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DATE INTO FDA: 03/09/01

TO: BERNARD A SCHWETZ HF-1

FROM: LINDA F GOLODNER, NCL, NATIONAL CONSUMERS LEAGUE

SYNOPSIS: COMMENTS ON IRRADIATION LABELING DOCKET #98N-1038 AND ENCLOSES A RECENTLY RELEASED BROCHURE: "FOOD IRRADIATION... WHAT YOU SHOULD KNOW"

LEAD OFFICE: HFS-1

HOME OFFICE: HF-40

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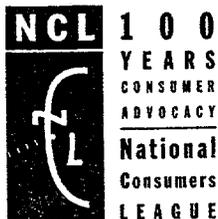
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COORDINATION:

SIGNATURE REQUIRED: COMMISSIONER

REFERRALS FROM HF-40

ASSIGNED TO	ACTION	DUE DATE
HFS-1 LEVITTJ	PREPARE RESPONSE FOR SIGNATURE	03/19/01



Linda F. Golodner
President

NATIONAL CONSUMERS LEAGUE

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March 6, 2001

Bernard A. Schwetz, DVM, Ph.D.
Acting Principal Deputy Commissioner
U.S. Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Re: Irradiation Labeling, Docket No. 98N-1038

The National Consumers League is writing to urge FDA to support clear labeling of irradiated foods. As America's oldest nonprofit advocacy organization, NCL is quite concerned that the current federal regulations requiring that irradiated foods be labeled with the terms "Treated with Radiation," or "Treated by Irradiation" will be replaced with other terms such as "Cold Pasteurization" or "Electronic Pasteurization," terms that mean nothing to consumers. This would be a mistake and would serve to confuse and mislead the public.

Consumers want and deserve clear, factual information about the foods they eat, including irradiated foods. Conspicuous, easy-to-read labeling, using the terms "Treated with Radiation," or "Treated by Irradiation" is the only way that consumers can make an informed choice about irradiated products. Further, we strongly support that such declarative statements be located on the principal display panel, accompanied by the radura symbol, and printed in a typeface large enough to be read easily by elderly consumers or others with limited vision.

Numerous studies have demonstrated that consumers support labeling to indicate that a food has been irradiated, and overwhelmingly prefer the current terminology "Treated with Radiation," or "Treated by Irradiation" to euphemisms such as "Cold Pasteurization" or "Electronic Pasteurization." FDA should act to ensure that consumers are adequately protected and properly informed about the food products available in the marketplace by requiring clear and accurate labeling of irradiated food products.

NCL stands ready to help educate the public about this important food safety issue. NCL has recently released a new brochure: "Food Irradiation... What You Should Know." The guide provides clear answers to common consumer questions about irradiation such as how it's regulated, what foods are irradiated, and the effects of irradiation on food. I am enclosing a copy for your review. Thank you for your consideration in this important matter.

Sincerely,

A handwritten signature in black ink, appearing to read "Linda F. Golodner".

LINDA F. GOLODNER
President

01-1221

Resources

To learn more about food safety and food irradiation, call the Food and Drug Administration at 1-888-SAFE-FOOD (1-888-723-3366), your local library, health department, or visit NCL's Web site, www.nclnet.org/foodsafety, which includes links to online resources, brochures, and other valuable information.



National Consumers League

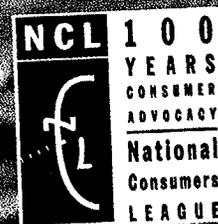
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The National Consumers League thanks
IBA-Food Safety Division
for an unrestricted educational grant.



Food Irradiation

...what you need to know



Food Irradiation and food safety



There are few hotter topics these days than food safety. Highly publicized cases of foodborne illness have heightened consumer awareness of the importance of food safety and cleanliness. But there remains a good deal of confusion. For example, you may have heard that some foods are irradiated to make them safer, but not understood

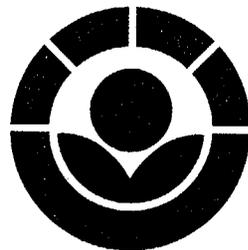
what that means.

Food irradiation is a technology that can add an extra measure of safety to foods.

Irradiation drastically reduces or eliminates harmful bacteria such as

E. coli O157:H7, *Salmonella*, *Campylobacter*, and *Listeria*.

Although irradiated foods are just beginning to be available in US supermarkets, food irradiation is not a new technology. It has been researched for more than 50 years and approved by the Food and Drug Administration as a safe treatment for certain foods.



The Nuclear Regulatory Commission licenses and regulates gamma ray facilities, while the FDA and state agencies regulate e-beam and x-ray facilities (as they do medical x-ray machines). All irradiation facilities must meet the requirements of the Occupational Safety and Health Administration, regarding worker safety, and the Environmental Protection Agency.

What can I do if I don't want to eat irradiated foods?

Consumers who want to avoid irradiated foods should have no trouble. Generally, all irradiated foods must be labeled with the radura logo (a flower-like image that is the international symbol for irradiation) (see Glossary) and the words "treated with radiation" or "treated by irradiation." If an irradiated food is not packaged (such as loose fruit), the irradiation labeling must appear on signs next to the food.

Irradiation labeling is not required for processed foods that contain only some irradiated ingredients (such as irradiated spices in a hot dog that has not itself been irradiated). However, irradiated meat or poultry ingredients (such as irradiated beef in a beef and pork hot dog) must be identified in the list of ingredients on the label. Irradiation labeling is currently not required for restaurant foods.

Should irradiated foods be handled differently from other foods?

No. *All* foods, including irradiated foods, should be handled properly. Irradiated foods are not sterilized and may still contain small amounts of harmful bacteria that can multiply and cause illness if the food is not properly cooked or refrigerated. Irradiated foods can also be contaminated by food handlers who do not wash their hands or by contact with contaminated foods.

For more information on proper food safety handling techniques, call or visit NCL's Web site for our brochure "Keep It Clean, Keep It Healthy." (1-800-639-8140; www.nclnet.org)

Today, there is little controversy in the scientific community about the safety of irradiated foods. For a full listing of organizations and experts that endorse irradiation, visit our Web site, www.nclnet.org.

Glossary

Food irradiation. Exposing food to high energy rays (gamma rays, x-rays, or e-beams) in order to kill harmful bacteria, extend shelf life, or control insect pests. It is sometimes referred to as *cold pasteurization* or *electronic pasteurization*.

Free radicals. Atoms or molecules with an unpaired electron. They are unstable and react with other molecules to form more stable products.

Ionizing energy. Energy that is high enough to change atoms by knocking an electron from them to form an ion, but not high enough to split atoms and thereby cause exposed objects to become radioactive.

Pathogen. A bacterium, virus, or parasite that causes illness. Bacteria that may cause foodborne illness include *Salmonella*, *E. coli* O157:H7, *Campylobacter jejuni*, and *Listeria monocytogenes*. Illness-causing parasites include the protozoa *Cyclospora* and *Toxoplasma gondii*.

Radioisotopes. An element that is radioactive (i.e., that emits radiant energy as it decays). Some irradiation plants use a radioisotope, such as cobalt-60, to irradiate foods.

Radiolytic products. Chemicals produced in foods as a result of irradiation. These are known chemicals that already exist in the food supply and are produced in such small amounts that they do not pose any health hazard.

Radura. The flower-like symbol indicating that a food has been irradiated



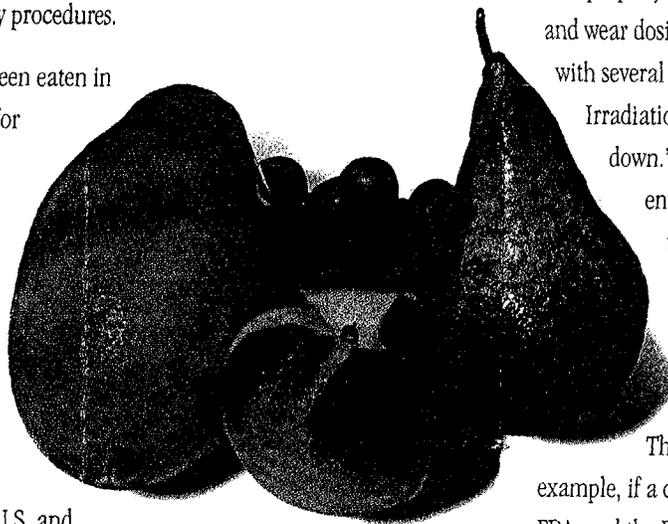
Before approving the use of irradiation for a particular food, the FDA carefully considers any vitamin loss. The FDA considers what vitamins would be lost as a result of irradiation and what effect that loss would have on a person's total diet. For each approved use, the FDA must determine that vitamin loss from irradiation would not have a significant impact. Check the food label to learn the levels of important nutrients.



How many foods are being irradiated today?

Most foods are not irradiated. This may be changing, however, as more and more food processors adopt irradiation to eliminate harmful bacteria that may slip through their other safety procedures.

Some irradiated foods have been eaten in the U.S. and other countries for many years. In the U.S. and several other countries, a significant percentage of spices are irradiated. Much of the papaya and other tropical fruits shipped to the mainland U.S. from Hawaii are irradiated.



A number of hospitals in the U.S. and England use irradiation to sterilize foods for patients with weakened immune systems, and NASA astronauts eat irradiated foods during space missions.

Is irradiation safe for workers and the environment?

Irradiation already has a record of more than 30 years of safe use in the United States. There are currently about 40 irradiation facilities in the U.S., most of which are used to sterilize medical products such as surgical gloves and sutures,

and consumer goods such as contact lens solution and baby pacifiers.

In a properly run irradiation plant, workers are not exposed to any radiation and wear dosimeters to ensure this is the case. Irradiation plants are designed with several layers of protection to safeguard workers from exposure.

Irradiation plants are not nuclear reactors and cannot have a "melt-down." In a properly run facility, no radioactivity is released into the environment at all. Irradiation plants produce little or no radioactive waste.

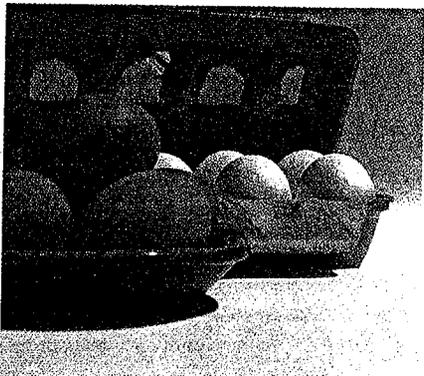
How does the government regulate irradiated food?

The FDA must review and approve each new use of irradiation. For example, if a company wants to irradiate eggs, it must submit a petition to the FDA, and the FDA must review and approve it before irradiated eggs may be marketed to the public. If the petition is for irradiation of meat or poultry, or ingredients in meat or poultry products, the FDA will also consult with the U.S. Department of Agriculture.

So far, the FDA has approved irradiation of the following foods to enhance their safety: raw meat, raw poultry, shell eggs, seeds for growing sprouts, and herbs and spices. The FDA has also approved low-dose irradiation of foods to kill insect pests and to extend shelf life.

What chemical changes occur in food when it is irradiated, and are these hazardous?

Irradiation may produce "free radicals," unstable atoms that react with other atoms to produce minor chemical changes in the treated food. The end result of these reactions is tiny amounts of certain chemicals, such as hydrogen peroxide, which are already naturally present in the food supply or are formed when foods are cooked. These radiolytic products (i.e., products of irradiation) are known chemicals and are produced in such small amounts that they are not believed to pose a health hazard.



Will irradiation produce "super germs"?

No. Food irradiation will not produce radiation-resistant strains of bacteria. This can only happen if bacteria are subjected to repeated, closely spaced, sublethal doses of radiation.

Can irradiation be used to conceal a food's spoiled taste or appearance?

No. Irradiation cannot disguise spoiled food. It cannot reverse the spoilage process or camouflage the bad odor and taste of spoiled food.

Is irradiation being used instead of good sanitation practices?

No. Irradiation is not, and should not be, a substitute for good sanitation. If a food is too heavily

contaminated, irradiation will not be effective. Just as milk must meet certain sanitation standards before it can be pasteurized, so must foods meet sanitation standards before they can be irradiated.

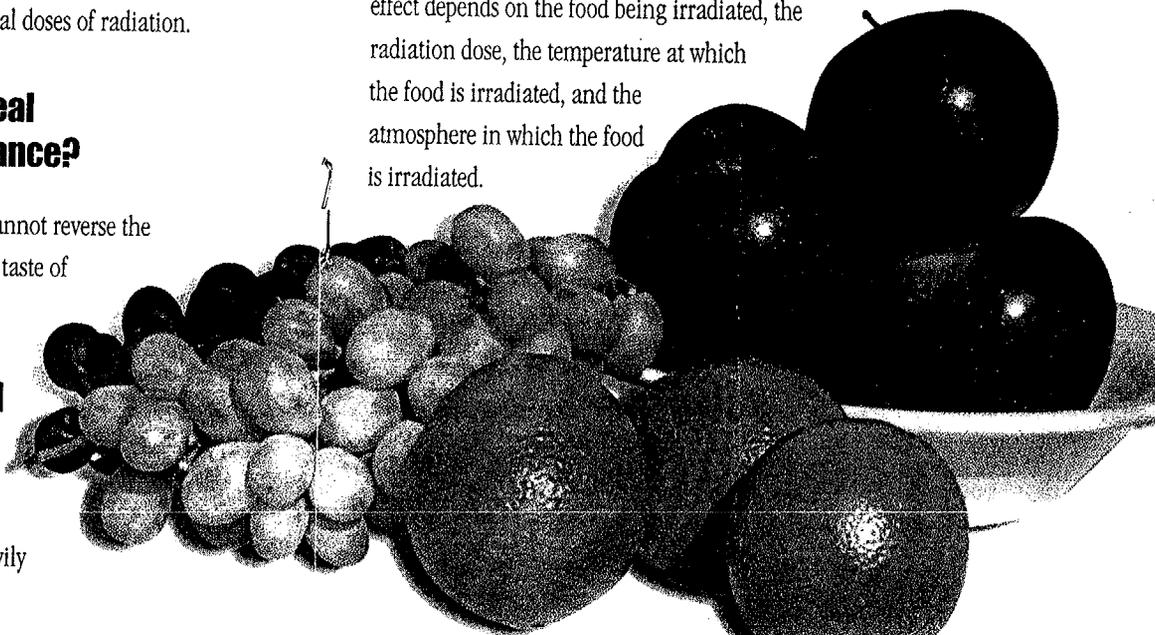
Is irradiation replacing government inspection of food?

No. Irradiated foods will continue to be subject to daily inspection by USDA (for meat and poultry) and periodic inspection by FDA and state food safety officials (for all other foods).

Are irradiated foods less nutritious than other foods?

Irradiation has no significant effect on proteins, carbohydrates, and fats. It has no effect at all on trace elements and minerals, such as calcium, iron, and potassium.

Irradiation may, however, affect some vitamins. The nature and extent of the effect depends on the food being irradiated, the radiation dose, the temperature at which the food is irradiated, and the atmosphere in which the food is irradiated.



Why be concerned about foodborne illness?

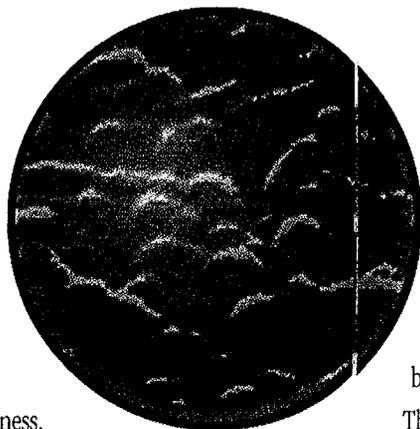
Foodborne illness can be more than just an upset stomach. It may also cause long-term or permanent illness, or even death. Children, senior citizens, pregnant women, and people with weakened immune systems are generally most vulnerable to foodborne illness.

Some foods are more likely to carry harmful bacteria than others. For example, foods derived from animals that are sold raw (e.g., raw meat or poultry, raw oysters) are more likely to carry bacteria than cooked foods. Ground meats are more likely to harbor harmful bacteria than whole cuts of meat. Only a “kill step” (such as pasteurizing milk and eggs, cooking ground meat thoroughly, or irradiating some foods) can eliminate the harmful bacteria.

What is irradiation?

Food irradiation is the treatment of food with ionizing energy. High energy rays pass through the product, killing virtually all harmful bacteria and parasites in or on the food. Yet, the food remains raw and undergoes only minor chemical changes.

There are three types of food irradiation: gamma—uses radioisotopes (e.g., cobalt-60) specifically designed to treat food; electron beam—directs an “e-beam” of electrons at the food product to kill bacteria; and x-rays—aims an e-beam through a metal plate to generate x-rays. Both e-beam and x-ray are produced by machines that can be turned off and do not use any radioactive materials.



Why irradiate foods?

With some foods, even the best sanitation and standard antibacterial treatments cannot ensure safety. For example, there is no guarantee that raw ground beef or raw sprouts will be free of certain harmful bacteria like, *E. coli* O157:H7 or *Salmonella*. These foods provide a favorable environment for bacterial growth and their production process does not include a “kill step,” such as cooking or pasteurization. For these foods, irradiation provides a “bacteria-killing” step without cooking the food.

Foods may also be irradiated to extend shelf life, and imported fruits and vegetables may be irradiated to kill insect pests that might otherwise threaten U.S. agriculture.

Is irradiated food safe to eat?

Yes, irradiated food is safe to eat.

Does irradiation make food radioactive?

No. It does not make food radioactive.

