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UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION

OFFICE OF SECRETARY
RULEMAKINGS AND
ADJUDICATIONS STAFF

BEFORE THE COMMISSION

In the Matter of)
Pa'ina Hawaii, LLC) Docket No. 030-36974-ML
)
Materials License Application) ASLBP No. 06-843-01
)

APPLICANT PA'INA HAWAII, LLC'S RESPONSE TO MARCH 27, 2008
MEMORANDUM AND ORDER OF NUCLEAR REGULATORY COMMISSION

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April 10, 2008

TEMPLATE = SECY-021

SECY-DS-03

UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION

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Pa'ina Hawaii, LLC) Docket No. 030-36974
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I. INTRODUCTION

Applicant PA'INA HAWAII, LLC ("Pa'ina") submits herein its Response to the Nuclear Regulatory Commission's March 27, 2008 "Memorandum and Order," CLI-08-04, wherein the NRC requested input from the parties to this case on two issues.

The two issues on which the NRC wishes to learn the views of the parties were stated as follows: (1) whether the NRC lacks authority to reject an irradiator license for non-radiological food safety reasons and therefore need not consider food safety under NEPA; and (2) whether in light of NEPA's "rule of reason," FDA's comprehensive review and regulation of the safety of irradiated foods, including NEPA reviews, excuse NRC from considering food safety in its own NEPA reviews.

The instant litigation has been pending since June 27, 2005, when Pa'ina applied for a materials license to construct a

Category III, pool-type irradiator near (but outside the boundaries of) Honolulu International Airport. (See ML052060372)

In passing, it is significant to note that in its original Petition filed October 3, 2005, Petitioner CONCERNED CITIZENS OF HONOLULU ("Citizens") raised a similar challenge to the irradiator, i.e., the genotoxic effects found in irradiated papayas and mangoes constituted a "special circumstance" requiring NEPA review of the irradiator. (ML052970026) In other words, in 2005 Citizens already argued that the irradiation of food by Pa'ina required (at the least) preparation of an Environmental Assessment ("EA") rather than "categorical exclusion" from NEPA documentation.

However, in its January 24, 2006 Memorandum and Order the Atomic Safety and Licensing Board denied the Citizens' contention with the following words:

"Finally, the Petitioner's contention raises a question concerning the health effects of irradiated fruit, specifically the genotoxic effects of compounds found in irradiated papayas and mangos, as a third category of special circumstances requiring NEPA review. Although the Petitioner [Citizens] acknowledges that fruits and vegetables were generically approved for irradiation by the FDA in 1986, it argues that the Commission did not contemplate the irradiation of any food when it promulgated the categorical exclusion of irradiators and, therefore, the specific environmental impacts of irradiating papayas and mangos must be addressed. As support, the Petitioner relies on the declaration of its expert, Dr. William W. Au, who asserts that compounds created by the irradiation of papaya and mango may present health risks. The Applicant contends that challenges related to irradiated foods are outside the jurisdiction of the NRC and must be addressed by either the

United States Food and Drug Administration (FDA) or the United States Department of Agriculture (USDA). For its part, the Staff argues that the Petitioner has 'failed to explain how irradiation of food differs from any other possible paths of human consumption already considered or to offer any factual basis to support a contention.

Although the Petitioner argues that the irradiation of papayas and mangos causes adverse human health impacts, it presents only speculation, not facts, to support its claim. The Petitioner's own expert states that 'in the final analysis, the only thing certain about the impacts on human health associated with the consumption of irradiated food, including papayas and mangos, and other produce proposed to be processed at the Pa'ina Hawaii facility, is that it is the subject of considerable scientific debate.' Further, in its hearing request, the Commission noted that it is the responsibility of the FDA and the USDA to determine the food types used for human consumption that may be safely irradiated. In light of these factors, the Petitioner's speculative claim concerning the possible health effects of irradiating papayas and mangos does not arise to the level of special circumstances necessary to invoke the exception under 10 C.F.R. Sec. 51.22(b) for the categorical exclusion of irradiators. Accordingly, the portion of the Petitioner's second environmental contention related to the safety of irradiated food is inadmissible." (Emphasis added) See LBP-06-04, 63 NRC 99 (2006)

Thus, Citizens in this administrative proceeding has already raised a contention based upon the alleged effects of irradiation on certain foods, and that contention has already been rejected by the Board.

In this Response, Pa'ina will briefly address both questions raised by the Commission in its March 27th Memorandum and Order.

II. PA'INA BELIEVES THAT THE NRC LACKS AUTHORITY TO REJECT AN IRRADIATOR LICENSE FOR NON-RADIOLOGICAL FOOD SAFETY REASONS, AND THEREFORE NEED NOT CONSIDER FOOD SAFETY UNDER NEPA.

It is Pa'ina's position that the NRC need not consider food safety under the National Environmental Policy Act because for at least four reasons: (1) it is the FDA and USDA which have jurisdiction over food purity, food contamination and it is those agencies which discretionary power to order food seizures or recalls;¹ (2) the NRC has the authority to assure the safe construction and operation of irradiator facilities, but Pa'ina is unaware of any authority granting the NRC the discretion to issue food recalls or to seize irradiated food products;² (3), Pa'ina is not aware that the NRC has the expertise to study the effects of irradiation upon food, as do the FDA and USDA;³ and (4), in any event, both the FDA and the USDA must comply with NEPA in their administrative activities.

¹ Thus, for example, the FDA can enjoin, criminally prosecute and seize food or other contaminated or mislabeled products when warranted. See 21 U.S.C. Sections 332(c), 333, and 334. Other substances, such as animal biologics, are under the jurisdiction of the USDA. See 21 U.S.C. Sec. 151 et seq. Certain types of drugs or other substances come under the jurisdiction of both the FDA and the USDA. United States v. Pro-Ag, Inc., 968 F.2d 681 (9th Cir. 1992)

² The "critical feature" in the Supreme Court's unanimous decision in Dept. of Transportation v. Public Citizen, 541 U.S. 752 (2004) was the fact that, there, the Federal Motor Carrier Safety Administration (FMCSA) had no authority to exclude Mexican motor carriers from operating within the United States. 541 U.S. at 766. By analogy, Pa'ina is unaware of any statutory authority giving the NRC sanctioning authority (such as to impose food seizures or recalls) over food that has been irradiated.

³ Thus, for example, the FDA studied the effects of irradiation upon fresh or frozen molluscan shellfish. 70 Fed. Reg. 48,057-58 (August 16, 2005)

III. UNDER THE PREVAILING "RULE OF REASON," PA'INA BELIEVES THAT THE FDA'S COMPREHENSIVE REVIEW AND REGULATION OF THE SAFETY OF IRRADIATED FOODS, INCLUDING NEPA REVIEWS, EXCUSE THE NRC FROM CONSIDERING FOOD SAFETY IN ITS OWN NEPA REVIEWS.

In Dept. of Transportation v. Public Citizen, 541 U.S. 752 (2004), the Supreme Court emphasized the "rule of reason" which governs an agency's determinations regarding whether, and to what extent, an EIS must be prepared. When the preparation of an EIS would serve "no purpose" in light of NEPA's overall regulatory scheme, then the agency need not prepare an EIS.

Here, it is the FDA and the USDA which have comprehensive regulatory powers over food, food irradiation and deleterious effects of various matters upon food. Individuals and advocacy groups may freely petition the FDA and the USDA for new regulations applicable to food purity, and may otherwise fully participate in those agency proceedings to argue for or against regulation.⁴

Pa'ina is unaware of any FDA or USDA rule-making proceedings in which Citizens participated, or in which Citizens submitted expert testimony, regarding irradiated foods. Pa'ina

⁴ Thus, for example, Citizens' expert, Dr. William Au was permitted to fully participate in the FDA's study of the effects of irradiation upon fat containing food. 70 Fed. Reg. 48,067 (August 16, 2005) In light of the FDA's existing regulatory scheme which permits for full and democratic public participation in the rule-making process, Pa'ina believes that it is unreasonable for Citizens to use this NRC licensing proceeding in its quest to impose what it could not achieve before the FDA.

is aware that Dr. William Au has been a frequent advocate before the FDA or USDA, but Pa'ina is unaware that Dr. Au has ever succeeded in any of his efforts.

Consequently, Pa'ina believes that it is "unreasonable" to impose by fiat in this proceeding, a brand new rule that the NRC suddenly has authority over the effects of irradiation on food. The FDA and USDA already hold and invite public participation in rule-making proceedings involving the effects of irradiation upon food. Citizens' explicit or implied contention that new rules can be arbitrarily imposed by fiat in this NRC licensing proceeding should be rejected.

IV. CONCLUSION.

Pa'ina believes that the NRC does not need to consider food safety under the auspices of NEPA, because both the FDA and the USDA have comprehensive regulatory schemes to review food safety and the effects of irradiation upon food. The FDA and the USDA also have the authority to sanction the sale or transmission of impure or contaminated foods. On the other hand, Pa'ina is unaware that the NRC has any statutory authority (or budget, or regulatory scheme) to unilaterally expand its functions to study food safety. Pa'ina is also unaware of any

statutory authority allowing the NRC to recall or seize irradiated food.

Pa'ina also believes that it would be "unreasonable" to impose upon the NRC (through this licensing proceeding) a new rule requiring the NRC to study food safety as part of NEPA. Pa'ina believes that it would be doubly unreasonable, and would also constitute a grievous waste of time, where Citizens' expert, Dr. William Au, has already raised and argued the same irradiated food safety arguments before the FDA and/or USDA, apparently all to no avail.

DATED: Honolulu, Hawaii

April 10, 2008



FRED PAUL BENCO
Attorney for Applicant
Pa'ina Hawaii, LLC

CERTIFICATE OF SERVICE

I hereby certify that copies of "APPLICANT PA'INA HAWAII, LLC'S RESPONSE TO MARCH 27, 2008 MEMORANDUM AND ORDER OF NUCLEAR REGULATORY COMMISSION" in the captioned proceeding have been served as shown below by deposit in the regular United States mail, first class, postage prepaid, this 10th day of April, 2008. Additional service has also been made this same day by electronic mail as shown below:

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DATED: Honolulu, Hawaii, April 10, 2008


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April 10, 2008

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Re: Docket No. 030-36974-ML
Re: Applicant Pa'ina Hawaii, LLC's
Response To March 27, 2008
Memorandum and Order of Nuclear
Regulatory Commission

Dear Office:

I represent the legal interests of Pa'ina Hawaii, LLC, which has applied for a Materials License.

On March 27, 2008 the Commission by Memorandum and Order invited the parties to brief two issues.

Pursuant to your regulations, please find enclosed an original and two (2) copies of Applicant's Response.

This document was e-mailed to your office and to all parties on the Certificate of Service on this date. Hard copies were also mailed to each of the parties on this date.

If you have any questions or comments, please feel free to contact my office. Tel: 808-523-5083; Fax: 808-523-5085; e-mail: fpbenco@yahoo.com. Thank you.

Very respectfully yours,

/s/ Fred Paul Benco
Fred Paul Benco

Encls.

cc: All parties on Certificate of
Service