POLICY FORUM: FOOD SAFETY

Food Irradiation—The Neglected Solution to Food-Borne Illness

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Food-borne pathogens cause thousands of deaths and tens of millions of cases of food-borne illness each year in the United States (*1*). Although most food-borne illness involves only nausea and diarrhea, many people develop serious complications, including rheumatoid, cardiac, hepatic, and neurological problems (*1, 2*). Food-borne disease is declining little if at all, despite major new food safety initiatives (*3–5*). The best way to prevent a substantial part of those deaths and illnesses is food irradiation, which all major international public health organizations have endorsed because it is safe and effective (*6*).

Irradiation is extremely effective at reducing pathogens. Irradiation of frozen ground meat products with a 7-kilogray (kGy) dose—a dose already approved by the U.S. Food and Drug Administration (FDA)—could eliminate *Escherichia coli* 0157:H7, a particularly hazardous pathogen (*7*). Irradiation destroys *Staphylococcus aureus* and *Campylobacter jejuni*, which are together responsible for more than 2.6 million food-borne illnesses per year (*1*), as effectively as it reduces *E. coli* 0157:*H7* (*7*). Reductions in numbers of viable organisms would be dramatic for other important pathogens: irradiation of meat reduces *Salmonella* levels by factors of 10 billion to 100 trillion (*7*). It is also effective for seafood, eggs, precooked meats, and produce (*8*).

Irradiation of food does not pose risks to consumers (*6*). The World Health Organization (WHO) has advised that "as long as sensory qualities of food are retained and harmful microorganisms destroyed, the actual amount of ionizing radiation applied is of secondary consideration" (*9*). At high doses, irradiation can cause some loss of vitamins, but at currently permitted doses "...there's less vitamin degradation than you get with microwaving or cooking" (*10*). Almost two decades ago, the WHO concluded that "irradiation of food up to an overall average dose of 10 kGy produced no toxicological hazard and introduced no special nutritional or microbiological problems" (*11*). In 1997, WHO added that "food irradiation is perhaps the most thoroughly investigated food processing technology" (*9*). It concluded that "...one can go as high as 75 kGy, as has already been done in some countries, and the result is the same—food is safe and wholesome and nutritionally adequate" (*9*). Joining the WHO in endorsing food irradiation to improve food safety are the Codex Alimentarius Commission, the American Medical Association, the American Dietetic Association, and the health authorities of approximately 40 countries (*6*).

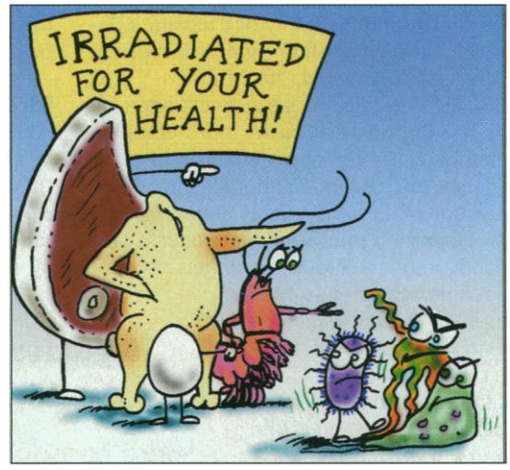
Market data in the United States suggest many informed consumers prefer irradiated foods (*12*). In retail trials, irradiated chicken had a market share of 43% when sold at the same price as other chicken (*12*). When sold for a 10% premium—a markup much greater than the costs of irradiation—its share of the market was about 25% (*12*). Indeed, many different types of medical, pharmaceutical, and consumer products are already irradiated (*13*).

U.S. Government Regulation

In the United States, two separate government agencies are responsible for regulation of food. The U.S. Department of Agriculture (USDA), through its Food Safety and Inspection Service, has responsibility for all meat and poultry and related products, whereas the Food and Drug Administration, part of the Department of Health and Human Services, regulates all other foods. According to the Federal Food, Drug, and Cosmetic Act, irradiation of food, including meat and poultry, is prohibited without a determination by the FDA that food irradiation at particular doses and for particular uses is safe. This dual, overlapping responsibility for irradiation of meat and poultry has contributed to delays in bringing irradiation of these foods to market.

Despite the well-established benefits of irradiation, federal regulations now permit irradiation to control pathogens only for poultry and spices (*6, 14*). The USDA's regulations restrict poultry irradiation: it is permissible only at a dose of 3 kGy (*15*) and with labeling statements that consumers can mistake for warnings. The USDA has proposed to allow meat irradiation and is expected to announce regulations this month. Regulatory decisions to approve irradiation of seafood, precooked meats, and eggs, all of which are linked to food-borne illnesses and death, are years from completion (*16*). Faster government action could prevent illness and death associated with those foods.

Congress is partly responsible for delays in bringing food irradiation to market. The Federal Food, Drug, and Cosmetic Act defines sources of irradiation used to treat food as "food additives" and prohibits the use of food additives without an explicit determination of their safety (*17*). That definition delays the marketing of irradiated foods. In effect the Act directs FDA to address the wrong question—whether irradiation is safe—rather than whether food irradiation reduces risks to public health, taking into account both the reduced incidence of food-borne illness and any loss of safety from increased irradiation.



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The regulatory agencies have also delayed the benefits of food irradiation by creating a redundant and complicated two-step approval process that is avoidable under current law. The first step is a determination by the FDA that food irradiation at particular doses is safe for particular uses (*7*). The second step is a determination by the USDA that the use of irradiation is (i) in compliance with applicable FDA requirements, (ii) does not render the product adulterated or misbranded or otherwise out of compliance with the requirements of the Federal Meat Inspection Act, (iii) is functional and suitable for the product, and (iv) is permitted only at the lowest level necessary to accomplish the stated technical effect as determined in specific cases. The second step is required not by the Federal Food, Drug, and Cosmetic Act, but

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by USDA's interpretation of its own regulations, which prohibit use of a "substance" in the preparation of any meat product unless such a determination is made (*18*).

That two-step process, while arguably sensible for additives that do not improve public health, substantially delays delivery of the benefits of food irradiation to consumers. The FDA approved irradiation of meat 3 years after receiving a petition; however, the USDA, which must also approve, has taken two more years to issue its own rule (*19*). In their recent rulemakings about meat irradiation, the agencies do not cite any recent scientific discoveries confirming the safety of irradiation. Instead, they cite safety evidence most of which is 20 years old (*20, 21*).

The slow pace of government approval of irradiation has causes more complex than bureaucratic inertia and lack of interagency leadership. Cautionary or critical positions taken by several public interest groups play a role. Food and Water, a stridently anti-irradiation group, has paid for advertisements and organized telephone and letter campaigns against food irradiation (*22*). Consumers Union, the publisher of *Consumer Reports*, has been studiously neutral on the subject (*23*). Other influential groups, including Center for Science in the Public Interest, National Consumers League, and Consumer Federation of America, take a slightly more supportive stand, but still manage to impede improvements in public health by advocating conspicuous labeling and even increased testing of irradiated foods (*24*). Such views, because they are presented by "public interest" groups, can deter agencies that seek to regulate by consensus from implementing regulatory changes that would promote public health, unless there is strong political leadership.

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Industry Performance

Industry has also been slow to irradiate poultry, although the USDA allowed it in 1992. The market share of irradiated poultry is only about 1% (*7*). Why isn't irradiated poultry found in supermarkets today, given that market trials suggest it could sell at a profit? One possible reason is that grocers may be reluctant to stock "safer" poultry because it would raise questions about the safety of their other poultry products. In addition, their contracts with major poultry suppliers may include volume discounts that discourage the introduction of new products that hurt established brands. Those explanations are not fully satisfactory, but they suggest that factors limiting market share include market barriers, as well as restrictions on labeling and dose. More creative marketing may be needed to bring irradiated foods to U.S. consumers.

Irradiation of meat, when approved by USDA, may become more widespread than poultry irradiation, because people like rare hamburgers. Many restaurants have already stopped selling medium-rare hamburgers because of safety concerns (*25*).

Recommendations

Although the USDA has recently proposed to allow irradiation of meat, the USDA's rulemaking is late and should have been expedited. Millions of illnesses and thousand of deaths per year could be avoided by irradiation of meats, and the USDA's delays postpone these benefits.

Furthermore, the USDA proposal is too limited (*16*). It would unnecessarily restrict producers' ability to market irradiated meats by mandating the content and placement of certain statements on food labels and by offering no guidelines for labeling claims like "*Salmonella*-free" (*7*). It takes no steps to promote irradiation of precooked meats, eggs, and seafood. It would leave in place redundant testing requirements and performance standards for *Salmonella* (*7*).

There are several ways the government can improve its regulation of food irradiation. First, the USDA should not require any labeling that could be misinterpreted as a warning; instead, it should require only that irradiation be identified as food preservatives are now. In addition, the USDA should allow labels that inform consumers how irradiated foods reduce the risk of food-borne disease and death. Second, the USDA should revise its rules so that firms that irradiate at a given dose would be exempt from redundant requirements to test for pathogens on those products. Third, the FDA—which under the Act must determine the safety of irradiation at particular doses for particular purposes—should allow irradiation of precooked meats, eggs, and seafood.

Regulatory agencies will have to become much more supportive of food irradiation if consumers are to enjoy all the health benefits that it promises. The FDA should promptly determine that irradiation of any food is generally recognized as safe, based on the findings of the World Health Organization and other scientific and public health organizations. In addition, the White House should make up for its recent lack of leadership on this issue and demonstrate the benefits of irradiated food by serving irradiated turkey at the next state dinner.

References and Notes

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9. World Health Organization, "Food irradiation," press release (WHO/68, 19 September 1997).
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11. WHO, "Wholesomeness of irradiated food: Report of a joint FAO/IAEA/WHO expert committee." *WHO Tech. Rep. Ser. 659* (1981).
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13. These include bandages, cotton balls, surgical gloves, baby bottle nipples, cosmetics, dairy and juice containers, pacifiers, teething rings, and tampons. See (*2*).
14. Pork can be irradiated, but only to control *Trichinella spiralis*, which causes trichinosis; the maximum permitted dose is too low to be effective against other pathogens.
15. FDA, 55 Federal Register 85, 18539 (1990).
16. R. Lutter, "An analysis of the U.S. Department of Agriculture's proposal to allow irradiation of meat" (AEI–Brookings Joint Center, Regulatory Analysis 99-2, 1999).
17. 21 U.S. Code 321(s), 348(a) and (a)(*2*), and 348(c)(*1*)(A).
18. Code of Federal Regulations, § 318.7.
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