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# **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*

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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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Or contact Public Citizen at:

Public Citizen

215 Pennsylvania Ave. S.E.

Washington, D.C. 20003

(v) 202-546-4996

(f) 202-547-7392

(e) [cmep@citizen.org](mailto:cmep@citizen.org)

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**“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*

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## ***The Authors***

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**“I told him, ‘This is just poor research.’  
I could not in good conscience allow it.  
It was bad data and bad studies,  
and I wouldn’t stand for it.  
He was really pissed off.”**

– Former FDA Commissioner James Goddard,  
recent interview with Public Citizen

*remembering the day in 1968 when he told Glenn Seaborg,  
chair of the Atomic Energy Commission and a Nobel laureate,  
that the AEC’s experiments on irradiated food  
hadn’t proven it safe for human consumption*

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**How the FDA Legalized –  
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Food Irradiation Without  
Testing It for Safety**

*by*

**Mark Worth**

*Senior Researcher, Public Citizen's Critical Mass Energy and Environment Program*

**Wenonah Hauter**

*Director, Public Citizen's Critical Mass Energy and Environment Program*

**Samuel Epstein, M.D., D.Path., D.T.M&H**

*Chair, Cancer Prevention Coalition;  
Professor of Environmental and Occupational Medicine,  
School of Public Health, University of Illinois Medical Center-Chicago*

Research assistance by **Emily Chapman** and **Nathan Willcox**, Public Citizen

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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*

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# 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.<sup>1</sup>

A Congress member remarked after learning of the previously hidden Army documents, “We were guinea pigs.”<sup>2</sup>

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.”<sup>3</sup>

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.”<sup>4</sup>

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.<sup>5</sup> The panel recommended animal testing for high-level irradiation,<sup>6</sup> but the battery of tests was far less comprehensive than the battery normally used by the FDA.<sup>7</sup>

Two years later, a second FDA panel reviewed 409 toxicology studies on irradiated food and labeled all but five of them “deficient.”<sup>8</sup> Though none of the five studies met FDA standards, they formed the foundation of FDA rulings to legalize the irradiation of spices in 1983;<sup>9</sup> pork in 1985;<sup>10</sup> fruit, vegetables and spices in 1986;<sup>11</sup> poultry in 1990;<sup>12</sup> beef and lamb in 1997;<sup>13</sup> and eggs this past July.<sup>14</sup>

*(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.<sup>15</sup>

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.<sup>16</sup> (*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.”<sup>17</sup>

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.<sup>18</sup>

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.

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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).<sup>19</sup> 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.<sup>20</sup>

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."<sup>21</sup>

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;<sup>22</sup> a doubling of mutations in fruit flies;<sup>23</sup> and "significantly" impaired cell division of plants grown in an irradiated environment.<sup>24</sup>

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.”<sup>25</sup>

### **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).<sup>26</sup> 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.”<sup>27</sup>

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.<sup>28</sup> 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.<sup>29</sup>

In 1990, the FDA relied on 10 “deficient” studies in legalizing the irradiation of poultry.<sup>30</sup> 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.<sup>31</sup> 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.<sup>32</sup> 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”<sup>33</sup>

In the FDA’s latest major ruling, agency officials this past July legalized the irradiation of fresh shell

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eggs.<sup>34</sup> 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.<sup>35</sup> (*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.<sup>36</sup> Josephson made no mention of the health problems suffered by lab animals fed irradiated food in Army experiments.<sup>37</sup>

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.”<sup>38</sup>

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.”<sup>39</sup>

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.”<sup>40</sup> 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”<sup>41</sup>; and the fact that AEC-funded research found in 1965 that fruit flies grown on irradiated food experienced a twofold increase in mutations.<sup>42</sup>

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

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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”<sup>43</sup>—asked the FDA to legalize the irradiation of “ready-to-eat” foods, which comprise about a third of the typical American’s diet.<sup>44</sup>

- In February 1999, FDA officials announced that they are looking to change existing federal regulations that require irradiated food be so labeled.<sup>45</sup> 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.<sup>46</sup> 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,<sup>47</sup> and from the National Fisheries Institute and Louisiana Agriculture and Forestry Department to irradiate shellfish.<sup>48</sup>

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.<sup>49</sup> 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.”<sup>50</sup>

## **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:

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(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.

*(One)*

# **Food Irradiation: Roots and Reasons**

On May 9, 1955—less than two years after the end of the Korean War—a group of Army brass told a group of Congress members about a new technology that could solve the age-old problem of keeping soldiers fighting in far-flung places well fed.

“The basic method for sterilizing food has remained the same for 150 years, since Appert devised, for Napoleonic armies, the first successful method for canning foods.” Maj. Gen. Kenner Fisher Hertford went on to explain to the Joint Committee on Atomic Energy that nuclear technology—which helped bring an end to World War II—could also bring an end to the military’s difficulties in sending food to troops fighting halfway around the planet. Hertford held up a picture of a normal looking beef tenderloin that had undergone “radiation sterilization.”

“It is obvious,” said Hertford, a chemical engineer and National War College graduate, “that the military advantages from the development of this process are of tremendous magnitude, which the Armed Forces can ill afford to pass up.”<sup>51</sup>

Forty-five years of history has shown that the Army has not been alone in thinking that food irradiation is a process that shouldn’t be passed up.

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, 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.

## **Army Failures**

It took more than a decade. But eventually, the Army managed to send a few thousand pounds of irradiated bacon to military personnel in Vietnam during the mid-1960s. In 1968, however, five years after the Army won permission from the Food and Drug Administration to irradiate bacon, FDA officials revoked the permit when they reviewed previously unreleased Army records indicating that lab animals fed irradiated food suffered premature death, cancer, reproductive dysfunction and other problems.<sup>52</sup>

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Then-FDA Commissioner James Goddard remembers breaking the news to Atomic Energy Commission (AEC) Chair Glenn Seaborg, a Nobel laureate who worked closely with the Army. “I told him, ‘This is just poor research.’ I had no choice. I could not in good conscience allow it. It was bad data and bad studies, and I wouldn’t stand for it. He was really pissed off.”<sup>53</sup>

A Congress member remarked after learning of the previously hidden Army documents, “We were guinea pigs.”<sup>54</sup>

Later attempts by the Army to demonstrate that irradiated food was safe for human consumption ended in failure. A private firm hired by the Army in 1975 to test irradiated beef and pork on lab animals was taken off the project within two years because of shoddy work. Following an investigation into the Army’s program, the U.S. General Accounting Office stated in 1978, “Data from these studies have been determined [to be] useless.”<sup>55</sup> After 27 years and more than \$50 million, the Army ended its food irradiation program in 1980.

## **The International Stage**

Though the bacon fiasco marked, in the words of one government official, the “low point” for food irradiation, international interest in the technology had grown significantly by the late 1960s—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.

The breakthrough came in the spring of 1964, when officials from the International Atomic Energy Agency (IAEA) and two divisions of the United Nations, the Food and Agriculture Organization (FAO) and World Health Organization (WHO), met for eight days in Rome.

Three years earlier in Brussels, officials from the three agencies listened as researchers discussed how irradiated food caused lower white blood cell counts in rats and chromosomal aberrations in plant cells. “These effects should not be overlooked, and only further research can clarify their relevance to the wholesomeness problem,” a Swedish biochemist said. “[They] may be one link in the chain of events leading to cancer.” The officials also listened to a French physicist warn that low-dose irradiation can induce radioactivity in food, though at minuscule levels. Others explained how irradiation destroys amino acids, depletes nutrients and generates potentially harmful free radicals.<sup>56</sup>

Once in Rome, however, officials from the three agencies turned their attention away from the wholesomeness problem and toward the regulation problem. Their solution was to “influence legislation in various countries. . . and thus, through a common approach to legislation, facilitate international acceptance of the process.”<sup>57</sup>

The importance of influencing legislation in the United States was underscored by the fact that two of the FAO’s four advisors were intimately involved with food irradiation research in the U.S. One of them, Edward Josephson, directed the ill-fated Army program for more than a decade and, despite the failures, remains active in the field today. (This year, he won the FDA’s approval to irradiate eggs without presenting any toxicological evidence that irradiated eggs are safe for human consumption.<sup>58</sup>)

In 1969 the three agencies reconvened in Geneva—this time, specifically to address the wholesomeness problem. Like in Rome, however, evidence suggesting the unwholesomeness of irradiated

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food was downplayed. When the proceedings of the meeting were published, a 32-page report describing in great detail the mutagenic and cytotoxic effects of irradiated food—published in the WHO's official journal and written by a University of Pittsburgh radiation chemistry professor working under an AEC grant<sup>59</sup>—was reduced to four sentences.<sup>60</sup>

From 1968, when the FDA revoked the Army's permit to irradiate bacon, until 1980, the FDA lay virtually dormant on the issue of food irradiation. There was much activity, however, on the international scale and within other U.S. government agencies.

As a result of six major conferences held in Europe between 1972 and 1980, the international standard for irradiating food was set at 1 million rads<sup>61</sup>—a dose far beyond what the FDA had ever considered. The standard, however, was not established without the input of the agency. FDA toxicology director Hubert Blumenthal, for many years a key figure in setting U.S. food irradiation policy, sat on the joint FAO/IAEA/WHO committee throughout the 1970s, serving as chair in 1976.<sup>62</sup>

By the end of the 1970s, officials with the three international agencies had redoubled their commitment to the global proliferation of food irradiation: "It is obviously important for the relevant national regulations governing food irradiation to be harmonized. ...It is necessary that a legal framework be developed which could serve as a basis for harmonization of national legislation and regulatory procedures that will enhance confidence among trading nations."<sup>63</sup>

Though listed side by side, the FAO, IAEA and WHO did not stand on equal footing. In 1959, the WHO signed an agreement extending to the IAEA "primary responsibility for encouraging, assisting and coordinating research on, and development and practical application of, atomic energy for peaceful purposes throughout the world."<sup>64</sup> Additionally, the landmark 1976 decision by the joint FAO/IAEA/WHO committee to endorse irradiation for several classes of food was based on research by the International Project in the Field of Food Irradiation in Karlsruhe, Germany<sup>65</sup>—a project established by the IAEA, and funded by the IAEA and U.S. Department of Energy (DOE).<sup>66</sup>

## **The Radioactive Waste Connection**

Meanwhile, the 1970s saw pressure mount on DOE officials to solve their radioactive waste problems, particularly at two nuclear bomb factories—Hanford in Washington and Savannah River in South Carolina. Half of the radioactive "heat" at the two facilities is generated by cesium-137—some 77 million curies of which (enough for at least 10 irradiation plants) was extracted from Hanford's underground waste tanks from 1967-84.<sup>67</sup> As part of their Byproducts Utilization Program, DOE officials saw food irradiation as an answer to their problems. (They also suggested irradiating sewage sludge and adding the "treated" material to fertilizer, and to feed for cattle and sheep.<sup>68</sup>)

DOE official F. Charles Gilbert made the department's intentions known to a House Armed Services subcommittee in 1983: "The utilization of these radioactive materials simply reduces our waste handling problem, at least in the near future, 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."<sup>69</sup>

Like the Army, DOE has failed to bring its food irradiation program to fruition. On June 6, 1988,

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a leaking cesium-137 capsule—one not designed or intended for commercial use—contaminated a medical equipment irradiation facility near Atlanta. The resulting cleanup took more than two years and cost U.S. taxpayers more than \$30 million.<sup>70</sup>

Plans to use nuclear bomb wastes for food irradiation are still in the works, however. The U.S. Department of Agriculture (USDA) is assisting GrayStar Inc. of New Jersey in its design of a cesium-137 irradiator.<sup>71</sup> Until his death last year, former AEC Chair Glenn Seaborg invested in GrayStar and promoted the idea, which has also drawn the attention of the McDonald's fastfood chain. "I am convinced that this concept is important," Seaborg wrote to then-DOE Secretary Hazel O'Leary.<sup>72</sup>

### **FDA Gets Back on Track**

With interest at the DOE and within international agencies peaking, the FDA in 1979 appointed the first of two panels to study the wholesomeness of irradiated food. The formation of the Irradiated Food Committee (IFC) marked the FDA's first significant action on the issue since the agency revoked the Army's bacon irradiation permit 11 years earlier.

Three years after chairing the landmark conference where food irradiation won its first international endorsement, and while still serving on the joint FAO/IAEA/WHO committee that sought to "influence" legislation in the U.S. and other countries, FDA toxicology director Hubert Blumenthal called for the creation of the IFC: "There has been little in the way of positive regulatory response. Indeed, petitioners have been frustrated by what they perceive as a continuation of often excessive regulatory requirements. [There] has obviously been a failure in understanding."<sup>73</sup>

In addition to recommending irradiation for certain foods, the 1976 international conference Blumenthal chaired also called for "further identification of radiolytic products"; "chemical, nutritional and toxicological studies on the radiolytic products of lipids"; "comparison of the toxicological properties of volatile compounds of irradiated and non-irradiated foods"; and "comparison of the losses of nutritional value produced by irradiation with those produced by other processes."<sup>74</sup>

When the IFC released its final report in 1980, however, none of these recommendations were adopted. Instead, the panel recommended—based on a theoretical calculation of how many new chemicals are formed in irradiated food—no further testing for food irradiated at low levels and for food comprising a small percentage of the typical American's diet.<sup>75</sup> The panel recommended animal feeding experiments for high-level irradiation,<sup>76</sup> but the battery of tests was far less comprehensive than the battery normally used by the FDA.<sup>77</sup>

Two years later, the second FDA panel completed a review of 409 toxicology studies on irradiated food and labeled all but five of them "deficient."<sup>78</sup> Though none of them met the FDA's standards for food additive experiments, the studies formed the foundation of three FDA rulings to legalize the irradiation of spices from 1983-85,<sup>79,80,81</sup> a 1985 ruling to legalize the irradiation of pork,<sup>82</sup> and a 1986 ruling to legalize irradiation of fruit, vegetables and spices.<sup>83</sup> The FDA went on to legalize the irradiation of poultry in 1990,<sup>84</sup> beef and lamb in 1997,<sup>85</sup> and eggs this past July.<sup>86</sup> (*See Chart 1 for maximum irradiation doses for each class of food.*)

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The three spice rulings and the pork ruling came under the authority of Margaret Heckler, a former Congress member who President Reagan appointed FDA commissioner in 1983 after she lost a reelection bid. Heckler represented the congressional district that included the Army's food irradiation laboratory in Natick, Massachusetts—from 1967, when the FDA began to learn about the Army's research problems, to 1983, three years after the Army dropped the program entirely.

Heckler made no secret of where her sympathies lay. In 1978 she attempted to engineer the outcome of a U.S. General Accounting Office investigation of the Army's food irradiation program: "Radiation," she wrote to U.S. Comptroller General Elmer Staats, "should be considered a 'food process' similar to 'thermal processing,' rather than a 'food additive.' I hope [you] will consider a recommendation to Congress to this effect, since this change would facilitate the commercialization of the food irradiation process."<sup>87</sup>

In each of their irradiation rulings since 1983, FDA officials failed to comply with a federal regulation that mandates the establishment of a 100-fold safety factor for people. Under the regulation, humans shall not be exposed to more than one-hundredth the amount of a food additive that causes harm to lab animals.<sup>88</sup>

Additionally, FDA officials have failed to publicly certify that any of the studies they relied upon to demonstrate the safety of irradiated food during the past 17 years met current testing protocols. For

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### **Chart 1**

#### **Maximum Irradiation Doses**

Since 1983, the FDA has legalized irradiation for several classes of food. Here are the maximum allowable doses for each class, and the equivalent number of chest x-rays to which the food would be exposed at maximum levels.

<b>Class of food</b>	<b>Year Approved</b>	<b>Max. Dose</b>	<b># Chest X-rays</b>
<b>Spices</b>	<b>1986</b>	<b>30 million rads</b>	<b>1 billion</b>
<b>Frozen red meat*</b>	<b>1997</b>	<b>700,000 rads</b>	<b>233 million</b>
<b>Unfrozen red meat*</b>	<b>1997</b>	<b>450,000 rads</b>	<b>150 million</b>
<b>Chicken and turkey</b>	<b>1990</b>	<b>300,000 rads</b>	<b>100 million</b>
<b>Eggs</b>	<b>2000</b>	<b>300,000 rads</b>	<b>100 million</b>
<b>Fruit / vegetables</b>	<b>1986</b>	<b>100,000 rads</b>	<b>33 million</b>

\* beef, pork, lamb, horse

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that matter, only four studies on food irradiation have appeared in peer-reviewed journals since the FDA approved its “Omnibus Rule” in 1986—and none since 1990.

The most frequent beneficiary of the FDA rulings was Radiation Technology Inc., a New Jersey-based company founded by former AEC reactor physicist Martin Welt. Welt secured five FDA food irradiation approvals despite the fact that his company twice lost its license and Welt himself was sentenced to two years in federal prison for covering up safety violations and lying to federal investigators.

(Trial testimony revealed that Welt ordered his employees to deny FDA inspectors access to certain documents and equipment. Welt also dumped radioactive waste onto the ground and illegally irradiated shellfish and frog legs delivered to his plant in unmarked trucks on weekends. Wrote the federal prosecutor on the case: “One must conclude that Martin Welt believes that he is higher than the law and thus need not follow it.”)<sup>89</sup>

## **To the Marketplace**

Despite the FDA’s failure to demonstrate the safety of irradiated food, irradiated ground beef went on public sale for the first time this past May—almost 45 years to the day since Maj. Gen. Hertford showed a picture of an irradiated steak to Congress. Available in stores in Iowa, Minnesota, North Dakota, South Dakota and Wisconsin, the meat was “treated” by a linear accelerator in Sioux City, Iowa, owned by defense contractor Titan Corporation, which adapted technology it originally developed for the 1980s “Star Wars” program..

Later in the summer, irradiated meat appeared in Florida and Nebraska, though poor response from consumers led some store owners to pull the meat off of their shelves. Wal-Mart, the largest retailer in the world, announced plans to test market irradiated meat in June; thus far, however, these plans have not been carried out.

Consumer ambivalence aside, interest in irradiation among food producers has grown rapidly during the decade, as illnesses and recalls caused by *E. coli*, *Salmonella*, *Listeria* and other food-borne pathogens have reached record levels.<sup>90</sup> Interest has also grown as the federal government’s meat inspection system was scaled back and privatized during the Reagan-Bush and Clinton-Gore administrations.

American Foodservice, Cargill, Emmepak, IBP, Schwan’s and Tyson Foods are among the major meatpackers that have signed contracts with Titan.<sup>91</sup> In the wake of an FAO/IAEA/WHO recommendation to allow irradiation at “any dose appropriate to achieve the intended technological objective,”<sup>92</sup> multinational conglomerates Kraft and Del Monte also signed with Titan.<sup>93</sup>

(See “*Food Irradiation Timeline*,” Appendix I.)

*(Two)*

# **New Chemicals Never Studied**

In 1937, FDA official George Larrick dispatched nearly his entire force of 240 investigators to track down the remnants of Sulfanilamide, a new strep throat drug that, unbeknownst to the more than 100 people who died after taking it and the hundreds of others sickened by it, contained diethylene glycol—better known as antifreeze.<sup>94</sup>

Nineteen years later, as commissioner of the FDA, Larrick was in front of Congress talking about the importance of thoroughly testing irradiated food before allowing people to eat it.

Speaking in support of proposed legislation to strengthen the federal Food, Drug and Cosmetic Act, Larrick told House members in 1956 that the law should “be made clearly applicable not only to radioactive substances that might be introduced into food, either deliberately or unavoidably, but also to any changes in food, or new substances formed in food, by subjecting it to radiation.”<sup>95</sup>

Larrick did his job. In 1958, Congress passed the Food Additives Amendment to the Food, Drug and Cosmetic Act, requiring irradiated food to undergo the same battery of tests as any other food additive before being approved for human consumption. (Larrick did his job again in 1961, keeping the birth defect-inducing sleeping pill Thalidomide off of the market.)

Have those following in Larrick’s footsteps as head of the FDA done their job to ensure the safety of irradiated food? A close examination of the agency’s record strongly suggests that the answer is ‘No.’

FDA officials have not only failed to follow the agency’s general rules for testing food additives, they have also failed to follow the specific testing guidelines that were established for irradiated food—even though the specific guidelines are less stringent and comprehensive than the general rules.

## **The Rules**

Before legalizing a food additive for human consumption, the FDA is required by federal regulations to establish “a reasonable certainty in the minds of competent scientists that the substance is not harmful under the intended conditions of use.”<sup>96</sup> While acknowledging “it is impossible in the present state of scientific knowledge to establish with complete certainty the absolute harmlessness of the use of any substance,”<sup>97</sup> federal regulations state that FDA officials must establish at least a 100-fold safety factor before legalizing an additive. 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.<sup>98</sup>

En route to making such a determination, FDA officials are required to follow the current testing

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protocols established by the National Academy of Sciences/National Research Council (NAS/NRC).<sup>99</sup> Based on these protocols, the FDA in 1982 published *Toxicological Principles for the Safety Assessment of Direct Food Additives and Color Additives Used in Food*. These principles represent the government's bible for determining the wholesomeness of food additives.

At nearly 250 pages in length, *Toxicological Principles* leaves little to the imagination. The document describes in great detail which tests must be performed for a proposed additive—based on the additive's toxicological potency and how much of the additive a typical person would be expected to consume. It also describes in great detail how each of these tests is to be performed, down to, for instance, which individual sections of a lab animal's small intestine must undergo a histopathological examination.

In the case of irradiated food, the “additive” is comprised of new chemical compounds called radiolytic products that are formed in food when it is exposed to radiation. These chemicals are formed because the type of radiation used in the process is ionizing radiation, meaning that it has the capacity to dislodge electrons, which can then react with other molecules to form new chemical compounds.

Early experiments, however, conducted during the 1950s and 1960s by the U.S. Army and Atomic Energy Commission (AEC) made no attempt to measure—much less identify—these radiolytic products. Instead, researchers simply irradiated food at very high doses, fed it to lab animals (at times in large quantities), and then went in search of tumors, organ damage, reproductive abnormalities and other problems in the animals.

Though these tests long predated the publication of *Toxicological Principles* and would not have met most of the document's requirements, the experiments did reveal some apparent health problems from eating irradiated food. These problems included higher mortality rates among pre-weaned rats, low weight gain among rats and dogs, and malignant tumors in rats, including pituitary carcinomas (described by an FDA official as “a particularly disturbing finding since this is an extremely rare type of malignant tumor”).<sup>100</sup>

The revelation of these problems in 1968 led the FDA to rescind the Army's permission granted five years earlier to irradiate bacon and serve it to military personnel during the Vietnam War.<sup>101</sup> The revelation also led the Army to withdraw its petition to irradiate ham,<sup>102</sup> and it coincided with decisions by the Army and AEC to withdraw petitions to irradiate lemons, oranges and strawberries.<sup>103</sup>

## **Problems Recognized**

Among the first public acknowledgements that radiolytic products could create major challenges in attempting to demonstrate the safety of irradiated food was made in 1967.

During a speech at a staff seminar held that spring by the FDA's Bureau of Science, staffer Jacqueline Verrett said: “Since irradiated food and its unknown components will be added to the ever-growing pool of chemicals in the human environment, the possibilities of potentiation of toxic effects, already formidable, become even more so... [We] must be able to assure the public that each individual food that is approved is safe and as free of any toxicological hazard as our present knowledge and methods

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will permit it to be.”<sup>104</sup>

It would not be until 1977, however—19 years after Congress approved the Food Additives Amendment—that the first in-depth analysis of the radiolytic products formed in irradiated food was released. The tests were conducted by the Federation of American Societies of Experimental Biology (FASEB) of Bethesda, Md., under a contract with the Army’s Medical Research and Development Command.

After irradiating beef, FASEB scientists measured the concentrations of 65 chemical compounds. Of these, five were unique radiolytic products (or URPs)—that is, they could not be identified as naturally occurring in beef or any other food: two aldehydes (octadecenal, pentadecanal) and three hydrocarbons (hexadecadiene, pentadecadiene, undecyne).<sup>105</sup>

In addition to these five URPs, FASEB scientists found 35 other chemicals not naturally occurring in beef. Fifteen others appeared in higher concentrations in irradiated beef than non-irradiated beef. They measured, for example, a 650 percent increase in the concentration of benzene—a “known human carcinogen” according to the U.S. Environmental Protection Agency.<sup>106</sup> In total, 55 of the 65 chemicals identified either were unique to all food, were unique to beef, or grew in concentration due to irradiation.<sup>107</sup> (*See Chart 2.*)

At the conclusion of the experiment, FASEB scientists became among the first researchers to publicly acknowledge the unlikelihood of identifying every new chemical formed in irradiated food and assessing their potential harm to humans: “Because no analysis, however exhaustive, can exclude the possibility of the presence of undetected constituents, no unequivocal demonstration of safety seems possible from the consideration of the individual radiolytic products alone... The possible presence of undetected substances can never be excluded.”<sup>108</sup>

Still, FASEB scientists said that more research should be conducted into the radiolytic products that *can* be identified. In particular, they said, two classes of chemicals formed by the radiation-induced degradation of fats should be studied further—diol diesters and alkylcyclobutanones. Because “insufficient data are available to allow judgment of the effects on health,” FASEB scientists said that “metabolic and toxicological studies of these compounds are desirable.”<sup>109</sup>

## **Problems Ignored**

The uncertainties about radiolytic products expressed by FASEB scientists resurfaced three years later. In the summer of 1980, the first of two committees impaneled by the FDA to study the wholesomeness of irradiated food released its final reports. Like FASEB scientists, the Irradiated Food Committee (IFC) determined that radiolytic products presented a difficult challenge: “The radiolysis data available in the scientific literature are insufficient to completely catalog the identity and quantity of each radiolytic product formed in any particular food.”<sup>110</sup>

Unlike FASEB scientists, however, the IFC did not recommend further studies in the case of foods irradiated at low levels (up to 100,000 rads) or for foods that comprise a very small portion of the typical American’s diet (up to 0.01 percent).

In making this determination, the IFC relied on a theoretical calculation in “estimating” the number

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### **Chart 2**

#### **Chemical compounds found in irradiated beef**

**Of 65 chemicals indentified in irradiated beef, 5 were not naturally appearing in any food, 35 were not naturally occuring in beef, and 15 grew in concentration due to irradiation.**

#### **Not natural to beef**

2-Methyl pentanal  
Butane  
Butene  
Decene  
Decyne  
Dimethyl sulfide  
Dodecanal  
Dodecane  
Dodecene  
Ethane  
Ethene  
Ethyl mercaptan  
Heptadecadiene  
Heptadecane  
Heptadecene  
Hexadecanal  
Hexadecane  
Hexadecenal  
Hexadecene  
Nonane  
Nonene  
Octadecanal  
Octene  
Pentadecane  
Pentadecene  
Propane  
Tetradecadiene  
Tetradecanal  
Tetradecane  
Tetradecene  
Tridecane  
Tridecene  
Undecanal  
Undecane  
Undecene

#### **Not natural to any food**

Hexadecadiene  
Octadecenal  
Pentadecadiene  
Pentadecanal  
Undecyne

#### **Grew in concentration**

2-Butanone  
2-Methyl butane  
2-Methyl pentane  
2-Methyl propane  
2-Methyl propene  
Acetone  
Benzene \*  
Decane  
Ethanol  
Heptane  
Heptene  
Hexane  
Octane  
Pentane  
Toluene

\* denotes a "known carcinogen," according to the U.S. Environmental Protection Agency.

Source: "Evaluation of the health aspects of certain compounds found in irradiated beef." Federation of American Societies for Experimental Biology, Bethesda. Prepared for U.S. Army Medical Research and Development Command, Fort Detrick, Maryland. August 1977. Supplements I and II, March 1979.

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of radiolytic products that would be formed in irradiated food. No specific evidence was presented to support this finding, merely a brief discussion about how many radiolytic products “may be” formed “assuming” certain conditions. The IFC acknowledged: “The true extent of the dietary ‘uniqueness’ of URPs is somewhat tenuous, due largely to the paucity of information.”<sup>11</sup>

Additionally, the IFC stated, without presenting specific evidence, that any unique radiolytic products (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: “Enzymatic hydrolysis by digestive enzymes is expected to process the majority of such URPs to yield normal molecular subunits, such as the fatty acids, amino acids, monosaccharides, and further subunits of these components, which would have resulted from the normal digestion of the original parent molecules.”<sup>12</sup>

In dismissing the potential health effects of URPs, and in comparing the chemical changes in irradiated food to those in cooked food, the IFC cited the work of University of Massachusetts food science Professor Wassef Nawar, a leading international expert in the field of radiation-induced lipid oxidation.

In the reference cited by the IFC, however, Nawar said that additional experiments were needed on the chemicals formed via radiation-induced degradation: “Few studies have been intentionally designed to compare the decomposition products formed by radiation and heat treatment. . . More studies are needed on radiolytic polymerization, effects on phospholipids and polyunsaturated fatty acids, and interaction with other food nutrients.”<sup>13</sup>

The IFC also presented no scientific evidence when it stated that the five URPs discovered in irradiated beef by the FASEB in 1977 “are typical of the molecules identified as occurring in other food volatiles, and are similar to natural food constituents.”<sup>14</sup>

Additionally, the IFC 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. This is a particularly notable omission, given that the IFC stated: “Foods, both irradiated and unirradiated, are chemically complex and may contain hundreds of discrete chemical species. Since many of these compounds are present in the low ppm (or ppb) range, the complete chemical characterization of food is technically not feasible.”<sup>15</sup>

## **More Problems Ignored**

On several occasions, the World Health Organization (WHO), on which FDA officials and government food safety officials have relied for a significant portion of their food irradiation information since the 1960s, has publicly acknowledged the difficulty in identifying radiolytic products and their potential. Most recently, in 1994, the WHO stated:

“Foods are extremely complex mixtures of chemicals, usually containing hundreds of thousands of different compounds in a wide range of concentrations. Consequently, the complete chemical characteristics of any food, whether irradiated or not, is virtually impossible. . . The information contained in the scientific literature is insufficient to enable all the reaction products in irradiated food to be completely identified and quantified. . . As it will be difficult to establish that [unique radiolytic] products

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exist, concern about their toxicological significance can only be speculative.”<sup>116</sup>

As for foods irradiated at doses above 100,000 rads and comprising more than 0.01 percent of the typical American’s diet, the IFC stated that “tests must be performed on [food] extracts in which the concentration of radiolytic products is maximized.” (emphasis in original).<sup>117</sup>

There is little or no discussion, however, 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;
- how researchers should ensure that radiolytic products are “maximized” when feeding lab animals;
- whether lab animals should be fed individual radiolytic products or in combination; 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 significantly less extensive than those detailed in the *Toxicological Principles*, which was published two years later. Specifically, the IFC stated that four short-term mutagenicity tests and two short-term toxicity studies should be conducted before approving irradiation at more than 100,000 rads for food comprising more than 0.01 percent of the typical American’s diets.<sup>118</sup>

According to *Toxicological Principles*, however, irradiated food must undergo a far more extensive battery of tests. *Toxicological Principles* requires 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 and teratology test on rodents.<sup>119</sup>

This battery of tests is required for “Concern Level III” food additives—the highest of three categories that gauge “the degree to which the use of an additive may present a potential hazard to the public health.”<sup>120</sup> Because the IFC estimated that food irradiated at 100,000 rads or above would contain a concentration of URPs of at least 3 parts per million (3 ppm),<sup>121</sup> this exceeds the level of 1 ppm that triggers a Concern Level III designation.<sup>122</sup>

Even at an irradiation dose of 50,000 rads, the IFC estimated that URPs would be formed at a concentration of 1.5 ppm.<sup>123</sup> This being the case, every class of food for which the FDA has legalized irradiation since *Toxicological Principles* was published in 1982 should have undergone the battery of tests detailed in the Concern Level III protocol.

## **Rules Ignored**

But, as a review of *Federal Register* filings and supporting documents reveals, the FDA neither fulfilled the Concern Level III testing requirements nor determined the highest no-adverse effect level for lab animals or 100-fold safety factor for humans when the agency legalized:

- Irradiation of pork at 100,000 rads in 1985;<sup>124</sup>

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- Irradiation of fruit and vegetables at 100,000 rads, and spices at 3 million rads in 1986;<sup>125</sup>
- Irradiation of poultry at 300,000 rads in 1990;<sup>126</sup>
- Irradiation of beef, lamb, pork and horse meat in 1997 at 450,000 rads and 700,000 rads for unfrozen and frozen meat, respectively;<sup>127</sup> and
- Irradiation of fresh shell eggs in July of this year at 300,000 rads.<sup>128</sup>

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 percent of the typical American's diet be used in tests in which “the concentration of radiolytic products is maximized.” (emphasis in original).<sup>129</sup> The agency, in fact, has failed to specifically address the issue of radiolytic products in its three most recent food irradiation rulings.

The FDA legalized the irradiation of beef in 1997 without formally reviewing any studies in which “maximized” concentrations of radiolytic products were fed to lab animals—despite acknowledging that five URPs are formed when beef is irradiated, that 35 chemicals not naturally occurring in beef are formed, and that 10 other chemicals grow in concentration when exposed to radiation. In short, the FDA does not know whether the new chemicals formed in irradiated beef could be harmful to humans.

Additionally, when the FDA legalized the irradiation of poultry in 1990 and eggs this past July, agency officials not only failed to formally review any lab animal experiments in which radiolytic products were maximized, they also failed to reveal any information regarding the identity or quantity of radiolytic products (unique or otherwise) that are formed in these foods when they are exposed to radiation.

## **The Big Picture**

In summary, FDA officials have:

- Failed to fulfill the requirements in *Toxicological Principles* by not formally reviewing studies complying with the Concern Level III protocol before legalizing the irradiation of spices, pork, fruit, vegetables, poultry, beef, lamb, horse meat and fresh shell eggs;
- Failed to meet the requirements in the U.S. Code of Federal Regulations and in *Toxicological Principles* by not establishing a 100-fold safety factor for humans or the highest no-adverse effect level for lab animals before legalizing irradiation of pork, fruit, vegetables, spices, poultry, beef, lamb, horse meat and fresh shell eggs;
- Failed to meet the requirements established by the Irradiated Food Committee that mandate the formal review of tests in which “the concentration of radiolytic products is maximized” before legalizing irradiation of poultry, beef, lamb, pork, horse meat and fresh shell eggs.” (emphasis in original);
- Ignored evidence that at least 40 radiolytic products are generated in irradiated beef, and failed to formally review any lab animal experiments in which these chemicals were tested for their potential cytotoxicity, carcinogenicity, mutagenicity, immunotoxicity or reprotoxicity; and
- Failed to identify or quantify radiolytic products that may be generated in irradiated spices, pork,

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fruit, vegetables, poultry, lamb, horse meat and fresh shell eggs before approving these classes of food for irradiation. Additionally, the FDA has failed to formally review any lab animal experiments in which any such chemicals were tested for their potential cytotoxicity, carcinogenicity, mutagenicity, immunotoxicity or reprotoxicity.

*(Three)*

# Flaws in the FDA's Key Studies

On April 18, 1986, then-FDA Commissioner Frank Young wrote a filing that appeared in the *Federal Register* that changed the course of history for the issue of food irradiation. In the filing, 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.<sup>130</sup> The ruling laid the foundation for subsequent FDA decisions to legalize the irradiation of poultry (1990), red meat (1997) and fresh shell eggs (2000).

In support of the Omnibus Rule, FDA officials cited the work of the agency’s blue-ribbon Irradiated Foods Task Group (IFTG), which reviewed 409 food irradiation experiments before concluding in 1982 that five studies were scientifically sound and demonstrated the wholesomeness of irradiated food.

Young—a former dean of the University of Rochester Medical School and among the longest-serving FDA commissioners of the post-war era—wrote in the *Federal Register* that the five studies “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.”<sup>131</sup>

Listed in the footnotes of the *Federal Register* of April 18, 1986, however, were *seven* studies—including a 1972 German study (Reichelt, D. et al) that the IFTG had actually declared “deficient” four years:

- Coquet, B. et al. “Study on mice concerning toxicity, effect on reproductivity, mutagenicity, and teratogenic potential of irradiated rice incorporated in the diet.” International Project in the Field of Food Irradiation, Karlsruhe, Germany. Technical Report Series, IFIP-R-40, Sept. 1976.

- Coquet, B. and Rondot, G. “Irradiated onions. Studies of toxicity and reproduction in rats.” International Project in the Field of Food Irradiation, Karlsruhe, Germany. Technical Report Series, IFIP-R-61, June 1982. (IFREB Report in WHO Irradiated Onion Monograph, 1980.)

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- Elias, P.S. “Toxicology Studies in Rats Fed a Diet Containing 15% Irradiated Kent Mangoes.” International Project in the Field of Food Irradiation, Karlsruhe, Germany. Technical Report Series, IFIP-R-58, Oct. 1981.

- Hickman, J.R. et al. “Rat Feeding Studies on Wheat Treated with Gamma Radiation. I. Repro-

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duction.” *Food and Cosmetics Toxicology*, 2:15-21, 1964.

- Radomski, J.L. et al. “Chronic Toxicity Studies on Irradiated Beef Stew and Evaporated Milk.” *Toxicology and Applied Pharmacology*, 7:113-121, 1965.

- Reichelt, D. et al. “Long-term animal feeding study for testing the wholesomeness of an irradiated diet with a high content of free radicals.” Institute for Radiation Technology, Federal Research Institute for Food Preservation, Karlsruhe, Germany, April 1972. (Translation by Universal Language Services Inc. for the U.S. Army Foreign Science and Technology Center, Charlottesville, Virginia.)

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 by Public Citizen under the U.S. Freedom of Information Act.

Beyond this as-yet unexplained discrepancy, an analysis of these seven studies reveals numerous problems that profoundly question not only the adequacy of the studies, but the credibility of the FDA officials who relied on them to legitimize their decision 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;

- 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.)

*(Note: In the interest of brevity, the seven studies will be identified as Coquet I, Coquet II, Coquet III, Elias, Hickman, Radomski and Renner. Complete citations are listed in Notes and Appendix III.)*

## **Not According to Protocol**

In 1982, the year that the IFTG completed its review of the 409 food irradiation studies, the FDA published a document that became the agency’s bible for determining the safety of food additives: *Toxicological Principles for the Safety Assessment of Direct Food Additives and Color Additives Used in Food*.

The document was in effect two years before the FDA published its proposed Omnibus Rule in the *Federal Register*, and four years before the agency published its final decision on the Omnibus Rule. Yet, none of the seven studies that formed the foundation of the Omnibus Rule and several subsequent FDA rulings fulfilled the testing protocols that are required for irradiated food, which is a “Concern Level III” food additive. (See “*New Chemicals Never Studied*,” above.)

According to the Concern Level III protocol, a battery of five experiments must be conducted before the FDA can approve a food additive for human consumption.<sup>132</sup>

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An analysis of the seven tests used by the FDA to support the Omnibus Rule reveals that none complied with the Concern Level III protocol. Additionally, several experiments—including those designed to gauge the potential carcinogenicity and mutagenicity of proposed food additives—were never officially reviewed by the FDA.

A breakdown of the five experiments detailed in the Concern Level III protocol follows. (*Comparisons between the protocols and the seven FDA studies are detailed in Appendix IV.*)

### ***Long-Term Toxicity Experiment on Rodents***

In this experiment, rodents (usually rats) are fed a proposed food additive daily for at least one year, with at least 20 females and 20 males in each of the groups eating the control and test diets. Throughout the experiment, they undergo numerous measurements, including body weight, food consumption, hematology readings, blood chemistry, urinalysis and eye exams. After sacrifice, a gross necropsy is performed, certain organs are weighed, and histopathological exams are performed on certain organs and tissues.<sup>133</sup>

Of the seven FDA studies, three could be considered long-term toxicity experiments on rodents—Elias, Radomski and Renner. For many reasons, none of the three fully comply with the specifications of the experiment. (*See Appendix IV.*) Among the others, each of the three Coquet studies lasted less than a year, and Hickman was not a toxicology study.

- In Elias, several required procedures failed to be performed, including eye exams, two blood chemistry measurements, portions of the necropsy, and several histopathological exams. The most significant flaw with Elias, however, is that rats ate a diet containing mangoes that were irradiated at only 75,000 rads—a level 25 percent lower than the level of 100,000 rads that the FDA ultimately approved for irradiating fruit for human consumption.<sup>134</sup> Additionally, Elias, director of the International Project in the Field of Food Irradiation in Karlsruhe, Germany, and among the world's leading experts in the field, did not actually conduct the study. In reality, the study was performed by two researchers at Raltech Research Services in Madison, Wisconsin<sup>135</sup>. One of them has published one article on food irradiation appearing in a peer-reviewed journal;<sup>136</sup> the other has never published such an article. For reasons that remain unknown, Elias has been listed as the study's author in several FDA *Federal Register* filings.

- In Radomski, more than half of the required procedures were not performed, including all blood chemistry measurements, the gross necropsy, eye exams, and histopathological exams for more than 20 organs and tissues, including mammary glands, bones and small intestine. Additionally, no data were reported for hematology readings and organ weights.<sup>137</sup>

- In Renner, more than three-fourths of the required procedures were not performed, including the gross necropsy, three of four blood chemistry measurements, two of four organ weights, and 34 of 40 histopathological exams. Additionally, body weights of animals fed irradiated food were lower than of those that ate non-irradiated food. "It appears as very probable," the researchers wrote, "that... these differences were caused by an insufficient supply of vitamins in the experimental animals [that ate irradiated food]. When vitamin supplements were given, no differences in body weight were found."<sup>138</sup> It is the Renner study that FDA officials listed in the footnotes of the *Federal Register* of April 18,

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1986, as one of the five studies endorsed by the agency's Irradiated Foods Task Group, which actually deemed it "deficient."

### ***Long-Term Toxicity Experiment on Dogs***

In this experiment, almost identical to the rat experiment (above), dogs are fed a proposed food additive daily for at least one year, with at least four females and four males in each of the groups eating the control and test diets. Throughout the experiment, the dogs undergo numerous measurements, including body weight, food consumption, hematology readings, blood chemistry, urinalysis and eye exams. After sacrifice, a gross necropsy is performed, certain organs are weighed, and histopathological exams are performed on certain organs and tissues.<sup>139</sup>

Of the seven FDA studies, only Radomski was a long-term toxicity experiment on dogs. For many reasons, the study did not fully comply with the specifications of the experiment. (*See Appendix IV.*) Dogs were not used in any of the other six studies.

- In Radomski, more than half of the required procedures were not performed, including blood chemistry measurements, the gross necropsy, eye exams, daily observations, two hematology tests and more than half of the histopathological exams. Additionally, data were not reported for hematology readings, organ weights and urinalysis.<sup>140</sup>

### ***Carcinogenicity Experiment on Two Rodent Species***

In this experiment, two different species of rodents (usually rats, and mice or hamsters) are fed a proposed food additive daily for at least two years, with at least 50 females and 50 males in each of the groups eating the control and test diets. Throughout the experiment, they undergo numerous measurements, including body weight and hematology readings. After sacrifice, a gross necropsy is performed, certain organs are weighed, and histopathological exams (more extensive than exams required for toxicological experiments) are performed on certain organs and tissues.<sup>141</sup>

Of the seven FDA studies, three could be considered carcinogenicity experiments on rodents—Elias, Radomski and Renner. For many reasons, none of the three fully comply with the specifications of the experiment, most notably because none of the studies used two different species of rodents. (*See Appendix IV.*) Among the others, each of the three Coquet studies lasted less than two years, and Hickman was not a carcinogenicity study.

- In Elias, several required procedures failed to be performed, including portions of the necropsy and several histopathological exams, including exams of the smooth muscle, peripheral nerve, rectum, fallopian tube and vagina. As mentioned earlier, the most significant flaw with Elias is that rats ate a diet containing mangoes that were irradiated at only 75,000 rads—a level 25 percent lower than the level of 100,000 rads that the FDA ultimately approved for irradiating fruit for human consumption.<sup>142</sup>

- In Radomski, more than half of the required procedures were not performed, including the gross necropsy and histopathological exams for more than 20 organs and tissues, including mammary glands, bones, small intestine, rectum, fallopian tube and vagina. Additionally, no data were reported for hematology readings and organ weights.<sup>143</sup>

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- In Renner, more than three-fourths of the required procedures were not performed, including the gross necropsy, two of four organ weights, and 37 of 43 histopathological exams. As mentioned earlier, body weights of animals fed irradiated food were lower than those that ate non-irradiated food.<sup>144</sup>

### ***Three-Generation Reproduction/Teratology Experiment***

In this experiment, animals (usually rats or mice) are fed a proposed food additive throughout three generations, with at least 20 females and 20 males in each of the groups eating the control and test diets. Throughout the experiment, the parents and offspring undergo numerous measurements, including body weight, behavioral changes and signs of toxicity. Living and stillborn offspring are counted and examined for gross abnormalities. After sacrifice, parents undergo a necropsy and histopathological exams; offspring are examined for gross malformations, visceral abnormalities and skeletal anomalies.<sup>145</sup>

Of the seven FDA studies, four could be considered reproduction/teratology experiments—Coquet I, Hickman, Radomski and Renner. For many reasons, none of the four fully comply with the specifications of the experiment. (*See Appendix IV.*) Among the others, Coquet 2 used a level of irradiation (15,000 - 30,000 rads) that was below the maximum level approved by the FDA (100,000 rads), Coquet III tested for only one generation, and Elias was not a reproduction experiment.

- In Coquet I, half of the required procedures either failed to be performed or included no data. Several body weight readings were not recorded, no data were listed for teratological exams of the fetuses, and no histopathological exams were performed on the organs of the parents, including the vagina, uterus, ovaries, testes and prostate. Additionally, mortality among the first set of offspring of parents that ate irradiated rice was 183 percent higher than those of parents that ate non-irradiated food.<sup>146</sup> Additionally, Coquet I, as well as Coquet II and Coquet III, were originally written in French. When asked for copies of the studies, FDA officials produced them in French. In their *Federal Register* listings, FDA officials cited brief summaries that appeared in English in a 1981 World Health Organization publication. No raw data were presented.<sup>147</sup> Public Citizen translated the three Coquet studies into English, revealing numerous flaws.

- In Hickman, more than three-fourths of the required procedures failed to be performed, including teratological exams of the fetuses, histopathological exams of the parents, most body weight measurements and daily observations. Reproductive performance was not broken down by generation. Additionally, parents that ate a diet containing wheat irradiated at 200,000 rads experienced 134 percent more stillbirths and litter sizes 8.4 percent smaller than parents that ate non-irradiated food. Researchers acknowledged that they added alpha-tocopherol (vitamin E) “to avoid the reproductive difficulties noted with...irradiated foods, difficulties that were attributed to destruction of vitamin E induced by radiation.” Researchers did not speculate whether the addition of vitamin E prevented the reproductive performance among parents that ate irradiated food from being poorer still.<sup>148</sup>

- In Radomski, more than half of the required procedures failed to be performed, including teratological exams of the fetuses, complete histopathological exams of the parents, most body weight measurements and daily observations. Reproductive performance was not broken down by generation.<sup>149</sup>

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• In Renner, more than half of the required procedures failed to be performed, including complete teratological exams of the fetuses, complete histopathological exams of the parents, most body weight measurements and daily observations. Additionally, mortality rates among the first two generations experienced “very high losses.” In response to the problem, researchers wrote: “The suspicion that the animals had obtained too little vitamin E was certified correct upon analysis of the feed. Before the animals of the F1 group were paired until the end of the experiment, all three diets were supplemented with vitamin E. Starting with the F2 generation and going to the end of the experiment, a notable improvement in offspring survival was shown for all three dietary groups.”<sup>150</sup>

### ***Short-Term Experiments for Carcinogenicity Potential***

In this battery of five experiments, bacteria, mammalian cells and *Drosophila melanogaster* (fruit flies) are grown in environments containing a proposed food additive to determine whether the additive could cause mutations in humans:<sup>151</sup>

- A bacterial mutagenesis test (using the Ames test on histidine-requiring strains of *Salmonella typhimurium*);
- A mammalian mutagenesis test (using cultured mouse lymphoma cells);
- A generalized DNA damage test (using primary rat hepatocytes);
- A mammalian cell transformation test (using cell lines from the mouse or hamster); and
- A sex-linked recessive lethal mutation test in *Drosophila melanogaster*.

The FDA initially legalized food irradiation without formally reviewing any experiments detailed in this battery. (See *Appendix IV*.)

Subtle experiments of these varieties are relatively recent in development, and were not widely used when research into food irradiation began in earnest in the early 1950s. As it was stated in *Toxicological Principles* in 1982: “The last quarter century has been a period of change and progress in the fields of regulatory toxicology and analytical chemistry. ...Not only have test requirements become generally more sophisticated, but scientists understand more fully the public health significance of test results.”<sup>152</sup>

Fourteen years earlier, in 1968, then-FDA Associate Commissioner Daniel Banes said as much during a congressional hearing on food irradiation—held seven years after the birth defect-inducing sleeping pill Thalidomide was banned from the U.S. market:

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. Since that time, our information and our knowledge in this area has increase manyfold. 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 than they were 8 or 10

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years ago. I submit, sir, that the same situation obtains with respect to irradiated food.<sup>153</sup>

At the hearing, the findings of several researchers who asked subtle questions about the potential carcinogenic and mutagenic effects of irradiated food were submitted to Congress members. Among the findings, some of which resulted from government-funded research: the chromosomes of human white blood cells became “shattered” and “pulverized” when placed in an irradiated sucrose solution;<sup>154</sup> mutations in *Drosophila melanogaster* (fruit flies) doubled when cultured in irradiated food;<sup>155</sup> *Salmonella* underwent inhibited growth and reduced survival when cultured in an irradiated sucrose solution;<sup>156</sup> and cell division of plants grown in an irradiated environment was “significantly” impaired.<sup>157</sup>

In this context, the complete failure of the FDA to formally review any short-term experiments to gauge the carcinogenic and mutagenic potential of irradiated food before approving the Omnibus Rule in 1986, which laid the foundation for several subsequent major rulings, is of notable concern—particularly since the results of several experiments suggesting potential harm were presented to Congress more than 30 years ago.

(Four)

# Major FDA Rulings Based on ‘Deficient’ Science

On March 25, 1982, a panel of FDA staff toxicologists completed a year-long review of 409 toxicology studies, conducted by dozens of government and private-sector researchers from throughout the world, that explored the question: Is irradiated food safe for human consumption?

High-ranking FDA officials appointed the panel, called the Irradiated Foods Task Group (IFTG), at a critical moment for the agency and for the food irradiation industry. A year earlier the FDA had announced in the *Federal Register*—on its own accord, not in response to an industry petition—that the agency was working on a new rule to legalize the irradiation of certain types of food.<sup>158</sup> The conclusions of the IFTG would go a long way toward shaping this rule, which, as history has shown, went on to become the foundation of subsequent FDA rulings to legalize the irradiation of pork, poultry, beef, lamb, horse meat and eggs.

The panel’s formation also came a year after the World Health Organization (WHO), in 1981, released a landmark report asserting that no further toxicology testing was required for irradiating food at levels up to 1 million rads.<sup>159</sup> This level was 10 times higher than the limit set a year earlier by the FDA’s Irradiated Food Committee.<sup>160</sup>

For a variety of reasons—mainly because many of the studies dated from the late 1950s to mid-1970s, and predated modern laboratory standards—the FDA’s IFTG rejected all but five of the 409 toxicology studies as being “deficient.” Specifically, the panel said the studies that were “determined to be deficient” lacked crucial information (e.g. the number of lab animals tested, the radiation dose used, contents of the diet), and/or suffered from methodological shortcomings (e.g. inadequate post-mortem tissue examinations, not enough animals tested, poorly compiled data).<sup>161</sup>

Though 99 percent of the 409 studies ultimately were declared “deficient,” the IFTG did put its stamp of approval on five studies. And, as expected, those five studies became the heart of the FDA’s so-called “Omnibus Rule.”

Published in the *Federal Register* in the spring of 1986, the rule legalized the irradiation of fruit, vegetables and spices. Then-FDA Commissioner Frank E. Young wrote that the five studies “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... indicate no adverse effects from the irradiated foods fed to test animals.”<sup>162</sup>

In this ruling, however, is the most notable instance of what would become 107 instances in which FDA officials—spanning a 14-year period beginning in 1986—relied on studies to demonstrate the safety of irradiated food that actually had been labeled “deficient” by the agency’s own Irradiated

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Foods Task Group in 1982. These 107 instances manifested themselves in the FDA's *Federal Register* filings in various forms:

- They were specifically discussed and cited within the text of the *Federal Register*, and footnoted at the end of the filing;
- They were listed in footnotes of the *Federal Register*; and/or
- They were discussed and cited within the pages of internal FDA memoranda that were discussed and/or cited in the *Federal Register*.

In some cases, FDA officials relied on certain “deficient” studies on more than one occasion. Of the 107 instances, a total of 79 “deficient” studies were cited. For instance, one study was cited four times—when FDA officials rejected two appeals of the Omnibus Rule, legalized the irradiation of poultry, and legalized the irradiation of red meat. (*See Chart 3 and Appendix II for breakdowns of the 79 studies and 107 instances.*)

As for studies the FDA has relied upon to legalize irradiation that were conducted after the IFTG

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### Chart 3

#### **‘Deficient’ Studies Used by the FDA to Legalize Irradiation (Totals)**

**In 107 instances since 1986, the FDA has relied on studies deemed “deficient” by the agency’s Irradiated Foods Task Group to support rulings that legalized the irradiation of several classes of food. Here is a breakdown of these instances and the rulings in which FDA officials have used “deficient” studies to legalize irradiated food. (*See Appendix II for a listing of the individual studies.*)**

<b><u>Food Class</u></b>	<b><u>FDA Ruling</u></b>	<b><u>Date</u></b>	<b><u># of ‘Deficient’ Studies Cited</u></b>
Fruit / Vegetables / Spices <sup>1</sup>	Final Rule	April 18, 1986	29
	Public Hearing Denied <sup>2</sup>	Feb. 23, 1987	10
	Public Hearing Denied <sup>2</sup>	Dec. 30, 1988	9
Poultry	Final Rule	May 2, 1990	10
Beef / Lamb / Pork / Horse	Final Rule	Dec. 3, 1997	46
Eggs	Final Rule	July 21, 2000	3
<b>Total Instances</b>			<b>107</b>

<sup>1</sup> Also known as the “Omnibus Rule.”

<sup>2</sup> Public hearing on pork ruling of July 22, 1985, also denied.

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finished its work in 1982, the agency has not publicly certified that any of them comply with modern scientific standards.

### **The Beginning: The ‘Omnibus Rule’**

In the footnotes in the *Federal Register* of April 18, 1986, the FDA lists a study conducted by two German scientists as being among the studies endorsed by the Irradiated Foods Task Group.<sup>163</sup> Four years earlier, however, IFTG Chair Marcia van Gemert wrote that the study, conducted in Karlsruhe, 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.”<sup>164</sup>

FDA officials did not publicly explain why the German study, declared “deficient” by the agency’s own Irradiated Foods Task Group in 1982, was listed in the *Federal Register* in 1986 as one of the studies that, as then-Commissioner Young said, “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.” Further, FDA officials did not publicly reconcile the apparent health effects suffered by the lab animals that ate irradiated food and Young’s statement that the study “indicate[s] no adverse effects from the irradiated foods fed to test animals.”

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 by Public Citizen under the U.S. Freedom of Information Act.

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. (*See Appendix II.*)

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. They did not seek to explain, for instance, whether a “rejected” study initially labeled “accepted with reservation” could be used to demonstrate the safety of irradiated food in some circumstances but not others.

### **Public Hearings Denied**

In response to the Omnibus Rule, and in response to the FDA’s separate decision to legalize the irradiation of pork in 1985, the agency received 304 letters of objection. Three groups—the Coalition for Alternatives in Nutrition and Healthcare, the National Coalition to Stop Food Irradiation, and Public Citizen’s Health Research Group—formally requested that the two regulations be kept off the books until their concerns about the potential health hazards of irradiated food could be resolved.<sup>165</sup>

FDA officials denied the request. In doing so, the FDA once again relied on studies that had been labeled “deficient” by the agency’s Irradiated Foods Task Group. In their *Federal Register* filing in

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early 1987, FDA officials listed 10 IFTG-rejected studies, nine of which—including the German study—previously had been listed in the Omnibus Rule.

Within a month after the FDA denied the stay, 20 more requests were made for a public hearing on the Omnibus Rule and the pork decision, including requests from the Environmental Policy Institute and the Health and Energy Institute.<sup>166</sup>

Again, FDA officials denied the request. And again, the agency relied upon studies labeled “deficient” by the agency’s Irradiated Foods Task Group. In their *Federal Register* filing in late 1988, FDA officials listed nine “deficient” studies, including two by the German researchers and two that had been referenced in earlier filings.

Another of the nine “deficient” studies, referenced by the FDA for the first time in this *Federal Register* filing, was conducted by Peter Elias, at the time one of the most prominent food irradiation researchers in the world. Elias directed the International Project in the Field of Food Irradiation in Karlsruhe, Germany, which conducted dozens of experiments from 1970 to 1982. Of those experiments reviewed by the IFTG, most of them were declared “deficient”—including four of the five authored or co-authored by Elias.

## **The Poultry Ruling**

Two years would pass before the FDA’s next major ruling on food irradiation. In the spring of 1990, agency officials granted a request by New Jersey-based Radiation Technology Inc. to irradiate poultry.<sup>167</sup>

Once again, the FDA relied on studies that the agency’s own Irradiated Foods Task Group had labeled “deficient.”

Of the four studies that formed the foundation of the agency’s ruling, three were conducted at the Central Institute for Nutrition and Food Research in The Netherlands.<sup>168, 169, 170</sup> All three had been rejected by the IFTG, largely because researchers added a potent antioxidant called ethoxyquin to the diets of lab rats and dogs. Researchers said they added ethoxyquin to prevent chicken fat in the animals’ diet from turning rancid, a process that irradiation accelerates.

In their *Federal Register* filing, FDA officials asserted that an insufficient amount of ethoxyquin was added to the lab animals’ diets to significantly alter the outcome of the three Dutch experiments. Missing from FDA files, however, is the internal memo that recounted a meeting of the agency’s Cancer Assessment Committee during which this issue was discussed. In the end, FDA officials concluded that the Dutch studies “provide no evidence of treatment-related adverse toxicological effects.”<sup>171</sup>

Another internal FDA memo, however, suggested otherwise. In one of the studies, rats fed a diet containing irradiated chicken suffered a “fairly high incidence” of cysts in the ultimobranchial gland, an endocrine gland that contributes C cells to the thyroid.<sup>172</sup> The matter was referred to the FDA’s Cancer Assessment Committee to further investigate the “toxicological implications” of the findings,<sup>173</sup> but the memo generated from the meeting is missing from the FDA’s files.

The fourth “deficient” study the FDA relied upon to legalize the irradiation of poultry was con-

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ducted in 1971 by BioResearch Laboratories (BRL) of Ottawa, Canada, on behalf of Atomic Energy of Canada Ltd. (the world's largest supplier of cobalt-60, the most widely used radioactive material in gamma-ray irradiation facilities). During the experiment, mice were fed irradiated chicken and had-dock.

Internal FDA memos indicate that the experiment suffered from several shortcomings. In one memo, an FDA staffer wrote that histopathological exams were “done only on animals showing evidence of tumor formation.” The staffer continued: “More importantly, the tables do not show the number of tumors by time intervals by specific tumor types. In addition, the number of tumors in these total tumor tables are not even based on histopathology.” The staffer worried that “there is a fair to good chance” of tumors going undiscovered when only cursory exams are performed.<sup>174</sup>

When BRL staffers themselves went back to review the original experiment materials in 1985—14 years after the experiment was conducted—they discovered that the quality of the slides was “poor, . . . probably attributable to the long and inadequate storage of the slides resulting in deterioration of the mounting medium.”<sup>175</sup> Though BRL staffers succeeded in retrieving some of the original data, the FDA staffer said that “individual animal data still indicates that the vast majority of the organ tissues were not examined histopathologically (65%-79% in the various treated and control groups).”<sup>176</sup>

(Seven years later, in 1997, when FDA officials denied a request by the environmental-advocacy group Food and Water for a public hearing on the poultry ruling, the agency itself acknowledged that a different BRL study on the potential carcinogenicity of irradiated food contained “deficiencies.”<sup>177</sup> Additionally, of the four studies conducted by the lead researcher of the 1971 BRL study that the IFTG reviewed, all were rejected.<sup>178</sup> )

In addition to the three Dutch studies and the Canadian study, the FDA also relied on six other “deficient” studies to legalize the irradiation of chicken in 1990.<sup>179</sup>

Marking the first such occurrence, internal FDA memos reveal that staff members raised concerns about “deficient” studies but did nothing to keep them from being used to legitimize the approval of an irradiation petition. In addition to the concerns of the Irradiated Foods Task Group eight years earlier, an FDA staffer reviewing the chicken petition also raised concerns about the adequacy of the studies. Among the flaws the FDA staffer cited:

- “since the duration of this study was not reported, this [study] is of little value for our safety evaluation”;
- “the in-depth review of this study raised questions about the procedures used; e.g. not all test strains were subjected to positive controls, and the high protein content of the extracts may be a compromising factor for this test;” and
- “of limited value because of procedural flaws.”<sup>180</sup>

Nevertheless, FDA officials relied on these admittedly flawed studies—without explaining whether they contained any scientifically adequate elements whatsoever—and proceeded to legalize the irradiation of poultry. (*See Appendix V, studies #218, #265, #353.*)

## The Meat Ruling

In December 1997, in the same edition of the *Federal Register* in which they denied a public hearing on the poultry ruling, FDA officials granted a petition by Isomedix—another New Jersey-based irradiation company with a history of safety violations—to irradiate the flesh and organs from cows, pigs, sheep and horses.<sup>181</sup>

In doing so, FDA officials relied on 46 studies that the agency’s Irradiated Foods Task Group had rejected 15 years earlier—more than 10 percent of the total collection of “deficient” studies.

In previous rulings, FDA officials specifically referenced most or all of the “deficient” studies only in the footnotes of the *Federal Register*. In the meat ruling, however, all but six of the “deficient” studies were referenced within the pages of internal FDA memos. A review of these memos reveals what had been, up to that point, the most thorough use of flawed science since the FDA’s renewed interest in food irradiation began in 1979.

Among the 46 “deficient” studies were:

- The three Dutch experiments that formed the foundation of the FDA’s poultry irradiation ruling;
- Two studies that were cited in the poultry ruling despite specific criticisms by FDA staffers; and
- An IFTG-rejected study that was also thrown out by FDA staffers working on the poultry petition: “This study was considered to be flawed by experimental design and cannot be used for support of non-mutagenicity.”<sup>182</sup>

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”:<sup>183</sup>

- A 1970 study conducted by the Academy of Medical Science in Moscow, in which rats fed irradiated fish experienced high mortality from pneumonia and other illnesses; “rather unfavorable” metabolism abnormalities, which suggested liver dysfunction; and “an unfavorable effect on gonads, reproductive function and progeny,” including low sperm count, atrophied testes and extended estrous cycles.<sup>184</sup>

- A 1969 study conducted by the United Kingdom Atomic Energy Authority, in which the ovaries, uteri and testes of rats fed irradiated cod were significantly more atrophied than rats fed a normal diet.<sup>185</sup>

- A 1966 study conducted at the Vanderbilt University School of Medicine for the U.S. Army Surgeon General, in which rats fed irradiated beef were significantly more likely to die by the age of 18 months than those fed non-irradiated food.<sup>186</sup>

- A 1961 study conducted by the Syracuse University Research Institute for the U.S. Army Surgeon General, in which rats fed irradiated chicken stew and cabbage experienced significantly lower levels of alkaline phosphatase in their small intestines than those fed a non-irradiated diet, an indication of possible adrenal dysfunction, protein deficiency or malnutrition.<sup>187</sup>

- A 1961 study conducted at the U.S. Army Medical Research and Nutritional Laboratory in

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Denver, in which rats fed a composite irradiated diet containing nine different foods including ground beef, beans and peaches experienced significantly higher levels of the enzyme cytochrome oxidase than those fed a non-irradiated diet, indicating the possible destruction of essential fatty acids.<sup>188</sup>

FDA officials gave no public explanation as to how these studies—which the agency’s own Irradiated Foods Task Group said both were “deficient” and “claimed to show adverse effects of irradiated food”—could be used to demonstrate the safety of irradiated food.

Among the other studies cited in the FDA’s 1997 meat ruling in which lab animals suffered health problems, rats fed a composite irradiated diet suffered lesions of the auricle that caused their hearts to rupture.<sup>189</sup> Animals that did not die from the condition experienced weight loss and anemia. When milk was irradiated and fed to the rats, 83 percent of them died or were killed because of the heart lesions. No heart lesions appeared in rats fed a normal diet.<sup>190</sup>

### **The Egg Ruling**

In the FDA’s latest major ruling, agency officials on July 21 of this year legalized the irradiation of fresh shell eggs.<sup>191</sup> In doing so, the FDA relied on three studies that the Irradiated Foods Task Group had labeled “deficient.”

FDA staffers acknowledged that the studies were “deficient,” as they did with the “deficient” Dutch studies in the 1990 poultry ruling. Unlike the Dutch studies, however, FDA staffers made little or no effort to explain why the studies at hand could be used to legitimize a finding that irradiated eggs are safe to eat.

The egg irradiation petition was filed by Edward Josephson, a food irradiation researcher since 1961 who directed the Army’s ill-fated program in Massachusetts for 15 years before becoming a professor at M.I.T. and the University of Rhode Island. Despite his nearly 40 years of experience, Josephson did not submit to the FDA any toxicology studies evaluating the safety of irradiated eggs. Instead, an FDA staffer wrote in an internal memo, the petition “is based on international reports and review articles.”<sup>192</sup> The response by FDA staffers was not to request the information of Josephson, but to try to find it for themselves.

The staffer referenced three studies retrieved from FDA’s files, all of which had been declared “deficient” by the agency’s Irradiated Foods Task Group:

- A 1959 study conducted for the U.S. Army Surgeon General<sup>193</sup> that the staffer wrote was rejected by the IFTG because “there were many studies in the report and each study was not clearly stated and, thus, hard to follow.”<sup>194</sup>

- A 1972 study conducted at the Laboratoire de Radiobiologie in Paris<sup>195</sup> that the staffer wrote “was identified as a weak study because only a few toxicological parameters were measured and reported, and no histopathological data [were] available. Thus, the data were not suitable for evaluation [of the] carcinogenicity of eggs.”<sup>196</sup>

- A 1974 study conducted at the Laboratoire Central de Recherches Veterinaires in Paris<sup>197</sup> that the staffer wrote “was only a summary report.”<sup>198</sup>

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Despite these shortcomings, the staffer wrote: “the totality of evidence from these data/studies indicates that irradiated foods present no harm when tested in animal feeding studies.”<sup>199</sup> (*See Appendix VI, items 1, 2, 3.*)

### **The Big Picture**

In total, FDA officials relied on 79 studies that the agency’s Irradiated Foods Task Group had declared “deficient” in FDA rulings that legalized the irradiation of pork (1985); fruit, vegetables and spices (1986); poultry (1990); beef, pork, lamb and horse (1997); and fresh shell eggs (2000).

Because some of these studies were referenced on more than one occasion, there were a total of 107 instances in which FDA officials relied on “deficient” studies in the course of making these five rulings. Only rarely did FDA officials attempt to explain how a “deficient” study could be used to legitimize a finding that irradiated food is safe for human consumption. And in only a few cases did FDA officials acknowledge using studies that their own Irradiated Foods Task Group had declared scientifically inadequate.

*(Five)*

# Congress Not Given the Whole Truth

Despite the fact that formal, government-sponsored research into food irradiation dates back to 1948, that numerous federal agencies have had a role in researching and regulating food irradiation, and that irradiation has been legalized for most major classes of food, the process has undergone a disproportionately small amount of oversight in Congress.

Since 1955, food irradiation has been the primary topic of discussion and inquiry at 10 congressional hearings—and just three since 1979, when the FDA renewed its interest in the technology by appointing the Irradiated Food Committee.

At each of these hearings, Congress members put direct questions about the safety, effectiveness, and technological and economic feasibility of food irradiation to officials with the FDA, Army, Atomic Energy Commission (AEC), Department of Energy (DOE) and other federal agencies. Though Congress members expected direct answers, they didn't always get them.

A review of the transcripts from these hearings reveals that high-ranking government officials—including an FDA commissioner—downplayed the potential hazards of irradiated food. In some cases, Congress members have been misled. At the three congressional hearings held during the 1980s—a decade during which the FDA legalized the irradiation of fruit, vegetables, beef, pork and lamb—federal officials said nothing about the pioneering research that revealed numerous health problems in lab animals that ate irradiated food.

As a result, has the effectiveness of congressional oversight of the FDA's regulation of irradiated food been reduced? Would proposed legislation to ban the irradiation of pork and block implementation of the Omnibus Rule in 1987 have gone further had Congress members known the whole truth about the history of food irradiation research?

## **'We Were Guinea Pigs'**

During the 1950s and 1960s, congressional oversight of food irradiation was the responsibility of the Joint Committee on Atomic Energy and its Subcommittee on Research, Development and Radiation. Illinois Democrat and World War II Army veteran Melvin Price chaired the subcommittee in 1966 when the head of the Army's food irradiation program appeared before the panel. Edward Josephson, head of the Army's food irradiation lab in Natick, Massachusetts, was asked by Price to discuss "what you consider to be the vital and most important" challenges faced by the program.<sup>200</sup>

The "significant problems," Josephson explained to Price and the rest of the committee, concerned radiation-induced resistance of the bacteria that causes botulism, limiting the textural changes in irradi-

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ated food, and ensuring safe operation of irradiation equipment. Josephson made no mention of the health problems suffered by lab animals fed irradiated food in Army experiments.<sup>201</sup>

As history would soon show, Josephson knew about these problems. They were serious problems at that, but not serious enough for him to reveal to the subcommittee, and not serious enough to prevent the Army from sending irradiated bacon to military personnel serving in Vietnam (though in “very limited quantities”).<sup>202</sup>

Two years later, Josephson was back in front of Price’s subcommittee, along with several other officials from the Army as well as the FDA and AEC. 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 health problems in lab animals that ate irradiated food.

Then-FDA Commissioner James Goddard described the problems in a letter to Army officials. Among them, rats fed irradiated bacon and fruit suffered a 23 percent reduction in live births—“adverse effects on the animal reproduction process,” Goddard wrote, “that are highly unlikely to be due to chance.” In other experiments, rats died younger, dogs and mice gained less weight, dogs and rats had lower red blood cell counts, and rats developed more malignant tumors, including pituitary cancer. “Since this is a rarely occurring type of cancer,” Goddard wrote, “this could be very significant.”<sup>203</sup>

The Army submitted the data with its 1966 petition to irradiate ham, but hadn’t included it with its bacon application four years earlier.<sup>204</sup>

“You mean it was withheld?” Rep. Chet Holifield asked FDA Associate Commissioner Daniel Banes. “No, sir; it was not withheld. Neither was it submitted. It was not provided by the Army... Our evaluation of the raw data led us to believe that there were suggestions of adverse effects and that, therefore, the safety of these irradiated meats had not been established... [We] had no knowledge of tumors associated with irradiated bacon. I assure you that if we had, we would not have concluded that safety had been proven.”<sup>205</sup>

Banes—speaking seven years after George Larrick kept Thalidomide off the market—warned that, in the absence of thorough, modern testing of irradiated food, one disaster could follow another:

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. Since that time, our information and our knowledge in this area has increase manyfold. 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 than they were 8 or 10 years ago. I submit, sir, that the same situation obtains with respect to irradiated food.<sup>206</sup>

Along these lines, the work of several researchers who asked subtle questions about the effects of

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irradiated food were submitted at the hearing. Among their findings:

- The chromosomes of human white blood cells became “shattered” and “pulverized” after they were placed in an irradiated sucrose solution;<sup>207</sup>
- Mutations in *Drosophila melanogaster* (fruit flies) doubled when cultured in irradiated food;<sup>208</sup>
- *Salmonella* underwent inhibited growth and reduced survival when cultured in an irradiated sucrose solution;<sup>209</sup> and
- Cell division of plants grown in an irradiated environment was “significantly” impaired.<sup>210</sup>

Rep. Holifield, who advised President Truman on nuclear bomb testing at Bikini Atoll, 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. Now we find that many of these scientists are dead or unobtainable for any questioning by this committee. Now some 8 or 10 years later we come up with a rehash of old data and a different conclusion. What are we to think of in regard to the competency of the original group of scientists that came in before this committee and testified in regard to this matter?<sup>211</sup>

Rep. William Bates, a World War II Navy veteran, was also dismayed. “We were told several years ago that bacon was all right. We proceeded to eat it.” A few moments later, Price responded, “We were guinea pigs.”<sup>212</sup>

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.”<sup>213</sup>

Josephson, testifying less than two weeks after the FDA proposed revoking the Army’s bacon irradiation permit, said that lab animals’ health problems were not “statistically significant.” He then offered some firsthand evidence demonstrating the safety of irradiated food: “I have put on quite a few pounds since I first started to appear before this committee, and I attribute that to my constant nibbling of these irradiated goodies all day long in the laboratory.”<sup>214</sup>

## **Maintaining the Silence**

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 was asked by a member of a House Appropriations subcommittee, “How do you evaluate these foods from the safety standpoint to assure there are no adverse effects associated with the radiation process?” E. Eugene Fowler, then director of the AEC’s Isotope Development Division, replied: “We have not seen adverse factors which would sug-

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gest that radiation processed food is unsafe.”<sup>215</sup>

Fowler made this statement despite the fact that:

- AEC officials told Congress a year earlier that they wanted to eliminate their food irradiation program (though an official said “this action was taken solely for reasons of budgetary stringency, and does not imply any adverse ... wholesomeness [or] safety findings”).<sup>216</sup>

- The AEC in 1967 withdrew an application to irradiate strawberries after rats fed irradiated peaches developed “significant numbers of tumors.”<sup>217</sup> Then-FDA Commissioner Goddard wrote to Fowler’s boss, AEC Chair Glenn Seaborg (a Nobel laureate and co-discoverer of plutonium), “I was most disappointed at some of the material presented in support of the proposed regulation.”<sup>218</sup> Also that year, the AEC withdrew a petition to irradiate oranges and lemons.<sup>219</sup>

- An AEC-funded researcher at the University of Pittsburgh described, in a 32-page report published in the *Bulletin of the World Health Organization* in 1967, the “mutagenic and cytotoxic agents in irradiated media.”<sup>220</sup> In three other AEC-funded papers published before the 1970 hearing, radiation chemistry Professor Jack Schubert wrote that “under certain circumstances deleterious compounds are produced in irradiated sucrose solutions;”<sup>221</sup> that “radiomimetic effects of irradiated media are well known;”<sup>222</sup> and that “deleterious effects...have been observed when plant and mammalian cells...are immersed in irradiated sucrose solutions.”<sup>223</sup>

- AEC-funded research in 1968 found that bean roots grown in an irradiated environment experienced an increase in chromosomal aberrations.<sup>224</sup>

- AEC-funded research in 1965 found that fruit flies grown on irradiated food experienced a two-fold increase in mutations.<sup>225</sup>

## **Lips Still Sealed**

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

In 1984, veteran FDA officials Sanford Miller and Clyde Takeguchi appeared before a House Science and Technology subcommittee to discuss the history of the FDA’s role in regulating irradiated food. In his prepared statement, Miller, the director of the Center for Food Safety and Applied Nutrition, said this about the Army’s difficulties during the 1960s:

The first approved use of irradiation in the United States was for the radiation sterilization of canned bacon in 1963. However, this regulation was rescinded in 1968 because a later examination of the raw data for the animal feeding studies showed major deficiencies in the way some of the experiments were designed and conducted. Thus, because of experimental deficiencies, FDA could no longer conclude that the irradiation of bacon (and ham) had been shown to be a

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safe process.<sup>226</sup>

Miller said nothing about the various health problems experienced by lab animals that ate irradiated food—problems that then-FDA Commissioner Goddard stated “are highly unlikely to be due to chance.” Miller also said nothing about the roles of the Army and AEC, and nothing about the AEC’s withdrawal of petitions to irradiate strawberries, oranges and lemons.

In 1987 Rep. Douglas Bosco (D-CA) introduced the Food Irradiation Safety and Labeling Requirement Act. As in the mid-1960s, the momentum behind the legalization of food irradiation was building. Within the previous three years, the FDA had approved irradiation of pork, fruit, vegetables and spices, and the agency was reviewing proposals to irradiate poultry, beef and lamb.

Not convinced that the wholesomeness of irradiated food had been sufficiently established, Bosco wrote a bill that would have blocked the most recent irradiation rulings from taking effect. It also called for study of several issues, including the potential health effects of eating irradiated food, the potential harm to people working in or living near irradiation facilities, and the potential for environmental damage caused by material used in the facilities.

Bosco told a House Energy and Commerce subcommittee:

A growing number of scientists, consumers and over 80 members of Congress are concerned about the FDA’s approval of pork and produce irradiation on the grounds that proper safety studies have not been conducted... Unable to prove irradiation safe, the FDA simply decided to allow only a relatively small dose of radiation to be used in food under the assumption that less exposure would logically be more safe. Mr. Chairman, if I had here beside me a pile of 100 rocks and started tossing them at you, it’s likely that you would feel greatly endangered. Yet if I had only 10 rocks beside me and started throwing them, would you feel safe? This is the very logic the FDA has used in approving food irradiation.<sup>227</sup>

The first government official called to testify was then-FDA Commissioner Frank Young. Like Miller three years before, Young glossed over the reasons that the agency revoked the Army’s permit to irradiate bacon during the Vietnam War. Describing the decision as “the low point for food irradiation,” Young said—without mentioning the roles of the Army and AEC—that “the safety of radiation-preserved bacon had not been sufficiently demonstrated.”<sup>228</sup>

Also like Miller, Young made no mention of the serious health problems experienced by lab animals that ate irradiated food, nor the AEC’s withdrawal of applications to irradiate strawberries, oranges and lemons.

(Six)

# 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.

Additionally, the FDA is under pressure from certain members of Congress and numerous food industry groups to change federal labeling requirements to allow food companies to use euphemisms such as “cold pasteurized” and “electronically pasteurized” to describe food that has been irradiated. And, for the first time, irradiated food legally could be imported into the United States.

Among the most significant proposals pending before the FDA and USDA:

• Last December, the National Food Processors Association (NFPA)—“the voice of the \$460 billion food processing industry”<sup>229</sup>—asked the FDA to legalize the irradiation of “ready-to-eat” foods, which comprise about a third of the typical American’s diet. The petition covers prepared foods made with meat, fruit or vegetables, such as juices, frozen fruit and vegetables, cut and packaged salads, luncheon meat and hot dogs, seeds, beef jerky and frozen fried chicken.<sup>230</sup>

More than 30 food industry trade groups co-sponsored the petition, including:

- American Association of Meat Processors
- American Bakers Association
- American Meat Institute
- American Spice Trade Association
- Food Marketing Institute
- Grocery Manufacturers of America
- Institute of Shortening and Edible Oils
- International Association of Color Manufacturers
- International Fresh Cut Produce Association
- National Cattlemen’s Beef Association
- National Chicken Council
- National Meat Association
- National Restaurant Association
- North American Meat Processors
- Ozark Food Processors Association

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- Pacific Seafood Processors Association
- Snack Food Association
- Society of the Plastics Industries.<sup>231</sup>

Several major food irradiation companies are also listed as co-sponsors, including Food Technology Service of Mulberry, Fla.; SteriGenics of Chicago; STERIS/Isomedix of Mentor, Ohio; and Titan of San Diego.<sup>232</sup>

In response to a request by the NFPA, the FDA has agreed to review the petition on an “expedited” basis, meaning that it is being “reviewed ahead of other pending food additive petitions.”<sup>233</sup> It remains to be seen whether, as a result of their “expedited” review, FDA officials will devote less attention to the shortcomings in the NFPA’s petition.

The NFPA, for instance, did not state that a 100-fold safety factor for humans was determined, as required by the U.S. Code of Federal Regulations. The NFPA also failed to state that testing protocols established by the National Academy of Sciences/National Research Council were followed, as required by the code. Also, the NFPA acknowledged that journal articles submitted with the petition “do not indicate whether the studies were conducted in compliance with good laboratory practices. . . . The reason for any noncompliance that might exist is not known to the petitioner.”<sup>234</sup>

- In February 1999, the FDA announced its intentions to change a federal regulation requiring that irradiated food be labeled accordingly.<sup>235</sup>

Current law requires a “written statement that discloses that a food has been intentionally subject to irradiation.”<sup>236</sup> To date, “Treated by Irradiation” is the phrase that food companies have used most often. In 1997, however, a congressional committee report attached to the Food and Drug Administration Modernization Act directed the FDA to change its rules by November 1998 to allow labels “that would not be perceived to be a warning or give rise to inappropriate consumer anxiety.”<sup>237</sup>

As the FDA failed to meet the deadline, the message was reiterated by the House and Senate appropriations committees this past summer, led by Sens. Thad Cochran (R-Miss.) and Tom Harkin (R-Iowa), and Rep. Tom Latham (R-Iowa). The Senate language directed the FDA to change its regulations to allow “alternative truthful and non-misleading labeling” that “should not be perceived as a warning” to consumers. FDA officials were given another year to change the regulation.<sup>238</sup>

Weakening the labeling regulation—the desire of the NFPA and dozens of other food industry trade groups—would allow food companies to tell consumers that irradiated food has been “cold pasteurized” or “electronically pasteurized.” These phrases are misleading. Pasteurization is a process by which food (usually dairy products) is rapidly heated and cooled. Additionally, irradiation is not a “cold” process because it can cause food to be heated by several degrees.

- This past May, the USDA’s Animal and Plant Health Inspection Service (APHIS) proposed a rule that would allow imported fruit and vegetables to be irradiated. Specifically, irradiation was proposed to control 11 species of fruit flies and one species of seed weevil.<sup>239</sup> The proposed rule includes no analysis of the likelihood that surviving insects could mutate due to radiation exposure. APHIS proposed the rule on its own initiative, and not in response to a petition from the food industry.

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- Last year, the FDA received petitions from Caudill Seed Co. to legalize the irradiation of alfalfa and other sprouting seeds,<sup>240</sup> and from the National Fisheries Institute and Louisiana Agriculture and Forestry Department to irradiate shellfish.<sup>241</sup> Like the ready-to-eat food petition, FDA officials are conducting “expedited” reviews of these two petitions.

- Last December, the USDA asked the FDA to legalize the irradiation of unrefrigerated meat,<sup>242</sup> and to increase the irradiation dose for poultry.<sup>243</sup> USDA officials filed the petitions on their own initiative, and not in response to a request from the food industry. FDA officials are conducting “expedited” reviews of both petitions.

- This past February, the Illinois Institute of Technology asked the FDA to legalize the use of several new types of packaging material with food being irradiated by linear accelerators (so-called “e-beam” technology).<sup>244</sup> FDA officials granted a one-year trial approval, despite the acknowledgment of a high-ranking USDA official that “we have no data specifically supporting [the] assumptions” that allowing the materials to be used “would pose any risks to consumers.”<sup>245</sup>

If all of these petitions and proposed rules are approved, irradiation will be legal for every class of food except dairy and fin fish. (Irradiation is generally considered inappropriate for dairy products due to high fat content, and inappropriate for fin fish because of changes to flavor and texture, and because of concerns that the process may not adequately eliminate the bacteria that causes botulism.)

The use of irradiation to “treat” nearly every class of food was not envisioned by scientists and health officials until recently. When a vast majority of research was conducted—from the early 1950s through the late 1970s—scientists and policymakers were pondering the potential health downfalls of irradiated food based on the notion that it would not soon comprise a large portion of the typical American’s diet.

The FDA’s Irradiated Food Committee, for instance, stated in 1980: “The committee utilized estimates of a) total food consumption, b) dietary items proposed for irradiation and, c) the percent of each dietary item which may be irradiated. ...A rough estimate based on these factors suggests that 10% of the total diet may consist of irradiated food in the near future.”<sup>246</sup>

If every petition and proposed rule before the FDA and USDA is approved, however, more than 90 percent of the typical American’s diet will be eligible for irradiation.<sup>247</sup>

*(Seven)*

# 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 satisfactory completion of (5) through (8) following, the approval of all petitions and proposed rules related to food irradiation, including but not limited to:

- a proposed rule to amend food irradiation labeling requirements (Docket No. 98N-1038),
- a petition to legalize the irradiation of fresh or frozen molluscan shellfish (Docket No. 99F-4372),
- a petition to legalize the irradiation of pre-processed meat and poultry, raw and pre-processed agricultural products, and certain multi-ingredient food products (Docket No. 99F-5522),
- a proposed rule to legalize the irradiation of imported fruits and vegetables (Docket No. 98-030-1),
- a petition to legalize the use of materials permitted under 21 CFR §179.45 to prepackage meat and poultry for irradiation by electron beam and x-rays (Docket No. 00F-0789),
- 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 petition to legalize the irradiation of alfalfa and other sprouting seeds (Docket No. 99F-2673).

(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 to explore and assess all real and potential health effects of irradiated food, including but not limited to comprehensive carcinogenic, mu-

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tagenic, reprotoxic, teratogenic and cytotoxic testing of any and all radiolytic products (unique or otherwise) formed in irradiated food. This testing regime should be designed and implemented in accordance with:

- The current edition of the FDA's *Toxicological Principles*,
- Food additive principles and procedures stated in current publications of the National Academy of Sciences/National Research Council, as mandated by 21 CFR §170.20, and
- Any and all applicable provisions of the U.S. Code and Code of Federal Regulation.

(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, including but not limited to the actions of current and former FDA officials most materially involved with the issue. Findings of the panel shall be made publicly available, and shall be forwarded to all congressional committees and subcommittees with direct or indirect oversight responsibility over the FDA.

(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. The index shall be made publicly available, and shall be forwarded to all congressional committees and subcommittees with direct or indirect oversight responsibility over the FDA.

(8) Compile a complete index of all organizations and facilities engaged in the production, distribution, transportation, marketing, wholesaling and/or retailing of irradiated food in the United States. The index shall be made publicly available, and shall be forwarded to all congressional committees and subcommittees with direct or indirect oversight responsibility over the FDA.

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, including but not limited to the Senate Governmental Affairs Committee, the House Government Reform Committee, and the Subcommittee on Health and Environment of the House Commerce Committee.

# Notes

- <sup>1</sup> Spiher, A.T. Jr. "Food irradiation: An FDA report." *FDA Papers*, October 1968.
- <sup>2</sup> "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.
- <sup>3</sup> *The Technical Basis for Legislation on Irradiated Food*. Technical Report Series No. 316, Geneva: World Health Organization, 1966.
- <sup>4</sup> "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.
- <sup>5</sup> "Recommendations for evaluating the safety of irradiated foods." Final Report, Irradiated Food Committee, prepared for the Bureau of Foods, FDA, July 1980.
- <sup>6</sup> *Ibid.*
- <sup>7</sup> *Toxicological Principles for the Safety Assessment of Direct Food Additives and Color Additives Used in Food*. Bureau of Foods, FDA, 1982.
- <sup>8</sup> FDA Memorandum from Marcia van Gemert to W. Gary Flamm, April 9, 1982.
- <sup>9</sup> 48 Federal Register 30613, July 5, 1983.
- <sup>10</sup> 50 Federal Register 29658, July 22, 1985.
- <sup>11</sup> 51 Federal Register 13376, April 18, 1986.
- <sup>12</sup> 55 Federal Register 18538, May 2, 1990.
- <sup>13</sup> 62 Federal Register 64107, December 3, 1997.
- <sup>14</sup> 65 Federal Register 45280, July 21, 2000.
- <sup>15</sup> U.S. Code of Federal Regulations, Title 21, §170.22.
- <sup>16</sup> Integration Risk Information System. National Center for Environmental Assessment, Office of Research and Development, U.S. Environmental Protection Agency. ([www.epa.gov/ngispgm3/iris/](http://www.epa.gov/ngispgm3/iris/)).
- <sup>17</sup> *Ibid.*
- <sup>18</sup> *Toxicological Principles for the Safety Assessment of Direct Food Additives and Color Additives Used in Food*. Bureau of Foods, FDA, 1982.
- <sup>19</sup> Irradiated Food Committee, *op. cit.*
- <sup>20</sup> 51 Federal Register 13376, April 18, 1986.

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- <sup>21</sup> Ibid.
- <sup>22</sup> 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.
- <sup>23</sup> Ibid, citing Rinehart, R.R. and Ratty, F.J. "Mutation in *Drosophila melanogaster* cultured on irradiated food." *Genetics*, 52:1119-1126, 1965.
- <sup>24</sup> 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.
- <sup>25</sup> "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.
- <sup>26</sup> Ibid.
- <sup>27</sup> FDA Memorandum from Marcia van Gemert to Clyde Takeguchi, Dec. 28, 1992.
- <sup>28</sup> 52 Federal Register 5450, Feb. 23, 1987.
- <sup>29</sup> 53 Federal Register 53176, Dec. 30, 1988.
- <sup>30</sup> 55 Federal Register 18538, May 2, 1990.
- <sup>31</sup> FDA Memorandum from Janet Springer to W. Gary Flamm, July 26, 1985.
- <sup>32</sup> 62 Federal Register 64107, December 3, 1997.
- <sup>33</sup> van Gemert, April 9, 1982, op. cit.
- <sup>34</sup> 65 Federal Register 45280, July 21, 2000.
- <sup>35</sup> Ibid.
- <sup>36</sup> "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.
- <sup>37</sup> Ibid.
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## The Authors

### Mark Worth

Mr. Worth is the Senior Researcher for Public Citizen's Critical Mass Energy and Environment Program. Prior to joining Public Citizen this year, he worked as an investigative reporter, independent newsmagazine publisher, and community activist in Florida, California and Washington. In 1995 he won the nation's top investigative reporting award for an exposé on chemically injured factory workers at Boeing. He has won other national and regional journalism awards. He has worked for numerous political campaigns and nonprofit organizations concerned with the environment, affordable housing, sustainable development, media reform, and government and corporate accountability.

### Wenonah Hauter

Ms. Hauter is the Director of Public Citizen's Critical Mass Energy and Environment Program. Prior to joining Public Citizen in 1997, she was Environmental Policy Director for Citizen Action, where she directed campaigns to maintain the Superfund program, reduce pesticide contamination, and protect consumers and the environment from the effects of electric utility deregulation. Before that she was Senior Organizer at the Union of Concerned Scientists, where she coordinated sustainable energy campaigns in several states, and also worked on poverty and aging issues in rural and urban Virginia. She is a trainer for the Midwest Academy, and has a Master's Degree in anthropology from the University of Maryland.

### Samuel Epstein, M.D., D.Path., D.T.M&H

Dr. Epstein is a Professor of Environmental and Occupational Medicine at the School of Public Health, University of Illinois Medical Center Chicago. He has published some 260 peer-reviewed scientific articles and has authored or co-authored 10 books, including *Safe Shopper's Bible* (1995), *The Politics of Cancer, Revisited* (1998) and *The Breast Cancer Prevention Program* (1998). He is the Chair of the Cancer Prevention Coalition. Dr. Epstein is well recognized as a leading international authority on the causes and prevention of cancer.

His past committee and society involvements include: Chair of the Air Pollution Control Association Committee on Biological Effects of Air Pollutants; Founder and Secretary of the Environmental Mutagen Society; President of the Society of Occupational and Environmental Health; and President of the Rachel Carson Council, Inc.

He has served as a consultant to and drafted legislation for the U.S. Senate Committee on Public Works; has frequently been invited to testify before congressional committees on food safety and other concerns; and has been a lead member of key federal agency advisory committees, including the EPA's Health Effects Advisory Committee and the Department of Labor Advisory Committee on the Regulation of Occupational Carcinogens.

He has been the key expert involved in the banning of hazardous products and pesticides, including DDT, Aldrin and Chlordane. He presented the "Legislative Proposals for Reversing the Cancer Epidemic" to the Swedish Parliament in 1998, and to the U.K. All Parliamentary Cancer Group in 1999.

Dr. Epstein's numerous honors and awards include the 1977 National Conservancy Award of the National Wildlife Federation, the 1981 Henry Kaiser Award, the 1989 Environmental Justice Award, and the 1998 Right Livelihood Award (the Alternative Nobel Prize) for international contributions to cancer prevention.

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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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**Public Citizen**  
**Critical Mass Energy and Environment Program**

215 Pennsylvania Ave. S.E.  
Washington, D.C. 20003  
tel: (202) 546-4996  
fax: (202) 547-7392  
web: [www.citizen.org](http://www.citizen.org)

**Cancer Prevention Coalition**  
**University of Illinois School of Public Health**

2121 W. Taylor St.  
Chicago, IL 60612  
tel: (312) 996-2297  
fax: (312) 996-1374  
web: [www.preventcancer.com](http://www.preventcancer.com)

**Global Resource Action Center for the Environment**

15 East 26th St., Room 915  
New York, NY 10010  
tel: (212) 726-9161  
fax: (212) 726-9160  
web: [www.gracelinks.org](http://www.gracelinks.org)

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