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UNITED STATES OF AMERICA  
NUCLEAR REGULATORY COMMISSION

BEFORE THE COMMISSION

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RULEMAKINGS AND  
ADJUDICATIONS STAFF

In the Matter of )  
Pa'ina Hawaii, LLC )  
(Materials License Application) )  
\_\_\_\_\_ )

Docket No. 30-36974-ML

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INTERVENOR CONCERNED CITIZENS OF HONOLULU'S OPENING BRIEF  
RE: NRC'S OBLIGATION TO ANALYZE POTENTIAL HEALTH  
IMPACTS OF CONSUMING IRRADIATED FOOD FROM PROPOSED IRRADIATOR

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I. INTRODUCTION

Pursuant to the Commission's order in CLI-08-04, intervenor Concerned Citizens of Honolulu hereby files its opening brief regarding (1) whether the Nuclear Regulatory Commission ("NRC") lacks authority to reject an irradiator license for non-radiological food safety reasons and therefore need not consider food safety under the National Environmental Policy Act ("NEPA") and (2) whether, in light of NEPA's "rule of reason," the U.S. Food and Drug Administration's ("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. CLI-08-04 at 2-3.

As discussed more fully below, the Atomic Energy Act ("AEA") empowers the NRC to regulate the use of radioactive material as it "may deem necessary or desirable ... to protect health or to minimize danger to life." 42 U.S.C. § 2201(b). Since the NRC has broad statutory authority to regulate the use of byproduct material, the limitation on NEPA announced in Department of Transportation v. Public Citizen, 541 U.S. 752 (2004), "does not apply in this case." Oregon Natural Resources Council ("ONRC") v. Brong, 492 F.3d 1120, 1134 n.20 (9<sup>th</sup>

Cir. 2007); see Part IV.A, infra. Moreover, even if the NRC lacked statutory authority to regulate food irradiation, NEPA would still mandate that it consider and disclose “the impact on the environment which results from the incremental impact” of a decision to license Pa‘ina’s proposed irradiator, including the impact of increasing the supply of irradiated food for human consumption. Public Citizen, 541 U.S. at 769 (quoting 40 C.F.R. § 1508.7); see Part IV.B, infra. The NRC must perform its own “independent assessment” of these impacts; it “cannot rely on another’s examination of environmental effects under NEPA.” The Steamboaters v. Federal Energy Regulatory Comm’n, 759 F.2d 1382, 1393-94 (9<sup>th</sup> Cir. 1985) (quoting Southern Oregon Citizens Against Toxic Sprays v. Clark, 720 F.2d 1475, 1480 (9<sup>th</sup> Cir. 1983), cert. denied, 469 U.S. 1028 (1984)); see Part V, infra.

## II. FACTUAL AND PROCEDURAL BACKGROUND<sup>1</sup>

On June 27, 2005, the NRC received a license application from Pa‘ina Hawaii, LLC, that would authorize the possession and use of sealed radioactive sources in a commercial pool-type industrial irradiator at the Honolulu International Airport. 70 Fed. Reg. 44,396, 44,396 (Aug. 2, 2005); Final Environmental Assessment (“EA”) at 1 (ML071150121). The proposed irradiator “would primarily be used for phytosanitary treatment of fresh fruit and vegetables bound for the mainland from the Hawaiian Islands and similar products being imported to the Hawaiian Islands ... .” Final EA at 1.

On October 3, 2005, Concerned Citizens timely filed a request for hearing on Pa‘ina’s license application (ML052970026). Among other issues, Concerned Citizens challenged the NRC’s failure to explain its application of a categorical exclusion to Pa‘ina’s proposed irradiator

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<sup>1</sup> The facts of this case have been set forth in detail several times. Accordingly, Concerned Citizens will focus here on only those facts most relevant to the questions posed in CLI-08-04.

(Environmental Contention 1) and failure to prepare an EA or environmental impact statement (“EIS”) (Environmental Contention 2). 10/3/05 Hearing Request at 15, 19-25.

On January 24, 2006, the Board granted Concerned Citizens’ request for hearing, finding Concerned Citizens had standing and its two environmental contentions were admissible. LBP-06-04, 63 NRC 99 (2006).

On April 27, 2006, the Board accepted the NRC Staff’s and Concerned Citizens’ joint stipulation settling Environmental Contentions 1 and 2. 4/27/06 Board Order (Confirming Oral Ruling Granting Motion to Dismiss Contentions). The stipulation provided, among other things, that the Staff would prepare an EA for Pa’ina’s proposed irradiator to determine whether to prepare an EIS or a finding of no significant impact (“FONSI”) and that, prior to making any final FONSI for the proposed irradiator, the Staff would put a draft decision out for public review and comment. 3/20/06 Joint Stipulation and Order Regarding Resolution of Concerned Citizens’ Environmental Contentions at ¶¶ 1-2 (ML060820592).

In December 2006, the Staff issued the Draft EA (ML063470231). See 71 Fed. Reg. 78,231 (Dec. 28, 2006). On February 9, 2007, Concerned Citizens timely filed environmental contentions relating to matters discussed in the Draft EA (ML070510116). See 1/10/07 Board Order at 2. Among other things, Concerned Citizens challenged the Draft EA’s failure to discuss potential health impacts associated with human consumption of the irradiated food Pa’ina’s proposed facility would produce. 2/9/07 Contentions at 23-24.

On June 21, 2007, the Board issued an order directing Concerned Citizens to “wait and file any additional new or amended contentions until after the issuance of the Final EA.” 6/21/07 Board Order at 2. On July 18, 2007, the Board issued an order specifying that it would “refrain from ruling on [Concerned Citizens’] currently pending environmental contentions until receipt



of the final [EA] and any amended contentions derived therefrom.” 7/18/07 Board Order (Regarding Environmental Contentions) at 2.

On August 13, 2007, the Staff served its Final EA (ML071150121). See ML072250561. On September 4, 2007, Concerned Citizens timely filed amended contentions relating to matters discussed in the Final EA (ML072530634). In Amended Environmental Contention 3, Concerned Citizens renewed its challenge to the Staff’s refusal to discuss and disclose potential adverse effects on human health associated with consuming irradiated food from Pa’ina’s proposed facility. 9/4/07 Amended Contentions at 29-30; see also 10/1/07 Reply re: Amended Contentions at 38-39 (ML072780350).

On December 21, 2007, the Board ruled on the admissibility of Concerned Citizens’ amended environmental contentions. Among other claims, the Board admitted Concerned Citizens’ contention that the Final EA violated NEPA by failing to consider the health effects of consuming irradiated food from Pa’ina’s proposed facility. 12/21/07 Order (Ruling on Admissibility of Intervenor’s Amended Environmental Contentions) at 20-23.

In CLI-08-04, the Commission decided to take *sua sponte* review of the “threshold legal question” in the Board’s December 21, 2007 order whether “NEPA requires the NRC to consider potential health effects of consuming irradiated food.” CLI-08-04 at 2.

### III. STATUTORY FRAMEWORK

#### A. The National Environmental Policy Act.

NEPA “is our “basic national charter for protection of the environment.” Klamath-Siskiyou Wilderness Center v. Bureau of Land Management, 387 F.3d 989, 993 (9<sup>th</sup> Cir. 2004) (quoting 40 C.F.R. § 1500.1(a)). In enacting NEPA, Congress sought to ensure that all federal agencies – including the NRC – would “assess the environmental consequences of their actions

before those actions are undertaken.” Id. As the Supreme Court explained in Marsh v. Oregon Natural Resources Council, 490 U.S. 360 (1989), “NEPA promotes its sweeping commitment to ‘prevent or eliminate damage to the environment and biosphere’ by focusing Government and public attention on the environmental effects of proposed agency action.” Id. at 371 (quoting 42 U.S.C. § 4321).

“For ‘major Federal actions significantly affecting the quality of the human environment,’ ... the agency is required to prepare an [EIS].” Klamath-Siskiyou Wilderness Center, 387 F.3d at 993 (quoting 42 U.S.C. § 4332(2)(C)).<sup>2</sup> “Where an agency is unsure whether an action is likely to have ‘significant’ environmental effects, it may prepare an EA.” Id. The EA “is a document that ... provides ‘sufficient evidence and analysis for determining whether to prepare an [EIS] or a [FONSI];’ (2) aids an agency’s compliance with NEPA when no EIS is necessary; and (3) facilitates preparation of an EIS when one is necessary.” National Parks & Conservation Ass’n v. Babbitt, 241 F.3d 722, 728 (9th Cir. 2001) (quoting 40 C.F.R. § 1508.9(a)).

Regardless of whether an EA or EIS is prepared, NEPA requires the agency to take “a ‘hard look’ at the potential environmental consequences of the proposed action.” Klamath-Siskiyou Wilderness Center, 387 F.3d at 993; see also Ocean Advocates v. U.S. Army Corps of Engineers, 402 F.3d 846, 864 (9<sup>th</sup> Cir. 2005); Blue Mountains Biodiversity Project v. Blackwood, 161 F.3d 1208, 1212 (9th Cir. 1998) , cert. denied, 527 U.S. 1003 (1999).

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<sup>2</sup> NEPA defines the “human environment” broadly, including “the natural and physical environment and the relationship of people with that environment.” 40 C.F.R. § 1508.14. Effects that must be considered include ecological, aesthetic, historic, cultural, economic, social, and health effects, whether direct, indirect, or cumulative. 40 C.F.R. §§ 1508.8, 1508.25(c).

B. The Atomic Energy Act.

In enacting the Atomic Energy Act, Congress sought to ensure “the development, use, and control of atomic energy shall be directed so as to make the maximum contribution to the general welfare.” 42 U.S.C. § 2011(a). To carry out that overarching policy, Congress recognized that “utilization of source, byproduct, and special nuclear material must be regulated in the national interest and in order ... to protect the health and safety of the public.” Id. § 2012(d); see also id. § 2013(d) (atomic energy use must be “consistent with” public health).

The AEA grants the NRC broad authority to “establish by rule, regulation, or order, such standards and instructions to govern the ... use of special nuclear material, source material, and byproduct material as the Commission may deem necessary or desirable ... to protect health or to minimize danger to life.” 42 U.S.C. § 2201(b). Pursuant to that authority, the NRC has promulgated regulations that generally govern domestic licensing of byproduct material, as well as specific requirements for the issuance of licenses authorizing the use of sealed sources containing radioactive materials in irradiators. 10 C.F.R. pts. 30, 36.

IV. THE NRC HAS BROAD STATUTORY AUTHORITY TO REGULATE THE USE OF RADIOACTIVE MATERIAL TO PROTECT PUBLIC HEALTH AND MUST CONSIDER FOOD SAFETY UNDER NEPA

Citing Public Citizen, the Commission directed the parties to address “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.” CLI-08-04 at 2.<sup>3</sup> The answer to the

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<sup>3</sup> By characterizing the potential adverse health effects of consuming irradiated food as “non-radiological,” Concerned Citizens assumes the Commission means that, following treatment, the irradiated food is not itself radioactive. As explained in the September 29, 2005 declaration of Dr. William Au (which Concerned Citizens filed in support of its amended environmental contentions), the use of radiation to treat food destined for human consumption generates radiolytic products, including compounds that may promote colon cancer and cause

Commission's initial question is twofold. First, under the AEA, the NRC has broad authority to regulate the use of radioactive material "to protect health or to minimize danger to life," and, thus, has statutory authority to determine the extent to which byproduct material should be used to irradiate food for human consumption. 42 U.S.C. § 2201(b). Second, even if the NRC lacked statutory authority to place limitations on the use of byproduct material for food irradiation, it still would be obliged under NEPA to evaluate "the impact on the environment which results from the incremental impact" of granting Pa'ina's application, including the effect of increasing the supply of irradiated food for human consumption. Public Citizen, 541 U.S. at 769 (quoting 40 C.F.R. § 1508.7).

A. The NRC Has Statutory Authority To Regulate The Use Of Byproduct Material To Irradiate Food For Human Consumption.

In Public Citizen, the Supreme Court held that the Federal Motor Carrier Safety Administration ("FMCSA") did not need to consider in its EA the environmental effects of cross-border operations of motor carriers, since the agency had no ability to prevent those operations. 541 U.S. at 770. In that case, Congress had enacted a two-year moratorium prohibiting Mexican motor carriers from obtaining certifications to operate within the United States, and had authorized the President to extend the moratorium, as well as to lift it if he determined that doing so was in the national interest. Id. at 759. The President announced his intention to lift the moratorium in 2001. Id. at 760. Congress then enacted legislation prohibiting the expenditure of certain federal funds to process Mexican motor carrier applications until FMCSA had promulgated rules governing safety-monitoring of Mexican

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genotoxic effects. Since these radiolytic products are the product of the application of radiation, the associated potential health hazards are, in common parlance, "radiological." Merriam Webster's Collegiate Dictionary at 963 (10<sup>th</sup> ed. 1993).

carriers and applications for permission to enter and operate. Id. at 760-61. FMCSA's EA for the proposed rules did not consider "any environmental impact that might be caused by the increased presence of Mexican trucks within the United States" because the entry of Mexican trucks was not an "effect" of its regulations, but rather was caused by the President's decision to lift the moratorium. Id. at 761. The Court upheld the adequacy of FMCSA's EA, reasoning that, "where an agency has no ability to prevent a certain effect due to its limited statutory authority over the relevant actions, the agency cannot be considered a legally relevant 'cause' of the effect." Id. at 770 (emphasis added).

The Ninth Circuit has emphasized that "[t]he 'critical feature' of the case was the fact that 'FMCSA has no ability to countermand the President's lifting of the moratorium or otherwise categorically to exclude Mexican motor carriers from operating within the United States.'" Center for Biological Diversity ("CBD") v. National Highway Traffic Safety Admin., 508 F.3d 508, 546 (9<sup>th</sup> Cir. 2007) (quoting Public Citizen, 541 U.S. at 766). Rather:

FMCSA has only limited discretion regarding motor vehicle carrier registration: It must grant registration to all domestic or foreign motor carriers that are "willing and able to comply with" the applicable safety, fitness, and financial-responsibility requirements. FMCSA has no statutory authority to impose or enforce emissions controls or to establish environmental requirements unrelated to motor carrier safety.

Id. (quoting Public Citizen, 541 U.S. at 758-59; emphasis in CBD); see also 49 U.S.C. § 13902(a)(1).

Unlike FMCSA in Public Citizen, there are no "statutory mandates" that oblige the NRC, in regulating the use of byproduct material, to ignore potential public health effects associated with the consumption of irradiated food. 541 U.S. at 766; see also CBD, 508 F.3d at 546; ONRC, 492 F.3d at 1134 n.20. On the contrary, the AEA empowers the NRC to use its discretion to establish whatever regulations "govern[ing] the ... use of ... byproduct material as

the Commission may deem necessary or desirable ... to protect health or to minimize danger to life.” 42 U.S.C. § 2201(b); see also Indiana Regional Cancer Center, LBP-94-21, 40 N.R.C. 22, 29 (1994) (“the agency’s authority to protect the public health and safety is uniquely wide-ranging”); Oncology Services Corp., LBP-94-2, 39 N.R.C. 11, 21 (1994) (same). Should the NRC, based on the information provided in its NEPA review, determine that restrictions on the use of byproduct material to irradiate food for human consumption – such as limiting the use of byproduct material to irradiate foods like mangos and papayas, which are susceptible to generation of potentially harmful radiolytic products – are desirable from a public health standpoint, it is free under the AEA to impose them. See Au Declaration at ¶ 6 (discussing potential health risks); cf. CBD, 508 F.3d at 546 (National Highway Transportation Safety Administration “could have, in exercising its discretion, set higher [fuel economy] standards if an EIS contained evidence that so warranted”); ONRC, 492 F.3d at 1134 n.20 (Bureau of Land Management “has significant authority (under [Federal Land Policy and Management Act]) to regulate private activities on public land, including Boise Corporation’s use of public roads”).

Unlike FMCSA, which had only “limited statutory authority over the relevant actions,” the NRC has statutory “authority to prevent the effect.” 541 U.S. at 767.<sup>4</sup> Accordingly, “Public Citizen’s limitation on NEPA does not apply in this case.” ONRC, 492 F.3d at 1134 n.20; see also CBD, 508 F.3d at 546.

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<sup>4</sup> That the NRC’s regulations governing the issuance of materials licenses do not include criteria involving the safety of food irradiated using byproduct material does not alter the analysis. See 10 C.F.R. § 30.33(a); id. pt. 36. As the Ninth Circuit recently noted in CBD, “[t]he holding in Public Citizen extends only to those situations where an agency has ‘no ability’ because of lack of ‘statutory authority’ to address the impact.” 508 F.3d at 546 (quoting Sierra Club v. Mainella, 459 F.Supp.2d 76, 105 (D.D.C. 2006)). It does not apply where an agency “is only constrained by its own regulation from considering impacts.” Id. (quoting Sierra Club, 459 F.Supp.2d at 105).

B. Even If The NRC Lacked Statutory Authority To Regulate The Use Of Byproduct Material To Irradiate Food For Human Consumption, It Still Would Have To Comply With NEPA's Command To Take A Hard Look At The Effects Of Granting Pa'ina's Application For An Irradiator License.

Even assuming, for the sake of argument, that the NRC lacked statutory authority to regulate the use of byproduct material based on harm to human health from consuming irradiated food, it still would have to comply with NEPA's command to evaluate all impacts "caused by the action" of granting Pa'ina's irradiator license. 40 C.F.R. § 1508.8. Notably, in Public Citizen, FMCSA did not limit its NEPA review to only impacts related to the "safety, fitness, and financial-responsibility requirements" relevant to implementation of its "statutory mandates." 541 U.S. at 758-59. Rather, it considered the full range of environmental effects that were "likely to arise" from implementing its regulations, such as the "increase in emissions" and "noise from the trucks" during "roadside inspections of Mexican trucks and buses due to the proposed regulations," as well as "socioeconomic factors, and environmental justice." Id. at 761.

The Supreme Court never suggested FMCSA could ignore the air quality or noise impacts associated with implementing its proposed regulations, even though the agency "has no statutory authority to impose or enforce emissions controls or to establish environmental requirements unrelated to motor carrier safety." Id. at 759. Nor is there any suggestion in Public Citizen that NEPA did not require FMCSA to consider socioeconomic or environmental justice impacts, which likewise could not justify a decision to grant or deny motor carrier registration. See 40 C.F.R. § 1508.8 (NEPA requires consideration of effects that include "ecological ..., aesthetic, historic, cultural, economic, social, or health"); Public Citizen, 541 U.S. at 766 (discussing mandate of 49 U.S.C. § 13902(a)(1)).

The limited question in Public Citizen was whether "the increase in cross-border operations of Mexican motor carriers ... is an 'effect' of FMCSA's issuance" of its regulations.

541 U.S. at 764. The Supreme Court decided it was not, since the increase in Mexican motor carriers was due to “the lifting of the moratorium” by the President, which “FMCSA has no ability to countermand.” Id. at 766. In contrast, for changes in the status quo that were “due to the issuance of the regulations,” rather than “the result of the modification of the moratorium by the President,” the Court acknowledged FMCSA’s obligation under NEPA to consider all impacts, not just those related to the factors the agency could, under its governing statute, take into account in deciding whether to grant motor vehicle carrier registration. Id. at 761 (internal quotation omitted).

Thus, the Court held that NEPA “required FMCSA to consider the ‘incremental impact’ of the safety rules themselves, in the context of the President’s lifting of the moratorium and other relevant circumstances.” Id. at 769-770. As noted above, the impacts FMCSA considered included “air quality, noise, socioeconomic factors, and environmental justice,” id. at 761, none of which could influence implementation of its statutory mandate to register any motor carrier “‘willing and able to comply with’ the applicable safety, fitness, and financial-responsibility requirements.” Id. at 759 (quoting 49 U.S.C. § 13902(a)(1)). Far from holding that NEPA obliges agencies to consider only those impacts that are within their jurisdictions, the Court affirmed that “FMCSA appropriately and reasonably examined the incremental impact of its safety rules assuming the President’s modification of the moratorium.” 541 U.S. at 770.

In this case, granting Pa’ina’s request to use byproduct material to irradiate food – the proposed irradiator’s primary purpose – would increase the supply of irradiated food for human consumption. In the same way the Final EA considered the socioeconomic effects of providing food producers with “potentially cheaper treatment alternatives” and “impacts to ecology in regard to controlling invasive species” (neither of which has anything to do with the regulatory



criteria for granting an irradiator license), the NRC was obliged to consider the health effects of increased consumption of the irradiated food that would be produced by Pa'ina's facility. Final EA at 8; see also 10 C.F.R. pts. 30, 36. These health effects are part of "the incremental impact" of the NRC's licensing decision, which Public Citizen affirmed agencies must include in their NEPA analyses. Public Citizen, 541 U.S. at 769 (quoting 40 C.F.R. § 1508.7); cf. Ocean Advocates, 402 F.3d at 868 ("reasonably close causal relationship" between permit issuance and environmental effect of increased vessel traffic triggers "duty to explore this relationship" in NEPA document) (quoting Public Citizen, 541 U.S. at 767).<sup>5</sup>

V. THE FDA'S REGULATION OF FOOD SAFETY DOES NOT EXCUSE THE NRC FROM EVALUATING THE INCREMENTAL IMPACTS ASSOCIATED WITH PA'INA'S PROPOSAL TO INCREASE THE SUPPLY OF IRRADIATED FOOD

In CLI-08-04, the Commission also asked the parties to address "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." CLI-08-04 at 2-3. The Commission's question is readily answered by well-established legal precedent that "[o]ne agency cannot rely on another's examination of environmental effects under NEPA." Southern Oregon Citizens Against Toxic Sprays, 720 F.2d

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<sup>5</sup> NEPA requires agencies to include within the scope of their analyses the "indirect" impacts of their actions. 40 C.F.R. § 1508.25(c). Such impacts "are caused by the action and are later in time or farther removed in distance, but are still reasonably foreseeable." Id. § 1508.8(b); see also id. § 1508.8 (requirement to evaluate impacts includes indirect health effects).

In addition, there can be no serious dispute that Pa'ina's irradiator "would not be built but for the contemplated" sale of irradiated food for human consumption. Thomas v. Peterson, 753 F.2d 754, 758 (9<sup>th</sup> Cir. 1985); see also 71 Fed. Reg. at 78,231 ("The irradiator would primarily be used for phytosanitary treatment of fresh fruit and vegetables bound for the mainland from the Hawaiian Islands and similar products being imported to the Hawaiian Islands"). Since the irradiator and the contemplated sale of irradiated food "are inextricably intertwined," they "are 'connected actions' within the meaning of the CEQ regulations," requiring the Final EA to analyze potential health impacts. Thomas, 753 F.2d at 759; see also 40 C.F.R. § 1508.25(a)(1).

at 1480 (quoting Oregon Environmental Council v. Kunzman, 714 F.2d 901, 905 (9<sup>th</sup> Cir. 1983)); see also id. (“the mere fact that a program involves use of substances” approved by another agency “does not exempt the program from the requirements of NEPA”); The Steamboaters, 759 F.2d at 1393; Calvert Cliffs’ Coord. Comm. v. Atomic Energy Comm’n, 449 F.2d 1109, 1123 (D.C. Cir. 1971).<sup>6</sup> To comply with NEPA’s command to take a hard look at potential impacts, the NRC “must independently assess the consequences” of granting Pa’ina’s license request, including evaluating potential health impacts associated with the increased supply of irradiated food the facility would produce. The Steamboaters, 759 F.2d at 1394; see also Northwest Coalition for Alternatives to Pesticides v. Lyng, 844 F.2d 588, 596 (9<sup>th</sup> Cir. 1988); Southern Oregon Citizens Against Toxic Sprays, 720 F.2d at 1480.

This does not mean the NRC must reinvent the wheel to analyze potential health impacts from consuming irradiated food. Since the FDA “has jurisdiction by law [and] special expertise with respect to” food safety, NEPA mandates that the NRC consult FDA and “obtain [its] comments.” 42 U.S.C. § 4332(2)(C); see also 40 C.F.R. §§ 1503.1(a)(1), 1503.2. Moreover, the NRC is free to incorporate by reference any NEPA reviews or other studies the FDA has prepared regarding the health effects of consuming the types of food Pa’ina proposes to irradiate, as long as the FDA documents are “reasonably available for inspection by potentially interested

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<sup>6</sup> North Carolina v. City of Virginia Beach, 951 F.2d 596 (4<sup>th</sup> Cir. 1991), which the Commission cited in footnote 9 to CLI-08-04, is not to the contrary. In that case, the Fourth Circuit emphasized that “[t]his is not a case in which we are asked to permit construction on property under FERC jurisdiction without a NEPA review.” 951 F.2d at 605; see also id. (enjoining construction “of those portions of the pipeline that will fall within [agency’s] jurisdiction” until NEPA review completed). Here, in contrast, Concerned Citizens challenges the NRC’s grant of a materials license – an action under the NRC’s sole jurisdiction – in the absence of adequate NEPA review.

persons within the time allowed for comment.” 40 C.F.R. § 1502.21.<sup>7</sup> The key to NEPA compliance is whether the EA reflects the NRC’s “independent assessment” of potential health impacts. The Steamboaters, 759 F.2d at 1394.<sup>8</sup>

In reviewing a NEPA document’s adequacy, the Ninth Circuit “employs a ‘rule of reason’ that asks whether [it] contains a ‘reasonably thorough discussion of the significant aspects of the probable environmental consequences.’” Seattle Audubon Soc’y v. Espy, 998 F.2d 699, 703 (9<sup>th</sup> Cir. 1993) (quoting Idaho Conservation League v. Mumma, 956 F.2d 1508, 1519 (9<sup>th</sup> Cir. 1992)); see also Klamath-Siskiyou Wilderness Center, 387 F.3d at 993. Here, the NRC Staff failed to include in its EA any evaluation of the potential health effects associated with Pa’ina’s proposal to increase the supply of irradiated food for human consumption. The complete omission of any discussion of these impacts falls far short of the “‘hard look’ at the potential environmental consequences of the proposed action” necessary to satisfy NEPA’s “rule of reason.” Klamath-Siskiyou Wilderness Center, 387 F.3d at 993.

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<sup>7</sup> While the NRC can incorporate by reference the FDA’s past NEPA reviews, the NRC still bears the responsibility to ensure the adequacy of the analysis. Notably, the FDA’s EA for irradiation of fresh fruits and vegetables was prepared over twenty years ago and, thus, did not evaluate recent studies raising concerns about the safety of consuming irradiated foods. See 49 Fed. Reg. 5,714, 5,721 (Feb. 14, 1984); see also 40 C.F.R. § 1500.1(b) (public scrutiny “essential to implementing NEPA”).

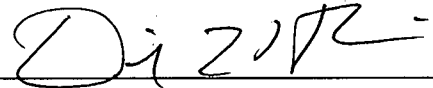
<sup>8</sup> Among other things, the NRC’s NEPA analysis must disclose and address any expert views that disagree with the FDA’s assessment of the safety of consuming irradiated foods. See 40 C.F.R. § 1502.9(a); California v. Block, 690 F.2d 753, 771 (9<sup>th</sup> Cir. 1982) (noting “the paramount Congressional desire to internalize opposing viewpoints into the decision-making process to ensure that an agency is cognizant of all the environmental trade-offs that are implicit in a decision”). The Federal Register notices the Commission cited in CLI-08-04 reveal substantial scientific controversy over potential health impacts. See, e.g., 70 Fed. Reg. 48,057, 48,062-71 (Aug. 16, 2005). Even if the NRC ultimately agrees with the FDA’s conclusions, it still must address opposing views in its NEPA analysis. See Earth Island Inst. v. U.S. Forest Service, 442 F.3d 1147, 1160 (9<sup>th</sup> Cir. 2006) (“Agencies have wide discretion in assessing scientific evidence, but they must ‘take a hard look at the issues and respond[ ] to reasonable opposing viewpoints’”); Center for Biological Diversity v. U.S. Forest Service, 349 F.3d 1157, 1167 (9<sup>th</sup> Cir. 2003) (agency’s “failure to disclose and analyze these opposing viewpoints violates NEPA”).

VI. CONCLUSION

For the foregoing reasons, Concerned Citizens respectfully submits that the Board properly admitted the portion of Amended Environmental Contention 3 that challenges the Final EA's omission of any discussion of the potential health effects of consuming irradiated food from Pa'ina's proposed facility.

Dated at Honolulu, Hawai'i, April 10, 2008.

Respectfully submitted,



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CERTIFICATE OF SERVICE

The undersigned hereby certifies that, on April 10, 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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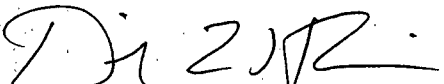
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