



THE CENTER FOR FOOD SAFETY

August 11, 2004

Lane A. Highbarger
Office of Food Additive Safety, HFS255
FDA/CFSAN
5100 Paint Branch Parkway
College Park, MD 20740-3835

Re: ~~Docket 2003-P0544, petition to modify existing food additive regulation~~

Dear Mr. Highbarger,

With respect to the above-referenced petition filed in November, 2003, by the Center for Food Safety (CFS) and Public Citizen, when I recently asked you about its status your reply email to me dated Aug. 4 stated:

“The citizen petition that you submitted consists of material that you have previously submitted as comments to the irradiation petitions that are currently under review. In light of the fact that we are currently reviewing those comments, it would be inappropriate to make a conclusion on the request of the citizen petition prior to completing the review of the other five irradiation petitions.”

For the record, not all of the information supporting our irradiated ground beef revocation petition was previously submitted by us in the form of comments on the other five pending irradiation petitions. Our petition itself provides extensive additional information. This includes: flaws in the 1997 FDA approval for irradiated meats (pp. 3-6); new evidence regarding probable consumption of irradiated ground beef especially by vulnerable school children (pp. 12-14), plus additional scientific support and analysis throughout. Thus, your justification for delaying consideration of the ground beef revocation petition appears superficial.

Further, even if the bulk of the supporting information was earlier filed with comments on the other petitions, that is not directly relevant to the issues presented in the CFS and Public Citizen petition. Rather than seeking to expand food irradiation as the other five pending petitions do, ours seeks to reduce it because of unresolved health risks. Our petition covers only irradiated ground beef and ground beef byproducts whereas the other petitions cover a wide variety of other foods. Our petition is more important to resolve first because if FDA determines that it has merit, the agency would need to take follow-up steps to protect the public health and it would be very unlikely that the agency would grant the other petitions.

Also, as further evidence in support of this petition, and in opposition to the other pending petitions,

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enclosed is a peer-reviewed article that is "In Press" in the *International Journal of Hygiene and Environmental Health*, by B.C. Ashley, P.T. Birchfield, *et al.*, entitled, "Health Concerns Regarding Consumption of Irradiated Food". It analyses the toxicity issues surrounding irradiated foods. The article is being sent separately to the Dockets Management Branch by way of additional comment by CFS on all of the pending irradiation petitions. Some key quotes:

"Although the application of the food irradiation procedure has been heavily promoted and recommended, unresolved health concerns related to the consumption of irradiated food remain." (p. 4)

"[C]onsumption of irradiated food can possibly result in a significant accumulation of 2-ACBs in the adipose tissues of consumers. The long-term health consequences of this observation are unclear at this time." (p. 9)

"[C]ompounds found exclusively in irradiated dietary fats may promote colon carcinogenesis in animals treated with a known carcinogen and identifies a new area of toxicity that the FDA and WHO have yet to examine. The 2-ACB tumor promotion activities should be further investigated, and their effects evaluated systematically." (pp. 9-10)

"In summary, it is quite clear that additional research is needed in order to fully address the issue and concerns of irradiated food. The toxicity of unique radiolytic products should be tested vigorously, especially in regards to the tumor promoting activities. Animal bioassays should be conducted systematically and comprehensively with whole food and with unique radiolytic products to generate a dose-response understanding of the toxicity and safety of irradiated food. It would prove beneficial to establish a dose that does not cause any observable toxic effects in an experimental animal model. The data obtained would better substantiate extrapolation and application in human health risk evaluation. In addition, as of now, there are no extensive human trials available to assess irradiated food safety in human populations. Regulatory agencies in the US and around the world need to be proactive in resolving these health concerns prior to the ubiquitous consumption of irradiated food. It is notable that the European Parliament has halted the addition of new food products for irradiation and has chosen to maintain the 10kGy limit on irradiation." (p. 18)

FDA is urged to follow the authors' recommendations of being proactive in resolving the health concerns. Undertaking the additional research that the authors' say it is "quite clear" is needed would be a good start. Above all, irradiated ground beef should not be fed *en masse* to vulnerable school children, as USDA intends to begin when the school year starts in the next few weeks.

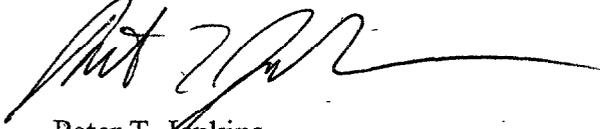
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In closing, you are requested to please promptly (in the next few weeks) affirm FDA's intention to respond substantively in the future to the CFS and Public Citizen petition on irradiated ground beef and to state approximately when we should expect your full substantive response. Feel free to contact me if you would like additional information.

Very truly yours,



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CC: FDA Dockets Management Branch for Dockets No. 2003-P0544, 99F-5522; 01F-0047; 99F-4372; 99F-5321; 99F-5322

Laura Tarantino, Ph.D., Director, OFAS, FDA CFSAN
Ms. Patty Lovera, Public Citizen

Enclosure