Expert Affidavit on Safety Issues of Irradiated Food for School Children

By: William W. Au, Ph.D.
Date: December 10, 2002.

William Au, being duly sworn, hereby deposes and says:

A. My address is: Division of Environmental Toxicology, Department of Preventive Medicine and Community Health, Ewing Hall, 700 Harborside Drive, University of Texas Medical Branch, Galveston, Texas 77555-1110, where I have been employed as a Professor since 1991. My Curriculum Vitae is attached hereto indicating my professional qualifications as a toxicologist. My primary research interest is in conducting molecular and cellular studies to elucidate toxicological mechanisms for the induction of human disease. Since obtaining my Ph.D. from the University of Cincinnati, I have more than 20 years of experience teaching, conducting and publishing peer-reviewed research, consulting and speaking internationally, editing professional publications, and serving on numerous expert committees. I am a member of the major scientific societies related to toxicology and have received approximately one dozen awards recognizing my professional contributions. I have delivered more than 35 invited lectures internationally and published or co-published more than 200 articles in the toxicology field.

B. I submit this Affidavit to the United States Department of Agriculture with respect to its public comment period on food safety technologies for use in its commodity purchase programs pursuant to the recent Farm Bill, specifically on the agency's consideration of allowing the use of ionizing radiation on food served to school children.

C. I submit this Affidavit on behalf of two Washington, DC, non-profit groups, the Center for Food Safety and Public Citizen, who have retained me as a consulting expert. Prior to this consultation I had no prior involvement with those or any other non-profit groups involved in food irradiation issues.

D. In formulating my opinion, I have reviewed relevant documents and studies and conducted independent research.

E. My opinion, based on a reasonable degree of scientific certainty, is as follows:

1) The use of radiation to decontaminate/sterilize foods destined for human consumption should be evaluated for health concerns very carefully. Radiolytic products are formed during the irradiation of food (Schubert, 1969). Their potential health hazards have not been adequately evaluated. More research is needed on the products that are unique to the irradiation process. A recently-discovered unique class of radiolytic products that are generated from the irradiation of fat-containing food is 2-alkylcyclobutanone (2-ACB) with saturated and mono-unsaturated alkyl side chain: 2-decyl-, 2-dodecyl-, 2-dodecenyl-, 2-tetradecyl- and 2-tetradecenyl-cyclobutanone (Miesch et al., 2002).

2) Since 1998, concern regarding health hazards from the consumption of irradiated food has been focused on the toxicity of 2-ACB. Using in vitro assays, 2-ACB has been shown to be genotoxic and mutagenic (Delincee and Pool-Zobel, 1998; Delincee et al., 1998; Delincee et al., 2002; Burnouf et al., 2002). 2-ACB has also been tested in experimental animals. In one report (Horvatovich et al., 2002), laboratory rats were fed a very low concentration of 2-ACB in drinking water, and the absorption and excretion of the chemical were monitored. The study showed that less than 1% of the administered chemical was excreted in feces. A portion of the chemical crossed the intestinal barrier, entered the blood stream and accumulated in the adipose tissues of the animal. It follows that consumption of irradiated food for a long time can cause accumulation of toxic 2-ACB in the adipose tissues of human consumers, including school children.

3) The recent findings by Raul et al. (2002) raised a high level of concern. Although the detail of the study is not available yet, the summary of the report indicates that 2-ACB is a promoter for colon cancer in rats. A promoting agent does not usually cause cancer by itself but alters cellular functions (Zheng et al., 2002; Yamagata et al., 2002). The unique concern with promoters is that they can significantly enhance the carcinogenic effects of known carcinogens (Hecker et al., 1980; Slaga, 1983; Langenbach et al., 1986). Experimental animals that are treated with both promoters and carcinogens develop tumors much earlier and have more tumor nodules than animals treated with the carcinogens alone. Animals treated with the promoters alone would not develop tumors more often than the untreated animals.

4) Colon cancer (as was discovered in the rat study on 2-ACBs) is a serious health problem in humans, causing approximately 60,000 deaths per year in the United States. Consumption of improper diet is a major cause for colon cancer: foods that are high in fat especially from animal sources, meat cooked with high heat, charred meat, and food with high content of aromatic/heterocyclic amines (Colon cancer folder in the American Cancer Society website – www.cancer.org; Lang et al., 1986; Vineis and McMichael, 1996). Therefore, consumption of the improper diet together with food that contains 2-ACB which acts as a tumor promoter can increase the risk for the development of colon cancer. Under this scenario, individuals who would normally outlive the risk for colon cancer might develop the cancer. As there has not been a systematic investigation in the population, this cancer promotion concern remains unaddressed.

5) Numerous other peer-reviewed published reports have long indicated the mutagenic activities of irradiated foods fed to mammals (Anderson et al., 1980; Bhaskaram and Sadasivan, 1975; Bugyaki et al, 1968; Maier et al., 1993; Moutschen-Dahmen, et al., 1970; Vijayalaxmi, 1975, 1976, 1978; Vijayalaxmi and Rao, 1976; Vijayalaxmi and Sadasivan, 1975). The health concerns from consumption of irradiated food simply cannot be considered to have been resolved (Louria, 2001).

6) Only two published studies have been conducted to investigate mutagenicity hazards in people who consumed freshly irradiated food. In one study, malnourished children who were fed freshly irradiated wheat had more chromosome aberrations than those who were

fed non-irradiated or stored irradiated wheat (Bhaskaram and Sadasivan, 1975). In the other study, healthy adults were fed irradiated food for three months and no increased chromosome aberrations were observed (Institute of Radiation Medicine, 1987). However, upon reanalysis of the data, an increase in chromosome aberrations with borderline statistical significance was reported (Louria, 1990). The data indicate that consumption of irradiated food can cause genotoxic effects and therefore health hazards in the population. More importantly, there may be subpopulations such as undernourished children who are most susceptible to toxic effects of irradiated food. Strong reasons exist for considering children generally to be especially susceptible to toxic materials (Au 2002). Undernourished schoolchildren in the United States are the population segment most likely to consume a high percentage of their daily food intake from the school meal programs (breakfast, snack, and lunch), as their parents have fewer alternative choices due to economic reasons.

7) Effects that have significant public health implications such as polyploidy, genetic alterations, and tumor promotion are critically important not to ignore when children are involved, especially when those children may be undernourished and have few practical alternatives, therefore are physically and economically vulnerable. Furthermore, exposing human beings to hazardous substances at an early age will increase the likelihood that the induced health effects will be manifested within their lifespans. The wisdom and fairness of compelled exposure to these effects should be considered seriously and explicitly by USDA with respect to the pending proposal for school food irradiation. Irradiating the food to be eaten by millions of growing children would expose them to toxicity hazards for which it would very difficult, if not impossible, to obtain truly informed consent from them or their parents.

Dated this _____ day of December 2002, at _____, Texas.

_____
Signature

State of Texas
:ss.
County of _____

Subscribed and sworn to before me this _____day of December, 2002.

_____
Notary Public

C.V. attached

References

Anderson, D., Clapp, M.J.L., Hodge, M.C.E., Weight, T.M. Irradiated laboratory animal diets – dominant lethal studies in the mouse. Mutat. Res. 80, 333-345, 1981.

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

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

Bugyaki, L., Deschreider, A.R., Moutschen, J., Moutschen-Dahmen, M., Thijs, A., Lafontaine, A. Do irradiated foodstuffs have a radiomimetic effect? II. Trials with mice fed wheat meal irradiated at 5 Mrad. Atompraxis 14:112-118, 1968.

Burnouf D, Delincée H, Hartwig A, Marchioni E, Miesch M, Raul F, Werner D. "Etude toxicologique transfrontalière destinée à évaluer le risque encouru lors de la consommation d'aliments gras ionisés / Toxikologische Untersuchung zur Risikoberwertung beim Verzehr von bestrahlten fetthaltigen Lebensmitteln – Eine französisch-deutsche Studie im Grenzraum Oberrhein". Rapport final / Schlussbericht Interreg II. Projet / Projekt No 3.171, 2001.

Delincee, H., Pool-Zobel, B.L. Genotoxic properties of 2-dodecylcyclobutanone, a compound formed on irradiation of food containing fat. Radiat. Phy. Chem. 52:39-42,1998.

Delincee, H., Pool-Zobel, B.L., Rechkemmer, G. Genotoxicity of 2-dodecylcyclobutanone. Food Irradiation: Fifth German Conference, Report EFE-R-99-01, Federal Nutrition Research Institute, Karlsruhe, Germany, 1998.

Delincee, H., Soika, C., Horvatovich, P., Rechkemmer, G., Marchioni, E. Genotoxicity of 2-alkylcyclobutanones, 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.

Hecker, E. Cocarcinogenesis and Biological Effects of Tumor Promoters. Raven Press, NY, 1982.

Horvatovich, P., Raul, A.F., Miesch, M., Burnouf, C.D., Delincee, D.H., Hartwig, E.A., Werner, F.D., 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.

Institute of Radiation Medicine. Safety evaluation of 35 kinds of irradiated human foods. Chin. Med. J. 100, 715-718, 2000.

Lang, N.P., Chu, D.Z., Hunter, C.F., Kendall, D.C., Flammang, T.J., Kadlubar, F.F. Role of aromatic amine acetyltransferase in human colorectal cancer. Arch. Surg. 121, 1259-1261, 1986.

Louria, D.B. Zapping the food supply. Bull. Atomic Sci. 46, 34-36, 1990.

Louria, D.B. Food irradiation: unresolved issues. Clin. Infect. Dis. 33, 378-380, 2001.

Langenbach, R., Elmore, E., Barrett, J.C. Tumor Promoters: Biological Approaches for Mechanistic Studies and Assay Systems. Raven Press, NY, 1988.

Maier, P., Wenk-Siefer, I., Schawalder, H.P., Zehnder, H., Schlatters, J. Cell-cycle and ploidy analysis in bone marrow and liver cells of rats after long-term consumption of irradiated wheat. Fd. Chem. Toxic. 31:395-405, 1993.

Miesch, M., Miesch, L., Horvatovich, P., Burnouf, D., Delincee, H., Hartwig, A., Raul, F., Werner, D., Marchioni, E. Efficient reaction pathway for the synthesis of saturated and mono-unsaturated 2-alkylcyclobutanones. Radiat. Phy. Chem. 65, 233-239, 2002.

Moutschen-Dahmen, M., Moutschen, J., Ehrenberg, L. Pre-implantation death of mouse eggs caused by irradiated food. Internat. J. Rad. Biol. 18: 201-216, 1970.

Raul, F., Gosse, F. Delincee, H., Hartwig, A., Marchioni, E., Misech, M., Werner, D., Burnouf, D. Food-borne radiolytic compounds promote experimental carcinogenesis, Nutr. Cancer, in press, 2002.

Schubert, J. Mutagenicity and cytotoxicity of irradiated foods and food components. Bull. World Hlth. Org. 41:873-904,1969.

Slaga, T.J. Mechanisms of Tumor Promotion. CRC Press, Boca Raton, Fla., 1984.

Vijayalaxmi. Cytogenetic studies in rats fed irradiated wheat. Int. J. Radiat. Biol. 7:283-285,1975.

Vijayalaxmi. Genetic effects of feeding irradiated wheat to mice. Canad. J. Genet. Cyto. 18:231-238,1976.

Vijayalaxmi. Cytogenetic studies in monkeys fed irradiated wheat. Toxicology 9:181-184,1978.

Vijayalaxmi and Sadasivan, G. Chromosome aberrations in rats fed irradiated wheat. Int. J. Radiat. Biol. 27:135-142,1975.

Vijayalaxmi and Rao, K.V. Dominant lethal mutations in rats fed on irradiated wheat. Int. J. Radiat. Biol. 29:93-98,1976.

Vineis, P., McMichael, A. Interplay between heterocyclic amines in cooked meat and metabolic phenotype in the etiology of colon cancer. Cancer Causes Control 7, 479-486, 1996.

Yamagata, T., Yamagata, Y., Nishimoto, T., Nakanishi, M., Nakanishi, H., Minakata, Y., Mune, M., Yakawa, S. The impact of phorbol ester on the regulation of amiloride-sensitive epithelial sodium channel in alveolar type II epithelial cells. Exp. Lung Res. 28, 543-562, 2002.

Zheng, X., Ravatn, R., Lin, Y., Shih, W.C., Rabson, A., Strair, R., Huberman, E., Conney A., Chin K.V. Gene expression of TPA induced differentiation in HL-60 cells by DNA microarray analysis. Nucl. Acid Res. 30, 4489-4499, 2002.