



Irradiated Food in School Lunches

The most recent Farm Bill passed by Congress contains an anti-consumer provision that draws into question the safety of what our children eat. The food irradiation industry was successful in inserting language that directs the Secretary of Agriculture to purchase irradiated food for the various nutrition programs the USDA runs including the National School Lunch Program.

The Farm Bill allows our children to be "guinea pigs" for irradiated food. Section 4201 (b)(3) directs the Secretary of Agriculture not to prohibit commodities that have been treated with irradiation to be used in the various nutrition programs USDA administers. Among those programs are the National School Lunch Program and the Child Nutrition Program.

This section attempts to accomplish legislatively what USDA could not achieve administratively in 2001. Last year, the Agricultural Marketing Service (AMS) issued revised specifications for commodity contracts for the National School Lunch Program that would permit the purchase of irradiated food for the program. A public outcry against the inclusion of irradiated food in the National School Lunch Program forced Secretary of Agriculture Ann Veneman to rescind the revised contract specifications.

The sale of irradiated food in supermarkets has been dismal. Since 2000, supermarkets in Minnesota, Wisconsin, Florida, and California have stopped carrying irradiated hamburgers due to poor sales. The food irradiation industry has been looking to the government to bail it out, and they view the School Lunch Program as a way to stay in business.

There is an appalling lack of research into the health effects of consuming the unique chemicals created when foods are irradiated. Recent research conducted by German scientists into one class of these chemicals, called cyclobutanones, showed that they caused genetic damage in laboratory and promoted cancer growth.

There is even less research into the long-term health effects experienced by children who are exposed to toxic chemicals in foods. Dr. William Au, a toxicologist at the Department of Preventive Medicine and Community Health, University of Texas Medical Branch in Galveston, has argued that "the scientific community and regulatory agencies have very little knowledge regarding how children respond to insult from toxic chemicals. These concerns also apply to toxicological risk with respect to eating irradiated food."

Furthermore, current regulations do not require that parents, teachers, or students be informed that their meals at school have been prepared with irradiated foods. Parents, teachers, and children deserve the right-to-know what is being served in the nutrition programs offered in school. Using children as experimental subjects or to create a market for a technology that consumers don't want is irresponsible.

Working With Local School Boards

While sending letters to federal government officials (representatives and senators) concerning food irradiation in schools can be effective, working with local officials is also vital. Some tips for working with your local school board to keep irradiated food out of school lunches:

Step 1: Get broad-based support with other parents and teachers! This is important, and probably the most time-consuming step. The more members of the community concerned about irradiation in school lunches, the better chance you will have of getting a moratorium passed with the school board.

Ways to gain support:

- Share information with family, neighbors, and friends (sample one-page background information enclosed)
- Talk with the local PTA and sharing information with them about irradiation.
- Have community members who support this moratorium sign a petition (sample enclosed.) A petition is a great way to get names that you can call to come to the school board meeting.
- Write a letter to the editor of your local paper about the problems with irradiation, your local effort, and how to become involved. (Be sure to include your contact information.)

Step 2: Once you have support behind you, determine the date of the next school board meeting and try to get on the agenda.

Step 3: Send background packets to all school board members before the meeting

Background packets should include:

- Top 10 Problems with Food Irradiation
- The Health Problems of Irradiated Food: What The Research Shows
- Irradiated Food in School Lunches
- Dr. Au Statement
- Broken Record Executive Summary
- Bad Taste Executive Summary

Step 4: Have two or three people present at the board meeting for 2-3 minutes each. Be sure to call the petitioners and ask them to attend the meeting. The more people present to show support, the better the results will be.

Topics presented should include:

- Background of food irradiation: Effect on Nutrients, Creation of New Chemicals,
- Meat Industry Trends
- Politics of Irradiation: Poor FDA Approval Process, Poor WHO Approval Process, Lack of long term studies
- Labeling: None required in schools!

Emphasize that parents have a right to know what their children are eating, and irradiated food does not have to be labeled in schools. Do not accuse the school of serving irradiated food to children. School boards may be very sensitive and it is more important to have them willing to work with you on this issue.

Step 5: Present a resolution (sample enclosed) and request a moratorium on the future use of irradiated food in the district.

Step 6: Be sure to keep in contact with the board keep up the pressure for follow through. Periodic appearances at meetings, petitions, and letters to the editor in local papers are all tools that can help you keep the issue on their agenda.

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Packet Contents

- Don't Let Your Child Eat Irradiate Food! (Parent outreach tool)
- Petition to District School Board (Parent/teacher/community outreach tool)
- Sample resolution to school board calling for a moratorium on irradiated food in the district
- Statement by Dr. William Au, toxicologist at the Department of Preventive Medicine and Community Health, University of Texas Medical Branch in Galveston
- Top 10 Problems with Food Irradiation
- The Health Problems of Irradiated Food: What The Research Shows
- Broken Record Executive Summary
- Bad Taste Executive Summary



Don't Let Your Child Eat Irradiated Food!

As the national debate about security expands to include our food system, some in the meat and food processing industries have taken the opportunity to promote a technology called *food irradiation* as a solution. The sale of irradiated food in supermarkets has been dismal, so the food irradiation industry has been looking to the government to bail it out. And now, through a provision in the most recent Farm Bill, they have accessed the National School Lunch Program as a way to stay in business.

There is an appalling lack of research into the long-term health effects experienced by children who are exposed to irradiated foods. Dr. William Au, a toxicologist at the Department of Preventive Medicine and Community Health, University of Texas Medical Branch in Galveston, has argued that “the scientific community and regulatory agencies have very little knowledge regarding how children respond to insult from toxic chemicals. These concerns also apply to toxicological risk with respect to eating irradiated food.”

Facts on Irradiation

- Irradiation exposes food to a dose of ionizing radiation that is equivalent to millions of chest x-rays.
- Irradiation disrupts the chemical composition of everything in its path – not just harmful bacteria. It creates chemicals called “unique radiolytic products” that do not occur naturally in food and that the FDA has never studied for safety.
- Research dating to the 1950s has revealed a wide range of problems in animals that ate irradiated food, including premature death, a rare form of cancer, stillbirths, genetic damage, organ malfunctions, low weight gain and vitamin deficiencies.
- In legalizing food irradiation, the US Food and Drug Administration (FDA) did not determine a level or radiation to which food can be exposed and still be safe for human consumption.
- Irradiation destroys vitamins, essential fatty acids and other nutrients in food.
- Irradiation masks and encourages filthy conditions in slaughterhouses and food processing plants.

Prevent Irradiated Food From Entering [DISTRICT NAME] School District!

Irradiated foods in schools *do not have to be labeled!* In addition, in the latest Farm Bill, the irradiation industry was granted the right to use the term “pasteurization” on their products. Teachers, parents, and children deserve the right-to-know what is being served in school cafeterias.

[GROUP NAME] will submit a resolution to the [DISTRICT NAME] School Board on [SCHOOL BOARD MEETING DATE] calling for a moratorium on irradiated food in the school district. *The school board needs to hear from parents that they don't want their children subjected to this questionable technology!* Help keep irradiated food out of school lunches by coming to the meeting, contacting the school board members and voicing your support for the moratorium, and/or signing a petition. Contact [GROUP NAME] to find out how you can get involved in this effort!

Using children as experimental subjects or to create a market for a technology that consumers don't want is irresponsible. In schools, the children's health should come first.

[GROUP NAME]
[CONTACT INFORMATION]

For more information on irradiation check out www.citizen.org/cmep/foodsafety
Or call 202-546-4996

A Resolution in Support of Keeping Food Safe for All Students

Submitted by: [Group or Individual Name]

WHEREAS: Each day, [DISTRICT NAME] school district students trust that the foods they eat in cafeterias are wholesome and safe; and

WHEREAS: The school board is charged with the responsibility of ensuring the safety of foods provided at schools within the [DISTRICT NAME] school district for human consumption; and

WHEREAS: Despite the fact that much of the research done on irradiated foods is over twenty years old and expressed the need for more long-term research on the unique radiolytic products created in irradiated food, current US laws regulating the production and retail of irradiated foods are still based on these studies and the FDA has never studied the long-term effects of consuming irradiated food; and

WHEREAS: Recent research in Germany, using more technologically advanced techniques and equipment, has led to the belief by many scientists, here and abroad, that irradiated foods are unsafe; and

WHEREAS: Current federal laws do not require irradiated foods served in schools to be labeled as such, and because schools are increasingly being targeted by the food irradiation industry through such programs as the National School Lunch Program, there is increasing likelihood that children may consume unsafe foods without their knowledge or the consent of their parents; and

WHEREAS: Current federal laws do not require certain irradiated food ingredients to be labeled, there is likelihood that the school district may be unknowingly purchasing irradiated foods.

FURTHER RESOLVED : The [DISTRICT NAME] school district shall not purchase any food products that can be reasonably believed to have been processed using any form of ionizing radiation (irradiation).

Susceptibility of children to environmental toxic substances

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Abstract

Our understanding of toxicity of environmental substances is based mainly on investigations using adult human populations and matured animals. Therefore, the scientific community and regulatory agencies have very little knowledge regarding how children respond to insult from toxic chemicals. However, certain scientific data indicate that children are more susceptible to toxic exposure than adults because they have proportionally more intake of food contaminants, active developmental processes, multiple exposure pathways and susceptible socio-behavioral activities. More emphasis should therefore be focused on addressing the information gap for improving the health of our children.

Introduction

Traditionally, our understanding of toxicity of environmental substances is based on human experience and from studies using experimental animals. The knowledge is therefore generated mainly from studies involving adult human populations (workers) or matured animals. As a result, protection and regulatory standards that are developed from these data are used universally for adults and children. However, concerns have been raised that there can be profound differences between children and adults from exposure to toxic substances. Chemical exposures during childhood or in utero could increase health problems such as cancer during childhood or later in life (National Research Council, 1993; Quang and Woolf, 2000). This concern is supported by the reported increases in rates of brain cancer in children and of testicular cancer in young adults (Charnley and Putzrath, 2001). It becomes clear that the regulatory policies that are developed based on observations in adults are not adequate in protecting children. This led to the signing of the executive order by former president Clinton, Protection of Children from Environmental Health Risk and Safety Risks (Executive Order, 1997). In response to the Executive Order, several regulatory and public health agencies have set up specific programs to address children's environmental health issues.

Health consequences from exposure to toxic chemicals

Numerous studies have been conducted to elucidate how toxic environmental chemicals induce cancer. Therefore, environmental cancer will be used as a model in this

commentary to provide a general explanation on the development of health problems from exposure to environmental toxicants.

Upon exposure to a chemical carcinogen, the chemical is absorbed, distributed and metabolized in various tissues and organs in the body. From the metabolic process, metabolites are produced which may be more reactive than the original chemical or may be inactive. Differences in an individual's ability to metabolize chemicals contribute significantly to variations in toxicological responses to hazardous chemicals. Many of these variations have recently been shown to be due to the inheritance of variant chemical metabolizing genes (Au et al., 2001). The toxicological effects may range from the expression of DNA damage, chromosome aberrations, gene mutation and perturbation of cell proliferation. These effects are known to be some of the initial events in the development of cancer (Greenblatt et al., 1994; Bonassi and Au, 2002).

Children specific activities

Children are more active than adults. As a result, they drink more water, breathe more air and eat more food per pound of body weight compared to adults. Therefore, they are proportionally exposed to more toxic chemicals from the environment and from materials they ingest than adults, making them susceptible to toxicants. Furthermore, children have unique activities and behavior that may increase their susceptibility. The hand-mouth behaviors of toddler put them at risk of ingestion of a variety of contaminated materials. Children are less aware of standard hygiene such as the avoidance of contaminated food and their dietary preferences may cause them to consume a proportionally large amount of a particular type of food. Children are less likely than adults in reading information labels on food products and warning labels. Children have their own social activities. Some activities may involve the consumption of large amount of certain dietary ingredient that can cause overt toxicity, leading to the need for emergency care. An example is the abuse of nutmeg, an aromatic chemical, by a 13-year-old female who ended up in an emergency room in New York (Sangalli and Chiang, 2000). Nutmeg is used as spice for food preparation and, based on conventional assessment, one would not expect the consumption of nutmeg is of health concern.

Age as a susceptibility factor

The embryos, fetuses and children undergo tremendous developmental changes and most of these changes are absent in the adult. These changes involve complex and integrated activities that lead to the expression of unique processes such as differentiation, organogenesis, morphogenesis, rapid and controlled cell division and developmental stage-specific gene activities. How these developmental changes alter children's response to toxicological insult in comparison to adult remains to be elucidated (Faustman et al., 2000). However, in some rare occasions, the age-dependent susceptibility phenomenon has been documented. The carcinogenic activity of diethylstilbestrol is a good example. The standard rodent cancer bioassay would not have predicted the in utero carcinogenic effects of this chemical. Other supportive evidence is from the cancer incidence among the Japanese atomic bomb survivors. The incidences

for leukemia and breast cancer are much higher for those who were exposed to the atomic bomb fall-out at a younger age than those at an older age (Upton, 1984). In the methyl isocyanate accident in Bhopal, India, children are disproportionately affected, as documented in increased seizures, coma and lethality (Mehta et al., 1990). Fetuses and children are much more sensitive to the toxicity of environmental toxicants than adults, as demonstrated in the Minamata Bay, Japan, methylmercury contamination problem (Powell, 1991; Koos and Longo, 1976). It should also be stated that, in some cases, children are less susceptible than the adults.

Contaminants in food can be accumulated in the mother and passed on to the embryos and fetuses via the placenta. In addition, infants are further exposed to the contaminants via the human milk. Certain man-made chemicals that have long-half lives, e.g. polychlorinated biphenyls and organochlorine pesticides, are present in higher concentrations in milk of mothers from industrialized countries than from under-developed countries (Przyrembel et al., 2000).

Physiological differences

Besides differences from adult in the intake of chemicals, physiological differences in the absorption of chemicals via the gastrointestinal track have been documented. For example, young children absorb approximately 50% of ingested lead compared to 10% among adults (Royce, 1992). Detoxification of hazardous chemicals is a critical event in the defense against their toxic effects. However, infants are deficient in such defense mechanism, as most chemical metabolizing enzyme activities evolve within a few days to weeks after birth (Linakis, 1998).

Conclusions

The scientific community and regulatory agencies have very little knowledge regarding how children respond to insult from toxic chemicals. However, certain scientific data indicate that children are more susceptible to toxic exposure than adults because they have proportionally more intake of food contaminants, active developmental processes, multiple exposure pathways and susceptible socio-behavioral activities. Therefore, a national committee has previously stated that “an uncertainty factor up to ten-fold ... be consider ... when data from toxicity testing relative to children are incomplete.” (National Research Council, 1993; Landrigan et al., 2001). The recommendation was adopted by the 1996 Food Quality Protection Act with respect to pesticides. In addition, test for prenatal developmental toxicity and the 2-generation reproductive study protocol are recommended for pesticides (Kimmel and Makris, 2001). The Executive Order in the US offers a tremendous stimulus towards a concerted effort in addressing children-specific susceptibility to environmental and ingested toxicants. Since developing countries have significantly more children in the populations than developed countries, the consideration of children susceptibility should be a global concern. These investigations may range from standard toxicological studies to molecular studies on genetic susceptibilities. The investigations should target exposure from environmental contamination and exposure through the food chain. From vigorous evaluation of the

toxicology of chemicals and understanding children's susceptibility, regulatory agencies will be able to set better guidelines for protecting children's health.

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National Research Council: Pesticides in the Diets of Infants and Children. Washington, DC: National Academy Press (1993).

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The Top 10 Problems With Irradiated Food

Food irradiation companies, food industry lobbying groups and even federal government officials have insisted for nearly a half-century that Americans who eat irradiated food have nothing to worry about. They say it's nutritious, safe, wholesome and tastes just like regular food. Here are 10 reasons why they're wrong.

1) In legalizing food irradiation, the U.S. Food and Drug Administration (FDA) did not determine a level of radiation to which food can be exposed and still be safe for human consumption, which federal law requires.^{1,2}

2) In legalizing food irradiation, the FDA relied on laboratory research that did not meet modern scientific protocols, which federal law requires.^{3,4}

3) Research dating to the 1950s has revealed a wide range of problems in animals that ate irradiated foods, including premature death, a rare form of cancer, stillbirths and other reproductive problems, genetic damage, organ malfunctions, stunted growth and vitamin deficiencies.^{5,6,7,8}

4) Irradiation masks and encourages filthy conditions in slaughterhouses and food processing plants.^{9,10} Irradiation can kill most bacteria in food, but it does nothing to remove the feces, urine, pus and vomit that often contaminates beef, pork, chicken and other meat.

5) Irradiation destroys vitamins, essential

fatty acids and other nutrients in food — sometimes significantly. The process destroys 80 percent of vitamin A in eggs and 48 percent of beta carotene in orange juice, but the FDA nonetheless legalized irradiation for these products.^{11,12}

6) Irradiation can change the flavor, odor and texture of food — sometimes disgustingly so. Pork can turn red; beef can smell like a wet dog; fruit and vegetables can become mushy; and eggs can lose their color and become runny.^{13,14,15}

7) Irradiation disrupts the chemical composition of everything in its path — not just harmful bacteria, which the food industry often asserts. Scores of new chemicals called “radiolytic products” are formed by irradiation — chemicals that do not naturally occur in food and that the FDA has never studied for safety. One such chemical, called 2-DCB, was recently found to promote the cancer-development process in rats, cause genetic damage in rats, and cause genetic and cellular damage in human and rat cells.^{16,17,18,19,20,21}

8) The World Health Organization did not follow its own recommendation to study the toxicity of “radiolytic products” formed in high-dose irradiated food before proposing in Nov. 2000 that the international irradiation dose limit — equal to 330 million chest x-rays — be removed.^{22,23}

9) Soon, some irradiation plants may use cesium-137, a highly radioactive waste material left over from the production of nuclear weapons. This material is dangerous and unstable. In 1988, a cesium-137 leak near Atlanta led to a \$40 million, taxpayer-funded cleanup.²⁴

10) Because it increases the shelf life of food and utilizes large, centralized facilities, irradiation encourages globalization and consolidation of the food production, distribution and retailing industries. These trends have already forced multitudes of family farmers and ranchers out of business, reduced the diversity of products in the marketplace, disrupted local economies in developing nations, and put American farmers and ranchers at a great economic disadvantage.²⁵

Notes

- ¹ U.S. Code of Federal Regulations, Title 21, § 170.22.
- ² Federal Register, various filings, 1983-2000.
- ³ U.S. Code of Federal Regulations, Title 21, § 170.20.
- ⁴ Federal Register, various filings, 1983-2000.
- ⁵ *A Broken Record: How the FDA Legalized — and Continues to Legalize — Food Irradiation Without Testing it for Safety*. Washington, D.C.: Public Citizen, Cancer Prevention Coalition, Global Resource Action Center for the Environment, Oct. 2000.
- ⁶ Kesavan, P.C., Swaminathan, M.S. “Cytotoxic and mutagenic effects of irradiated substrates and food material.” *Radiation Botany*, 11:253-181, 1971.
- ⁷ Schubert, J. “Mutagenicity and cytotoxicity of irradiated foods and food components.” *Bulletin of the World Health Organization*, 41:873-904, 1969.
- ⁸ Spiher, A.T. “Food Irradiation: An FDA Report.” *FDA Papers*, Oct. 1968.
- ⁹ Nestor, F. and Hauter, W. *The Jungle 2000: Is America's Meat Fit to Eat?* Washington, D.C.: Government Accountability Project, Public Citizen, Sept. 2000.
- ¹⁰ Piccioni, R. “Food irradiation: Contaminating our food.” *The Ecologist*, 18:2:48-55.

- ¹¹ FDA Memorandum, from Kim Morehouse, Ph.D. to William Trotter, Ph.D. April 11, 2000.
- ¹² FDA Memorandum, from Antonio Mattia, Ph.D. to William Trotter, Ph.D. Nov. 2, 1999.
- ¹³ Webb, T. et al. *Food Irradiation: Who Wants It?* Rochester, Vermont: Thorsons Publishers, 1987.
- ¹⁴ Huang, S. et al. “Effect of electron beam irradiation on physical, physicochemical and functional properties of liquid egg during frozen storage.” *Poultry Science*, 76:1607-15, 1997.
- ¹⁵ Wong, Y.C. et al. “Comparison between irradiated and thermally pasteurized liquid egg white on functional, physical and microbiological properties.” *Poultry Science*, 75:803-808, 1996.
- ¹⁶ Murray, D. *Biology of Food Irradiation*. Somerset, England: Research Studies Press Ltd., 1990.
- ¹⁷ Op. cit. Note 5.
- ¹⁸ Delincee, H. and Pool-Zobel, B. Genotoxic properties of 2-dodecylcyclobutanone, a compound formed on irradiation of food containing fat. *Radiation Physics and Chemistry*, 52: 39-42, 1998.
- ¹⁹ Delincee, H. et al. Genotoxicity of 2-dodecylcyclobutanone. Food Irradiation: Fifth German Conference, Karlsruhe, November 11-13, 1998.
- ²⁰ Delincée, H. et al. “Genotoxicity of 2-alkylcyclobutanones, markers for an irradiation treatment in fat-containing food.” (Abstract) Presented at the 12th International Meeting on Radiation Processing, March 25-30, 2001, Avignon, France.
- ²¹ “Information about the toxicity of 2-alkylcyclobutanones, a group of substances exclusively formed upon irradiation of food containing fat.” International Consultative Group on Food Irradiation.
- ²² *International Consultative Group on Food Irradiation: Review of Data on High Dose (10-70 kGy) Irradiation of Food*. Report of a Consultation, Karlsruhe, 29 August - 2 September 1994. Geneva: World Health Organization, 1994.
- ²³ *High-Dose Irradiation: Wholesomeness of Food Irradiated with Doses Above 10 kGy*. Report of a Joint FAO/IAEA/WHO Study Group. Technical Report Series 890. Geneva: World Health Organization, 1999.
- ²⁴ “Last radioactive capsules taken from DeKalb plant.” *Macon Telegraph*, Nov. 20, 1990.
- ²⁵ *A Citizen's Guide to Fighting Food Irradiation*. Washington, D.C.: Public Citizen's Critical Mass Energy and Environment Program, 2000.



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The Health Problems of Irradiated Foods: What the Research Shows

In the course of legalizing the irradiation of beef, chicken, pork, fruit, vegetables, eggs, juice, spices and sprouting seeds – a process that has spanned nearly 20 years – the U.S. Food and Drug Administration has dismissed and ignored a substantial and growing body of evidence suggesting that irradiated foods may not be safe for human consumption. The following is a sampling of research – much of which was funded by government agencies and performed at major universities – that raise questions about the FDA's assertion that people who eat irradiated foods have nothing to worry about.

Health Problems in Humans [I]

Fifteen children suffering from severe protein-calorie malnutrition...receiving freshly irradiated wheat developed polyploid cells and certain abnormal cells in increasing number as the duration of feeding increased... Though the biological significance of polyploidy is not clear, its association with malignancy makes it imperative that the wholesomeness of irradiated wheat for human consumption be very carefully assessed.

- Bhaskaram, C., and G. Sadasivan. "Effects of feeding irradiated wheat to malnourished children." *Amer Journ Clin Nutr*, 28:130-135, 1975.

Health Problems in Humans [II]

[After eating gamma-irradiated potatoes for 14 weeks], it was evident that the haemoglobin values were significantly higher *during* the period than *before*. The values were also significantly higher *during* than *after*. An additional comparison of the values *before* with the values *after* shows that a small effect still remains.

- Jaarma, Maire. "Studies of chemical and enzymatical changes in potato tubers and some higher plants caused by ionizing radiation, including studies on the wholesomeness of γ -irradiated potato tubers and effects on some carbohydrates *in vitro*." Biokemiska institutionen, Kungl. Universitetet i Stockholm, 1967.

Health Problems in Humans [III]

Ten young men served as test subjects for this study, [and were fed] pork loin which had been ground ... and subjected to gamma radiation... It is apparent...that there may very well be differences in the digestibility of the foodstuffs from irradiated or non-irradiated meat, and in the ability of protein in irradiated or non-irradiated meat to maintain nitrogen balance.

- Plough, I.C. et al. "An evaluation in human beings of the acceptability, digestibility and toxicity of pork sterilized by gamma radiation and stored at room temperature." U.S. Army Medical Nutrition Laboratory, Fitzsimons Army Hospital, Denver. Report No. 204, May 1957.

Health Problems in Humans [IV]

Thirteen young men served as test subjects, [and were fed] an irradiated food diet...of 8 different food items... The excretion of indophenol-reducing substances was significantly higher ($p < .005$) during the irradiated food periods... Irradiation decreased the thiamine and ascorbic acid content and increased the "browning reaction" derivatives, fat soluble carbonyl compounds, and thiobarbituric acid reactants.

- Bierman, E.D. et al. "Short-term human feeding studies of foods sterilized by gamma radiation and stored at room temperature." U.S. Army Medical Nutrition Laboratory, Fitzsimons Army Hospital, Denver. Report No. 224, July 1958.

Chromosomal Aberrations in Human Blood Cells [I]

Irradiated sucrose solutions...were extremely toxic to human lymphocytes. Mitoses were inhibited... Degenerated mitoses were observed and the chromosomes were grossly damaged. The chromatin [DNA] material was clumped or the chromosomes appeared shattered or pulverized... In contrast, treatment with unirradiated sucrose at the same concentration had no apparent effect on the mitotic rate and the chromosomes were not visibly damaged.

- Shaw, M.W. and Hayes, E. "Effects of irradiated sucrose on the chromosomes of human lymphocytes in vitro." *Nature*, 211:1254-1255, 1966.

Chromosomal Aberrations in Human Blood Cells [II]

Leukocyte cultures from four different healthy human males [underwent] a considerable inhibition of mitosis and chromosome fragmentation. [Additional] research would be extremely prudent.

- Kesavan, P.C. and Swaminathan, M.S. "Cytotoxic and radiomimetic activity of irradiated culture medium on human leukocytes." *Current Science*, 16:403-404, 1966.

A Summary of Problems

Numerous studies have been carried out to ascertain whether cytotoxic effects occur when unirradiated biological test systems are cultured or fed with irradiated media or food. In such studies, adverse physiological (growth retardation and inhibition), cytological (mitotic inhibition and chromosome aberrations) and genetical effects (forward and reverse mutations) have been observed in a wide range of test systems, ranging from bacteriophages to human cells... The available data suggest that [a variety of free radicals] may act as the toxic and mutagenic agents.

- Kesavan, P.C. and Swaminathan, M.S. "Cytotoxic and mutagenic effects of irradiated substrates and food material." *Radiation Botany*, 11:253-281, 1971.

A Thalidomide Warning [I]

The thalidomide disaster might have been prevented if an easily performed investigation of possible cytotoxic effects in plant cells had been made. It must be acknowledged that any compound causing [cellular] damage must be considered a potential hazard to any living cell or cell system – including man.

- Lofroth, G. "Toxic effects of irradiated foods." *Nature*, 211:302, 1966.

A Thalidomide Warning [II]

Irradiating can bring about chemical transformations in food and food components resulting in the formation of potential mutagens, particularly hydrogen peroxide and various organic peroxides... It is now realized, especially since the thalidomide episode, that [older testing] protocols do not detect the more subtle population hazards such as mutagens and teratogens... In view of the serious consequences to the human population which could arise from a high level of induced mutations, it is desirable that protocols for irradiated food should include in *vivo tests* on mammals for possible mutagenicity.

- Schubert, J. "Mutagenicity and cytotoxicity of irradiated foods and food components." *Bulletin of the World Health Organization*, 41:873-904, 1969. (Co-sponsored by the U.S. Atomic Energy Commission and Food and Drug Administration)

A Cancer Warning

An increase in concentration of a mutagen in food by irradiation will increase the incidence of cancer... It will take four to six decades to demonstrate a statistically significant increase in cancer due to mutagens introduced into food by irradiation... When food irradiation is finally prohibited, several decades worth of people with increased cancer incidence will be in the pipeline.

- Tritsch, G.L. "Food Irradiation." *Nutrition*, 16:698-701, 2000.

Unique, Toxic Chemicals Formed in Irradiated Food Containing Fat [I]

When food containing fat is treated by ionizing radiation, a group of 2-alkylcyclobutanones is formed... To date, there is no evidence that the cyclobutanones occur in unirradiated food... *In vitro* experiments using rat and human colon cells indicate that 2-dodecylcyclobutanone (2-DCB)...is clearly cytotoxic and genotoxic... [M]ore experiments than these preliminary ones are required.

- Delincee, H. and Pool-Zobel, B. "Genotoxic properties of 2-dodecylcyclobutanone, a compound formed on irradiation of food containing fat." *Radiation Physics and Chemistry*, 52:39-42, 1998. (Co-sponsored by the International Consultative Group on Food Irradiation.)

Unique, Toxic Chemicals Formed in Irradiated Food Containing Fat [II]

In this study, *in vivo* experiments were conducted on rats, which received two different doses of 2-DCB by way of pharyngeal probe... Slight but significant DNA damage was observed in the experimental group that received the higher concentration of 2-DCB (14.9 mg/kg body weight). Further studies are needed to clarify the relevance of these results to an evaluation of risk from the consumption of irradiated foods.

- Delincée, H. et al. "Genotoxicity of 2-dodecylcyclobutanone." Food Irradiation: Fifth German Conference, Report BFE-R-99-01, Federal Nutrition Research Institute, Karlsruhe, Germany, 1998.

Unique, Toxic Chemicals Formed in Irradiated Food Containing Fat [III]

To date, there is no evidence that 2-alkylcyclobutanones [2-ACB's] occur in unirradiated food, and therefore, it is advisable to determine the toxicological potential... [Human colon tumor cells were incubated with 2-tetradecylcyclobutanone, one particular ACB.] After prolonged incubation times, (1-2 days) at higher concentrations (>50iM), cytotoxicity did appear.

- Delincée, H. et al. "Genotoxicity of 2-alkylcyclobutanones, markers for an irradiation treatment in fat-containing food – Part I: Cyto- and genotoxic potential of 2- tetradecylcyclobutanone." *Radiation Physics and Chemistry*, 63:431-435, 2002.

Unique, Toxic Chemicals Formed in Irradiated Food Containing Fat [IV]

[U]sing an experimental colon carcinogenesis model in rats, 2-ACB's [2-alkylcyclobutanones], when tested at a high concentration, potentiate the effect of an inducing carcinogen on the long term. This was revealed by the increase of colonic neoplastic lesions and the development of a higher number of colon tumours with larger size... This suggests that, in this experiment, 2-ACB's, although they do not induce carcinogenesis, *per se*, rather promote the colonic carcinogenesis process. Finally, it was shown that small fractions of 2-ACB's had been stored in rat adipose tissues and excreted in faeces of the treated rats. This indicates that most of the 2-ACB's is metabolically transformed or stored in other organs...[I]n our opinion further investigations...will help to elucidate a possible risk associated with the consumption of irradiated fat-containing foods.

- Marchioni, E. et al. "Toxicological study to assess the risk associated with consumption of irradiated fat-containing food." (Summary) International Consultative Group on Food Irradiation, Dec. 2001.

Radioactivity in Organs and Excrement of Rats

Considerable amounts of radioactivity were present in the liver, kidney, stomach, gastrointestinal tract, and blood serum of rats [fed irradiated sucrose solutions]... Radioactivity was present in urine and feces samples.

- De, A.K. et al. "Biochemical effects of irradiated sucrose solutions in the rat." *Radiation Research*, 37:202-215, 1969.

Fatal Internal Bleeding in Rats [I]

A significant number of rats consuming irradiated beef died from internal hemorrhage within 46 days, the first death of a male rat coming on the 11th day of feeding. This rat became sluggish on the 8th day of the regimen and started refusing food. He continued [to be] morbid during the next two days, did not eat any food, lost weight and appeared anemic. He was found dead on the 11th day. Post-mortem examination showed hemothorax, the blood had not clotted; there was bleeding also in the epididymis.

- Metta, V.C. et al. "Vitamin K deficiency in rats induced by feeding of irradiated beef." *Journal of Nutrition*, 69:18-21, 1959. (Co-sponsored by the Surgeon General of the U.S. Army)

Fatal Internal Bleeding in Rats [II]

Hemorrhagic death had occurred in all males fed irradiated diets by day 34... There is evidence to suggest that inefficient absorption of vitamins, i.e. vitamin K, from the intestinal tract may contribute to a deficiency state.

- Mellette, S.J. and Leone, L.A. "Influence of age, sex, strain of rat and fat soluble vitamins on hemorrhagic syndromes in rats fed irradiated beef." *Federation Proceedings*, 19:1045-1048, 1960. (Co-sponsored by the Surgeon General of the U.S. Army)

Fatal Vitamin E Deficiency in Rats

A considerable number of the second litter of the experimental group [of rats that ate irradiated beef] died... Symptoms observed were marked edema of the face, ruffled hair coat, general incoordination, spastic hopping gait, and sometimes complete loss of movement with dragging of the hind quarters. Those pups most severely affected often became completely prostrated a short time before death... In no case were these symptoms

noted in the control group... The probability [is that the pups] were suffering from the characteristic muscular dystrophy syndrome (commonly referred to as nutritional muscular dystrophy) known to result from a marginal vitamin E intake.

- Poling, C.E. et al. "Growth, reproduction, survival and histopathology of rats fed beef irradiated with electrons." *Food Res*, 20:193-214, 1955.

Prenatal Deaths in Mice [I]

Freshly irradiated diets produced elevated levels of early deaths in [mice fetuses]... The increase in early deaths would suggest that the diet when irradiated has some mutagenic potential.

- Anderson, D. et al. "Irradiated laboratory animal diets: Dominant lethal studies in the mouse." *Mutation Research*, 80:333-345, 1981.

Prenatal Deaths in Mice [II]

Feeding of mice for two months before mating with 50 percent of the standard complete diet irradiated with [gamma rays] provokes a significant increase of embryonal deaths,... probably to be interpreted as a dominant lethal mutation associated with gross chromosomal aberrations, such as breaks repeatedly found to be induced by irradiated materials.

- Moutschen-Dahmen, M. et al. "Pre-implantation death of mouse eggs caused by irradiated food." *Inter Journ Rad Biol*, 18:201-216, 1970.

Chromosomal Aberrations in Monkeys

The increased incidence of cells with numerical aberrations in animals which received a diet containing freshly irradiated wheat...must be considered significant.... Also, the disappearance of these cells, following the replacement of freshly irradiated wheat with unirradiated wheat, clearly indicates that the appearance of the abnormal cells was due to the ingestion of freshly irradiated wheat.

- Vijayalaxmi. "Cytogenetic studies in monkeys fed irradiated wheat." *Toxicology* 9:181-184, 1978.

Chromosomal Aberrations and Blood Disorder in Rats; Mutations in Mice

[A]n increase of chromosomal aberrations which was significant at the 5 percent level [was observed]... [Later experiments] demonstrated beyond a doubt that this effect is real, and running experiments also indicate an increase of intrauterine foetal death, possibly dominant lethal mutations in the mouse... [A] 15-20 percent decrease of the absolute lymphocyte numbers in the peripheral blood of the rat [was observed]... [T]he lymphopenia produced by irradiated food increased with increasing age of the rats.

- Lofroth, G. et al. "Biological effects of irradiated food. II: Chemical and biological studies of compounds distilled from irradiated food." *Arkiv. Zool.* 18:529-547, 1966.

Chromosomal Aberrations in Mice

Feeding of freshly irradiated wheat resulted in significantly increased incidence of polyploidy cells in bone marrow, aneuploid cells in testis, reduction in number of spermatogonia...as well as a higher mutagenic index... [S]ome toxic substance(s) may be formed during irradiation.

- Vijayalaxmi. "Genetic effects of feeding irradiated wheat to mice." *Canadian Journal of Genetics and Cytology*, 18:231-238, 1976.

Chromosomal Aberrations in Rats

Feeding irradiated wheat to rats was associated with an increase in the number of polyploid cells in the bone-marrow... Irrespective of the protein content in the diet, animals which received irradiated wheat had polyploid cells in their bone-marrow.

- Vijayalaxmi and G. Sadasivan. "Chromosomal aberrations in rats fed irradiated wheat." *Inter Journ Rad Biol*, 27:135-142, 1975.

Chromosomal Aberrations in Hamsters

The proportion of [bone marrow] cells with polyploidy increased between 4 to 5 times the control level... When feeding of the irradiated diet stopped, the proportion of polyploid cells returned to the control level.

- Renner, H.W. "Chromosome studies on bone marrow cells of chinese hamsters fed a radiosterilized diet." *Toxicology*, 8:213-222, 1977.

Genetic Damage in Rats

Well-fed rats, when switched over to a diet of irradiated wheat, showed a higher mutagenic index than those given unirradiated wheat.

- Vijayalaxmi and K.V. Rao. "Dominant lethal mutations in rats fed on irradiated wheat." *Inter Journ Rad Biol*, 29:93-98, 1976.

Immune Dysfunction in Rats

Rats given diets containing freshly irradiated wheat showed significantly lower mean antibody titres to four different antigens, decreased numbers of antibody-forming cells in the spleen and rosette-forming lymphocytes... [T]he consumption of irradiated wheat is associated with changes in the immune status of the animal.

- Vijayalaxmi. "Immune response in rats given irradiated wheat." *British Journal of Nutrition*, 40:535-541, 1978.

Immune Dysfunction in Hamsters

The irradiated fish diet has apparently caused an even greater immunological response than unirradiated fish... [T]he possibility of a mutagen remaining undetected must be considered.

- Renner, H.W. et al. "An investigation of the genetic toxicology of irradiated foodstuffs using short-term test systems. III – *In vivo* tests in small rodents and in *Drosophila melanogaster*." *Food Chemistry and Toxicology*, 20:867-878, 1982.

Reproductive Dysfunction, Cancer, Stunted Growth in Mammals

A careful analysis by FDA of all [Army] data present (including 31 looseleaf notebooks of animal feeding test results) showed significant adverse effects produced in animals fed irradiated food... What were these adverse effects?... A decrease of 20.7 percent in surviving weaned rats... A 32.3 percent decrease in surviving progeny of dogs... Dogs weighing 11.3 percent less than animals on the control diets... Carcinomas of the pituitary gland, a particularly disturbing finding since this is an extremely rare type of malignant tumor.

- Spiher, A.T. "Food irradiation: An FDA report." *FDA Papers*, Oct. 1968.

Reproductive Dysfunction in Rats [I]

Very high losses of litter in the [first] and [second] generations [80 and 85 percent, respectively] in spite of a high fertility rate and normal size of litter in all dietary groups caused at first great difficulty. The suspicion that the animals had obtained too little vitamin E was certified correct.

- Reichelt, D. et al. "Long-term animal feeding study for testing the wholesomeness of an irradiated diet with a high content of free radicals." Federal Research Institute for Food Preservation, Institute for Radiation Technology, Karlsruhe, Germany, 1972.

Reproductive Dysfunction in Rats [II]

An impairment in the fertility of the male and an increased mortality in litters, which [researchers] believed was due to vitamin E destruction.

- DaCosta, E. and Levenson, S.M. "Effect of diet exposed to capacitron irradiation on the growth and fertility of the albino rat." U.S. Army Medical Nutrition Laboratory, Fitzsimons Army Hospital, Denver. Report No. 89, 1951. Cited in Kraybill, H.F. and Huber, T.E. "The wholesomeness of irradiated food and its military implications." Paper to be presented at 63rd Annual Convention, Association of Military Surgeons, United States of America, Hotel Statler, Washington, D.C., Nov. 12-14, 1956.

Reproductive Dysfunction in Mice [I]

Cytogenic examinations of the developing spermatogonia in 30 mice of each group revealed that cytogenetic abnormalities were significantly more frequent in the group fed irradiated flour than in the control group... [T]he incidence of litters [with non-viable offspring] was significantly higher in the group fed irradiated flour... [O]n the average the losses [of young mice] were about 35% higher in the test group than in the controls. The life span of mice fed irradiated flour was slightly shorter than in the control mice.

- Bugyaki, L., A.R. Deschreider, J. Moutschen, M. Moutschen-Dahmen, A. Thijs, and A. Lafontaine. "Do irradiated foodstuffs have a radiomimetic effect? II. Trials with mice fed wheat meal irradiated at 5 Mrad." *Atompraxis* 14:112-118, 1968.

Reproductive Dysfunction in Mice [II]

The mice raised on the irradiated diet exhibited some impairment in lactational performance.

- Luckey, T.D. et al. "Nutritional adequacy of a semi-synthetic diet sterilized by steam or cathode rays." *Food Research*, 20(2):180, 1955. Cited in Kraybill, H.F. "Problems in food processing by ionizing radiations with special reference to wholesomeness studies on irradiated foods." Paper to be presented at Fifth Annual Conference sponsored by Pennsylvania Public Health Association, Pennsylvania Health Council, Medical Society of Pennsylvania, Pennsylvania Department of Health, held at Pennsylvania State University, University Park, Pennsylvania, August 21, 1956.

Reproductive Dysfunction in Fruit Flies

The production of *Drosophila* offspring in cultures containing gamma irradiated chicken meat was much lower... The production...was not increased by changing the basal medium or by adding a vitamin supplement.

- Raltech Scientific Services Inc., Madison, Wisconsin. "Final Report: Evaluation of the mutagenicity of irradiated sterilized chicken by the sex-linked recessive lethal test in *Drosophila melanogaster*." Contract DAMD 17-76-C-6047, submitted to U.S. Army Medical Research and Development Command, Fort Detrick, Frederick, Maryland. June 15, 1979.

Mutations in Fruit Flies [I]

An increase in the rate of mutation has been found in *Drosophila melanogaster* reared on a basic medium that was irradiated with a sterilizing dose (150,000 rads) of cobalt-60 gamma rays... Visible changes were two to six times more frequent in the irradiated series than in the controls,...[such as] half-thorax, vestigial wings and incurved wings.

- Swaminathan, M.S. et al. "Mutations: Incidence in *Drosophila melanogaster* reared on irradiated medium." *Science*, 141:637-638, 1963.

Mutations in Fruit Flies [II]

[S]everal experimental variables in culture medium may be associated with increased mutation frequencies in *Drosophila*; namely irradiated whole food... The increased mutation frequencies associated with flies cultured on aged food implies that the [toxic products] are long lived.

- Rinehart, R.R. and Ratty, F.J. "Mutation in *Drosophila melanogaster* cultured on irradiated whole food or food components." *Intern Journ Rad Biol*, 12(4):347-354, 1967.

Mutations in Fruit Flies [III]

There was an approximate twofold increase in sex-linked recessive lethality [in *Drosophila melanogaster* cultured in irradiated medium]. This increase can be attributed largely to an increase in gonial mutants.

- Rinehart, R.R. and Ratty, F.J. "Mutation in *Drosophila melanogaster* cultured on irradiated food." *Genetics*, 52(6):1119-1126, 1965.

Mutations in Fruit Flies [IV]

[A] small but constant increase in sex-linked and autosomal recessive lethal frequencies [was observed in *Drosophila melanogaster* cultured in irradiated medium]... A linear relationship of dose and effect was obtained with regard to dominant lethals.

- Kesavan, P.C. and Swaminathan, M.S. "Mutagenic effects of irradiated culture media in *Drosophila melanogaster*." *Indian Journal of Genetics*, 29:173-183, 1969. Cited in Kesavan, P.C. and Swaminathan, M.S. "Cytotoxic and mutagenic effects of irradiated substrates and food material." *Radiation Botany*, 11:253-281, 1971.

Stunted Growth of Rats

In general, the irradiated foods produced a depressed growth rate... The effect of the radiation variable is significant... Higher intake coupled with the lower growth rates of rats on the rations containing irradiated carrots resulted in a lower [food] efficiency.

- Tinsley, I.J. et al. "The growth, reproduction, longevity, and histopathology of rats fed gamma-irradiated carrots." *Toxicology and Applied Pharmacology*, 16:306-317, 1970.

Mutations in Salmonella

Groups of Swiss albino mice (SPF) fed with normal and gamma-irradiated food at doses of 0.75, 1.5, and 3.0 Mrad, were injected intraperitoneally with *Salmonella typhimurium* TA 1530 for the host mediated assay test of mutagenesis. The results indicate that there is a significant increase in mutation frequency induced by the 3 Mrad sterilized food.

- Johnston-Arthur T., M. Brena-Valle, K. Turanitz, R. Hruby, and G. Stehlik. "Mutagenicity of irradiated food in the host mediated assay system." *Studia Biophysica*, (Berlin), 50:137-141, 1975.



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A Broken Record

**How the FDA Legalized $\frac{3}{4}$
and Continues to Legalize $\frac{3}{4}$
Food Irradiation Without
Testing it for Safety**

A special report by

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

The Cancer Prevention Coalition

and

Global Resource Action Center for the Environment

October 2000

Executive Summary

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

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

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

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

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

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

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

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

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

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

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

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

Food Irradiation: Roots and Reasons

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

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

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

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

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

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

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

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

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

New Chemicals Never Studied

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

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

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

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

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

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

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

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

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

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

Flaws in the FDA's Key Studies

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

Then-FDA Commissioner Frank Young wrote in the *Federal Register* that five studies endorsed by the agency's blue-ribbon Irradiated Foods Task Group (IFTG) “were considered by agency reviewers to be properly conducted, fully adequate by 1980 toxicological standards, and able to stand alone in the support of safety. The reports of these...studies indicate no adverse effects from the irradiated foods fed to test animals.”²¹

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

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

? None of the seven studies met the FDA's own testing protocols that the agency must follow to determine the safety of food additives; (*See Appendix IV.*)

? Some of the seven studies actually suggest irradiated food may not be safe for human consumption. In two of the studies, researchers added vitamin E and other nutrients for the specific purpose of reversing the harmful effects of consuming irradiated food; and

? Three of the seven studies were written in French, of which FDA officials possess no English translations. (Public Citizen translated the studies for the purposes of this report.)

Perhaps most alarming, none of the seven FDA studies included short-term experiments to gauge the carcinogenic and mutagenic potential of irradiated food. This failure is of notable concern in light of research presented to Congress in 1968 (some of which was funded by the government) that revealed severe chromosomal damage to human white blood cells;²² a doubling of mutations in fruit flies;²³ and “significantly” impaired cell division of plants grown in an irradiated environment.²⁴

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

Major FDA Rulings Based on ‘Deficient’ Science

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

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

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

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

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

In 1990, the FDA relied on 10 “deficient” studies in legalizing the irradiation of poultry.³⁰ Among them was a “deficient” Canadian study that lacked certain histopathological examinations, leading an FDA staffer to write in an internal memo that “there is a fair to good chance” of tumors going undiscovered when only cursory exams are performed.³¹ Marking the first such occurrence, internal FDA memos reveal that staff members raised concerns about the “deficient” studies, but did nothing to keep them from being used to legalize the irradiation of poultry. (See *Appendix V*, studies #218, #265, #353.)

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

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

Congress Not Given the Whole Truth

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

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

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

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

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

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

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

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

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

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

The Present

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

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

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

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

? Last year, the FDA received petitions from Caudill Seed Co. to legalize the irradiation of alfalfa and other sprouting seeds,⁴⁷ and from the National Fisheries Institute and Louisiana Agriculture and Forestry Department to irradiate shellfish.⁴⁸

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

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

Our Recommendations

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

(1) Revoke all food irradiation permits issued by the FDA since 1983.

(2) Establish a joint committee with the U.S. Department of Agriculture to encourage the implementation of sustainable farming, ranching, and food production and transportation practices that will reduce the incidence of food-borne disease—including but not limited to slowing down slaughterlines and restoring the integrity of carcass-by-carcass meat inspection.

(3) Conduct an Inspector General's investigation of the FDA's role in regulating food irradiation since the FDA revoked the Army's permit to irradiate bacon on August 15, 1968.

(4) Forestall, until the completion of (5) through (8), the approval of all petitions and proposed rules related to food irradiation.

(5) Appoint an independent panel—comprised of no members who have had involvement with the FDA's food irradiation program—to oversee a testing regime in accordance with the current scientific protocols.

(6) Appoint an independent panel—comprised of no members who have had involvement with the FDA's food irradiation program—to investigate the agency's role in regulating food irradiation since the FDA revoked the Army's permit to irradiate bacon on August 15, 1968.

(7) Compile a complete index of all organizations and facilities engaged in the practice of food irradiation in the United States, including the types and quantities of food that have been irradiated since the organizations and facilities began operation.

(8) Compile a complete index of all groups and facilities engaged in the production, distribution, transportation, marketing, wholesaling and/or retailing of irradiated food in the U.S.

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

BAD TASTE



THE DISTURBING TRUTH ABOUT
THE WORLD HEALTH ORGANIZATION'S
ENDORSEMENT OF FOOD IRRADIATION

EXECUTIVE SUMMARY

WHO, IAEA and FAO officials
falsely stated in 1980:

“All the
toxicological studies
have produced
no evidence of
adverse effects
as a result of
irradiation.”

BAD TASTE

THE DISTURBING TRUTH ABOUT THE WORLD HEALTH ORGANIZATION'S ENDORSEMENT OF FOOD IRRADIATION

A special report by **Public Citizen and GRACE**

October 2002

Prepared by Mark Worth

Executive Summary

This document can be viewed or downloaded at
www.citizen.org/cmep or www.gracelinks.org/nuke/food



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



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GRACE works to form new links with the research, policy and grassroots communities to preserve the future of the planet and protect the quality of the environment.

“Any word or statement
containing the
word ‘radiation’ or
‘radiate’ would **inspire**
fear of a nonexistent
danger and therefore
will cause the
product to be
avoided.”

– International Atomic Energy Agency
consultant, 1982

Executive Summary

THE WORLD HEALTH ORGANIZATION is the most important and influential agency of its kind on the planet. Created in 1948 by the United Nations, the WHO pursues a mission nothing short of preserving the health of the Earth's population – “a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity.”¹

Headquartered in Geneva, the WHO has grown from 61 member nations at its founding to 193 today, from Algeria to Zimbabwe. Its more than 100 initiatives encompass virtually every health problem imaginable, from anthrax and adolescent reproductive health, to vitamin A deficiency and violence against women.²

When the WHO speaks, the world listens.

In 1999, the WHO announced that any food could be “treated” with ionizing radiation and still be safe for human consumption. Even though this radiation – in the form of gamma rays emanating from radioactive cobalt-60 or cesium-137, or near-speed-of-light electrons fired by linear accelerators – could be as high as the equivalent of several billion chest x-rays, a WHO report proclaimed that irradiating food “does not result in any toxicological hazard.”³

WITH IRRADIATION'S PROMISE of killing *E. coli*, *Salmonella*, *Listeria* and other food-borne pathogens; neutralizing fruit flies, mango seed weevils and other exotic pests; and delaying the spoilage of meat, fruit and vegetables, this proclamation holds the potential to dramatically alter the way food is produced, distributed and sold around the globe. As far as the world's food supply is concerned, the proclamation is one of the most significant in recent memory.

In the process of assessing the safety and wholesomeness of irradiated foods, did

the World Health Organization fulfill its mission to preserve the health of the Earth's population?

How could irradiated foods be declared safe and wholesome if animals fed irradiated foods in experiments dating back 50 years have suffered dozens of health problems, including premature death, mutations and other genetic abnormalities, fetal death and other reproductive problems, immune system disorders, fatal internal bleeding, organ damage, tumors, stunted growth and nutritional deficiencies?^{3a}

Has the WHO's assessment been made independent of efforts to further the legalization, commercialization and consumer acceptance of irradiated foods?

Has the WHO's analysis been uncorrupted by efforts to resuscitate the nuclear industry – an analysis that could have been tainted by an agreement giving the IAEA the ultimate control over nuclear research?

THESE QUESTIONS YIELD disturbing answers – answers that challenge the reliability of the WHO's stamp of approval. An in-depth review of the WHO's 40-plus-year involvement in assessing whether irradiated foods are safe for human consumption reveals the following:

- The WHO has played a role in abandoning the original research agenda that it co-drafted in 1961, which urged that a wide range of experiments be conducted into the safety and wholesomeness of irradiated foods. These experiments, the drafters wrote, should analyze whether irradiated foods are toxic or radioactive; whether they could cause cancer or nutritional deficiencies; or whether the scientific expertise even existed to answer these fundamental questions. Most of the items on this research agenda were not followed up in key WHO reports.

- The WHO has ceded an inordinate amount of authority to the International Atomic Energy Agency, going so far as to hand the IAEA the ultimate power to research the safety of irradiated foods. The IAEA – whose mission is preserving the nuclear industry, not the health of people – has exercised this power to a significant extent. The IAEA has published 19 of the 29 major international reports on food irradiation since 1962, and all but four of the reports issued during the formative period from 1973 to 1993. These later

reports led to the proclamation that any food could safely be irradiated at any dose.

- With the WHO assuming a backseat role, the IAEA is leading a campaign to further the legalization, commercialization and consumer acceptance of irradiated foods worldwide. Toward accomplishing this goal, the IAEA has published all eight of the major international reports related to these issues. One IAEA publication states: “We must confer with experts in the various fields of advertising and psychology to put the public at ease... Any word or statement containing the word ‘radiation’ or ‘radiate’...will cause the product to be avoided...and should not be required on the label.”⁴

- The WHO has played a role in dismissing and misrepresenting evidence suggesting that irradiated foods may not be safe for human consumption. The WHO, along with the IAEA and the United Nations' Food and Agriculture Organization (FAO), took research that revealed health problems in animals that ate irradiated foods, and stated that the research actually revealed no health problems that could be attributed to irradiation. Moreover, some research that the WHO, IAEA and FAO initially claimed yielded adverse effects were later omitted from key reports.

- The WHO has played a role in dismissing recent evidence that unique chemical byproducts formed in irradiated foods – cyclobutanones – promoted the cancer-forming process in rats, caused the development of tumors and lesions in rats, and caused genetic damage in rats and in human cells. Cyclobutanones have never been found to occur naturally in any food. Furthermore, a prominent U.S. Army researcher falsely stated in a 1989 IAEA publication that no such unique chemicals have ever been detected in irradiated foods.

Despite efforts to downplay the potential hazards of cyclobutanones, the European Union and the Codex Alimentarius Commission (which sets food-safety standards for more than 160 nations) have delayed proposals to expand food irradiation. At this writing, the EU is conducting a formal inquiry into the potential hazards of cyclobutanones.

A full airing of these shortcomings and swift actions to remedy them are needed to help ensure that the increasing proliferation of irradiated foods throughout the world will not endanger the health of people who eat these products. By assuming, in the face of mounting evidence to the contrary, that irradiated foods are safe for human consumption, the World Health Organization has taken a leap of faith that could threaten the health of millions of people living in more than 50 countries where these products can legally be sold.

DUE TO THE IRREGULARITIES in the process by which the World Health Organization, the International Atomic Energy Agency, and the United Nations' Food and Agriculture Organization have endorsed food irradiation, Public Citizen makes the following recommendations:

- The WHO, IAEA and FAO should promptly place a moratorium on any further recommendations to expand food irradiation in any fashion.

- The WHO, IAEA and FAO should promptly withdraw the conclusions and suspend the recommendations issued in the 1999 report, *High-Dose Irradiation: Wholesomeness of Food Irradiated with Doses Above 10 kGy*, which endorsed irradiation for all foods at any dose – no matter how high. The agencies should inform all member nations of this action and recommend that they not proceed with food irradiation of any kind.

- The WHO should promptly conduct, commission or otherwise foster published, peer-reviewed research into the core safety and wholesomeness issues raised at the FAO/IAEA/WHO meeting on the wholesomeness of irradiated food held in Brussels, 23-30 October 1961. Research should also be conducted into key safety and wholesomeness issues raised since the Brussels meeting, including the toxicity of cyclobutanones, and the radiation-induced formation and increased concentration of chemicals known or suspected to cause cancer, birth defects and other health problems. These chemicals include benzene, toluene and methyl ethyl ketone.

- A 1959 agreement giving the IAEA “the primary responsibility” to research and develop nuclear technologies, and to require the WHO to consult with the IAEA on overlapping projects, should be dissolved.

- The United Nations should promptly appoint an independent panel of experts from the fields of toxicology, food science, radiation chemistry, nutrition and other relevant fields to conduct a comprehensive review into the activities of the WHO, IAEA and FAO related to food irradiation. This panel should review all WHO, IAEA and FAO publications, and identify and correct all inaccurate, misleading and incomplete statements regarding food irradiation.

This panel should also investigate the role played by the IAEA in the process of endorsing food irradiation, and whether the agency's role has corrupted the integrity of the analysis of the safety and wholesomeness of irradiated foods. Meetings of this panel should be open to the public, and all materials and findings should be distributed to member nations and be made available to the public.

NOTES

- ¹ Preamble to the Constitution of the World Health Organization, as adopted by the International Health Conference, New York City, 19-22 June 1946.
- ² World Health Organization, Web site, <<http://www.who.in>>
- ³ *High-Dose Irradiation: Wholesomeness of Food Irradiated with Doses Above 10 kGy*. Report of a Joint FAO/IAEA/WHO Study Group, Geneva, 15-20 September 1997. Geneva: World Health Organization, 1999.
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