RAS-I-12



UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION

BEFORE THE COMMISSION

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| In the Matter of | ) | |
| Pa'ina Hawaii, LLC | ) | Docket No. 30-36974-ML |
| | ) | |
| (Materials License Application) | ) | |
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INTERVENOR CONCERNED CITIZENS OF HONOLULU'S REPLY
RE: NRC'S OBLIGATION TO ANALYZE POTENTIAL HEALTH
IMPACTS OF CONSUMING IRRADIATED FOOD FROM PROPOSED IRRADIATOR

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TEMPLATE=SECY-035

SECY-02

Pursuant to the Commission's order in CLI-08-04, intervenor Concerned Citizens of Honolulu responds to the opening briefs filed by the Nuclear Regulatory Commission ("NRC") Staff and applicant Pa'ina Hawaii, LLC.

## I. THE NRC MAY NOT AVOID COMPLIANCE WITH NEPA BY CONSTRUING ITS AUTHORITY TO REGULATE BYPRODUCT MATERIAL NARROWLY

The Commission should reject the Staff's cramped interpretation of the NRC's statutory authority to regulate the use of byproduct material "as the [NRC] may deem necessary or desirable ... to protect health or to minimize danger to life." 42 U.S.C. § 2201(b). The Staff apparently believes that, if it asserts the Atomic Energy Act ("AEA") "vests the Commission with the authority to regulate only radiological hazards" often enough, repetition will make it so. Staff Brief at 11. The statute's plain language does not, however, contain any such limitation. See United States v. Rodgers, 466 U.S. 475, 484 (1984) (plain language controls unless it leads to results that are "absurd or glaringly unjust"). Rather, the AEA broadly authorizes federal regulation of all aspects of the "utilization of ... byproduct ... material ... in order to ... protect the health and safety of the public." 42 U.S.C. § 2012(d); see also id. § 2201(b).

Section 81 of the AEA does not provide, as the Staff baldly asserts, that "the NRC may deny an application seeking a materials license ... only where the applicant is not equipped to comply with the NRC's radiological safety requirements." Staff Brief at 14 (emphasis added). As a threshold matter, section 81 does not mandate the issuance of a license for use of byproduct material to anyone. By providing that "[t]he Commission is authorized to issue ... licenses," Congress granted the agency discretion to decide whether to issue a license; it did not mandate license issuance. 42 U.S.C. § 2111(a) (emphasis added); see also Matter of Bugge, 99 F.3d 740, 744 & n.4 (5th Cir. 1996) (term "is authorized" provides agency "with an option, but not a duty").

Section 81 does constrain the NRC's discretion to grant materials licenses, listing situations in which the NRC may not "permit the distribution of any byproduct material to any licensee, and shall recall or order the recall of any distributed material ... ." 42 U.S.C. § 2111(a).[1] It does not, however, limit the grounds for denial to only where "the applicant is not equipped to observe the NRC's ... "radiological safety standards," as the Staff claims. Staff Brief at 14. Rather, Section 81 mandates compliance with all "safety standards to protect health as may be established by the Commission," regardless of whether those standards focus on radiological or nonradiological safety. 42 U.S.C. § 2111(a).

Moreover, the inability to comply with safety standards is only one possible basis for triggering automatic denial of a materials license. Section 81 also requires the NRC to deny byproduct material to anyone "who uses such material in violation of ... regulation of the Commission." Id. The statute's use of the disjunctive between the prohibitions on possession of byproduct material by anyone "who is not equipped to observe or who fails to observe [NRC] safety standards" and those "who use[] such material in violation of" NRC regulations makes clear license denial is required even when no safety regulation is involved. See In re Pacific-Atlantic Trading Co., 64 F.3d 1292, 1302 (9th Cir. 1995) ("In construing a statute, a court should interpret subsections written in the disjunctive as setting out separate and distinct alternatives"). The plain language of the statute does not support the Staff's claim the NRC is limited to regulating only the radiological impacts of an irradiator's use of byproduct material.

Nor is such a limitation supported by the AEA's legislative history. The Staff relies primarily on New Hampshire v. Atomic Energy Comm'n, 406 F.2d 170 (1st Cir. 1969), a case

[1] Nothing in Section 81 suggests this is an exhaustive list of the grounds for license denial. Just because the NRC must deny byproduct material licenses under certain circumstances does not prohibit the exercise of discretion to decline to issue licenses for other reasons.

with no precedential value in the Ninth Circuit (where Pa'ina proposes to locate its irradiator) and in which, unlike here, there was no evidence that "human consumers of [food] would be harmed." Id. at 172 n.1. In concluding the AEA's legislative history "reveals that Congress, in thinking of the public's health and safety, had in mind only the special hazards of radioactivity," the New Hampshire court failed to come to terms with Congress's clearly expressed intent to authorize the Atomic Energy Commission ("AEC"), the NRC's predecessor, to establish health and safety regulations for the use of byproduct material "to minimize the danger from explosion, radioactivity, and other harmful or toxic effects, incident to the presence of such materials." Id. at 174 & n.4 (quoting S. Rep. No. 79-1211 (1946), reprinted in 1946 U.S. Code Cong. Service 1327, 1335; emphasis added). If "the special hazards of radioactivity" were, in fact, Congress's exclusive concern, there would have been no reason for Congress to include dangers from "other harmful or toxic effects" among the threats the AEC was authorized to address through health and safety regulations. Id.[2]

Congress's addition of Section 84 to the AEA in 1978 does not support the Staff's argument the NRC lacks authority to regulate the nonradiological hazards of the byproduct material Pa'ina seeks to possess and use. See Staff Brief at 11-12. As its name suggests, the Uranium Mill Tailings Radiation Control Act of 1978 ("UMTRCA") narrowly focused on a specific problem: "to provide for the disposal, stabilization and control in a safe and

[2] Notably, nine years after issuing its decision in New Hampshire, the First Circuit held the AEA authorizes the NRC to consider nonradiological issues in its licensing proceedings. See Public Service Co. of New Hampshire v. Nuclear Regulatory Comm'n, 582 F.2d 77 (1st Cir.), cert. denied, 439 U.S. 1046 (1978). The Sixth Circuit reached the same conclusion in Detroit Edison v. Nuclear Regulatory Comm'n, 630 F.2d 450 (6th Cir. 1980). The Staff inaccurately suggests those decisions assumed NEPA "provide[s] the NRC with the substantive authority to deny a license or impose license conditions." Staff Brief at 8. In fact, neither case reached the question "whether NEPA is an independent source of substantive jurisdiction;" the courts focused instead on the NRC's authority under the AEA. Detroit Edison, 630 F.2d at 452; see also Public Service Co., 582 F.2d at 81 n.7.

environmentally sound manner" of wastes from the uranium ore milling process. H.R. Rep. No. 95-1480 at 13 (1978), reprinted in 1978 U.S.C.C.A.N. 7433, 7435. In UMTRCA, Congress did not address the type of byproduct material Pa'ina seeks, which the AEC and NRC had, by then, been regulating for over three decades (since passage of the Atomic Energy Act of 1946). Thus, the Commission should draw no inferences from the fact Congress saw no need to revisit the scope of the NRC's authority over that byproduct material under Sections 81 and 161 (which had themselves been in effect for over twenty years).[3]

Indeed, even had Congress, in enacting UMTRCA, offered opinions on the NRC's regulatory authority under the AEA's original provisions, "the views of a subsequent Congress form a hazardous basis for inferring the intent of an earlier one." South Dakota v. Yankton Sioux Tribe, 522 U.S. 329, 353 (1998); see also Securities & Exchange Comm'n v. Capital Gains Research Bureau, 375 U.S. 180, 200 (1963) (disregarding "[o]pinions attributed to a Congress twenty years after the event"). The Supreme Court has instructed that "the intent of Congress must be culled from the events surrounding the [original legislation's] passage." Securities & Exchange Comm'n, 375 U.S. at 199. As discussed above, the AEAs' legislative history supports a finding Congress intended to grant the NRC the authority to enact health and safety regulations to address "harmful or toxic effects" unrelated to radioactivity. S. Rep. No. 79-1211, reprinted in 1946 U.S. Code Cong. Service at 1335.

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[3] Prior to UMTRCA's enactment, the NRC had taken steps "to control future uranium milling operations," but lacked clear authority to "remedy existing public health hazards resulting from the unstabilized piles of wastes produced in prior decades." H.R. Rep. No. 95-1480 at 12, reprinted in 1978 U.S.C.C.A.N. at 7434. Congress enacted UMTRCA to provide the NRC with "necessary authority to comprehensively regulate the uranium mill operations and activities." Id. at 13, reprinted in 1978 U.S.C.C.A.N. at 7435. Thus, without altering the NRC's pre-existing authority to regulate the type of byproduct material Pa'ina seeks, UMTRCA easily satisfied "the canon of statutory construction requiring a change in language to be read, if possible, to have some effect." American Nat'l Red Cross v. S.G., 505 U.S. 247, 263 (1992).

While the NRC's regulations governing irradiator licenses do not currently address nonradiological hazards, the relevant inquiry is not whether the NRC has promulgated such regulations, but whether it "has statutory authority" to do so. Center for Biological Diversity ("CBD") v. National Highway Traffic Safety Admin., 508 F.3d 508, 546 (9th Cir. 2007). In answering that question, the Commission must bear in mind NEPA's command to comply "to the fullest extent possible" with the statute's mandate to evaluate the environmental impacts of proposed agency action. 42 U.S.C. § 4332. Congress included this language to ensure agencies would not "attempt to avoid any compliance with NEPA by narrowly construing other statutory directives to create a conflict with NEPA." CBD, 508 F.3d at 546. Given that the AEA is "virtually unique in the degree to which broad responsibility is reposed in the [NRC], free of close prescription in its charter as to how it shall proceed in achieving the statutory objectives," Nuclear Information Resource Serv. v. Nuclear Regulatory Comm'n, 969 F.2d 1169, 1177 (D.C. Cir. 1992) (en banc), Concerned Citizens respectfully submits the NRC has statutory authority to regulate the use of byproduct material to irradiate food for human consumption, should it deem such regulation "necessary or desirable ... to protect health." 42 U.S.C. § 2201(b).[4]

## II. EVEN IF THE NRC COULD REGULATE ONLY RADIOLOGICAL HAZARDS, IT STILL WOULD HAVE TO EVALUATE AND DISCLOSE ALL OF THE IMPACTS OF A DECISION TO LICENSE PA'INA'S IRRADIATOR

To support its claim the NRC lacks statutory authority to regulate nonradiological hazards, the Staff relies substantially on Natural Resources Defense Council ("NRDC") v. Environmental Prot. Agency, 822 F.2d 104 (D.C. Cir. 1987). As that case makes clear, even if

[4] The NRC does not need authority "to issue food recalls or to seize irradiated food products." Pa'ina Brief at 4. It could achieve similar results by prohibiting the use of byproduct material to irradiate food, should it find an unacceptable health threat. See 42 U.S.C. § 2111(a) (licenses authorized for only "useful applications" of byproduct material).

the Commission were to agree with the Staff regarding the limits of the NRC's statutory authority, it would not alter the NRC's obligation under NEPA to evaluate and disclose all impacts that would result from a decision to license Pa'ina's proposed irradiator, including impacts associated with increasing the supply of irradiated food for human consumption. In NRDC, the court emphasized that NEPA "broaden[s] the range of factors that an agency must consider to encompass environmental effects, even those over which the agency has no control." Id. at 129 (emphasis added).

As discussed in Concerned Citizens' opening brief, the Supreme Court's recent decision in Department of Transportation v. Public Citizen, 541 U.S. 752 (2004), confirms the NRC must evaluate "the impact on the environment which results from the incremental impact" of granting Pa'ina a materials license, including impacts the agency could not consider in evaluating Pa'ina's application. Id. at 769 (quoting 40 C.F.R. § 1508.7); see also Concerned Citizens Brief at 10-12. To comply with NEPA's command to take a hard look at the potential impacts of its actions, the NRC may not pick which nonradiological impacts it wants to evaluate, addressing socioeconomic, ecological, and visual impacts (albeit cursorily) while ignoring food safety. See Staff Brief at 15-16.[5] Since licensing Pa'ina's proposed irradiator would increase the amount of irradiated food for human consumption, the NRC was obliged to consider potential health impacts. See Public Citizen, 541 U.S. at 770; see also id. at 761 (Federal Motor Carrier Safety Administration ("FMCSA") evaluated "increase of inspection-related emissions" and noise); City of Davis v. Coleman, 521 F.2d 661, 677 (9th Cir. 1975) ("The argument that the principal object of a federal project does not result from federal action contains its own refutation").

[5] As discussed below, the environmental assessment's ("EA's") citation to U.S. Food and Drug Administration ("FDA"), U.S. Department of Agriculture ("USDA"), and Animal and Plant Health Inspection Service ("APHIS") sources did not satisfy NEPA.

## III. THE "RULE OF REASON" DOES NOT EXCUSE THE NRC'S FAILURE TO EXAMINE THE IMPACT OF INCREASING THE SUPPLY OF IRRADIATED FOOD FOR HUMAN CONSUMPTION

Public Citizen does not support the Staff's claim that "NEPA's rule of reason provides an independent basis" for the Staff's refusal to evaluate the health effects of authorizing Pa'ina to use byproduct material to increase the supply of irradiated food for human consumption. Staff Brief at 1. Rather, Public Citizen stands for the limited proposition that NEPA's "rule of reason" does not "require an agency to prepare a full [environmental impact statement ("EIS")] due to the environmental impact of an action it could not refuse to perform." Public Citizen, 541 U.S. at 769. Where the agency's action itself would have an "incremental impact," the Court affirmed the agency must evaluate that impact, regardless of whether its statutory authority allows it to consider that factor in making its ultimate decision. Id. (quoting 40 C.F.R. § 1508.7).

Thus, in Public Citizen, the Court affirmed that FMCSA was obliged to evaluate "the impact on the environment which results from the incremental impact" of implementing its regulations (such as increases in emissions and noise "from the increase in the number of roadside inspections ... due to the proposed regulations"), even though the Court recognized FMCSA "has no statutory authority to impose or enforce emissions controls or to establish environmental requirements unrelated to motor carrier safety." Id. at 759, 761, 769 (quoting 40 C.F.R. § 1508.7). Likewise, in this case, the NRC was obliged to evaluate the incremental impact of allowing Pa'ina to use byproduct material to increase the supply of irradiated food, an incremental change resulting from a decision to grant Pa'ina's license application.

In its EA, the Staff understood its obligation under NEPA to assess the socioeconomic and ecological effects of authorizing Pa'ina to use byproduct material to increase the amount of food treated with irradiation. Final EA at 8-9 (ML071150121). The Staff assessed these factors

(concluding potential benefits were insignificant) despite the lack of any relevant criteria in the NRC's regulations governing the grant of an irradiator license. It failed, however, to provide a complete picture of the impacts that would result from a decision to grant Pa'ina's license, refusing to evaluate the potential for irradiated food from Pa'ina's irradiator to cause adverse health impacts. To satisfy its duty to take a "hard look" at potential environmental consequences, the Staff was obliged to analyze and disclose these effects as well. Klamath-Siskiyou Wilderness Center v. Bureau of Land Management, 387 F.3d 989, 993 (9th Cir. 2004).

The Staff's and Pa'ina's claim that potential health impacts are too speculative to warrant examination misconstrues both the Licensing Board's orders and NEPA's requirements. As the Board explained in admitting Admitted Environmental Contention 3, its January 24, 2006 holding was limited to a determination "that the 'possible health effects of irradiating papayas and mangos do[] not rise to the level of special circumstances necessary to invoke the exception under 10 C.F.R. § 51.22(b) for the categorical exclusion of irradiators.'" 12/21/07 Board Order (Ruling on Admissibility of Intervenor's Amended Environmental Contentions) at 21 n.75 (quoting LBP-06-04, 63 NRC 99, 114-15 (2006)). Once the Staff stipulated to prepare an EA, the question whether special circumstances existed, triggering NEPA review, became moot. Amended Environmental Contention 3 "raise[d] the completely different legal issue of whether, once having undertaken to prepare the [EA], the Staff must consider the possible health effects of human consumption of irradiated tropical fruits in order to comply with NEPA." Id.

To comply with NEPA, the NRC must consider "the degree to which" health impacts "are likely to be highly controversial," "are highly uncertain," or "involve ... unknown risks." 40 C.F.R. § 1508.27(b)(4), (5). That the health effects of consuming irradiate food are the subject of scientific debate and not yet fully understood militates in favor of preparing an EIS, not

ignoring those impacts altogether. See National Parks & Conservation Ass'n v. Babbitt, 241 F.3d 722, 731-33, 736-37 (9th Cir. 2001). In addition, having received numerous comments on the draft EA expressing concerns about health impacts, the NRC was obliged to respond to them. 40 C.F.R. § 1503.4(a); see also Sierra Nevada Forest Protection Campaign v. Weingardt, 376 F. Supp. 2d 984, 991 (E.D. Cal. 2005) ("an EA, like an EIS, must ... respond to public comments").

Concerned Citizens agrees with the Staff that NEPA allows agencies to rely on environmental analyses prepared by other agencies, as long as those documents are properly incorporated by reference and adequately address the relevant impacts. That is not, however, the case here. None of the three APHIS rules the Final EA cites analyzes the potential health impacts of consuming irradiated food, focusing instead solely on irradiation's efficacy in controlling pests and on economic issues. 71 Fed. Reg. 4,451 (Jan. 27, 2006); 69 Fed. Reg. 7,541 (Feb. 18, 2004); 68 Fed. Reg. 5,796 (Feb. 5, 2003).[6] The Staff's claim "the 2006 rulemaking was based on an EA prepared by the USDA," Staff Brief at 19, is irrelevant, since the Staff's EA did not cite this document, "much less summarize ... the issues and reasoning of the ... study as is required when incorporating such environmental documents." 12/21/07 Board Order at 18-19 (citing 40 C.F.R. § 1508.28); see also 40 C.F.R. §§ 1502.20, 1502.21.[7]

The EA's citation to, and summary of, the FDA's position on human consumption of irradiated food similarly does not satisfy the NRC's obligation to take a hard look at potential health impacts. See Final EA at C-8 to -9, C-17. The document presents only FDA's side of the

[6] The only rule that even mentions food safety concerns asserts they are "[o]utside the [s]cope of APHIS' [a]uthority" and simply defers to FDA. 71 Fed. Reg. at 4,451.

[7] Had the Staff's EA properly tiered to the USDA's EA, it still would not have satisfied the NRC's duty to examine health impacts. The USDA prepared its EA over a decade ago, and, thus, even if the study were otherwise adequate, it does not address the latest studies on potential adverse health effects from consuming irradiated food. Contrast San Francisco Baykeeper v. United States Army Corps of Eng'rs, 219 F. Supp. 2d 1001, 1013 (N.D. Cal. 2002) (other agency's analysis "addressed the same issues that faced the Corps when producing its EA").

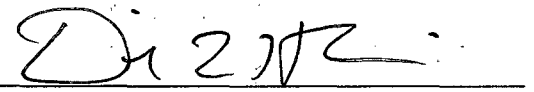
story, stating flatly that irradiation "does [not] cause harmful chemical changes" to food. FDA, "Food Irradiation: A Safe Measure," at http://www.fda.gov/opacom/catalog/irradbro.htlm. The document notes cursorily that "[s]ome special interest groups oppose irradiation," id., but provides no information regarding "the view of others in the scientific community" who question the safety of consuming irradiated food. League of Wilderness Defenders-Blue Mountains Biodiversity Project v. Zielinski, 187 F.Supp.2d 1263, 1270 (D. Or. 2002). The EA's failure to disclose and discuss these "opposing viewpoints" violated NEPA's command to take a "'hard look' at [food safety] issues." League of Wilderness Defenders, 187 F.Supp.2d at 1270; see also 40 C.F.R. § 1502.9(b); see also California v. Block, 690 F.2d 753, 770 (9th Cir. 1982).

## IV. CONCLUSION

For the reasons set forth herein and in its opening brief, Concerned Citizens respectfully submits the Commission should affirm the Board's decision to admit the portion of Amended Environmental Contention 3 that challenges the Final EA's failure to discuss and disclose the possible health effects of human consumption of the food that Pa'ina proposes to irradiate using byproduct material under license from the NRC.

Dated at Honolulu, Hawai'i, April 17, 2008.

Respectfully submitted,



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CERTIFICATE OF SERVICE

The undersigned hereby certifies that, on April 17, 2008, a true and correct copy of the foregoing document was duly served on the following via e-mail and first-class United States mail, postage prepaid:

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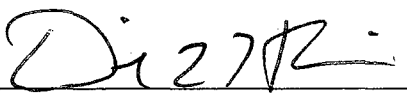

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