

April 17, 2008

UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION

BEFORE THE COMMISSION

In the Matter of)	
)	
PA'INA HAWAII, LLC)	Docket No. 30-36974
)	
Material License Application)	ASLBP No. 06-843-01

NRC STAFF'S REPLY TO PARTIES' BRIEFS ON CLI-08-04

INTRODUCTION

On March 27, 2008, the Commission invited the parties to brief two issues relevant to determining whether, in its Environmental Assessment (EA) for the irradiator proposed by Pa'ina Hawaii, LLC (Licensee), the Staff had to consider certain nonradiological risks allegedly linked to the consumption of irradiated food. *Pa'ina Hawaii, LLC*, CLI-08-04, 67 NRC __ (2008) (slip. op. at 2–3). The Staff, the Licensee, and Concerned Citizens of Honolulu (Intervenor) all filed initial briefs on April 10, 2008. The Staff herein responds to the Intervenor's brief and to a limited portion of the Licensee's Brief.

DISCUSSION

In its March 27, 2008 order, the Commission asked the following questions:

(1) whether the NRC lacks authority to reject an irradiator license for nonradiological 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.

CLI-08-04, 67 NRC __ (2008) (slip. op. at 2–3). Both questions raise issues similar to those addressed by the Supreme Court in *Department of Transportation v. Public Citizen*, 541 U.S. 752 (2004). In *Public Citizen*, the Court held 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.* Accordingly, in such circumstances, the agency need not consider the effect in determining whether its action is a "major federal action" requiring preparation of an environmental impact statement (EIS) under the National Environmental Policy Act of 1969, 42 U.S.C. §§ 4321–4437 (NEPA). *Id.* at 770. The Court further held that inherent in NEPA and its implementing regulations is a "rule of reason," which ensures that agencies determine whether and to what extent to prepare an EIS based on the usefulness of any new potential information to the decisionmaking process. *Id.* at 767. Applying this rule, the Court found that "[w]here the preparation of an EIS would serve 'no purpose' in light of NEPA's regulatory scheme as a whole . . . no rule of reason worthy of that title would require an agency to prepare an EIS." *Id.* at 767–68 (citations omitted).

In its initial brief, the Staff explained that, because neither NEPA nor the Atomic Energy Act of 1954, 42 U.S.C. §§ 2011–2297 (AEA), grants the NRC the authority to reject an irradiator license for nonradiological food safety reasons, the Staff did not have to consider hazards allegedly linked to the consumption of irradiated food in its EA for Pa'ina's irradiator. The Staff also argued that, consistent with NEPA's rule of reason, the NRC did not need to consider alleged food safety hazards where those hazards have been comprehensively analyzed by both the Food and Drug Administration (FDA) and United States Department of Agriculture (USDA).

The Intervenor, in its initial brief, argued that the NRC has broad authority to regulate the use of radioactive material and, therefore, must consider food safety under NEPA.¹ The Intervenor further argued that, even if the NRC lacks such authority, NEPA requires the Staff to consider the cumulative effect that licensing Pa'ina's irradiator will have on the environment

¹ Intervenor's Brief at 6–9.

because Pa'ina's facility will increase the supply of irradiated food for human consumption.²

Finally, while acknowledging that a "rule of reason" exists under NEPA, the Intervenor claimed that rule is inapplicable here, where the Staff did not conduct an "independent assessment" of potential health effects related to the consumption of irradiated food.³

The Intervenor's arguments are without merit. As discussed below, the Intervenor fails to identify any statutory provision that grants the NRC the authority to deny an irradiator application for nonradiological food safety reasons.⁴ The Intervenor therefore fails to show that the NRC needs to consider the particular effect it alleges—an increased risk of a certain type of cancer allegedly linked to the consumption of irradiated papayas and mangos—in determining whether to prepare an EIS.⁵ Further, although the Intervenor claims that NEPA requires an

² *Id.* at 10-12.

³ *Id.* at 12-14.

⁴ The Intervenor challenges the premise of the Commission's first question, arguing that the alleged health hazards are "radiological" because they are linked to the consumption of foods containing "radiolytic products," *i.e.*, products that result from the application of radiation. Intervenor's Brief at 6–7 n.3 (citing "Declaration of William W. Au in Support of Petitioner's Areas of Concerns" (September 29, 2005)). But this stretches the definition of "radiological" too far. As the Intervenor acknowledges, irradiated food is not itself radioactive. Moreover, even if certain changes in food resulting from irradiation might be described as radiological in nature, this does not mean the human health effects of consuming that food are also radiological. Were that the case, the NRC's regulatory authority would arguably extend not just to the licensing of irradiators, but to the sale of irradiated food itself. The NRC clearly does not have that authority. As the Licensee notes, the authority to regulate the sale of irradiated food is within the FDA's statutory mandate. Licensee's Brief at 4 n.1.

⁵ Throughout its brief, the Intervenor characterizes the issue before the Commission as whether the Staff has to consider "public health effects associated with the consumption of irradiated food." *E.g.*, Intervenor's Brief at 8. But that is not the precise issue raised by the Intervenor's contention, which alleges an increased risk of colon cancer linked to radiolytic products found in irradiated papayas and mangos. The Staff opposes any attempt by the Intervenor, at this late stage in the proceeding, to broaden its contention or to shift the burden to the Staff to prove that it did, in fact, consider all reasonably foreseeable health effects related to the consumption of irradiated food. In any event, a broad claim that the Staff failed to consider "public health effects" in its EA would not be adequate under the NRC's contention rules. See *Private Fuel Storage, LLC* (Independent Spent Fuel Storage Installation), CLI-04-22, 60 NRC 125, 139 (2004) (holding that, at the pleading stage, the petitioner must show a genuine dispute warranting a hearing and that it is not enough to suggest there may be undiscussed NEPA consequences).

agency to consider the cumulative effects of a licensing action regardless of whether the agency has authority over those effects, the Intervenor fails to identify any cumulative effect that the Staff overlooked in the EA for Pa'ina's irradiator. Finally, the Intervenor seeks to redefine NEPA's "rule of reason" so that, rather than being used to determine whether an agency needs to consider an effect under NEPA, the rule is applied only to decide whether an agency has discharged its duty where it has already been determined that an effect needs to be considered.

I. The Intervenor Fails to Explain on What Basis the Staff Might Deny an Irradiator License for Nonradiological Food Safety Reasons.

The Intervenor argues that the NRC has broad authority to regulate the use of radioactive material. Although true, the Intervenor does not address the limits of that authority. The NRC's authority has frequently been described as "virtually unique in the degree to which broad responsibility is reposed in the administrative agency, free of close prescription to its charter as to how it shall proceed *in achieving statutory objectives.*" *Environmental Defense Fund v. NRC*, 902 F.2d 785, 788 (10th Cir. 1990) (emphasis added); *Carstens v. NRC*, 742 F.2d 1546, 1551 (D.C. Cir. 1984), *cert. denied*, 471 U.S. 1136 (1985); *Detroit Edison Co. v. NRC*, 630 F.2d 450, 453 (6th Cir. 1980). This leads directly to the first question posed by the Commission, which asks whether rejecting an irradiator application for nonradiological food safety reasons falls *outside* the NRC's statutory objectives. The Intervenor's only answer to this question is that Section 81 of the AEA, on its face, grants the NRC authority over nonradiological hazards associated with the use of byproduct material. But the Intervenor fails to explain why Section 81 never mentions such hazards. Nor does the Intervenor address other sections of the AEA that, in contrast to Section 81, specifically mention nonradiological hazards.

Further, the Intervenor fails to address the AEA's legislative history, which shows that, in adopting the statute, Congress "had in mind only the special hazards of radioactivity."⁶

The Intervenor also seeks to turn the first question posed by the Commission on its head, arguing that there are no "statutory mandates" that "*oblige the NRC . . . to ignore the potential public health effects associated with the consumption of irradiated food.*"⁷ The issue raised by *Public Citizen* is not whether an agency must ignore health effects, but whether it "*has the ability to prevent a certain effect[.]*" 541 U.S. at 770 (emphasis added). In *Public Citizen*, the Supreme Court did not base its ruling on any statutory provision affirmatively denying the FMCSA the ability to prevent emissions from the cross-border operations of Mexican motor carriers. Rather, the Court relied on the limited nature of the FMCSA's statutory authority, which is confined to prescribing safety, fitness, and financial-responsibility requirements for motor carriers. *Id.* at 758–59. For the reasons set forth in its initial brief, the Staff submits that the NRC does not have the ability to reject an irradiator application based solely on nonradiological food safety reasons.⁸

The Intervenor also suggests that the NRC could regulate nonradiological impacts indirectly by imposing more stringent radiation safety requirements on irradiators. A similar argument was made in *Public Citizen* with respect to the FMCSA's authority, where that agency

⁶ *New Hampshire v. AEC*, 406 F.2d 170, 174, n.4 (1st Cir. 1969), *cert. denied*, 395 U.S. 962 (1969) (citation omitted).

⁷ Intervenor's Brief at 8 (emphasis added).

⁸ In the area of food safety, it is the FDA and USDA—not the NRC—that have authorized the sale of irradiated food for human consumption. The NRC's role is limited to establishing radiological safety requirements for certain facilities used to irradiate such food. The NRC cannot stop the sale of irradiated food in the United States, and the NRC cannot categorically deny licenses to otherwise-qualified applicants based on nonradiological food safety reasons. Further, even if the NRC could ban the irradiation of certain foods, these same foods could be irradiated elsewhere and imported into the United States. See 7 C.F.R. § 305.31(b) (USDA regulation permitting facilities used for the irradiation of imported food to be located outside the United States).

arguably could have adopted more rigorous safety-monitoring regulations that would effectively have reduced the number of Mexican motor carriers entering the United States and, in that manner, limited the emissions from such carriers. The Court did not find that to be a sufficient basis for concluding the FMCSA had authority to limit emissions, noting that the connection between enforcement of motor carrier safety and the alleged environmental harms was “tenuous at best.” 541 U.S. at 765. “Nor is it clear,” the Court added, “that FMCSA could, consistent with its limited statutory mandates, reasonably impose on Mexican carriers standards beyond those already required in its proposed regulations.” *Id.* As in *Public Citizen*, the Intervenor here fails to establish a connection between the NRC’s safety requirements and the environmental harms it alleges. The Intervenor proposes a ban on the irradiation of papayas and mangos,⁹ but it does not explain how such a ban would have any connection to radiation safety at irradiators. The Intervenor’s argument appears to be that the NRC should adopt radiation safety requirements having no connection to radiological safety for the express purpose of limiting an alleged nonradiological effect. The Staff submits that this would be inconsistent with *Public Citizen*, where the Court indicated that an agency following such an approach would be acting outside its statutory mandate. *Id.*

II. The Intervenor is Unable to Show that Licensing Pa’ina’s Irradiator Will Cause Cumulative Effects Related to Food Safety that the Staff Must Consider.

The Intervenor argues that, even if the NRC lacks the authority to deny an irradiator license for nonradiological food safety reasons, under 40 C.F.R. § 1508.8(b) the Staff still needs to consider that issuing Pa’ina a license will have a cumulative effect on human health because it will increase the supply of irradiated food for human consumption.¹⁰ The Intervenor draws an

⁹ The Intervenor suggests this approach at page 9 of its Brief.

¹⁰ Intervenor’s Brief at 10–12.

analogy to *Public Citizen*. There, the Supreme Court noted that in its EA the FMCSA had considered emission increases potentially related to the issuance of its safety-monitoring regulations themselves, such as emissions related to an increased number of roadside inspections due to the proposed regulations. 541 U.S. at 761.

This analogy does not help the Intervenor. The Intervenor has not challenged the NRC's radiation safety requirements for irradiators, but rather their application in a particular licensing proceeding. To the extent the Intervenor is suggesting that the NRC's radiation safety requirements in Part 36 have any impact on the safety of irradiated food, that claim has not been raised before the Board and should not be considered here.¹¹ The proper analogy is between the FMCSA's issuance of licenses to specific motor carriers and the Staff's action in the present proceeding. That is the point on which the Staff focused at page 14 of its initial brief.¹²

III. The Intervenor's Interpretation of NEPA's "Rule of Reason" Does Not Comport with *Public Citizen*

The Intervenor concedes that a "rule of reason" exists under NEPA, but fails to acknowledge how the Supreme Court applied this rule in *Public Citizen*. The Intervenor cites Ninth Circuit cases holding that an agency may under certain conditions rely on another

¹¹ Such a claim would, in essence, be an argument that the NRC's Part 36 rulemaking failed to comply with NEPA and would be, at this late date, an impermissible challenge to the regulations.

¹² The Intervenor also claims that the Staff did, in contrast, consider other cumulative effects in its EA for Pa'ina's irradiator, including socioeconomic benefits from providing food producers with "potentially cheaper treatment alternatives" and "impacts to ecology in controlling invasive species." Intervenor's Brief at 11. In the context of the EA, it is clear that the Staff's discussion was included in part because it explained the purpose of the irradiator, and also because public comments raised those very issues. See Final EA at 6-7 (need for the proposed action), C-11 through C-13 (comment responses). As indicated in the Staff's Initial Brief, even though the NRC is not required to consider nonradiological impacts in an EA, agency practice has been to discuss such impacts in certain instances where the discussion would further NEPA's public information purpose. Staff's Initial Brief at 15-16 and n.34.

agency's environmental analysis to discharge its own duty to consider effects under NEPA.¹³ These cases do not address the situation in *Public Citizen*, where the Court held that NEPA's rule of reason is also relevant to determining whether an agency has to consider an effect altogether. The Court specifically held that "where the preparation of an EIS would serve 'no purpose' in light of NEPA's regulatory scheme as a whole . . . no rule of reason worthy of that title would require an agency to prepare an EIS." *Id.* at 767–68 (citations omitted). The Court did not base its holding on the FMCSA's incorporation of another agency's NEPA analysis in its EA. Rather, the Court relied on the fact that another agency had already comprehensively addressed the environmental effects of cross-border operations involving Mexican motor carriers. *Id.* at 769. As explained in the Staff's Initial Brief, applying NEPA's rule of reason here, the comprehensive evaluations of irradiated food by both the FDA and USDA obviate any need for the Staff to consider food safety in its EA for Pa'ina's irradiator.

Further, even if the Commission were to evaluate the Staff's EA under the more limited "rule of reason" applied in the cited Ninth Circuit cases, the EA complies with NEPA. The EA reflects that the Staff considered USDA studies analyzing the safety of irradiated food, as well as the FDA's regulation of irradiated food.¹⁴ In particular, the Staff reviewed three USDA rulemaking documents, one of which incorporated an EA specifically addressing health risks potentially linked to the consumption of irradiated food.

¹³ Intervenor's Brief at 12–13.

¹⁴ Final EA at 14–15 (citing rules issued by USDA's Animal and Plant Health Inspection Service); C-18 (FDA's position).

IV. The Licensee Correctly Notes that the Board Rejected the Intervenor's Initial Contention on Food Safety, Which Raised the Same Issues as Those in its Amended Contention.

The Licensee devotes most of the introductory section of its brief to arguing that the Board has, in this very same licensing action, already rejected food safety challenges similar to those raised by the Intervenor here.¹⁵ The Staff agrees that the critical issues raised in the Intervenor's amended food safety contention have already been addressed by the Board in its ruling on the Intervenor's initial food safety contention. The supporting basis for the Intervenor's initial contention was the declaration of purported expert William Au, Ph.D., dated September 29, 2005.¹⁶ The supporting basis for the Intervenor's amended contention is the very same declaration.¹⁷ Given that the Board has already found the declaration's analysis of food safety risks to be based on "only speculation, not facts,"¹⁸ it is difficult to see how the Board could come to a different conclusion in ruling on the Intervenor's amended contention. This is significant because, if the food safety hazards alleged by the Intervenor are merely speculative, under NEPA they are not considered "effects" of licensing Pa'ina's irradiator.¹⁹ And, if the alleged hazards are not effects of licensing Pa'ina's irradiator, there is no basis for requiring the Staff to consider them in an EA.

¹⁵ Licensee's Brief at 2–3.

¹⁶ Request for Hearing by Concerned Citizens of Honolulu (October 3, 2005) (ADAMS ML052970026) at 22–24.

¹⁷ Intervenor Concerned Citizens of Honolulu's Amended Environmental Contentions #3 through #5 (September 4, 2007) (ADAMS ML072530634) at 29–30.

¹⁸ Memorandum and Order (Ruling on Petitioner's Standing and Environmental Contentions), LBP-06-4, 63 NRC 99, 114 (2006).

¹⁹ See 40 C.F.R. § 1508.8(b) (defining "indirect effects" as effects that are reasonably foreseeable); § 1508.7 (defining "cumulative impacts" as encompassing "reasonably foreseeable future actions").

CONCLUSION

The Intervenor fails to identify any statutory provision that grants the NRC authority to reject an irradiator application for nonradiological food safety reasons. Further, the Intervenor fails to explain why, under NEPA's rule of reason, the NRC would have to consider potential nonradiological effects that have been comprehensively reviewed by both the FDA and the USDA. For the reasons set forth here and in the Staff's Initial Brief, the Commission should find that the Staff did not have to consider the food safety risks alleged by the Intervenor in the EA for Pa'ina's irradiator.

Respectfully submitted,

/RA/

Michael J. Clark
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Dated at Rockville, Maryland
this 17th day of April, 2008

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CERTIFICATE OF SERVICE

I hereby certify that copies of "NRC STAFF'S REPLY TO PARTIES' BRIEFS ON CLI-08-04" in the above-captioned proceedings have been Served on the following by deposit in the United States mail; through deposit in the Nuclear Regulatory Commission's internal system as indicated by an asterisk (*), and by electronic mail as indicated by a double asterisk (**) on this 17th day of April, 2008.

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