UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

CENTER FOR SCIENCE IN THE PUBLIC INTEREST, *et al.*, **Plaintiffs,** **v.** **UNITED STATES FOOD AND DRUG ADMINISTRATION, *et al.*,** **Defendants.**	**Civil Action No. 14-375 (JEB)**

MEMORANDUM OPINION

Mercury is toxic, especially to young children and developing fetuses. Because seafood contains mercury, the Environmental Protection Agency and the Food and Drug Administration have posted online recommendations for seafood consumption targeted at young children and women of child-bearing age. Plaintiffs Center for Science in the Public Interest and Mercury Policy Project, concerned that these recommendations were not reaching at-risk members of the public, petitioned FDA in 2011 to initiate a rulemaking that would require versions of the online recommendations to be included in seafood labels and posted where seafood is sold. The agency has neither approved nor denied the petition.

At the time Plaintiffs petitioned the Administration, it was in the midst of a large-scale scientific inquiry designed to reevaluate its approach to mercury. The problem FDA faces is that, although mercury found in seafood has a deleterious effect on early neurodevelopment, the seafood itself provides nutrients that promote healthy growth. The agency, accordingly, has long been working to develop a method to accurately assess potential risks posed by mercury, balanced against the known benefits of eating fish. That project has now drawn to a close, and,

as a result, FDA and EPA are currently drafting new recommendations to replace those currently posted online.

In the meantime, several years have passed since Plaintiffs petitioned FDA. On March 10, 2014, they brought this suit, seeking an order compelling the Administration to act on their petition. The parties now cross-move for summary judgment. Because the Court finds that FDA's delay in responding to Plaintiffs is not so egregious as to warrant intervention at this time, it will grant Defendants' Motion for Summary Judgment and deny Plaintiffs'.

I. Background

A. 2004 Advisory

Airborne mercury, emitted from sources like coal-fired power plants, is deposited into the ocean, is converted into methylmercury, and enters the human body through our consumption of seafood. See Compl., ¶¶ 37-38. Methylmercury – which the Court will for convenience refer to simply as "mercury" – is toxic. See id. It is particularly harmful to fetuses and young children, for whom it can impair neurodevelopment. See id., ¶ 38. In 2004, due to these risks, FDA and EPA issued an online advisory entitled, "What You Need to Know About Mercury in Fish and Shellfish." See id., ¶ 39; Pl. Mot., Declaration of Summer Kupau-Odo, Exh. 4 (2004 Advisory).

The 2004 Advisory informs consumers that "some fish and shellfish contain higher levels of mercury that may harm an unborn baby or young child's developing nervous system." See 2004 Advisory at 1. Noting that the health "risks from mercury in fish and shellfish depend on the amount . . . eaten and the levels of mercury in the fish," id., FDA and EPA issued three recommendations for women who might become pregnant, pregnant women, women who are nursing, and children ("Target Group"): (1) do not eat shark, swordfish, tilefish, or king mackerel; (2) limit albacore tuna consumption to six ounces per week; and (3) eat up to twelve

ounces of low-mercury seafood per week. Id. at 2; Compl., ¶ 39. The advisory suggests the same for young children, but with reduced portions. See 2004 Advisory at 2.

B. Plaintiffs' Citizen Petition

On July 5, 2011, relying on studies showing that many consumers still did not know about the risks posed by mercury in seafood, Plaintiffs petitioned FDA to initiate a rulemaking to better disseminate the 2004 Advisory, which could otherwise only be found online. See Kupau-Odo Decl., Exh. 7 (Plaintiffs' Petition) at 15. They asked FDA to consider regulations that would:

> a. "Provide for informational labeling on packaged seafood to generally reflect the [2004 Advisory]";
>
> b. "Require grocery stores to post the seafood consumption recommendations [contained in the 2004 Advisory] at the point of sale of unpackaged, fresh seafood, simplified into a user-friendly chart that is aimed at the TARGET GROUP"; and
>
> c. "Provide for informational mercury level and consumption limit labeling, on packaging and/or at the point of sale, for seafood species with moderate and high mercury content that are not otherwise listed in the [2004 Advisory], to specify the level of mercury content and/or the recommended consumption limit for the TARGET GROUP . . . ."

Id. at 5-6 (footnote omitted); Compl., ¶ 45.

FDA has the power to compel this type of labeling on commercial fish by authority set out in the Federal Food, Drug, and Cosmetic Act (FDCA). Specifically, the Administration may require information to appear in food labels if it determines that, absent that information, the labels would be false or misleading. See 21 U.S.C. §§ 371(a), 343(a)(1), 321(n).

It is undisputed that citizens may petition FDA to issue regulations and orders in this manner. See 21 C.F.R. §§ 10.30, 10.25(a)(2). In this case, the Administration acknowledged receipt of the petition, but Plaintiffs did not receive any further communication for the next six

months. See Compl., ¶ 49. On January 26, 2012, Plaintiffs alerted the agency to its failure to respond. See id. Six months later, on August 8, 2012, FDA sent Plaintiffs a tentative response letter, stating that it "had not yet reached a decision on [the P]etition because . . . the ongoing review and analysis of the science [was] not yet completed." See id., ¶ 50; Kupau-Odo Decl., Exh. 10 (Tentative Response). In the letter, the agency noted that it "hope[d] to be able to complete this review in the near future," that it was "actively considering the issues raised by [the] citizen petition," and that it "intend[ed] to issue a final response as soon as possible after this review is completed." See Tentative Response.

C. FDA Action on Mercury

At the time Plaintiffs petitioned FDA, it was in the process of evaluating its approach to mercury in seafood. According to the Administration, since publishing the 2004 Advisory, substantial evidence has emerged that fish consumption by pregnant women and young children can improve neurodevelopment even though fish contain mercury. See Def. Mot. & Opp., Declaration of Michael Landa, ¶ 12. To address this issue, starting in approximately 2006, FDA began developing a methodology for assessing the net effects of fish consumption on neurodevelopment, and in January 2009, after obtaining peer review, issued the draft recommendations for public comment. Id., ¶¶ 13, 18, 19.

On June 10, 2014, FDA published its Final Assessment, entitled "Quantitative Assessment of the Net Effects on Fetal Neurodevelopment from Eating Commercial Fish (As Measured by IQ and also by Early Age Verbal Development in Children)." See id., ¶ 15; id., Exh. 1 (Final Assessment). At the same time, FDA and EPA issued a draft updating its 2004 Advisory – the same advisory Plaintiffs had petitioned to be included in seafood labeling – and solicited public comment on these updated recommendations. See id., ¶ 25; id., Exh. 3 (Draft

Advisory). The Draft Advisory represents FDA's proposed position on how to maximize the benefits of seafood consumption for the Target Group and was influenced by the Final Assessment. See id., ¶ 25. According to the Administration, the next step in finalizing this draft comes when FDA's Risk Communication Advisory Committee meets this month to discuss it. Id., ¶ 27. Moving forward, the comment period will then remain open for 30 days after this or any other subsequent public meetings. Id. Before publishing a final advisory, FDA will consider any comments together with the view of the Advisory Committee, and it will confer with EPA regarding any changes to the Draft Advisory. See id.; 79 Fed. Reg. at 33559-02. According to the agency, finalizing the Draft Advisory "may require further analysis and significant policy discussion." Landa Decl., ¶ 27.

D. This Suit

Plaintiffs filed this lawsuit on March 10, 2014, seeking an order compelling FDA to respond to their petition. They principally allege that FDA's delay is unreasonable and therefore merits judicial intervention. The parties now cross-move for summary judgment.

II. Legal Standard

Summary judgment may be granted if "the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a); see also Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 247-48 (1986); Holcomb v. Powell, 433 F.3d 889, 895 (D.C. Cir. 2006). A fact is "material" if it is capable of affecting the substantive outcome of the litigation. See Liberty Lobby, 477 U.S. at 248; Holcomb, 433 F.3d at 895. A dispute is "genuine" if the evidence is such that a reasonable jury could return a verdict for the nonmoving party. See Scott v. Harris, 550 U.S. 372, 380 (2007); Liberty Lobby, 477 U.S. at 248; Holcomb, 433 F.3d at 895. "A party asserting that a fact cannot be or is genuinely

disputed must support the assertion" by "citing to particular parts of materials in the record" or "showing that the materials cited do not establish the absence or presence of a genuine dispute, or that an adverse party cannot produce admissible evidence to support the fact." Fed. R. Civ. P. 56(c)(1). The moving party bears the burden of demonstrating the absence of a genuine issue of material fact. See Celotex Corp. v. Catrett, 477 U.S. 317, 323 (1986).

A motion for summary judgment must generally be "accompanied by a statement of material facts as to which the moving party contends there is no genuine issue . . . ." LCvR7(h)(1). An opposition, likewise, must "be accompanied by a separate concise statement of genuine issues setting forth all material facts as to which it is contended there exists a genuine issue necessary to be litigated . . . ." Id. Plaintiffs fault FDA for not including such a statement in its Opposition. See Pl. Opp. & Rep. at 1 n.1. This requirement, however, does "not apply to cases in which judicial review is based solely on the administrative record. In such cases, motions for summary judgment and oppositions thereto shall include a statement of facts with references to the administrative record." LCvR7(h)(2). Because this case falls under the APA, it can be fairly interpreted as one that does not require a separate statement of material facts. FDA, moreover, has included a Declaration to support its Motion, and it does not dispute the facts included in Plaintiffs' Statement. See Def. Rep. at 1 n.1. The Court, therefore, has a record adequate to rule on the opposing Motions.

III. Analysis

The APA requires an agency to "proceed to conclude a matter presented to it" within "a reasonable time," 5 U.S.C. § 555(b), and directs courts to "compel agency action . . . unreasonably delayed." Id. § 706(1). Together, "[t]hese provisions give courts authority to review ongoing agency proceedings to ensure that they resolve the questions in issue within a

reasonable time." Pub. Citizen Health Research Group v. Comm'r, Food & Drug Admin., 740 F.2d 21, 32 (D.C. Cir. 1984). Plaintiffs invoke this authority in seeking an order compelling FDA to respond to their petition. "In the context of a claim of unreasonable delay," the Court must consider whether the agency's failure to respond is "so egregious" as to warrant relief. See Telecommunications Research & Action Ctr. v. FCC, 750 F.2d 70, 79 (D.C. Cir. 1984) (TRAC). In making this assessment, moreover, the Court bears in mind "the limits of [its] institutional competence in the highly technical area at issue in this case." Grand Canyon Air Tour Coal. v. FAA, 154 F.3d 455, 476 (D.C. Cir. 1998).

In determining whether FDA's delay has been unreasonable, the parties agree that this case is governed by the "hexagonal contours of a standard" identified in TRAC, 750 F.2d at 80. In that case, the D.C. Circuit identified the following six considerations as relevant in evaluating agency delay:

> (1) the time agencies take to make decisions must be governed by a rule of reason; (2) where Congress has provided a timetable or other indication of the speed with which it expects the agency to proceed in the enabling statute, that statutory scheme may supply content for this rule of reason; (3) delays that might be reasonable in the sphere of economic regulation are less tolerable when human health and welfare are at stake; (4) the court should consider the effect of expediting delayed action on agency activities of a higher or competing priority; (5) the court should also take into account the nature and extent of the interests prejudiced by delay; and (6) the court need not find any impropriety lurking behind agency lassitude in order to hold that agency action is unreasonably delayed.

Id. (citations and quotation marks omitted).

These considerations cohere into three basic inquiries in this case. First, is there any rhyme or reason – congressionally prescribed or otherwise – for FDA's delay (factors one and two)? Second, what are the consequences of delay if the Court does not compel the

Administration to act (factors three and five)? Finally, how might forcing the agency to act thwart its ability to address other priorities (factor four)? In what follows, the Court finds that the answers to these questions counsel against intervention at this time.

A. Reasonableness

The first TRAC factor asks whether FDA's timeline in responding is "governed by a 'rule of reason,'" and the second provides that the content of such a rule may be found in a "timetable or other indication . . . in the enabling statute." TRAC, 750 F.2d at 80. In other words, these factors get at whether the agency's response time complies with an existing specified schedule and whether it is governed by an identifiable rationale. Plaintiffs contend that FDA's delay in this case violates both precepts. First, they claim that the Administration's three-year delay does not comport with a rule of reason, because – among other things – it is well beyond the agency's own regulatory timetable for responding to citizen petitions. Second, they point to a similar petition that FDA did deny and surmise from this that the agency has long been equipped to respond to Plaintiffs' petition as well. Neither argument, however, shows that the time FDA has taken to respond in this case approaches an egregious standard.

First, Plaintiffs highlight the fact that FDA has 180 days to "[a]pprove," "[d]eny," or "[p]rovide a tentative response, indicating why the agency has been unable to reach a decision on [a citizen] petition." 21 C.F.R. § 10.30(e)(2). While they acknowledge that the Administration has technically complied with this regulation, they nonetheless argue that, beyond its literal application, this deadline also provides a framework within which to gauge FDA's delay in issuing a final response. In other words, the timeliness of the agency's ultimate action should be scaled to this regulatory scheme – especially when health and welfare are at stake. Congress has, after all, charged FDA with "promot[ing] the public health by promptly and efficiently reviewing

clinical research and taking appropriate action on the marketing of regulated products in a timely manner . . . ." 21 U.S.C. § 393(b)(1) (emphases added). A delay of years in the face of a six-month regulatory timeline, Plaintiffs conclude, is unreasonable.

The Court is unpersuaded. To begin with, Plaintiffs' allusion to the regulatory timetable is a false trail. While these regulations give 180 days for a tentative response, they say nothing about how long FDA has to issue an ultimate response to a citizen petition. The only applicable standard against which to measure that action is the APA's requirement that FDA act "within a reasonable time." 5 U.S.C. § 555(b). Upon reflection, this makes sense. Whether the Administration has unreasonably delayed its response to a petition can only be measured by reference to the complexity of the task. The more complex the petition, the more time an agency may need to adequately respond. See Mashpee Wampanoag Tribal Council, Inc. v. Norton, 336 F.3d 1094, 1102 (D.C. Cir. 2003) (whether delay is unreasonable "cannot be decided in the abstract, by reference to some number of months or years beyond which agency inaction is presumed to be unlawful, but will depend in large part . . . upon the complexity of the task at hand, the significance (and permanence) of the outcome, and the resources available to the agency"). Courts, moreover, routinely defer to the judgment of agencies when assessing timelines that involve complex scientific and technical questions. See, e.g., In re United Mine Workers of Am. Int'l Union, 190 F.3d 545, 555 (D.C. Cir. 1999) ("[I]t is difficult for us to second-guess" the agency's time projections "in light of the host of complex scientific and technical issues involved."); Sierra Club v. Thomas, 828 F.2d 783, 798-99 (D.C. Cir. 1987) ("EPA must be afforded the amount of time necessary to analyze" "complex scientific, technological, and policy questions."). In the present case, the Court lacks the competence to ascertain how long it might take to measure the risks of mercury on childhood development, to

gauge the effects any regulations might have on mercury consumption, or to predict the benefits or detriments that might occur if mercury warnings are placed where seafood is sold. These are tasks for FDA.

The Administration, in fact, appears to be busy trying to address these very concerns. At the time Plaintiffs petitioned FDA to initiate a rulemaking, in part based on the 2004 Advisory, the agency was in the process of evaluating its overall approach to mercury in seafood. According to FDA, substantial evidence had emerged that fish consumption by pregnant women and young children can improve neurodevelopment despite mercury intake. See Landa Decl., ¶ 12. For this reason, starting in 2006, FDA began developing a methodology for assessing the net effects of fish consumption on neurodevelopment. See id., ¶¶ 15, 25. The Administration has now published its Final Assessment, and, in light of its conclusions, FDA and EPA have issued a draft to replace the 2004 Advisory, which they are working to finalize. See id., ¶ 27. The Administration has not responded to Plaintiffs' petition, it explains, because it is waiting on the content of the revised advisory. See Def. Rep. at 4.

That explanation makes sense. It is perfectly understandable that FDA would want to wait on the final content of its revised recommendations before determining what point-of-sales labeling might be required by law. Until this advice is finalized, FDA is not in a position to determine what the content of any such recommendations might be. Contrary to Plaintiffs' contentions, moreover, see Pl. Opp. & Rep. at 10, even at this stage, the Draft Advisory includes small but possibly significant changes to the FDA's approach to optimizing the benefits of seafood consumption for the Target Group. As FDA points out, the 2004 Advisory recommends against eating more than twelve ounces of low-mercury fish each week, but does not recommend a minimum amount. See 2004 Advisory at 1. The Draft Advisory, on the other hand, suggests

eating at least eight ounces of fish in this category each week. See Draft Advisory. It would be imprudent, FDA reasonably explains, to act on a petition requesting mandatory labeling based on outdated advice when new advice is nearing completion.

Plaintiffs, however, are not done. To support their position, they invoke the decision in Muwekma Tribe v. Babbitt, 133 F. Supp. 2d 30 (D.D.C. 2000). In that case, too, there was no "preemptory requirement in [the enabling] statute, regulations or guidelines that would require [agency action] . . . within any predetermined time frame." See id. at 38-39. The court nonetheless concluded that Congress did not intend requests for agency action to "languish . . . indefinitely." Id. Plaintiffs urge that the Administration's vague "hope" that it will complete its review "in the near future" is exactly the kind of indefinite non-response considered unreasonable in that case. See id. at 37 (agency's "noncommittal estimate" for completing review of petition supported finding of unreasonable delay).

Plaintiffs' reliance on Muwekma is misplaced. That case centered on a Native American tribe's petition for federal recognition. See id. at 31-32, 38. The tribe spent six years dealing with the Bureau of Indian Affairs before its petition was considered "filed" and three more trying to make its way onto a list of cases "ready for active consideration." Id. at 36. Over a year after finding out it had been placed on that list, the tribe learned it would take up to four more years before the appropriate branch of the BIA would begin considering its petition. See id. at 37. The court in that case found that the agency's "noncommittal estimate coupled with the specific history of interaction between th[e] parties [gave] rise to a finding of 'unreasonable delay.'" Id. In addition, the record there did not "support the notion that resources [were] being dispatched in a manner consistent with mitigating unreasonable delay." Id. at 40. Here, in contrast, FDA has been at work reviewing the relevant scientific issues, has progressed in that work – evidenced by

the Final Assessment and Draft Advisory – and has done so in the context of a complex scientific inquiry. Its explanation for delay also provides a general horizon over which it will be able to act on Plaintiffs' petition – namely, once it has finalized its Draft Advisory. This is not the kind of egregious and unexplained delay that merits intervention.

Plaintiffs' second argument fares no better. They point to a petition involving similar issues that FDA did respond to as evidence that the agency has been in a position to respond to Plaintiffs' petition for some time. The other petition was filed by GotMercury.org, a project of the Turtle Island Restoration Network, and the Center for Biological Diversity. See Kupau-Odo Decl., Exh. 11 (CBD Petition). Like Plaintiffs', the CBD Petition requested that FDA "[r]equire seafood distributors, retailers, restaurants and all institutions that sell seafood to post the [2004 Advisory] at 'point-of-sale' locations and/or label fish products that are known to be high in mercury." Id. at 3. Unlike its tentative response to Plaintiffs' petition, however, the Administration denied this one, concluding that it had "not provide[d] FDA with a basis to make a determination that the information [it had] Request[ed] be included in the labeling of commercial fish [was] 'material' with[in] the meaning of . . . the [FDCA]." See Kupau-Odo Decl., Exh. 12 (CBD Denial Letter) at 17. According to Plaintiffs, the denial of what they consider a substantially identical petition demonstrates that FDA has long had any and all resources it might need to act on their request. If the Administration could deny the CBD Petition, Plaintiffs conclude, it could deny theirs. See In re Am. Rivers & Idaho Rivers United, 372 F.3d 413, 420 (D.C. Cir. 2004) (noting an agency's delay "uncharacteristic of the relatively swift treatment it routinely gives similar petitions").

Plaintiffs' contention, however, overlooks the significant differences between the petitions. True, the CBD Petition included a request that the 2004 Advisory be posted where

seafood is sold, but this was a minor inclusion in a petition that dealt primarily with lowering regulatory thresholds for mercury in seafood to 0.5 parts per million. See CBD Petition at 3. Relatively little of the CBD Petition was dedicated to the issue of labeling, and in response to the sparse support this request cited, FDA determined that the petition had "provide[d] no basis upon which to conclude" that the 2004 Advisory "constitutes a 'material fact' with respect to commercial fish," such that nondisclosure would render labeling "false or misleading." CBD Denial Letter at 17.

Plaintiffs' petition, in contrast, was fully dedicated to point-of-sale labeling. Their arguments dug deeper and reached more broadly than those found in the CBD petition. Plaintiffs devoted pages to the issue of FDA's legal authority to require the requested labeling and provided the Administration with several alternative bases for their proposed action. See Plaintiffs' Petition at 19-34. These differences sufficiently answer Plaintiffs' allegations of inconsistent treatment. In other words, FDA's rationale in denying the CBD Petition was that petitioners there had not provided a basis for FDA to act. This response says nothing of whether Plaintiffs here have done so. At bottom, FDA may deny a summary request like that found in the CBD Petition yet refuse to act on a more developed request because the agency must conduct further research to evaluate claims in the latter that were not forwarded in the former.

Plaintiffs' petition, moreover, went well beyond merely disseminating the 2004 Advisory. They requested several sets of labels, the inclusion of consumption recommendations for seafood not otherwise listed in the 2004 Advisory, and the placement of placards near unpackaged fish. See Plaintiffs' Petition at 5-6. It is hardly a stretch that, as to these more detailed requests, FDA would need to rely upon the conclusions of the Final Assessment and potentially incorporate the language of the Draft Advisory in responding. See Def. Rep. at 7.

After all, the agency must draw both scientific and policy conclusions in deciding exactly what action to take on Plaintiffs' petition.

In sum, FDA is addressing the mercury issue and will soon publish updated advice for the Target Group on how best to consume seafood. It is not unreasonable for the agency to wait for the results of this regulatory action before acting on Plaintiffs' petition, which seeks dissemination of that very advice. TRAC factors one and two, therefore, weigh against issuing relief.

B. Effects of Delay

The third and fifth factors identified in TRAC run together in this case. The third looks to whether "human health and welfare are at stake" – in which case compulsion is more justified – and the fifth assesses the "nature and extent of the interests prejudiced by delay." See 750 F.2d at 80. Because Plaintiffs seek to compel FDA action principally out of a desire to protect human health and welfare, the consequence of inaction for Plaintiffs and the public are one and the same.

Plaintiffs' argument on this front makes sense. FDA admits that mercury is toxic, that the young are the most susceptible to its effects, and that exposure to mercury can be reduced by eating fish lower in mercury. Those at risk, however, can limit mercury exposure only if they know how – yet many do not. See Pl. Opp. & Rep. at 6-9. Without a final response, Plaintiffs are unable to alert this population to the risks of mercury either through FDA action or a court order. See Pl. Mot. at 13-15. Plaintiffs conclude, therefore, that because FDA's inaction threatens health and welfare, it is unreasonable. See Pub. Citizen, 740 F.2d at 34 (evidence suggested unreasonably dilatory decisionmaking where "[a]ll scientific evidence in the record point[ed] to a link between salicylates and Reye's Syndrome"); Pub. Citizen v. Heckler, 602 F.

Supp. 611, 612 (D.D.C. 1985) (ordering action where agency admitted in lawsuit "that the consumption of certified raw milk [was] linked to the outbreak of serious disease" yet still had not acted) (quotation marks, citations, and alterations omitted); Pub. Citizen Health Research Grp. v. Auchter, 702 F.2d 1150, 1157 (D.C. Cir. 1983) ("Three years from announced intent to regulate to final rule is simply too long given the significant risk of grave danger [ethylene oxide] poses to the lives of current workers and the lives and well-being of their offspring.").

FDA counters that public safety is its *raison d'être*; its entire docket involves issues of "human health and welfare." TRAC, 750 F.2d at 80. The agency, consequently, constantly faces difficult questions relating to food contamination, nutritional information, and epidemics. See Def. Mot. & Opp. at 23. Because everything the Administration does involves health and welfare, it contends, the fact that Plaintiffs' petition also implicates these concerns is far less significant than it might otherwise be. This is correct. As the D.C. Circuit has noted, "[A]lthough this court has required greater agency promptness as to actions involving interests relating to human health and welfare, . . . this factor alone can hardly be considered dispositive when, as in this case, virtually the entire docket of the agency involves issues of this type." Thomas, 828 F.2d at 798.

FDA also emphasizes the evidence that fish consumption may in fact be more beneficial than harmful for the Target Group. Uncertainty on the exact balance of risk to reward in seafood consumption distinguishes this case from those relied upon by Plaintiffs, where no one disputed the dangers at issue. See Pub. Citizen, 740 F.2d at 34 ("All scientific evidence in the record points to a link between salicylates and Reye's Syndrome . . . ."); Heckler, 602 F. Supp. at 613 ("Officials at the highest levels of [the agency] have concluded that certified raw milk poses a serious threat to the public health."); Auchter, 702 F.2d at 1157 (noting the "[a]mple evidence in

the record indicat[ing] a significant risk that some workers, who [were] actually being exposed to levels of [ethylene oxide] greater than the 10 ppm 'average'" encountered "a potentially grave danger to both their health and the health of their progeny"). The risk analysis here, on the other hand, is made complex by the countervailing benefits of seafood consumption. In fact, FDA's Final Assessment estimates that for the vast majority of commercial fish, average or above consumption levels will likely result in net benefits for fetal development. See Final Assessment at 104-07. Based on these considerations, the Court is persuaded that the action FDA has delayed here – namely, approving or denying Plaintiffs' request – does not carry with it the certain danger involved in the cases upon which Plaintiffs rely.

The Court thus finds that TRAC factors three and five run against Plaintiffs.

C. Competing Priorities

Finally, the Court considers "the effect of expediting delayed action on agency activities of a higher or competing priority." TRAC, 750 F.2d at 80 (fourth factor). Plaintiffs' central argument here is that mercury in seafood is a high-priority action for FDA, and there is thus no reason it cannot address their petition. The Administration, by its own admission, is "currently evaluating whether it should promulgate regulations to require that consumers be provided with additional information regarding mercury in fish and shellfish." Pl. Mot. at 14 (citing Ans., ¶¶ 16, 19, 52). Nothing stands in the way of addressing this priority, Plaintiffs maintain, because the Final Assessment and Draft Advisory support, without qualification, FDA's longstanding conclusion that women and children should choose lower-mercury fish. Id. at 12-13. Plaintiffs conclude, therefore, that acting on their request will do nothing to jeopardize FDA's other actions in this high-priority area.

In response, the Administration acknowledges that mercury is a high priority for the agency. It explains, however, that rushing a decision on Plaintiffs' detailed labeling recommendations at this juncture would force it to take action without due deliberation and would thereby draw resources from actually resolving issues related to mercury consumption. See Def. Mot. & Opp. at 27. Again, the Court finds this a sensible reason to wait in responding, considering that Plaintiffs' petition seeks to disseminate recommendations that are in the process of revision. The Court also notes that, by virtue of its very mission, FDA routinely faces daunting decisions about how to prioritize safety initiatives. Recent issues the agency has addressed include safety-oversight regulation in an increasingly globalized food industry, implementation of a new regulatory framework for infant formula, and upgrades to nutrition panels. See Landa Decl., ¶¶ 31-33. Due to its expertise, the Administration must be permitted flexibility in navigating the tough choices that come along with its expansive safety docket. See Sierra Club, 828 F.2d at 798 (noting EPA's "very broad mandate" but "finite resources"). The Court will, therefore, not second-guess FDA's "unique – and authoritative – position to view its projects as a whole, estimate the prospects for each, and allocate its resources in the optimal way." See In re Barr Laboratories, Inc., 930 F.2d 72, 76 (D.C. Cir. 1991) (refusing mandamus relief even where FDA had violated a statutory deadline, because so doing, although beneficial to the plaintiff, would likely impose offsetting burdens on other parties equally worthy of agency action). The fourth TRAC factor, accordingly, gives the Court further reason not to intervene.

* * *

In conclusion, the Court finds that – given FDA's contemporaneous efforts to address mercury in seafood and because the agency has provided a general endpoint in the future at which time it will be equipped to act on Plaintiffs' petition – the agency's delay does not warrant

judicial intervention at this juncture. This calculus may change, of course, once FDA and EPA finalize what is now their Draft Advisory on seafood consumption. At some point thereafter, further delay could well become unreasonable. The Court will not provide a precise timeline for action now, but it does urge FDA to act with alacrity once the task it has identified is completed.

IV. Conclusion

For the foregoing reasons, the Court will grant Defendants' Motion for Summary Judgment and deny Plaintiffs'. A separate Order so stating will issue this day.

/s/ James E. Boasberg
JAMES E. BOASBERG
United States District Judge

Date: November 21, 2014