



THE CENTER FOR FOOD SAFETY

660 PENNSYLVANIA AVE., SE , SUITE 302, WASHINGTON, DC 20003

(202) 547-9359 • FAX (202) 547-9429

2601 MISSION ST., SUITE 803, SAN FRANCISCO, CA 94110

(415) 826-2770 • FAX (415) 826-0570

WWW.CENTERFORFOODSAFETY.ORG

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Corrected Comments on Irradiation as a Processing Aid

Pursuant to the notice found at 73 *Federal Register* 52001 (Sept. 8, 2008) the Center for Food Safety (CFS) submits the following comments in response to the Food Safety Inspection Service's (FSIS) possible use of "Irradiation as a Processing Aid." CFS is a non-profit membership organization that works to protect human health and the environment by curbing the proliferation of harmful food production technologies and by promoting organic and other forms of sustainable agriculture. CFS represents members throughout the country that support organic agriculture and regularly seek to avoid purchasing irradiated food products. See generally <http://www.centerforfoodsafety.org>

In its notice, FSIS discusses a petition from the American Meat Institute (AMI) seeking approval of low dose irradiation as a processing aid as having "merit." As discussed below, CFS does not agree and does not support defining the application of "low dose" irradiation on beef carcasses as a "processing aid."

I. Irradiation Is Not A Processing Aid

(1). FDA Has Never Considered Irradiation a Processing Aid.

Granting the AMI Petition request would radically alter the manner in which irradiation has been regulated and defined by federal agencies for well over thirty years. As FSIS has indicated, the agency has relied upon the FDA regulations on processing aids and points directly to 21 C.F.R.

§101.100(a)(3)(ii)(c).¹ Without statutory authority to redefine irradiation as a processing aid, FSIS must defer to FDA's interpretation of irradiation as a food additive and not a processing aid. FDA has specifically argued against such a determination stating:

Several comments argued that a retail label requirement was inappropriate because irradiation was used in place of chemical fumigants and FDA does not require that these chemicals be identified on the retail label. One comment stated that “there is no more rational basis for labeling irradiated foods (at the retail level) than for labeling pesticide residues present in agricultural commodities, indirect additives from packaging, flour and bread from fumigated wheat, or the current fumigated spices themselves.” Another comment pointed out that FDA has long held the position that nonfunctional secondary additives need not be declared on the label and that the policy codified at 21 CFR 101.100 should apply to foods that have been irradiated.

The issue here is whether the irradiation of food is a material fact that must be disclosed to the consumer to prevent deception. As stated earlier, irradiation may change the characteristics of a food in a manner that is not obvious in the supermarket. Packaging materials and incidental additives such as processing aids that have no technical or functional effect in the food and thus do not ordinarily affect the characteristics of the food may be exempted under 21 CFR 101.100 from the normal labeling requirements under the act. Furthermore, Congress specifically exempted pesticide chemicals under section 403(1) of the act from a retail labeling requirement when the food has been removed from its shipping container.²

Additionally, as part of its notice, FSIS ignores its past statements on this issue and points instead to its allowance of lactic acid and organic acids as possible models for deregulating irradiation as a “processing aid.”³ This suggestion, however, flies in the face of past FSIS recognition that irradiation technology is not similar to “antimicrobial carcass washes.” For example, as part of its announcement of its HACCP system FSIS stated:

One part of the July proposal that was criticized in the comments is the requirement that the antimicrobial treatment be limited to application prior to the chilling or cooling system. Some commenters indicated that certain antimicrobial treatments for use in the chilling or cooling systems are more effective than treatments applied before this point. Additionally, some held that certain post-chill treatments, such as

¹ 73 Fed. Reg. 52001, 52002/2.

² 51 Fed. Reg. 13376,13388-89 (Apr. 18, 1986)(emphasis added).

³ Id.

irradiation, may provide a more effective treatment option. FSIS's intent was, and is, that poultry entering chill tanks be as clean as possible. However, FSIS invites comments on whether mandated antimicrobial treatments should be restricted to pre-chill application, as proposed above.

Irradiation is another issue related to this proposal on antimicrobial treatments. Irradiation is statutorily defined as a "food additive" under the Federal Food, Drug, and Cosmetic Act (FFDCA) and thus its safety is evaluated by FDA, which must approve its use as a food additive in a regulation specifying safe and lawful conditions of use. FDA has approved irradiation for use in controlling foodborne pathogens on uncooked poultry (21 CFR 179.26), and FSIS has promulgated regulations under the PPIA specifying inspection requirements for establishments using that process (9 CFR 181.149). FDA currently is considering a petition to permit use of irradiation to control pathogens on uncooked meat. Irradiation is not being considered an antimicrobial treatment for purposes of this proposal because irradiation facilities are to date extrinsic, stand-alone operations that cannot easily be integrated into a slaughter operation--the focus of the present effort. Furthermore, although irradiation has been shown to be a highly effective pathogen control mechanism, it is a capital-intensive process largely unavailable to most inspected slaughter establishments. Notwithstanding these considerations, firms would be able to use irradiation on raw poultry under existing regulations, in addition to the antimicrobial treatments now being proposed.⁴

Approval of the AMI Petition would alter this long held policy. Moreover, if accepted, the action will have been justified by a petition supported by one preliminary study and one incomplete meta-analysis concerning micro and macro nutrient content. An agency such as FSIS cannot alter such long standing regulatory policy based on such scant support. To do so would be arbitrary and capricious.⁵

(2). Irradiation Has a Technical Effect on Chilled Beef Carcasses

To qualify as a processing aid irradiation must be a substance that is “added to food for [its] technical or functional effect in processing but [is] present in the food at insignificant levels and do not have any technical or functional effect in food.” 21 C.F.R §101.100 (a)(3)(ii)(c). Just because something is present in small quantities does not make it a processing aid. FDA has stated where something present in the

⁴ 60 Fed. Reg. 6774, 6790-91 (Feb 3, 1995)(emphasis added).

⁵ See e.g. Western States Petroleum Assoc. v. EPA, 87 F.3d 280, 284-85 (9th Cir. 1996) (“[an agency] must clearly set forth the ground for its departure from prior norms so that we may understand the basis of the [agency’s] action and judge the consistency of that action with the [agency’s] mandate.”)

food can cause problems in very small quantities (such as allergens) it cannot be a processing aid.⁶ As a result, low dose irradiation cannot be considered a processing aid because the use of irradiation adds a substance to the final food that has a technical and functional effect in the food. This is particularly apparent in that the AMI petition and FSIS do not consider the resulting creation of cyclobutanones in beef carcasses irradiated at low doses.

Alkylcyclobutanones (ACBs) are produced solely as a result of irradiation and not other processing methods.⁷ They are unique radiolytic products formed from fatty acids. They are not known to be formed by cooking or any other heat-processing method. The AMI petition would allow treatment of beef carcasses with doses of 1.0 kGY (up to 1.6 kGY internal).⁸ Even at these purported “low levels” ACBs have been found. For example:

- Stevenson has shown that 2-DCB is present in beef irradiated at irradiation doses of 1 kGY.⁹ “[2-DCB] has never been detected in any unirradiated or microbiologically spoiled samples and has always been found in irradiated samples even at doses as low as 0.5 kGY.”¹⁰
- Gadgil (2002) used gamma and e-beam to irradiate ground beef at doses including e-beam .9 kGY and 1.7 kGy (.1 kGy more than admitted absorbed dose). At these levels 2-DCB was detected. There is also concern that at higher levels the e-beam showed higher 2-DCB levels than gamma irradiation stating, “The increased amount of 2-DCB in the electron beam irradiated samples was an unexpected and interesting result that requires further investigation.”¹¹

The presence of ACBs has a technical effect on the end product beef. Several studies have indicated the potential cytotoxic and other biological effects of 2-DCB.¹² Delincee, *et al* observed a genotoxic effect in isolated rat and human colon cells.¹³ Animal models treated with 2-ACBs have been shown to have

⁶ FDA, Annex 5, HACCP Guidelines (Dec. 11, 2001) at 11 *available at* <http://www.cfsan.fda.gov/~acrobot/fc01-a5.pdf>.

⁷ P. Gadgil, et al., “2-Alkylcyclobutanones as Irradiation Dose Indicators in Irradiated Ground Beef Patties,” J. AGRICULTURAL AND FOOD CHEMISTRY (2002).

⁸ AMI Petition at 3-4.

⁹ M. Stevenson, “Identification of Irradiated Foods,” FOOD TECHNOLOGY (May 1994).

¹⁰ Id.

¹¹ Gadgil, et al *supra* note 6.

¹² B. Ashley, et al., “Health Concerns Regarding Consumption of Irradiated Foods,” INT’L J OF HYGIENE AND ENV. HEALTH (2004).

¹³ H. Delincee, et al, “Genotoxic Properties of 2-dodecylcyclobutanone, A Compound Formed on Irradiation of Food Containing Fat,” RADIAT. PHYS. CHEM. (1998).

marked increase in colon tumors compared to controls.¹⁴ Recent experiments have found that 2-DCB has genotoxic potential and caused chromosomal aberrations in human colon cells.¹⁵ In sum, these findings make it quite clear additional research needs to be completed on the toxicity of unique radiolytic products.¹⁶ The AMI petition ignores this issue entirely.

In addition, there is some evidence that irradiating beef at 1 kGY can promote the increase in the presence of trans fatty acids. Brito, *et al* found that irradiation of ground beef at 1 kGY levels increased trans fatty acids by 3.4%.¹⁷ Increasing levels of trans fat is certainly a technical effect on the food. As the FDA has stated “it’s important to know about trans fat because there is direct, proven relationship between diets high in trans fat content and LDL (“bad”) cholesterol levels, and therefore, an increased risk of coronary heart disease - a leading cause of death in the US.”¹⁸

As a result, there is far more evidence showing a technical and functional change in beef and food after it has been irradiated even at doses of 1 kGY than evidence suggesting no such changes occur. As such, the irradiation doses requested for use by AMI cannot meet the legal definition of a processing aid.

II. Labeling

Consumers have a right to know that irradiation has been used on food products. FSIS proposed actions should not undermine this right. As the FDA has recently stated, “[r]adiation-induced chemical changes . . . may cause changes in the organoleptic properties of the food.”¹⁹ As discussed above, evidence suggests there are changes in irradiated beef at low doses that consumers will be unaware of absent labeling, including the presence of 2-DCBs and an increase in trans fat. Moreover, the Arthur, *et al* study submitted as principle support for the AMI Petition shows significant differences in off-aroma, tenderness, juiciness and off-flavor in ground beef patties made from a mixture of only 5% of beef

¹⁴ F. Raul, et al., “Food-Borne Radiolytic Compounds (2-Alkylcyclobutanones) May Promote Experimental Colon Carcinogenesis,” NUTRITION AND CANCER (2002).

¹⁵ N. Knoll, et al., “2-Dodecylcyclobutanone, a Radiolytic Product of Palmitic Acid, Causes DNA Strand Breaks and Chromosomal Aberrations in Human Colon Adenoma Cells,” MUTAT. RES. (2006).

¹⁶ Ashley, *et al.*

¹⁷ M.S. Brito, et al, “Effects of Irradiation on Trans Fatty Acids in Ground Beef,” RADIAT. PHYS. CHEM. (2002).

¹⁸ FDA, “Fact Sheet: What Every Consumer Should Know About Trans Fatty Acids” (jul. 9, 2003) available at http://www.fda.gov/oc/initiaives/transfat/q_a.html.

¹⁹ 73 Fed. Reg. 49593, 49595 (Aug. 22, 2008).

irradiated at a low dose.²⁰ These organoleptic changes are consistent with the findings of a number of studies concerning the organoleptic changes caused in beef by irradiation.²¹ Consumers must be made aware of these changes in their food through continued use of mandatory labeling. Designating low dose irradiation as a processing aid to avoid mandatory labeling would run contrary to existing labeling requirements and would undermine consumers' fundamental right to know how their food is raised and processed.

III. Irradiation is Not Allowed Organic

In its March 4, 2008, letter to Dr. Tarantino of the FDA, USDA states that it "will confer with Agriculture Marketing Service (AMS) regarding any concerns they may have regarding application of irradiation as a processing aid and labeling related to organic beef."²² Whether or not irradiation is considered a food additive or a processing aid makes no difference to the organic regulations. Under 7 C.F.R. §205.105(f), beef and beef products in any form that are labeled "organic" or "made with organic beef" must not be produced with the use of ionizing radiation. Further, 7 C.F.R. § 205.270 (c)(1) dictates that a handler of organic agricultural products cannot use irradiation. This prohibition also covers all labeled organic products. 7 C.F.R. §205.301(f).

IV. USDA Determination Should Be Subject to Review Under NEPA

Under the existing USDA regulations, actions of the FSIS are categorically excluded from NEPA unless the agency Administrator "determines that an action may have a significant environmental effect." 7 C.F.R. §1b.4. Such an environmental effect is present and stems, in part, from the moral hazard created by redefining irradiation as processing aid. Allowing beef processing facilities to use low dose irradiation on chilled carcasses will insulate them from the risk of their current unsanitary practices and prevent them from taking action as if it were fully exposed to the food borne illness liability created by their industrial agricultural practices. Granting of the AMI Petition would alleviate the meat processing industry of the need to address the full consequences of its actions that contribute to pervasive *E. coli* contamination and other pathogens of food borne illness. Low dose irradiation of carcasses will encourage the industry to act less carefully than it otherwise would, and leave consumers and the environment to bear responsibility for the consequences of the industry's actions.

²⁰ T. Arthur, "Effects of Low-Dose, Low-Penetration Electron Beam Irradiation of Chilled Beef Carcass Surface Cuts on *Esherichia coli* 0157:H7 and Meat Quality; J. FOOD PROTECTION (2005) at Table 5.

²¹ See CFS, FWW "Food Irradiation: A Gross Failure (2006) available at http://www.centerforfoodsafety.org/pubs/Food_Irradiation_Gross_Failure.pdf.

²² Letter from Anonymous, Director, Risk Management Division, Office of Policy and Program Development, USDA, FSIS, to Dr. Laura Tarantino, Office of Food Additive Safety, CFSAN, FDA dated March 4, 2008.

The Administrator, therefore, should determine that there is a significant environmental impact from this action and its disincentive for the beef industry to address numerous inherently damaging activities that impact both the human health quality of the meat it produces and the environment. FSIS should assess the impacts this action will have on industry's failure to eliminate and reduce the upstream environmental impacts associated with industrial agriculture including but not limited to, issues such as animal husbandry practices, hormone use, manure management, feeding practices, ground water contamination, and climate change.

Conclusion

As discussed above, CFS believes that FSIS AMI Petition must be denied.

Respectfully submitted,

/s/

Joseph Mendelson III
Legal Director