

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

<hr/>)
STYRENE INFORMATION AND)
RESEARCH CENTER, INC., and)
)
DART CONTAINER CORPORATION,)
)
Plaintiffs,)
)
v.	Civil Action No. 11-1079 (RBW))
)
KATHLEEN SEBELIUS,)
Secretary, United States Department of)
Health and Human Services, and)
)
UNITED STATES DEPARTMENT OF)
HEALTH AND HUMAN SERVICES,)
)
Defendants, and)
)
UNITED STEEL, PAPER AND FORESTRY,)
RUBBER, MANUFACTURING, ENERGY,)
ALLIED INDUSTRIAL AND SERVICE)
WORKERS INTERNATIONAL UNION, et al.,)
)
Intervenor Defendants.)
<hr/>)

MEMORANDUM OPINION

The plaintiffs, Styrene Information and Research Center, Inc. (the “Styrene Center”) and Dart Container Corporation, bring this action under the Administrative Procedure Act (“APA”), 5 U.S.C. § 704 (2006), challenging the decision of the United States Department of Health and Human Services (“HHS”) to list the substance styrene in its Twelfth Report on Carcinogens. Complaint for Declaratory and Injunctive Relief (“Compl.”) ¶ 1. Currently before the Court are cross-motions for summary judgment filed by the plaintiffs; defendants HHS and Kathleen Sebelius, the Secretary of HHS (the “Secretary”); and intervenor defendants United Steel, Paper

and Forestry, Rubber, Manufacturing, Energy, Allied Industrial and Service Workers International Union, Environmental Defense Fund, and Peter Orris (the “Intervenors”).¹ Upon careful consideration of the parties’ submissions,² the Court concludes for the following reasons that the defendants’ motions must be granted, and the plaintiffs’ motion must be denied.

I. BACKGROUND

A. The Report on Carcinogens

The Public Health Service Act directs the Secretary to “publish a biennial report which contains . . . a list of all substances . . . which either are known to be carcinogens or may reasonably be anticipated to be carcinogens.” 42 U.S.C. § 241(b)(4) (2006). This so called “Report on Carcinogens” is an “informational scientific and public health document that identifies and discusses agents, substances, mixtures, or exposure circumstances . . . that may pose a hazard to human health by virtue of their carcinogenicity.” A.R. at 2467. The Report on Carcinogens is prepared by the HHS’s National Toxicology Program (“NTP”), which is staffed by scientists from three HHS components: the National Institutes of Health, the Centers for Disease Control and Prevention, and the Food and Drug Administration. Fed. Defs.’ Mem. at 3.

A substance under consideration for listing in the Report undergoes a four step review process. A.R. at 2472. First, the NTP nominates and selects candidate substances, announcing the nominees and soliciting public comments through notices in the Federal Register and NTP

¹ The Court will refer to HHS, the Secretary, and the Intervenors collectively as the defendants.

² In addition to the filings already identified, the Court considered the following submissions in rendering its decision: the Administrative Record (“A.R.”); the Plaintiffs’ Memorandum in Support of its Motion for Summary Judgment (“Pls.’ Mem.”); the Memorandum in Opposition to Plaintiffs’ Motion for Summary Judgment and in Support of Defendants’ Cross-Motion for Summary Judgment (“Fed. Defs.’ Mem.”); the Intervenor-Defendants’ Memorandum in Opposition to Plaintiffs’ Motion for Summary Judgment and in Support of Defendants’ and Intervenor Defendants’ Cross-Motions for Summary Judgment (“Intervenor Defs.’ Mem.”); Styrene Information and Research Center, Inc.’s Corrected Opposition to Defendants’ and Intervenor-Defendants’ Cross-Motions for Summary Judgment and Reply to Defendants’ and Intervenor-Defendants’ Oppositions to Plaintiffs’ Motion for Summary Judgment (“Pls.’ Opp’n”); the Reply in Support of Defendants’ Cross-Motion for Summary Judgment (“Fed. Defs.’ Reply”); and the Intervenor-Defendants’ Reply in Support of Defendants’ and Intervenor-Defendants’ Cross Motions for Summary Judgment (“Intervenor Defs.’ Reply”).

publications. Id. Second, after the candidate substances are selected, each substance undergoes a scientific review that entails “(1) preparation of [a] draft background document, (2) review by an expert panel at a public meeting, and (3) internal review by two independent federal committees.” Id. Third, the NTP—taking into consideration the listing recommendations of the expert panel, two other scientific review groups, and public comments—drafts substance profiles with listing recommendations for each candidate substance. A.R. at 2473. The draft substance profiles are then peer reviewed by the NTP’s Board of Scientific Counselors, which “prepares and submits a peer review report to the NTP that describes the nature and scope of its findings and conclusions concerning the NTP’s draft substance profiles.” Id. Fourth, the NTP responds to the Board of Scientific Counselors’ peer review report, drafts the next edition of the Report on Carcinogens, and transmits the final draft of the report to the Secretary for review and approval. Id. Upon being approved by the Secretary, the Report on Carcinogens is transmitted to Congress and disseminated to the public through notices in the Federal Register and NTP publications. Id.

In determining whether a substance is either “known” or “reasonably anticipated” to be a carcinogen and thus warrants listing in the Report on Carcinogens, the NTP applies the following criteria:

Known To Be Human Carcinogen:

There is sufficient evidence of carcinogenicity from studies in humans, which indicates a causal relationship between exposure to the agent, substance, or mixture, and human cancer.

Reasonably Anticipated To Be Human Carcinogen:

There is limited evidence of carcinogenicity from studies in humans, which indicates that causal interpretation is credible, but that alternative explanations, such as chance, bias, or confounding factors, could not adequately be excluded,

or

there is sufficient evidence of carcinogenicity from studies in experimental animals, which indicates there is an increased incidence of malignant and/or a combination of malignant and benign tumors (1) in multiple species or at multiple tissue sites, or (2) by multiple routes of exposure, or (3) to an unusual degree with regard to incidence, site, or type of tumor, or age at onset,

or

there is less than sufficient evidence of carcinogenicity in humans or laboratory animals; however, the agent, substance, or mixture belongs to a well-defined, structurally related class of substances whose members are listed in a previous Report on Carcinogens as either known to be a human carcinogen or reasonably anticipated to be a human carcinogen, or there is convincing relevant information that the agent acts through mechanisms indicating it would likely cause cancer in humans.

Conclusions regarding carcinogenicity in humans or experimental animals are based on scientific judgment, with consideration given to all relevant information. Relevant information includes, but is not limited to, dose response, route of exposure, chemical structure, metabolism, pharmacokinetics, sensitive sub-populations, genetic effects, or other data relating to mechanism of action or factors that may be unique to a given substance. For example, there may be substances for which there is evidence of carcinogenicity in laboratory animals, but there are compelling data indicating that the agent acts through mechanisms which do not operate in humans and would therefore not reasonably be anticipated to cause cancer in humans.

A.R. at 2468 (footnotes omitted).

B. The Listing of Styrene in the Twelfth Report on Carcinogens

On May 19, 2004, the NTP set in motion the above described review process by nominating twenty-one substances for listing in the Twelfth Report on Carcinogens (the “Report”). See 69 Fed. Reg. 28,940 (May 19, 2004). Among these candidate substances was styrene, id. at 28,943, a liquid derived from petroleum and natural gas byproducts that is used to manufacture a variety of consumer goods, Compl. ¶ 11. The NTP nominated styrene based on the International Agency for Research of Cancer’s finding “of limited evidence of

carcinogenicity in animals and limited evidence of carcinogenicity in humans” associated with styrene. 69 Fed. Reg. at 28,943.

After selecting styrene as a candidate substance, the NTP prepared a 405-page draft Background Document for the substance, which it released and solicited public comments on in May 2008. See A.R. at 419; 73 Fed. Reg. 29,139 (May 20, 2008). The draft Background Document did not opine on whether styrene should be listed in the Report; rather, it surveyed relevant scientific data on styrene, exploring topics such as human exposure, human cancer studies, studies of cancer in experimental animals, and toxicity. See A.R. at 443-45.

In July 2008, the NTP convened a panel of experts (the “Expert Panel”) to peer review the draft Background Document on styrene and recommend whether the substance should be listed in the Report. A.R. at 1110. After conducting this review, the Expert Panel recommended several revisions to the draft Background Document and voted 10-0 that the document, with the panel’s recommended changes, was “adequate for drawing conclusions about the carcinogenicity of styrene and for applying the [Report on Carcinogens] listing criteria.” A.R. at 1110-11. The Expert Panel further recommended, by a vote of 8-2, “that styrene . . . be listed in the [Report] as reasonably anticipated to be a human carcinogen based on limited evidence of carcinogenicity in humans and sufficient evidence in animals.” A.R. at 1697. The two members who voted against the panel’s decision did so because, in their opinion, “styrene should be listed as known to be a human carcinogen.” Id. The Expert Panel’s majority recommendation was based on the following considerations:

- (1) evidence of past and present human exposure to styrene in the United States;
- (2) evidence of cancer in styrene-exposed workers;
- (3) induction of lung tumors in mice by styrene by two routes of exposure;
- (4) the established carcinogenicity in animals and genotoxicity of a styrene metabolite, the 7,8-oxide;
- (5) evidence for styrene-related DNA adducts and cytogenetic effects in styrene-exposed workers.

Id.

Following the Expert Panel's July 2008 meeting, the NTP finalized the Background Document "based on the peer review recommendations of the expert panel and public comments received on the draft document." A.R. at 1194. The NTP also invited public comment on the Expert Panel's listing recommendation for styrene through a notice published in the Federal Register. 73 Fed. Reg. 52,059 (Sept. 8, 2008).

Next, the NTP convened two panels of scientists to review the body of knowledge relating to styrene (including the Background Document, the Expert Panel Report, and any public comments), and recommend a listing status for the substance. A.R. at 2473. The first of these panels, the Interagency Scientific Review Group, recommended by a vote of 6-2 "that styrene . . . be listed in the [Report] as Reasonably Anticipated to be a Human Carcinogen based on limited evidence in humans, sufficient evidence in experimental animals and supporting mechanistic data." A.R. at 1766. The two members who voted against the panel's decision did so because "they felt styrene should be listed as known to be a human carcinogen because of evidence in human cancer studies and mechanistic data (DNA adducts and chromosomal aberrations in humans)." Id. (emphasis added). The second panel, the National Institute of Environmental Health Sciences/NTP Scientific Review Group, recommended by a vote of 7-1 "that styrene . . . be listed in the [Report] as Reasonably Anticipated to be a Human Carcinogen based on limited evidence in humans, sufficient evidence in experimental animals and supporting mechanistic data." A.R. at 1773. The dissenting member of the panel "did not think the available evidence in experimental animals and humans [was] sufficiently convincing to list styrene in" the Report. Id.

The NTP then prepared a draft Substance Profile and listing recommendation for styrene, A.R. at 1779, taking into account the recommendations of the Expert Panel, the scientific review groups, and public comments, A.R. at 2473. It solicited public comments on the draft Substance Profile in December 2008. 73 Fed. Reg. 78,364 (Dec. 22, 2008).

In February 2009, the NTP convened another panel of experts, the Board of Scientific Counselors (the “Board”), to peer review the draft Substance Profile for styrene. See A.R. at 1799, 1814. Unlike the other expert review groups, the Board is not responsible for making a listing recommendation for candidate substances. A.R. at 2473. Rather, it is charged with determining “whether the scientific information cited in the draft substance profile for a candidate substance is technically correct, clearly stated and supports the NTP’s policy decision regarding its listing in the” Report on Carcinogens, after which it “prepares and submits a peer review report to the NTP that describes the nature and scope of its findings and conclusions concerning the NTP’s draft substance profiles.” Id. In the case of styrene, the Board’s findings and conclusions are set forth in the minutes of its February 2009 meeting. See A.R. at 1868-76, 1883.

After considering the Board’s peer review comments, the NTP revised and finalized the Substance Profiles to be listed in the Report. A.R. at 1883. The Secretary then approved the Report, including its listing of styrene, and released it to the public on June 10, 2011. 76 Fed. Reg. 36,923 (June 23, 2011). The Report lists styrene as “reasonably anticipated to be a human carcinogen based on limited evidence of carcinogenicity from studies in humans, sufficient evidence of carcinogenicity from studies in experimental animals, and supporting data on mechanisms of carcinogenesis.” A.R. at 2847.

On the same day the Secretary released the Report, the plaintiffs instituted this lawsuit. Plaintiff Styrene Center is a trade association whose membership comprises 95% of the North American styrene industry, and plaintiff Dart Container Corporation is a manufacturer of styrene-based products. Compl. ¶¶ 2-3. Their complaint challenges HHS's listing of styrene in the Report on the grounds that (1) the NTP failed to follow its own procedures in violation of the APA; and (2) HHS's actions in creating and reviewing the Report (a) contravened the Public Health Service Act, and (b) were arbitrary and capricious, not in accordance with law, and constituted an abuse of discretion, all in violation of the APA. Compl. ¶¶ 70-75. The plaintiffs further allege that HHS violated the Information Quality Act, 44 U.S.C. § 3516 note (2006), by constructively denying plaintiff Styrene Center's request for correction of information. Id. ¶¶ 76-77.

By Minute Order dated June 19, 2012, the Court granted the Intervenors' motion to intervene in this action as conceded, based on the parties' lack of opposition to the motion. See Local Civ. R. 7(b). The Intervenors consist of a union that represents workers who are exposed to styrene in the workplace, a non-profit organization that seeks to minimize the health and environmental risks of chemicals, and a doctor who specializes in occupational medicine. See ECF No. 42-1 at 5-6.

The parties have now filed cross-motions for summary judgment.

II. STANDARD OF REVIEW

“Summary judgment is the proper mechanism for deciding, as a matter of law, whether an agency action is supported by the administrative record and consistent with the APA standard of review.” Loma Linda Univ. Med. Ctr. v. Sebelius, 684 F. Supp. 2d 42, 52 (D.D.C. 2010) (citing Stuttering Found. of Am. v. Springer, 498 F. Supp. 2d 203, 207 (D.D.C. 2007), aff'd, 408

F. App'x 383 (D.C. Cir. 2010)); see also Richards v. INS, 554 F.2d 1173, 1177 & n.28 (D.C. Cir. 1977). But due to the limited role of a court in reviewing the administrative record, the typical summary judgment standards set forth in Federal Rule of Civil Procedure 56 are not applicable. Stuttering, 498 F. Supp. 2d at 207. Rather, “[u]nder the APA, it is the role of the agency to resolve factual issues to arrive at a decision that is supported by the administrative record, whereas ‘the function of the district court is to determine whether or not as a matter of law the evidence in the administrative record permitted the agency to make the decision it did.’” Id. (quoting Occidental Eng'g Co. v. INS, 753 F.2d 766, 769-70 (9th Cir. 1985)). In other words, “when a party seeks review of agency action under the APA, the district judge sits as an appellate tribunal,” and “[t]he ‘entire case’ on review is a question of law.” Am. Bioscience, Inc. v. Thompson, 269 F.3d 1077, 1083 (D.C. Cir. 2001) (footnote and citations omitted).

III. ANALYSIS

A. The Plaintiffs’ Challenge to the NTP’s Listing Criteria

The Court first turns to the plaintiffs’ assertion that the criteria applied by the NTP in listing styrene (“the Listing Criteria”) “were contrary to the Congressional mandate”—as stated in the Public Health Service Act and that statute’s legislative history—“that a substance be ‘reasonably anticipated to cause cancer in humans’ and not merely ‘suspected’ of doing so.” Pls.’ Mem. at 55-56. Although not explicitly framed as such, this claim presents a facial challenge to the Listing Criteria, insofar as the plaintiffs are contending that the criteria violate the Public Health Service Act as applied to any substance, not just styrene. See Intervenor Defs.’ Mem. at 15-16 (characterizing the plaintiffs’ claim as a facial challenge to the Listing Criteria); Pls.’ Opp’n at 23-25 (not disputing this characterization). The Secretary and Intervenors move for summary judgment as to this claim on several grounds, which the Court will address in turn.

1. Timeliness

The Intervenor Defendants argue that the plaintiffs' challenge to the Listing Criteria is time-barred. Intervenor Defs.' Mem. at 15. "Unless another statute prescribes otherwise, a suit challenging final agency action pursuant to section 704 [of the APA] must be commenced within six years after the right of action first accrues." Harris v. FAA, 353 F.3d 1006, 1009 (D.C. Cir. 2004) (citing 28 U.S.C. § 2401(a)). And a "right of action" under the APA "first accrues on the date of the final agency action." Id. (citation omitted). This limitation provision constitutes "'a jurisdictional condition attached to the government's waiver of sovereign immunity.'" P & V Enterps. v. U.S. Army Corps of Eng'rs, 516 F.3d 1021, 1026 (D.C. Cir. 2008) (citation omitted).

Construing the Listing Criteria as an HHS regulation, the Intervenor Defendants contend that the plaintiffs' claim accrued when HHS first promulgated the Listing Criteria in 1996.³ Intervenor Defs.' Mem. at 15-16. Because the plaintiffs filed suit in 2011, more than fifteen years after the Listing Criteria were promulgated and well outside of the APA's six-year limitation period, the Intervenor Defendants assert that the plaintiffs' claim is time-barred. Id. at 16. The plaintiffs respond that their claim is timely "[b]ecause the [L]isting [C]riteria were first applied to styrene just days before suit was filed." Pls.' Opp'n at 25. The Court agrees with the plaintiffs.

A "court will entertain challenges beyond a statutory time limit to the authority of an agency to promulgate a regulation . . . following enforcement of the disputed regulation." Cellular Telecomms. & Internet Ass'n v. FCC, 330 F.3d 502, 508 (D.C. Cir. 2003); see also P & V Enterps., 516 F.3d at 1026 ("[O]ur conclusion that P & V's facial challenge to the 1986 rule is untimely does not immunize the rule from all challenge: If the [agency] applies the rule to P &

³ The plaintiffs also treat the Listing Criteria as a regulation. See Pls.' Opp'n at 23 (characterizing the plaintiffs' attack on the Listing Criteria as a challenge "to the authority of an agency to promulgate a regulation." (emphasis added and citation omitted)). This characterization of the Listing Criteria is consistent with Circuit precedent. See Tozzi v. HHS, 271 F.3d 301, 311 (D.C. Cir. 2001) (treating the Listing Criteria as an "HHS regulation," in case where the petitioner did not argue otherwise).

V's property, . . . then P & V would be able to challenge the rule notwithstanding that the limitations period has run."); NLRB Union v. FLRA, 834 F.2d 191, 195-97 (D.C. Cir. 1987) ("An agency's regulations may be attacked . . . once the statutory limitations period has expired" when "a party who possesses standing . . . challenge[s] regulations directly on the ground that the issuing agency acted in excess of its statutory authority in promulgating them."). Underlying this principle is the rationale that "administrative rules and regulations are capable of continuing application," and thus "limiting the right of review of the underlying rule would effectively deny many parties ultimately affected by a rule an opportunity to question its validity." NLRB Union, 834 F.2d at 196 (citation omitted).

Here, it is undisputed that HHS first listed styrene in the Report on Carcinogens in June 2011. Nor is there any quarrel that the plaintiffs—a trade association representing the styrene industry and a manufacturer of styrene-based products—have been adversely affected by this application of the Listing Criteria to styrene. Under these circumstances, the plaintiffs may challenge the legality of the Listing Criteria, "notwithstanding that the limitations period has run." P & V Enterps., 516 F.3d at 1026. The Court therefore has jurisdiction to consider the plaintiffs' challenge to the Listing Criteria.

2. Exhaustion / Waiver

The Intervenors next assert that the plaintiffs failed to exhaust available administrative remedies for their claim challenging the Listing Criteria. Intervenor Defs.' Mem. at 16. "A party must first raise an issue with an agency before seeking judicial review." Tesoro Ref. & Mktg. Co. v. FERC, 552 F.3d 868, 872 (D.C. Cir. 2009) (citation omitted). This doctrine, which courts have interchangeably referred to as "issue exhaustion" and "issue waiver," recognizes that "[s]imple fairness . . . requires as a general rule that courts should not topple over administrative

decisions unless the administrative body . . . has erred against objection made at the time appropriate under its practice.” Advocates for Highway & Auto Safety v. Fed. Motor Carrier Safety Admin., 429 F.3d 1136, 1149-50 (D.C. Cir. 2005) (citation omitted). The doctrine applies both in the contexts of agency adjudication and rulemaking. See id. In the rulemaking context, the District of Columbia Circuit has provided the following articulation of the rule: “a party will normally forfeit an opportunity to challenge an agency rulemaking on a ground that was not first presented to the agency for its initial consideration.” Id. at 1150; see also Nat’l Mining Ass’n v. Dep’t of Labor, 292 F.3d 849, 874 (D.C. Cir. 2002) (declining to consider challenge to regulation because the petitioner “failed to raise it during the notice-and-comment period”); Nat’l Wildlife Fed’n v. EPA, 286 F.3d 554, 562 (D.C. Cir. 2002) (“It is well established that issues not raised in comments before the agency are waived and this Court will not consider them.”).

The parties do not contest that the plaintiffs were required to raise any issues concerning the Listing Criteria with HHS prior to seeking judicial review; instead, their disagreement concerns whether the plaintiffs did, in fact, raise their challenge to the Listing Criteria at the administrative level. See Intervenor Defs.’ Mem. at 16-17; Pls.’ Opp’n at 25-26. The record reveals that they did not.

Between 2004 and 2008, the NTP provided the public with four opportunities to comment upon the process of preparing the Report and the potential listing of styrene in the Report. See 69 Fed. Reg. 28,940 (May 19, 2004); 73 Fed. Reg. 29,139 (May 20, 2008); 73 Fed. Reg. 52,059 (Sept. 8, 2008); 73 Fed. Reg. 78,364 (Dec. 22, 2008). Although the plaintiffs submitted several comments in response to these invitations, at no point did they raise the argument currently being advanced—that the Listing Criteria violate the Public Health Service Act because they permit a substance to be listed as “reasonably anticipated to be a human

carcinogen” based on a “mere suspicion” of carcinogenic association. Pls.’ Opp’n at 30. Indeed, the plaintiffs’ arguments at the administrative level were directed not at the validity of the Listing Criteria themselves, but at the manner in which the NTP was applying those criteria. See A.R. at 15254 (“[O]ur reading of the legislative history of the [Report on Carcinogens] reveals the need for a more stringent interpretation of the criteria associated with the category ‘reasonably anticipated to be a human carcinogen’ than has been recommended by the staff in their review of styrene.”); see also A.R. at 2184-86; Pls.’ Opp’n, Appendix (Dec. 20, 2010 Letter). In fact, the plaintiffs previously made representations to the NTP and even this Court indicating their general approval of the Listing Criteria. See A.R. at 15254 (“[A] change in the way in which [the] criteria are interpreted and applied, consistent with the legislative history, is what [the Styrene Center] is suggesting, rather than a change in the criteria.” (emphasis added)); Memorandum of Points and Authorities in Support of Plaintiffs’ Motion for a Preliminary Injunction, ECF No. 3-1 at 12 (“The plain language of HHS’ policy correctly interpreted Congress’ mandate, but HHS failed to follow that policy.” (emphasis added)). Only now, in their summary judgment brief, do the plaintiffs directly challenge the Listing Criteria. This comes too late. Accordingly, because the plaintiffs failed to raise their claim challenging the lawfulness of the Listing Criteria with HHS prior to instituting this lawsuit, that claim is waived.

B. The Plaintiffs’ Procedural Challenges

The plaintiffs argue that the Report was issued “without observance of procedure required by law,” 5 U.S.C. § 706(2)(D), in violation of the APA for several reasons. As explained below, the Court finds none of the plaintiffs’ procedural challenges persuasive.

1. The Expert Panel's Alleged "Re-analysis" of Peer-Reviewed Data

The plaintiffs first argue that the Expert Panel⁴ improperly re-analyzed data found in publicly available, peer-reviewed studies, rather than simply reporting that data without alteration. See Pls.' Mem. at 38-42. This, in the plaintiffs' view, violated two procedural guidelines set forth by the NTP in the Report: one which states that certain data in the Background Document "must come from publicly available, peer-reviewed sources," A.R. at 2472, and another which directs the Expert Panel "to peer review the background document," not conduct a new analysis, A.R. at 2473. The defendants assert that this claim is unreviewable because it challenges "agency action . . . committed to agency discretion by law." 5 U.S.C. § 701(a)(2); see Fed. Defs.' Mem. at 28-29; Intervenor Defs.' Mem. at 33-34. The plaintiffs do not respond to this argument in their opposition brief, so it is conceded. See Lewis v. Dist. of Columbia No. 10-5275, 2011 WL 321711, at *1 (D.C. Cir. Feb. 2, 2011) (per curiam) ("It is well understood in this Circuit that when a plaintiff files an opposition to a dispositive motion and addresses only certain arguments raised by the defendant, a court may treat those arguments that the plaintiff failed to address as conceded.") (citation omitted).

However, even if the Court were to address the merits of the plaintiffs' claim, it would agree with the defendants' position. "[T]he APA explicitly excludes from judicial review those agency actions that are 'committed to agency discretion by law.'" Sierra Club v. Jackson, 648 F.3d 848, 855 (D.C. Cir. 2011) (quoting 5 U.S.C. § 701(a)). This exclusion applies both "in those rare instances where statutes are drawn in such broad terms that in a given case there is no law to apply," Citizens to Pres. Overton Park, Inc. v. Volpe, 401 U.S. 402, 410 (1971) (quotation

⁴ Recall that the Expert Panel was the first of the scientific panels involved in the listing review process; it was charged with peer reviewing the draft Background Document and making a listing recommendation for styrene. See supra at 5.

marks and citations omitted), abrogated on other grounds by Califano v. Sanders, 430 U.S. 99 (1979), and when “the statute is drawn so that a court would have no meaningful standard against which to judge the agency’s exercise of discretion,” Heckler v. Chaney, 470 U.S. 821, 830 (1985). “Agency actions in these circumstances are unreviewable because ‘the courts have no legal norms pursuant to which to evaluate the challenged action, and thus no concrete limitations to impose on the agency’s exercise of discretion.’” Sierra Club, 648 F.3d at 855 (citation omitted). “To determine whether a matter has been committed to agency discretion, [courts] ‘consider both the nature of the administrative action at issue and the language and structure of the statute that supplies the applicable legal standards for reviewing that action.’” Id. (citation omitted). “[J]udicially manageable standards may be found in formal and informal policy statements and regulations as well as in statutes.” Sec’y of Labor v. Twentymile Coal Co., 456 F.3d 151, 158-59 (D.C. Cir. 2006) (citation omitted). If, after reviewing all these sources, no “‘judicially manageable standards’ are discernable, meaningful judicial review is impossible, and agency action is shielded from the scrutiny of the courts.” Drake v. FAA, 291 F.3d 59, 70 (D.C. Cir. 2002) (quoting Chaney, 470 U.S. at 830).

The plaintiffs have not identified, nor does the Court discern, any “judicially manageable standards” against which the Court could evaluate the Expert Panel’s peer review process. The Public Health Service Act does not establish any particular procedures that HHS must follow in preparing the Report on Carcinogens. See 42 U.S.C. § 241(b)(4). And the HHS has promulgated no regulation establishing legal criteria for the Expert Panel’s peer review process. The only “standards” referenced by the plaintiffs are the Report’s statements that certain data in the Background Document “must come from publicly available, peer-reviewed sources,” A.R. at 2472, and that the Expert Panel is “to peer review the background document,” A.R. at 2473. See

Pls.’ Mem. at 38-41. But these statements do not provide sufficient criteria for the Court to review the plaintiffs’ claim; in fact, they raise more questions than they answer. What does it mean, for instance, for the Expert Panel to “peer review” a document, and how does the Court determine whether the Expert Panel exceeded the permissible bounds of that review in this case? No legal norms are available to guide the Court’s consideration of these questions. As a result, the Court cannot meaningfully review the plaintiffs’ claim that the Expert Panel conducted an improper re-analysis of peer-reviewed studies.

The plaintiffs suggest (but do not explicitly argue) that the Information Quality Act (“IQA”), 44 U.S.C. § 3516 note, and guidelines issued by the Office of Management and Budget (“OMB”) to implement the IQA, provide standards governing the Expert Panel’s peer review process.⁵ See Pls.’ Mem. at 17 & n.4; Pls.’ Opp’n at 18-19. However, as the defendants point out, several courts have held that “[n]either the IQA or the OMB Guidelines provide judicially manageable standards” because they vest agencies with unfettered discretion to determine “when correction of information contained in informal agency statements is warranted.” Salt Inst. v. Thompson, 345 F. Supp. 2d 589, 602 (E.D. Va. 2004), aff’d sub nom. on other grounds, Salt Inst. v. Leavitt, 440 F.3d 156 (4th Cir. 2006); accord Family Farm Alliance v. Salazar, 749 F. Supp. 2d 1083, 1095 (E.D. Cal. 2010) (holding that “[t]he IQA itself contains no standards concerning peer review, committing such matters to agency discretion,” and that “[t]he OMB IQA Bulletin for Peer Review specifically disclaims that its contents create any enforceable rights, thereby preserving the agency’s discretion to interpret and apply the OMB IQA Bulletin for Peer

⁵ The IQA directs the Director of the OMB to issue guidelines that

provide policy and procedural guidance to Federal agencies for ensuring and maximizing the quality, objectivity, utility, and integrity of information (including statistical information) disseminated by Federal agencies in fulfillment of the purposes and provisions of chapter 35 of title 44, United States Code, commonly referred to as the Paperwork Reduction Act.

44 U.S.C. § 3516 note (a).

Review”). The plaintiffs offer nothing to rebut this argument, so it is conceded. See Lewis, 2011 WL 321711, at *1. In any event, even without the plaintiffs’ concession, the Court would adopt the persuasive reasoning of the foregoing caselaw and conclude that the IQA and OMB guidelines do not provide judicially manageable standards.

Because the Court has “no law to apply” with respect to the plaintiffs’ claim challenging the Expert Panel’s purported re-analysis of peer-reviewed data, judicial review of this claim is precluded under 5 U.S.C. § 701(a).

2. The NTP’s Alleged Premature Finalization of the Background Document

The plaintiffs next contend that the Report was issued “without observance of procedure required by law,” 5 U.S.C. § 706(2)(D), because the NTP finalized the Background Document before the public comment period expired for a separate document issued by the Expert Panel. See Pls.’ Mem. at 41-42. As a threshold matter, it is unclear what Expert Panel document the plaintiffs are referencing because, much to the Court’s confusion, they inexplicably change positions in their briefs. In their opening brief, the plaintiffs argue that the NTP erred in finalizing the Background Document before the public comment period closed for the Expert Panel’s listing recommendation (Part B of the panel’s report). See id. at 41-42 (citing 73 Fed. Reg. 52,059 (Sept. 8, 2008) (notice soliciting public comments on the listing recommendation)). But then, in their opposition brief, the plaintiffs assert that the NTP erred in finalizing the Background Document before the public comment period closed for the Expert Panel’s peer review comments (Part A of the panel’s report). See Pls.’ Opp’n at 19-20. Since the plaintiffs’ opposition brief was filed later, the Court will construe that brief as stating their current position.

In claiming that the NTP prematurely finalized the Background Document, the plaintiffs do not assert that the NTP violated the notice and comment provisions of the APA or any other

statute; they instead argue that the NTP violated its own procedures as set forth in the Report. See Pls.’ Opp’n at 19-20. Specifically, they rely upon the following passage from the Report: “Following the expert panel meeting, NTP staff reviews and considers the expert panel’s peer review comments and any public comments as it finalizes the background document on the candidate substance.” A.R. at 2473 (emphasis added). According to the plaintiffs, the “fairest reading” of this review process is that (1) the NTP issues the draft Background Document; (2) the NTP convenes the Expert Panel and requests public comments, first on the draft Background Document and then on the Expert Panel’s peer review comments; and (3) based upon the public comments on both of these documents, the NTP finalizes the Background Document. Pls.’ Opp’n at 20.

The plaintiffs’ argument is not persuasive. Admittedly, the language they quote from the Report concerning the NTP’s consideration of “any public comments” during its finalization of the Background Document is ambiguous—it does not clarify what particular set of public comments it is referring to. But when considered in context, the Court finds that language refers to public comments on the draft Background Document, not the Expert Panel’s peer review comments. This reading makes the most sense because the NTP never even solicited public comments on the Expert Panel’s peer review comments. Thus, at the time the NTP finalized the Background Document, there were no public comments on the Expert Panel’s peer review comments available for the NTP to review. The NTP did, by contrast, solicit public comments on the draft Background Document. See 73 Fed. Reg. 29,139 (May 20, 2008). So the “any public comments” language most plausibly refers to those comments that the NTP had actually solicited—those concerning the draft Background Document.⁶

⁶ Insofar as the plaintiffs may be arguing that the “any public comments” language required the NTP to conduct another round of public comments specifically for the Expert Panel’s peer review comments, this argument likewise

Based on the representations made in their opening brief, the plaintiffs' real problem, it seems, is with the NTP's decision to stagger the public comment periods for the draft Background Document and the Expert Panel's listing recommendation, rather than have those periods coincide. See Pls.' Mem. at 41-42. While the plaintiffs may question the wisdom of this approach, they have not shown that the NTP failed to observe a "procedure required by law." 5 U.S.C. § 706(2)(D) (emphasis added). Accordingly, the Court rejects the plaintiffs' claim that the NTP prematurely finalized the Background Document.

C. The Plaintiffs' IQA Claims

In their complaint, the plaintiffs allege that HHS violated the IQA by constructively denying the Styrene Center's request for information correction. Compl. ¶ 77. The plaintiffs have not, however, raised any argument concerning this claim in their summary judgment briefs. The Court will therefore deem this claim abandoned. See Grenier v. Cyanamid Plastics, Inc., 70 F.3d 667, 678 (1st Cir. 1995) ("Even an issue raised in the complaint but ignored at summary judgment may be deemed waived."); Noble Energy, Inc. v. Salazar, 691 F. Supp. 2d 14, 23 n.6 (D.D.C. 2010) (same).

The plaintiffs also assert that HHS's listing of styrene violated the IQA's requirement that information disseminated by federal agencies be both objective and useful. See Pls.' Mem. at 54-55, 34. Perhaps recognizing the cases holding that the IQA "creates no legal rights in any third parties," e.g., Salt Inst., 440 F.3d at 159, the plaintiffs stress that they "do not seek to enforce the IQA," but rather assert that the "NTP's failure to comply with the IQA is further evidence that the [Report] is arbitrary, capricious or otherwise not in accordance with the law," Pls.' Mem. at 55. As explained above, however, the plaintiffs have conceded the defendants'

fails. Reaching this conclusion would require the Court to make a sweeping and unjustified inference, and there is no indication in the record that the NTP contemplated such a review process.

argument that the IQA provides no judicially manageable standards sufficient to enable judicial review, and that APA claims challenging noncompliance with the IQA are consequently unreviewable pursuant to 5 U.S.C. § 701(a). See supra at 16-17. This concession is fatal to the plaintiffs' hybrid APA-IQA claim.

D. The Plaintiffs' Arbitrary and Capricious Claim

The plaintiffs also assert that HHS's listing of styrene in the Report was arbitrary and capricious in violation of the APA. Before reaching the merits of this claim, the Court must address a preliminary matter concerning the scope of its review.

1. Scope of the Court's Review

The plaintiffs contend that the listing of styrene was arbitrary and capricious because the Secretary's decision was based on misleading and incomplete information contained in two memoranda from the Director of the NTP, Dr. Linda Birnbaum ("Birnbaum Memoranda").⁷ Pls.' Mem. at 42-43. The defendants respond that this argument improperly focuses on the mental processes of HHS decisionmakers rather than the agency's stated reasons for its decision. See Fed. Defs.' Mem. at 44-46; Intervenor Defs.' Mem. at 24-26. The Court agrees with the defendants.

"It is a widely accepted principle of administrative law that the courts base their review of an agency's actions on the materials that were before the agency at the time its decision was made." IMS, P.C. v. Alvarez, 129 F.3d 618, 623 (D.C. Cir. 1997). This review generally must be based on the "whole record"—no more or no less. See Overton Park, 401 U.S. at 420 ("[R]eview is to be based on the full administrative record that was before the [agency] at the time [it] made [its] decision." (emphasis added)); Walter O. Boswell Mem'l Hosp. v. Heckler,

⁷ The plaintiffs also contend that the Secretary was misled by a letter from Dr. Christopher Portier, Director of the Agency for Toxic Substances and Disease Registry, but they offer no argument as to why Dr. Portier's representations were misleading. See Pls.' Mem. at 42-53.

749 F.2d 788, 792 (D.C. Cir. 1984) (“If a court is to review an agency’s action fairly, it should have before it neither more nor less information than did the agency when it made its decision.”). There is no dispute here that the Birnbaum Memoranda were “before the agency” at the time of its decision; indeed, HHS acknowledged as much by including the memoranda as part of the administrative record. See A.R. at 2301b-g, 2301h-l. The memoranda are therefore within the universe of documents that the Court may consider in adjudicating the plaintiffs’ APA claim.

But that does not mean that the Birnbaum Memoranda will be determinative of the Court’s analysis. On the contrary, where, as here, there is a “contemporaneous explanation of the agency decision[,] . . . [t]he validity of the [agency’s] action must . . . stand or fall on the propriety of that finding, judged, of course, by the appropriate standard of review.” Camp v. Pitts, 411 U.S. 138, 143 (1973) (emphasis added). If the agency’s contemporaneous explanation is “not sustainable on the administrative record made, then the [agency’s] decision must be vacated and the matter remanded to [it] for further consideration.” Id. And because “the reasonableness of the agency’s action is judged in accordance with its stated reasons” under the arbitrary and capricious standard of review, “the actual subjective motivation of agency decisionmakers is immaterial as a matter of law—unless there is a showing of bad faith or improper behavior.” In re Subpoena Duces Tecum, 156 F.3d 1279, 1279 (D.C. Cir. 1998) (emphasis added); see also Overton Park, 401 U.S. at 420 (“[W]here there are administrative findings that were made at the same time as the decision,” any “inquiry into the mental processes of administrative decisionmakers is usually to be avoided,” absent a “strong showing of bad faith or improper behavior.”).

The “contemporaneous explanation” for the Secretary’s decision to list styrene in the Report is found in the Report itself, specifically in the substance profile for styrene, which

includes a summary of the evidence for styrene's carcinogenicity and citations to supporting data. See A.R. at 2470, 2847-55. Insofar as this document sets forth the stated reasons for the Secretary's decision to list styrene, it must be the focus of the Court's review, not the Birnbaum Memoranda.

In resisting this conclusion, the plaintiffs argue that the record shows that the Birnbaum Memoranda were prepared at the Secretary's request, and that the Report cites several of the studies discussed in the memoranda. See Pls.' Opp'n at 16. According to the plaintiffs, these factors suggest that the Secretary relied upon the Birnbaum Memoranda in deciding to list styrene in the Report, thus making the accuracy of the memoranda relevant to their APA challenge. Id. The problem with this argument is that the Report does not expressly reference the Birnbaum Memoranda, so the plaintiffs are effectively asking the Court to infer what documents the Secretary relied upon and the extent to which she relied on those documents in deciding to list styrene. Making this assessment would require the Court to speculate as to the Secretary's mental processes and her subjective motivations for the listing decision, which is forbidden by bedrock principles of administrative law absent a showing of bad faith or improper behavior.⁸ See Overton Park, 401 U.S. at 420; In re Subpoena Duces Tecum, 156 F.3d at 1279. The plaintiffs have made no such showing here.

The Court's conclusion is consistent with the case upon which the plaintiffs chiefly rely, National Small Shipments Traffic Conference, Inc. v. ICC, 725 F.2d 1442 (D.C. Cir. 1984). That case arose in the context of informal rulemaking. Id. at 1451. The petitioners claimed that staff at the Interstate Commerce Commission had improperly concealed from agency

⁸ The Court's conclusion might be different if the Secretary had expressly relied on analyses set forth in the Birnbaum Memoranda in support of the decision to list styrene. In that instance, the Court would not have to speculate about what role, if any, the memoranda played in the agency's decision because the memoranda would be incorporated by reference in the Secretary's final decision.

decisionmakers negative public comments concerning a study relevant to the rulemaking at issue. Id. at 1450. In addressing the legal consequences of this alleged conduct, the Circuit stated:

Under existing law, an agency decisionmaking body such as the Commission may delegate detailed consideration of the administrative record to its subordinates while retaining the final power of decision for itself. Rather than wade through the entire record personally, then, members of the body are free to rely on summaries prepared by agency staff. Because of the strong presumption of regularity in administrative proceedings, reviewing courts will not normally entertain procedural challenges that members of the body inadequately considered the issues before reaching a final decision, or that staff reports on which the body relied imperfectly summarized the record under review.

At some point, however, staff-prepared synopses may so distort the record that an agency decisionmaking body can no longer rely on them in meeting its obligations under the law. More particularly, in informal rulemaking employing notice-and-comment procedures, dependence on severely skewed staff summaries may breach the decisionmaker's statutory duty to accord "consideration" to relevant comments submitted for the record by interested parties. See 5 U.S.C. § 553(c) (1982). Certainly, if subordinates systematically eliminated from their reports all mention of record comments adverse to the agency's final action, the consideration requirement would not be satisfied unless the decisionmakers took independent steps to familiarize themselves with withheld portions of the record.

Id. at 1450-51 (emphasis added) (footnotes and some internal citations omitted). The court ultimately rejected the petitioners' procedural challenge because the record revealed that the "Commission members were thoroughly familiar with adverse comments in the rulemaking record," and, even assuming that they were not, the petitioners had "adduced no evidence suggesting bad faith or improper behavior on the part of ICC personnel." Id. at 1451-52.

Relying on the language from National Small Shipments emphasized above, the plaintiffs assert that the Birnbaum Memoranda were so misleading that they "distorted the record," such that the Secretary could not rely on them in discharging her statutory duties. Pls.' Opp'n at 15. Although the plaintiffs acknowledge that National Small Shipments arose in a different procedural context (i.e., informal rulemaking employing notice and comment procedures under §

553(c)) than this case, they contend that the court's rationale is equally applicable here because "reliance . . . on a skewed summary that fundamentally distorts the record is arbitrary, capricious and contrary to law." Id. at 15 n.8.

National Small Shipments does not help the plaintiffs for several reasons. First, despite the plaintiffs' argument to the contrary, it is not clear that the rationale of that decision applies outside the context of informal rulemaking under § 553(c). At most, the Circuit's analysis indicates that an agency's reliance on inaccurate summaries of public comments may violate § 553(c), which expressly directs agencies to "consider[]" public comments before adopting a rule. No similarly explicit statutory directive applies in the present context, and the plaintiffs present no basis for extending the Circuit's rationale to the facts of this case. Second, even assuming National Small Shipments applies in this context, that decision makes clear that courts should not entertain "procedural challenges that members of the body inadequately considered the issues before reaching a final decision, or that staff reports on which the body relied imperfectly summarized the record under review" absent "evidence of bad faith or other improper behavior." Id. at 1450 & n.11 (internal citations omitted); see also id. at 1452 ("Because [the petitioners] have adduced no evidence suggesting bad faith or improper behavior on the part of ICC personnel, petitioners have failed to establish their final procedural challenge."). As previously noted, the plaintiffs have offered no such evidence here. Finally, for the plaintiffs to prevail even under their reading of National Small Shipments, they would have to show that the Secretary relied on the Birnbaum Memoranda in deciding to list styrene. See id. at 1450-51 ("[S]taff-prepared synopses may so distort the record that an agency decisionmaking body can no longer rely on them in meeting its obligations under the law." (emphasis added)). As discussed above, the plaintiffs have failed to show such reliance in this case, and instead invite the Court to

undertake the impermissible task of speculating about the unstated bases for the Secretary's decision—an invitation the Court must decline.

For all of these reasons, the Court concludes that the plaintiffs' singular emphasis on the Birnbaum Memoranda is misguided, and that the focus of the Court's review must be the contemporaneous explanation for the Secretary's listing decision: the substance profile for styrene.

2. Whether the Listing of Styrene was Arbitrary and Capricious

Having framed the proper scope of its review, the Court finally turns to the question whether the Secretary acted arbitrarily and capriciously in listing styrene in the Report. "The 'arbitrary and capricious' standard of review as set forth in the APA is highly deferential," and the Court must "presume the validity of agency action." Am. Horse Prot. Ass'n v. Yeutter, 917 F.2d 594, 596 (D.C. Cir. 1990). Although the "court is not to substitute its judgment for that of the agency[,] . . . the agency must examine the relevant data and articulate a satisfactory explanation for its action including a rational connection between the facts found and the choice made." Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 43 (1983) (citations and quotation marks omitted). And where, as here, a court is reviewing an agency's evaluation of "scientific data within its technical expertise," the arbitrary and capricious standard of review is "extreme[ly] deferential." Nuclear Energy Inst., Inc. v. EPA, 373 F.3d 1251, 1289 (D.C. Cir. 2004) (citation omitted). This is because courts "review scientific judgments of the agency 'not as the chemist, biologist, or statistician that we are qualified neither by training nor experience to be, but as a reviewing court exercising our narrowly defined duty

of holding agencies to certain minimal standards of rationality.’”⁹ Troy Corp. v. Browner, 120 F.3d 277, 283 (D.C. Cir. 1997) (citation omitted).

The Secretary’s stated reasons for listing styrene in the Report—as set forth in styrene’s substance profile—more than satisfy these “minimal standards of rationality.” The Report lists styrene as “reasonably anticipated to be a human carcinogen based on limited evidence of carcinogenicity from studies in humans, sufficient evidence of carcinogenicity from studies in experimental animals, and supporting data on mechanisms of carcinogenesis.” A.R. at 2847 (emphasis omitted). Under the Listing Criteria, this finding justifies listing styrene as reasonably anticipated to be a human carcinogen on two, independent grounds: “limited evidence” of carcinogenicity in humans, and “sufficient evidence” of carcinogenicity in animals. See A.R. at 2468. As to this first ground, the NTP based its finding on “studies of workers exposed to styrene that showed (1) increased mortality from or incidence of cancer of the lymphohematopoietic system and (2) increased levels of DNA adducts and genetic damage in lymphocytes from exposed workers.” A.R. at 2847. As for the second ground, the Report relies on studies in which “[s]tyrene caused lung tumors in several strains of mice and by two different routes of exposure.” A.R. at 2849. The Report also provides a detailed discussion of mechanistic data in support of the decision to list styrene. See A.R. at 2849-50.

The plaintiffs have taken a scattershot approach in attacking the Secretary’s listing decision, with little discussion of the actual justification for the decision set forth in the substance profile for styrene. Insofar as the plaintiffs do attack that document, though, their arguments fall

⁹ The plaintiffs assert, for the first time in their opposition brief and without citing any case authority, that HHS’s listing of styrene is entitled to no deference because (1) the recommendations of the scientific review panels were not binding on HHS; (2) the listing process is biased toward approval; and (3) the scientific review was fractured and limited. See Pls.’ Opp’n at 2-7. Setting aside that these arguments were likely waived since they were not first presented to the agency, see Advocates for Highway & Auto Safety, 429 F.3d at 1149-50, none of the arguments present legal grounds for withholding deference to HHS’s scientific judgments.

flat. For instance, the plaintiffs contend that the substance profile for styrene misconstrues a 2006 study of men employed in the synthetic rubber industry conducted by Dr. Elizabeth Delzell and others (“Delzell Study”) as supporting the proposition that humans exposed to styrene face an increased risk of non-Hodgkin’s lymphoma. Pls.’ Opp’n at 10; see A.R. at 5088. Yet, contrary to the plaintiffs’ assertion, the Delzell Study’s abstract explicitly states that “[s]tyrene” was “associated positively with NHL [non-Hodgkin’s lymphoma].” A.R. at 5088. Consistent with this finding, the Report cites the Delzell Study along with two other studies in observing that “[i]ncreased risks for leukemia, lymphoma, or all lymphohematopoietic cancer were found among styrene-exposed workers in both the reinforced-plastics and styrene-butadiene rubber industries.” A.R. at 2847. The Court does not discern, nor do the plaintiffs explain, how this statement misconstrues the Delzell Study. And even if it did, that misconstruction would not be fatal to the Secretary’s listing decision because the substance profile cites several other studies (which the plaintiffs do not address) showing “[e]levated risks of lymphohematopoietic cancer” among workers exposed to styrene. See A.R. at 2847-49. The plaintiffs thus have not shown that the Report’s finding of “limited evidence for the carcinogenicity of styrene in humans,” A.R. at 2847, was arbitrary and capricious. Because this provides an independently sufficient basis to list styrene in the Report under the Listing Criteria, the Secretary’s listing decision can be upheld on this ground alone. See Casino Airlines, Inc. v. Nat’l Transp. Safety Bd., 439 F.3d 715, 717 (D.C. Cir. 2006) (“We have consistently held that ‘[w]hen an agency relies on multiple grounds for its decision, . . . we may . . . sustain the decision as long as one is valid and the agency would clearly have acted on that ground even if the other were unavailable.’” (citation omitted)).

The plaintiffs further assert that HHS’s application of the Listing Criteria was arbitrary and capricious because the scientists who participated in the Expert Panel and the Board of

Scientific Counselors each “relied on the data in his or her field of expertise in evaluating styrene” (i.e., epidemiologists analyzed the human data and animal pathologists analyzed the animal data), and there consequently was “no true consensus” on the ultimate decision to list styrene. Pls.’ Opp’n at 32, 4-5. But there is nothing arbitrary about having experts review only the data that they are qualified to analyze. And although the plaintiffs claim this process led to a lack of consensus regarding the ultimate listing decision, that argument overlooks the bifurcated nature of the Listing Criteria, which allows listing based on either “limited evidence” of carcinogenicity in humans or “sufficient evidence” of carcinogenicity in animals. See A.R. at 2468. Given these criteria, it was not arbitrary and capricious for HHS to have different scientists reviewing different sets of data during the listing review process.

In short, the Report provides a rational explanation for the Secretary’s decision to list styrene as a reasonably anticipated human carcinogen, and this explanation is adequately supported by the administrative record. The APA requires no more. Accordingly, the plaintiffs’ arbitrary and capricious challenge fails.

IV. CONCLUSION

For the foregoing reasons, the defendants’ cross-motions for summary judgment are granted, and the plaintiffs’ motion for summary judgment is denied.

SO ORDERED this 15th day of May, 2013.¹⁰

REGGIE B. WALTON
United States District Judge

¹⁰ The Court will contemporaneously issue an Order consistent with this Memorandum Opinion.