

To: Docket No. 99F-5322



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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; 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**

Greetings,

The FDA is considering the five above-referenced food additive petitions to irradiate a much greater portion of the food supply. The Center for Food Safety (CFS), together with Public Citizen, has filed numerous earlier sets of comments opposing these petitions on grounds of serious safety issues stemming from scientific studies indicating that certain irradiated foods may cause mutagenic, genotoxic, and tumor-promoting effects in lab animals as well as in humans.

CFS submits this further comment in opposition to the five petitions, including the attached information, which is incorporated herein by reference.

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**Attachment 1.** Marchioni, E., F. Raul, D. Burnouf, M. Miesch, H. Delincée, A. Hartwig, and D. Werner. 2004. Toxicological study on 2-alkylcyclobutanones - results of a collaborative study. *Radiation Physics and Chemistry* 71:147-150.

This summarizes the European testing of 2-alkylcyclobutanones (2-ACBs), which we have cited to repeatedly in earlier unpublished and separately-published reports. The significance of this publication is that it concisely reiterates the ground-breaking 2-ACB program. Again, per the authors (p.149): “the in vitro and the in vivo experiments with laboratory animals demonstrated that 2-ACBs have potential toxicity.” The paper concludes that as far as the possibility of health hazards from consuming irradiated food, “further research is highly required.” Unfortunately, no comprehensive research on the toxicity of 2-ACBs has been undertaken to date, leaving this uncertainty as a huge obstacle to FDA’s making a reliable decision on the five pending petitions.

**Attachment 2.** Kesavan, P., and M. Swaminathan. 1971. Cytotoxic and mutagenic effects of irradiated substrates and food material. *Radiation Botany* 11:253-81.

In a sweeping review more than three decades ago, Kesavan and Swaminathan documented that numerous studies from the 1950s and ‘60s had found a variety of toxic effects in animal feeding studies as well as *in vitro* studies, which on the whole cast doubt on the safety of the technology. We ask FDA to take a closer look now at the host of past positive studies cited therein (several of which we previously cited to you in our earlier comments on these dockets, e.g., of May 14, 2001, but others of which we did not), particularly in light of the new findings on 2-ACBs. If the agency does that, we are confident it will conclude that on the whole these older studies demonstrated a consistent pattern of troubling effects related to animals eating irradiated diets that were not found in the control animals.

Attempts to discount all of the past positive findings as aberrations, products of chance, or artifacts of dietary deficiencies will no longer suffice. These studies need further FDA review, particularly in view of the 2003 Codex Alimentarius standard revision that allowed for higher absorbed doses of radiation than previously permitted.<sup>1</sup> Indeed, no specific upper dose limit exists at all now. Several of the older animal feeding studies found effects at high doses that previously were considered unrealistic, until this recent loosening of the Codex Standard.

**Attachment 3.** Verschuren, H., G. Van Esch, and J. Van Kooy. 1966. Ninety - day rat feeding study on irradiated strawberries. *Food Irradiation - Quarterly International Newsletter* 7(1-2):A17-

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Codex Alimentarius, General Standard for Irradiated Foods, 2003 Revision, Sec. 2.2 on “Absorbed Dose.” Formerly, this standard imposed an unconditional maximum of 10 kGy, whereas the revision allows this level to be exceeded whenever “necessary to achieve a legitimate technological purpose.”

A21. In this study (which we were not aware of previously), large groups of rats were fed two versions of irradiated strawberry supplements to their diets, one in liquid form, the other in powder form. The study found that male rates on the irradiated strawberry powder supplement showed a statistically significant growth deficit compared to the control animals fed the same diet, including the powder supplement, but which was unirradiated.

FDA's internal reviewers in 1981 and 1982 (reviews are attached to study) twice classified the Verschuren et al. study as one the agency should "accept," without reservations, only to be later overridden by a third reviewer who was able to reclassify the study as "reject." This change was based on the third reviewer's suggestion that the study was hampered by "inadequate diet and restricted food intake," a surprising suggestion as nothing in the study supported that conclusion. Indeed, the first FDA reviewer specifically commented that the deficit "cannot be explained by decreased food intake," an observation reiterated in the study, at p. A-18. The suggestion by the FDA's third reviewer that the diet was deficient is belied by the fact that it was a standard laboratory diet and the irradiated powder constituted only 5% of the total diet.

FDA should review this and the other positive studies we have cited in light of the criticism reiterated in Kesavan and Swaminathan, above, at p. 266, of a "credibility gap between observed parameters and the recurring conclusions that there is not apparent toxic hazard involved in the ingestion of irradiated food."<sup>2</sup> FDA needs to reassure the public that its current internal process for evaluating positive studies is fully credible.

We are confident that you will find that too much risk remains to approve any of the pending food irradiation petitions. For more information, please contact Peter T. Jenkins, Policy Analyst; tel: 202.547.9359 x13; email: [peterjenkins@icta.org](mailto:peterjenkins@icta.org).

Sincerely,



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Attachments (3)

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

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<sup>2</sup> Quoting a letter of Sept. 12, 1968, from Dr. G. Lofroth, an experienced irradiation researcher, to the then-Department of Health, Education and Welfare.