

UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION

BEFORE THE SECRETARY

In the Matter of)
Pa'ina Hawaii, LLC) Docket No. 030-36974
)
Materials License Application)
_____)

**DECLARATION OF DR. WILLIAM W. AU
IN SUPPORT OF PETITIONER'S AREAS OF CONCERNS**

I, William W. Au, declare that if called as a witness in this action I could testify of my own personal knowledge as follows:

1. Since 1991, I have been employed as a Professor in the Department of Preventive Medicine and Community Health, University of Texas Medical Branch, in Galveston, Texas. My office 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.

2. My curriculum vitae indicating my professional qualifications as a toxicologist is attached hereto as Exhibit "A." 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.

3. I have been retained by Concerned Citizens of Honolulu as an expert witness in a proceeding before the U.S. Nuclear Regulatory Commission (NRC), regarding an application by Pa‘ina Hawaii, LLC for a license to build and operate a commercial pool type industrial irradiator in Honolulu, Hawai‘i, to treat tropical fruit and other produce grown in Hawai‘i for fruit flies, so that the produce may be exported to the continental United States.

4. The purpose of this declaration is to provide an evidentiary basis for Concerned Citizens’ contention that, due to the significant scientific controversy surrounding the health impacts of consuming the irradiated food that the Pa‘ina Hawaii irradiator would produce, “special circumstances” exist that distinguish this project from more common medical instrument sterilization and other non-food irradiators, precluding the NRC’s use of a categorical exclusion from the National Environmental Policy Act’s mandate to prepare either an environmental assessment or environmental impact statement for the proposed license. 10 C.F.R. § 51.22(b); see also id. § 2.335(b); 40 C.F.R. § 1508.4.

5. In formulating my opinions, I have reviewed relevant documents and studies and conducted independent research. I have also published a paper in an international, peer-reviewed journal on health hazards from the consumption of irradiated food (Ashley et al., 2004).¹

6. My opinions, based on a reasonable degree of scientific certainty, are as follows:

a. The use of radiation to treat produce destined for human consumption for fruit flies and other agricultural pests should be evaluated for health concerns very carefully.

Radiolytic products are formed during the irradiation of food (Schubert, 1969). Some radiolytic

¹ Full citations to the studies cited herein are attached to this declaration as Exhibit “B” and incorporated herein by reference.

products are unique to the food irradiation process, and there are scientific data indicating their potential health hazards. More research is needed on the products that are unique to the irradiation process.

b. 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). Studies have confirmed the presence of 2-ACBs in irradiated mango and papaya, two types of fruit proposed for processing at the Pa‘ina Hawaii facility, should it be approved (Ndiaye et al. 1999; Stewart et al., 2000).

c. 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.

d. The recent findings by Raul et al. (2002) raise a high level of concern. In the study, Wistar rats received a daily solution of 2-tetradecylcyclobutanone or 2-(tetradec-5'-enyl)-cyclobutanone and a known colon carcinogen (azoxymethane [AOM]). Observations were made at two distinct intervals. At three months after initiation of the exposure, no significant changes

in the number of pre-neoplastic colonic lesions were observed among the rats (all were exposed to AOM). At six months, however, the total number and the overall size of tumors were markedly increased in the 2-ACB-AOM treated rats as compared to the ethanol-AOM control rats. This demonstrates that compounds 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 neither the U.S. Food and Drug Administration nor the World Health Organization has yet examined.

e. 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.

f. 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). 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.

g. 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). While the health concerns from consumption of irradiated food simply cannot be considered to have been resolved conclusively (Louria, 2001), the data indicate that consumption of irradiated food can cause genotoxic effects and therefore health hazards in the population. Moreover, there may be subpopulations, such as 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).

h. In the final analysis, the only thing certain about the impacts on human health associated with the consumption of irradiated food, including the papayas, mangos, and other produce proposed to be processed at the Pa‘ina Hawaii facility, is that it is the subject of considerable scientific debate. A recent article I co-authored summarizing the controversy over this issue (Ashley et al., 2004) is attached hereto as Exhibit “C” and incorporated herein by reference.

I declare under penalty of perjury that I have read the foregoing declaration and know the contents thereof to be true of my own knowledge.

Dated at Galveston, Texas, September 29, 2005.

WILLIAM W. AU

EXHIBIT B

References

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