An abstract of shortcomings in risk assessment of irradiated food for human consumption.

Prepared by: William W. Au, Ph.D., Professor of Toxicology, Univ. of Texas Medical Branch; August 22, 2003.

- Irradiation of food with high doses of ionizing radiation produces unique radiolytic products and higher concentrations of certain other substances than are present in unirradiated foods (Delincee et al., 2002; Byun et al., 2000; Diehl et al., 1978; Jakubick et al., 1978). These products have not been adequately identified and their adverse effects to human health have not been systematically characterized (Au, 2001, 2003).
- 2) 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. In addition, the feeding conditions may cause nutritional imbalances that can affect the outcome of the investigations. Consequently, inconsistent results have been extensively reported. Therefore, both positive and negative effects from these studies cannot be used reliably to assess risks for humans.
- 3) The extent of potential adverse effects in humans who consume irradiated food has not been adequately tested: cancer promotion, birth defects, allergy, etc.
- 4) The existence of susceptible populations to potential adverse effects among consumers of irradiated foods has not been considered: especially children and malnourished individuals (Au, 2002; Bhaskaram & Sadasivan, 1975).
- 5) The adverse health effects from consumption of meat that contains 2-ACBs, unique radiolytic products, have not been fully and adequately characterized (Horvatovich et al., 2002). Two 2-ACBs were briefly tested for tumor promoting activities in an experimental colon tumor model and one was active (Raul et al., 2002). In irradiated food for human consumption, the concentration of 2-ACBs is estimated to be low, e.g. 0.5 ug/gram of lipid at 5 kGy (WHO, 1999). However, in a different but well-established tumor promotion animal model, the dose that was needed to promote tumors was lower than 0.5 ug per mouse, delivered two times per week for 25 weeks (Saleem et al., 2001). Another way to consider the dosage situation is that the concentration of tumor promoters is usually hundreds of times less than the cancer inducing chemicals. Therefore, 2-ACB in irradiated food can potentially be hazardous to humans.
- 6) Consumers often will be unaware of their consumption of irradiated food, particularly if the food is multi-ingredient or is served in a restaurant or other public setting or, as is proposed, is served to children in school lunches. Therefore, it will not be possible to associate the development of any adverse

health effects with the irradiated food by the consumers themselves or by public health scientists.

References:

Au WW. Expert Affidavit on Safety of Irradiated Food. Oct., 2001. Submitted to FDA by the Center for Food Safety and Public Citizen with public comment dated October 13, 2001, on five pending food irradiation petitions.

Au WW. Susceptibility of children to environmental toxic substances. Int. J. Hygiene and Environ. Health 205, 501-503, 2002.

Au WW. Comments on health hazards of irradiated food. Unpublished report submitted to Public Citizen, January, 2003.

Bhaskaram C, Sadasivan G. Effects of feeding irradiated wheat to malnourished children. Am. J. Clin. Nutri. 28:130-135,1975.

Byun MW, Kim JH, Lee JW, Park JW, Hong CS, Kang IJ. Effects of gamma radiation on the conformational and antigenic properties of a heat-stable major allergen in brown shrimp. J. Food Prot. 63:940-944, 2000.

Delincee H, Soika C, Horvatovich P, Rechkemmer G, Marchioni E. Genotoxicity of 2alkylcyclobutanones, markers for an irradiation treatment in fat-containing food – Part I: cyto- and genotoxic potential of 2-tetradecyclcyclobutanone. Radiat. Phys. Chem. 63, 431-435, 2002.

Diehl JF, Adam S, Delincee H, Jakubick V. Radiolysis of carbohydrates and of carbohydrate-containing foodstuffs. J. Agric. Food Chem. 26:15-20, 1978.

Horvatovich P, Raul AF, Miesch M, Burnouf CD, Delincee DH, Hartwig EA, Werner FD, Marchioni E. Detection of 2-alkylcyclobutanones, markers for irradiated foods, in adipose tissues of animals fed with these substances. J. Food Prot. 65, 1610-1613, 2002.

Jakubick V, Delincee H. Radiation-induced aggregation of proteins: binding of amino acids to myoglobin. Z. Naturforsch. 33:203-209, 1978.

Raul F, Gosse F, Delincee H, Hartwig A, Marchioni E, Miesch M, Werner D, Burnouf D. Food-borne radiolytic compounds promote experimental colon Carcinogenesis. Nutr. Cancer. 44:188-191, 2002.

Saleem M, Ahmed SU, Alam A, Sultana S. Tephrosia purpurea alleviates phorbol esterinduced tumor promotion response in murine skin. Pharmacol. Res. 43:135-144, 2001.

WHO. High-dose irradiation: wholesomeness of food irradiated with doses above 10 kGy. WHO, Geneva, 1999.