

December 21, 2001

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U.S. Food and Drug Administration Dockets Management Branch, 5630 Fishers Lane Room 1061- HFA-305 Rockville, MD, 20852

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Re: FDA Food Additive Docket No.: 99F-5522; Food Additive Petition 9M4697, Use of ionizing radiation for pre-processed meat and poultry; both raw and pre-processed vegetables, fruits and other agricultural products of plant origin; and certain multi-ingredient food products.

Greetings,

Please consider the attached report in Food Safety Review, entitled Irradiation Revisited, as a further comment of the Center for Food Safety in opposition to the above-referenced Petition. If you would like further information, please contact me at 202.547.9359 x13 or email: peterjenkins@icta.org

Sincerely

Peter T. Jenkins

Attorney/Policy Analyst

Enclosure

99F-55ZZ

sup 2

A PUBLICATION OF THE CENTER FOR FOOD SAFETY

The mission of the Center for Food Safety (CFS) is to protect human health and the environment through the promotion of sustainable agriculture. CFS provides national leadership in legal, scientific, and grassroots efforts to influence national and international policymaking on important food safety issues.

More than one-third of stud-

ies on irradiated foods have

demonstrated that these

foods may cause genetic or

cellular damage in animals

or people who eat them.

Irradiation Revisited: As FDA Considers Expanded Use, New Health Concerns Arise

etween the farm and our dining room tables, corporate food processors want to douse a growing portion of our food supply with potentially hazardous radiation. Their goal is to kill microscopic organisms that cause spoilage and human disease. They employ mar-

keting experts and lobbyists to claim that everybody wins-food processors can extend the shelf-life of their products (thereby increasing their profits and expanding their export markets), and consumers are protected from outbreaks of food poisoning. These advocates neglect, however, to reveal the more ominous side of irradiated food-if you eat

too much of it, it may cause genetic damage, cancer, and other serious diseases.

Despite the potential danger spelled out in numerous published studies by well-respected labs showing that irradiated foods may cause genetic damage in people who eat them, the food processing industry is pressing the government to expand the application of the controversial sterilization technique. Aiding and abetting their efforts, the Food and Drug Administration (FDA) has shown a bias towards approving uses of irradiation, has disregarded evidence of its danger, and appears poised to approve its use on an even wider variety of foods.

Molecular Changes: From Food to Mutagen

Food irradiation uses high-energy gamma rays, electron beams, or X-rays (all of which are millions of times more powerful than standard med-

ical X-rays) to break apart the bacteria and insects that can hide in meat, grains, and other foods. Radiation is one of the more destructive forces in nature, and simple logic dictates that doses powerful enough to kill living organisms are also powerful enough to funda-

things to food, creating substances called "unique radiolytic products." This category of irradiation byproducts includes a variety of mutagens—substances that can cause gene mutations, polyploidy, chromosome aberrations, and dominant lethal mutations† within human cells.² Making matters worse, many mutagens are also carcinogens.

mentally alter the food itself. Scientific studies bear this out. In fact, radiation exposure does strange

† "Polyploidy" is an abnormal condition in which cells contain more than two sets of chromosomes; "chromosome aberrations" are often associated with cancerous cells; a "dominant lethal mutation" is a change in a cell that prevents that cell from reproducing.

he Food Safety Review is a publication of the Center for Food Safety designed to provide our membership with detailed information and in-depth analysis on significant food safety issues. Volume 1 of the Review, "The Hidden Health Hazards of Genetically Engineered Foods," proved very popular and remains relevant. If you have not received a copy of the first volume and would like one, please call CFS Project Manager Juliana Jones at 1-800-600-6664.

This current issue of the *Review* analyzes the serious health risks of irradiation, another controversial food-production technology currently used by segments of the food industry. As the main article in this issue points out, scientific research on the safety of irradiated food has yielded as many questions as answers. In fact, more than one-third of published studies found evidence that irradiated foods may cause cellular or genetic damage. Yet, the U.S. Food and Drug Administration (FDA) has approved the irradiation of many foods, and several corporations are currently selling irradiated foods to the public.

As we bring you Volume 2 of the *Food Safety Review*, the issue of food irradiation is a particularly timely one. For one thing, the FDA has requested public comments on five separate proposals that would likely expand the use of irradiation on our food supply (See "Take Action!" on p. 7). Also, recent terrorist attacks using anthrax spores as a biological weapon have prompted the U.S. Postal Service to begin irradiating small samples of the

mail, which could create a false impression that all uses of irradiation are safe, or even desirable (See "In the News" on p. 7). We hope this *Review* will allow you to properly sort through the numerous media stories on irradiation that, to our dismay, consistently fail to accurately inform consumers about its potential downside. Additionally, we hope that once you have the full story regarding food irradiation you will join CFS in our attempt to stop its expanded use.

The Center for Food Safety, publisher of the Food Safety Review, is a non-profit national membership organization at the forefront of numerous legal and grassroots campaigns to protect consumers and the environment from the hazards of genetic engineering and food irradiation, while promoting strong organic food standards, sustainable agriculture, and animal welfare. Our goal is to educate policymakers, while creating better public awareness and understanding of food safety issues through our newsletters, updates, and action alerts. Learn about CFS's latest initiatives and legal actions at our website: www.centerforfoodsafety.org.

If you have not already done so, we hope that after reading the *Food Safety Review* and becoming more familiar with our activities, you will support our work by joining CFS as a member. §

Andrew Kimbrell
January 2002

CFS Petitions the Federal Government for Moratorium on Genetically Engineered Fish

CFS has filed legal petitions with the FDA and four other federal agencies demanding a moratorium on the marketing and importation of genetically engineered (GE) fish. CFS also seeks a permanent ban on the release of transgenic fish into open waters, including net pens and ponds. Over 70 consumer-protection, environmental, and commercial fishing organizations have signed on as co-petitioners, and some 15,000 individuals have sent comments in support of the petitions to FDA.

There are now over thirty-five species of transgenic fish under development, and at least one company, A/F Protein, has requested FDA's approval to market transgenic fish to consumers as food. While no federal laws specifically govern the regulation of

genetically engineered animals raised for human consumption, the FDA has decided to regulate transgenic fish under its authority to review "new animal drugs." This approach means the FDA need not consider the human health or environmental impacts of these fish. What's worse, FDA does not even have the expertise to review the marine ecosystem impacts that the introduction of GE fish into the wild may cause. Nonetheless, FDA is the only federal agency now reviewing the licensing of GE fish.

For additional information on GE fish and on how to submit comments to the FDA on this issue, visit our action website at www.foodsafetynow.org or call us toll-free at 1-800-600-6664. §

The main problem with high-energy irradiation is that it can break apart molecular bonds on a chemical level and create mutagens within otherwise safe food. When it comes to safety testing of irradiated food, mutagenicity is researchers' leading concern. At least 27 *in vivo*, or live animal, feeding studies published in scientific journals examine the potential mutagenicity of irradiated diets in mice, rats, monkeys, and humans. Also, at least 13 published journal articles report *in vitro* studies on mammal or human cells grown on, or exposed to, irradiated substances in a laboratory setting.'

Since FDA has approved the use of irradiation on portions of our food supply, we might naturally assume that the overwhelming majority of these studies revealed no mutagenic effects. Not so! It turns out, based on the Center for Food Safety's (CFS) careful review, that more than one-third of both *in vivo* and *in vitro* studies have found mutagenic effects. (See Table 1.)

Many of these published studies state in frighteningly clear terms the potential hazards posed by these foods (emphasis added):

- ◆ "Freshly irradiated ... diet fed to male mice of both strains caused an *increase in early deaths of offspring* of females mated to the males in week 7 and to a lesser extent in week 4."⁴
- ◆ "Cytogenetic [i.e., related to cell DNA] 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."
- ◆ "Feeding of mice (males and females) for two months before mating with 50% of the standard complete diet (solid cakes) irradiated with 5 Mrads of radiation provokes a significant increase of pre-implantation embryonal deaths." ⁶
- ♦ "The children receiving freshly-irradiated wheat developed polyploid cells and certain abnormal cells in increasing numbers as the duration of feeding increased and showed a gradual reversal to basal level of nil after withdrawal of the irradiated wheat. In marked contrast, none of the children fed unirradiated diet developed any abnormal cells."

Imagine if one-third of the studies on vitamin supplements showed that they damaged human cells, or if repeated lab studies with animals and humans showed that using them could make your unborn children more likely to suffer "embryonal death" or be born with "cytogenetic abnormalities!" Would anyone in their right mind take them?

Scientific evidence raising doubts about the safety of irradiated foods continues to accumulate. The most recent studies have focused on a particular group of byproducts that fall in a class of chemicals known as cyclobutanones. This research is par-

ticularly important because these byproducts are inevitably formed during the irradiation of certain foods and because the results suggest that these chemicals may pose serious health hazards.

Nearly 80% of consumers in a CBS News poll said that they would not eat irradiated food. Yet, FDA officials seem poised to approve expanded use of irradiation on our food supply.

A Case Study: Cyclobutanones

Thirty years ago, a research team from the University of Massachusetts discovered that the irradiation of certain fats found in common foods such as eggs, beef, pork, lamb, chicken, and turkey produces unique chemical byproducts

classified as cyclobutanones.* These byproducts are ubiquitous in irradiated meat products, nonexistent in unirradiated products, and can persist in food samples for a decade or longer. In fact, researchers can so easily detect these cyclobutanones in irradiated foods that they can conclusively test for irradiation based on the presence of the chemicals. On the surface, this seems like a good thing—regulators have an effective means of determining whether a particular food has undergone irradiation.

However, in 1998 scientists at Germany's prestigious Karlsruhe irradiation research facility found that 2-dodecylyclobutanone (2-DCB), a common cyclobutanone and a byproduct of irradiated palmitic acid, caused genetic and cellular damage in human and rat cells and also produced genetic damage in live rats fed the chemical. Palmitic acid is the most concentrated or second most concentrated type of fat in beef, pork, lamb, chicken, and turkey. It is also common to numerous processed foods, including ready-to-eat sauces, pizzas, and snacks."

Perhaps even more frightening than what we know about cyclobutanones is what we do not

Table 1.Summary Results of Published Studies on Mutagenic Effects of Irradiated Foods

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	Found	Not Found
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(including human)		
studies	10 (37%)	17 (63%)
In vitro studies	5 (38%)	8 (62%)

Source: CFS Analysis

know. Scientists have identified a number of these substances (aside from 2-DCB) created during the irradiation of other types of common fats. While these cyclobutanones are present in irradiated foods, they have never been tested for their potential to cause cellular or genetic damage in people who consume them.¹⁰

Tests performed over the past decade demonstrate that the amount of irradiation required to produce cyclobutanones falls well below levels used by the food irradiation industry. For example, 2-DCB forms in liquid whole egg zapped with a 2.5 kiloGray (kGy) dose of radiation, well within the FDA's legal limit of 3 kGy. In a subsequent study, irradiation doses of 1 kGy produced 2-DCB and other cyclobutanones in thawed beef, lamb, and pork; the FDA currently allows irradiation of these products at up to 4.5 kGy." In fact, formation of cyclobutanones occurs at even lower radiation doses. A leading researcher in the field, M. Hilary Stevenson of Queen's University of Belfast, stated, "2-DCB has never been detected in any unirradiated or microbiologically spoiled samples, and has always been found in irradiated samples even at doses as low as 0.5 kGy."12

Additional tests show that cyclobutanones are not confined to irradiated meat and animal products. The potentially dangerous byproducts have also turned up in irradiated peanuts, pistachios, and instant soup mix." Currently, the FDA prohibits irradiation of these foods. However, several industry-supported proposals now under consideration by the agency would permit the irradiation of these and a wide variety of other ready-to-eat products.

FDA officials are fully aware of these studies. They also know that cyclobutanones persist in irradiated foods for years and that cooking does nothing to diminish their concentrations. Undoubtedly,

these dangerous chemicals exist within portions of our food supply. Why are we cating foods that some studies have shown to damage our cells and our genes? It stretches the imagination to believe FDA would approve this technology, while barely mentioning, or even ignoring, studies that show it is unsafe. Yet, this is exactly what has happened.

Government Bias

Why would regulators disregard the well-documented health risks associated with food irradiation? It seems that the actions of government agencies and officials favoring irradiation reveal a long-standing institutional bias in favor of the technology. This comment from two irradiation researchers is disturbing:

It is difficult to escape from the feeling that all findings which are in favour of the wholesomeness of irradiated foods are readily accepted, while observations which raise doubts and question this stand are either viewed with suspicion, either covertly or overtly, or outrightly rejected.¹⁴

CFS's analysis of a major international report put out in 1999 by the United Nations Food and Agriculture Organization, the International Atomic Energy Agency, and the World Health Organization reveals clear evidence of such bias. The report clearly misclassifies at least four important studies. Researchers in these four studies unambiguously documented mutagenic effects in lab animals fed irradiated diets, but the report nevertheless classifies these studies as "negative," that is, as showing no mutagenic effects. The CFS analysis points to a blatant attempt by a small group of national and international officials to dodge results they don't like.

Similarly, the public interest organization Public Citizen, in a report entitled A Broken Record: How the FDA Legalized—And Continues to Legalize—Food Irradiation Without Testing It for Safety, has clearly documented the pro-irradiation sentiments at FDA.¹⁷ The report attributes this bias, in large part, to a "groupthink" mentality among a small number of irradiation officials working in an esoteric but controversial field. Groupthink refers to faulty decision-making by groups that do not consider all alternative views and desire unanimity at the expense of quality decisions. FDA and the international regulatory officials—by misclassifying or ignoring contrary information—are exhibiting classic groupthink.

Further motivation is economic. FDA regula-

tors may feel a strong urge to help American food processing companies, which in turn see the use of irradiation as a potential means of boosting profits. In fact, these massive corporations' prime motivation for expanding irradiation to additional categories of food is not necessarily to get rid of diseasecausing organisms, but rather, to further increase their market shares in the international import and export trade. Irradiation sterilization can dramatically lengthen shelf-life for some perishable foods. This affords marketing and transportation flexibility, making it easier for large companies to move their production/packing operations to countries with lower labor costs and lower sanitary and safety standards. A shrinking number of companies will dominate global markets, and as a result American food production/packing workers—and ultimately American farmers and ranchers—may lose their jobs.

In other words, food irradiation supports globalization at its worst. Concerns over long-term health risks carry less weight than the lure of expanded markets.

When it comes to ensuring the health of our food supply, it is crucial that the ingrained bias and faulty reasoning associated with groupthink not sway decision makers. A solution to this problem is to seek independent expert reviews of food safety issues. With fully one-third of published studies raising questions about the safety of irradiated food, too much is at stake to base policy decisions on biased science or corporate pressure.

Shoppers Don't Want It

So far, irradiated food has not made up a significant portion of Americans' diets. Food manufacturers and processors have been reluctant to market irradiated products because those introduced to date have not sold well. In fact, irradiated products currently for sale include only a tiny percentage of beef patties, sold mostly in the upper Midwest, some papayas from Hawaii, and a few other foods. The most commonly irradiated foods are spices.¹⁸ However, spices constitute only a small part of most people's diets, and it is likely that few of these products' users actually read the labels and realize they are buying irradiated foods.

While marketplace behavior provides anecdotal evidence that people don't want to buy foods zapped by high-energy beams, scientific opinion polls provide hard data. A 1997 consumer opinion poll by CBS News found that 73% of Americans opposed food irradiation, and 77% said they would

True Lies: The Labeling Controversy

Longstanding federal regulations require labels on irradiated foods to say "treated with irradiation" or "treated by radiation," and to display the rather innocent-looking green radura symbol.

One corporate strategy for overcoming consumer disdain for irradiation is to simply drop the word "irradiated" from the current labeling requirement, replacing it with an unknown and deceptive euphemism like "cold pasteurized." It is a very old marketing plan—if you have a product consumers don't like, simply change the name and put it back on the market without addressing any of your potential buyers' actual concerns. If you can't win them over, try misleading them!

That is exactly what irradiation advocates have done, with the help of friendly politicians like Sen.

Tom Harkin of lowa, who happens to have the country's biggest irradiation plant in his state. Sen. Harkin and others put non-binding rider language in with the 2001 Agriculture Appropriations bill that aims to push the FDA to adopt the "cold pasteurized" label. They blatantly ignored consumer surveys showing that by a 6 to 1 margin the public thinks the new language is a



The Radura

bad idea and prefers the current "irradiated" label.

FDA has tested consumer perceptions of the proposed new terminology, and consumers completely rejected it. CFS has participated as an advisor and observer in this "focus group" process. Six different panels of consumers definitively stated that using the pasteurization label was deceptive, misleading, and "sneaky." Nevertheless, the irradiation industry has mounted a brazen \$10 million ad campaign in support of the change. CFS and Public Citizen have filed false advertising complaints against five companies, and we hope that the Federal Trade Commission will enforce the truth-in-advertising laws. The companies are: Agbeta, Biosterile Technology, Oasis-Santa Barbara, Scanmex LLC, and Titan/Surebeam.

If the irradiation industry has its way with FDA, it will be one of the first cases where the government ordered a deliberately misleading label used in place of a truthful and informative label, one that consumers strongly prefer. It would be an amazing subterfuge of the Food, Drug, and Cosmetic Act, a major thrust of which is to allow relatively unregulated markets to work, but only so long as products do not carry misleading labels. Should the FDA and FTC fail to rectify the labeling problem, the CFS legal team is poised to take further action.

refuse to eat irradiated products.19

Despite the limited market impact of these products so far, we may be approaching a cross-roads in the debate over irradiated food. A number of food processors, bolstered by their support within government agencies, are now driving efforts to expand irradiation. Consumer dissatisfaction, it seems, may not be sufficient to stop irradiation proponents from trying to foist the technology on the public.

A Potential Growth Industry

Efforts to expand food irradiation are apparently gaining momentum. As noted, the food-processing and irradiation industries have supporters in feder al regulatory agencies eager to expand irradiation. Several members of Congress have also jumped on the pro-irradiation bandwagon. Also, irradiation has been around so long as an issue that it seems to have dropped off the radar screens of some consumer groups.

In the meantime, industry and government are charging ahead. The FDA is poised to approve industry petitions this year to allow irradiation of much larger portions of the food supply, including all ready-to-eat foods. This would include deli meats, hot dogs, snacks, and packaged salads—even baby food! Plus, shellfish and other foods are soon to be on tap.

What's Next for CFS?

CFS and our allies at Public Citizen are leading the effort to expose the dangers of irradiated food and to challenge FDA's approval of the technology. Our strategies now include coordinating public education campaigns, organizing grassroots efforts, filing citizen petitions, employing an independent toxicology expert, bringing legal challenges, and pressuring companies and the government to be honest with consumers about the dangers associated with irradiated food. With your help, we can win!

The Organic Food Example

One earlier attempt to broaden the use of food irradiation withered in the face of overwhelming public opposition. The original draft of the Department of Agriculture's Organic Rule would not have specifically prohibited some irradiated foods from being labeled "organic." After the agency received hundreds of thousands of opposing public comments and felt strong pressure from the organic community and public interest groups (including CFS), USDA backed off its initial stance and approved a final Organic Rule that excludes irradiated foods.

Unfortunately, most food consumed in the United States is not certified organic, and unless we once again demand that the government protect our food supply, a growing portion of it is soon likely to be irradiated.

ENDNOTES

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- 15. 1999 FAO/IAEA/WHO Technical Report #890. High-Dose Irradiation: Wholesomeness of Foods Irradiated Above 10 kGy. WHO, Geneva.
- 16. Table 32, at p. 114-118. Studies misclassified as "negative" are: Anderson et al. 1981, cited above; Bugyaki et al. 1970, cited above; Moutschen-Dahmen et al. 1970, cited above; and Johnston-Arthur et al. "Mutagenicity of irradiated food in the host mediated assay system." Studia Biophysica, Berlin (1975) 50:137-141.
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- 19. A Citizen's Guide to Fighting Food Irradiation. Public Citizen report. Washington, DC: July 2000, p. 14.

Take Action!

Write to the FDA

The Food and Drug Administration is considering five separate proposals to weaken food irradiation rules, and has asked for public comments on each proposal. Your letters will tell regulators that consumers do not want irradiated food and that the use of irradiation should not be expanded. Faced with an overwhelming response from us, FDA will no longer be able to ignore the wishes of the public.

Our website (<u>www.centerforfoodsafety.org</u>) has sample text you may include in your comments. Send your comments to Acting Principal Deputy FDA Commissioner Bernard A. Schwetz, and copies of your comments to the FDA Docket Management Branch. The address for both is: Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Be sure to reference the following Docket Numbers in your letters.

Docket No. 99F-4372, FAP 9M4682

Ionizing radiation for the control of Vibrio and other food-borne pathogens in fresh or frozen molluscan shellfish

Docket No. 99F-5321, FAP 9M4695
Use of ionizing radiation to treat unrefrigerated (as well as refrigerated) uncooked meat, meat products, and certain meat food products

Docket No. 99F-5322, FAP 9M4696

Increase the maximum dose of ionizing radiation permitted in the treatment of poultry products

Docket No. 99F-5522, FAP 9M4697
Use of ionizing radiation for pre-processed meat and poultry; both raw and pre-processed vegetables, fruits and other agricultural products of plant origin; and certain multi-ingredient food products

Docket No. 01F-0047, FAP 1M4727

Use of ionizing radiation for control of food-borne pathogens in crustaceans and processed crustaceans

Take Direct Action

Beyond writing to regulatory officials, as consumers we can effectively continue to vote against irradiated foods with our pocketbooks. Spread the news: inform friends and family members that numerous scientific studies raise doubts about the safety of irradiated food. Distribute copies of this *Review*. Tell the managers at your local grocery stores that they should not stock irradiated foods—consumers don't want them.

Rather than purchasing foods zapped with high energy beams, you can opt to support organic farmers and suppliers who have eschewed the use of irradiation in favor of food production techniques that are less threatening to human health and less injurious to the environment. §

In the News

Post Office Pays Millions to Irradiate Mail Despite Safety, Effectiveness Problems

The U.S. Postal Service, in the wake of recent terrorist anthrax attacks, has begun irradiating a very small portion of the mail at facilities in Ohio and New Jersey.

Unfortunately, this effort to assuage postal customers' anthrax fears could create a false impression that food irradiation is safe and effective. As the Los Angeles *Times* reports, "The ongoing anthrax scare appears to be helping the nation's irradiation companies do something they've been unable to do themselves: sell consumers on their controversial germ-zapping technology."

In fact, however, a closer examination reveals that irradiation of the mail is raising additional questions. A

major concern is that the dose of radiation needed to kill anthrax spores is up to six times the maximum FDA allows for use on meat. Experts have raised the possibility that doses this high could damage electronics, compact discs, film, food, prescription drugs, and other frequently mailed items. Customers have already complained that some irradiated letters arrived sticky, smelly, or discolored. At least twice, an irradiation facility has set batches of mail on fire.

Additional worries center on effectiveness (some types of irradiation do not penetrate thick packages) and worker safety (the Post Office has not said how it will protect workers from radiation exposure).

Meanwhile, the Postal Service is pushing ahead. It has already paid \$3.9 million to use the irradiation facilities in Ohio and New Jersey (including the one that set mail on fire) and has signed a contract to purchase eight irradiation machines for \$40 million. §

IDEED OF WINDERS HOLD SANDER

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