

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA**

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STYRENE INFORMATION AND)	
RESEARCH CENTER, INC., and)	
)	
DART CONTAINER CORPORATION)	
)	
Plaintiffs,)	
)	
v.)	Civil Action No. 11-1079 (RBW)
)	
KATHLEEN SEBELIUS,)	
Secretary of United States Department of)	
Health and Human Services, and)	
)	
UNITED STATES DEPARTMENT OF)	
HEALTH AND HUMAN SERVICES,)	
)	
Defendants.)	
_____)	

MEMORANDUM OPINION

The plaintiffs, Styrene Information and Research Center, Inc. and Dart Container Corporation, seek declaratory and injunctive relief requiring the United States Department of Health and Human Services (“HHS”) to withdraw the Twelfth Annual Report on Carcinogens (“Report on Carcinogens”) with respect to the chemical styrene. Complaint (“Compl.”) ¶ 1. The plaintiffs assert claims under the Administrative Procedure Act (“APA”), 5 U.S.C. §§ 701-706 (2006); the Public Health Service Act (“PHSA”), 42 U.S.C. § 241 (2006); the Information Quality Act (“IQA”), 44 U.S.C. § 3516 (2006); and the Due Process Clause of the Fifth Amendment of the United States Constitution. Compl. ¶¶ 70-77. Currently before the Court is the plaintiffs’ Motion to Complete the Administrative Record and to Compel Discovery. Upon

careful consideration of the plaintiffs' motion, all related memoranda of law, and the administrative record ("A.R."),¹ the Court grants in part and denies in part the plaintiffs' motion.

I. BACKGROUND

The following facts are either undisputed or part of the administrative record. The Public Health Service Act requires the Secretary of HHS to publish a list of all substances known or reasonably anticipated to be carcinogens. 42 U.S.C. § 241(b)(4). Pursuant to this statutory directive, HHS's National Toxicology Program (the "NTP") prepares a biennial Report on Carcinogens. See 72 Fed. Reg. 18999 (Apr. 16, 2007). A substance under consideration for listing undergoes a multi-step review process. Compl. ¶ 25. First, the NTP publishes notice in the Federal Register, and prepares a draft background document reviewing the scientific literature and the public comments. Id. Next, a panel of scientific experts ("the Expert Panel") conducts a peer review of the background document and issues a report containing comments and a listing recommendation. Id. Based on the Expert Panel report and the public comments, the NTP prepares a draft Report on Carcinogens, and submits it to the Secretary of HHS for approval. Id.

On May 19, 2004, the NTP set this process in motion when it nominated the chemical styrene for listing in the Twelfth Report on Carcinogens. Compl. ¶ 29; 69 Fed. Reg. 28940 (May 19, 2004). Derived from petroleum and natural gas byproducts, styrene is used to manufacture a variety of consumer goods, including food containers. Compl. ¶ 11. After preparing a draft background document on styrene, based on publicly available scientific literature, the NTP

¹ In addition to the filings already identified, the Court considered the following submissions in rendering its decision: (1) the Memorandum in Support of Plaintiffs' Motion to Complete the Administrative Record and to Compel Responses to Plaintiffs' First Request for Production of Documents ("Pls.' Mem."); (2) the Defendants' Opposition to Plaintiffs' Motion to Complete the Administrative Record and to Compel Discovery ("Defs.' Opp'n"); and (3) the Plaintiffs' Reply to Defendants' Opposition to Plaintiffs' Motion to Complete the Administrative Record and to Compel Discovery ("Pls.' Reply").

convened an Expert Panel to peer-review the document on July 21 and 22, 2008. Id. ¶¶ 26, 37. The Expert Panel was divided into subgroups based on areas of expertise, with each subgroup drafting a section of the Expert Panel report. Defs.’ Opp’n at 10; see, e.g., Pls.’ Mem., Exhibit (“Ex.”) 2 (Styrene Expert Panel Report A) at 11 (including comments from “Subgroup 2”). The full panel then reviewed the subgroups’ reports and decided whether they should be rejected or incorporated into the final Expert Panel report, with or without modification. Defs.’ Opp’n at 10.

Ultimately, the Expert Panel voted 8-2 to recommend that “styrene . . . be listed in the [Report on Carcinogens] as reasonably anticipated to be a human carcinogen based on limited evidence of carcinogenicity in humans and sufficient evidence in animals.” Answer ¶ 38. Based on this recommendation, the NTP finalized the background document and proceeded to produce a draft substance profile on styrene for inclusion in the Twelfth Report on Carcinogens. Compl. ¶¶ 50-51. On June 10, 2011, HHS Secretary Kathleen Sebelius signed the final Twelfth Report on Carcinogens, which listed styrene. Id. ¶¶ 1, 69.

Later that same day, the plaintiffs instituted this action for declaratory and injunctive relief, seeking the withdrawal of the Twelfth Report on Carcinogens with respect to styrene. Id. at 1. The plaintiffs allege that HHS acted arbitrarily and capriciously in its procedures and substantive listing decision. Id. ¶ 1. The plaintiffs further allege, among other things, that the Expert Panel performed independent, non-peer-reviewed analysis rather than a peer review of publicly available scientific literature, id. ¶¶ 38-49; that the Expert Panel was biased, id. ¶ 39; that the NTP failed to weigh all relevant evidence, id. ¶¶ 56-59; and that the NTP’s conclusion that styrene is “reasonably anticipated” to be a human carcinogen is inconsistent with the findings of the Agency for Toxic Substances and Disease Registry (“ATSDR”), an operating

division of HHS, which findings were based on the same scientific evidence as the NTP's listing decision, id. ¶¶ 21, 24.

On August 9, 2011, the plaintiffs served on the defendants a request for production of documents which, in the plaintiffs' view, should have been included in the administrative record. Pls.' Mem., Ex. 4 (Plaintiffs' August 9, 2011 Letter Regarding the First Request for Production of Documents). In their letter in reply, the defendants refused to comply with the document request, noting that "discovery is generally inappropriate in record review cases." Id., Ex. 5 (Defendants' September 8, 2011 Letter in Reply to First Request for Production of Documents). Apparently seeking to fulfill their obligation to meet and confer as required by Local Civil Rule 7(m), the plaintiffs responded by e-mail on September 22, 2011, seeking to discuss the possibility of "limited discovery," despite the "definitive language in [the defendants'] letter." Pls.' Reply, Ex. A (Plaintiffs' September 22, 2011 E-mail) at 1. Four days later, and before receiving a reply to their September 22, 2011 e-mail, the plaintiffs filed the present Motion to Complete the Administrative Record and to Compel Discovery.

The plaintiffs' motion asserts that the defendants improperly excluded from the administrative record certain materials that were before the agency when it decided to list styrene in the Twelfth Report on Carcinogens. Pls.' Reply at 1. Specifically, the plaintiffs seek to "complete" the record with "(1) documents relating to the work performed by the various subgroups of the Expert Panel, (2) independent analyses conducted by the [NTP] or others of data from the studies reported in the [s]tyrene [b]ackground [d]ocument, [and] (3) documents relating to the [ATSDR's] Cancer Policy Chart and the Portier Letter." Id. at 1-2.² The plaintiffs

² The plaintiffs have withdrawn a fourth request for documents regarding the work performed by consultants on the styrene background document. Pls.' Reply at 2. Accordingly, the Court will address the plaintiffs' request for the foregoing three categories only.

contend that the subgroup reports, the independent analyses, and the ATSDR Cancer Policy Chart were considered by the agency in its listing decision, and hence were improperly excluded from the administrative record. See id. 6-10. The plaintiffs further argue that background documents relating to a letter by the director of the ATSDR, Dr. Christopher Portier (“the Portier Letter”), are unprivileged and discoverable because they were prepared as “collusive document[s] . . . as a defensive response to a letter from [p]laintiffs’ counsel.” Id. at 10-11.

The defendants oppose adding any of the requested documents to the record on several grounds. First, they argue that the motion should be summarily dismissed because the plaintiffs failed to confer with the defendants, “either in person or by telephone,” to discuss resolving discovery disputes, as required by Local Civil Rule 7(m).³ Defs.’ Opp’n at 1. Second, the defendants argue that supplementing the administrative record is inappropriate because the plaintiffs failed to allege bad faith or an improper agency motive that would justify including extra-record evidence. Id. at 5-6. Third, the defendants contend that some of the requested materials are already included in the administrative record. Id. at 13. Finally, the defendants argue that certain requested materials were properly excluded from the administrative record because they were not actually considered by the NTP, id. at 13, or because they are privileged deliberative documents, id. at 15-16.

II. STANDARD OF REVIEW

Section 706 of the APA governs judicial review of the Report on Carcinogens as mandated by the Public Health Service Act, 42 U.S.C. § 241 (2006). See Tozzi v. U.S. Dept. of

³ Local Civil Rule 7(m) requires that counsel confer with opposing counsel, either in person or by telephone, prior to filing any nondispositive motion. Full compliance “necessitates something more than an exchange of letters or a chain of e-mail correspondence.” Equal Rights Ctr. v. Post Props., Inc., 246 F.R.D. 29, 31 (D.D.C. 2007). While reliance on e-mail falls short of this requirement, the Court will not dismiss the plaintiffs’ motion on Rule 7(m) grounds, in the interest of judicial economy. Nonetheless, the Court admonishes counsel to pay greater heed to their duty to confer during the course of this litigation.

Health & Human Services, 271 F.3d 301, 310-11 (D.C. Cir. 2001). Ordinarily, judicial review under the APA is confined to “the full administrative record that was before the Secretary at the time he made his decision.” Citizens to Preserve Overton Park, Inc. v. Volpe, 401 U.S. 402, 420 (1971), abrogated on other grounds by Califano v. Sanders, 430 U.S. 99 (1977). The agency must compile for the court an administrative record that includes “all information it considered either directly or indirectly.” Marcum v. Salazar, 751 F. Supp. 2d 74, 78 (D.D.C. 2010); accord Bar MK Ranches v. Yuetter, 994 F.2d 735, 739 (10th Cir. 1993).

“[A]bsent clear evidence to the contrary, an agency is entitled to a presumption that it properly designated the administrative record.” Calloway v. Harvey, 590 F. Supp. 2d 29, 37 (D.D.C. 2008). However, in exceptional cases, this presumption of regularity may be rebutted and a court may either (1) supplement an incomplete record with materials that were before the agency and were considered directly or indirectly by the agency decisionmaker, or (2) permit the introduction of “extra-record evidence.” Marcum, 751 F. Supp. 2d at 78.

Supplementation of the record is appropriate in three circumstances: “(1) if the agency deliberately or negligently excluded documents that may have been adverse to its decision, (2) if background information was needed to determine whether the agency considered all the relevant factors, or (3) if the agency failed to explain administrative action so as to frustrate judicial review.” City of Dania Beach v. F.A.A., 628 F.3d 581, 590 (D.C. Cir. 2010) (citing American Wildlands v. Kempthorne, 530 F.3d 991, 1002 (D.C. Cir. 2008)) (internal quotation marks omitted). To rebut the presumption of regularity, the party seeking supplementation must “put forth concrete evidence that the documents it seeks to ‘add’ to the record were actually before the decisionmakers.” Marcum, 751 F. Supp. 2d at 78. Conclusory statements will not suffice; rather, the plaintiff “must identify reasonable, non-speculative grounds for its belief that the

documents were considered by the agency and not included in the record.” Id. (quoting Pac. Shores Subdivision Cal. Water Dist. v. U.S. Army Corps of Eng’rs, 448 F. Supp. 2d 1, 6 (D.D.C. 2006)) (internal quotation marks and emphasis omitted). “If an agency did not include materials that were part of its record, whether by design or accident, then supplementation is appropriate.” Id.; see also Natural Res. Def. Council, Inc. v. Train, 519 F.2d 287, 291 (D.C. Cir. 1975) (holding that review of a “partial and truncated record” by the district court was error and case remanded for review on the “entire administrative record”).

A separate standard governs extra-record evidence, which “consists of ‘evidence outside of or in addition to the administrative record that was not necessarily considered by the agency.’” Calloway, 590 F. Supp. 2d at 37 (quoting Pac. Shores, 448 F. Supp. 2d at 5). In Esch v. Yeutter, 876 F.2d 976, 991 (D.C. Cir. 1989), the District of Columbia Circuit stated that extra-record evidence was reviewable if it fell within one of eight exceptions.⁴ Since then, the Circuit appears to have narrowed these exceptions to four: (1) when the agency failed to examine all relevant factors; (2) when the agency failed to explain adequately its grounds for decision; (3) when the agency acted in bad faith; or (4) when the agency engaged in improper behavior. See IMS, P.C. v. Alvarez, 129 F.3d 618, 624 (D.C. Cir. 1997); see also Cape Hatteras Access Pres. Alliance v. U.S. Dep’t. of Interior, 667 F. Supp. 2d 111, 116 (D.D.C. 2009) (noting the Circuit’s narrowing of the Esch exceptions in its IMS decision). “Underlying all of these exceptions is the

⁴ Specifically, the court stated that consideration of extra-record evidence may be warranted in the following circumstances:

- (1) when agency action is not adequately explained in the record before the court;
- (2) when the agency failed to consider factors which are relevant to its final decision;
- (3) when an agency considered evidence which it failed to include in the record;
- (4) when a case is so complex that a court needs more evidence to enable it to understand the issues clearly;
- (5) in cases where evidence arising after the agency action shows whether the decision was correct or not;
- (6) in cases where agencies are sued for a failure to take action;
- (7) in cases arising under the National Environmental Policy Act; and
- (8) in cases where relief is at issue, especially at the preliminary injunction stage.

Esch, 876 F.2d at 991.

assessment that ‘resort to extra-record information [is necessary] to enable judicial review to become effective.’” Calloway, 590 F. Supp. 2d at 38 (quoting Esch, 876 F.2d at 991).

III. ANALYSIS

A. The Expert Panel Subgroup Reports

The plaintiffs seek to supplement the administrative record with reports prepared by the Expert Panel subgroups during the peer review of the NTP’s draft background document. Pls.’ Reply at 6. To implement the peer review process, the Expert Panel “divided itself into subgroups based on areas of expertise, and each subgroup drafted a section of the peer review report.” Id. These drafts were then “considered by the full panel and incorporated into the final version of the report, with any changes the full panel found appropriate.” Defs.’ Opp’n at 10. However, the full Expert Panel rejected certain subgroup draft reports and omitted these from the final report that it submitted to the NTP. See id. The plaintiffs argue that these rejected reports were “indirectly considered by the [d]efendants in the decision to list styrene.” Pls.’ Reply at 7. Essentially, the plaintiffs rely on a two-step theory of influence: the subgroup reports influenced the Expert Panel’s recommendation to the NTP, and in turn, the Expert Panel’s recommendation influenced the NTP’s decision to list styrene. Pls.’ Reply at 6-7. Thus, the plaintiffs contend that all of the subgroup reports should have been included in the administrative record. Id. at 8.

In response, the defendants argue that the NTP never considered the subgroup reports, because they were not included in the Expert Panel’s final report. Defs. Opp’n at 10. Reasoning that the subgroup reports were not before the NTP, the defendants contend that these reports would only be permissible extra-record evidence upon a “‘strong showing of bad faith or improper behavior’ or that the ‘record is so bare that it prevents effective judicial relief.’” Id. at 4 (quoting Commercial Drapery Contractors v. United States, 133 F.3d 1, 7 (D.C. Cir. 1998)).

The Court disagrees with the defendants. It appears that the subgroup drafts were an integral part of the Expert Panel's peer review process and influenced the Expert Panel's recommendation, upon which the NTP based its listing determination. The mere fact that the subgroup drafts were not ultimately passed on to the final decisionmaker does not lead to the conclusion that they were not before the agency. See Amfac Resorts, L.L.C. v. U.S. Dep't. of the Interior, 143 F. Supp. 2d 7, 12 (D.D.C. 2001) (observing that if the agency's final decision was based "on the work and recommendations of subordinates, those materials should be included as well"). Accordingly, the subgroup draft documents are not extra-record evidence, subject to the more exacting standards applied in the cases on which the defendants rely. Cf. Commercial Drapery, 133 F.3d at 7 (applying bad faith standard to broad discovery requests and extra-record affidavits); Coalition on Sensible Transp. v. Dole, 826 F.2d 60, 72 (D.C. Cir. 1987) (affirming denial of an "unlimited discovery" request for evidence that agency failed to consider certain impacts of highway widening). Rather, the plaintiffs' request for the subgroup reports should be reviewed under the less stringent standard for supplementation of the administrative record.

Under that standard, the plaintiffs have rebutted the "presumption of regularity" by presenting concrete evidence that the missing subgroup reports "were actually before the decisionmakers." Marcum, 751 F. Supp. 2d at 78. This finding is supported by the fact that the administrative record contains several references to omitted subgroup reports. E.g., Pls.' Mem., Ex. 2 (Styrene Expert Panel Report A) (referencing comments made by "Subgroup 2," discussing scientific literature, and making recommendations for the draft background document). In addition, part of one subgroup report was included in the record, as an attachment to the Expert Panel's report. Pls.' Mem. Ex. 6 (Attachment 1 to Section 4 Subgroup Report).

These references suggest that the Expert Panel substantively considered scientific information and advice contained in the subgroup reports, and was aware of the Expert Panel's reliance on this information and advice. Finally, the fact that the Expert Panel adopted some subgroup reports, but rejected others, lends some credibility to the plaintiffs' suggestion that the rejected reports may contain evidence adverse to the Expert Panel's recommendation to list styrene.

Because the subgroup reports influenced the Expert Panel report, and the Expert Panel report influenced the NTP's listing decision, the Court is satisfied that the NTP considered—at least indirectly—the subgroup reports. Access to the evidence that was considered and rejected by the Expert Panel would therefore assist the Court in conducting its arbitrary and capricious review under the APA. And it does not appear that adding the subgroup reports to the administrative record would be overly burdensome for the agency, as it already possesses the reports. In short, the plaintiffs have offered non-speculative grounds for their belief that the subgroup reports were considered by the agency, and that they contained pertinent scientific information. The Court will therefore order that the administrative record be supplemented with the missing subgroup reports.

B. The NTP's Independent Analyses of Data Reported in the Styrene Background Document

The plaintiffs also assert that the defendants improperly excluded unspecified independent analyses of data performed by the NTP or by its contractor. Pls.' Mem. at 8. During the peer review of the draft styrene background document, the Expert Panel received supplemental information from a contractor. *Id.*, Ex. 3 (Styrene Expert Panel Report A) (noting that “[d]uring the styrene review the contractor provided trend tests for several sites, which the Panel much appreciates.”). The Expert Panel also noted that some studies in the draft styrene background document “did not report significance values with as great precision as is of

interest.” A.R. at 1123. The Expert Panel observed that for some, but not all, of these studies, the NTP had performed its own “pairwise comparisons and trend tests” to report the statistical significance of findings of interest. Id. The Expert Panel recommended that the NTP perform such tests for all findings of interest. Id. In response, the NTP provided “trend tests” and reported the results in the styrene background document, placing them “in brackets to indicate [that they were] not contained in the original study.” Defs.’ Opp’n at 11-12; see, e.g., A.R. at 1124 (“In response to a request during the peer review . . . , [the] NTP provided for the sites in Table 4-1 the exact Cochran-Armitage trend tests.”).

The plaintiffs contend that the administrative record is incomplete because it contains only results, and not the NTP’s underlying statistical analyses. Pls.’ Mem. at 8. In response, the defendants argue that reporting the results is sufficient. Defs.’ Opp’n at 11. The distinction between the analyses and their results is immaterial, the defendants argue, because “the two tests for statistical significance referenced by the Expert Panel . . . are straightforward calculations that, . . . [are] never ‘shown’ in published studies.” Defs.’ Opp’n at 12. The defendants also attack the plaintiffs’ claim of missing calculations as speculative, contending that the NTP either performed a recommended analysis and reported its result, or explained its reasons for not doing so. See id. at 13.

The Court agrees that the plaintiffs’ request is speculative. In contrast to the request for the subgroup reports, the plaintiffs’ request for the NTP’s independent analyses lacks concrete detail and specificity. As a result, the Court finds that the plaintiffs have not rebutted the presumption that the agency properly designated the administrative record with respect to these documents.

The plaintiffs rely solely on several references in the Expert Panel’s report to tests performed by the NTP or its contractor. See Pls.’ Reply at 8. However, the defendants correctly note that the plaintiffs have not specifically identified a single “test that is missing or incorrectly calculated” out of the “551 scientific studies and other reports referenced in the [b]ackground [d]ocument.” Defs.’ Opp’n at 14. The plaintiffs’ non-specific request is similar to the supplementation request denied in Franks v. Salazar, 751 F. Supp. 2d 62, 73-74 (D.D.C. 2010). The plaintiffs in Franks challenged the Secretary of the Interior’s denial of elephant trophy import licenses. Id. at 66. Pointing to an e-mail from an outside biologist to an agency official alleging errors in the agency’s count of trophies taken from Mozambique, the plaintiffs sought all documents relating to these alleged errors. Id. at 72-73. The court held that supplementation was inappropriate because the plaintiffs failed to “offer[] nonspeculative grounds for their belief that the requested documents exist, much less that the Service considered them.” Id. at 73-74.

Here, the plaintiffs have failed to offer non-speculative grounds for believing that the NTP excluded any calculations without explanation, or that the NTP’s reporting of results is so inadequate that it impairs judicial review. The record shows that the NTP either performed the recommended calculations and reported the results, or explained why it did not. See A.R. at 1172-75. This record is therefore sufficient to determine whether the agency acted arbitrarily and capriciously. Thus, the plaintiffs’ request for the NTP’s independent analyses of data is denied.

C. Documents Relating to the Portier Letter and the ATSDR Cancer Policy Chart

Finally, the plaintiffs request that they be provided “all non-privileged documents relating to the ATSDR Cancer Policy Chart and the Portier Letter.” Pls.’ Reply at 11. Although the plaintiffs’ request for these documents was initially couched as a discovery request, Pls.’ Mem.

at 9, the plaintiffs request in their reply that documents be made part of the administrative record, Pls' Reply at 9. Accordingly, the Court will address these requests under the standards for supplementing the administrative record or for the inclusion of extra-record evidence.

1. Documents Relating to the Portier Letter

The plaintiffs seek to include in the administrative record “documents relating to the May 6, 2010 letter from Dr. Christopher Portier, Director of the [ATSDR,] to the Secretary of [HHS],” Pls.’ Mem. at 3, including “drafts of the letter, requests to Dr. Portier for a letter, and documents relating to consideration of the letter by Secretary Sibelius,” Pls.’ Mem., Ex. 4 (Request for Production of Documents) at 8. The Portier Letter is already included in the administrative record. See A.R. at 2301a. In that letter, Dr. Portier opines that the NTP’s decision to list styrene as “reasonably anticipated to be a human carcinogen” does not contradict the ATSDR’s November 2010 Toxicology Profile on Styrene, which found that styrene “may possibly be a human carcinogen.” Id.

Contending that the Portier Letter was drafted “to rebut arguments made to counsel for the Department of Health and Human Services,” the plaintiffs seek Dr. Portier’s drafts and other intra-agency correspondence in order to reveal the “reasons and basis for that letter.” Pls.’ Reply at 9-10. The defendants argue that any documents relating to the letter’s request, drafting, or consideration are shielded by the deliberative process privilege because they are part of the consultative process and reveal the Secretary’s mental processes. Defs.’ Opp’n at 14-15.

“Two requirements are essential to the deliberative process privilege: [1] the material must be predecisional and [2] it must be deliberative.” In re Sealed Case, 121 F.3d 729, 737 (D.C. Cir. 1997) (citations omitted). “[D]eliberative intra-agency memoranda and other such records are ordinarily privileged, and need not be included in the record.” Amfac Resorts,

L.L.C. v. U.S. Dep't of the Interior, 143 F. Supp. 2d 7, 13 (D.D.C. 2001). Documents that are predecisional and deliberative are excluded from the administrative record because, under arbitrary and capricious review, the reasonableness of the agency's action "is judged in accordance with its stated reasons." In re Subpoena Duces Tecum Served on Office of Comptroller of Currency, 156 F.3d 1279, 1279-80 (D.C. Cir. 1998). "[T]he actual subjective motivation of agency decisionmakers is immaterial as a matter of law—unless there is a showing of bad faith or improper behavior." Id.

The Court finds that the drafts of the Portier Letter and any correspondence relating to that letter are both predecisional and deliberative. First, the Portier Letter is dated May 6, 2010, and thus predates the signing of the Twelfth Report on Carcinogens on June 10, 2011. See Compl. ¶ 69; A.R. at 2301a. The plaintiffs mistakenly assert that the letter is not predecisional because its date falls five months after the release of the ATSDR's Toxicological Profile for Styrene. See Pls.' Reply at 9. However, as shown in the document itself, the letter was written in response to comments "by industry representatives in correspondence to the General Counsel" of HHS regarding the NTP's "proposed Report on Carcinogens," a proposal which was later adopted by the Secretary of HHS in the June 10, 2010 Report on Carcinogens. A.R. at 2301a; see also Judicial Watch, Inc. v. FDA, 449 F.3d 141, 151 (D.C. Cir. 2006) ("We deem a document predecisional if it was generated before the adoption of an agency policy"); Senate of Puerto Rico ex. rel. Judiciary Comm. v. United States, 823 F.2d 574, 585 (D.C. Cir. 1987) ("A document is 'predecisional' if it precedes, in temporal sequence, the 'decision' to which it relates."). Correspondence by agency staff with the Secretary of HHS that predated the June 10, 2010 Report is therefore predecisional.

Second, the documents' deliberative nature is apparent from the plaintiffs' request. The plaintiffs seek documents that reveal the Secretary's consideration of the letter and whether she requested it from Dr. Portier. See Pls.' Mem. at 9. This attempt to "probe the mental processes of the Secretary" is impermissible. United States v. Morgan, 313 U.S. 409, 422 (1941). As the Circuit has pointed out, disclosure of this type of intra-agency communication is likely to stifle the candor of consultations. See Russell v. Dep't of the Air Force, 682 F.2d 1045, 1048 (D.C. Cir. 1982) (noting that the privilege protects "creative debate and candid consideration of alternatives" (citation omitted)). And the plaintiffs' conclusory allegation that the Portier letter is a "collusive document" does not persuade the Court that the agency was acting in bad faith such that the agency's motives should be probed. Thus, the plaintiffs' request for access to deliberative documents relating to the Portier Letter is denied.

2. Documents Relating to the ATSDR Cancer Policy Chart

Finally, the plaintiffs seek to have included in the administrative record "[a]ll documents relating to" (1) "the creation of the ATSDR Cancer Policy Chart" ("the Cancer Policy Chart," "the chart"); (2) "any consideration of changing [the chart]; and (3) "any consideration, discussion, recommendation, or request to remove [the chart] from the ATSDR website." Pls.' Mem., Ex. 4 (Request for Production of Documents) at 8. The chart appeared as Appendix A of the ATSDR's 1993 Cancer Policy Framework. Compl. ¶ 21. It compares the various classification standards for carcinogenicity between several federal agencies, including the NTP. Pls.' Reply, Ex. E (Letter from Peter L. de la Cruz to Mark B. Childress, December 20, 2010, Enclosure B) at 22.

The plaintiffs claim that the chart demonstrates a contradiction between the NTP's and the ATSDR's carcinogenicity standards. Compl. ¶ 21. The plaintiffs also argue that the

documents relating to the chart were placed in issue by the defendants in their Opposition to Plaintiffs' Motion for a Preliminary Injunction, and that these documents should have been included in the administrative record. Pls.' Reply at 10-11. In response, the defendants argue that the requested documents are (1) extra-record evidence requiring a showing of bad faith or improper agency behavior, (2) irrelevant, and (3) privileged as deliberative documents. Defs.' Opp'n at 4, 16.

The Court must first determine whether the plaintiffs are requesting extra-record evidence or supplementary material that was actually before the agency. The plaintiffs do not allege that the NTP possessed any of the ATSDR's documents concerning the chart's creation in 1993, or that the NTP considered these documents in deciding to list styrene. The Court therefore agrees with the defendants that these documents, created by a separate agency, nearly twenty years ago, are extra-record evidence. Thus, receipt of these documents would require a "strong showing of bad faith or improper behavior," Commercial Drapery, 133 F.3d at 7, or an agency's failure to examine all relevant factors or explain adequately the grounds for its decision, IMS, 129 F.3d at 624.

The plaintiffs have not made this strong showing. First, they allege neither bad faith nor improper conduct. They instead argue that the defendants opened the door to extra-record review by referring to the ATSDR's Cancer Policy Chart in response to the plaintiffs' motion for a preliminary injunction. Pls.' Reply. at 10. Yet, the plaintiffs offer no legal support for the proposition that reference to documents in a litigation brief is a basis for extra-record review. Indeed, this proposition is inconsistent with the Supreme Court's instruction that "the focal point for judicial review should be the administrative record already in existence, not some new record made initially in the reviewing court." Camp v. Pitts, 411 U.S. 138, 142 (1973) (per curiam).

Second, the plaintiffs have not identified any specific factors that the agency failed to consider, and which might be illuminated by the documents relating to the Cancer Policy Chart. And, as the Portier Letter shows, the record already includes the agency's stated explanation for any apparent inconsistency between the NTP's carcinogenicity standards and those of the ATSDR. See Defs.' Opp'n at 14; A.R. at 2301a. Finally, the chart is self-explanatory and provides a sufficient basis for the Court to determine whether the NTP acted arbitrarily and capriciously in its interpretation of the terms "reasonably anticipated to be" and "may probably be." A.R. at 2301a. In sum, the plaintiffs have failed to rebut the presumption of regularity and failed to demonstrate that the administrative record is so bare that extra-record evidence is needed to make judicial review effective. The plaintiffs' request for inclusion of the documents relating to the ATSDR Cancer Policy Chart is accordingly denied.

IV. CONCLUSION

For the foregoing reasons, the Court concludes that the plaintiffs' motion to supplement the record must be granted in part and denied in part. Specifically, the motion is granted as to the plaintiffs' request for the subgroup reports of the Expert Panel. However, the plaintiffs' motion to supplement the record with the NTP's independent analyses and statistical calculations of data from the styrene background document must be denied. The Court also concludes that the plaintiffs' motion to supplement the record must be denied with respect to documents relating to the Portier Letter and the ATSDR Cancer Policy Chart as identified in the plaintiffs' document requests. See Pls.' Mem., Ex. 4 (Plaintiffs' First Request for Production of Documents) at 8-10.

SO ORDERED this 30th day of March, 2012.⁵

REGGIE B. WALTON
United States District Judge

⁵ The Court will contemporaneously issue an order consistent with this memorandum opinion.