

2: Ticket 120: 99F-5321



January 26, 2005

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**Re: Food Additive Petition 9M4697, Use of ionizing radiation for pre-processed meat and poultry; both raw and pre-processed vegetables, fruits and other agricultural products of plant origin; and certain multi-ingredient food products; FAP 1M4727, Use of ionizing radiation for control of foodborne pathogens in crustaceans and processed crustaceans; FAP 9M4682, Ionizing radiation for the control of Vibrio and other foodborne pathogens in fresh or frozen molluscan shellfish; FAP 9M4695, Use of ionizing radiation to treat unrefrigerated (as well as refrigerated) uncooked meat, meat products, and certain meat food products; FAP 9M4696, Increase the maximum dose of ionizing radiation permitted in the treatment of poultry products; and Citizen Petition 2003-P0544, To modify existing food additive regulation to revoke approval for irradiated ground beef**

Dear Drs. Brackett, Tarantino, and Pauli:

Public Citizen and the Center for Food Safety are pleased to submit this public comment on the above-referenced petitions. On January 12, 2005, representatives from our organizations met with you and other staff members from the FDA's Center for Food Safety and Applied Nutrition. Thank you for that meeting. A presentation we made then – "Remarks by Mark Worth, Research Director, Energy and Environment Program, to the U.S. Food and Drug Administration, College Park – Jan. 12, 2005" is attached with supporting documents and incorporated herein.

At the meeting, CFSAN staff members stated:

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- The 1980 report of the Irradiated Food Committee (IFC), attached, “had very little effect” on FDA’s approving the Omnibus Rule in 1986.

= In fact, the Omnibus Rule quotes the IFC report extensively, mainly the IFC’s position that foods irradiated at 1 kGy or less needn’t undergo toxicological testing.<sup>1</sup>

- The IFC did not examine toxicological issues.

= In fact, one of the Committee’s main tasks was to “establish those toxicologic [sic] requirements appropriate for assessing the safety of irradiated food consistent with the level of human exposure.” (See “Introduction and Background.”)

- The IFC report was “not an agency report.”

= In fact, the Committee was comprised of FDA staffers from four divisions. (See “Membership of the Irradiated Food Committee.”)

- They did not recall the phrase “worst-case” appearing in the IFC report.

= In fact, the report says: “A worst-case estimate would predict that 40 percent of the human diet would consist of irradiated food.” (See p. III-10.) This actually suggests the consumption of irradiated foods should be limited. Today, roughly half of the food supply can legally be irradiated – and this portion would increase if pending petitions are approved.

- They could not explain a comment made to the *New York Times* on Oct. 15, 2003, in which an FDA official said the agency decided by 1987 that there was no need to test individual radiolytic products formed in irradiated foods.<sup>2</sup>

= This was a 180 degree departure from the IFC report, which stated: “Based on what we have learned from our review of all aspects of food irradiation, it is apparent that any toxicological testing requirements must also be predicated on the amounts of new chemical constituents generated by the irradiation process (URPs). (See p. 15, “1980 Policy Recommendations.”) The IFC report also stated that “tests must be performed on extracts in which the concentration of radiolytic products is maximized.” (Emphasis in original.) (See “Testing,” p. 18.)

It seems that CFSAN staff now are attempting to diminish and mischaracterize the IFC’s role. This is disturbing, as the IFC detailed the toxicological testing regime that the FDA was supposed to follow when assessing the safety of foods irradiated at more than 1 kGy – including poultry, beef, eggs and sprouting seeds. We are not suggesting any intent to deceive. However, basic facts cannot be ignored.

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<sup>1</sup> Federal Register, Vol. 51, pp. 13377-8, April 18, 1986.

<sup>2</sup> Burros, Marian “Eating Well: Questions on Irradiated Food” *New York Times*, Oct. 15, 2003.

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We agree with the statement Dr. Brackett made at our January 12 meeting that examining the “totality of science is critical.” In regard to 2-ACBs, the totality of science suggests that these chemicals – which do not occur naturally in any food – pose health risks. As 2-ACBs have been detected in irradiated beef now on the market, consumers are unwittingly ingesting these potentially hazardous chemicals. The time has come for the FDA to publicly acknowledge the existence of 2-ACBs and conduct a thorough toxicological assessment.

We also strongly agree with Dr. Brackett’s statement, “We don’t want to rely on the status quo.” In terms of unique radiolytic products such as 2-ACBs, the FDA’s status quo is unsatisfactory. On three occasions from 1986 to 1997, the agency stated in Federal Register notices that radiolytic products are “typically identical to substances that occur naturally in foods;”<sup>3</sup> that they “are likely to be toxicologically similar to other food components;”<sup>4</sup> and that “there is no evidence, or any reason to believe, that the toxicity or carcinogenicity of any unique radiolytic products is different from that of other food components.”<sup>5</sup> These statements simply are no longer true. The status quo must change.

Allow us to remind you that the FDA, in a 1984 Federal Register notice,<sup>6</sup> specifically cited the study by the Federation of American Societies for Experimental Biology (FASEB), attached, that stated, “Nothing is known of the fate and toxicity” of 2-ACBs, and that “metabolic and toxicological studies of these compounds are desirable.” **Whether or not the FDA accidentally or intentionally ignored the study, the failure to act on these clear warning signals is a flagrant example of the agency’s botched regulation of food irradiation.**

FASEB’s recommendation is identical to concerns raised recently by a consortium of French and German scientists, who stated:

“[A] very small part of the 2-ACB...was stored in the adipose tissues of the rat, whereas a similar small part was excreted in the faeces. These results indicate that 2-ACBs are largely metabolized or possibly stored in other parts of the body. These results indicated that most of the 2-ACB is metabolically transformed (or stored in other parts of the body). It seems, therefore, very important to perform further studies about the metabolism of the 2-ACB... To characterize the potential risk, hazards need to be identified, the exposure, the exact dose-response and particularly the kinetics and metabolism of 2-ACB in the living organism should be elucidated. All these studies are deemed necessary to gain insight into the mechanisms of the toxic effects. Numerous questions still remain to be answered, and much research is left to be done, before a qualified risk assessment can be performed.”<sup>7</sup> (pp. 5-6, emphasis added.)

<sup>3</sup> Federal Register, Vol. 62, p. 64102, Dec. 3, 1997.

<sup>4</sup> Federal Register, Vol. 51, p. 13376, April 18, 1986.

<sup>5</sup> Federal Register, Vol. 52, p. 5450, Feb. 23, 1987

<sup>6</sup> Federal Register, Vol. 49, p. 5721, Feb. 14, 1984.

<sup>7</sup> Etude toxicologique transfrontalière destinée à évaluer le risque encouru lors de la consommation d'aliments gras ionisés – Toxikologische Untersuchung zur Risikobewertung beim Verzehr von bestrahlten fetthaltigen Lebensmitteln. Eine französisch-deutsche. Studie im Grenzraum Oberrhein. Rapport final / Schlussbericht

Also, we would like to bring to your attention a recently discovered study, attached, conducted by the U.S. Atomic Energy Commission at Columbia University in 1954. In a two-year experiment, rats were fed a diet that included irradiated whole wheat. The reproductive performance of female rats fed irradiated food suffered substantially. The number of litters born, for example, was 22 percent lower than females fed non-irradiated food.<sup>8</sup> These findings support other studies that yielded adverse health effects, which our organizations have previously submitted to this docket.

We are very encouraged by Dr. Brackett's desire to "reduce consumer concerns rather than snooker them." The need for credibility at the FDA has never been greater.

In summary, the above-referenced Food Additive Petitions do not present adequate information to meet the legal standards for safety in Title 21 - Food and Drugs, Pt. 170 - Food Additives. Therefore, the Center for Food Safety and Public Citizen again strongly urges you to deny the petitions. This comment also serves to support the above-referenced Citizen Petition that we filed specifically seeking a revocation of FDA's approval for irradiated ground beef.

Thank you for your attention to this comment. For further information about the issues herein, please contact us.

Sincerely,

  
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Attachments

cc (with attachments): FDA FAP Docket No.s: 99F-5522; 01F-0047; 99F-4372; 99F-5321; 99F-5322; Citizen Petition Docket No. 2003-P0544

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INTERREG II Projet / Projekt No 3.171. Berichte der Bundesforschungsanstalt für Ernährung, BFE-R--02-02. Federal Research Center for Nutrition (Bundesforschungsanstalt für Ernährung) Karlsruhe, Germany, 2002. (Available at <http://www.bfa-ernaehrung.de/Bfe-Deutsch/Information/e-docs/bfer0202.pdf>)

<sup>8</sup> "Food Irradiation and Associated Studies: Termination Report - Part I." United States Atomic Energy Commission, Technical Information Service, Oak Ridge, Tennessee. NYO-3320, Contract No. AT(30-1)-1186, September 15, 1954,