

Recommendations to the Food and Drug Administration on health risk assessment of irradiated food

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The conference telephone call on September 23, 2003 with scientists and officials of the Food and Drug Administration (FDA) and with members of the organizations, Public Citizens and Center for Food Safety, was highly successful in that we were able to share the knowledge and concerns regarding health risk from the consumption of irradiated food. From the discussion, it was clear that there are still serious information gaps in some key areas regarding the health concerns. Therefore, I have prepared a list of recommendations for the FDA to consider.

- 1) Document and characterize radiolytic products in irradiated food: Products that are unique or are produced in much higher concentrations than expected in food from the irradiation process need to be identified. These products should then be prioritized based on their uniqueness and/or high concentrations for further characterization. Products with the highest priority should be targeted for in-depth characterization, e.g. for their physical, chemical and toxicological properties.
- 2) Conduct systematic evaluation of health risk from the consumption of irradiated food: The standard animal bioassay system is not designed to demonstrate adverse effects from exposure to low concentrations of toxic substances like those in irradiated food. The traditional protocol is to test pure products in several concentrations, with the highest concentration reaching the maximal tolerated dose for the experimental animal. The dose-response observations from such study allow scientists to validate and to understand the toxicological property of the test product. More importantly, the dose-response observation is used by scientists to extrapolate the toxicological information from the high doses to the human consumption low doses for assessment of potential health risk among consumers. Without using the appropriate animal assay protocol, the results from the existing animal studies on irradiated food are unlikely to support confident assessment of health risk in consumers. Therefore, extensive toxicological evaluation of the prioritize products in irradiated food is needed. On the other hand, the FDA is also interested in evaluating the wholesomeness of irradiated food. In the latter case, animal should be fed a balanced diet that is made up of food irradiated with maximal allowable doses and with lower doses for a long-term study. Complete toxicological evaluation should be performed with all animals to generate dose response observations.
- 3) Tumor promotion properties of 2-ACB: 2-ACBs are unique radiolytic products from irradiated food. In a brief investigation, 2 of the products were found to have tumor promoting properties in an experimental colon cancer model (Raul et al., 2002). This finding raises a new concern because tumor promotion requires

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only low concentrations of the products. In addition, 2-ACBs are generated in lipids from the irradiation process and lipid is an important contributing factor for colon cancer in human. The co-existence of cancer causing and promoting agents in the same food source is a serious health concern. Therefore, the tumor promoting activities of 2-ACB needs to be characterized in detail.

- 4) Susceptible populations: A large portion of the population may consume irradiated food. It is well known that the population is made up of individuals with vastly different responses to toxic substances. These include children, malnourished individuals, elderly, etc. (Bhaskaram and Sadasivan, 1975; Au et al., 2002). Therefore, FDA should investigate the potential health impact of consuming irradiated food in susceptible populations.
- 5) Comprehensive risk evaluation and consumer protection: Based on the recommended studies as shown in items 1-4 above, FDA will be able to generate more reliable assessment of health risk from the consumption of irradiated food. In setting regulatory decisions, FDA should consider the use of the Precautionary Principle. In addition, consumers should be provided adequate information for them to make informed decision in choosing the type of foods for consumption.

References:

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