Docket Clerk  
U.S. Department of Agriculture  
Food Safety and Inspection Service  
FSIS Docket Room  
1400 Independence Avenue SW, Room 2534  
Washington, DC 20250

**RE: Docket No. FSIS-2008-0028, Request for Comment on Irradiation as a Processing Aid.**

The Center for Science in the Public Interest (CSPI) appreciates this opportunity to comment on defining electron beam (e-beam) irradiation of beef carcasses as a “processing aid” that would not have to be labeled on products derived from a treated carcass [Docket No. FSIS-2008-0028, Sept. 8, 2008]. CSPI is a non-profit consumer advocacy and education organization that focuses largely on food safety and nutrition issues. It is supported principally by the more than 950,000 subscribers to its *Nutrition Action Healthletter* and by foundation grants.

We believe that irradiation has potentially positive public-health utility, but that it is by no means a panacea ensuring food safety. CSPI strongly supports the continued use of irradiation labeling based on the use or non-use of irradiation processing, and not on the level or extent of that processing. This position is consistent with the Food Additives Amendment of 1958, which explicitly defines the source of radiation as the additive under consideration, and the regulatory history behind today’s meat irradiation labeling rules. It is also consistent with consumers’ interest in disclosure and choice with regard to products that have been irradiated.

For the reasons listed below, CSPI requests that the Food Safety Inspection Service (FSIS) deny the citizen’s petition submitted by the American Meat Institute (AMI).
1. CSPI contends that as a matter of law, even if FSIS defines low-dose, low-penetration e-beam irradiation as a processing aid, it must nonetheless require meat from carcasses subjected to e-beam treatment to be labeled as irradiated. Therefore, the core purpose of the petition is moot and it should be denied.

2. CSPI is concerned that studies cited in the AMI petition fail to support the claim that low-dose, low-penetration e-beam irradiation will be effective at eliminating pathogenic bacteria on beef carcasses. Therefore, even if FSIS had authority, it should nonetheless deny the petition until independently conducted substantiating research is done.

I. Background and Purpose of the Petition

Three years ago, AMI submitted a citizen’s petition requesting FSIS recognize use of e-beam irradiation as a processing aid for reducing the number of pathogenic bacteria on beef carcasses.\(^1\) The reason for making this request was to permit meat processors to use the technique without having to label the end product as irradiated.\(^2\) The agency published a notice of availability of petition and public meeting along with a request for written comments Sept. 8, 2008.

The notice requested comment on four questions:

- Is there any additional evidence to support or contradict the evidence presented in the AMI petition on the specific application of low penetration of 20mm and low surface dosage of \(\leq 1.0 \text{ kGy} \) electron beam irradiation on the surfaces of chilled beef carcasses as a processing aid?

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\(^1\) Citizen’s Petition from Dr. Randall Huffman, Vice President Scientific Affairs, Am. Meat Inst., to Philip Derfler, Assistant Adm’r, Office of Policy, Program and Employee Dev., FSIS, requesting recognition for the use of e-beam on carcasses as a processing aid (July 8, 2005) [hereinafter “Petition”].

\(^2\) Id., Irradiation as a Processing Aid, 73 Fed. Reg. 52001, 52002 (Sept. 8, 2008).
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- Is there any evidence indicating that FSIS should consider the cumulative effects of the absorbed dose delivered in accordance with the AMI petition and any subsequent absorbed dose, such as a result of further irradiation of ground beef?
- Should FSIS consider requiring irradiation process controls if irradiation is considered a processing aid? If so, what would they be and what impact would they have on the low dose irradiation of chilled carcasses?
- Are there factors that FSIS has not considered? If so, what are they and what impact would they have? 3

The agency held the public meeting Sept. 18, 2008. At the conclusion of that meeting, the agency announced it was considering three potential actions on the petition.

1. Determine and announce that low-dose, low-penetration e-beam irradiation is a processing aid without further action to amend current regulations.
2. Determine there is a need to revise its regulations on irradiation and initiate a rulemaking.
3. Determine not to move forward (i.e. deny the petition).

II. Regardless of How E-beam Irradiation is Defined, Irradiated Meat Should be Labeled.

Meat processors are allowed to use e-beam irradiation to control foodborne pathogens under current regulations. 4 The only issue raised by the petition is whether FSIS by redefining low-dose, low-penetration e-beam irradiation as a processing aid would allow meat processors to use the technology without having to label end products as irradiated. For the following reasons, CSPI contends the agency should deny the petition because (A) it cannot provide the relief from labeling requirements intended and (B) even if it could provide the relief intended, consumers still should be informed of products that have been processed by irradiation.


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A. The Request for Exemption Fails as a Matter of Law

The petition operates from a false assumption that radiation is the additive under consideration in FSIS regulations on labeling of irradiated meat. The term “food additive” includes “any source of radiation” intended for use in processing food. In general, the ingredients in a food item must be labeled and specifically meat that is irradiated must be labeled under 9 C.F.R. § 424.22(c)(4). There is no question about irradiation being a processing aid. The Food Additives Amendments Act of 1958 recognized irradiation is a process, but defined the source of radiation as the additive. The record shows that Congress understood that irradiation is a processing aid when it adopted the Act, but elected to treat it as an indirect food additive. AMI argues that FSIS should define low-dose, low-penetration e-beam irradiation as a “processing aid” that does not need to appear on the labels of meat derived from the carcass. Its argument that labeling is not needed because the meat is unaltered fails to grasp the construction of the statute that underpins regulation of irradiated products. Acting in a precautionary manner, Congress did not ask whether the end product would be altered, but looked at the source of radiation as the additive regulators were to consider. FDA highlighted this difference when it first approved irradiation of meat.

In this particular case, the additive is not, literally, added to food. Instead, a source of radiation is used to process or treat food such that, analogous to other food processes, its use can affect the characteristics of the food. In the subject petition, the intended technical effect is a change in the microbial load of the food, specifically, a reduction in the numbers of microorganisms, both

6 “A reading of the legislative history of the 1958 Amendment makes clear that both Congress and the Administrative agencies were well aware that food irradiation is a process and never gave any indication otherwise. They did conclude, however, that this process should be demonstrated to be safe before it is used. They implemented this conclusion by defining sources of radiation… intended for use in processing food as ‘food additives.’” George H. Pauli and Clyde A. Takeguchi, Irradiation of Foods - An FDA Perspective, Food Reviews International, 2(1) 79, 81 (1986).
7 Petition, supra note 1, at 2.
pathogenic and nonpathogenic, in or on meat. It is important to realize, however, that the petitioner is not required to show, nor is FDA permitted to consider, that irradiation of meat has benefits, health or otherwise, for consumers of irradiated meat.\(^8\)

Defining irradiation as a processing aid does not change the statutory treatment of the source of radiation as the additive that must be labeled.

AMI’s petition cannot rely on treating irradiation as an incidental additive. Most processing aids are exempt from labeling requirements as “incidental additives” by 21 C.F.R. § 101.100(a)(3)(ii).\(^9\) Incidental additives are substances that have no technical or functional effect [subparagraph (i)], processing aids [subparagraph (ii)], and substances migrating to the food from equipment or packaging that are not defined as additives under 21 U.S.C. § 321(s) [subparagraph (iii)].\(^{10}\) AMI’s petition focuses attention on the exemption for processing aids, but ignores the clear statutory definition of a source of radiation as a food additive subject to section 101.100(a)(3)(iii). As an additive defined in section 321(s), a source of radiation cannot be redefined by the agency as an “incidental additive” falling under subparagraph (ii). Since irradiation is already understood to be a processing aid that nonetheless must be labeled as an additive, for FSIS to define irradiation as a processing aid should have no effect on the labeling requirement.

Even if by defining low-dose, low-penetration e-beam irradiation of beef carcasses as a processing aid provided the relief AMI is seeking, FSIS still should require meat from the carcasses to be labeled as irradiated.

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\(^{10}\) Food Exemptions from Labeling, 21 C.F.R. § 101.100(a)(3) (2008).
B. Industry Should Focus on Consumer Education Rather than Circumvention.

Proper labeling is important to enabling consumers who are wary of irradiated foods to avoid them, but also allow consumers who want to buy irradiated food to choose to do so. In a 1999 poll commissioned by CSPI and the American Association of Retired Persons (AARP), 88.6 percent of respondents supported labeling of irradiated foods to indicate that they have been irradiated. As a result, CSPI believes a better approach is for the industry to educate consumers on the benefits of irradiation. Industry studies have generally found that if consumers are educated about irradiation, they are more willing to buy the products.\textsuperscript{11} According to a survey conducted by Food Practice Consulting Group and CMF&Z in 1999, of the 54 percent of consumers surveyed who were aware of food irradiation, 68 percent were likely to purchase irradiated meat, 67 percent were likely to purchase irradiated poultry, and 68 percent were likely to purchase irradiated dairy.\textsuperscript{12} Given the potential food safety benefits of irradiation, industry can and should undertake a campaign to educate consumers on the processing technique.

III. Further Study on Whole Beef Carcasses Is Needed to Confirm AMI’s Claims.

In addition to the issues noted above, the agency should also deny the petition because it is not adequately supported by the reports submitted on testing of low-dose, low-penetration e-beam irradiation.

The studies submitted by AMI in support of its petition support the effectiveness of e-beam irradiation at reducing pathogens on meat cuts, but do not establish that it can be equally


\textsuperscript{12} 1999 Food Safety Survey Results, Food Practice Consulting Group and CMF&Z, \textit{Consumer Awareness of Food Irradiation and Of Those Consumers Who Were Aware, Percentage Likely to Purchase Irradiated Foods}.  

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effective on whole carcasses. Achieving a uniform dose on the irregular surface of a carcass presents significant obstacles, according to Dr. Dennis Olson, professor of animal science and director of Iowa State University’s Linear Accelerator Facility.\textsuperscript{13} To get a uniform dose will require different power levels for different areas of the carcass.\textsuperscript{14} The studies cited by AMI were carried out on cuts laid on flat surfaces. For example, one study made an effort to use cuts that approximated the surface matrix of a beef carcass, but subjected the cuts to e-beam irradiation while arranged on a pan.\textsuperscript{15} Because none of the studies explored the range of power levels that would be required for irregularly shaped beef carcasses, they do not demonstrate the technology can achieve similar pathogen reduction and preservation of quality attributes on whole carcasses. FSIS should require further studies of low-dose, low-penetration e-beam irradiation under the conditions of its anticipated use before considering AMI’s petition.

In requesting further studies, FSIS should be conscientious of consumer wariness of industry-led studies into the safety of irradiation. A 2002 survey found that consumers are less trusting of industry than of government on claims that irradiation is safe.\textsuperscript{16} The studies cited in support of AMI’s petition were all funded by the meat industry. It would strengthen consumer acceptance if the studies were conducted by independent researchers.

IV. Conclusion

Irradiation may provide positive public-health benefits and, therefore, CSPI encourages the agency and industry to continue research into and application of this technology. But,

\textsuperscript{14} Id.
\textsuperscript{15} Petition, supra note 1, at 3 (citing, Terrance M. Arthur, et al., Effects of Low-Dose, Low-Penetration Electron Beam Irradiation of Chilled Beef Carcass Surface Cuts on Escherichia coli O157:H7 and Meat Quality, 68 J. of Food Protection 666 (2005)).
irradiation is not a panacea, and FSIS must continue to require a range of safety interventions during meat processing to assure the food that reaches consumers is wholesome and safe to eat. CSPI strongly believes that labeling of irradiated food is both a legal mandate and strongly supported by consumers. Not only is AMI’s petition deficient because it seeks to circumvent labeling requirements, the petition also lacks appropriate research showing low-dose, low-penetration e-beam irradiation can be effective in the application AMI envisions. For the reasons above, FSIS should deny the petition.

Respectfully submitted,

[Signature]

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