FOOD IRRADIATION:

WHY AREN'T WE USING IT?

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Introduction

Food safety is widely recognized as an increasingly significant public health concern in the United States. Recent history has included too many examples of recalls necessitated by the presence or suspected presence of foodborne pathogens such as *E. coli*, *Listeria*, and *Salmonella*. The increasing emphasis on the problem of food safety led to the creation of the President's Council on Food Safety and Applied Nutrition (CFSAN). Even unsophisticated consumers have become more attuned to the potential dangers of food-related illness in the wake of media coverage of foodborne pathogens, notably the outbreak of mad cow disease in Europe.

In the face of growing concern about food-related illness, food irradiation has entered the picture. Irradiation is not a new technology by any measure. In modern society, irradiation is routinely used to sterilize medical equipment, including most of the disposable items used in hospitals every day. Nor is irradiation of food itself a new development. FDA has approved irradiation of food for limited purposes since 1963, and NASA has used irradiated food on its space missions for decades as a precaution against foodborne pathogens. But it is only within the last 20 years that irradiation has been approved for the types of usage that would have a substantial impact of the presence of foodborne pathogens.

Despite its conceded effectiveness against foodborne pathogens, the use of irradiation is still uncommon in the food industry. The question is why a technology that is both extremely effective and safe by any scientific measure would be greeted with such hesitancy by the food industry. The goal of this paper is to provide some insight into that question. The first part of this paper provides background on the technology of food irradiation, the problem of foodborne microbial pathogens, and the effectiveness of food irradiation on that problem. The second part turns to the arguments against food irradiation, including scientific and economic arguments as well as irrational arguments (i.e., those arguments implicating concerns apart from safety or economic efficiency). The paper concludes with a discussion of the implications of these arguments for the future of food irradiation technology.

PART I – THE TECHNOLOGY OF FOOD IRRADIATION

§1. What Is Food Irradiation?

The term food irradiation may be applied to any process that exposes food either to electromagnetic radiation or to high-energy particles.[1] Electromagnetic energy can be generated by radioactive isotopes, as in the case of gamma ray irradiation, or by bombardment of thin metal films with high-energy electron beams to produce radiation, as in the case of X-ray irradiation.[2] Alternatively, a high-energy electron beam (e-beam) can be directed at the food itself.[3] In all of these cases, the radiation is absorbed by the food, and more particularly, by the microbial organisms in the food. This absorption disrupts the complex organic molecules of the microbes, either preventing the microbes from reproducing or killing them outright.[4] The effectiveness of the treatment varies based on the type of radiation used, the intensity of the radiation, and the microbe in question. The relative advantages and disadvantages of the three forms of food irradiation (gamma ray, X-ray and e-beam) used today are discussed below.

Regardless of form, food irradiation is fundamentally about how much energy is absorbed by the target food. It is helpful to have a measurement for what dosage of radiation will be required independent of the amount of food to be irradiated. For this reason, radiation doses are measured in *kiloGray* (kGy).[5] A dosage of one kGy indicates that the target sample receives 1000 Joules (metric units of energy, abbreviated J) per kilogram of sample mass.[6]

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[1] *See* Center for Disease Control, *Frequently Asked Questions about Food Irradiation* (last reviewed Sept. 29, 1999) <http://www.cdc.gov/ncidod/dbmd/diseaseinfo/foorirradiation.htm> [hereinafter *CDC Irradiation FAQ*] at 2.

[2] *See id.*

[3] *See id.*

[4] *See id.* at 4.

[5] *See* Kim M. Morehouse, Ph. D., *Food Irradiation: The Treatment of Foods with Ionizing Radiation*, Food Testing and Analysis, June/July 1998 edition (Vol. 8., No. 3) at 9.

[6] *See id.*

When measuring the effect of radiation on the microbe population of food, it is useful to have a measurement that does not depend on the number of microbial organisms in a particular sample of food. For this reason, the effect of radiation on microbes is measured by a dosage called the *D value*. The D value is the dosage of radiation required to reduce the microbe population of a sample by 90%.[7] If a particular organism has a D value of 0.5 kGy in a particular kind of food, then exposing a 1 kg sample of that food containing the organism to 500 J of radiation will kill 90% of the population of that organism. An additional amount of dosage equal to the D factor will reduce the remaining microbe population by 90%.[8] Thus, exposing the sample in the example above to 1000 J of radiation would reduce the microbe population by 99%; 1500 J would remove 99.9% of the microbe population; etc. Varying the power of the source or the duration of exposure controls the amount of radiation the target receives. The energy of electron guns used for e-beams and X-rays is typically measured in electron volts (eV), units of energy convertible to J.[9]

The D value will depend primarily on the type of food irradiated and the type of organism to be eradicated by irradiation. Generally, the more complex the organism, the more sensitive the organism will be to radiation, since the operation of complex microbes is easier to disrupt.[10] Viruses, the simplest form of life, are most difficult to destroy.[11] Many bacteria collapse into a dormant state known as a *spore* (as contrasted with the *vegetative* state) when conditions are unfavorable to growth (e.g., when the oxygen or temperature levels are too low).[12] The D value for spores is higher than the corresponding D value for the vegetative state.[13]

Other factors that affect the D value are the strain of organism involved, the state of the food (frozen or unfrozen), ambient oxygen and temperature.[14] The difference between frozen and unfrozen food is particu-

[7] *See CDC Irradiation FAQ* at 3.
[8] *See id.*
[9] *See id.* at 4.
[10] *See id.*
[11] *See id.*
[12] *See* Irradiation in the Production, Processing and Handling of Food, 62 Fed. Reg. 64,107, 64,115 (1997) (amending 21 C.F.R. pt. 179).
[13] *See id.* at 64,116.
[14] *See id.* at 64,115.

larly important, since one of the most effective ways of controlling microbial pathogens in food is to keep the food below a temperature at which the pathogen can grow.[15] More radiation is required to kill microbes in frozen food,[16] and the slight heating that results from incidental absorption of radiation by the food has the danger of raising the food to a temperature that would allow pathogenic organisms to grow. Consequently, temperature effects must be carefully monitored in most foods.

Gamma Ray Irradiation

The simplest form of irradiation, at least in concept, is gamma ray irradiation. In this form of irradiation, the source of radiation is a radioactive element that emits photons in the gamma ray range of the electromagnetic spectrum.[17] Gamma ray photons have a higher frequency (and therefore energy) than either ultraviolet or X-ray photons. Gamma rays can penetrate a target food (or medical product) to a depth of several feet and reach microbial contaminants anywhere within that range.[18]

While simple in concept, gamma ray irradiation can be difficult in practice. The first difficulty is selecting a radioactive source element. In addition to radiating gamma rays, many radioactive elements also produce alpha rays (helium nuclei), beta rays (high- energy electrons or positrons) and/or high-energy neutrons. Alternatively, they might decay into another radioactive substance that generates these other forms of radiation. The other forms of radiation are undesirable because they have the potential to make the target food (or medical product) radioactive.[19] To date, the only radioactive isotopes approved as having the proper radiation profile are Cobalt 60 and Cesium 137, with only Cobalt 60 being actually used for food irradiation at the present time.[20] These radioactive isotopes are produced by exposure of the ordinary element to a nuclear reactor core,[21] and their availability may be conditioned on the continued availability of nuclear

[15] *See id.* at 64,116.
[16] *See id.*
[17] *See CDC Irradiation FAQ* at 2.
[18] *See id.*
[19] *See id.*
[20] *See* General Accounting Office, *Food Irradiation: Available Research Indicates That Benefits Outweigh Risks*, August 2000, at 1, *available in* <http://www.gao.gov/new.items/rc.PDF> [hereinafter *GAO Irradiation Report*].
[21] *See CDC Irradiation FAQ* at 7.

power.

Even after a source is selected, there are logistical complications in gamma ray irradiation. Radioactive elements do not have an off switch, nor do they come equipped with directional or intensity controls. Gamma rays can be contained by immersion of the source in a sufficient quantity of water, but the source must be removed from the pool in order to irradiate the target food.[22] In order to prevent inadvertent gamma ray exposure, the source must be insulated from the outside world by several feet of concrete.[23]

<u>E-beam irradiation</u>

E-beam irradiation, though it uses the same term as gamma ray irradiation, is a completely different kind of treatment. High-energy electron beams are produced in an electron gun, a larger version of the cathode ray gun found in devices such as televisions and monitors.[24] The electrons can be directed by a magnetic field to a target food. The term irradiation is really a misnomer, since the food not exposed to electromagnetic radiation or beta rays (electrons produced by a radioactive source). Nevertheless, the process has a similar effect to that of gamma ray irradiation. E-beam irradiation requires shielding as well, but nothing like the concrete bunkers used in gamma ray irradiation.[25] The disadvantage of the e-beam is its short penetration depth (about an inch), preventing its application to many foods and limiting the amount of food that can be processed in bulk.[26]

<u>X-Ray Irradiation</u>

X-ray irradiation is a relatively new technique that combines many of the advantages of the other two methods. Like gamma ray irradiation, X-ray irradiation consists of exposing food to high-energy photons with a long penetration depth. In this case, however, bombarding a metal film with a high-energy electron beam

[22] *See id.* at 2.
[23] *See id.*
[24] *See id.*
[25] *See id.*
[26] *See id.*

produces the photons, allowing the radiation to be turned on and off.[27] The device is a more powerful version of the X-ray machines used in medical offices. The device still requires heavy shielding, although the amount of shielding required is less than that for gamma ray irradiation.[28] No radioactive substances or by-products are used in, or result from, the process.[29]

[27] *See id.*
[28] *See id.*
[29] *See id.*

§2. Knowing the Enemy: A Primer on Foodborne Microbial Pathogens

Food irradiation cannot be understood without reference to the problem to which it is directed. One of the biggest problems with the acceptance of food irradiation in society is that few people are fully aware of how serious the problem of foodborne illness can be. In a way, this reflects well on our existing food safety measures, since it presumably indicates a great deal of consumer confidence in the quality of the food they purchase. Consumers quite rightly perceive the food supply in the U.S. to be the safest in the world, but there is always room for improvement. In the case of foodborne illness, there are productivity losses from illness that can be avoided and even human lives that can be saved.

Even given the relative safety of the food supply, the harm created by food-related illness is nothing short of staggering. According to estimates by the Economic Research Service of the U.S. Department of Agriculture (ERS), five common foodborne pathogens were responsible for an estimated 6.9 *billion* dollars worth of lost productivity in last year alone![30] The Center for Disease Control (CDC) carefully tracks the reported incidence of food-related illness and makes estimates for unreported cases based on those statistics. From the CDC estimates, foodborne pathogens kill as many as 5000 Americans every year.[31]

Salmonella

Various species of the *Salmonella* genus are responsible for an estimated 1.5 million cases of food-related gastroenteritis.[32] Although rarely fatal (less than one percent of hospitalized cases result in death[33]), the

[30] *See* Economic Research Service, *ERS Estimates Foodborne Disease Costs at 6.9 Billion Per Year* (updated March 12, 2001) <http://www.ers.usda.gov/Emphases/SafeFood/features.htm>.

[31] *See* Paul S. Mead, Laurence Slutsker, Vance Dietz, Linda F. McCaig, Joseph S. Bresee, Craig Shapiro, Patricia M. Griffin, and Robert V. Tauxe (Centers for Disease Control and Prevention, Atlanta, Georgia), *Food-Related Illness and Death in the United States*, Emerging Infectious Diseases, Sept.-Oct. 1999 (Vol. 5, No. 5) [hereinafter *CDC Foodborne Disease Report*] at 607.

[32] *See id.* at 610.

[33] *See id.*

sheer number of people affected by *Salmonella* makes it a serious concern for public health. *Salmonella* is responsible for an estimated 556 deaths per year, over 30% of the total from foodborne pathogens.[34] *Salmonella* is most common in poultry products, including eggs, but it also can appear in meat and milk.[35] *Salmonella* presents a distinctive problem from a regulatory perspective in that FDA does not treat food as adulterated merely because the food contains *Salmonella*.

Foods like poultry and eggs are understood to contain *Salmonella* as a matter of course, and consequently, FDA does not seize these foods or demand their recall. Of course, foods that do not naturally contain *Salmonella* but later become contaminated with the bacteria would be subject to regulatory sanctions.

One reason that FDA is tolerant of *Salmonella* is that foods that contain *Salmonella* are safe for human consumption with proper preparation. Unfortunately, consumer compliance with food safety standards is notoriously unreliable. For example, few consumers realize that thawing chicken out of the refrigerator allows *Salmonella* to reproduce to numbers that may not be eliminated by cooking. Using the same cutting board, countertop or kitchen utensils for meat products followed by vegetables or other foods that will not be cooked can taint the uncooked foods with *Salmonella* unless the area or utensil is carefully cleaned. Products that use raw eggs, such as the dressing commonly used on Caesar salads, can present a hidden risk for *Salmonella*.[36] Such mistakes combine to cause an estimated $2.4 billion dollars in economic loss every year attributable to *Salmonella*.[37]

Escherichia coli

Unlike *Salmonella*, *E. coli* bacteria are not naturally present in any kind of food. Serious outbreaks of *E. coli* poisoning have only recently drawn much attention, and they principally result from contamination of

[34] *See id.*

[35] *See* Economic Research Service, *Economics of Foodborne Disease: Food and Pathogens* (updated Feb. 22, 2001) <http://www.ers.usda.gov/briefing/FoodborneDisease/foodandpathogens/index.htm>

[36] *See id.*

[37] *See* Economic Research Service, *supra* n. 30.

beef at some point during processing. Ground beef, because it requires the most processing, presents the greatest risk for *E. coli*.[38] *E. coli* contamination can also result from mishandling at the point of service, such as salad bars. Like *Salmonella*, *E. coli* is rarely fatal if treated (less than one percent of hospitalized cases result in death[39]).

FDA considers food tainted with *E.coli* to be adulterated and thus subject to all of the regulatory sanctions at FDA's disposal. Historically, FDA has made every effort to locate the source of *E.coli* outbreaks in order to sterilize the area and to avoid any future contamination. Given the concern created by publicized outbreaks of *E. coli*, manufacturers have a substantial incentive to recall contaminated products voluntarily. Despite these efforts, *E. coli* cost an estimated one billion dollars in lost productivity and 78 deaths in 2000.[40]

Listeria monocytogenes

Listeria is a bacterial pathogen most notorious for its outbreaks in hot dogs.[41] Like *E. coli*, *Listeria* does not naturally occur in food, and contaminated food is seized or recalled. In addition to causing gastroenteritis, *Listeria* poses an even greater risk to pregnant women. Fetuses exposed to *Listeria*, if they are not killed outright, may be permanently harmed by the exposure.[42] In the year 2000, *Listeria* cost an estimated $2.3 billion dollars[43] and 499 human lives.[44]

Campylobacter jejuni and coli

The *Camplylobacter* strains are most commonly found in poultry, but also appear in a variety of other foods as well.[45] In terms of economic harm, *Campylobacter* ranks behind only *Salmonella*, causing an estimated

[38] *See* Economic Research Service, *supra* n. 35.
[39] *See CDC Foodborne Disease Report* at 610.
[40] *See* Economic Research Service, *supra* n. 30.
[41] *See* Economic Research Service, *supra* n. 35.
[42] *See* Economic Research Service, *supra* n. 30.
[43] *See id.*
[44] *See CDC Foodborne Disease Report* at 610.
[45] *See* Economic Research Service, *supra* n. 35.

$1.2 billion in 2000.[46] Although *Campylobacter* is not often fatal (causing only 99 deaths per year[47]), it can have chronic effects in the form of Guillain-Barre' syndrome, making it difficult to identify the source of the illness.[48]

Vibrio

Bacteria of the *Vibrio* genus are found most commonly in oysters and, to a lesser extent, in other shellfish.[49] Because oysters are eaten raw, the danger of human exposure to *Vibrio* is appreciable. *Vibrio* is considerably more dangerous to humans that any of the pathogens discussed previously. One species, *V. vulnificus*, has a 39% fatality rate for hospitalized cases, even though an estimated 91% of those infected do make it to the hospital.[50] Fortunately, *Vibrio* itself is relatively rare, but for the unlucky few exposed to *Vibrio*, the effects can be deadly (33 deaths in 2000).[51]

[46] *See* Economic Research Service, *supra* n. 30.
[47] *See CDC Foodborne Disease Report* at 610.
[48] *See id.* at 611.
[49] *See* Economic Research Service, *supra* n. 35.
[50] *See CDC Foodborne Disease Report* at 610.
[51] *See id.*

§3. The Effects of Food Irradiation on Microbial Pathogens

Just how effective is food irradiation? As discussed below[52], FDA and USDA have approved doses of 3.0 kGy for poultry, 4.5 kGy for other unfrozen meats, and 7.0 kGy for other frozen meats. Comparing those doses to the D value reveals the percentage of the microbe that will be killed by irradiation at the allowed dose. Some illustrative examples follow.

Salmonella

Depending on strain of bacteria and other factors, the D value of *Salmonella* ranges from 0.4 to 0.8 kGy.[53] At the 3.0 kGy dose approved for poultry, irradiation would kill over 99.9% of the most radiation-resistant strains of *Salmonella*.

E. coli

E. coli is even more radiation sensitive that *Salmonella*; it has a D value ranging from 0.2 to 0.4 kGy.[54] Exposure of beef to a 4.5 kGy dose would reduce the amount of *E. coli* in the sample by a factor of 100 billion. Considering that *E. coli* is not ordinarily present in beef, food irradiation could effectively eradicate the problem of *E. coli* in beef products.

Listeria

Listeria in beef, pork and lamb has a D value ranging from 0.40 to 0.48 kGy.[55] Using the 4.5 kGy approved dose would reduce the *Listeria* population by a factor of one billion. Unfortunately, irradiation has not yet been approved for processed meat products such as hot dogs, a common source of *Listeria*.

Campylobacter

[52] *See* Part I, § 4 of this paper.
[53] *See* Irradiation in the Production, Processing and Handling of Food, 62 Fed. Reg. at 64,115.
[54] *See id.*
[55] *See id.*

Campylobacter is one of the more radiation-sensitive bacteria, with the *C. jejuni* species having a D value ranging from 0.18 to 0.24 kGy.[56] The approved poultry dose of 3.0 kGy would leave only one trillionth of the original *Campylobacter* population. Considering that *Camplylobacter*'s effects are often chronic and difficult to trace back to food, food irradiation could prevent a great deal of food-related illness that might be undetectable and effectively unavoidable otherwise.

Radiation-resistant microbes

Most of the discussion thus far has been confined to the most common non-viral pathogens. For the sake of completeness, a few more organisms should be mentioned. *C. botulinum*, for example, is one of the more deadly pathogens (although not quite so virulent as *Vibrio vulnificus*); nearly 8% of hospitalized cases of botulism result in the patient's death.[57] *C. botulinum* also happens to be quite radiation-resistant in its spore phase, having a D value of between 2 and 4 kGy.[58] Irradiation, at least at conventional doses, would have a limited effect on *C. botulinum.*

Viruses also play a significant role in food-related illness, and they are much more resistant to radiation that other microbial pathogens. Since people exposed to a virus can often develop immunity to the virus, much of the incidence of food-related viral illness is found in children. For example, all children are exposed to rotavirus and astrovirus in early childhood, so that these viruses pose no threat in later life.[59] Recently, scientists have begun using new detection techniques to study Norwalk-like viruses (NLVs), believed to be a source of as many as 23 million cases of food poisoning last year.[60]

Hepatitis A is the most notorious of the viral food-related illnesses. About 5% of all cases of hepatitis A are traced back to food, but since 50% of all hospitalized cases have an indefinite source, the actual number

[56] *See id.*
[57] *See CDC Foodborne Disease Report* at 610.
[58] *See* Irradiation in the Production, Processing and Handling of Food, 62 Fed. Reg at 64,116.
[59] *See CDC Foodborne Disease Report* at 621.
[60] *See id.*

of food-related cases may be significantly higher.[61] Again, irradiation at conventional doses is unlikely to have a significant impact on hepatitis A, and sufficient irradiation could have undesirable effects on the characteristics of infected food (e.g., it might kill raw oysters, reducing shelf life).

Another class of disease unlikely to be affected by irradiation is bovine spongiform encepalopathy (aka, mad cow disease). Although the cause of the disease is still under study, scientists currently believe the culprit to be *prion particles*, simple collections of protein lacking DNA.[62] Their simple structure makes them resistant to disruption by radiation.[63]

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[61] *See id.* at 622.
[62] *See CDC Irradiation FAQ* at 4.
[63] *See id.*

§4. The Regulatory History of Food Irradiation

Section 201(s) of the Federal Food, Drug, and Cosmetic Act defines a food additive as any substance the intended use of which results or may reasonably be expected to result... in its [the substance] becoming a component or otherwise affecting the characteristics of any food (including... any source of radiation intended for any such use).[64] (Note: For simplicity's sake, Food, Drug and Cosmetic Act sections will be referred to by FDC Act §x rather than by USC citations.) FDC Act §409(c)(3)(A) (2001) requires that additives cannot be approved for a particular use unless the evidence establishes that the additive is safe for that use; i.e., unless the evidence shows to a reasonable certainty that no harm will result from the proposed use. Determinations for what constitutes a demonstration of safety for a particular case are left to the scientific expertise of FDA.

In addition, many of the products subject to irradiation are also subject to the provisions of the Federal Meat Inspection Act (21 USC §§ 601 et seq.), the Poultry Products Inspection Act (21 USC §§ 451 et seq.) and the Egg Products Inspection Act (21 USC §§ 1031 et seq.). These laws give the Food Safety and Inspection Service (FSIS) of the U.S. Department of Agriculture (USDA) joint authority with FDA to regulate the inspection of certain foods, such as meat and eggs. Irradiation of these foods must therefore be approved by both agencies in order for the process to be used lawfully. USDA can adopt processes previously approved by FDA provided that those processes also meet the requirements of the laws governing USDA.

Excluding ultraviolet radiation, the first approved use of food irradiation took place in 1963, when FDA approved the use of irradiation in doses from 0.2 kGy to 0.5 kGy to control mold and insects in wheat flour.[65] In the next year, FDA approved limited doses of radiation (0.05-0.15 kGy) to inhibit sprouting in white potatoes.[66] Somewhat surprisingly, food irradiation would not be approved for use against parasites and microbial pathogens for nearly 20 years. Around this time (in the period from 1953-1980), the U.S. Army

[64] 21 USC § 321(s) (2001).
[65] *See CDC Irradiation FAQ* at 5; *GAO Irradiation Report* at 28.
[66] *See GAO Irradiation Report* at 28.

and Atomic Energy Commission conducted studies of food irradiation under the National Food Irradiation Program (taken over by USDA in 1980).[67] Also during this time, NASA used food irradiation in order to protect its astronauts from the possible dangers resulting from food-related illness during space missions. Much of the data concerning the safety of food irradiation for humans comes from studies conducted on astronauts who consumed irradiated food.

The next wave of approvals for food irradiation would not come until the eighties. In this period, FDA finally began to approve food irradiation in order to control parasites, insects and microbes for a substantial number of foods. Starting in 1983, FDA approved doses of up to 10 kGy for the control of insects and microbes in spices and other dried vegetables (later raised to 30 kGy in 1986[68]). Also in 1986, FDA approved irradiation at doses up to 1 kGy to control Trichina parasites in pork.[69] That same year, FDA approved irradiation of fruits as a desirable alternative to pesticides for controlling insects and as a means to increase shelf life.[70]

In the nineties, food irradiation continued to expand, particularly into areas in which the products went directly to consumers. In 1990, FDA approved poultry irradiation at doses up to 3 kGy for bacterial pathogen reduction.[71] Two years later, USDA approved a like rule for doses ranging from 1.5-3.0 kGy as necessary.[72] In 1994, Isomedix, Inc., submitted a far-reaching petition for approval of food irradiation of edible mammalian tissue (including ground and other minimally processed forms thereof) in order to reduce the microbial population of those products.[73] In December 1997, FDA approved the petition for doses of up to 4.5 kGy for unfrozen meats and up to 7.0 kGy for frozen meat.[74] USDA subsequently approved its version

[67] *See id.*
[68] *See* Irradiation in the Production, Processing and Handling of Food, 51 Fed. Reg. 13,376 (1986) (amending 21 C.F.R. pt. 179).
[69] *See id.*
[70] *See id.*
[71] *See* Irradiation in the Production, Processing and Handling of Food, 55 Fed. Reg. 18,538 (1990) (amending 21 C.F.R. pt. 179).
[72] *See* Irradiation of Poultry Products, 57 Fed. Reg. 43,588 (1992) (amending 9 C.F.R. pt. 381).
[73] *See* Isomedix, Inc.; Filing of Food Additive Petition, 59 Fed. Reg. 43,848 (1994).
[74] *See* Irradiation in the Production, Processing and Handling of Food, 62 Fed. Reg. 64,107 (1997) (amending 21 C.F.R. pt. 179).

of the rule in February 2000.[75]

To a large extent, FDA's approval process for irradiation has been quite responsive to concerns about foodborne pathogens. This is probably in part due to the influence of the Council on Food Safety and Applied Nutrition (CFSAN), which serves an advisory role to other agencies in matters of food safety and which has promulgated guidelines for expedited consideration for food additives intended to reduce foodborne pathogens. FDA has expedited the approval process by relying on previous research to summarily conclude that conventional irradiation processes pose no environmental risk, thus removing an entire layer of regulatory approval.[76] FDA has reacted quickly to public health threats as well, as in the case of relatively rapid approval for beef irradiation following several publicized *E. coli* outbreaks. Perhaps the best example of these factors working together is the lightning-quick turnaround (in a regulatory sense) of the approval of sprout irradiation.

Sprouts gained increasing notoriety as a source of foodborne pathogens among food safety experts in the late nineties.[77] Although much of the contamination in sprouts comes from the point of service (e.g., at salad bars), sprouts pose a particular health hazard because they are too fragile for the vigorous washing used to clean other vegetables.[78] Because chemicals cannot be washed off of sprouts, there is a limit to how much chemical treatment can be applied. Historically, then, it had been virtually impossible to reduce significantly the natural microbial population of sprouts. Irradiation of seeds from which sprouts are grown provides a valuable alternative solution to the problem.

In 1995 laboratory tests, the Agricultural Research Service of USDA found that a combination of irradiation and submerging the seeds in a mild chlorine solution could eradicate *E. coli* and *Salmonella* from

[75] *See* Irradiation of Meat Food Products, 64 Fed. Reg. 72150 (1999) (amending 9 C.F.R. pts. 381 and 424 effective February 22, 2000).
[76] *See, e.g.,* Irradiation in the Production, Processing and Handling of Food, 62 Fed. Reg. at 64,119.
[77] *See Food Safety: Combo Method Protects Alfalfa Seed, Sprouts*, Food Ingredient News, *available in* 1999 WL 12866754 (1999).
[78] *See id.*

sprouts.[79] Four years later, Caudill Seed Co., Inc., submitted a petition (announced on August 16, 1999) to allow irradiation of seeds for sprouts without the need of chlorine.[80] Within a scant 13 months, FDA announced a final rule allowing irradiation at doses up to 8 kGy to reduce microbial pathogens in seeds for sprouts.[81] Notably, FDA was able to rely on data from previously approved irradiation processes, particular the extensive petition for meat irradiation, in order to expedite approval of the specific case.[82] Concerns about irradiation affecting the viability of the seeds themselves were apparently unfounded, as irradiated seeds sprouted normally and sustained no significant or dangerous changes in their chemical composition.[83]

The approval process for food irradiation continues unabated. It took only 27 months (from March 1998 to July 2000) for FDA to approve a rule allowing irradiation of fresh shell eggs, with USDA approval presumably coming in the near future.[84] Several food industry associations, health organizations, academic and consumer groups have joined together to create petitions for irradiation of a wide array of ready-to-eat foods (such as precooked meats and juices), many of which have been submitted in a single large petition.[85]

The National Fisheries Institute (NFI) has also been active in pursuing food irradiation for seafood. In October 1999, NFI and the Louisiana Department of Agriculture and Forestry jointly submitted a petition (under review) to allow irradiation of molluscan shellfish to control *Vibrio* and other foodborne pathogens.[86]

In February 2001, NFI submitted a similar petition (also pending) to allow irradiation of crustaceans and processed crustaceans.[87]

Labeling Requirements

[79] *See id.*

[80] *See* Caudill Seed Co., Inc.; Filing of Food Additive Petition, 64 Fed. Reg. 44,530 (1999).

[81] *See* Irradiation in the Production, Processing and Handling of Food, 65 Fed. Reg. 64,605 (2000) (amending 21 C.F.R. pt. 179).

[82] *See id.*

[83] *See id.*

[84] *See* Irradiation in the Production, Processing and Handling of Food, 65 Fed. Reg. 45,280 (2000) (amending 21 C.F.R. pt. 179).

[85] *See* Food Irradiation Coalition c/o National Food Processors Association; Filing of Food Additive Petition, 65 Fed. Reg. 493 (2000).

[86] *See* The National Fisheries Institute and Louisiana Department of Agriculture and Forestry; Filing of Food Additive Petition, 64 Fed. Reg. 56,351 (1999).

[87] *See* The National Fisheries Institute; Filing of Food Additive Petition, 66 Fed. Reg. 9086 (2001).

Since food irradiation is classified as a food additive, its presence must be disclosed on a label under FDA regulations. According to those regulations, the product must bear a legend saying either Treated with radiation or Treated by irradiation.[88] The legend must be accompanied by a symbol known as a *radura*, an international symbol designed specifically to indicate food irradiation.[89] Prior to 1997, the regulations did not specify the relative size or prominence of food irradiation labels.[90] As a result, irradiation was often indicated in a manner that connoted the presence of a dangerous substance (similar to a warning label) in order for manufacturers to be certain that they had fulfilled their labeling obligations. As part of the FDA Modernization Act of 1997, Congress amended the FDC Act to create §403C, which provides that the radiation disclosure on a product need not be any more prominent that the ingredients label for that product.[91] This measure, at least in part, seems to be an effort to reduce public concern over the dangers of irradiation. In a similar vein, second-stage products need not be labeled as irradiated; for example, sprouts from irradiated seeds or products incorporating irradiated spices do not need to be labeled as irradiated.[92]

[88] *See* Irradiation in the Production, Processing and Handling of Food, 63 Fed. Reg. 43,875, 43,875 (1998) (amending 21 C.F.R. pt. 179).
[89] *See id.*
[90] *See id.*
[91] *See id.*
[92] *See* Irradiation in the Production, Processing and Handling of Food, 65 Fed. Reg. at 64,606-64,607.

§5. Summary of Part I

Food irradiation has tremendous potential to significantly reduce the amount of food-related illness in the U.S. No earlier means of sanitizing food have been able to remove *Salmonella* from poultry, exposing consumers to great risk from improperly prepared food. Irradiation at the levels prescribed by regulation virtually eliminates the problem. If irradiation were consistently used on ground beef, the problem of *E. coli* contamination could be eradicated, at least at the manufacturer's end. Similar headway could be made against *Listeria*, a serious danger for pregnant women; *Campylobacter*, whose chronic effects are difficult to trace to food; *Vibrio*, a particularly virulent foodborne pathogen; as well as a host of other less common organisms.

FDA has acknowledged the importance of food irradiation and created a friendly regulatory atmosphere for irradiation petitions. As a result, the number of approved uses has steadily increased through the nineties. The food industry has worked with government agencies and other groups to make sure that allowed uses of irradiation continue to expand. Given the support from both the private and the public sectors, one would expect that irradiation would be just as common for food as it is for medical supplies.

Unfortunately, food irradiation is nowhere near being common; in practice, food irradiation is hardly even used on approved foods. The only exception to the general principle is irradiation of spices, and even then, only an estimated 9.5% of spices sold to consumers are irradiated.[93] Poultry irradiation has been approved for nearly 10 years, yet the rate of irradiation for consumer poultry is a paltry 0.2%![94] This seems particularly incredible given the scope of economic losses attributable to *Salmonella* (an estimated $2.4 billion[95]), and the relative lack of expense required to irradiate food.

In light of this baffling and even self-destructive behavior, a responsible society must ask what causes this inefficiency. The remainder of this paper will be devoted to answering that question. The analysis surveys

[93] *See GAO Irradiation Report* at 11.
[94] *See id.*
[95] *See* Economic Research Service, *supra* n. 30.

the arguments and real-world factors that have limited the use of irradiation, and where possible, provides responses to those arguments. Looking at the obstacles facing food irradiation helps to devise strategies to implement this technology more effectively, rather than disarming a powerful weapon against foodborne illness.

PART II – THE ARGUMENTS AGAINST FOOD IRRADIATION

§1. Scientific Concerns about Irradiaiton

Although food irradiation is an effective tool, there are legitimate scientific arguments that can be made against food irradiation. FDA has investigated most of these arguments in detail, and it has determined whether the objections have any merit. Even though the arguments have been substantially refuted, they are still often recited by those unfamiliar with the science of food irradiation. Furthermore, it is useful to understand that there are some tradeoffs for the increased safety given by food irradiation. While the tradeoffs are minimal, they should at least be acknowledged.

Mutant Strains of Foodborne Pathogens

One of the principal concerns about food irradiation was that insufficient doses of radiation might serve as a mutagenic catalyst that could create even more dangerous microbes. Conversely, if sufficient doses were used, the systematic eradication of the less radiation-resistant microbes could create evolutionary pressure toward radiation-resistant strains, in the same way that certain strains of microbes have developed resistance to antibiotics. This argument has been advanced in a variety of ways, but the essence is a concern that widespread use of irradiation will have the effect of creating more dangerous microbes.

Although theoretically irradiation could pose such a risk, toxicity studies failed to demonstrate any such propensity for more dangerous organisms.[96] The finding is hardly surprising, given that the amount of irradiation used is so toxic to the microbes that they are reduced to below detectable levels. The microbes that do survive the process actually tend to be less heat-resistant and therefore more likely to be killed during food preparation.[97] At any rate, as noted above, the irradiation dose for a particular species is calibrated

[96] *See* Irradiation in the Production, Processing and Handling of Food, 62 Fed. Reg. at 64,113-64,114.
[97] *See GAO Irradiation Report* at 17.

based on the profile of radiation resistance among existing strain, and always involves doses several times the maximum D value. This effectively makes irradiation an equal opportunity killer for all members of a target species.

Effects of Irradiation on the Microbial Profile

Another concern about food irradiation is the effect it might have on non-targeted species. In particular, FDA scientists looked at the effect of irradiation on (a) other foodborne pathogens that are resistant to irradiation and (b) spoilage bacteria that indicate unsuitability of food for human consumption.[98] With regard to (a), the concern is that the alteration of the natural (non-irradiated) microbial profile of the irradiated food will encourage the growth of the remaining microbes that were less affected by the irradiation process. For (b), the worry is that irradiation will kill spoilage bacteria as well, so that consumers will be unable to detect characteristic signs that food is unfit for consumption.

In studying the first problem, FDA focused on *C. botulinum*, a particularly virulent foodborne pathogen responsible for botulism.[99] *C. botulinum* also happens to have a spore form that is quite resistant to radiation (with D values as high as 4 kGy).[100] In theory, removing competing species could increase the population of *C. botulinum* relative to non-irradiated food. In practice, *C. botulinum* is relatively rare in the food products like meat, and the remaining *C. botulinum* population poses a minimal threat to human health.[101] Even in the cases where *C. botulinum* had significant growth resulting from temperature abuse (i.e., storing the food at a higher temperature than that required to inhibit microbial growth), the growth of *C. botulinum* was accompanied by a much more significant growth in spoilage bacteria.[102] The spoilage was a more-than-adequate indicator that the food posed a health risk.

This finding also demonstrated that irradiation did not stop spoilage. Again, this finding lines up with

[98] *See* Irradiation in the Production, Processing and Handling of Food, 62 Fed. Reg. at 64,116.
[99] *See id.* at 64,116-64,117.
[100] *See id.* at 64,116.
[101] *See id.* at 64,117.
[102] *See id.* at 64,116.

expectations, since spoilage bacteria are more numerous, grow more quickly, and grow in a wider variety of conditions (e.g., lower temperatures) that foodborne pathogens.[103] Even with a somewhat disproportionate reduction by irradiation, spoilage still outpaces the growth of foodborne pathogens. The overall reduction of the spoilage bacteria has the desirable effect or prolonging shelf life as well.

It is important to remember that the results for meat products may not apply to all foods, such that irradiation may have dangerous effects on the microbial profile of other foods. However, the general principle that non-pathogenic spoilage bacteria will significantly outnumber pathogenic microbes should apply equally to all foods. No evidence has ever suggested that hypothetical changes in the microbial population would be harmful to humans, but in each individual case, FDA will examine the evidence to verify that the principle still holds true.

Radiolytic Chemicals

Radiolytic products are chemicals created by the interaction of radiation with a substance such as food.[104] For food irradiation to be safe, radiolytic products must pose no danger for human consumers. The radiation chemistry of food has been the subject of intensive study, so radiolytic products are well known to the scientific community.[105] Most radiolytic products are formed by the radiation breaking molecular bonds in water, leaving free radicals that in turn either recombine into water or react with other chemicals.[106] Other radiolytic products form when complex protein molecules are broken into smaller units.[107]

The radiolytic products formed by food irradiation are all found naturally in non-irradiated food, and the additional amount of these compounds formed is basically insignificant.[108] The types of compounds formed by irradiation are identical to those formed during the cooking process, and compared to irradiation, cooking

[103] *See id.*
[104] *See id.* at 64,110.
[105] *See id.*
[106] *See id.*
[107] *See id.*
[108] *See id.* at 64,110-64,111.

results in a much higher proportion of those compounds.[109] From the standpoint of radiation chemistry, then, irradiation is no more dangerous than cooking food.

The presence of radiolytic products may produce changes in the taste, odor, color or texture of food.[110] While these changes are not in themselves dangerous, consumers may react negatively to the unfamiliar characteristics of these foods. For example, irradiation of fresh shell eggs can change the white of the eggs from clear to milky white, a characteristic many consumers would associate with the eggs not being fresh.[111] Such eggs may be undesirable for certain cooking applications as well. In most foods, these effects can be minimized by irradiating in a low-oxygen, low-temperature environment, which reduces the probability of the chemical reactions that form radiolytic products.[112] Another option is to use smaller doses of radiation, as USDA regulations often provide.

Nutrition Effects of Irradiation

Macronutrients (proteins, fats and carbohydrates) and minerals (e.g., iron, phosporous and calcium) are substantially unaffected by radiation doses at approved levels.[113] Some vitamins, particularly thiamine, undergo an appreciable reduction when exposed to radiation.[114] In approving irradiation of meat, FDA acknowledged that maximal use of food irradiation on meat would result in a decline in the amount of B vitamins consumed in the average person's diet.[115] In the totality of the diet, however, FDA determined that the average person's intake of these vitamins would be well above the RDA even in the extreme case in which all meats approved for irradiation were irradiated under approved conditions that would be most destructive to vitamins.[116]

Summary

[109] *See id.* at 64,111.
[110] *See id.* at 64,110.
[111] *See CDC Irradiation FAQ* at 4.
[112] *See* Irradiation in the Production, Processing and Handling of Food, 62 Fed. Reg. at 64,110.
[113] *See id.* at 64,114-64,115.
[114] *See id.* at 64,114.
[115] *See id.* at 64,115.
[116] *See id.*

Irradiation under approved conditions has been demonstrated to have no dangerous effects on food, either chemical or microbial in nature. Although irradiation does reduce non-pathogenic spoilage bacteria (thereby increasing shelf life), the population of spoilage bacteria still exceeds that of pathogenic bacteria, so that the ordinary characteristics of spoiled food will still been present before the food has reached a dangerous state. Irradiation can have undesired side effects on sensory qualities of the food, but such effects tend to be minimal, especially when manufacturers take conscious steps to avoid them. Irradiation also has the potential to reduce the amount of vitamins in the target food, but in the context of an overall diet, an average consumer would still receive well in excess of the RDA for all nutrients no matter how much food is irradiated.

§2. Economic Considerations Impacting Food Irradiation [117]

Some of the hesitance about widespread use of food irradiation results from economic considerations. Irradiation, after all, is not free, and for the process to be adopted, its costs must be borne by some party or parties, be they manufacturers, consumers, capitalists or government agencies. The prevalence of irradiation will therefore be influenced by a complex interaction of consumer preferences, technological limitations and supply. Consumer preferences may not be completely rational with respect to irradiation, and this can reduce the use of irradiation below objectively rational levels. Similarly, market inefficiencies may prevent costs from being effectively communicated between market actors, resulting in smaller expenditures on safety measures like irradiation. This section will focus on the latter problem, while the next section will delve into the irrational preferences consumers may have.

Inefficient Transfer of Information

As mentioned earlier, food-related illness had an estimated cost of $6.9 billion last year alone. Rationally, then, market actors ought to be able to spend any amount up to $6.9 billion in order to avoid these costs. Of course, the estimates themselves cannot be completely accurate nor can irradiation completely eliminate them, but they at least establish a baseline for how much ought to be invested in irradiation technology. The existence of food irradiation technology and the prevalence of irradiation in the medical context demonstrate that the costs of irradiation are far less than several billion dollars. Since the costs of irradiation are far less than the evils created by food-related illness, it would be efficient for irradiation to be much more prevalent than it is today, absent substantial regulatory impediments.

The reality is that irradiation hardly makes a dent in the costs of food-related illness. Generally, mismatches in expenditures on safety and costs avoided result when market actors fail to assess costs accurately or when

[117] This section is primarily theoretical in its orientation, but examples of behavior in the actual food industry have been included where possible.

they are insulated from costs that efficiency would require them to bear. It turns out that these inefficiencies are particularly common in the case of food safety.

<u>Consumer Assessment of Costs</u>

The most consistent truth of food safety is that the average consumer will be grossly undereducated on food safety matters. If consumer error in food handling could be eliminated, the issue of foodborne pathogens might have lapsed into insignificance by now. Even after consumers commit errors in food preparation, they may not make the connection between those errors and the food-related illness they may suffer later (and in most cases, they will be unaware that they have committed errors at all).

Assuming that consumers correctly identify their symptoms as resulting from tainted food, they will more than likely undervalue the economic harm that results from these symptoms. Most of the economic losses from food-related illness come in the form of losses to the consumer's employer rather than any direct cost to the consumer. Employees are poorly situated to evaluate the harm to their employers resulting from to lost work hours. Instead, the sick employee will evaluate the cost in terms of lost wages or lost leisure time, a sum that will be less than the amount of productivity lost. Medical expenses introduce another level of complexity, since many consumers are either insulated from actual medical costs by insurance or discouraged from seeking medical attention by high costs, even when such treatment might be efficient for the overall market.

Where irradiation is concerned, efficiency faces yet another hurdle. At the present level of technology, it is impossible for individual consumers to use irradiation as a means to protect themselves from foodborne pathogens. This means that consumers must find some way to convey information about the costs of food-related illness to market actors in a position to employ food irradiation technology. As a matter of course, the only means of communication between consumers and those actors is through the market itself (including such mechanisms as focus group studies). Such communication will never be perfectly accurate. Manufacturers are likely to underspend in these cases because they are insulated from many of the costs facing consumers, and in close cases, they will err on the side of saving money.

Manufacturers' Incentives

Manufacturers have access to much more information about food safety than do consumers, but even if they had perfect information, their position in the market gives them incentives that may run counter to efficiency. As noted above, manufacturers are insulated from many of the economic costs associated with food-related illness, and this provides an incentive to disregard, or at least undervalue, those costs in their calculations. To some extent, other mechanisms compensate for this problem. For example, manufacturers may face tort liability or, more commonly, a loss of consumer confidence resulting from having sold contaminated food. Still, given how much consumers undervalue the harms resulting from foodborne pathogens, it is unlikely that these mechanisms will provide anything close to perfect efficiency.

With respect to their actions in the market, manufacturers face a significant free rider problem associated with new technology. This situation results when a new technology requires significant expenditures up front, but which will become significantly less expensive and available to competitors once it catches on. For irradiation to catch on, certain manufacturers must be willing to accept the costs of developing irradiation as a commercial technology even though competitors will be able to reap the benefits of that expenditure.

Fortunately, there is reason to believe that some manufacturers will be willing to accept those costs. Certain manufacturers will be more vulnerable to costs associated with contaminated food, either because their high sales volume exposes them to massive tort liability or because their brand name has a great deal of value. An example of the first type of company is Tyson Chicken, which chose to begin irradiating its chicken in order to limit the liability exposure from its position as the world's largest single producer of chicken products.[118] The calculations of the Omaha Steaks Company are more suggestive of the latter rationale. Omaha Steaks began irradiating all of its products, presumably realizing that the firm's reputation as a provider of high-quality beef would be jeopardized by an outbreak of *E. coli* traceable to the company.[119] At the same time, as a precaution against consumer backlash, the company opted not to include the fact that they irradiated its beef in any of its advertising, instead disclosing that fact only on the label of shipped products.[120] This is exactly the type of balancing that one would expect from a company with a great deal at stake[121] in its brand equity.

Economies of Scale

At least one reason for the use of irradiation falling below its economically efficient level is that there just are not that many commercial food irradiation facilities. As of August 2000, the General Accounting Office observed that only two facilities in the United States were used primarily for gamma ray irradiation of food.[122] E-beam irradiation has been observed more in academic settings than commercial ones, in part because of the technological limitations associated with its short penetration depth. Consequently, only one e-beam facility for commercial food irradiation existed at the time of the GAO report, although the market was expected to expand.[123] X-ray irradiation is perhaps the most promising alternative, but the technology for this process is still under development. In its current stage, X-ray irradiation is significantly more expensive than the other forms of irradiation.[124]

[118] *See Titan to Irradiate Tyson Chicken*, Food Ingredient News, October 1, 1999, *available in* 1999 WL 12866829.
[119] *See* Marian Burros, *Irradiated Beef: In Markets, Quietly*, N.Y. Times (New England Final Edition), February 28, 2001, at D1.
[120] *See id.*
[121] Author's note: Believe it or not, this pun was unintentional. My wife brought it to my attention.
[122] *See GAO Irradiation Report* at 6.
[123] *See id.*
[124] *See id.*

Like the free rider problem, the market probably includes enough manufacturers in special situations to support expansion of irradiation technology. For example, producers of fruit in Hawaii often encounter difficulties in shipping their products to the mainland due to limited shelf life. Such fruit producers have an incentive to invest in irradiation technology, since irradiation prolongs shelf life, kills insects that pose a threat to the mainland and reduces foodborne pathogens. These benefits would allow Hawaii fruit producers to extend their sales to a much larger consumer base. In fact, this theoretical incentive has already been demonstrated in practice, as Hawaii is the site of a new X-ray irradiation facility.[125]

Since at least some individual manufacturers will have incentives to invest in irradiation technology, one would expect irradiation to reach more commercially viable forms in the near future. Once that technological plateau is reached, especially in the case of X-ray irradiation, commercial food irradiators should be able to take advantage of economies of scale to greatly expand the market for food irradiation. As costs become increasingly lower, more manufacturers will be willing to expend the money to make their products safer. By this reasoning, the current limited use of food irradiation represents only a temporary phenomenon, and once the technology catches up with the market, irradiation will reach much greater proportions.

Summary

Because consumers habitually undervalue the economic loss attributable to food-related illness, market actors in a position to exploit irradiation are unlikely to spend as much on irradiation as they should from an efficiency standpoint. Manufacturers are effectively insulated from many costs related to tainted products. The irradiation market has yet to reach a sufficiently large scale and level of technology to make irradiation a commercially viable technique with respect to food as it is in the medical field. There is some disincentive to pioneer developments in food irradiation because of the potential free rider problem.

Despite these disincentives, certain specific firms will still have motivation to make sure that irradiation

[125] *See id.*

technology develops. In particular, firms that face massive tort liability and/or large potential for reputation damages will be eager to avoid the costs that can result from their food products being contaminated. Other firms have economic motivations for developing irradiation, particularly when irradiation will allow the firm to enter markets that were previously unavailable for practical reasons such as shipping time. These forces will likely drive the food irradiation market toward expansion in the near future.

§3. Irrational Arguments against Food Irradiation

The previous sections have dealt with scientific and economic considerations that work against increased use of food irradiation technology. This sections turns to arguments that are irrational; i.e., arguments that are not cognizable by scientific principles or that do not concern rational market actors. Note that pure consumer preferences are neither rational nor irrational for these purpose; they simply exist. Thus, for example, if consumers were to decide that raduras were ugly and were to buy fewer irradiated foods on that basis, economics would make no judgment on whether that preference was correct. However, there are certain positions that one can assume no rational consumer will prefer; e.g., no one wants to get food poisoning. Decisions in which consumers suffer the disvalue of food-related illness without receiving a corresponding increase in value would be irrational.

When judging the irrational arguments against food safety, it is important to remember that irrational is not necessarily a pejorative term, since these arguments may reflect legitimate concerns about social policy apart from pure scientific or economic concerns. Judging the merits of these arguments requires evaluation in a context that takes into account the role that government agencies (such as FDA) and market actors *ought* to play. This section attempts to point out the choice of priorities that results implicitly from following these arguments to their logical conclusion.

Political Objections

Several groups have raised objections to food irradiation that are not related to the process itself but instead are based an overall political orientation that food irradiation impacts only tangentially. While the political motivation and sophistication of the arguments may vary, the core of the argument always involves the selection of some priority above that of food safety. Scientific agencies like FDA tend to dismiss such arguments out of hand, but the food industry itself does not always have the luxury of ignoring them.

Groups opposed to nuclear power are one source of political opposition to food irradiation. In particular, these groups fear that increased reliance on gamma ray irradiation will create a risk for workers and the environment and will cause increased dependence on the nuclear power plants used to create radioisotopes. Realistically, the trivial amount of radioisotopes used in food irradiation would be irrelevant to policy decisions regarding construction of nuclear power plants, and the safety record of the radioisotopes used has been impeccable.[126] As a matter of principle, these groups are caught on the horns of a dilemma, in that they cannot logically attack food irradiation without also attacking the much more significant use of radioisotopes in medical sterilization. Of course, anti-nuclear groups are not going to volunteer to point out this flaw in their argument. The continued use of radiation sterilization on medical equipment ranging from baby bottles to bandages would seem to imply that most consumers are willing to accept the use of radiation as a precaution against microbial infection. Such consumers, if they are rational and informed, ought to be willing to accept food irradiation as a precaution against foodborne pathogens, since people presumably expect the same kind of sterility in food as they would in medical supplies. Of course, it is also plausible that consumers are ignorant about medical sterilization as well, and the anti-nuclear groups would doubtless argue that consumers would reject radiation-sterilized medical equipment if they knew radiation was used. That argument strains at the boundaries of credibility, however, and it seems much more likely that the anti-nuclear groups are just exploiting a gap in consumer knowledge to drum up public opposition to food irradiation.

This is not to say that all political groups rely on such devious tactics. Many political groups are motivated to protect consumers rather than exploit them as a source for political leverage. For example, some groups fear that irradiation will be perceived by consumers and even by government agencies as a cure-all for the problem of foodborne pathogens. For consumers, they fear that irradiation will instill a false sense of security, and therefore discourage consumers from taking their own precautions against foodborne pathogens. With regard to government agencies, consumer advocacy groups fear that companies will use irradiation as an

[126] *See GAO Irradiation Report* at 18-19.

excuse to argue that inspections at earlier stages in the process are unnecessary.

Unlike arguments that exploit consumer ignorance, the arguments by consumer advocacy groups contribute positively to the policy debate over irradiation. Safety measures like increased consumer education, persistent government supervision, and industry awareness at all points along the HACCP (hazard analysis and critical control point) chain can be valuable complements to a food industry that includes irradiation. Even calls for delays in the approval process or for further study of irradiation's effects can serve a social purpose by acting as a watchdog for FDA.

A third kind of political group includes advocacy groups that are relatively neutral on the impact of food safety on consumers, but wish to incorporate an outside consideration into the policy debate on irradiation. For example, animal rights groups sometimes oppose food irradiation because they fear it will result in less sanitary conditions for animals in earlier stages of processing. The difficult question is to determine how much concern for the humane treatment of animals ought to affect our views of the food industry, or even whether such considerations have any place at all in the debate.

Marketing and Consumer Choices

In some cases, economically interested parties may attempt to skew customer choices in order to reflect their own interests. Advertising, for example, uses brand pushing as well as information to attempt to steer consumer preferences in the direction of the advertiser's product. In the food industry, however, history has shown some examples of manufacturers turning product characteristics that many consumers consider drawbacks into positives and vice versa. Technically, this might not qualify as irrational behavior from an economic perspective, but its consequences seem sufficiently perverse that they bear mention in this section. Perhaps no example illustrates this as well as the movement toward organic foods, in which irradiation was turned from a benefit into a drawback.

The organic food movement was formed by synergy between a market segment with peculiar preferences and manufacturers' desire to reduce costs and to increase profit margins. Organic foods are welcomed by a segment of the market particularly concerned with health, environmental concerns and preservation of more traditional forms of farming. As a result, they actually disfavor foods that are processed by artificial methods such as pesticide treatment even though the result is that their food contains much more filth than similar processed food. Manufacturers actually prefer this situation, since it allows them to produce food at lower cost while simultaneously charging a higher premium for satisfying the submarket's additional preference. For the most part, organic food is a win-win situation, so much so that USDA has endorsed a national organic food program for the benefit of farmers.[127] Unfortunately, in the case of irradiation, the organic movement took a step toward food that was not only filthier but also more dangerous than its conventional counterparts by pushing through a regulation that forbade irradiated food from being classified as organic.[128] The reason behind this move is unclear, since irradiation has no deleterious effects on either personal health or the environment. A benign interpretation is simply that consumers of organic foods are more likely to be members of groups that are politically opposed to food irradiation, so that the decision reflected nothing more than consumer preference. A more cynical interpretation is that the producers of organic food realized they could create a rule that would prevent them from ever needing to spend money on irradiation in order to keep up with competitors. Whatever the reason, the effect was to close irradiation out of a significant market segment.

[127] *See* Organic Food Program, 65 Fed. Reg. 80,548 (2000) (codified at 7 C.F.R. pt. 205).
[128] *See id.* at 80,551.

PART III – ANALYSIS AND CONCLUSION

So what are we to take away from this survey of food irradiation? What is the outlook of this technology in the near future? What can be done to overcome the obstacles to widespread acceptance of food irradiation? The previous parts of the paper illustrate several key points for answering these questions.

The first salient point is that the scientific evidence in favor of the safety and efficacy of food irradiation is overwhelming. Scientists have data from direct observation of the food products themselves, as well as theoretical analyses and experimental verification through animal testing. That information alone would be sufficient to make a good scientific case for food irradiation, but information about food irradiation goes even farther than that. Scientists have had the luxury of genuine long-term studies of the effects of human consumption of irradiated food, since NASA has used irradiated food for years. Irradiation has been used for decades in the related field of medical sterilization, again illustrating how irradiation is perfectly compatible with, and quite beneficial for, human health.

Hopefully, the profound weight of scientific evidence will eventually overpower the resistance to food irradiation. After all, additives like aspartame have been approved and employed universally on the basis of much less evidence than that amassed in support of irradiation. Many of the widely used alternatives to irradiation, such as nitrites (used to control bacteria) and pesticides (used to control insects) are actually known to be more dangerous and less effective than irradiation. Irradiation is a rare if not unique scientific discovery, in that it provides significant benefits with virtually no significant drawbacks.

The second major theme that emerges is that education can play a pivotal role in the future of irradiation. Much of the economic inefficiency that interferes with the widespread acceptance of irradiation can be explained by lack of information on the part of the consumers. Similarly, many of the irrational arguments against irradiation lose their persuasive power when targeted consumers are educated about the dangers of food safety and the benefits of food irradiation. At a more basic level, helping to change consumer preferences to encourage food irradiation will increase demand for irradiated food and therefore provide the economic impetus to encourage the development of food irradiation as a large-scale, commercially affordable technology.

The flip side is that irradiation may prove fruitless if not accompanied by consumer education. If consumers view irradiation as a magical solution to problems of food safety, they may become careless in their own food safety habits. If manufacturers are permitted to use irradiation as an excuse for carelessness in other phases of processing, the end result may be a less sanitary product. It is important not to let exuberance for the benefits of irradiation lead us to the point where irradiation is shouldering too much of the food safety burden, rather than providing a valuable backstop for an already-sanitary food industry.

Last but not least, there are optimistic signs for the future of irradiation. The regulatory climate has been, and continues to be, hospitable to food irradiation as a food safety technique. Recent trends toward quick approval combined with the demonstrated diligence of both private and public entities in filing new petitions should allow the rapid expansion of approved uses for irradiation to continue. On the economic side, the willingness of notable companies like Tyson Chicken and Omaha Steaks to begin irradiating their products bodes well for the future. As more money is invested in the technology, the odds of developing more commercially practical technology increase. X-ray irradiation in particular seems to be a promising technology that is on the verge of a commercial breakthrough.

Ultimately, the future of irradiation must be left in the hands of consumers. It may be tempting, particularly for an organization as scientifically oriented as FDA, to effectively require irradiation by cracking down even more severely on foodborne pathogens in order to make an example of companies that choose not to irradiate. With all of the positive indications, however, it seems that irradiation will eventually expand to the scale that its considerable benefits would justify. Attempting to artificially accelerate this process through regulatory sanctions would only squander resources that could be better spent on consumer education. The government can play its most valuable role by spreading the gospel of food irradiation in order to counter the misperceptions that the public may have received and to encourage the transition to a safer future.

ENDNOTES