

Comment to: Docket No. 99F-5322



November 14, 2003

Mr. Joseph Levitt
U.S. Food and Drug Administration
CFSAN HFS-001
Harvey W. Wiley Federal Building
5100 Paint Branch Parkway
College Park, MD 20740-3835

Dr. Laura Tarantino
U.S. Food and Drug Administration
CFSAN OFAS, HFS-200
Harvey W. Wiley Federal Building
5100 Paint Branch Parkway
College Park, MD 20740-3835

Dr. Alan Rulis
U.S. Food and Drug Administration
CFSAN OFAS, HFS-200
Harvey W. Wiley Federal Building
5100 Paint Branch Parkway
College Park, MD 20740-3835

Dr. George Pauli
Associate Director for Science and Policy
U.S. Food and Drug Administration
CFSAN OFAS, HFS-205
1110 Vermont Ave., N.W. Rm. 1250
Washington DC 20201

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; Food Additive Petition 1M4727, Use of ionizing radiation for control of foodborne pathogens in crustaceans and processed crustaceans; Food Additive Petition 9M4682, Ionizing radiation for the control of Vibrio and other foodborne pathogens in fresh or frozen molluscan shellfish; Food Additive Petition 9M4695, Use of ionizing radiation to treat unrefrigerated (as well as refrigerated) uncooked meat, meat products, and certain meat food products; and Food Additive Petition 9M4696, Increase the maximum dose of ionizing radiation permitted in the treatment of poultry products

Dear Mr. Levitt and Drs. Rulis, Tarantino, and Pauli:

This is a further joint comment letter on the five above-referenced food additive petitions to irradiate a much greater portion of the food supply. We appreciate your meeting with us on September 23rd. We want to bring your attention to additional matters related to the safety of food irradiation in the attached tabbed

materials, which are incorporated in this comment.

Tab 1. Au abstract of risk assessment shortcomings. This memo dated Aug. 22, 2003, by William Au, Ph.D., a toxicologist and mutagenicity specialist at the University of Texas, was presented at the meeting and is now filed formally in the dockets. Dr. Au points out that:

The standard toxicological tests, especially animal bioassays, were not designed to detect adverse effects of low concentrations of radiolytic products in food therefore they have low sensitivity to such test conditions.....[B]oth positive and negative effects from these studies cannot be used reliably to assess risks for humans.

Dr. Au also comments on the urgency of the Raul et al. colon tumor promotion findings, stating that in other toxicological situations, the concentration of tumor promoters can be hundreds of times less than the concentrations of direct carcinogens. Thus, the relatively low levels of the tumor-promoting 2-ACBs found in some irradiated foods that have been assayed do not indicate that they are safe 2-ACB levels. Further, many other foods that would be covered under the five pending petitions have never been assayed for 2-ACBs. Dr. Au's bottom line is that safe levels have not been broadly established.

Tab 2. Au recommendations on health risk assessment. Dr. Au followed up on his participation in the Sept. 23 meeting with his proposals, dated Oct. 11, for further research if FDA wants to reliably determine whether irradiated foods are safe. Specifically, he calls on FDA to:

- document and characterize radiolytic products in irradiated foods;
- conduct systematic evaluation of health risk from the consumption of irradiated foods;
- characterize the tumor promotion properties of 2-ACBs;
- investigate potentially susceptible human populations; and
- conduct a comprehensive risk evaluation.

We urge you to undertake these tasks. They are within the scope of your duties with respect to the petitions.

Tab 3. Burros New York Times article. This article by noted food writer Marian Burros, dated Oct. 15, 2003, at p. D-6, entitled "Questions on Irradiated Food," discusses various toxicity concerns. Notably, the second-to-last paragraph contains a cautionary quote from Dr. Francis Raul, Research Director of the French National Institute of Health, who was the lead researcher on colon tumor promotion associated with 2-ACBs. Plainly, this leading authority thinks it is unwise and premature to feed irradiated ground beef to schoolchildren, as USDA is undertaking. Dr. Au and Dr. C.V. Rao (his opinion was discussed in our July 8, 2003, comment to you on the five pending petitions), as well as several other leading experts have raised the same concerns. It appears obvious that no scientific agreement exists that food irradiation is safe, particularly for children.

Tab 4. Lebensmittel report on irradiated ground beef Irradiated ground beef is potentially covered in two of the pending petitions: FAP 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; and FAP 9M4695, Use of ionizing radiation to treat unrefrigerated (as well as refrigerated) uncooked meat, meat products, and certain meat food products. In view of the potential risks, Public Citizen and the Center for Food Safety hired a well-established food testing lab, Lebensmittel Consulting of Fostoria, Ohio, to test a variety of commercially available, irradiated ground beef products for the presence of 2-ACBs, both raw and cooked, as well as unirradiated controls. The results are indicated in the report, which also includes analysis of volatile chemicals.

The irradiation levels applied to these commercially-purchased samples are not known precisely, but presumably they were at or near the allowed maximum dose of 4.5 kGy for refrigerated product and 7.0 kGy for frozen product. The two types of 2-ACBs that have been associated with colon tumor promotion in rats, and cellular and genetic damage in human cells – 2-tDeCB and 2-tDCB – were detected in all three irradiated ground beef products tested. Cooking of the irradiated samples generally, but not always, reduced the amount of 2-ACBs. No 2-ACBs were detected in the unirradiated ground beef, whether raw or cooked.

Note that the presence of 2-ACBs in various irradiated foods also was documented in a chapter of the study that we translated and submitted to you in an earlier comment, i.e., the French/German consortium study that examined the toxic potential of 2-ACBs extensively.¹ As discussed at p. 5 of our February 26, 2003 comment to you, Chap. 2.5 therein includes quantification of the levels in “hamburger”. Table 1, below compares those levels to the highest levels found in the cooked ground beef in the Lebensmittel report.

¹ Marchioni, E., P. Horvatovich, and D. Werner. Determination of the Levels of 2-Alkylcyclobutanones in Irradiated Foods, in Burnouf, H. Delincée, A. Hartwig, E. Marchioni, M. Miesch, F. Raul, D. Werner (2001), 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 d'étude Interreg II, projet N° 3.171. BFE-R--02-02, Federal Research Centre for Nutrition, Karlsruhe, Germany.

Table 1: Formation of two key 2-alkylcyclobutanones in irradiated ground beef.

<i>Study</i>	2-tDCB	2-tDeCB
Marchioni et al. [raw - 1 sample] [units: µg/g fat/kGy]	0.355	0.501
Lebensmittel [cooked - highest level sample, Surebeam #2] [units: µg/g fat]	0.034	0.14

Another study out of Kansas State University by Gadgil et al. also found other 2-ACBs in irradiated raw ground beef.² FDA must note that both the Lebensmittel and the Gadgil et al. studies found the highest 2-ACB levels in their electron beam irradiated samples compared to their gamma irradiated samples. Neither authors could explain this phenomenon. Gadgil et al. stated, at p. 5749, “At this point the reason for the increased level of 2-DCB in the electron beam samples remains unclear.” Richard Basel, Ph.D., the author of the Lebensmittel report also has stated that the reason for the difference is unclear (pers. comm.)

FDA must assess these differences in the two irradiation sources as far as their impacts not only on ground beef, but on all other foods covered by the five pending petitions. The fact that the reasons for the increases are not explainable urges additional research and special caution regarding the electron beam source. “E-beam” irradiation may also cause unpredictable increases in harmful 2-ACBs in other foods.

Tab 5. Bibliography of Research on 2-ACBs. This collection by Public Citizen of 72 literature citations addressing 2-ACBs provides a useful entry to the literature that must be fully examined and assessed with respect to the vital toxicity issues raised.

Tab 6. What’s in the Beef report. This detailed report by Public Citizen and the Center for Food Safety summarizes the scientific objections to irradiated ground beef. It makes a convincing case to not approve the pending petitions to the extent they would include irradiated ground beef.

Tab 7. Study on oxidation of irradiated egg powder. The 1992 paper by Lebovics et al. “Cholesterol oxides in γ -irradiated spray-dried egg powder” *J. Sci. Food Agric.* 60: 251-254, found, at p. 253, that “the application potential of radiation treatment of whole egg powder and powdered egg yolk is reduced

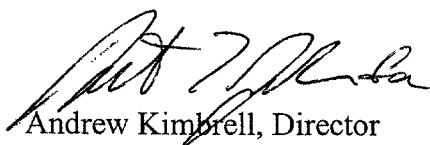
² Gadgil, P., K. Hachmeister, J. Smith, and D. Kropf. 2002. 2-Alkylcyclobutanones as irradiation dose indicators in irradiated ground beef patties. *J. Agric. Food Chem.* 50:5746-5750.

by the enhancement of formation of cholesterol oxidation products by ionizing radiation.” The authors also noted, at p. 251: “Certain compounds formed during the spontaneous oxidation of cholesterol have potentially undesirable biological activities such as atherogenicity, cytotoxicity, mutagenicity, carcinogenicity and inhibition of cholesterol biosynthesis.” Irradiated egg powder has more such harmful oxidation products than unirradiated egg powder, and the study’s authors as a result recommended against the technology’s use. They also recommended further studies on other irradiated foods of animal origins as far as potentially harmful oxidation products.

FDA did not address these impacts in its 2000 approval of irradiated fresh whole eggs, 65 Fed. Reg. 45280-45282. Clearly, FDA must thoroughly address the oxidation impacts of irradiation on cholesterol found in “formulated” ready-to-eat foods (see Food Additive Petition 9M4697, the “ready-to-eat foods” petition, at pp. 30-31), including in the numerous conceivable multi-ingredient formulated foods that may contain egg powder, a common baking and food processing ingredient. FDA also must address these oxidation impact in other high-cholesterol ready-to-eat foods, beyond those containing irradiated egg powder. Failure to do so would constitute ignoring potentially harmful impacts.

In sum, numerous unresolved toxicity and other issues remain for the five pending irradiation petitions. For the reasons stated here and in our earlier comments to you they should not be approved.

Sincerely,



Andrew Kimbrell, Director
Center for Food Safety
660 Pennsylvania Ave., S.E.
Suite 302
Washington, DC 20003



Wenonah Hauter, Director
Public Citizen, Critical Mass Energy and Env't Program
215 Pennsylvania Ave., S.E.
Third Floor
Washington, DC 20003

Attachments (7)

cc: FDA Food Additive Petition Docket No.s: 99F-5522; 01F-0047; 99F-4372; 99F-5321, 99F-5322
(with attachments)

William Au, Ph.D.