UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION

COMMISSIONERS:

Dale E. Klein, Chairman
Gregory B. Jaczko
Peter B. Lyons
Kristine L. Svinicki

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SERVED 8/13/08

In the Matter of	
PA'INA HAWAII, LLC (Materials License Application)	Docket No. 30-36974-ML

CLI-08-16

MEMORANDUM AND ORDER

I. INTRODUCTION

This proceeding stems from an application for an underwater irradiator to be located in Honolulu, Hawaii. The Pa'ina Hawaii irradiator is intended, among other purposes, for the phytosanitary treatment of fresh fruits and vegetables.[1] While the NRC has implemented a categorical exclusion for irradiators,[2] and therefore typically does not prepare an environmental analysis of irradiator facilities, the NRC Staff agreed to prepare an Environmental Assessment

[1] *See Final Environmental Assessment Related to the Proposed Pa'ina Hawaii, LLC Underwater Irradiator in Honolulu, Hawaii* (August 2007)(ADAMS ML071150121)(Final EA) at 1, 6-7. Other intended purposes include sterilization of cosmetics, pharmaceutical products, and fruit fly pupae, and as a research tool for the benefit of Hawaii agriculture.

[2] *See* 10 C.F.R. § 51.22(c)(14)(vii).

EA) of the Pa'ina irradiator as part of a settlement agreement with intervenor Concerned Citizens of Honolulu (Concerned Citizens).[3]

Following issuance of the NRC's EA, Concerned Citizens submitted a contention claiming that the EA failed to analyze the potential health effects of consuming irradiated foods. The Atomic Safety and Licensing Board admitted this contention, among others.[4] In CLI-08-04, the Commission noted that "[w]hether NEPA requires the NRC to consider potential health effects of consuming irradiated food raises the 'kind of broad legal question' appropriate for Commission interlocutory review."[5] Because Concerned Citizens' claim raised "a threshold legal question going to the proper scope of this proceeding, and . . . a matter with potential new significant NEPA implications for the NRC," the Commission found it appropriate to take *sua sponte* review of this legal question, and we requested briefs from the parties.[6]

For the reasons outlined below, the Commission concludes that it was sufficient for the NRC to credit the food safety determinations of the Food and Drug Administration (FDA), the expert agency tasked by Congress to evaluate whether and under what conditions irradiated foods are safe to consume. In its rulemakings governing whether specific uses of food irradiation are safe, the FDA has considered and continues to consider the precise health concern the intervenors raise – whether consumption of irradiated food may lead to an increased risk of cancer or other health harm. Concerned Citizens' contention provides insufficient basis for the NRC to undertake its own analysis or otherwise second guess the FDA's regulations and their underlying safety determinations on what is, at bottom, a non-

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[3] *NRC Staff and Concerned Citizens of Honolulu Joint Motion to Dismiss Environmental Contentions* (Mar. 20, 2006)(ADAMS ML060820592).

[4] Memorandum and Order (Ruling on Admissibility of Intervenor's Amended Environmental Contentions)(Dec. 21, 2007)(unpublished).

[5] CLI-08-4, 67 NRC 171, 172 (2008), quoting *Louisiana Energy Services, L.P.* (National Enrichment Facility), CLI-05-21, 62 NRC 538, 540 (2005).

[6] *Id.*

environmental food processing and consumer food safety issue, squarely within the FDA's long-held expertise on food toxicity and its statutorily-assigned responsibility to evaluate and regulate irradiated food safety.

Before turning to the parties' arguments, we provide below a brief background on the FDA's role in evaluating and authorizing specific uses of food irradiation.

II. BACKGROUND

Under the 1958 Food Additives Amendment to the Federal Food, Drug, and Cosmetic Act, Congress placed the process of food irradiation under the definition of "food additives," and thereby entrusted the FDA with the responsibility to determine whether specific uses of food irradiation are safe. The Act's definition of "food additive" encompasses any substance that reasonably may be expected to affect the characteristics of food, including any source of radiation intended to affect food characteristics.[7] Congress made clear that "[s]ources of irradiation (including radioactive isotopes, particular accelerators and X-ray machines) intended for use in processing food are included in the term 'food additives.'"[8]

More importantly, the Food Additives Amendment established a regulatory scheme whereby any food that has been "intentionally subjected to irradiation" is considered "adulterated" and "unsafe," and therefore cannot be marketed legally, unless the FDA Secretary has issued a regulation finding the specific use of the food irradiation safe, and prescribing the conditions under which the irradiation source – the "food additive" – may be safely used.[9] In

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[7] *See* Section 201(s) of Federal Food, Drug, and Cosmetics Act, 21 U.S.C. § 321(s).

[8] *See* Final Rule, Irradiation in the Production, Processing, and Handling of Food, 51 Fed. Reg. 13,376 (Apr. 18, 1986)(quoting S.Rept. 2422, 85th Cong., 2d Sess. 63 (1958))(Final Rule, Fresh Foods).

[9] *See* Federal Food, Drug, and Cosmetics Act, §§ 402(a)(7) (21 U.S.C. § 342 (a)(7)); 409(a)(2) (21 U.S.C. § 348(a)(2)).

short, the Food Additives Amendment creates a "presumption that a food additive is 'unsafe'" until demonstrated otherwise.[10]

Notably, for the FDA to determine that a food additive is safe, it must find, after a "fair evaluation of the data,"[11] that that "there is a *reasonable certainty* in the minds of competent scientists" that the substance is not harmful under all "intended conditions of use."[12] Factors the FDA must consider include (1) the probable consumption of the additive and of any substance formed in or on food because of its use; and (2) the cumulative effect of the additive in the diet, taking into account any chemically or pharmacologically related substance or substances in the diet.[13] A decision on the safety of a food additive must "give due weight to the anticipated levels and patterns of consumption of the additive."[14] Moreover, "no additive shall be deemed to be safe if it is found to induce cancer when ingested by man or animal, or if it is found, after tests which are appropriate for the evaluation of the safety of food additives, to induce cancer in man or animal."[15]

If the FDA determines that a food additive is safe under prescribed uses, "the regulation [authorizing use] is granted *generically*; anyone [e.g., any licensed irradiator facility] can use the additive in conformance with the specified conditions of use permitted under the regulation."[16]

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[10] *Public Citizen v. Foreman*, 631 F.2d 969, 972 (D.C. Cir. 1980); *see also U.S. v. 29 Cartons of *** An Article of Food, Etc.,* 987 F.2d 33, 35 (1st Cir. 1993).

[11] *See* Section 409(c)(3)(A), Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 348(c)(3)(A).

[12] *See* 21 C.F.R. § 170.3(i)(emphasis added).

[13] *See* Section 409(c)(5), Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 348(c)(5); *see also* 21 C.F.R. § 570.3(i).

[14] 21 C.F.R. § 570.20(a).

[15] Section 409(c)(3)(A) of Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 348(c)(3)(A).

[16] *See* "Irradiation of Food and Packaging: An Overview" (Kim Morehouse and Vanee Komolprasant), U.S. Food and Drug Administration, Office of Food Additive Safety, Center for Food Safety and Applied Nutrition, at 4 (emphasis added), *available at* http://www.fda.gov (posted April 2007).

The FDA can revoke a food additive regulation if it changes its conclusions on the safety of the additive, and members of the public can petition the FDA to revoke a regulation authorizing a particular food additive.[17]

We turn now to the arguments on the EA for the Pa'ina irradiator facility.

III. ANALYSIS

At issue is Concerned Citizens' claim that the NRC's EA improperly fails to discuss potential health impacts associated with irradiating food for human consumption.[18] The contention focuses upon potential harm from so-called "radiolytic products," chemical by-products formed in irradiated foods. In particular, the contention calls attention to "[a] recently discovered unique class of radiolytic products that are generated from the irradiation of fat-containing food," referred to in abbreviated form as "2-ACB."[19] The contention explains that since 1998, concerns over irradiated foods have "focused on the toxicity of 2-ACB."[20] Concerned Citizens further claims that "[r]ecent studies have demonstrated that 2-ACB compounds, which are found exclusively in irradiated dietary fats, may promote colon carcinogenesis in animals," and that "[t]hese studies indicate that consumption of irradiated food containing 2-ACB, such as the fruit Pa'ina proposes to process, may increase the risk of

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[17] *See* 21 C.F.R. § 10.30 (Citizen Petition).

[18] *See Intervenor Concerned Citizens of Honolulu's Amended Environmental Contentions #3 Through #5* (Sept. 4, 2007) at 29-30 (Amended Contentions)(ADAMS ML072530634).

[19] Amended Contentions at 29.

[20] *Id.*

humans developing colon cancer."[21] The contention states that this is a "new area of toxicity" that neither the FDA nor the World Health Organization "has yet examined."[22]

The NRC Staff did not conduct its own analysis to determine whether there are potential health impacts from consuming irradiated foods. Instead, in responding to public comments, the Final EA notes that irradiation does not make food radioactive, and that the FDA has the role of determining the safety of food irradiation and has authorized irradiation of several particular foods (including fresh fruits and vegetables) after "determin[ing] that this process is safe" for the approved items. [23] It also notes that current "federal rules require irradiated foods to be labeled as such."[24] The Final EA further states that it does not provide a more detailed response to comments on food irradiation because this issue does not "relate to the environmental effects" of the irradiator licensing, and therefore falls outside the scope of the NEPA review.[25]

The Final EA appropriately credits the food safety determinations of the FDA, the federal agency with expertise in food toxicity and overall responsibility in evaluating irradiated food safety.[26] This is particularly the case given that the FDA's review by law must encompass the same health concerns that the intervenor raises, including potential cumulative dietary impacts from consuming irradiated foods and potential for cancer risk. As the Staff explains, the "FDA

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[21] *Id.* at 29-30.

[22] *Id.* at 29.

[23] *See* Final EA at C-8, C-9; *see also id.* at C-19.

[24] *Id*. at C-9.

[25] *Id.* at C-3.

[26] The United States Department of Agriculture's (USDA) Animal and Plant Health Inspection Service (APHIS) approves methods for treatment of imported fruits and vegetables (including those moved interstate from Hawaii to the continental United States), to assure that harmful plant pests will not spread to the continental United States. APHIS-approved treatment methods for imported produce may include irradiation. In approving irradiation treatment methods, APHIS relies upon FDA determinations "that approved radiation doses do not render foods unsafe to eat." *See*, *e.g.*, Final Rule, Treatments for Fruits and Vegetables, 71 Fed. Reg. 4451 (Jan. 27, 2006).

and USDA have regulations specifically addressing the issues raised by the Intervenor here," and "[t]he rulemaking of the FDA . . . fully encompasses all the hazards alleged by the Intervenor."[27] Assuring that irradiated foods are safe to consume is the raison d'être of the FDA's rulemaking review for specific new uses of food irradiation. Both when it first authorized irradiation of fresh fruits, and in more recent food irradiation rulemakings, the FDA publicly considered the issue of potential harm from radiolytic products that may form in food, and it has made clear its conclusion that it is safe to consume foods that have been approved for irradiation at established dose limits.[28]

Here, the FDA has determined generically by regulation that ionizing radiation to treat fresh fruits is safe if the radiation dose does not exceed 1 kGy (100 krad).[29] By license condition, the Pa'ina facility must conform to FDA regulations.[30] Further, the FDA's regulation authorizing irradiation of fresh fruits represents the agency's determination that there is a "reasonable certainty" among scientists that fruit irradiated at the established dose limit is safe

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[27] *NRC Staff's Initial Brief in Response to CLI-08-04* (April 10, 2008)(Staff Initial Brief) at 17. Unlike some other kinds of agency permits or authorizations, the FDA's review does not take into account commercial interests, or whether "such approval will be beneficial to the producer of the additive," but is squarely focused upon assuring that that there is "proof of a reasonable certainty that no harm will result" from a proposed use of an additive. *See, e.g.,* Final Rule, Fresh Foods, 51 Fed. Reg. at 13,382 (quoting S.Rept. 2422, 85th Cong., 2d Sess. 6 (1958)).

[28] *See* Final Rule, Fresh Foods, 51 Fed. Reg. 13,376, 13,378-80, 13,382-87; *see also generally* Final Rule, Irradiation in the Production, Processing, and Handling of Food, 70 Fed. Reg. 48,057, 48,065-68 (Aug. 16, 2005)(Final Rule, Molluscan Shellfish); "U.S. Regulatory Requirements for Irradiating Foods" at 4, *available at* http://www.fda.gov.

[29] *See* 21 C.F.R. § 179.26; *see also* Final Rule, Fresh Foods, 51 Fed. Reg. 13,376. Specifically, the FDA has approved irradiation of fresh fruits at doses up to 1 kGy for insect disinfestation and for inhibiting growth and maturation. Currently pending before the FDA is a petition to allow for many new uses of food irradiation, including irradiation of both raw and pre-processed fruits at doses up to 4.5 kGy, for control of food-borne pathogens. *See, e.g.*, Notice, Food Irradiation Coalition c/o National Food Processors Assoc.; Filing of Food Additive Petition, 65 Fed. Reg. 493 (January 5, 2000); Food and Color Additive Petitions (posted August 2008), Food and Drug Administration, *available at* http://www.fda.gov, noting pending Food Additive Petition (FAP) 9M4697 (original docket no. 99F-5522).

[30] Pa'ina Hawaii, LLC Materials License, No. 53-29296-01, at 3.

to consume.[31] "[C]onformity of [a] proposed action to federal regulations governing other aspects of that action's interrelationship with the environment" will "buttress[]" a finding of no significant impact.[32]

Further, as the Staff claims, Concerned Citizens' contention provides insufficient basis for questioning the FDA's ongoing approval of the use of irradiation for use on irradiated fruits and vegetables.[33] The contention rests largely on the notion that the FDA has not "yet examined" the potential for 2-ACB compounds to promote colon cancer, when in fact the FDA has done so, a point the Commission earlier noted when it invited briefs from the parties.[34]

Even if Concerned Citizens' contention presented a compelling reason to question the FDA's safety findings, NEPA would not require the NRC to assess the safety of consuming

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[31] As the Staff emphasizes, only those indirect effects that can be said to be "reasonably foreseeable" need be analyzed under NEPA. *See* Staff Initial Brief at 6 n.25 (citing 40 C.F.R. § 1508.8(b)). Given the nature of the findings the FDA must make before it can issue a regulation generically authorizing a particular use of food irradiation, it was reasonable for the Staff to assume no "reasonably foreseeable" significant impacts from consumption of irradiated fruits and vegetables.

[32] *Glass Packaging Inst. v. Regan,* 737 F.2d 1083, 1092 (D.C. Cir.), *cert. denied*, 469 U.S. 1035 (1984); *see generally Public Citizen v. Traffic Safety Admin.*, 848 F.2d 256, 268 (D.C. Cir. 1988)(agency could presume that increases in emissions that still fell within Clean Air Act limits would be insignificant); *Okanogan Highlands Alliance v. Williams*, 1999 WL 1029106, at *4-*5 (D. Or. Jan. 12, 1999)(in assessing impacts agency may rely on other specialized agencies with jurisdiction to enforce related permits and measures), *aff'd on other grounds,* 236 F.3d 468 (9th Cir. 2000).

[33] Staff's Initial Brief at 19.

[34] CLI-08-4, 67 NRC at 173 n.9. Indeed, as the licensee points out, Concerned Citizens' food expert, Dr. William Au, participated in a 2005 food irradiation rulemaking where he had the opportunity to present his concerns on potential harm from 2-ACBs in irradiated foods. *See Applicant Pa'ina Hawaii, LLC's Response to March 27, 2008 Memorandum and Order of NRC* (April 10, 2008) at 5 n.4. In that public rulemaking, the FDA considered but found "incorrect" Dr. Au's claims that radiolytic products have been insufficiently studied, and considered but found unpersuasive a 2003 study by Raul et. al – highlighted by the intervenors – on the potential for 2-ACBs to promote colon cancer. *See* Final Rule, Molluscan Shellfish, 70 Fed. Reg. 48,057, 48,066-68 (finding no reason to "alter the agency's conclusion that the consumption of irradiated fat-containing foods does not present *any* health hazard")(emphasis added).

irradiated foods. As the Final EA correctly points out, this food safety matter is not related to environmental effects of the irradiator, and is therefore not a NEPA issue.

Concerned Citizens argues that the EA must analyze potential health effects associated with Pa'ina's proposal to "increase the supply of irradiated food for human consumption."[35] But NEPA does not require an agency to assess "*every* impact or effect of its proposed action," only effects on the environment.[36] To be encompassed by NEPA, there needs to be a "reasonably close causal relationship between a *change in the physical environment* and the effect at issue."[37] Increasing the supply of irradiated food for human consumption is no more an environmental effect than increasing the supply of any other processed food that may pose a potential health risk, but one not *causally* related to an actual change in the physical environment. Any number of food processing actions can change food characteristics by inducing chemical or other reactions in food, but that does not make the impact an environmental effect that must be studied under NEPA. NEPA encompasses effects on health only when they are linked to a "change in the environment."[38] Otherwise, "the words 'adverse environmental effects' might embrace virtually any consequence" of a proposed federal action "that some one thought 'adverse.'"[39]

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[35] *Intervenor Concerned Citizens of Honolulu's Opening Brief Re: NRC's Obligation to Analyze Potential Health Impacts of Consuming Irradiated Food From Proposed Irradiator* (April 10, 2008)(Intervenor's Brief) at 11,14; *see also id.* at 12-13; *Intervenor Concerned Citizens of Honolulu's Reply Re: NRC's Obligation to Analyze Potential Health Impacts of Consuming Irradiated Food From Proposed Irradiator* (Apr. 17, 2008)(Intervenor's Reply) at 6-7.

[36] *Glass Packaging,* 737 F.2d at 1091 (quoting *Metropolitan Edison Co. v. People Against Nuclear Energy,* 460 U.S. 766, 772 (1983)(emphasis in original)).

[37] *Metropolitan Edison*, 460 U.S. at 774 (emphasis added); *see also Ranchers Cattlemen Action Legal Fund United Stockgrowers of America v. U.S. Dep't of Agriculture*, 415 F.3d 1078, 1103-04 (9th Cir. 2005); *Glass Packaging*, 737 F.2d at 1091.

[38] *Metropolitan Edison,* 460 U.S. at 771-72; *accord Ranchers Cattlemen*, 415 F.3d at 1103.

[39] *Glass Packaging,* 737 F.2d at 1091 (quoting *Metropolitan Edison*, 460 U.S. at 772).

"[A]lthough NEPA states its goals in sweeping terms of human health and welfare, these goals are *ends* that Congress has chosen to pursue by *means* of protecting the physical environment."[40] That is why a potential harm that is "solely a matter of human health," and not also closely connected to an "injury to the physical environment" is not a harm encompassed by NEPA.[41] Unlike, for example, the spraying of pesticides, which affects soil, air, water, in this case fruits that already have been removed from where they are grown – including potentially, fruits arriving from the mainland United States, thousands of miles away – would be brought inside a building and processed with a source of radiation that does not render the foods radioactive. Concerned Citizens' worry – a possible increased risk of disease that could result from eating the processed food – does not stem from any effect on the physical environment.

"If a harm does not have a sufficiently close connection to the physical environment, NEPA does not apply," regardless of the gravity of the harm.[42] Concerned Citizens' health concerns are a consumer food safety matter not causally related to a change in the physical environment.

It simply is not NEPA's purpose to "transplant specific regulatory burdens from those expert agencies otherwise authorized to redress specific nonenvironmental problems and pointlessly to reimpose those objectives on other unqualified agencies."[43] The FDA "already

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[40] *Ranchers Cattlemen*, 415 F.3d at 1103 (quoting *Metropolitan Edison*, 460 U.S. at 773) (emphasis in original).

[41] *Id.* (NEPA zone of interests did not encompass potential increased risk of "mad cow" disease from resumed importation of Canadian beef because asserted injury was not "connect[ed] to injury to the physical environment"); *see also Bicycle Trails Council of Marin* v. *Babbitt*, 82 F.3d 1445, 1466-67 (9th Cir. 1996); *Ashley Creek Phosphate Co. v. Norton*, 420 F.3d 934,943-44 (9th Cir. 2005)(NEPA does not encompass "concern that is not tethered to the [physical] environment"), *cert. denied*, 548 U.S. 903 (2006).

[42] *Ranchers Cattlemen*, 415 F.3d at 1103 (quoting *Metropolitan Edison*, 460 U.S. at 778).

[43] *Glass Packaging*, 737 F.2d at 1092.

has the specific statutory authority"[44] to evaluate and enforce potential health harms from food irradiation. We note, further, that the FDA has pending before it now similar arguments on potential health impacts of consuming irradiated foods, largely encompassing Concerned Citizens' concerns about radiolytic products, 2-ACBs and cancer risk. These have been filed in opposition to still-pending petitions requesting the FDA to issue new food additive regulations, authorizing new uses of food irradiation.[45]

If at any time the FDA comes to conclude that there no longer is "reasonable certainty" that consuming irradiated fresh fruits and vegetables at the currently approved dose is safe, it could revoke or modify the existing authorization for fresh fruit irradiation, a risk assumed by Pa'ina.[46] Indeed, the FDA's regulation generically authorizing fresh fruit and vegetable irradiation, issued in 1986 and still valid today, is the legally relevant or proximate cause of any potential effects of consuming irradiated fruits, "lengthen[ing] the causal chain beyond the reach of NEPA."[47] The NRC has no authority to revoke or change the FDA's generically applicable food additive regulations, to ban the importation of imported irradiated foods, or to prohibit operation of facilities that might use machine sources of radiation (such as electron beam or X-ray machines) to irradiate food. In the context of NEPA, one "must look at the underlying

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[44] *See id.* (where FDA already had statutory authority to address issue of potential tampering with bottles).

[45] *See* Food and Color Additive Petitions (posted August 2008), Center for Food Safety and Applied Nutrition, Office of Food Additive Safety, *available at* http://www.fda.gov, and under Docket Nos. FAP 1M4727; FAP 3M4744; FAP 9M4695; FAP 9M4696; FAP 9M4697.

[46] Concerned Citizens claims that the Pa'ina facility is "inextricably linked" to the contemplated sale of irradiated food. *See* Amended Contentions at 30. But additional uses are already specifically intended for the facility, *see* Final EA at 1, 6-7, and apparently other yet undetermined uses are envisioned. *See* Application for a Material License (June 20, 2005) at 8.

[47] *Metropolitan Edison*, 460 U.S. at 775.

policies or legislative intent in order to draw a manageable line between those causal changes that make an actor responsible for an effect and those that do not."[48]

IV. CONCLUSION

For the reasons outlined above, we *reverse* the Board's admission of Concerned Citizens' contention on the need for a NEPA analysis of the potential impacts of increasing the supply of irradiated food.

IT IS SO ORDERED.

For the Commission

/RA/

ANNETTE L. VIETTI-COOK
Secretary of the Commission

Dated at Rockville, Maryland
this 13th day of August, 2008.

[48] *Id.* at 774.