

# Public Citizen

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Joan Claybrook, President

Jan. 21, 2005

Division of Dockets Management  
HFA-305  
Food and Drug Administration  
5630 Fishers Lane – Room 1061  
Rockville, MD 20852

**Re: Docket No. 1993F-0357 – “Irradiation in the Production, Processing, and Handling of Food”**

To whom it may concern:

Under the provisions of 21 CFR §12, Public Citizen is requesting a formal evidentiary public hearing for the purposes of revoking the Food and Drug Administration’s Final Rule on Docket No. 1993F-0357 – “Irradiation in the Production, Processing and Handling of Food” (at 69 FR 76401-76404).

We have identified and seek to present at a public hearing genuine and substantial issues containing evidence that raises material issues of fact and questions in a material way the rationale of this Rule.

(1) The Rule does not state how the neutrons will be produced, how they will be collimated, or what the energy spectrum (profile) is – that is, how many neutrons of what energy were used in the petitioner’s calculations. Public Citizen is requesting a formal evidentiary public hearing on this matter.

(2) The Rule does not state the source of neutrons, how a monoenergetic beam will be created, or what fraction of the neutrons will be below 1 MeV. The Oak Ridge National Laboratory (ORNL) report referenced in the Rule cites backup calculations that used “thermal” neutrons, which are of even lower energy than those proposed by the petitioner. While this is a more conservative approach, it is not the same as the proposal, and the energy profile used in the calculations is not stated in the Rule. Public Citizen is requesting a formal evidentiary public hearing on this matter.

(3) The ORNL report states that the elemental composition of foods used by the petitioner is significantly different than those in the USDA database referenced in the report. For example, the ratios of the USDA database to the petitioner’s elemental composition of Fe and Se in beef are 9.25 and 870 respectively. The ORNL report acknowledges (page 4): “Overall, the elemental composition presented in the petition, as compared with a more modern database, appears to be

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of adequate, but not optimal quality.” The ORNL report provides no evidence to support its conclusion that this problem is of no concern. Public Citizen is requesting a formal evidentiary public hearing on this matter.

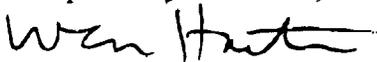
(4) The ORNL report states that foods could be exposed to neutron radiation for up to 5 minutes, in which case consumers could receive an annual dose of 0.01 mSv (page 7). This is equal to 3.57 percent of what a person receives annually from all terrestrial sources, and 0.33 percent of all sources. The ORNL report provides no evidence to support its conclusion that this problem is of no concern. Public Citizen is requesting a formal evidentiary public hearing on this matter.

(5) There is no known analysis of chemical, physical, or other changes caused by the use of neutrons to irradiate food. Any additives created by this process, including, but not limited to, chemical byproducts or radioactivity, must be assessed for safety. The FDA did not comply with 21 CFR §170.22, which states: “Except where evidence is submitted which justifies use of a different safety factor, a safety factor in applying animal experimentation data to man of 100 to 1, will be used; that is, a food additive for use by man will not be granted a tolerance that will exceed 1/100th of the maximum amount demonstrated to be without harm to experimental animals.” This non-compliance includes not only the failure to conduct any animal experiments using foods irradiated under the provisions of this Rule, but also the failure to calculate a 100-to-1 safety factor or submit evidence that justifies the use of a different safety factor. Public Citizen is requesting a formal evidentiary public hearing on this matter.

(6) The FDA did not comply with 21 CFR §170.20, which states that “the Commissioner will be guided by the principles and procedures for establishing the safety of food additives stated in current publications of the National Academy of Sciences-National Research Council.” Public Citizen is requesting a formal evidentiary public hearing on this matter.

Taken together, these flaws in the FDA’s Rule represent genuine and substantial issues containing evidence that raises material issues of fact and questions in a material way the rationale of the ruling. We request that a formal evidentiary public hearing be held at the earliest possible date.

Respectfully submitted,



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Director

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