IRRADIATION: IT'S WHAT'S FOR DINNER AND POSSIBLY EVEN LUNCH

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I. INTRODUCTION

> "Today, somewhere in Iowa or Florida or North Dakota, someone is biting into a hamburger that has been irradiated with the equivalent of 150 million chest x-rays—and maybe sprinkling it with spices that have been "treated" with the equivalent of 1 *billion* chest x-rays."[1]

Although food irradiation is present in as many as thirty different countries worldwide, the general public seems to be relatively uninformed of the process.[2] Irradiation uses energy in the form of ionizing radiation to treat food to

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1. MARK WORTH ET AL., A BROKEN RECORD: HOW THE FDA LEGALIZED—AND CONTINUES TO LEGALIZE—FOOD IRRADIATION WITHOUT TESTING IT FOR SAFETY 9 (2000), http://www.citizen.org/documents/brokenrecordfinal.pdf.

2. Michael D. Mehta, *Public Perceptions of Food Safety: Assessing the Risks Posed By Genetic Modification, Irradiation, Pesticides, Microbiological Contamination and High Fat/High Calorie Foods*, 1 PIERCE L. REV. 69, 71 (2002).

control pest infestation, contamination, and spoilage.[3] Although "only limited amounts of irradiated foods are available in the United States[,]"[4] in 2004 the United States Department of Agriculture (USDA) approved the use of irradiated food in the National School Lunch Program (NSLP)[5] in an apparent attempt to increase the popularity of irradiated food.[6] After the relative failure of irradiated food in the NSLP and continued wary consumers, in 2007 the Food and Drug Administration (FDA) proposed to remove the labeling indicating that the food had been irradiated.[7] Although this flow of events may suggest otherwise, the FDA contends that it has no bias on the safety of irradiated foods for consumption.[8]

Today, with food borne illness often headlining news, irradiation seems to be a great contender in the battle against pathogens.[9] But is it harmless? The FDA has found irradiation to be safe, with relatively few, if any, negative side effects.[10] However, many consumers feel they should be able to make their own decisions about whether or not to purchase and consume irradiated products.[11] The right of children to choose was infringed upon by the USDA's choice to allow irradiated food in school lunches, and this decision was met with some hot debate on the subject.[12] The proposal of the FDA to completely remove labeling

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3. INT'L CONSULTATIVE GROUP ON FOOD IRRADIATION, FACTS ABOUT FOOD IRRADIATION 3, (1999), http://www.iaea.org/programmes/nafa/d5/public/foodirradiation.pdf.

4. Informa Economics, Inc., *Benefits of Irradiation Outweigh the Risks, Says Government Agency*, FOOD & DRINK WKLY., Oct. 9, 2000, http://www.allbusiness.com/retail-trade/food-beverage-stores/652614-1.html.

5. Audrey Hill, *The New Beef: Irradiated Burgers for School Children*, NEW LIFE J. (2005), http://www.newlifejournal.com/FebMar05/hill.shtml.

6. *See id.* (explaining the food industry's enthusiasm for irradiation due to the bad publicity after several food-borne illness outbreaks).

7. Irradiation in the Production, Processing and Handling of Food, 72 Fed. Reg. 16291 (proposed Apr. 4, 2007).

8. Irradiation in the Production, Processing, and Handling of Food, 70 Fed. Reg. 48057, 48064 (Aug. 16, 2005) (to be codified at 21 C.F.R. pt. 179).

9. *See* INT'L CONSULTATIVE GROUP ON FOOD IRRADIATION, *supra* note 3, at 4-5.

10. *See generally* Ctr. for Disease Control and Prevention, Food Irradiation, Oct. 15, 2005, http://www.cdc.gov/ncidod/dbmd/diseaseinfo/foodirradiation.htm; Irradiation in the Production, Processing and Handling of Food, 73 Fed. Reg. 49593, 49,600 (Aug. 22, 2008) (to be codified at 21 C.F.R. pt. 179).

11. Alicia T. Simpson, Note, *Buying and Eating in the Dark: Can the Food and Drug Administration Require Mandatory Labeling of Genetically Engineered Foods? Alliance for Bio-Integrity v. Shalala, et al., 116 F. Supp. 2d 166 (2000)*, 19 TEMP. ENVTL. L. & TECH. J. 225, 226-27 (2001) (discussing the "consumer right-to-know").

12. *See* News Release, Organic Consumers Association, San Francisco Bans Irradiated Food in Schools! (Apr. 27, 2004), *available at* http://www.organicconsumers.org/school/ban 042904.cfm (discussing that irradiated food in lunch rooms would not have to be labeled as irradiated).

that indicates food as irradiated further infringes upon the consumer's right to choose what types of food to consume.[13]

This note will indicate the importance of consumer choice in deciding whether or not to consume irradiated food. In doing so, the note will: (1) provide a definition of irradiation and the processes used; (2) examine the positive aspects of irradiation, including: (a) bacterial elimination and (b) extended shelf-life; and (3) examine the negative aspects of irradiation, including: (a) health risks; (b) changes in quality of the food; and (c) a negative impact on other sanitation practices. Finally, this note will address (4) the use of irradiation in school lunches, along with (5) the labeling regulations and proposed changes to them.

II. WHAT IS IRRADIATION?

Irradiation is one of many processes developed to "reduce, prevent, or eliminate pathogenic bacteria in poultry and fresh meats."[14] Irradiation may also slow down ripening of certain fruits and vegetables.[15] The food is irradiated inside its package; therefore, it is safe from recontamination until opened by the consumer.[16] Due to continued outbreaks of food-borne pathogens, "[i]rradiation is considered as a method to ensure the hygienic quality of food, as a . . . sanitary . . . treatment of food . . ., as a quarantine treatment of [fresh fruits and vegetables], and as a substitute for fumigants. . . ."[17] There are many different foods that are currently treated with irradiation such as poultry, beef, spices, many fruits and vegetables,[18] pork, shell eggs, molluscan shellfish, and most recently iceberg lettuce and spinach.[19]

When used for treatment of food, irradiation uses radiation in the form of gamma rays, X-rays, or high voltage electrons from radioactive or machine sources.[20] Gamma rays use radiation that is emitted from a radioactive substance

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13. *See* Simpson, *supra* note 11, at 226-27 (discussing the "consumer right-to-know").

14. D. N. Parke et al., *Review: Meat Irradiation*, 21 PROF. ANIMAL SCIENTIST 75, 75 (2005); s*ee also The Truth About Irradiated Meat*, CONSUMER REPS., Aug. 2003, at 34 (noting that irradiation is, however, ineffective against the infectious proteins that cause mad cow disease because they contain no DNA).

15. INT'L CONSULTATIVE GROUP ON FOOD IRRADIATION, *supra* note 3, at 12.

16. D. N. Parke et al., *supra* note 14, at 75.

17. Kim M. Morehouse & Vanee Komolprasert, *Irradiation of Food and Packaging: An Overview*, *in* IRRADIATION OF FOOD AND PACKAGING 7 (Vanee Komolprasert & Kim M. Morehouse eds., 2004).

18. Mehta, *supra* note 2, at 71.

19. *See* Ionizing Radiation for the Treatment of Food, 21 C.F.R. § 179.26 (2005).

20. Marsha A. Echols, *Food Safety Regulation in the European Union and the United States: Different Cultures, Different Laws*, 4 COLUM. J. EUR. L. 525, 538 (1998).

like Cobalt 60 or Cesium 137.[21] Gamma rays may penetrate food to a depth of several feet, but do not give off neutrons, meaning that nothing around the gamma rays becomes radioactive.[22] X-ray irradiation — using a more powerful version of the X-ray machines used in hospitals — can pass through thick foods, yet does not involve any radioactive substances like cesium.[23] An electron beam consists of a "stream of high energy electrons" that is unable to penetrate food as far as the other two options, but it involves no radiation.[24] These different types of irradiation create energy that damages the DNA of the microbe present in the food causing the microbe to die when it tries to duplicate itself,[25] therefore delaying the maturation of the food.[26] The rays used for irradiation are very powerful with the typical dose for meat being 1.5 kiloGrays.[27] This dose is "15 million times the energy involved in a single chest X-ray, or 150 times the dose capable of killing an adult."[28]

A. *A Brief History of Irradiation in the United States*

Irradiation has a long history in the United States and has been studied since the early 20th Century.[29] In 1953, the "[United States] Army and Atomic Energy Committee formed the [United States] National Food Irradiation Program."[30] In the mid-1960s, the Army "sent irradiated bacon to military personnel in Vietnam. . . ."[31] In July 1985, rules were instituted by the FDA allowing the irradiation of pork to control Trichina.[32] This was followed by the Food Service and Inspection Service (FSIS) allowing pork to be irradiated in January of 1986.[33] The FDA declared irradiation of poultry safe for use in May 1990 and the FSIS

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21. Ctr. for Disease Control and Prevention, *supra* note 10.
22. *Id.*
23. *Id.*
24. *Id.*
25. *Id.*
26. D. N. Parke et al., *supra* note 14, at 76.
27. CONSUMER REPORTS, *supra* note 14, at 34.
28. *Id.*
29. D. N. Parke et al., *supra* note 14, at 76.
30. *Id.*
31. MARK WORTH ET AL., *supra* note 1 at 17.
32. Press Release, USDA Food and Nutrition Services, Questions and Answers on Irradiated Ground Beef (May 29, 2003), http://www.fns.usda.gov/cga/PressReleases/2003/irradiation-qas.htm; *see* MedicineNet.com, Definition of Trichina Spiralis, http://www.medterms.com/script/main/art.asp?articlekey=12513 (last visited Oct. 19, 2008) ("Trichina is a parasitic worm that lives in the intestines and. . . usually enter[s] the body via raw or undercooked pork . . ." The eggs then hatch and migrate to other parts of the body and may cause death.).
33. USDA Food and Nutrition Services, *supra* note 32.

followed suit in February of 1992.[34] The FDA concluded that irradiation was safe for raw meat in December of 1997, and FSIS issued a final rule permitting the irradiation "of refrigerated or frozen raw meat and meat products" two years later.[35] Irradiated ground beef that had been treated at a facility in Sioux City, Iowa went on sale in May of 2000 in stores in Iowa, Minnesota, North Dakota, South Dakota, and Wisconsin.[36] In August 2008, the FDA issued a final ruling allowing lettuce and spinach to be irradiated to levels high enough to kill most disease-causing bacteria.[37]

B. *The Effect of Irradiation on Agriculture*

Irradiation has important implications for agriculture including replacing fumigation where toxic chemicals are commonly used on many foods to eliminate insects.[38] The Center for Disease Control (CDC) states that irradiation "can also inhibit the growth of molds, inhibit sprouting, and prolong the shelf life[,]"[39] which would help control food loss.[40] The Food and Agriculture Organization (FAO) estimates that about twenty-five percent of all food production worldwide is lost after harvesting because of insects and bacteria.[41] The USDA has even allowed irradiation to be used as a quarantine treatment to control for fruit flies.[42] Therefore, irradiation affects trade because it has the ability to reduce the pests and diseases that are known to inhibit the trade of goods.[43] However, "international harmonization is needed on issues such as inspection procedures, labeling, and appropriate control of irradiated foods" in order to facilitate trade.[44] But most importantly, irradiation is viewed by many to be an effective tool for keeping the food supply safe.[45] However, the downside of this new safe food supply may be "erosion of local agricultural production and regional food security[,]"

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34. *Id.*
35. *Id.*
36. MARK WORTH ET AL., *supra* note 1, at 22.
37. *See* FDA, *Irradiation: A Safe Measure for Safer Iceberg Lettuce and Spinach*, Aug. 22, 2008, http://www.fda.gov/consumer/updates/irradiation082208.pdf; *see also* Stephen J. Hedges, *Debate Lingers Over FDA Moves — Agency's Approval of Irradiation of Some Vegetables is the Latest to Cause Disagreement*, CHI. TRIB., Aug. 25, 2008, at News 3.
38. Ctr. for Disease Control and Prevention, *supra* note 10.
39. *Id.*
40. INT'L CONSULTATIVE GROUP ON FOOD IRRADIATION, *supra* note 3, at 4.
41. *Id.*
42. *Id.* at 34.
43. *Id.*
44. D. N. Parke et al., *supra* note 14, at 79.
45. *See id.*

because irradiation allows commodities to be shipped across increasingly greater distances.[46]

III. THE POSITIVE IMPACT OF IRRADIATION

A. *Bacterial Elimination*

The news is frequently reporting outbreaks of food borne illnesses as estimating that "'seventy-six million people get sick, more than 300,000 are hospitalized, and 5,000 Americans die each year from food borne illness. . . .'"[47] Although irradiation is not a panacea, it is one compelling option.[48] Irradiation is able to protect from food borne illness by controlling the disease causing agents that are present in the food.[49] Such disease-causing agents as E. coli O157:H7, Salmonella, and Campylobacter can be nearly eliminated from raw meat and poultry when treated with irradiation at a slaughter plant.[50] Although an effective end of the line solution, irradiation should not be treated as a substitute for cleanliness in the slaughterhouses.[51]

Aside from meat products, other foods including spices, herbs, and seasonings benefit from removal of bacteria as they are often heavily contaminated with microorganisms.[52] Irradiation is optimal for spices because it does not use heat, which can cause loss of flavor and aroma.[53]

Unlike chemical and heat treatments to remove bacteria, irradiation can treat foods without leaving residues or converting the food into a cooked product.[54] Because irradiation does not use heat or raise the temperature of the food, nutrient losses are claimed to be small.[55] However, the sensitivity of each vitamin varies as vitamins B_1, C, A, and E are highly sensitive to irradiation.[56] Al-

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46. Douglas A. Kysar, *Preferences for Processes: The Process/Product Distinction and the Regulation of Consumer Choice*, 118 HARV. L. REV. 525, 592 (2004).

47. Lisa Lovett, *Food for Thought: Consistent Protocol Could Strengthen Food Supply Security Measures*, 10 TEX. WESLEYAN L. REV. 465, 470 (2004) (*citing* Ctr. for Disease Control and Prevention, Food Safety Office, http://www.cdc.gov/foodsafety/ (last visited Oct. 16, 2008).).

48. Consumers' Research, Inc., *Fighting Foodborne Diseases with Radiation*, CONSUMERS' RES. MAG., Sept. 1996, at 28.

49. *Food Safety and Security*, Food Drug Cosm. L. Rep. (CCH) ¶ 50,065, 50,436 (2008).

50. Ctr. for Disease Control and Prevention, *supra* note 10.

51. *See generally* Lovett, *supra* note 47, at 488.

52. INT'L CONSULTATIVE GROUP ON FOOD IRRADIATION, *supra* note 3, at 11.

53. *Id*. at 11.

54. *Id.* at 15-16.

55. *Id.* at 28.

56. *Id.*

though they admit there is some vitamin loss with irradiation, the World Health Organization (WHO) indicated that irradiation will not lead to significant nutrient losses in food and it also must be considered that irradiated food would be part of a mixed diet.[57] The FDA also contends that a vitamin deficiency is not likely to result from the consumption of foods that have been irradiated.[58]

B. *Extended Shelf-Life*

In certain types of fruits and vegetables, the use of irradiation is able to inhibit sprouting and delay ripening.[59] The shelf-life of meat and poultry is also extended with irradiation.[60] The living cells in the food are damaged and killed along with the microbes prolonging the shelf-life of some foods.[61] For example, sprouting may be inhibited in potatoes with irradiation.[62] Due to the year round demand for potatoes and other sprouting vegetables, they must be able to be stored for many months to prevent the expense of importing them from other climatic zones.[63] This extension of shelf-life is also very important for many fruits and vegetables with short shelf lives.[64] For example, the shelf-life of strawberries may be extended to nearly fourteen days with irradiation.[65] This extension of shelf-life is dependent on the high initial quality of the fruit or vegetable[66] as "it cannot reverse spoilage that has already occurred."[67] However, irradiation is not suitable for all fruits and vegetables because of the changes it may cause to the color and texture.[68]

The impact of increased shelf-life may not be completely positive.[69] Irradiation may mean that more food can be imported due to the increase in shelf-life.[70] Thus, this indicates that your food is less likely to be locally or domestically grown, driving us further from a "sustainable, local food system. . . ."[71]

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57. *See id.* at 29.
58. D. N. Parke et al. *supra* note 14, at 77.
59. FDA, *Food Irradiation: A Safe Measure* (2000), *available at* http://www.fda.gov/opacom/catalog/irradbro.html.
60. Consumers' Research Inc., *supra* note 48, at 28.
61. Ctr. for Disease Control and Prevention, *supra* note 10.
62. INT'L CONSULTATIVE GROUP ON FOOD IRRADIATION, *supra* note 3, at 14.
63. *Id.*
64. *Id.* at 12.
65. *Id.*
66. *Id.*
67. D. N. Parke et al., *supra* note 14, at 79.
68. INT'L CONSULTATIVE GROUP ON FOOD IRRADIATION, *supra* note 3, at 12.
69. *See, e.g.*, Hill, *supra* note 5.
70. *See id*.
71. *Id.*

IV. THE NEGATIVE FACTORS OF IRRADIATION

While the FDA, USDA, CDC, and WHO contend that irradiation has many benefits including elimination of disease causing agents and extension of shelf-life that make irradiation a viable option for consumers,[72] there are many groups and consumers that contend that irradiation's negative factors are far more important than the governmental agencies recognize.[73]

A. *Are There Health Risks?*

There may be health risks to irradiating food.[74] Some of the early studies where food that had been irradiated at high doses was fed to lab animals revealed apparent health problems exemplified by higher mortality rates, low weight gain, and malignant tumors.[75] Research has also indicated that irradiation produces free radicals and peroxides from unsaturated fats.[76] In addition, irradiation has been found to produce some chemicals including benzene, a known carcinogen, and other unique radiolytic chemical products.[77] In fact, the FDA has admitted that "'it is nearly impossible to detect [and test radiolytic products] with current techniques,' on the basis of which the agency's claims of safety persist."[78] One of these radiolytic chemicals, called 2-ACB, was linked to cancer as well as genetic and cellular damage in rats.[79] A study of irradiated beef found that in addition to the five radiolytic products found that do not naturally occur in beef or any other food, thirty-five other chemicals were discovered that do not naturally

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72. *See* INT'L CONSULTATIVE GROUP ON FOOD IRRADIATION, *supra* note 3, at 1; *see also* Ctr. for Disease Control and Prevention, *supra* note 10.

73. *See generally* WORTH ET AL., *supra* note 1.

74. *Id.* at 11.

75. *Id.* at 24.

76. Samuel S. Epstein & Wenonah Hauter, *Preventing Pathogenic Food Poisoning: Sanitation, Not Irradiation*, 31 INT'L J. HEALTH SERVICES 187, 187 (2001); *see also* Hill, *supra* note 5 ("When food is irradiated, molecular bonds break apart and cause new and sometimes unique molecules to form." These radiolytic chemical products may cause cancer or genetic damage but much is unknown about them because they have never been found to naturally occur in food.); *see* Valigarm, *Controversy Over Irradiation*, ASSOC. CONTENT, Oct. 8, 2007, http://www.associatedcontent.com/article/404218/controversy_over_irradiation.html/?cat=58 (when foods that contain fatty acids are treated, the 2-ACBs are formed as a radiation byproduct of palmitic acid (*quoting* Xuetong Fan & Christopher H. Sommers, *Effect of Gamma Radiation on Furan Formation in Ready-to-Eat Products and Their Ingredients*, 71 J. FOOD SCI. c407 (2006).).

77. Epstein & Hauter, *supra* note 76, at 187-88.

78. *Id.* at 188.

79. Public Citizen, *The Top 10 Problems with Irradiated Food,* http://www.citizen.org/documents/Top10.pdf (last visited Oct. 3, 2008) (hereinafter Public Citizen, *Top 10 Problems*).

occur in beef.[80] Although some of the study results may seem daunting, it must be kept in mind that many of these studies were conducted at levels of irradiation much above those approved for human consumption.

The group conducting the studies, the Federation of American Societies of Experimental Biology (FASEB), recommended more testing on the 2-ACBs chemicals that were found because there was not enough data to judge the effects on health.[81] Other toxicologists agree, including Dr. William Au, a toxicologist at the University of Texas.[82] Dr. Au stated believes that there is not a clear indication that 2-ACB formed in irradiated meat does not pose health risks, and that studies need to be done on the long-term exposure to this chemical.[83] Consumer groups contend that the FDA legalized irradiation without further investigation into these chemicals.[84] The FDA contends that Dr. Au is mistaken and that the potential health risks have been evaluated and no studies of irradiated flesh foods which would contain 2-ACBs showed any adverse effects related to the irradiation.[85]

One would assume that the FDA has thoroughly tested the irradiation process; however, consumer groups contend that the FDA relied on only a few studies out of over 400 scientific studies when determining the safety of the procedure.[86] "In two of the studies, researchers used doses of radiation at or far below those approved by the FDA, rendering the studies virtually if not completely useless."[87] Citizen groups claim that the FDA is not following their own protocol requiring toxicological experiments before allowing irradiation as evidenced by the approval of irradiation for shell eggs in the year 2000 without any toxicological data.[88] The FDA is required to establish a 100-fold safety factor by determining the highest level of a proposed additive that does not harm laboratory animals

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80. WORTH ET AL., *supra* note 1, at 26.

81. *Id.* at 25.

82. *See NewsHour: FDA Weighs Approval of Irradiating Produce* (PBS television broadcast Feb. 8, 2007) (transcript *available at* http://www.pbs.org/newshour/bb/science/jan-june07/irradiation_02-08.html).

83. *Id.*

84. WORTH ET AL., *supra* note 1, at 25, 27 (The FDA did have two committees study radiolytic products in 1980 and found that they could not catalog and identify each product formed in the foods. The committees then did not order more studies done on these compounds for foods irradiated at low levels, or for those that were only a small part of the diet).

85. 70 Fed. Reg. at 48066.

86. Public Citizen, *Food Irradiation Q&A's*, http://www.citizen.org/documents/Radfood_Q&A.PDF (last visited Oct. 16, 2008) (hereinafter Public Citizen, *Q&A's*).

87. *Id.*

88. *Id.*; *see also* 70 Fed. Reg. at 48060 (The FDA allowed irradiation of shell eggs based on the toxicology studies of meat because they are both mainly composed of water, protein, and lipids).

and dividing that level by 100.[89] This would, in essence, expose humans to no more than one-hundredth of the amount that has caused harm to lab animals.[90] While this seems like a comforting standard, the FDA failed to meet this requirement "before legalizing the irradiation of pork, fruit, vegetables, spices, poultry, beef, lamb, horse meat and fresh shell eggs[.]"[91] Joseph Mendelson, the legal director for the Center for Food Safety stated, "[w]e have looked at studies that have gone on for several decades. And by our count and by our research, there's up to a third of them that have shown some problems with the end result of food irradiation and in the products or effects on humans."[92] In response to allegations of incomplete studies, the food industry vies that the claims made by Public Citizen are wrong and that "[t]he process by which FDA determines the safety of irradiation for use of various foods is both science-based and rigorous."[93]

However, the FDA contends that "[o]n the few occasions when studies reported adverse effects, the effects were not consistently reproduced in related studies conducted with similar foods irradiated to doses equal to or higher than those for which the adverse effects were reported, as would be expected if the reported effect were a toxic effect caused by a radiolysis product."[94] Further, the FDA found no evidence of toxicity attributable to foods containing 2-ACBs.[95]

However, because of these reported flaws in some of the studies that led the FDA to deem irradiation safe, there is still much consumer skepticism about the safety and health risks of the process.[96]

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89. WORTH ET AL., *supra* note 1, at 23.

90. *Id.* at 21; *see also* Consumers' Research Inc., *supra* note 48, at 28 (stating that "[i]t is unlikely that all meat and poultry products ever will be irradiated [because it] will be *chosen* by customers who desire [more] food safety[.]"(emphasis added)) .

91. WORTH ET AL., *supra* note 1, at 29; *see* INT'L CONSULTATIVE GROUP ON FOOD IRRADIATION, *supra* note 3, at 3-4 (A report the Joint Expert Committee on Food Irradiation (JECFI) stating that food irradiation has been deemed safe to such a degree that as of 1980 no further testing is needed. Further, the dosage of radiation applied is of little concern as long as the food retains its properties).

92. *NewsHour*, *supra* note 82.

93. Informa Economics, Inc., *Public Citizen Calls for End to Irradiated Food and Investigation into FDA's Role*, FOOD & DRINK WKLY., Oct. 9, 2000, *available* at http://www.findarticles.com/p/articles/mi_m0EUY/is_39_6/ai_66190182.

94. 70 Fed. Reg. at 48063 (citations omitted).

95. *Id.* at 48067.

96. *See* Vailgarm, *supra* note 76.

B. *Changes in Quality of Irradiated Food*

The FDA admits that irradiation may reduce the levels of some vitamins, but it is the extent to which they are reduced that is contested.[97] "The nutritional significance of vitamin loss caused by irradiation depends on the level of loss and the proportion of irradiated food in the diet."[98] Although there are currently limited amounts of irradiated foods available in the United States,[99] if all petitions currently before the FDA and USDA requesting legalization of irradiation for different products were approved, it is claimed that "more than ninety percent of the typical American's diet would be eligible for irradiation."[100] Some research claims that irradiation results in "major micronutrient losses, particularly vitamins A, C, and E, and the B complex[,]" and that this nutrient loss is further increased by cooking.[101] Some nutrient loss is further exacerbated by storage, worsening vitamin depletion.[102] Research does indicate that the vitamin loss in food may be serious; animals that ate diets of irradiated food had below average body weights, which the researchers attributed to an insufficient supply of vitamins. [103] Body weight did not differ if vitamin supplements were given.[104]

The FDA has found that irradiation causes no macronutrient loss, such as proteins, fats, and carbohydrates, but does acknowledge that certain levels of vitamins may be reduced by irradiation.[105] For instance, the FDA recently ruled that spinach may be irradiated up to 4.0 kGy.[106] Spinach is considered an excellent source of vitamin A, and vitamin A is one of the most radiation sensitive vitamins.[107] The FDA states in its final ruling that irradiation at doses up to 1.0 kGy did not affect the content of spinach; however, the final ruling approved spinach for doses up to 4.0 kGy.[108] Yet, the FDA states that the losses of vitamin A from the irradiation of lettuce and spinach will have little impact on the total dietary impact of the vitamin.[109] Further, "[s]pinach is an excellent source of folate[,]" and a recent study found that irradiation of spinach and other vegeta-

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97. 70 Fed. Reg. at 48059; *see also* Public Citizen, *Top 10 Problems*, *supra* note 79.
98. D. N. Parke et al., *supra* note 14, at 77.
99. Informa Economics, Inc., *Benefits of Irradiation*, *supra* note 4.
100. WORTH ET AL., *supra* note 1, at 15.
101. Epstein & Hauter, *supra* note 76, at 188 (citation omitted).
102. Hill, *supra* note 5.
103. WORTH ET AL., *supra* note 1, at 33.
104. *Id.*
105. 73 Fed. Reg. at 49597.
106. *Id.* at 49598.
107. *Id.* at 49597.
108. *Id.* at 49599.
109. *Id.* at 49598.

bles at 2.5 kGy had a folate loss of ten percent.[110] Yet again, the FDA fails to note that this vitamin loss was at a level of irradiation *lower* than had just been approved for spinach and lettuce.[111]

Aside from vitamin loss, irradiation may also change the quality of food by giving it a slightly different taste, texture or color.[112] Irradiation may cause off-odors likened to the smell of singed hair or a wet dog, and an off-taste in beef detectable by trained taste-testers.[113] As far as the color of the food goes, pork may turn red,[114] onions may turn brown,[115] and broccoli can lose its bright green color when treated with irradiation.[116] Eggs may become runny,[117] while fruit and vegetables may become mushy.[118] In the latest approval by the FDA of irradiation for spinach and iceberg lettuce, the FDA states that studies have indicated a negative effect on the sensory properties of the food at an irradiation level of 1.5 or 2 kGy.[119] However, the approval for lettuce and spinach allowed for irradiation up to 4.0 kGy.[120]

C. *Sanitation as an Alternative to Irradiation*

Irradiation is not a cheap method for cleaning up the food supply.[121] In fact, "[t]he expense of producing sanitary meat would be trivial compared with the high costs of irradiation, including possible nuclear accidents, which would be passed on to consumers."[122] The USDA has guessed that irradiated ground beef may cost thirteen to twenty cents more per pound.[123] Additionally, Public Citizen reported a survey that irradiated ground beef in the Midwest cost up to seventy-five cents more per pound and also contained a high level of fat.[124] Irradiation is not always the most expensive option.[125] The International Consultative

110. *Id.*
111. *See id.*
112. Jennifer L. Keller, *Physicians Committee for Responsible Medicine*, http://www.healthyschoollunches.org/changes/irradiated.cfm (last visited Oct. 16, 2008).
113. Consumer Reports, *supra* note 134, at 36; Public Citizen, *Q&A's*, *supra* note 86.
114. Public Citizen, *Top 10 Problems*, *supra* note 79.
115. Public Citizen, *Q&A's*, *supra* note 86.
116. Keller, *supra* note 112.
117. Public Citizen, *Q&A's*, *supra* note 86.
118. Public Citizen, *Top 10 Problems*, *supra* note 79.
119. 73 Fed. Reg. at 49599.
120. *Id.* at 49598.
121. Epstein & Hauter, *supra* note 76, at 189.
122. *Id.*
123. Press Release, USDA Food and Nutrition Service, *supra* note 32.
124. Public Citizen, *Q&A's*, *supra* note 86 (the survey was reportedly done by the Center for Science in the Public Interest).
125. INT'L CONSULTATIVE GROUP ON FOOD IRRADIATION, *supra* note 3, at 32.

Group on Food Irradiation reports that in some incidences, for example the disinfestations of fruit, irradiation may be less costly than other options like vapor heat treatment.[126] The FDA contends that although there are other methods to eliminate or reduce bacteria on food, the use of other safe methods, such as irradiation, should not be prohibited.[127]

While there are economical costs, irradiation may have high non-economical costs as well, such as masking the unsanitary conditions of the nation's slaughterhouses.[128] The focus of the radiation industries is directed at the clean-up of food, rather than preventing the contamination altogether by controlling flies and reducing overcrowding in feedlots.[129] It is claimed that E. coli O157:H7 could also be nearly eliminated by feeding hay rather than grain for seven days before slaughter[130] or spraying beef with lactic acid before grinding.[131]

Wide scale food irradiation may also lessen the quality control measures of food processors.[132] For example, "one Colorado meat processing plant that slaughtered on average about 5,500 cattle daily was 'cited more than 300 times for violating federal food safety regulations'. . . [and later] this same plant recalled almost nineteen million pounds of E. coli contaminated beef that was linked to 'twenty-seven illnesses and one death.'"[133] But, because the government believes irradiation to be very effective in the removal of bacteria, it allows ground beef tainted with E. coli O157:H7 to be sold to consumers after it has been irradiated.[134] It should be noted, however, that "[i]rradiation does nothing to remove the feces, urine, pus, vomit and tumors often left on beef, chicken, and lamb after processing in filthy. . . slaughterhouses."[135] The greater the initial contamination, the greater the level of irradiation needed to eliminate pathogens, so the CDC contends that there are still great efforts to improve processing plant contamination.[136]

Even vegetables suffer the effects when grown in unsanitary conditions.[137] After the 2006 E. coli outbreaks from spinach grown in California, the FDA began working up its most recent decision to allow irradiation of iceberg

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126. *Id.*
127. 70 Fed. Reg. at 48070.
128. Public Citizen, *Top 10 Problems*, *supra* note 79.
129. Epstein & Hauter, *supra* note 76, at 189.
130. *Id.*
131. Consumer Reports, *supra* note 14, at 35.
132. *See* Mehta, *supra* note 2, at 72.
133. Lovett, *supra* note 47, at 488.
134. Consumer Reports, *supra* note 14, at 35.
135. Public Citizen, *Q&A's*, *supra* note 86.
136. Ctr. for Disease Control and Prevention, *supra* note 10.
137. Hedges, *supra* note 37.

lettuce and spinach.[138] An investigation by the FDA found the E. coli outbreak stemmed from produce grown too close in proximity to a cattle operation and water tainted with cattle feces.[139] However, some organic consumers believe that the new allowance for irradiation of these foods is "the latest in a series of PR moves designed to mislead the public from the fact that the government is asleep at the wheel here[.]"[140] Many consumers feel more needs to be done with sanitation, rather than the end of the line fix — irradiation.[141]

V. THE USE OF IRRADIATION IN SCHOOL LUNCHES

One idea for using irradiated products was the NSLP, which feeds twenty-seven million children annually.[142] The possibility of using irradiated meat, which had previously been prohibited from the NSLP, came about when it was submitted into the 2002 Farm Bill by Senator Tom Harkin (D-IA).[143]

> The 2002 Farm Bill states that [the] USDA '*shall not prohibit the use of any technology to improve food safety that has been approved by the Secretary of Agriculture or has been approved or is otherwise allowed by the Secretary of Health and Human Services*' for use in various commodity purchase programs.[144]

Because of the food safety measures involved with irradiation, in January 2004 irradiation became available through the NSLP. [145]

In order for the irradiated meat to reach a child's lunch tray, the state department of education would buy irradiated beef from the federal government and then the individual school districts would purchase the beef from their state officials if they chose to do so.[146] The state and local school systems are in charge of ordering the irradiated goods as a result of the U.S. House of Representatives passing the Child Nutrition Act in June of 2004.[147] This Act states that the USDA may not mandate the use of irradiated products in school lunches and

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138. *Id.*
139. *Id.*
140. Hedges, *supra* note 37, at 3.
141. *See id.*
142. Monique Mikhail, *Irradiated Meat: A Sneak Attack on School Lunches*, WISE TRADITIONS IN FOOD, FARMING, AND THE HEALING ARTS (2003), http://westonaprice.org/modernfood/irradiatedmeat.html; Press Release, Wenonah Hauter, Dir. of Public Citizen's Food Program, Public Citizen Applauds Congress for Restricting School Lunch Use of Irradiated Food (June 24, 2004), *available at* http://www.citizen.org/pressroom/print_release.cfm?ID=1736.
143. Mikhail, *supra* note 142.
144. Food and Nutrition Service, *supra* note 32.
145. *Id.*
146. Mikhail, *supra* note 142.
147. Press Release, Hauter, *supra* note 142.

that the federal government may not subsidize its use.[148] The bill also required that the meat be labeled "irradiated."[149] Even before this act was passed, many school districts, including some in California, began banning the use of irradiated meat in their school districts.[150] Reportedly, three states did order the irradiated beef, but none received it due to official reluctance and/or high prices.[151] According to the USDA, prices were expected to be thirteen to twenty cents higher per pound for irradiated beef.[152] As of mid-2007, irradiated beef had not been used anywhere in the NSLP.[153]

There is a movement toward improving nutrition in school lunches,[154] and proponents of irradiated food opt for it because of the prevalence and danger of food poisoning with school outbreaks rising at a rate of ten percent per year.[155] Regardless of the possible benefits, the decision to allow irradiated food in the NSLP was met with much parental concern.[156] Of the more than 5,000 comments the government received, ninety-three percent were in opposition to the proposal to include irradiated meat in children's lunches.[157] Much of the controversy was about the safety and children's right to choose to eat the irradiated meat or not.[158] While the Child Nutrition Act requires the containers that the schools receive to be marked as irradiated, individual servings would not be marked.[159] Even if children were told that they were eating irradiated meat and did not want to, the more affluent children may be able to bring their own food from home, but the many children who use the free or reduced price lunch system might not have that option.[160] Parents are also worried about the use of irradiation because children may be more vulnerable to the chemical impacts because they are still grow-

148. *Id.*
149. *Id.*
150. Mikhail, *supra* note 142.
151. Hill, *supra* note 5.
152. Food and Nutrition Service, *supra* note 32.
153. Press Release, Patty Lovera, Food & Water Watch, Citizens, Consumer Groups Oppose Proposed Irradiation Labeling Change (July 3, 2007), *available at* http://www.centerforfoodsafety.org/IrradiationPR7_3_07.cfm.
154. Hill, *supra* note 5.
155. Marian Burros, *Eating Well; Irradiated Beef: A Question in Lunchrooms*, N.Y. TIMES, Jan. 29, 2003, at F3.
156. Mikhail, *supra* note 142.
157. *Id.*; Rose Marie Williams, Irradiated School Lunch Update, Oct. 2004, *available at* http://findarticles.com/p/articles/mi_m0ISW/is_255/ai_n6211949/pg_1.
158. Mikhail, *supra* note 142 (noting that because irradiated foods are not labeled, children and parents cannot know what is being served in the school cafeteria); *see also* Williams, *supra* note 157.
159. Williams, *supra* note 157.
160. Wenonah Hauter, *School Lunches Use Kids as Guinea Pigs*, PEOPLE'S WKLY. WORLD, Nov. 21, 2003, *available at* http://pww.org/article/articleprint/4440/.

ing.[161] Scientists have cautioned that more studies need to be done on irradiation and many parents feel that these studies should not be done on the children of the nation.[162] Further, many feel there are other less drastic solutions, including increased sanitation in cafeterias, to combat the contamination outbreaks in the nation's schools.[163] Carol Tucker Foreman, director of the Food Policy Institute at the Consumer Federation of America, has best summed up most parental concerns with her statement that "[t]here is nowhere in the world where a large population has eaten large amounts of irradiated food over a long period of time. It makes me queasy that we are going to feed it to schoolchildren."[164]

VI. LABELING REGULATIONS

There is another irradiation controversy in full swing: labeling.[165] Authority for food labeling is granted to the FDA under the Federal Food, Drug and Cosmetic Act (FDCA).[166]

In 2001, several focus groups were held by the FDA regarding labeling of irradiated products.[167] In the FDA's report to Congress, it stated that consumers agreed that irradiated foods should be honestly labeled.[168] The FDA requires special irradiation labeling which includes a "radura" symbol along with "treated with irradiation" or "treated by irradiation" on the retail package of the food.[169] Irradiation is the only processing technique that requires disclosure on the packaging of the food.[170] Although it is a process, labeling is required for irradiation because the FDA has concluded that the changes to the flavor and shelf-life of the foods could be seen as significant to the consumer.[171] "The agency stated, 'in absence of a statement that a food has been irradiated, the implied representation to consumers is that the food has not been processed.'"[172] Consumers have a fun-

161. *Id.*
162. *Id.*
163. *See id.*
164. Burros, *supra* note 155.
165. *See* Informa Economics, Inc., *FDA Moves Forward with Irradiation Labeling Policy Initiative*, FOOD & DRINK WKLY., July 16, 2007, http://findarticles.com/p/articles/mi_m0EUY/is_25_13/ai_n19379065.
166. Simpson, *supra* note 11, at 231.
167. FoodQualityNews.com, US Push for Irradiation Labeling Policy, Sept. 19, 2003, http://www.foodqualitynews.com/layout/set/print/layout/set/print/content/view/print/49385.
168. *Id.*
169. 21 C.F.R. § 179.26 (2008).
170. Frederick H. Degnan, *The Food Label and the Right-to-Know*, 52 FOOD & DRUG L.J. 49, 52 (1997).
171. *Id.*. at 52-53.
172. *Id.* at 53 (citations omitted).

damental right to make fully informed decisions about what they eat, and in order to do so, they must receive reliable and accurate information about that food.[173]

As the words "irradiation" and "radiation" could have negative implications and be fueling the low consumer acceptance, in the food industry want to change the labeling to "pasteurized" or "electronically pasteurized" in place of "irradiated."[174] However in past opinion polls, consumers do not want irradiation called 'pasteurization' because it is believed to be deceptive and misleading.[175] Market trials of irradiated food have shown that informed consumers are not against buying the irradiated products, but they want them to be labeled as irradiated.[176] In fact, consumers may find this labeling especially helpful if it also includes a reason for the irradiation for instance "irradiated to retard spoilage."[177]

Mandatory labeling has resulted in many food-makers staying away from irradiation because of the fear of scaring away customers.[178] In the past the FDA would not budge on the labeling requirements for the irradiation industry, but it became more receptive after the nation's public bouts with E.coli in the fall of 2006.[179] Finally, in April 2007, the FDA proposed to amend its labeling regulations for irradiated food.[180] The FDA proposed to remove the "radura" logo and the term "irradiated" altogether from packaging unless "the irradiation causes a material change in the food, or a material change in the consequences that may result from the use of food. . . ."[181] Further, a firm may use the term "pasteurized" rather than "irradiated" as long as it notifies the FDA that it meets the criteria of pasteurization.[182] This new terminology may be confusing to consumers as evidenced by the 1999 FDA comment period on the "treated by irradiation" labeling.[183] The majority of the 5,500 people responding thought that the FDA

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173. Letter from Joseph Mendelson III et al., Legal Dir., Ctr. for Food Safety, to Div. of Docket Mgmt., FDA, at 2 (July 2, 2007), *available at* http://www.centerforfoodsafety.org/pubs/irradiation tech. comm without sig.pdf.

174. Morehouse & Komolprasert, *supra* note 17, at 4.

175. Press Release, Public Citizen, Consumer Groups Run Ad Against Harkin's Farm Bill Food Irradiation Provisions (Mar. 11, 2002), *available at* http://www.citizen.org/pressroom/release.cfm?ID=1053.

176. INT'L CONSULTATIVE GROUP ON FOOD IRRADIATION, *supra* note 3, at 34.

177. *Id.*

178. Informa Economics, Inc., *FDA Moves Forward*, *supra* note 165.

179. *Id.*

180. Irradiation in the Production, Processing and Handling of Food, 72 Fed. Reg. 16291, 16291 (April 4, 2007) (codified at 21 C.F.R. pt. 179).

181. *Id.*

182. *Id.*

183. *See id.* at 16292.

should retain the current labeling on the package and that the words "cold pasteurization" and "electronic pasteurization" would confuse customers.[184]

Further, the term pasteurization has specific requirements as set forth by the FDA.[185] The FDA sets forth a standard of 99.99%, also known as a 5-log, reduction for E. coli, Listeria and Salmonella.[186] However, research studies indicate that irradiation at the levels approved by the FDA does not meet these requirements.[187] While irradiation did lower the bacteria count, it was not up to the standards of "pasteurization" and therefore, labeling irradiated food as "pasteurized" would mislead consumers.[188]

Under the proposed rule, the FDA only must label if there is a "material change" in the irradiated food. But this language has many wondering just what is a "material change," and who decides if the food has been "materially changed?" The FDA concedes that irradiation may cause changes in the characteristics of the food.[189] For instance, if bananas are irradiated to delay ripening, this is a material change because it changes a sensory (taste, color, odor, or feel), nutritional, or functional property of the food.[190] Since a consumer has an idea of how long it takes a normal banana to ripen, a consumer that was not aware a banana was irradiated would be unaware of this functional change and not be able to make banana bread in the time frame they had planned.[191] This type of material change would still need to be labeled under the new rule.[192] The control of food borne pathogens alone, however, is not an unexpected change in the food and would not require labeling under the proposed rule.[193]

The FDA developed the materiality test based on what consumers believed was important when evaluating food.[194] The FDA originally required labeling on all irradiated foods because irradiation itself was considered a material fact and something that consumers viewed as important.[195] The FDA was acting in the consumer's interests when requiring labeling on irradiated foods.[196] The

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184. *Id.*
185. *See* 21 U.S.C. § 343(h) (2008).
186. Letter from Mendelson et al., *supra* note 173, at 11.
187. *Id.* (stating that in order to achieve this 5-log reduction in pork, it would need to be irradiated at least 4.0kGy; however, the maximum approved for irradiation of pork is 1.0 kGy).
188. *Id.* at 12.
189. Irradiation in the Production, Processing and Handling of Food, 72 Fed. Reg. at 16293.
190. *Id*.
191. *Id*. at 16294.
192. *Id.*
193. *Id*. at 16295.
194. Simpson, *supra* note 11, at 239.
195. *Id.*
196. *Id.*

question then becomes, what has changed? As evidenced by the many consumer groups opposing irradiation to begin with, many people still view irradiation just as "material" as they did before.[197] In order to facilitate informed decision-making on the part of consumers, the label should indicate a food was irradiated regardless of the "material effect."[198]

Without labels indicating that food has been irradiated, the consumer could be eating meat that was in such a contaminated state that it would have been disposed of previously.[199] Because irradiation often is an effective procedure for elimination of bacteria, the meat could be "sanitized" and sold to an oblivious consumer. Removing the irradiation label is removing the consumer's ability to take important information into consideration when purchasing products.

Further, characteristics of food that consumers find material have required labeling in the past.[200] For instance, the FDA required labels for the source of protein hydrolysates was due to religious concerns and concern for vegetarians.[201] The FDA stated, "the food source of a protein hydrolysate is information of material importance for a person who desires to avoid certain foods for religious or cultural reasons."[202] As indicated by this example, the definition of materiality should not be restricted to information about changes in specific characteristics of the food.[203] Knowledge about whether the food has or has not been irradiated is a material fact to many consumers.[204] Therefore, it should be labeled as such.

Traditionally, there has been low consumer acceptance of irradiated foods with only 97 million pounds irradiated annually.[205] The biotechnology industry fears that consumers react negatively to a label indicating genetic engi-

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197. *See, e.g.*, WORTH ET AL., *supra* note 1, at 1, 28-29 (The fact that there are new chemicals formed which could be harmful to humans has not changed. Therefore, the materiality of irradiation has not changed either.).

198. Letter from Mendelson et al., *supra* note 173, at 8.

199. *Living on Earth, The Right to Know: Irradiated Food Labels (*radio broadcast, week of June 29, 2007) (transcript *available at* http://www.loe.org/shows/segments.htm?programID=07-P13-00026&segmentID=4) (discussing irradiation labeling with Dr. Urvashi Rangan, a health scientist and policy analyst).

200. Michael Hanson, *Comments of Consumers Union on the Food and Drug Administration's (FDA's) Docket No. 2005N-0272, "Irradiation in the Production, Processing and Handling of Food,"* July 3, 2007, http://www.consumersunion.org/pub/2007/07/004680print.html.

201. *Id.*

202. Food Labeling; Declaration of Ingredients, 56 Fed. Reg. 28592, 28600 (June 21, 1991).

203. Hanson, *supra* note 200.

204. *Id.*

205. Informa Economics, Inc., *Benefits of Irradiation*, *supra* note 4.

neering and avoid it.[206] Further hindering the cause is the fact that many consumers view "irradiation" to be a scary word.[207] In the beginning, the FDA recognized the potential disadvantages of labeling the food as irradiated but thought the voluntary label additions by producers with phrases similar to "irradiated to retard spoilage" would ease the apprehension of consumers.[208] Based on the current levels of irradiated foods, most consumers may still not be over that apprehension stage.[209] However, simply because the public is not excited about eating irradiated food when they are informed it is irradiated, does not indicate that consumers would be excited to have all their meat and produce irradiated without notice. There are no reasons given by the FDA as to why they are straying from their 1986 determination that a failure to require mandatory labeling of irradiated foods would be misleading to customers.[210] Consumers today would not be any less misled than they would have been in 1986.[211] It is, however, hard to avoid irradiated food if they fail to notify you that it is in fact irradiated.

VII. CONCLUSION

Irradiation is a controversial process with obvious positives but frightening negatives. The obvious benefits of longer shelf life and reduced pathogens could significantly alter trade. However, potential health detriments of irradiation leave many consumers crying out for stricter sanitation rather than irradiation. While irradiation is not a new technology, consumers are still not satisfied with the extent of the studies conducted. Consumers seem to have been leery of the technology from the beginning and it has never really gained any momentum in the United States.

Many agreed with Caroline Smith DeWaal, the Director of Food Safety at the Center for Science in Public Interest, when she stated, "I don't think the right place to start this is in the school lunch program. . . .It's essential parents be allowed to sign off before irradiated meat is allowed. If kids don't have the right to refuse and it's not labeled, it's really taking consumer choice away."[212]

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206. Lara Beth Winn, *Special Labeling Requirements for Genetically Engineered Food: How Sound are the Analytical Frameworks used by FDA and Food Producers?*, 54 FOOD & DRUG L. J. 667, 682 (1999).

207. *Id.*

208. *Id.* at 682-83.

209. Informa Economics, Inc., *Benefits of Irradiation*, *supra* note 4 (noting that "general consumer acceptance [is] a major reason for the limited availability of irradiated food.").

210. *See, e.g.*, Irradiation in the Production, Processing and Handling of Food, 72 Fed. Reg. 16291 (April 4, 2007).

211. Hansen, *supra* note 200.

212. Burros, *supra* note 155.

The biggest concern with removing the labeling altogether when there is no "material" effect on the food is consumer choice. In its own article, the FDA states "[c]onsumer choice mandates that irradiated food be adequately labeled and under the general labeling requirements, it is necessary that the food processor inform the consumer that the food has been irradiated."[213] Even if the proposal is accepted and labeling is no longer required, consumer choice still mandates it. There is no other way to select un-irradiated food if a consumer would choose to do so. The FDA should be striving to ensure that people are aware of what they are consuming, not misleading consumers into purchasing something they do not wish to purchase. Ignorance is not always bliss and, in this instance, consumer ignorance may potentially have health risks. The majority of people would like to be allowed to make informed choices about what they eat and would like the FDA to allow them to do so. It could take months or years for the final rule to be produced by the FDA, and until then, you may enjoy your burger with the peace of mind that it has not been contaminated "with the equivalent of 150 million chest X-rays[,]"[214] and if it has, the label would warn you.

213. Morehouse & Komolprasert, *supra* note 17, at 4.
214. *See* WORTH ET AL., *supra* note 1, at 9.