UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

NATURAL RESOURCES DEFENSE COUNCIL, INC., BREAST CANCER PREVENTION PARTNERS, CENTER FOR ENVIRONMENTAL HEALTH, CENTER FOR FOOD SAFETY, ENVIRONMENTAL DEFENSE FUND, and ENVIRONMENTAL WORKING GROUP,	:	19-CV-10005 (VSB)
Plaintiffs,	:	**OPINION & ORDER**
- against -	:	
U.S. FOOD AND DRUG ADMINISTRATION, and ROBERT M. CALIFF, M.D., in his official capacity as Commissioner of the Food and Drug Administration,	:	
Defendants.	:	

Appearances:

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VERNON S. BRODERICK, United States District Judge:

Plaintiffs Natural Resources Defense Council, Breast Cancer Prevention Partners, Center for Environmental Health, Center for Food Safety, Environmental Defense Fund, and Environmental Working Group (together, "Plaintiffs") seek declaratory and injunctive relief against Defendants United States Food and Drug Administration ("FDA") and Robert M. Califf, M.D. ("Califf") in his official capacity as Commissioner of the Food and Drug Administration[1] (together, "FDA"). Specifically, Plaintiffs seek declaratory and injunctive relief with respect to the FDA's denial of Plaintiffs' citizen petition regarding a Threshold of Regulation ("TOR") exemption that allowed the inclusion of the chemical compound sodium perchlorate monohydrate in plastic food-contact articles. Currently before me are Plaintiffs' motion for summary judgment on the grounds that the FDA's denial of its citizen petition violated the Administrative Procedure Act ("APA") and the Food Safety Act ("the Food Act"), and the FDA's cross-motion for summary judgment arguing that the decision did not violate either act and that its agency expert judgments are entitled to deference. Because I find the FDA's decision denying Plaintiffs' citizen petition was neither arbitrary nor capricious in violation of the APA and did not violate the Food Act, the FDA's motion for summary judgment is GRANTED and Plaintiffs' motion is DENIED.

[1] By operation of Rule 25(d) of the Federal Rules of Civil Procedure, Califf, as the successor to Norman E. Sharpless, "is automatically substituted as a party."

I. Factual Background[2]

Sodium perchlorate monohydrate ("perchlorate") is a chemical compound used as an additive in plastic packaging and other food-contact articles[3] to reduce the buildup of static charges resulting from the movement of dry foods, like cereal, flour, and spices. (Compl. ¶ 2; FDA 1821.) If the accumulated static charge reaches a high enough level, it can produce a spark that can ignite the dust and powder created in dry foods and cause a dust explosion. (Compl. ¶ 53; FDA 2473.) The purpose of an antistatic agent such as perchlorate is to dissipate the charge that accumulates from the flowing dry food. (Compl. ¶ 54; FDA 1487–88, 3145.) Historically, perchlorate has also been used in rocket fuel, ammunition, fireworks, and explosives. (Compl. ¶ 58; FDA 1936.) Once ingested, perchlorates can disrupt the human endocrine system and can affect normal growth and development in fetuses, infants, and children. (FDA 1886, 1948, 2191, 2195–202.)

A. *Regulatory and Statutory Background*

The Food Act prohibits the introduction of any "adulterated" food into interstate commerce. 21 U.S.C. § 331(a). A food is "adulterated" if it contains an "unsafe" "food additive." *Id*. § 342(a)(2)(C)(i). A "food additive" includes "any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food (including any substance

[2] The following factual summary is drawn from the allegations in the Complaint ("Complaint" or "Compl."), (Doc. 1), and the administrative record cited by the parties, (Doc. 24, "Administrative Record" or "Record"). I will cite to the Record as "FDA" followed by the page number to comport with the page number stamping within the Record. The parties previously agreed that Local Rule 56.1 statements of undisputed material fact were not necessary, and that the facts could be drawn from the Record. (Doc. 21.) To the extent that I reference allegations within the Complaint, such references should not be construed as a finding as to their veracity, and I make no such findings.

[3] The term "food-contact article" under the FDA regulation includes "food-packaging or food-processing equipment." 21 C.F.R. § 170.39. Plaintiffs refer to all materials that contact food, including packaging and food-handling equipment, as "food-contact articles." (Doc. 1, at 2 n.1.)

intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food[].]" *Id.* § 321(s); *see also id.* § 348(h)(6) (defining the subset of food additives known as "food contact substance[s]"). A "food additive" is "deemed unsafe," and thus food containing the additive is "adulterated," *id.* § 342(a)(2)(C), unless a "regulation issued under this section prescribing the conditions under which such additive may be safely used" is "in effect," and "such substance and the use of such substance are in conformity with" that regulation, *id.* § 348(a)(3). The Food Act requires that the FDA, "[i]n determining . . . whether a proposed use of a food additive is safe," consider "the cumulative effect of such additive in the diet of man or animals, taking into account any chemically or pharmacologically related substance or substances in such diet." *Id.* § 348(c)(5)(B).

The FDA has also developed the TOR procedures for any food additive that migrates from a food-contact article to food itself at such low concentrations as to be "below the threshold of regulation." 21 C.F.R. § 170.39(a). Under this procedure, such food additives are not subject to the requirement under 21 U.S.C. § 348 that a food-additive regulation be in effect. (Compl. ¶ 39.) To qualify for a TOR exemption, the "use in question" must be "shown to result in" or "be expected to result in. . . . dietary concentrations at or below 0.5 parts per billion," ("ppb"), which the FDA calculates as "corresponding to dietary exposure levels at or below 1.5 micrograms/person/day (based on a diet of 1,500 grams of solid food and 1,500 grams of liquid food per person per day)." 21 C.F.R. § 170.39(a)(2)(i). Once a TOR exemption is in place, any manufacturer may use the substance in accordance with the exemption, and use of a substance in accordance with a TOR exemption is not limited to use by the entity that requested the exemption. *Id.* § 170.39(g). The FDA did not receive any public comments advocating for lower thresholds or expressing safety concerns with the agency's TOR exemption proposal.

(FDA 1368–69.)

On June 17, 2005, Ciba Specialty Chemicals Corporation ("Ciba") submitted a request for a TOR exemption allowing for the use of sodium perchlorate monohydrate in a packaging material to be known as Irgastat P18. (Compl. ¶¶ 68–69; FDA 3124–47.) The FDA issued TOR Exemption No. 2005-006 ("TOR Exemption"), (Compl. ¶¶ 68–69; FDA 3153–54), which authorizes the use of perchlorate as a conductivity enhancer in antistatic agents, at a maximum concentration of 4% in the antistatic agent and 1.2% by weight in the finished article, for use in contact with dry foods, (Compl. ¶ 70; FDA 3153–54).

B. *The FDA Studies*

Since 1961, and on an ongoing basis, the FDA has conducted the Total Diet Study, which is intended to monitor the U.S. food supply for, among other things, chemical contaminants. (Compl. ¶ 72.) In 2008, FDA scientists published a peer-reviewed study estimating dietary intake of perchlorate and iodine from its Total Diet Study samples collected in 2005 and 2006 ("2008 Study"). (*Id*. ¶ 76; FDA 1633–42 (Murray et al., US Food and Drug Administration's Total Diet Study: Dietary intake of perchlorate and iodine at 572 (2008)).) The 2008 study reported detectable levels of perchlorates in 59% of all samples analyzed, including detectable levels in at least one sample of 74% of all foods. (FDA 1637.)

On December 21, 2016, FDA scientists updated the 2008 study with a published, peer-reviewed analysis of the Total Diet Study samples collected from 2008 to 2012 ("2016 Study"). (Compl. ¶ 77.) On May 3, 2017, the FDA published a summary of the 2016 Study, including more detailed data, on its website ("2017 Report"). (*Id*. ¶ 78.) That study showed that samples of those same types of foods collected in the years following the FDA's approval of the TOR Exemption had higher levels of perchlorate contamination. (*See* Abt et al., Update on dietary

intake of perchlorate and iodine from U.S. food and drug administration's total diet study: 2008-2012, 28 J. Exposure Sci. & Enviro. Epidemiology 21 (2018) (published online Dec. 14, 2019).)

C. *Plaintiffs' Petition*

Any "interested person may petition the [FDA] Commissioner to issue, amend, or revoke a regulation or order, or to take or refrain from taking any other form of administrative action." 21 C.F.R. § 10.25(a). Such petition may take "the form for a citizen petition in [21 C.F.R.] § 10.30." *Id.* § 10.25(a)(2). A citizen petition is a public document available for comment at www.regulations.gov. *Id.* § 10.30(b)(1).

In 2014, Plaintiffs, along with a number of other nonprofit organizations, petitioned the FDA to reconsider and revoke the TOR Exemption and to promulgate a rule banning the use of perchlorate in food-contact materials. (Compl. ¶¶ 1, 7; FDA 1674–77.) On May 4, 2017, the FDA denied this petition. (Compl. ¶¶ 1, 8, 85; FDA 1883–2459.) On June 4, 2017, Plaintiffs filed objections to the FDA's denial. (Compl. ¶ 13; FDA 2463–92.) The FDA denied Plaintiffs' objections in April 2019. (Compl. ¶ 86; FDA 3109–12.) On April 24, 2019, the FDA sent Plaintiffs a letter elaborating on its reasons for the denial, and explaining that any objection that raises new information not included within the original petition could only be considered in connection with a new citizen petition. (FDA 3113–23.)

II. Procedural History

Plaintiffs initiated this action by filing the Complaint on October 29, 2019. (Doc. 1.) Plaintiffs sought relief based upon three assertions: (1) The FDA violated the APA by ignoring data from the Total Diet Study samples and its own analyses of that data, (2) the FDA violated the Food Act and the APA by failing to consider the cumulative effects of perchlorate in the diet, and (3) the FDA violated the APA by failing to account for foods contacting multiple

perchlorate-containing food-contact articles. (*See* Compl.) The FDA filed its Answer on January 13, 2020. (Doc. 19.) On February 14, 2020, the parties submitted a joint letter proposing a briefing schedule for cross-motions for summary judgment. (Doc. 21.) The parties agreed it was unnecessary for either party to file a Rule 56.1 Statement because the case would be decided on the administrative record. (*Id*.) On February 18, 2020, I ordered the parties' proposed briefing schedule. (Doc. 22.)

On February 21, 2020, the FDA filed the Administrative Record. (Doc. 24.) On March 18, 2020, Plaintiffs filed a motion for summary judgment, (Doc. 30), accompanying memorandum of law, (Doc. 31 or "Pl. Br."), and supporting declarations attaching both the 2016 Study and 2017 Report as exhibits, (Docs. 33–46.) On April 24, 2020, the FDA filed a single brief in support of its cross-motion for summary judgment and in opposition to Plaintiffs' motion. (Doc. 50 or "FDA Br.") On May 22, 2020, Plaintiffs filed a brief in opposition to the FDA's cross-motion and in reply in support of its motion for summary judgment, (Doc. 51 or "Pl. Reply"), along with a supporting declaration, (Doc. 52.) On June 12, 2020, the FDA filed its reply brief in support of its cross-motion. (Doc. 53 or "FDA Reply.")

III. Legal Standards

A. *Rule 56 Motion for Summary Judgment*

Under Federal Rule of Civil Procedure 56, summary judgment is appropriate when "the parties' submissions show that there is no genuine issue as to any material fact and the moving party is entitled to judgment as a matter of law." *Fay v. Oxford Health Plan*, 287 F.3d 96, 103 (2d Cir. 2002); *see also* Fed. R. Civ. P. 56(a). "When a party seeks review of agency action under the APA, the 'entire case on review is a question of law' such that 'judicial review of agency action is often accomplished by filing cross-motions for summary judgment.'" *Just*

Bagels Mfg., Inc. v. Mayorkas, 900 F. Supp. 2d 363, 372 (S.D.N.Y. 2012) (quoting *Connecticut v. U.S. Dep't of Com.*, No. 3:04cv1271 (SRU), 2007 WL 2349894, at *1 (D. Conn. Aug. 15, 2007)). Accordingly, "the usual Rule 56 summary judgment standard does not apply in such cases, because the court is resolving legal questions when it determines if the agency acted in excess of statutory authorization, not in accordance with law, arbitrarily and capriciously, or in some other way that violates 5 U.S.C. § 706." *New York v. U.S. Dep't of Health & Human Servs.*, 414 F. Supp. 3d 475, 516 (S.D.N.Y. 2019) (internal quotation marks omitted).

"Generally, a court reviewing an agency decision is confined to the administrative record compiled by the agency when it made the decision." *Id.* at 517 (internal quotation marks omitted). "When courts evaluate an agency's compliance with the APA, 'the focal point for judicial review should be the administrative record already in existence, not some new record made initially in the reviewing court.'" *Saget v. Trump*, 375 F. Supp. 3d 280, 340 (E.D.N.Y. 2019) (quoting *Camp v. Pitts*, 411 U.S. 138, 142 (1973) (per curiam)). The Court may, in reviewing an agency decision under the APA, consider materials not included in the administrative record "to the limited extent that [the agency] is alleged to have 'entirely failed to consider an important aspect of the problem.'" *New York v. U.S. Dep't of Com.*, 351 F. Supp. 3d 502, 635 (S.D.N.Y. 2019) (quoting *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983) ("*State Farm*")), *aff'd in part, rev'd in part and remanded sub nom. U.S. Dep't of Com. v. New York*, 139 S. Ct. 2551 (2019). Extra-record evidence may also be considered "for the limited purpose[] of ascertaining whether the agency considered all the relevant factors." *Asarco, Inc. v. EPA*, 616 F.2d 1153, 1160 (9th Cir. 1980)); *see also Nat'l Audubon Soc'y v. Hoffman*, 132 F.3d 7, 14 (2d Cir. 1997) (explaining that supplementation with extra-record materials "may be necessary when the record does not support the agency action,

when the agency has not considered all relevant factors, or when the reviewing court simply cannot evaluate the challenged action on the basis of the record before it"). However, the relevant factors "must do more than raise nuanced points about a particular issue; they must point out an entirely new general subject matter that the defendant agency failed to consider." *Pinnacle Armor, Inc. v. United States*, 923 F. Supp. 2d 1226, 1234 (E.D. Cal. 2013).

B. *The Administrative Procedure Act*

Under the APA, a reviewing court shall "hold unlawful and set aside" agency action that is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A). An agency decision is unlawful under the APA "if the agency has relied on factors which Congress has not intended it to consider," has "entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise." *State Farm*, 463 U.S. at 43. An agency's action must be upheld if it is "rational, based on consideration of the relevant factors, and within the scope of the authority delegated to the agency by the statute." *Id.* at 42–43. "Courts should be particularly reluctant to second-guess agency choices involving scientific disputes that are in the agency's province of expertise. Deference is desirable." *Browning-Ferris Indus. of South Jersey, Inc. v. Muszynski*, 899 F.2d 151, 160 (2d Cir. 1990).

Where an agency denies a citizen petition, courts apply a "very narrow and deferential scope of review." *Henley v. FDA*, 873 F. Supp. 776, 781 (E.D.N.Y. 1995) (internal quotation marks omitted), *aff'd*, 77 F.3d 616 (2d. Cir. 1996). The agency's denial "must be sustained if it violates no law, is blessed with an articulated justification that makes a rational connection between the facts found and the choice made, and follows upon a hard look by the agency at the

relevant issues." *Id.* (quoting *WWHT v. FCC*, 656 F.2d 807, 817 (D.C. Cir. 1981)) (internal quotation marks omitted). Deference to the agency is at its height when a decision is "propelled by the agency's scientific expertise." *Henley*, 77 F.3d at 620.

IV. Discussion

Plaintiffs argue that (1) the denial of the petition ignored the FDA's own studies demonstrating that the TOR Exemption resulted in higher levels of perchlorate contamination in certain dry foods; (2) the FDA shirked its duty under the Food Act and its own TOR Regulation to consider the cumulative effect regarding whether exposure to perchlorates would be safe in combination with exposure to perchlorates from other sources and similar chemicals; and (3) the FDA ignored the likelihood that dry food will contact many perchlorate-containing articles, increasing the levels of contamination in food and resulting exposure. (Pl. Br. 15.)

There are two issues that I do not analyze and resolve. First, Plaintiffs devote a portion of their argument in support of their motion to establish they have standing to challenge the FDA's decision denying their petition. (Pl. Br. 30–33.) The FDA does not contest Plaintiffs' standing. (FDA Br. 18 n.12.) Because, based on Plaintiffs' claims, Plaintiffs' members are at a heightened risk of unavoidably consuming perchlorates and suffering health problems as a result, and because the FDA does not challenge their standing, I assume—without analyzing—for purposes of this Opinion & Order that Plaintiffs have standing. *See Atl. States Legal Found., Inc. v. Eastman Kodak Co.*, 933 F.2d 124, 125 n.1 (2d Cir. 1991) (affirming the district court's granting summary judgment without analyzing standing after noting that the defendant did not challenge the not-for-profit group's members' standing to bring claims that they were affected by the defendant's discharged wastewater); *Richards v. Princeton Ins. Co.*, 178 F. Supp. 2d 386, 391 (S.D.N.Y. 2001) (determining that the plaintiffs had standing to bring an action for

declaratory relief given their assertions of injury and that the "[d]efendants d[id] not challenge [the p]laintiffs' standing"); *New York ex rel. Spitzer v. Cty. of Delaware*, 82 F. Supp. 2d 12, 14 (N.D.N.Y. 2000) (same). Second, the FDA's decision denying Plaintiffs' petition stated that "[b]ecause [it] conclude[d] that [the TOR Exemption] remains supportable under § 170.39, [it] decline[d] to propose a regulation under part 189 prohibiting this use of perchlorate." (FDA 1893.) Plaintiffs' motion does not raise any arguments specific to this portion of the FDA's decision and, because I find that the FDA's decision was not unlawful, I will not address that issue here.

A. *The FDA's Failure to Consider Its Own Studies*

Plaintiffs challenge FDA's denial of their petition based on the FDA's failure to consider two studies—the 2008 Study and the 2016 Study—authored by FDA scientists estimating the dietary intake of perchlorate in the food supply, and the related 2017 Report of survey data of perchlorate. (Pl. Br. 16–20.) Plaintiffs argue that, by ignoring the data from its own studies, the FDA failed to consider the "whole record" and "important aspects of the problem," and its denial of the petition and reaffirmation of the TOR Exemption was arbitrary and capricious. (*Id*. at 16.) The FDA contends that Plaintiffs did not include the 2016 Study or the 2017 Report in their citizen petition, and therefore, under the agency's regulations, it was not required to consider them. (FDA Br. 26–32.) The FDA also argues that the information in the studies and report was not new, and did not rise to the level of demonstrating an important aspect of the problem. (*Id*.)

1. Applicable Law

FDA regulations allow parties to challenge TOR exemptions, 21 C.F.R. § 170.39(g), by filing citizen petitions under the procedures codified at 21 C.F.R. § 10.30. The applicable record for a citizen petition is comprised of: (1) the petition, including all information on which it

relies; (2) comments received on the petition and the information on which they rely; and (3) the agency's decision on the petition and the information on which it relies. *Id*. § 10.30(i). A citizen petition must also include "[a] full statement . . . of the factual and legal grounds on which the petition relies, including all relevant information and views." *Id*. § 10.30(b)(3). This record "is the exclusive record for the [agency's] decision." *Id*. § 10.30(j). "A petitioner may supplement, amend, or withdraw a petition without Agency approval and without prejudice to resubmission at any time until the Commissioner rules on the petition." *Id*. § 10.30(g). "The record of the administrative proceeding closes on the date of the [agency's] decision." *Id*. § 10.30(j). Following the decision, petitioners may submit new information, such as "views not included in the administrative record," in connection with "a new petition to modify the decision." *Id*.

When reviewing an agency's decision, a district court must review the whole record. *WildEarth Guardians v. Salazar*, 670 F. Supp. 2d 1, 4 (D.D.C. 2009). The whole record is "the full administrative record" that was before the agency at the time of the decision. *Citizens to Preserve Overton Park v. Volpe*, 401 U.S. 402, 420 (1971), *abrogated on other grounds by Califano v. Sanders*, 430 U.S. 99, 97 (1977). The whole record includes only those materials considered by agency decisionmakers, whether directly or indirectly. *New York v. Dep't of Com.*, 351 F. Supp. 3d at 632; *WildEarth Guardians*, 670 F. Supp. 2d at 4. "In other words, the administrative record should not include materials that were not considered by agency decisionmakers." *Pac. Shores Subdivision Cal. Water Dist. v. U.S. Army Corps of Eng'rs*, 448 F. Supp. 2d 1, 4 (D.D.C. 2006) (quotation marks omitted). When reviewing an agency's action on a petition, "the 'record' for purposes of review need only include the petition[,] comments pro and con where deemed appropriate, and the agency's explanation of its decision to reject the petition." *WWHT, Inc. v. FCC*, 656 F.2d 807, 817–18 (D.C. Cir. 1981).

2. Application

a. Plaintiffs' Failure to Include the Studies in the Citizen Petition

In their papers filed in support of their motion for summary judgment, Plaintiffs do not contest that their petition was a citizen petition under 21 C.F.R. § 10.30 rather than their originally-styled Food Additive Petition under 21 U.S.C. § 348, and Plaintiffs concede they were therefore obliged to comply with the procedures codified at 21 C.F.R. § 10.30. (Pl. Br. 14.) Plaintiffs also do not contest that they did not submit the 2016 Study or the related 2017 Report as part of their citizen petition.[4] Plaintiffs did not supplement or amend their petition after the original filing to include the 2016 Study or the 2017 Report, which the FDA regulation deems proper for consideration. *See* 21 C.F.R. § 10.30(g). It was not until Plaintiffs submitted their objections to the FDA's denial of their petition that they raised for the first time the issue of the 2016 Study and the 2017 Report. (FDA 2464–67.) Importantly, the FDA regulation provides that "[t]he record of the administrative proceeding closes on the date of the [] decision," 21 C.F.R. § 10.30(j), so Plaintiffs missed the timeframe for the FDA to consider the 2016 Study and the 2017 Report.

As noted above, in addition to supplementing or amending a petition, the FDA regulation allows an additional route for an individual or organization to submit "views not included in the administrative record" through "a new petition to modify the decision." *Id.* § 10.30(j).

[4] The FDA does not contest that Plaintiffs relied in part on the 2008 Study in their petition, but Plaintiffs argue that the FDA still ignored it in its decision. (Pl. Br. 17 n.7.) This is not so. The FDA expressly referred to the "new information . . . that perchlorate contamination of the food supply is widespread" in its decision. (FDA 1893.) Further, the FDA noted that Plaintiffs' new information did not "support a conclusion that the [TOR Exemption] is no longer supportable." (*Id.*) It also squarely addressed the TOR Exemption's impact on infants and children. (FDA 1890.) These are precisely the issues raised in the study. (FDA 1633–46.) Applying a "very narrow and deferential scope of review" to the denial of a citizen petition, *Henley*, 873 F. Supp. at 781, it is apparent the FDA made a "rational connection between the facts found and the choice made" after taking a "hard look . . . at the relevant issues," *WWHT*, 656 F.2d at 817, and I will not second guess the agency's reasoning regarding the 2008 Study.

Plaintiffs failed to submit a new petition to put the 2016 Study and 2017 Report before the FDA, or to supplement or amend the petition. Based on the text of the FDA's regulations, the 2016 Study and 2017 Report mentioned in Plaintiffs' objections and brief in support of their motion for summary judgment are thus not part of the record and did not mandate consideration by the FDA in its denial of Plaintiffs' petition. *See New York v. Dep't of Com.*, 351 F. Supp. 3d at 632; *WildEarth Guardians*, 670 F. Supp. 2d at 4.

Plaintiffs nonetheless argue that, because the FDA was obviously aware of its own 2016 Study and 2017 Report, it failed to consider the whole record when assessing Plaintiffs' petition and subsequently denying it. (Pl. Br. 19.) The FDA concedes that it did not consider the 2016 Study and the 2017 Report. (*See* FDA Reply 5.) However, Plaintiffs' argument misses the point. Even if the FDA was aware of the 2016 Study and 2017 Report, it was not required to consider them if Plaintiffs did not include them in their petition. *See* 21 C.F.R. § 10.30(i); *id.* § 10.30(b)(3). Plaintiffs do not cite to case law that dictates otherwise. The 2016 Study and 2017 Report were thus not part of the "whole record" and the FDA's failure to consider them in its decision denying Plaintiffs' petition was not arbitrary or capricious.[5] *See WildEarth Guardians*,

[5] Plaintiffs cite a number of cases for the proposition that the "whole record" includes materials indirectly and directly considered by the agency. But those cases stand for the proposition that the "whole record" includes extra-record materials that the agency *did* consider, often indirectly. *See, e.g.*, *New York v. Dep't of Com.*, 351 F. Supp. 3d at 632 ("[T]he 'whole administrative record' mandated by the APA 'consists of all documents and materials directly or indirectly considered by agency decision-makers . . . .'"); *Ctr. For Native Ecosystems v. Salazar*, 711 F. Supp. 2d 1267, 1274 (D. Colo. 2010) (the court can "complet[e] the record" when there are "materials which were actually considered by the agency, yet omitted from the administrative record."); *Fund for Animals v. Williams*, 391 F. Supp. 2d 191, 198 (D.D.C. 2005) (court can order supplementation if the agency in bad faith excludes materials it relied on from the record); *Environmental Defense Fund, Inc. v. Blum*, 458 F. Supp 650, 660 (D.D.C. 1978) (remanding where agency excluded material from record that it "admit[ted] it relied on"). Plaintiffs' cases are inapposite because the FDA did not directly or indirectly consider information outside of the materials put forth in Plaintiffs' citizen petition pursuant to 21 C.F.R. § 10.30(i). To follow Plaintiffs' logic in applying those cases to the issue here would require agencies to consider every potentially applicable material to the petition, whether it is before the agency or not. As the FDA points out, this would require the FDA to launch into a factfinding mission that is not within the scope of the regulations that confine its duties, *see* 21 C.F.R. § 10.30, and would improperly shift the burden onto the agency to second guess its own agency decision, when the burden inherently lies with the party seeking relief. *See* 5 U.S.C. § 556(d) ("Except as otherwise provided by statute, the proponent of a rule or order has the burden of proof."); *Schaffer ex rel. Schaffer v. Weast*, 546 U.S. 49, 62 (2005) ("The burden of proof in

670 F. Supp. 2d at 4 (noting that "whole record" includes the "documents and materials that the agency directly or indirectly considered and nothing more nor less" (internal quotation marks omitted)).

b. The FDA's Failure to Consider the Studies as "New Information"

Plaintiffs' next argument is that the FDA should have revoked its TOR Exemption because the 2016 Study and 2017 Report were "new information" that raises questions about the safety of perchlorates. (Pl. Reply 6 (citing 21 C.F.R. § 170.39(g).) This argument fails for several reasons. First, the FDA regulation requires the information be new. *See* 21 C.F.R. § 170.39(g) ("If the [FDA] receives significant new information that raises questions about the dietary concentration or the safety of a substance that the agency has exempted from regulation, the [FDA] may reevaluate the substance."); *see also id.* § 189.1(c) (providing that the FDA may prohibit the use of a substance if "any interested person who has submitted a petition" brings to its attention "new scientific evaluation or information"). In their petition, Plaintiffs urged the FDA to revoke the TOR Exemption based on the information they put before the agency. Plaintiffs cannot now claim that the FDA must consider additional new material they did not proffer to the agency in their petition. Put simply, there is nothing in the regulations indicating that the "new information" need not accord with the regulation's explicit requirements regarding the information the FDA can consider when reviewing a citizen petition. *See* 21 C.F.R. § 10.30(i). (*See also* Section IV.A.) If Plaintiffs wanted to present the 2016 Study and 2017 Report as new information after-the-fact, they should have filed a new citizen petition pursuant to the regulations. *See id.* § 10.30(j). ("A person who wishes to rely upon information or views not included in the administrative record shall submit them to the Commissioner with a

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an administrative hearing challenging [an agency decision] is properly placed upon the party seeking relief.").

new petition to modify the decision in accordance with this section.")

Second, to require the FDA to consider any and all extra-record "new information" that is potentially applicable to the agency decision would flip the burden to the agency. Not only would this model be inefficient and unworkable, but it would conflict with the longstanding administrative structure. *See* 5 U.S.C. § 556(d) ("Except as otherwise provided by statute, the proponent of a rule or order has the burden of proof"); H. R. Rep. No. 1980, 79th Cong., 2d Sess., 34 (1946) ("[E]very proponent of a rule or order or the denial thereof has the burden of coming forward with sufficient evidence therefor . . . ."). A citizen petition provides the opportunity for an organization or individual to request that the agency take a specific action. Plaintiffs requested that the FDA revoke the TOR Exemption and issue a rule banning perchlorate's use in food-contact materials pursuant to 21 C.F.R. § 10.25(a). The burden is undoubtedly on the petitioner—in this case, Plaintiffs—to propose its requested form of relief and to provide the necessary supporting information.

Third, the regulations provide that, upon receiving new information, the FDA "may" reconsider its decision concerning the substance. *Id.* § 170.39(g), § 189.1(c). Even if Plaintiffs' argument had merit, this permissive language does not create a mandatory obligation on the FDA. *See, e.g.*, *United States v. Dist. Council of New York City*, 311 F. Supp. 3d 638, 643 (S.D.N.Y. 2018) ("[P]ermissive and broad language grants [an entity] discretion in deciding whether to act."). The FDA was not required to consider the 2016 Study and 2017 Report after Plaintiffs failed to properly present them with their citizen petition.

c. The Court's Consideration of Extra-Record Materials

In a final attempt to argue the FDA acted unlawfully, Plaintiffs urge that, even if the 2016 Study and 2017 Report were not part of the record before the FDA, I should nonetheless consider

"materials not included in the administrative record to the limited extent that [the agency] is alleged to have entirely failed to consider an important aspect of the problem." (Pl. Br. 17; Pl. Reply 10 (quoting *State Farm*, 463 U.S. at 43).) This argument still misses the mark, and is also inconsistent with the law. Extra-record evidence may only be considered "for the limited purpose[] of ascertaining whether the agency considered all the relevant factors."[6] (*Id.* at 7 (quoting *Asarco, Inc. v. EPA*, 616 F.2d 1153, 1160 (9th Cir. 1980)); *see also Nat'l Audubon Soc'y. v. Hoffman*, 132 F.3d 7, 14 (2d Cir. 1997) (supplementation with extra-record materials "may be necessary when the record does not support the agency action, when the agency has not considered all relevant factors, or when the reviewing court simply cannot evaluate the challenged action on the basis of the record before it."). However, the relevant factors "must do more than raise nuanced points about a particular issue; they must point out an entirely new general subject matter that the defendant agency failed to consider." *Pinnacle Armor*, 923 F. Supp. 2d at 1234. Plaintiffs claim those factors include the cumulative exposure of perchlorates and that the 2016 Study and 2017 Report demonstrate that the TOR Exemption itself increased perchlorate exposure. (Pl. Br. 17; Pl. Reply 7–9.) The FDA did consider the food supply's exposure based on migration from multiple perchlorate-containing articles, discussed in more detail *infra*; did address the cumulative exposure to the extent it was required to, also discussed in more detail *infra*; and did consider the TOR Exemption's impact on the presence of perchlorates in comparison to the presence reported in the 2008 Study, (*see* Section IV.A. n.2; *see also* FDA 1893.) Neither of these alleged "relevant factors" are "new general subject matter," nor were they areas the FDA failed to consider. *Pinnacle Armor*, 923 F. Supp at 1234;

[6] A party can also seek consideration of extra-record evidence to show the agency's "bad faith or improper behavior." *Hadwan v. United States Dep't of State*, 340 F. Supp. 3d 351, 355 (S.D.N.Y. 2018). Plaintiffs do not raise this possibility, and I therefore need not address it.

Nat'l Audubon Soc'y, 132 F.3d at 14. In sum, the FDA considered the information Plaintiffs put forth in their petition, but found, based on its agency expertise, that it need not revoke the TOR Exemption or issue a new rule.

Plaintiffs did not utilize any of the available appropriate mechanisms to create a posture for the FDA to properly consider the 2016 Study and 2017 Report. *See, e.g.*, 21 C.F.R. § 10.30(i); *id*. § 10.30(g); *id*. § 10.30(j). After numerous opportunities to comply with the FDA's regulations and include the information for its review, Plaintiffs cannot now change the rules of the game and claim that the FDA acted unlawfully in not considering its 2016 Study and 2017 Report.

B. *The FDA's Failure to Analyze the Cumulative Effects of Perchlorate*

Plaintiffs argue that the FDA failed to evaluate the cumulative effects of perchlorates introduced through the TOR Exemption in combination with perchlorates introduced from other sources and related substances. (Pl. Br. 24–30; FDA 1482.) Plaintiffs claim that this expressly conflicts with the Food Act's text, which requires the FDA to ensure the safety of food and food additives, and to evaluate the cumulative effects of food additives in combination with related substances, and is contrary to the TOR Regulation itself. (Pl. Br. 24–29.) Plaintiffs also contend the FDA's refusal to consider cumulative effects was arbitrary and capricious because it flouts the Act's primary purpose—"to protect the health and safety of the public at large." (*Id*. (citing *POM Wonderful LLC v. Coca-Cola Co.*, 573 U.S. 102, 108 (2014).) The FDA argues that it was exempt from the requirement to consider the cumulative exposure of perchlorate under 21 U.S.C. § 348 because it had already determined that the level of migration into food of perchlorate is negligible and does not present a public health or safety concern. (FDA Br. 20.) The FDA emphasizes that the TOR Regulation provides an alternative pathway to establish that a

substance does not present public health or safety concerns, distinct from the food additive petition process in the Food Act. (FDA Reply 12.)

1. Applicable Law

"[I]n determining . . . whether a proposed use of a food additive is safe, the [FDA] shall consider . . . the cumulative effect of such additive in the diet of man or animals[.]" 21 U.S.C. § 348(c)(5)(B). The D.C. Circuit recognized in *Monsanto Co. v. Kennedy*, 613 F.2d 947 (D.C. Cir. 1979) that Congress "intend[s] the [FDA] to determine with a fair degree of confidence that a substance migrates into food in more than insignificant amounts" before triggering 21 U.S.C. § 348. *Id.* at 955. In that case, the court allowed the FDA discretion to "determine based on the evidence before [it] that the level of migration into food of a particular chemical is so negligible as to present no public health or safety concerns, even to assure a wide margin of safety." *Id.* The D.C. Circuit reasoned that the "authority derives from the administrative discretion, inherent in the statutory scheme, to deal appropriately with De minimis situations." *Id.* *Monsanto* establishes that the FDA has discretion, based on its agency expertise, to issue a TOR exemption to decline to regulate a substance as a "food additive," and thus to not apply § 348, if it results in a de minimis presence in the food supply. *See C & K Mfg. & Sales v. Yeutter*, 749 F. Supp. 8, 12 (D.D.C. 1990) ("[O]ur Court of Appeals made clear that for the [definition of "food additive"] to be satisfied, the FDA Commissioner must 'determine with a fair degree of confidence that a substance migrates into food in more than insignificant amounts.'" (citing *Monsanto*, 613 F.2d at 955)); *Washington Red Raspberry Comm'n v. United States*, 859 F.2d 898, 903 (Fed. Cir. 1988) ("[An a]gency has the authority, deriving from administrative discretion inherent in the statutory scheme, to deal with *de minimis* situations and exempt food additives from regulation despite the strictly literal terms of the statutory definition" (citing *Monsanto*, 613 F.2d 947 at

955).).

2. Application

a. The Food Act

The holding in *Monsanto Co. v. Kennedy* aligns with the FDA's position that it has discretion to determine whether perchlorates would migrate into food in an insignificant and negligible amount so as to not present any safety concerns. 613 F.2d at 955. When promulgating the TOR Regulation, the FDA relied on its own agency expertise and scientific toxicological studies to set a threshold of regulation of 0.5 ppb to ensure there is no significant risk of exposure to potentially toxic levels of the substance. (FDA 747, 1368.) Applying *Monsanto*, the FDA has wide discretion to "determine based on the evidence before [it] that the level of migration" of perchlorate into the food supply "is so negligible as to present no public health or safety concerns, even to assure a wide margin of safety," thus making 21 U.S.C. § 348 inapplicable. 613 F.2d at 955. This approach has even been endorsed by Congress. *See* Food and Drug Administration Modernization Act of 1997, S. Rep. No. 105–43, 105th Cong., 47 (1997) ("The TOR approach to regulating food additives is a thoroughly developed public policy, which has been widely and publicly debated.").

Plaintiffs nonetheless argue that this interpretation squarely contradicts the Food Act's text. (Pl. Br. 25.) The Act creates a presumption that a food additive is unsafe unless it meets certain conditions. 21 U.S.C. § 348. Plaintiffs argue that § 348 applies because "additives" subject to the TOR process are still "food additives." (Pl. Br. 29.) This is inconsistent with *Monsanto*, which stands for the proposition that the FDA has authority, pursuant to the "statutory scheme," to decline to define a substance as a "food additive" where "the level of migration into food of a particular chemical is so negligible as to present no public health or safety concerns."

613 F.3d at 954–55. The FDA is correct that if the agency was forced to apply § 348 every time it issued a TOR exemption, all food-contact articles would be subject to the provisions under § 348. (FDA Br. 20.) Such application would produce an absurd result given the TOR Regulation's specific exemption of substances from regulation as a food additive. *See* 21 C.F.R. § 170.39(a) ("A substance used in a food-contact article (e.g., food-packaging or food-processing equipment) that migrates, or that may be expected to migrate, into food will be exempted from regulation as a food additive because it becomes a component of food at levels that are below the threshold of regulation . . . .") Application in this manner would eviscerate the TOR Exemption and make it meaningless. *Monsanto* reinforces this authority through the assertion that the FDA may "decline to define a substance as a food additive, though it comes within the strictly literal terms of the statutory definition." 613 F.2d at 956 (internal quotation marks omitted). Moreover, there is nothing in the text of the FDA regulations or in the Food Act mandating that the FDA consider the cumulative effects when issuing a TOR exemption.

b. The Food Act's Purpose

Plaintiffs next argue that the TOR Exemption contradicts the Food Act's purpose of "protect[ing] the health and safety of the public at large" because cumulative exposure to perchlorate could result in concentrations above 0.5 ppb. (Pl. Reply 16–18 (citing *POM Wonderful*, 573 U.S. at 108).) In doing so, Plaintiffs posit a number of policy arguments, together suggesting that several de minimis substances can add up cumulatively to a significant threat. (Pl. Br. 28; Pl. Reply 17–18 (arguing that perchlorate and other substances are unsafe at levels below 1,000 ppb).) This is an inherent challenge to the FDA's TOR Regulation itself, which is based on the agency's expertise and underlying scientific research and studies. (FDA 747, 1891.) Like with the FDA's 2016 Study and 2017 Report, discussed *supra*, Plaintiffs

cannot now challenge the FDA's TOR Regulation without having petitioned for amendment or rescission of the original regulation. (*See supra* Section IV.A.2.)

Upon promulgating the TOR Regulation, the FDA, based on its agency expertise and scientific toxicological studies, reasonably selected a threshold regulation of 0.5 ppb before the substance would even come close to certain toxicity levels. 21 C.F.R. § 170.39(a)(2)(i). (*See also* FDA 747, 1891.) In this way, the FDA set a threshold low enough that it need not consider cumulative exposure in every application for a TOR exemption. (FDA 3120.) If Plaintiffs want to challenge this decision as arbitrary and capricious, they should have lodged a challenge when the Regulation itself was promulgated or in a petition to modify the TOR Regulation, not after-the-fact in their challenge to the FDA's denial of their citizen petition. *See DiGiovanni v. FAA*, 249 F. App'x 842, 844 (2d Cir. 2007) ("[O]ur review is necessarily limited to the narrow issues as defined by the denial of the petition for rulemaking, and does not extend to a challenge of the agency's original action in promulgating the disputed rule." (emphasis omitted)). The FDA's reasoned agency judgment in coming up with the 0.5 ppb threshold should be owed deference based on its agency expertise and own toxicological studies. (FDA 747, 1891); *see also Henley*, 77 F.3d at 620 (deference to the agency is highest when the decision was "propelled by the agency's scientific expertise"). Moreover, the 0.5 ppb threshold has been considered a de minimis injury in other cases involving potentially toxic substances. *See, e.g.*, *In re Methyl Tertiary Butyl Ether (MTBE) Prod. Liab. Litig.*, No. 04 CV 2389 SAS, 2007 WL 1601491, at *7 n.57 (S.D.N.Y. June 4, 2007) ("As a result, this 0.5 ppb constitutes the *de minimis* threshold for an injury."); *Hercules, Inc. v. EPA*, 598 F.2d 91, 103 (D.C. Cir. 1978) (noting the EPA's designation of the short-term lethal dose for toxaphene as 0.5 ppb); *Conde v. Velsicol Chem. Corp.*, 804 F. Supp. 972, 1015 (S.D. Ohio 1992), *aff'd*, 24 F.3d 809 (6th Cir. 1994) (chlordane

metabolite levels of 0.5ppb were considered de minimis).

c. The TOR Regulation

Lastly, Plaintiffs argue that the TOR Regulation itself requires the FDA to consider the cumulative exposure. (Pl. Br. 29.) Plaintiffs point to 21 C.F.R. § 170.39(g), which states "[i]f the [FDA] receives significant new information that raises questions about the dietary concentration or the safety of a substance that the agency has exempted from regulation, the [FDA] may reevaluate the substance." The FDA is correct that this subsection does not mandate its evaluation of a TOR application; subsection (a) does that. *Id.* § 170.39(a). Indeed, subsection (a) provides that a substance "presents no other health or safety concerns" if, among other things, "[t]he use in question has been shown to result in . . . dietary concentrations at or below 0.5 ppb." *Id.* § 170.39(a)(2)(i). The TOR Regulation expressly states the well-reasoned threshold as the standard for safety based on the agency's toxicological studies and expertise, (*see* FDA 747, 1891), and Plaintiffs cannot circumvent that reasoning to compel their desired result by focusing on a separate section of the regulation in isolation. Even if Plaintiffs' argument was valid, the permissive language in subsection (g) does not mandate the FDA to reevaluate its decision concerning the substance. (*See supra* Section IV.A.2.a. ("[P]ermissive and broad language grants [an entity] discretion in deciding whether to act." (quoting *Dist. Council of New York City*, 311 F. Supp. at 638)).

Plaintiffs further argue the TOR Regulation's use of the phrase "dietary concentration" refers to total dietary concentration, which includes cumulative exposure. (Pl. Reply 13–14.) The TOR Regulation requires the FDA to consider dietary concentration that results from the "use in question" of a substance. *See* 21 C.F.R. § 170.39(a)(2)(i); *see also id.* § 170.39(a)(2)(ii) (in a related provision, requiring FDA to consider "dietary exposure to the substance resulting

from the proposed use"); *id.* § 170.39(c)(4) (requiring TOR applicant to provide "[d]ata that will enable the [FDA] to estimate the daily dietary concentration resulting from the proposed use of the substance"). There is nothing in the text of the regulations requiring the FDA to take the extra step of considering the cumulative exposure; rather, a plain reading of the text requires the FDA to consider the "use in question." *Id*. As previously established, the FDA can grant a TOR exemption if "[t]he use in question has been shown to result in or may be expected to result in dietary concentrations at or below 0.5 parts per billion." *Id*. § 170.39(a). The FDA concluded that "because of the conservative assumptions ordinarily applied in estimating exposure, the cumulative exposure from a limited number of trivial food additive uses is not likely to be more than negligible." (FDA 1891.) There is nothing that requires the FDA to consider cumulative exposure, and the FDA's determinations based on its studies have already spoken to the issue.

Plaintiffs' proposed actions would also result in the situation that *Monsanto* sought to avoid. *See* 613 F.2d at 955 ("Although as a matter of theory the statutory net might sweep within the term 'food additive' a single molecule of any substance that finds its way into food, the Commissioner is not required to determine that the component element of the definition has been satisfied by such an exiguous showing."). If the FDA were required to consider the total dietary concentration, it would be forced to deny every TOR exemption for a substance if it expects any molecule at level 0.5 ppb to migrate into the food supply, which is significantly below the toxicity level and clearly an absurd result. (*See* FDA 747 (the 0.5 ppb threshold is "2,000 times lower than the dietary concentration at which the vast majority of studied compounds are likely to cause noncarcinogenic toxic effects.").) The agency's scientific reasoning is sound, and I will not second-guess it, especially when the result would be unworkable. That reasoned agency judgment, based on scientific research and studies, (FDA 747, 1891), should be owed deference

and not disturbed on review. *See Kisor*, 139 S. Ct. at 2417 (deferring to the agency's interpretation on a question of ambiguous text in the rule, particularly when the agency has technical expertise in the subject matter); *Henley*, 77 F.3d at 620 (deference to agency should be highest when a decision was "propelled by the agency's scientific expertise").

C. *The FDA's Failure to Consider Multiple Contacts with Perchlorate-Containing Plastics*

Plaintiffs' final argument is that the FDA underestimated the rate at which perchlorate infects the food supply because it failed to consider that foods will likely come into contact with many perchlorate-containing plastics, rather than just the final packaging or container. (Pl. Br. 20–24.) This is significant because the TOR Exemption allows for the use of perchlorates not only in the ultimate packaging, but also in any "polymeric finished articles . . . used in contact with [certain foods.]" (FDA 3153–54.) Plaintiffs challenge Ciba's utilization of a "single-use protocol" in its TOR application to calculate the concentration of perchlorate that migrates from food-contact articles into the food supply. (FDA 1888.) When applying for the TOR Exemption, Ciba multiplied the maximum level of perchlorate allowed in the packaging, the FDA's recommended factor of migration of perchlorate from packaging into dry foods (50 ppb), and the FDA's recommended consumption factor for dry foods in polymer packaging. (FDA 3133). Ciba calculated the estimate was below the 0.5 ppb threshold. (*Id.*)

The FDA contends that it did not act arbitrarily or capriciously because it in fact took a more conservative approach using a single-use migration protocol rather than repeated-use migration protocol.[7] (FDA Br. 35.) The FDA further argues that it is required to consider the

[7] The parties go into great detail as to whether I can consider the FDA's April 24, 2019 letter explaining its reasoning for its denial of Plaintiffs' petition, (FDA 3113–23), including its defense of its use of the migration study, or whether the letter qualifies as a "post-hoc rationalization." (Pl. Br., at 13–14; FDA Br., at 23 n.15, 34 n.19; Pl. Reply, at 20–23; FDA Reply, at 21–23.) I find that the FDA's reasoning articulated in its decision denying Plaintiffs' petition is sufficient to find it did not act arbitrarily or capriciously, and I need not decide whether the

"use in question," and not the cumulative exposure. (*Id.*)

1. Applicable Law

FDA regulations allow a TOR exemption only if the substance in question is "expected to result in dietary concentrations at or below 0.5 parts per billion." 21 C.F.R. § 170.39(a)(2)(i). The FDA is obliged to ensure that "the substance is not harmful under the conditions of its intended use." *Id.* § 170.3(i). To estimate the dietary concentration of a food additive in the diet, the FDA advises TOR applicants to consider two variables: (1) the rate at which the substance is likely to "migrate" from food-contact articles into the food ("the migration protocol") and (2) the percentage of the total diet that those contaminated foods make up ("the consumption factor"). (*See* FDA 2347.) The FDA's recommended migration protocol for substances used in contact with dry foods is 50 ppb. (FDA 2358.)

2. Application

Plaintiffs argue that the FDA's reasoning underlying its migration study, which the FDA used to determine the levels of migration of perchlorate into the food supply and whether the resulting contamination fell within the threshold and did not pose a safety risk, is flawed. Plaintiffs argue the FDA should have modified the consumption factor, rather than the migration factor, in its study. (Pl. Br. 22–23.) Plaintiffs further assert that "nothing in the Petition Denial show[s] that FDA grappled with the reality that foods are likely to contact multiple perchlorate-containing materials." (Pl. Reply 19.) This is wrong. The FDA explained in its decision denying Plaintiffs' petition that its reasoning underlying the migration study actually provided an "exaggerative" estimate of the contamination and is therefore more protective. (*See* FDA 1888). In its denial of Plaintiffs' petition, the FDA described how it modified the migration study used

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letter is a post-hoc rationalization or otherwise improper for my consideration.

to justify the TOR Exemption "without the use of a consumption factor." (FDA 1890.) The decision stated that this approach "overestimates" the exposure from the use, which still falls well within the 0.5 ppb threshold and is therefore not a safety risk. (*Id*.) The FDA explained this approach is significantly more conservative because it "assumes that finished articles containing sodium perchlorate monohydrate will come into contact with all foods in a consumer's diet instead of coming into contact with just non-fatty, dry foods." (*Id*.) The approach "also assumes that all food will come into contact with articles containing [perchlorate] at the maximum allowed use level, which is a conservative assumption because it can be expected that not all finished articles would utilize the substance at the maximum allowed use level." (*Id*.) Even further, the FDA's migration study utilized the "food mass-to-surface area ratio assumption for consumer (single use) packaging," even though it can be expected that such articles "have a much larger food mass-to-surface area ratio than consumer packaging," resulting in a higher migration value.[8] (*Id*.) The FDA also articulated in its decision that exposure values from repeated-use articles "are typically very small" because those articles "come into contact with significantly larger amount of food over their service lifetime than individual single-use articles." (FDA 1889.) As with the FDA's other well-reasoned aspects of the decision and explanations, I defer to the agency's expertise. *See Henley*, 873 F. Supp. at 781 (review of a citizen petition is "very narrow and deferential" and denial "must be sustained if it violates no law, is blessed with an articulated justification that makes a rational connection between the facts found and the

[8] In other words, "exposure values from repeated-use articles are typically very small in comparison to single-use articles because individual repeated-use articles come into contact with significantly larger amounts of food over their service lifetime than individual single-use articles. This results in a much greater food mass-to-surface area ratio for repeated-use articles than the 10g of food contacting each square inch of food-contact article assumption for single-use articles. The greater food mass-to-surface area ratio for repeated use articles means that the total amount of migration of a substance from a given food-contact surface area (the migration value) is diluted across a much larger amount of food in comparison to a single-use article, resulting in a significantly lower dietary concentration." (FDA 1889.)

choice made, and follows upon a hard look by the agency at the relevant issues" (internal quotation marks omitted)).

Plaintiffs' argument again asks the FDA to consider the cumulative exposure of multiple uses in the food supply chain. As concluded earlier, the FDA is correct that it grants TOR exemptions based on the "use in question," 21 C.F.R. § 170.39(a)(2)(i), and, as it has explained in great detail, the agency reasonably articulated why it need not consider cumulative exposure based on the wide margin of safety embedded in the TOR Regulation. (*See* FDA 1891 ("the cumulative exposure from a limited number of trivial food additive uses is not likely to be more than negligible"); *Monsanto*, 613 F.2d 947; *see also supra* Section IV.B.)

As with the TOR Regulation and TOR Exemption, the FDA again reasonably concluded in its decision denying Plaintiffs' petition, based on its expertise and toxicological studies, (*see* FDA 747, 1891), that the application of the single-use migration protocol is more protective than Plaintiffs' proposal to calculate exposure when a substance is used in both single- and repeated-use articles. I will not second guess this well-reasoned and articulated agency conclusion based on its expertise. *See Browning-Ferris Indus.*, 899 F.2d at 160 ("Courts should be particularly reluctant to second-guess agency choices involving scientific disputes that are in the agency's province of expertise. Deference is desirable.").

V. Conclusion

Accordingly, because I find that the FDA's decision denying Plaintiffs' citizen petition was not arbitrary or capricious in violation of the APA, and did not violate the Food Act, Plaintiffs' motion for summary judgment is DENIED, and the FDA's motion for summary judgment is GRANTED.

The Clerk of Court is respectfully directed to terminate docket entries 30 and 49, and to close this case.

SO ORDERED.

Dated: April 12, 2022
New York, New York

Vernon S. Broderick
United States District Judge