws that profoundly question not only the adequacy of the studies, but the credibility of the FDA officials who relied on them to legitimize their decisions to approve irradiated food for human consumption:

- None of the seven studies met the FDA's own testing protocols that the agency must follow to determine the safety of food additives; (*See Appendix IV.*)
- Some of the seven studies actually suggest irradiated food may not be safe for human consumption. In two of the studies, researchers added vitamin E and other nutrients for the specific purpose of reversing the harmful effects of consuming irradiated food; and
- Three of the seven studies were written in French, of which FDA officials possess no English translations. (Public Citizen translated the studies for the purposes of this report.)

Perhaps most alarming, none of the seven FDA studies included short-term experiments to gauge the carcinogenic and mutagenic potential of irradiated food. This failure is of notable concern in light of research presented to Congress in 1968 (some of which was funded by the

government) that revealed severe chromosomal damage to human white blood cells;²² a doubling of mutations in fruit flies;²³ and “significantly” impaired cell division of plants grown in an irradiated environment.²⁴

Then-FDA Associate Commissioner Daniel Banes warned Congress members: “Our knowledge 8 or 10 years ago about the teratogenic effect of drugs—for example, thalidomide and its effects on the embryo—was sketchy. In fact, it was practically nonexistent. The questions we ask now about the effects of drugs on the reproductive process and on metabolic systems and the biochemistry of the body are far more subtle and far more advanced. I submit, sir, that the same situation obtains with respect to irradiated food.”²⁵

Major FDA Rulings Based on ‘Deficient’ Science

When the FDA approved its “Omnibus Rule” in the *Federal Register* of April 18, 1986, the agency listed a study conducted by two German scientists as being among the seven studies endorsed by the FDA’s Irradiated Foods Task Group (IFTG).²⁶ Four years earlier, however, IFTG Chair Marcia van Gemert wrote that the study, conducted in Germany in 1972, was scientifically “deficient.” Ironically, van Gemert further wrote that the study, despite its shortcomings, actually “claimed to show adverse effects of irradiated food.”²⁷

Though the most notable example, the German study was but one of 29 “deficient” studies used by FDA officials to establish the soundness of their Omnibus Rule. Spanning a 14-year period beginning with that ruling, FDA officials have cited 79 “deficient” studies in 107 different instances when legalizing irradiation for various classes of food. (*See Chart 3 and Appendix II.*)

As for studies the FDA has relied upon to legalize irradiation that were conducted after the IFTG finished its work in 1982, the agency has not publicly certified that any of them comply with modern scientific standards.

In what would become a common occurrence in the years since the 1986 ruling, FDA officials made no mention in the Omnibus Rule that they were relying on studies labeled “deficient” by the agency’s own Irradiated Foods Task Force. FDA officials, in another oft-repeated occurrence, also did not explain how studies once considered of poor quality could become adequate for the purposes of legalizing irradiated food.

The pattern continued in 1987, when FDA officials rejected requests for a public hearing on the Omnibus Rule by citing 10 IFTG-rejected studies, nine of which—including the German study—previously had been listed when the Omnibus Rule was approved a year earlier.²⁸ In 1988, FDA officials rejected additional requests for a public hearing on the Omnibus Rule by citing nine “deficient” studies, including two by the German researchers.²⁹

In 1990, the FDA relied on 10 “deficient” studies in legalizing the irradiation of poultry.³⁰ Among them was a “deficient” Canadian study that lacked certain histopathological examinations, leading an FDA staffer to write in an internal memo that “there is a fair to good chance” of tumors going undiscovered when only cursory exams are performed.³¹ Marking the first

such occurrence, internal FDA memos reveal that staff members raised concerns about the “deficient” studies, but did nothing to keep them from being used to legalize the irradiation of poultry. (See *Appendix V*, studies #218, #265, #353.)

In 1997, FDA officials cited 46 “deficient” studies—the highest number to date—in legalizing the irradiation of beef, pork, lamb and horse meat.³² Most notably, however, the FDA relied on five studies that the agency’s Irradiated Foods Task Group had not only labeled “deficient,” but which the panel specifically stated, ironically, “claimed to show adverse effects of irradiated food”³³

In the FDA’s latest major ruling, agency officials this past July legalized the irradiation of fresh shell eggs.³⁴ In doing so, the FDA relied on three studies that the Irradiated Foods Task Group had labeled “deficient.” An FDA staffer acknowledged that the studies were “deficient,” but made little or no effort to explain how they could be used to legitimize a finding that irradiated eggs are safe to eat.³⁵ (See *Appendix VI*.)

Congress Not Given the Whole Truth

At the 10 congressional hearings devoted to food irradiation since 1955, Congress members put direct questions about the safety, effectiveness, and technological and economic feasibility of food irradiation to officials with the FDA, Army, AEC, Department of Energy, and other federal agencies. Though Congress members expected direct answers, they didn’t always get them.

In 1966, Rep. Melvin Price, chair of a key subcommittee of the Joint Committee on Atomic Energy, asked Edward Josephson, head of the Army’s food irradiation lab in Natick, Massachusetts, to discuss “what you consider to be the vital and most important” challenges faced by the program.³⁶ Josephson made no mention of the health problems suffered by lab animals fed irradiated food in Army experiments.³⁷

As history would soon show, Josephson knew about these problems.

Two years later, Josephson was back in front of Price’s subcommittee. The hearing was held shortly after the FDA revoked the Army’s permit to serve irradiated bacon to military personnel and suggested that the Army withdraw its application to irradiate ham. FDA officials took action after they examined previously unreleased raw data from experiments conducted by Army researchers and others that revealed serious health problems in lab animals that ate irradiated food, including premature death and cancer.

Rep. Chet Holifield did not react favorably to the notion that Congress had not been given the complete picture: “I am greatly disturbed by this line of testimony. It is a complete repudiation of what this committee has been told by what we thought were expert people, expert testimony from scientists that had conducted these experiments.”³⁸

Despite the revelation of health problems suffered by lab animals, Josephson told subcommittee members, “If there were any reservations as to the safety of irradiation processing, the program would surely not have been carried through to its present state of development.”³⁹

The resistance on the part of federal officials to acknowledge to Congress that irradiated food might not be safe for human consumption would continue on-and-off for the next two decades.

In the spring of 1970, a high-ranking AEC official told a House Appropriations subcommittee, "We have not seen adverse factors which would suggest that radiation-processed food is unsafe."⁴⁰ The AEC official made this statement despite the fact that his agency withdrew an application to irradiate strawberries in 1967 after rats fed irradiated peaches developed "significant numbers of tumors"⁴¹; and the fact that AEC-funded research found in 1965 that fruit flies grown on irradiated food experienced a twofold increase in mutations.⁴²

Less-than-forthcoming congressional testimony by FDA officials continued into the 1980s—a critical time in history, as the agency began a series of rulings that enabled the introduction of irradiated food to the retail grocery market on a mass scale.

In 1987 Rep. Douglas Bosco (D-CA) introduced the Food Irradiation Safety and Labeling Requirement Act, which would have blocked the most recent irradiation rulings from taking effect. Then-FDA Commissioner Frank Young glossed over the reasons that the agency revoked the Army's permit to irradiate bacon. Young made no mention of the roles of the Army and AEC, made no mention of the serious health problems experienced by lab animals that ate irradiated food, and made no mention of the AEC's withdrawal of applications to irradiate strawberries, oranges and lemons.

The Present

Coupled with rulings already on the books, pending before the FDA and USDA are petitions and proposed rules that, if approved by the agencies, would result in the legalization of irradiation for nearly every class of food—perhaps within a year. Among the most significant proposals pending before the FDA and USDA, most of which the government is reviewing on an "expedited" basis:

- Last December, the National Food Processors Association (NFPA)—"the voice of the \$460 billion food processing industry"⁴³—asked the FDA to legalize the irradiation of "ready-to-eat" foods, which comprise about a third of the typical American's diet.⁴⁴

- In February 1999, FDA officials announced that they are looking to change existing federal regulations that require irradiated food be so labeled.⁴⁵ Weakening labeling regulations could allow food companies to use the misleading phrases "cold pasteurized" or "electronically pasteurized."

- This past May, the USDA proposed allowing imported fruit and vegetables to be irradiated to control 11 species of fruit flies and one species of seed weevil.⁴⁶ The proposed rule includes no analysis of the likelihood that surviving insects could mutate due to radiation exposure.

- Last year, the FDA received petitions from Caudill Seed Co. to legalize the irradiation of alfalfa and other sprouting seeds,⁴⁷ and from the National Fisheries Institute and Louisiana

Agriculture and Forestry Department to irradiate shellfish.⁴⁸

If every petition and proposed rule before the FDA and USDA is approved, more than 90 percent of the typical American's diet will be eligible for irradiation.⁴⁹ Such penetration, however, was not envisioned during the 1950s, 1960s and 1970s, when researchers and policymakers made their decisions based on the notion that irradiated food would not soon comprise a large portion of the typical American's diet.

The FDA's Irradiated Food Committee, for instance, stated in 1980: "A rough estimate...suggests that 10% of the total diet may consist of irradiated food in the near future."⁵⁰

Our Recommendations

The U.S. Food and Drug Administration has repeatedly and consistently failed to abide by federal regulations and the agency's own policies regarding the regulation of food irradiation. Because of these failings, detailed in this report, the Department of Health and Human Services should take immediate action to:

- (1) Revoke all food irradiation permits issued by the FDA since 1983.
- (2) Establish a joint committee with the U.S. Department of Agriculture to encourage the implementation of sustainable farming, ranching, and food production and transportation practices that will reduce the incidence of food-borne disease—including but not limited to slowing down slaughterlines and restoring the integrity of carcass-by-carcass meat inspection.
- (3) Conduct an Inspector General's investigation of the FDA's role in regulating food irradiation since the FDA revoked the Army's permit to irradiate bacon on August 15, 1968.
- (4) Forestall, until the completion of (5) through (8), the approval of all petitions and proposed rules related to food irradiation.
- (5) Appoint an independent panel—comprised of no members who have had involvement with the FDA's food irradiation program—to oversee a testing regime in accordance with the current scientific protocols.
- (6) Appoint an independent panel—comprised of no members who have had involvement with the FDA's food irradiation program—to investigate the agency's role in regulating food irradiation since the FDA revoked the Army's permit to irradiate bacon on August 15, 1968.
- (7) Compile a complete index of all organizations and facilities engaged in the practice of food irradiation in the United States, including the types and quantities of food that have been irradiated since the organizations and facilities began operation.
- (8) Compile a complete index of all groups and facilities engaged in the production, distribution, transportation, marketing, wholesaling and/or retailing of irradiated food in the U.S.

Additionally, complete investigations into the FDA's role in regulating food irradiation since the agency revoked the Army's permit to irradiate bacon on August 15, 1968, should be undertaken by the appropriate committees of Congress.

Notes

- ¹ Spiher, A.T. Jr. "Food irradiation: An FDA report." *FDA Papers*, October 1968.
 - ² "Status of the Food Irradiation Program." Hearings before the Subcommittee on Research and Development of the Joint Committee on Atomic Energy, Congress of the United States. July 18/30, 1968. Washington, D.C.: U.S. Government Printing Office.
 - ³ *The Technical Basis for Legislation on Irradiated Food*. Technical Report Series No. 316, Geneva: World Health Organization, 1966.
 - ⁴ "Hearings on H.R. 2496, Department of Energy National Security and Military Applications of Nuclear Energy Authorization Act of 1984." Before the Procurement and Military Nuclear Systems Subcommittee of the Committee on Armed Services, House of Representatives, Congress of the United States. March 1-2, 1983. Washington, D.C.: U.S. Government Printing Office.
 - ⁵ "Recommendations for evaluating the safety of irradiated foods." Final Report, Irradiated Food Committee, prepared for the Bureau of Foods, FDA, July 1980.
 - ⁶ *Ibid.*
 - ⁷ *Toxicological Principles for the Safety Assessment of Direct Food Additives and Color Additives Used in Food*. Bureau of Foods, FDA, 1982.
 - ⁸ FDA Memorandum from Marcia van Gemert to W. Gary Flamm, April 9, 1982.
 - ⁹ 48 Federal Register 30613, July 5, 1983.
 - ¹⁰ 50 Federal Register 29658, July 22, 1985.
 - ¹¹ 51 Federal Register 13376, April 18, 1986.
 - ¹² 55 Federal Register 18538, May 2, 1990.
 - ¹³ 62 Federal Register 64107, December 3, 1997.
 - ¹⁴ 65 Federal Register 45280, July 21, 2000.
 - ¹⁵ U.S. Code of Federal Regulations, Title 21, §170.22.
 - ¹⁶ Integration Risk Information System. National Center for Environmental Assessment, Office of Research and Development, U.S. Environmental Protection Agency. (www.epa.gov/ngispgm3/iris/).
 - ¹⁷ *Ibid.*
 - ¹⁸ *Toxicological Principles for the Safety Assessment of Direct Food Additives and Color Additives Used in Food*. Bureau of Foods, FDA, 1982.
 - ¹⁹ Irradiated Food Committee, *op. cit.*
 - ²⁰ 51 Federal Register 13376, April 18, 1986.
-

A Broken Record

- ²¹ Ibid.
- ²² Ibid, citing Shaw, M.W. and Hayes, E. "Effects of irradiated sucrose on the chromosomes of human lymphocytes *in vitro*." *Nature*, 211:1254-1256, 1966.
- ²³ Ibid, citing Rinehart, R.R. and Ratty, F.J. "Mutation in *Drosophila melanogaster* cultured on irradiated food." *Genetics*, 52:1119-1126, 1965.
- ²⁴ Ibid, citing Holsten, R.D. et al. "Direct and indirect effects of radiation on plant cells: Their relation to growth and growth induction." *Nature*, 208:850-856, 1965.
- ²⁵ "Status of the Food Irradiation Program." Hearings before the Subcommittee on Research and Development of the Joint Committee on Atomic Energy, Congress of the United States. July 18/30, 1968. Washington, D.C.: U.S. Government Printing Office.
- ²⁶ Ibid.
- ²⁷ FDA Memorandum from Marcia van Gemert to Clyde Takeguchi, Dec. 28, 1992.
- ²⁸ 52 Federal Register 5450, Feb. 23, 1987.
- ²⁹ 53 Federal Register 53176, Dec. 30, 1988.
- ³⁰ 55 Federal Register 18538, May 2, 1990.
- ³¹ FDA Memorandum from Janet Springer to W. Gary Flamm, July 26, 1985.
- ³² 62 Federal Register 64107, December 3, 1997.
- ³³ van Gemert, April 9, 1982, op. cit.
- ³⁴ 65 Federal Register 45280, July 21, 2000.
- ³⁵ Ibid.
- ³⁶ "Review of the Food Irradiation Program." Hearing before the Subcommittee on Research and Development of the Joint Committee on Atomic Energy, Congress of the United States. Sept. 12, 1966. Washington, D.C.: U.S. Government Printing Office.
- ³⁷ Ibid.
- ³⁸ Ibid.
- ³⁹ Ibid.
- ⁴⁰ "Public Works for Water, Pollution Control, and Power Development and Atomic Energy Commission Appropriation Bill, 1971. Hearings before a Subcommittee of the Committee on Appropriations, House of Representatives, Congress of the United States. April 27, 1970. Washington, D.C.: U.S. Government Printing Office.
- ⁴¹ Letter from James L. Goddard, Commissioner of Food and Drugs, to Hon. Leonor K. Sullivan, House of Representatives, December 6, 1967. In "Status of the Food Irradiation Program." Hearings before the Subcommittee on Research and Development of the Joint Committee on Atomic Energy, Congress of the United States. July 18/30, 1968. Washington, D.C.: U.S. Government Printing Office.
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A Broken Record

- ⁴² Rinehart, R.R. and Ratty, F.J. "Mutation in *Drosophila melanogaster* cultured on irradiated food." *Genetics*, 52:1119-1126, 1965.
- ⁴³ National Food Processors Association, Washington, D.C. (www.nfpa-food.org).
- ⁴⁴ Food Additive Petition from the Food Irradiation Coalition c/o National Food Processors Association to the FDA, August 23, 1999.
- ⁴⁵ 64 Federal Register 7834, February 17, 1999.
- ⁴⁶ 65 Federal Register 34113, May 26, 2000.
- ⁴⁷ 64 Federal Register 44530, August 16, 1999.
- ⁴⁸ 64 Federal Register 56351, October 19, 1999.
- ⁴⁹ Ibid.
- ⁵⁰ "Recommendations for evaluating the safety of irradiated foods." Final Report, Irradiated Food Committee, prepared for the Bureau of Foods, FDA, July 1980.
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**‘The utilization of these radioactive materials
simply reduces our waste handling problem,
in that we get some of these very hot elements
like cesium and strontium out of the waste.
I frankly would like to see us use everything,
including the squeal, if you want to refer to pork,
we possibly can.’**

**U.S. Energy Department official F. Charles Gilbert,
March 1983**

*testifying to a House Armed Services subcommittee
about using highly radioactive waste from
nuclear weapons plants to irradiate the food supply*

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RECOMMENDATIONS FOR EVALUATING
THE SAFETY OF IRRADIATED FOODS

FINAL REPORT

JULY 1980

Prepared for the Director, Bureau of Foods, FDA

MEMBERSHIP OF THE IRRADIATED FOOD COMMITTEE

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Dr. Lawrence R. Valcovic
Division of Toxicology

Executive Secretary

Dr. Clyde A. Takeguchi
Division of Food and Color Additives

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From a number of studies on the radiation stability of vitamins, proteins, fats and other nutrients, it is known that several nutrients are sensitive to degradation by ionizing radiation (see also Appendix II) . This sensitivity, however, depends not only upon the nature and composition of the food system, but also on a number of controllable factors such as the dose, characteristics of the radiation used, temperature of the product being irradiated, and the relative presence or absence of oxygen in the product environment during irradiation. Hence, the destruction of labile nutrients can be minimized by careful selection of the conditions for irradiation. Some of the macronutrient components - amino acids such as cystine, methionine and tryptophan, for example - are more sensitive to irradiation than others. The amounts that are destroyed, however, are usually insignificant compared to the unirradiated food or to a product treated by a conventional process. Criteria for the safety evaluation of the nutritional adequacy of irradiated foods, are essentially identical with those expressed in the 1967 report. When irradiation results in the significant loss of important micronutrients, enrichment may be considered appropriate.

For past safety evaluation, toxicological indices and protocols were applied to irradiated foods as if the whole irradiated food was a discrete chemical entity similar to a "conventional" food additive. It was recognized that there were problems associated with such studies. The most significant of these problems was to achieve dietary concentrations of the food additive in the animal tests which would be multifold exaggerations of concentrations to which humans would be exposed. Many

accuracy, the actual amount of irradiated food to which the population will be exposed in the foreseeable future. A worst-case estimate would predict that 40 percent of the human diet would consist of irradiated food (Table II plus Table III).

However, from a practical point of view, it is anticipated that the actual human exposure will probably not exceed 10 percent of the diet in the near future. This rough estimate is based on the following factors: 1) many years will be required to develop commercial food irradiation facilities for the mass processing of irradiated foods, 2) not all food approved for irradiation will be irradiated due to economic comparison with other competing techniques used in food processing, e.g. canning and refrigeration and, 3) consumer acceptance of irradiated food versus non-irradiated food is expected to be low, initially, due to the stigma associated with the term "irradiation." A program instituted by the government or private industry in an attempt to educate the public, with respect to the safety of irradiated foods, may encounter considerable resistance on the part of the consumer. Thus, irradiation of major dietary items may not be acceptable as an alternative method of food processing for many years. Irradiation of minor dietary items such as spices may be acceptable to a greater extent than irradiation of major dietary items because of the lower perceived risk involved in their limited use.