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An Analysis of the U.S. Department of Agriculture's Proposal to Allow Irradiation of Meat

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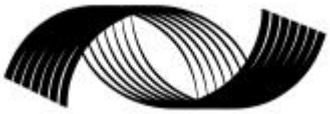

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In response to growing concerns about understanding the impact of regulation on consumers, business, and government, the American Enterprise Institute and the Brookings Institution have established the new AEI-Brookings Joint Center for Regulatory Studies. The primary purpose of the center is to hold lawmakers and regulators more accountable by providing thoughtful, objective analysis of existing regulatory programs and new regulatory proposals. The Joint Center will build on AEI's and Brookings's impressive body of work over the past three decades that has evaluated the economic impact of regulation and offered constructive suggestions for implementing reforms to enhance productivity and consumer welfare. The views in Joint Center publications are those of the authors and do not necessarily reflect the views of the staff, council of academic advisers, or fellows.

Executive Summary

Foodborne pathogens in the United States kill thousands and sicken millions each year, despite major efforts by federal agencies and industry to combat the problem. Food irradiation could safely prevent a substantial part of those deaths and illnesses and has been endorsed by all major public health organizations. Yet federal regulations prohibit the use of irradiation to kill pathogens on meat, eggs, and seafood and restrict its use on poultry, and so contribute to avoidable deaths and illnesses. The U.S. Department of Agriculture should expedite its rulemaking to allow irradiation of meat, and it should not require that food labels mention irradiation more prominently than they identify food additives. Most importantly, to boost food irradiation in the marketplace, the Food and Drug Administration should promptly determine that irradiation of *any* food, including precooked meats, eggs, and seafood, is generally recognized as safe.

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Foodborne disease is a serious health problem. Microbial pathogens in food cause an estimated 9,000 deaths and 6.5 million to 33 million cases of illness in the United States each year.[1] Although most nonfatal illnesses from foodborne pathogens involve only nausea and diarrhea, many cases develop secondary long-term illnesses, including rheumatoid, cardiac, and neurological problems.[2] Conservative estimates of the costs of foodborne illness for just six microbial pathogens range from $2.9 billion to $6.7 billion annually.[3] And the problem of foodborne disease is apparently not declining, despite major new food safety initiatives.[4]

Irradiation of food, a safe and effective process endorsed by all major public health organizations,[5] is the best possible single step towards a safer food supply. Further reductions in improper preparation and handling of food by consumers may be hard to achieve because food labels and supermarkets *already* display educational information.[6] Irradiation is extremely effective at reducing pathogens—more effective than measures recently required by federal regulation.[7] It reduces the most important pathogens found on meat, for example, by factors of more than a trillion and eliminates some altogether.[8] It also works on seafood, eggs, and precooked meats.[9] Furthermore, informed consumers prefer irradiated foods; roughly a third would pay a premium that exceeds the U.S. Department of Agriculture's (USDA) estimates of cost.[10]

Despite those important benefits, the federal regulatory bureaucracy has caused food irradiation to be missing in action in the fight against foodborne illness. Irradiation

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[1] See Buzby *et al.* (1996).
[2] Ibid.
[3] Ibid. Those estimates are conservative because they value mortality risk reduction using earnings and exclude pain and suffering from nonfatal illness.
[4] See Altekurse *et al.* (1997) and U.S. General Accounting Office (1996). See also U.S. Centers for Disease Control (1999).
[5] See Thayer *et al.* (1996).
[6] See USDA (1998, Chapter 9).
[7] See USDA (1996, 38967).
[8] See USDA (1999b, 9090). Hereafter, the Proposed Rule.
[9] See Wilkinson and Gould (1996).
[10] See Fox and Olson (1998).

to kill pathogens on foods is not permitted in the United States today, with the exception of its use on poultry and spices.[11] Even on poultry, it is permissible only at a low dose and with labeling statements that resemble warnings—unless firms get prior approval for other labels. U.S. consumers generally cannot choose to buy irradiated food, although it could prevent thousands of deaths and millions of cases of foodborne illness each year.

The most serious regulatory failure is a redundant and complicated two-step approval process.[12] The first step is a determination by the Food and Drug Administration (FDA) that food irradiation is safe for particular uses. That determination is required by the Federal Food Drug and Cosmetics Act, which defines sources of radiation used to treat food as "food additives" and prohibits the use of food additives without an explicit determination of their safety.[13] The second step is a determination by the Food Safety and Inspection Service (FSIS), which is part of the Department of Agriculture, that the use of irradiation in the preparation of a meat product

- is in compliance with applicable FDA requirements,
- does not render the product adulterated or misbranded or otherwise out of compliance with the requirements of the Federal Meat Inspection Act, and
- is functional and suitable for the product and 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 Act, but 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.[14]

While that two-step process may make sense for additives that do not promote public health, it leads to substantial delays in delivering the benefits of irradiated foods to consumers. Five to seven years may elapse between a petition to the FDA and a final approval by the USDA.[15]

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[11] See Thayer *et al.* (1996). Pork can be irradiated for trichinosis, but the maximum permitted dose is too low to be very effective against other pathogens.
[12] See USDA (1999b, 9089-9090).
[13] See 21 USC 321(s), 348(a) and (a)(2), and 348(c)(1)(A) (1998).
[14] See 9 CFR § 318.7 (1999).
[15] In 1994 the FDA published a notice that it had received a petition to allow irradiation of meat (59 FR 43848). It did not disclose the date it had received the petition.

The USDA and the FDA are not acting expeditiously to allow or even promote food irradiation, despite the fact that food irradiation has been known to be safe and effective for decades.[16] For example, in their own rulemakings, the agencies do not cite any recent scientific breakthroughs confirming the safety of irradiation. Instead, the evidence on safety that they cite is mostly twenty years old.[17]

The USDA has recently proposed to allow irradiation of meat and certain meat products and to make the determinations described above. Its proposal would establish maximum but not minimum doses of irradiation, set forth labeling requirements for irradiated foods, and identify specific meats that can be irradiated.

The USDA's proposal suffers from several serious flaws, although it would offer large net benefits. First and most important, it and the final rule planned by the USDA are too late. Public health suffers unnecessarily because the slow approval process prevents Americans from having access to irradiated foods today. Millions of illnesses and hundreds of deaths per year could be avoided by irradiation of meats; the USDA's delays postpone these benefits. The USDA should therefore expedite this important rulemaking.

Second, the government's policy fails to encourage food irradiation. The FDA should promptly make a determination that food irradiation is generally recognized as safe, based on the findings of the World Health Organization and other scientific and public health organizations.

Third, the USDA proposal is too limited in several ways. It would unnecessarily restrict producers' ability to market irradiated foods by requiring certain statements on labels. It would extend irradiation only to fresh or frozen meat and takes no steps to promote irradiation of pre-cooked meats, eggs, and seafood—all of which are linked to foodborne illness and death. It would leave in place redundant regulations.

There are several ways USDA can improve its proposed rule, apart from expediting its promulgation. First, the USDA should not require any labeling of irradiated food that could be misinterpreted as a warning. In addition, it should provide firms with greater flexibility to use food labels to inform consumers about the health benefits of irradiated foods. Second, the USDA should petition the FDA to develop and promptly

[16] See World Health Organization (1981).
[17] See FDA (1997) and USDA (1999a).

release regulations to increase the number of food products that could be irradiated. Third, the USDA should remove regulations that irradiation would make redundant.

In this regulatory analysis, I develop support for these recommendations. After providing background information about food irradiation, I analyze the delays and explain why the FDA should determine that food irradiation is generally recognized as safe. I then identify specific shortcomings of the USDA proposal, which include an overly prescriptive approach to the labeling of irradiated food, a continued ban on irradiation of seafood, eggs and pre-cooked meat, and unnecessary regulatory redundancy. I conclude with observations about why food irradiation is still rare.

Background

Regulations that permit food irradiation offer an unusual opportunity to achieve significant public health improvements in a way that helps consumers and industry alike. Firms and consumers would be better off with an opportunity to produce and buy irradiated products than with the current ban on irradiation of many food products. In addition, food irradiation may contribute to substantial public health gains.

Irradiation is extremely effective at destroying the most important pathogenic organisms found in food. The USDA concludes "there is a high probability that irradiation of frozen ground meat products with a 7 kilogray dose could eliminate *E. coli* O157:H7 [a hazardous pathogen] from the product [emphasis added.]"[18] Irradiation destroys other pathogens like *Staphylococcus aureus* and *Campylobacter jejuni* as effectively as it reduces *E.coli*.[19] Those two pathogens are each responsible for more than a million foodborne illnesses per year.[20] For other important pathogens, reductions would be less extreme but still dramatic: irradiation of meat would reduce *Salmonella* levels by factors of 10 billion to 100 trillion.[21]

[18] See the Proposed Rule, p. 9090. A 'Gray' is a unit of absorbed irradiation.
[19] Ibid.
[20] See Buzby *et al.* (1996, Table 2).
[21] See Proposed Rule, p. 9090.

Irradiation of food does not pose risks to consumers, because the food does not come in contact with the radiation source and cannot become radioactive.[22] In fact, 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."[23] At high doses, irradiation, like cooking, can cause some loss of vitamins, but at currently permitted doses "…there's less vitamin degradation than you get with microwaving or cooking."[24] Almost two decades ago, the WHO concluded that "irradiation of food up to an overall average dose of 10 [kilogray (kGy)] produced *no* toxicological hazard and introduced *no* special nutritional or microbiological problems [emphasis added]."[25] In 1997, the WHO added that "food irradiation is perhaps the most thoroughly investigated food processing technology."[26] 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."[27] 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 forty countries.[28]

Food irradiation also would pose no significant risks to the environment or worker safety. In a study of environmental risks, the FDA concluded that irradiation of meat and meat products "will not significantly affect the human environment"[29] and issued a finding of no significant impact. The Nuclear Regulatory Commission (NRC), which has authority to license facilities that use radioisotopes, concluded that they do "not individually or cumulatively have a significant effect on the human environment."[30] As required by the National Environmental Policy Act, the Department of Energy examined the potential environmental impact of one experimental food irradiation facility currently using a machine source of radiation instead of radioisotopes. It issued a finding of "no

[22] See Campbell-Platt (1990).
[23] See World Health Organization (1997).
[24] Michael Osterholm, state epidemiologist, Minnesota Department of Health, quoted in Manning (1999).
[25] See World Health Organization (1981).
[26] See World Health Organization (1997).
[27] Ibid.
[28] See Thayer *et al.* (1996).
[29] See U.S. FDA (1997, 64119).
[30] See 10 CFR 51.22 (a) (1999).

significant impact to the environment" for this facility.[31] The NRC and the Occupational Safety and Health Administration regulate worker safety in irradiation facilities. Federal regulations include requirements for careful measurement of occupational exposure, reporting of all accidents, development of emergency plans, and training.[32] Existing Department of Transportation and NRC regulations also cover all aspects of transportation of radioactive material.[33] Of fifty-two accidents in the course of transporting radioactive materials between 1971 and 1997, only one involved damage to the shipping container. But the packaging integrity was not compromised, and there was no radioactive release to the environment.[34] Based on this information, the USDA determined that "allowing the irradiation of fresh and frozen meat food products would pose no significant risk to the environment, worker or transportation safety."[35]

In granting the petition for irradiation of meat and meat products, the FDA accepted without adequate justification the petitioner's suggested maximum dose of 7.0 kGy for frozen meat and 4.5 kGy for fresh meat.[36] As the WHO points out, however, there is no safety reason for *any* upper limit to the dose of irradiation used to reduce food pathogens.[37] Moreover, the WHO notes that "in some instances, an upper limit of 10 kGy for the overall average dose could preclude the effective use of the technology."[38] Thus, the maximum dose of irradiation established by the FDA for meat may be too low and preclude feasible reductions in food-borne illness. Indeed, there is good evidence to suggest that the FDA's upper limit for the irradiation dose for poultry is too low. While the FDA allows irradiation of fresh and frozen poultry up to only 3 kGy,[39] the dose recommended by an authoritative reference guide is 3-5 kGy for frozen poultry.[40]

While very high irradiation doses may provoke undesirable *aesthetic* changes in food (and raise irradiation costs to the producer), aesthetic concerns do not provide a

[31] See U.S. Department of Energy (1990).
[32] See 10 CFR 20.1001-2402 (1999), and 29 CFR 1910.1096 (1999).
[33] See U.S. Department of Transportation (1979).
[34] Data from Sandia National Laboratories (Albuquerque, NM) Radioactive Material Incident Report Database, as cited in USDA (1999a).
[35] See USDA (1999a).
[36] See U.S. FDA (1997).
[37] See World Health Organization (1997).
[38] See World Health Organization (1997).
[39] See U.S. FDA (1990).
[40] See Wilkinson and Gould (1996, 127).

policy rationale for a mandatory ceiling on the dose. After all, food producers are allowed to sell mealy apples and highly sugared breakfast cereal without federal restrictions, because consumers are good at choosing foods that they like. There is no policy rationale for a maximum dose as stringent as the one established for frozen poultry by the FDA. The USDA should immediately petition the FDA to raise substantially that upper limit because such stringent limits preclude effective pathogen reduction.

Irradiation is more effective at reducing microbial pathogens than other approaches, such as those mandated by the USDA's most recent major rule addressing food safety. The USDA in 1996 required food manufacturing plants to adopt a system of science-based controls, procedures, and testing, called hazard analysis of critical control points (HACCP).[41] Yet the effectiveness of HACCP in limiting foodborne illness is quite uncertain. The USDA acknowledged it does not have "the knowledge to predict the effectiveness of the requirements in the rule to reduce illness."[42] HACCP may be ineffective even at reducing *pathogens* on food in establishments that *voluntarily* adopt it. In the 1996 HACCP rule, the USDA wrote:

> The Agency recognizes that the potential effectiveness of HACCP in reducing pathogens within a regulatory framework is unknown at the present time. FSIS conducted a pilot HACCP study in 9 establishments from 1991 to 1993. Findings regarding pathogen reduction effectiveness were inconclusive.[43]

That "inconclusive" finding stands in stark contrast to the dramatic billion-fold or trillion-fold reductions that irradiation can safely achieve at the doses the USDA proposed.

By the most common measure of the economic merit of a proposed policy – net economic benefits – food irradiation is a great idea. To see this, suppose that instead of banning irradiation, the FDA or the USDA had promoted and even required it for all meat and poultry, the main sources of foodborne pathogens in the United States. I assume for simplicity that the dose eliminates the risk. (As discussed above, this assumption is slightly optimistic because the FDA allows irradiation of meat only at doses that reduce pathogens by factors of 10 billion to more than 10 trillion.) For benefits I use the USDA's

[41] See USDA (1996).
[42] Ibid.
[43] Ibid, p. 38967. HACCP as specified in the final rule may differ from the controls, procedures and testing that were the subject of the pilot study.

estimates of the costs of illness from pathogens found in meat and poultry, after adjusting the value of mortality risk to reflect people's willingness to pay—an adjustment consistent with common practice and later work by the USDA.[44] The result is benefits of irradiating all meat and poultry from $11 billion to $28 billion per year. The costs would be about $1 billion per year, assuming that meat was irradiated at $.026 per pound and poultry at $.015 per pound. Since these estimates are based on engineering studies and not market prices, a more conservative assumption might be that costs are about twice as high, or about $2 billion. Given those figures, the net benefits are between $9 billion and $27 billion per year, though those estimates ignore the value of the reduced pain and suffering associated with reductions in nonfatal foodborne illness.

Another measure of the merit of irradiation, one that avoids assigning a dollar value to changes in mortality risk, is the cost per life saved.[45] However, the benefits from reduced nonfatal illness, even ignoring pain and suffering, exceed the cost of irradiation. Thus, the social cost per life saved is between *negative* $0.6 million and *negative* $3.2 million. That means that for every life saved, there is an additional benefit of $0.6 million to $3.2 million from reduced costs of illness. Those values are quite attractive relative to the cost-effectiveness of other government health and safety regulations.[46] Moreover, they are conservative because they ignore the pain and suffering associated with nonfatal illnesses and the reduced spoilage of irradiated food.[47] Irradiation of meat and poultry is therefore extremely cost-effective in reducing the risk of death.

Those estimates of the cost-effectiveness of irradiation, like many such estimates, ignore consumers' preferences, which are fundamental in economics. Many consumers are willing to buy irradiated food, according to recent experimental and market evidence, and those preferences provide another basis for estimating the net benefits of allowing food irradiation. Professors John Fox and Dennis Olson conducted studies in 1995 and 1996 of consumer demand for irradiated chicken and found that 43 percent of consumers bought irradiated chicken in retail trials when it was sold at the same price as other chicken. The irradiated product was labeled with an identifying symbol (called the

[44] See USDA (1996, Table 5). I adjusted the value of mortality risk using an estimate of $5 million per statistical life. All dollar values in this and the next paragraph are 1993 dollars.
[45] See Appendix for a detailed descriptions of the derivations.
[46] See, for example, Morrall (1986).

radura) and the statement "Treated by irradiation to control foodborne bacteria."[48] Many consumers would buy irradiated poultry even if it sold for a 10 percent premium. When irradiated chicken was sold in retail trials or in classroom experiments for a 10 percent premium, a markup greater than the costs of irradiation, approximately a quarter of consumers preferred it to nonirradiated chicken. Demand for irradiated food might rise further if it were effectively marketed or if labeling were more descriptive than bacterial "control."[49]

Those data suggest the net benefits of meat irradiation are much larger than the USDA's estimate. Assuming that 25 percent of ground beef is irradiated, the USDA estimates the value of the resulting health improvements at between $57 million and $140 million per year.[50] The USDA's mid-range cost estimate is $46 million per year, so mid-range estimates of benefits *net* of costs are about $10 million to $90 million per year, ignoring, for simplicity, the uncertainty in cost estimates. But those estimates are a small fraction of an alternative estimate based on the assumption that demand for irradiated ground beef is the same as demand for irradiated chicken. In figure 1, I present a demand curve for irradiated ground beef based on the demand that Fox and Olson estimated for irradiated chicken.[51] Given the USDA's mid-range estimate of the incremental cost of irradiating ground beef, 2.6 cents per pound, the net benefit of allowing irradiation of ground beef, measured as the area under the demand curve and above the supply curve, is about $900 million per year. Thus, the true benefit of allowing irradiation of ground beef may be ten times greater than the benefits estimated by the USDA. Taking into account the benefits of irradiating meat products other than ground beef, the total net benefits of the USDA's proposal may substantially exceed a billion dollars per year.

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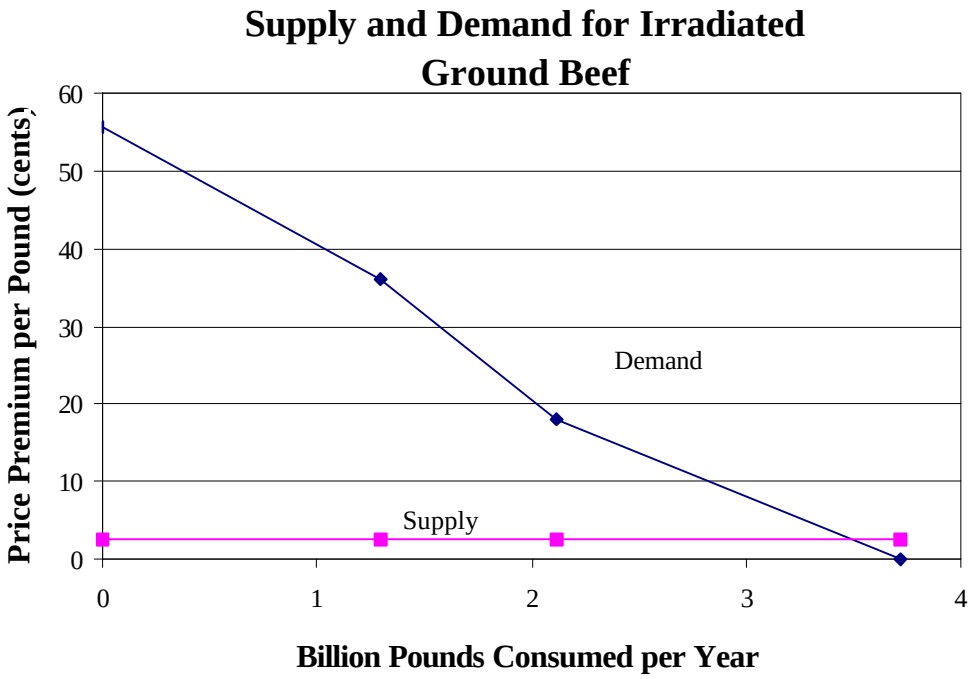
[47] See International Atomic Energy Agency (1993).
[48] Verbal communication with Dennis Olson, Ph.D., May 11, 1999.
[49] Figures in this paragraph are from Fox and Olson (1998).
[50] See Proposed Rule, Table 1.
[51] The underlying assumption is that the percentage premium that a given percentage of consumers is willing to pay for irradiated ground beef is the same as Fox and Olson estimated for chicken. Data on ground beef consumption and prices are taken from the proposed rule (p. 9097) the Economic Research Service's monthly price data for uncooked ground beef (www.econ.ag.gov/briefing/foodmark/cost/data/).



This analysis does not conform well with experience in the industry to date, however. Although irradiation of poultry has been permitted since 1992, and the market trials by Fox and Olson indicate that irradiated poultry could sell at a profit, [52] industry has been slow to offer the safer product to consumers. The USDA estimates that currently only about 1 percent of poultry is irradiated, [53] and none of the leading poultry producers offers an irradiated product. Various contacts in academia, public health organizations, and industry have offered different explanations of this lack of industry initiative. They ranged from companies' fears of anti-irradiation protests, [54] perceived lack of demand,[55] reluctance to be the first major company to market irradiated poultry,[56] and concerns as to how safety claims for an irradiated product would reflect on the safety of a company's nonirradiated product.[57] No explanation is completely satisfactory. My best guess is that grocers are reluctant to stock "safer" foods because such foods would raise questions about the safety of other foods already on supermarket shelves. In addition, their contracts with food suppliers typically include volume discounts that serve to discourage new products that would substantially hurt established brands. To the extent that meat

[52] See Fox and Olson (1998).
[53] See Proposed Rule, p. 9098.
[54] Private communication with John Marcy, Ph.D. Extension Food Scientist, Center of Excellence for Poultry Science, University of Arkansas, May 13, 1999.
[55] Private communication with Sara Risch, Institute of Food Technologists, May 17, 1999.
[56] Ibid.

producers are as slow to irradiate their products as chicken producers, the benefits of allowing irradiation may be much less than implied above.

Regulatory Delays

> **<u>Recommendation 1</u>: The USDA should expedite the proposed rule allowing irradiation of meat and meat products. The USDA should from now on develop rules to allow irradiation at the same time that the FDA determines conditions for the safe use of irradiation.**

Despite potentially large benefits and broad recognition that food irradiation is safe and effective, regulatory obstacles have delayed food irradiation. The FDA proposed to approve the use of ionizing radiation on spice and vegetable seasonings in 1983.[58] For pathogen control on poultry the USDA authorized use of irradiation only in 1992, although poultry is a prime source of the pathogens implicated in foodborne disease. Since 1992, the regulatory agencies have not approved irradiation of other foods.[59] Delays limit the availability of irradiated foods to American consumers and thereby lead to unnecessary illness and risk of death.

The key reason for delays in the approval of food irradiation is the two-step approval process required by USDA's regulations. Improving this process is difficult. Eliminating the first step—that is, the approval by the FDA—would require a legislative amendment to the Federal Food Drug and Cosmetic Act. That Act states: "A food additive shall be deemed to be unsafe unless there is in effect a regulation issued under this section prescribing the conditions under which such additive may be safely used."[60] Elsewhere that Act states "the Secretary [of Health and Human Services, who oversees the FDA] shall by order establish a regulation prescribing the conditions under which such [an] additive may be safely used."[61]

Eliminating the second step in the process, the approval by the USDA, would be time-consuming because it would require a rulemaking by the USDA to reform its own regulations. As described above, the USDA regulations prohibit a substance from being

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[57] Private communication with Pete Ellis, President, Food Technology Service, Inc. May 20, 1999.
[58] See Thayer *et al.* (1996).
[59] Ibid.
[60] See 21 USC 348(a) and (a)(2) (1998).
[61] See 21 USC 348(c)(1)(A) (1998).

used on foods regulated by the USDA unless a regulatory determination is made. The USDA could reform its regulations to make clear that irradiation is not a substance. Given that such interpretation delays the adoption of safe and effective means of improving food safety, the USDA's choice to treat food irradiation as a substance suggests that it is unlikely to act quickly in the pursuit of such reform.

Generally Recognized As Safe

> **<u>Recommendation 2</u>: To expedite and encourage food irradiation the FDA should determine that it is generally recognized as safe.**

The best way to encourage food irradiation involves the definition of food additive in the Federal Food Drug and Cosmetic Act.[62] The Act stipulates that "the term 'food additive' means any substance . . .(including any substance intended for use in producing, manufacturing, packing . . .; including any source of irradiation intended for such use), if such substance is not generally recognized, among experts qualified by scientific training and through scientific procedures, to be safe under the conditions of its intended use." The Food and Drug Administration could determine irradiation to be generally recognized as safe (GRAS) under the conditions of its intended use.

A determination that food irradiation is generally recognized as safe could be justified in the following ways. First, the WHO has found 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 [emphasis added]",[63] and it has recently recommended that no ceiling should be set.[64] In earlier GRAS determinations the FDA has relied heavily on findings of expert bodies like the WHO. For example, in a 1995 determination that maltodextrin derived from potato starch is safe, the FDA states

> The Joint Food and Agriculture Organization/World Health Organization (FAO/WHO) Expert Committee on Food Additives (JECFA) recognizes maltodextrin as an intermediate product in the production of enzyme-treated starches, a process that JECFA has stated results in the production of normal (meaning safe) food constituents.[65]

[62] See 21 USC 321(s) (1998).
[63] See World Health Organization (1981).
[64] See World Health Organization (1998).
[65] See U.S. FDA (1995, 48892).

The FDA could also justify a GRAS determination by citing the support and recommendations of the Codex Alimentarius Commission, the American Medical Association, the American Dietetic Association, the health authorities of approximately forty countries, and the respected Council on Agricultural Science and Technology.[66] Finally, the FDA could cite the U.S. Institute of Medicine, which recently wrote that "research in both the U.S. and other countries documented that irradiation is a safe and effective means of reducing the risk of exposure to foodborne pathogens."[67]

Assessing the public health cost of the delays in the current approval process—as opposed to a once-and-for-all GRAS determination—is difficult because many cases of foodborne illness are not confirmed, diagnosed, or even reported, and many therefore have no identifiable cause. Nonetheless, some data about reported food outbreaks permit a sketch of the total public health problem attributable to the consumption of contaminated foods that cannot now legally be irradiated. As shown in table 1, the number of *confirmed, diagnosed* cases of foodborne illness during outbreaks attributable to beef ranges from about 420 to 1400 per year.[68] The range results from uncertainty about whether beef is the cause of the illness when beef is only one of several ingredients in the suspected food and about what kind of meat was actually consumed. The number of confirmed, diagnosed deaths during outbreaks attributable to contaminated beef is between 0 and 1 per year. For all other nonpoultry foods, including eggs, fish, and pre-cooked meats, the numbers were much higher. For those foods, the number of confirmed diagnosed cases of foodborne illness during outbreaks is between about 4,400 per year and 14,000 per year, while the number of deaths is between four per year and fourteen per year. More recent reports suggest that the death count has risen.[69]

[66] See Thayer *et al.* (1996).
[67] See Committee to Ensure Safe Food from Production to Consuption (1998, 45). The Committee is associated with the National Academy of Science.
[68] See Bean *et al.* (1996).
[69] See Associated Press (1999).

Table 1

Confirmed Cases Of Foodborne Illness And Death
Annual Average For 1988 To 1992

Type of Food	Cases		Deaths	
	Lower Bound	Upper Bound	Lower Bound	Upper Bound
Beef	417	1424	0	1
All other non-poultry foods	4426	14239	4	14

Note: The upper-bound estimates cannot be added without double counting.
Source: Bean, Goulding, Lao, and Angulo (1996)

The total number of cases and deaths attributable to foodborne illness is likely to be much greater than those estimates. According to the Centers for Disease Control, "The outbreaks reported also include only a fraction of the cases of foodborne disease that occur; an average of 15,475 cases (14 deaths) each year was reported during 1988 to 1992, compared with a minimum [total] estimate of 6 million cases per year." [70] Reported estimates are low because they include only estimates from outbreaks, defined as instances in which two or more people suffer foodborne illness from the same source. Second, they exclude cases where people were afflicted but failed to seek medical attention. Third, they exclude cases that were diagnosed but not reported.

Delays in the approval of food irradiation have denied consumers access to foods that might avoid three thousand deaths and three million cases of foodborne illness each year. Reported illness and death from beef and other nonpoultry items account for at least a third, and possibly almost the total of all reported illness and death attributable to foodborne pathogens, according to the estimates presented above. If beef and all other nonpoultry items were implicated in the same proportion of all *estimated* illnesses and death, they would account for at least three million illnesses, and perhaps tens of millions of illnesses per year. A third of all estimated deaths would be about three thousand deaths per year.

[70] See Bean *et al.* (1996, 7).

Analysis of the USDA Proposal

Labeling

<u>Recommendation 3</u>: The USDA should allow irradiated foods to be labeled in a manner that is no more conspicuous and prominent than information about ingredients such as additives and preservatives. In addition, the USDA should not require any explanatory statement to appear as a qualifier next to the product name.

The USDA proposal increases the likelihood that consumers will react negatively to irradiated food by requiring prominent and conspicuous labeling of irradiated food and failing to authorize statements that irradiation reduces pathogen risks.

The proposal prescriptively mandates the placement of a required logo identifying the food as irradiated. The proposed rule states, "The [irradiation] logo must be placed prominently and conspicuously in conjunction with the required statement [e.g., treated with irradiation.]"[71] The USDA gives no reason why prominent and conspicuous placement is more appropriate than clear and legible placement. An alternative standard—that the statement be clear and legible—would ensure that people who do not want irradiated food are not misinformed, while reducing the risk that consumers misinterpret the logo as a warning.

The proposal also specifies, "The [explanatory] statement must appear as a qualifier contiguous to the product name."[72] The USDA gives no explanation for the requirement that the qualifier be contiguous to the product name. Since the government is treating the process of irradiation as an additive that it believes to be safe and effective at controlling pathogens, a more appropriate requirement would be to treat it like other added ingredients. Thus, the USDA could regulate the labeling for irradiation in the same way as the labeling for stabilizers or preservatives like monosodium glutamate. In that case, it would not require food manufacturers to do more than use a small radura and an explanatory statement placed next to the list of ingredients.

Both of the proposed requirements are more burdensome than requirements in the FDA's 1998 final rule on irradiation in the production, processing, and handling of

[71] See Proposed Rule, p.9102.
[72] Ibid.

food.[73] That rule states that "the radiation disclosure statement is not required to be more prominent than the declaration of ingredients".[74]

Some perspective on the burden inherent in these labeling requirements can be gained by a comparison with regulations for fresh produce. Although minute quantities of pesticides occur on most fresh produce, it is marketed without any federally mandated warning about the resulting risks. Yet the Environmental Protection Agency (EPA) acknowledges those risks and considers them when it approves the use of pesticides. The use of an approved pesticide in a given application increases consumers' risk of getting cancer over a lifetime by an average of four in a million, according to the EPA.[75] Even without mandatory labeling, however, consumers are informed about pesticide-free alternatives. Organic, pesticide-free produce is available in most stores and sells for a premium relative to other produce. By comparison, the USDA irradiation proposal would require labels to include information about irradiation, even though it has *no* known risks.

> **<u>Recommendation 4</u>: The USDA should authorize *qualitative* claims that irradiation substantially reduces pathogens, provided that firms can demonstrate that food products receive irradiation sufficient to achieve those reductions. The USDA should authorize *quantitative* claims of pathogen reductions, provided that a manufacturer can demonstrate that its food products receive irradiation sufficient to substantiate those claims.**

The USDA's proposal to require validation and prior approval of health claims is too restrictive. In the preamble the agency states that it would "consider for approval labeling statements for meat products indicating the elimination or reduction of certain pathogens."[76] The USDA states further that the "prerequisite for such statements on meat and poultry would be a HACCP plan or process schedule *validated* as achieving, through irradiation, the specific elimination or reduction in pathogens indicated by the labeling" [emphasis added].[77] Thus, food products subject to, for example, a 3 kGy dose of irradiation could not be labeled that they were irradiated to protect health by reducing

[73] See U.S. FDA (1997).
[74] Ibid, § 179.26(c)(1).
[75] See Van Houtven and Cropper (1996, Table IV).
[76] See Proposed Rule, p.9094.
[77] Ibid.

pathogens, *unless* a plan or schedule were first validated as achieving the specified reduction in pathogens, and the USDA approved such labeling.

The USDA's proposed requirement for validation and prior approval of health claims has three adverse effects:

- It creates uncertainty for the affected firms.
- It is more burdensome than a standard that claims cannot be unfair or deceptive, such as is used by the Federal Trade Commission.[78]
- By raising the costs of marketing irradiated foods, the proposed rule may deter the use of irradiation and thereby reduce food safety.

The research by Fox and Olson suggests that correct information about the beneficial effects of irradiation is necessary to ensure that consumers view irradiated foods positively. In a market experiment that replicated a retail trial but required that participants read about irradiation, 80 percent of participants purchased the irradiated product, well above the proportion of 43 percent observed in the retail trial, where consumers were not required to read about irradiation.[79] Thus, information regarding the health benefits of irradiation is vital to consumer acceptance, and restrictions on legitimate claims could have negative effects.

The Scope of the Proposal

<u>Recommendation 5</u>: The USDA should immediately ask the FDA to approve irradiation of eggs and shellfish. It should also promptly submit a petition for the irradiation of precooked meats.

The USDA's irradiation regulation would have much greater net benefits and result in larger public health benefits if its scope were extended to allow irradiation of more kinds of foods. As described above, the foods most likely to be implicated in foodborne illnesses are poultry, meat, fish, and eggs. Yet USDA rules now permit only poultry to be irradiated to reduce pathogens. The current USDA proposal, when promulgated, would authorize irradiation of uncooked meats but take no action to allow irradiation to control pathogens in precooked meats, seafood, eggs, or produce. Here I

[78] See USC Title 15, Chapter 2, §§ 44, 45, and 52 (1998).
[79] See Fox and Olson (1998). These percentages were for irradiated chicken at no price premium.

identify three instances of administrative delays or inaction responsible for the continued ban on irradiation of those foods.

Recently reported outbreaks suggest that precooked meats may contribute to foodborne illness in a manner similar to unprocessed meats. Outbreaks of listeriosis have prompted ten recalls of precooked meats this year alone. The USDA has considered issuing warnings on packaged ready-to-eat meats.[80] In one outbreak, fourteen deaths and ninety-seven illnesses were linked to contaminated hot dogs and deli meats.[81] Of course, the total incidence of such disease is probably much higher because most foodborne disease is not reported or properly diagnosed.

The USDA's proposal does not extend to precooked meats, although irradiation is as effective on pre-cooked meat as on unprocessed meat. Moreover, pre-cooked meat products are currently cleared for irradiation in eleven countries.[82]

The USDA's inaction in authorizing irradiation of pre-cooked meats is responsible for a share of these illnesses and deaths. While the USDA cannot allow irradiation of a food until the FDA approves it as a food additive,[83] nothing prohibits the USDA from petitioning the FDA to approve irradiation for specific foods. Indeed, the USDA could follow the precedent established when it petitioned the FDA to allow irradiation of poultry in 1987.[84] It could petition the FDA to approve the use of irradiation to reduce pathogens on pre-cooked meats.

According to the USDA, as many as 2.7 million eggs consumed annually in the United States may contain the bacteria *Salmonella enteritidis.* From 1985 to 1996 there were over ninety-five thousand documented cases attributable to the bacteria:[85] "Most of these outbreaks were attributed to eating undercooked, infected eggs."[86] The number of documented cases increased fairly steadily during that time-period. The total number of cases is estimated to be much larger, but trends in the total number are unknown.

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[80] See Avila (1999).
[81] See Associated Press (1999).
[82] See Olson (1999).
[83] The Food Additives Amendment to the Federal Food, Drug and Cosmetic Act, passed in 1958, gives the FDA the primary responsibility for approving the use of an additive prior to its inclusion in food.
[84] See U.S. FDA (1987).
[85] See Kurtzweil (1999).
[86] See Bean *et al.* (1996, 1).

Irradiation of eggs has long been advocated by industry safety analysts and has been shown to be a safe and effective method of reducing pathogens. Counts of *Salmonella enteritidis*, which is a leading cause of outbreaks, illnesses, and deaths attributable to foodborne bacterial pathogens in the United States,[87] can be reduced by a factor of approximately ten thousand by irradiation doses of 1.5 kGy.[88]

The FDA has not acted on a petition to approve irradiation of eggs. Dr. Edward Josephson, a recognized expert in the field of food irradiation who is also co-chair of a task force on irradiation convened by the independent Council for Agricultural Science and Technology (CAST), submitted a petition for irradiation of fresh shell eggs to kill *Salmonella* in 1998. Although it is currently under "expedited review" by the FDA, the agency has set no expected approval date.[89] Delays in the FDA's approval contribute to *Salmonella*-related illness caused by contaminated eggs.

Foodborne pathogens in fish accounted for 1,994 cases of illness and six deaths in the 180 outbreaks documented by the CDC during its most recent five-year surveillance period.[90] As noted earlier, experts believe that only a small percentage of illnesses and deaths caused by foodborne pathogens are ever reported; the actual health impact of foodborne pathogens in seafood is therefore far greater.[91]

Irradiation is recognized as an effective treatment for pathogens in certain types of seafood, and at least fifteen countries currently allow its use for microbial control in seafood and seafood products.[92] *Vibrio* species, found by some studies to infect close to 100 percent of oyster lots in summer months, have a 50 percent fatality rate for susceptible persons but can be eliminated by low dose-gamma irradiation.[93] *Listeria*, another potentially fatal pathogen found in up to 49 percent of raw seafoods tested,[94] can also be reduced by irradiation.

The FDA is holding in abeyance petitions to allow irradiation treatment of fresh seafood and shellfish because it found the petitions to be deficient. The FDA has said it

[87] See Bean *et al.* (1996).
[88] See Serrano *et al.* (1997).
[89] See U.S. FDA (1999b).
[90] See Bean *et al.* (1996).
[91] See Buzby *et al.* (1996).
[92] See International Consultative Group on Food Irradiation (1999).
[93] See U.S. FDA (1993).
[94] See Dillon and Patel (1992).

will reconsider those petitions only when these deficiencies are remedied.[95] Delays in permitting irradiation for pathogens in seafood result in more illness and deaths.

Regulatory Redundancy: no existing rules would be relaxed

> **<u>Recommendation 6</u>: The USDA should promptly act to reduce redundant regulations. It should exempt firms that adequately irradiate from the HACCP requirement to test for *Salmonella.***

The USDA did not propose any modification or reform of existing regulations as part of its irradiation proposal. When more effective pathogen controls are introduced, however, questions arise about the appropriateness of existing regulations.

Tests for *Salmonella* may be unnecessary for facilities that irradiate food. The HACCP rule stipulates mandatory numeric performance standards for *Salmonella* based on the results of tests to be conducted by the FSIS. Maintaining such a performance standard for *Salmonella* in a plant that uses irradiation to control pathogens makes little sense. If sampling for *Salmonella* is conducted prior to irradiation it is unnecessary because subsequent irradiation would destroy all or nearly all of the *Salmonella* and ensure that it poses no threat to public health. If such sampling is conducted after a well-monitored irradiation operation, it would provide no useful information. Therefore firms that adequately irradiate should be presumed to comply with the *Salmonella* performance standards and be exempt from the testing requirement.

The savings from eliminating such redundant requirements are potentially significant. In the HACCP regulation, the costs of compliance with the *Salmonella* standard ranged from $56 million to $243 million.[96] *Salmonella* testing costs were not separately estimated. If firms could exempt themselves from a large fraction of those costs by using irradiation, and a large fraction of eligible firms elected to use irradiation, cost savings could surpass $100 million.

[95] See U.S. FDA (1999a).
[96] See USDA (1996, 38946).

Conclusions

Given the evidence about the safety and effectiveness of food irradiation, why have the FDA and the USDA not proposed regulations to allow it or even to require it? A clue to this puzzle lies with cautionary or critical positions taken by several "public interest" groups, despite the ringing endorsement of irradiation by nearly all significant public health organizations. Food and Water, a stridently anti-irradiation group, has paid for ads and organized phone and letter-writing campaigns against the irradiation of food.[97] Consumers Union, which publishes Consumer Reports, has taken a position of studied neutrality on the subject,[98] despite the clear public health benefits of pathogen-reduced foods. 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 the process of public health protection by advocating conspicuous labeling and even *increased* testing.[99] Such additional testing would raise the costs of making food safer, provide a disincentive to producers, and thus would inhibit industry from making irradiated food available to consumers.[100] When such peculiar positions are adopted by well-recognized groups claiming to act in the public interest, government agencies seeking to regulate by consensus may not take controversial actions even when they are the best means of protecting public health.

Despite the unenthusiastic stances of the self-proclaimed public interest groups, the continued ban on irradiation of some foods by the federal health and safety agencies is seriously detrimental to public health. There are no health or safety justifications for banning irradiation, but there are many reasons to allow and promote its use. It is tragic that federal health and safety agencies have restricted and delayed the approval of a low-cost and effective method of improving public health that prominent scientific organizations have recommended and declared safe.

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[97] See Food and Water, Inc. (1996).
[98] See Consumers Union (1998).
[99] See Public Voice for Food and Health Policy (1998).
[100] See Hahn (1998).

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Appendix

The cost-per-life-saved calculation is based on a set of assumptions. I assume irradiation of meat and poultry eliminates all of seven key pathogens (the bacteria *Campylobacter jejuni* or *coli, Clostridium perfringens, Escherichia coli O157:7, Listeria monocytogenes, Salmonella, Staphylococcus aureus,* and the parasite *Toxoplasma gondii*.) I took the estimated number of cases, the estimated number of deaths, and total medical and productivity costs for foodborne illness (for meat and poultry) from the 1996 FSIS Final Rule for HACCP.[101] The FSIS estimated the annual number of deaths from foodborne illness associated with meat and poultry to range from 1436 to 4502, including fetal deaths.[102] To be conservative I use estimates that exclude the fetal deaths: 1381 to 4382. I calculate the annual value of nonfatal illness to be $3.8 to $5.9 billion. I subtract those values from the costs to develop estimates of the net cost, that is the net benefits unrelated to mortality.

Total costs of irradiation were based on 1993 estimates of meat and poultry consumption in the United States found in Putnam and Allhouse. Specifically, I used retail-weight "food disappearance" values for 1993 for beef, veal, lamb, pork, chicken and turkey.[103] The cost to irradiate red meats (beef, veal, lamb and pork) was taken from the 1999 FSIS Irradiation of Meat and Meat Products proposed rule, Table 2. Because the FSIS 'high cost' estimate is based on operating costs for the one U.S. plant that currently irradiates foods, which at the moment is operating far below full capacity, I used the FSIS midrange costs of $0.026/pound, which also includes labeling and transportation costs. For chicken, I used the highest estimated unit cost published in the 1992 FSIS proposed rule to allow irradiation of poultry products ($0.015/pound). This cost does not include transportation costs, because it is assumed that irradiation will be included as a final step in the processing plant. Total irradiation costs for meat and poultry in 1993 were approximately $1.09 billion. To test the sensitivity of the benefit-cost analysis to variations in irradiation cost (for example, if greater irradiation doses were required to ensure pathogen elimination), I simply included double that total cost in the range of the benefit-cost analysis.

To calculate morbidity costs resulting from these foodborne pathogens, I subtracted the cost of deaths estimated in the 1996 HACCP rule from the total costs of foodborne pathogens. The cost of death has to be determined separately for each pathogen.

- Buzby *et al*. specify an average cost per death for *Salmonella* and *Campylobacter* ($385,355, which includes only medical costs and productivity losses.)
- I calculated average cost per death (including both medical and productivity costs) for *E. coli* using data from Buzby *et al*. The average cost of a death due to *E. coli* was $1,225,000. This number is high compared to the value for other pathogens because the medical costs associated with *E. coli*, including

[101] See USDA (1996).
[102] See USDA (1996, p. 38964).
[103] Food disappearance is often used as a proxy for food consumption and has the benefit for my analysis of representing a conservative upper bound value (i.e. food disappearance is greater than food consumption, which makes the total food irradiation costs higher and the cost per life saved more conservative.)

dialysis and kidney transplants, are extremely high, and the age of onset is quite young (average age, four years).

- I calculated the average cost per death for *Listeria* using data from Buzby *et al*. The average cost of a death from listeriosis ($384,000) is closer to the average cost of death for *Salmonella* and *Campylobacter*. *Listeria* does cause newborn/fetal deaths, but the resulting increase in the average cost of death is slight because newborn/fetal deaths are only 3 to 15 percent of all deaths.[104]
- I assume the same cost per death for *Staphylococcus* and *Clostridium perfringens* as the value Buzby *et al.* had calculated for *Salmonella* and *Campylobacter* ($385,355.) Implicitly, I assume both illnesses have similar age distributions of fatalities and similar medical costs.
- In a discussion with Dr. Roberts about her paper on *Toxoplasma gondii* (which is the paper cited in the HACCP rule) she informed me that all deaths associated with the parasite are newborn/fetal deaths. The cost of death was therefore $1,097,792.

[104] Newborn/fetal deaths are valued using the Landefeld-Siskin productivity cost approach ($1,097,792) but have no associated medical costs, as the medical costs for the mother are assumed to be part of the mother's morbidity, not medical costs for the stillborn infant or aborted fetus. This matters only in the calculations for *Listeria* and *T. gondii*, as they are the only pathogens described by Buzby *et al.* or Roberts as causing newborn/fetal deaths.