**No. 17-72260 and consolidated cases**

**UNITED STATES COURT OF APPEALS**
**FOR THE NINTH CIRCUIT**

SAFER CHEMICALS HEALTHY FAMILIES, ET AL.,

Petitioners,

v.

U.S. ENVIRONMENTAL PROTECTION AGENCY, ET AL.,

Respondents.

On Petition for Review of Action by the U.S. Environmental Protection Agency

# EPA'S RESPONSE IN OPPOSITION TO PETITIONERS' MOTION TO "COMPLETE" THE ADMINISTRATIVE RECORD OR FOR JUDICIAL NOTICE

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## INTRODUCTION

The rules governing judicial review of agency actions are well-established. "The task of the reviewing court is to apply the appropriate [Administrative Procedure Act ("APA")] standard of review to the agency decision based on the record the agency presents" to the court. *Fla. Power & Light Co. v. Lorion*, 470 U.S. 729, 743-44 (1985) (citation omitted). The administrative record consists of the documents directly or indirectly considered by the agency in reaching its decision. However, documents that reflect an agency's deliberative process and documents that were not considered in forming the rule in question are excluded. This is because APA review requires the Court to judge the agency's action based on its stated rationale; the decision-maker's subjective intent and mental processes are irrelevant to the validity of an agency action. An agency's certified record is entitled to a presumption of regularity absent narrow extraordinary circumstances.

In September 2017, the United States Environmental Protection Agency ("EPA") compiled robust and distinct records for each of the two agency actions under review—the Prioritization Rule[1] and the Risk Evaluation Rule[2]—and recently amended the certified indices to include certain pre-proposal comments

[1] "Procedures for Prioritization of Chemicals for Risk Evaluation Under the Toxic Substances Control Act," 82 Fed. Reg. 33,753 (July 20, 2017).

[2] "Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act," 82 Fed. Reg. 33,726 (July 20, 2017).

that had been inadvertently overlooked. Now, over seven months after receiving the indices and on the same day they submitted their opening merits brief, Petitioners Safer Chemicals Healthy Families et al. have moved to expand both records or for the Court to take judicial notice, attaching 27 additional documents. *See* Petrs.' Mot. at Marks Exs. 1-24, Gartner Exs. 1-3, ECF No. 43-1.

None of the 27 documents attached to the Motion are part of the administrative records for either Rule because they were not considered by EPA. Many of these documents reflect pre-decisional deliberations within EPA and the Executive Branch. Others are simply irrelevant to the content and validity of the Rules, as Petitioners themselves concede by not relying on them in support of their merits brief arguments. Several of these, such as a personnel-related document and Petitioners' late-filed comment letter, appear to have been included in the Motion solely to attempt to color the Court's impression of an EPA employee. And Petitioners fail to raise *any* arguments (or to have conferred with EPA) about why 13 of these documents should be included in the records, despite citing several of these in their merits brief. The Court should deny Petitioners' Motion.

## BACKGROUND

### I. Factual and procedural background.

In these consolidated cases, Petitioners each seek judicial review of two final agency actions under the amended Toxic Substances Control Act ("TSCA"), 15

U.S.C. § 2605(b)(1). EPA's Prioritization Rule establishes the process EPA will use to identify chemicals as either high or low priority for purposes of conducting risk evaluations. The Risk Evaluation Rule establishes the process for conducting risk evaluations to determine whether individual chemicals present an unreasonable risk of injury to health or the environment under the chemicals' conditions of use, as required by section 6(b)(4) of TSCA, 15 U.S.C. § 2605(b)(4). The six original challenges to the Rules were eventually consolidated in this Court. *See* Transfer Order (4th Cir.) No. 17-1926, ECF 63 (Dec. 11, 2017).

In September 2017, while the cases were still pending in separate Courts of Appeals, EPA prepared and certified two administrative records, one for each Rule, containing the documents it considered in forming them. Notice of Certified Index to the Prioritization Rule, ECF 16-1; Notice of Certified Index to the Risk Evaluation Rule, No. 17-1926, ECF 28-1 (4th Cir., Sept. 20, 2017). These records include, for example, the extensive public comments EPA received as well as technical support documents. *See id*.

Seven months later, Petitioners informed EPA that they planned to move to supplement the two records to include the documents listed as Marks Exhibits 1-14, as well as certain pre-proposal comments on EPA's public docket. Upon review, EPA realized that the pre-proposal comments had been inadvertently overlooked because they resided in a separate docket folder than the comments on

the proposed rules, and corrected the error by informing Petitioners and amending the certified indices. Notice of Filing Supplemental Certified Indices, ECF 52. Petitioners did not confer with EPA about the documents listed as Marks Exhibits 15-24 or Gartner Exhibits 1-3. *See See* Cir. R. 27-1(5); Exs. A-B.

On April 16, 2018, Petitioners moved to "complete" the administrative records or, in the alternative, for judicial notice of certain of the documents. Petrs.' Mot., ECF 43. That same day, Petitioners filed their opening merits brief, citing some—but not all—of the documents attached to their Motion.[3] Petrs.' Br., ECF 44. Several of the documents Petitioners claim should be part of the records are not referenced in Petitioners' merits arguments, and others they do rely upon were not the subject of their required conferral with EPA or any arguments in their Motion about why the documents should be considered by this Court. *See generally* Petrs.' Br.

## II. The standard and scope of review of final agency actions.

Under the APA, EPA's action must be upheld unless it is found to be "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A). "The task of the reviewing court is to apply the . . . APA standard of review to the agency decision based on the record the agency

[3] Where Petitioners' merits brief cites documents attached to their Motion, the citations have a "MA" bates label prefix. *See* Petrs.' Br. at 14.

presents to the reviewing court." *Fla. Power & Light Co.*, 470 U.S. at 743-44 (citation omitted); *see also* 5 U.S.C. § 706.

The administrative record means documents "on which the administrative decision was based" and includes "all documents and materials directly or indirectly *considered* by agency decision-makers" in making the decision. *Thompson v. Dep't of Labor*, 885 F.2d 551, 555 (9th Cir. 1989) (emphasis altered) (internal quotation marks omitted). The relevant record is the one that exists "at the time [the Administrator] made his decision." *Citizens to Pres. Overton Park, Inc. v. Volpe*, 401 U.S. 402, 420 (1971). That record, rather than "some new record made initially in the reviewing court," is the "focal point" for judicial review. *Camp v. Pitts*, 411 U.S. 138, 142 (1973). The agency action "must . . . stand or fall on the propriety of [the agency's] finding[s]" in the contemporaneous explanation supporting that action. *Id*. at 142-43. If the Court is unable to evaluate the action on the basis of the record before it, then "the proper course, except in rare circumstances, is to remand to the agency for additional investigation or explanation." *Fla. Power & Light*, 470 U.S. at 744.

Internal agency deliberations are not part of an administrative record. *Voyageurs Nat'l Park Ass'n v. Norton*, 381 F.3d 759, 766 (8th Cir. 2004); *Town of Norfolk v. U.S. Army Corps of Eng'rs*, 968 F.2d 1438, 1455-58 (1st Cir. 1992); *In San Luis Obispo Mothers for Peace v. Nuclear Regulatory Comm'n*, 789 F.2d 26,

44-45 (D.C. Cir. 1986) (en banc) (citing *Overton Park*, 401 U.S. at 420). It is "not the function of the court to probe the mental processes" of the agency. *Morgan v. United States*, 304 U.S. 1, 18 (1938). "[S]uch inquiry . . . is usually to be avoided" except in the very rare circumstance where there is a "strong showing of bad faith or improper behavior." *Overton Park*, 401 U.S. at 420.

Certified records are entitled to a presumption of regularity; courts assume the agency properly designated the records absent *clear evidence* to the contrary. *Overton Park, Inc.*, 401 U.S. at 415; *Cook Inletkeeper v. EPA*, 400 F. App'x 239, 240 (9th Cir. 2010). Motions to "complete" the record are granted only if "the agency has relied on documents or materials not included in the record." *Portland Audubon Soc'y v. Endangered Species Comm.*, 984 F.2d 1534, 1548 (9th Cir. 1993). While this Circuit has not adopted an evidentiary standard beyond "clear evidence," several district courts in this Circuit require "concrete evidence" that the record is incomplete. *See, e.g.*, *Carlsson v. U.S. Citizenship & Immigration Servs.*, No. 2:12-cv-07893,2015 WL 1467174 (C.D. Cal. Mar. 23, 2015), at *7; *California v. U.S. Dep't of Labor*, No. 2:13-cv-02069, 2014 WL 1665290 (E.D. Cal. Apr. 24, 2014), at *5.[4]

[4] Petitioners point to a Northern District of California case, claiming that they need only identify reasonable, non-speculative grounds for the belief that documents were considered. *See* Petrs.' Mot. at 7 (quoting *Oceana, Inc. v. Pritzker*, No. 16-cv-06784, 2017 WL 2670733, at *2 (N.D. Cal. June 21, 2017). (*Continued*….)

## ARGUMENT

Of the five categories of documents that Petitioners expressly address in their Motion, Petitioners do not come close to rebutting the presumption of regularity[5] afforded the certified records or demonstrate that EPA considered any of the documents in forming the Rules. These include an irrelevant meeting log and handouts duplicative of record materials; pre-decisional memoranda that are plainly deliberative; a late-filed comment letter; an ethics opinion authorizing an EPA employee to work on the Rules; and scope documents for risk evaluations to be performed *under* the Risk Evaluation Rule. The Court should decline to consider the remaining 13 documents here or in Petitioners' merits brief, because Petitioners raise no arguments as to why they should be included in either record.

### I. Documents from a meeting held by the Office of Management and Budget (Marks Exs. 1-3) are not part of either administrative record.

Petitioners seek to supplement both records with an attendance log from a November 2016 meeting[6] held by the Office of Management and Budget

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However, such a standard would be inconsistent with the presumption of regularity afforded to the Agency's certified record. *Overton Park, Inc.*, 401 U.S. at 415.

[5] Petitioners' attempt to argue that EPA's recent amendment of the certified indices is evidence of irregularity and incompleteness is unfounded. *See* Petrs.' Mot. at 1, 8. The corrected indices are in fact evidence of regularity, because EPA took steps to correct the inadvertent exclusion of the pre-proposal comments.

[6] Oddly, Petitioners seek to add the meeting log and meeting handouts to the records for both the Prioritization Rule and the Risk Evaluation (*Continued*…)

("OMB"), an entity under the Executive Office of the President, with the American Chemistry Council ("ACC") and other trade associations, as well as two handouts brought by ACC to the meeting. Petrs.' Mot. at 9-10, 17, Marks Exs. 1-3.

EPA does not dispute that OMB held meetings with various members of the public, including not only ACC but also some of the Petitioners, during the pre-proposal stage for the Rules. It is also undisputed that ACC brought two handouts to its November 2016 meeting with OMB. *See* Petrs.' Mot. at Marks Exs. 2-3. But that does not establish that the attendance log or handouts were "considered" by EPA in the formation of the Rules. *See Thompson*, 885 F.2d at 555. The log itself does not reflect anything of substance for the Agency to consider. And the handouts simply summarize more extensive official public comments submitted by ACC, which EPA did consider and included in the administrative records. ECF 16-2, at 3 (including comment from ACC in certified record). While EPA employees may have seen these handouts, they are duplicative of items already in the administrative records. *See also* 5 U.S.C. § 553(b)(3) (no record required at pre-proposal stage beyond that which is necessary to provide notice of terms and substance of the Rules). Therefore, the Court should reject Petitioners' request to require EPA to add these documents to the administrative records.

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Rule despite the fact that the meeting log states that it was regarding the Prioritization Rule. Petrs.' Mot. at 9-10, Marks Ex. 1.

Importantly, Petitioners also do not demonstrate that the omission of these documents impede judicial review. They do not even rely on these documents in support of their merits brief arguments, tacitly admitting that these documents are not relevant to judicial review of the Rules. The meeting log in Marks Exhibit 1 is cited in Petitioners' merits brief only in a background section making insinuations about one of EPA's employees. *See* Petrs.' Br. at 14-15. The ACC handout in Marks Exhibit 2 appears in a "see also" citation in Petitioners' merits arguments only to show that ACC urged EPA to adopt a particular statutory interpretation, but this is duplicative of ACC's official comments. *Id*. at 36. And the handout in Marks Exhibit 3 is not cited *at all* in Petitioners' merits brief. Such irrelevant and duplicative materials will not help the Court determine whether the Rules may withstand arbitrary and capricious review, *see* 5 U.S.C. § 706(2)(A), or whether the Rules are supported by EPA's contemporaneous explanation of its findings, *see Camp*, 411 U.S. at 142-43.

## II. Pre-decisional, deliberative memoranda (Marks Exs. 4-6) are not properly part of an administrative record.

Petitioners seek to include in both records three internal, deliberative documents: two memoranda from EPA employees concurring with comments on

the Risk Evaluation Rule[7] (Marks Exs. 4-5); and a draft of EPA's response to interagency comments about early drafts of EPA's scoping documents for the first 10 chemicals under review, an entirely different administrative procedure[8] (Marks Ex. 6). Petrs.' Mot. at 10-13; *see also id.* at Marks Ex. 6 (stating "Deliberative, Pre-Decisional" on every page). These documents were properly excluded because they are pre-decisional, deliberative documents reflecting the Agency's mental process.

Deliberative materials are outside the scope of APA review and thus are not part of the administrative record. *In San Luis Obispo Mothers for Peace*, 789 F.2d at 44-45 (transcript of agency meeting not part of record). "Judicial examination of [documents reflecting deliberations] would represent an extraordinary intrusion into the realm of the agency." *Id*. at 44. "Just as a Judge cannot be subjected to such scrutiny, so the integrity of the administrative process must be equally respected." *Id*.; *see also In re Subpoena Duces Tecum Served on Office of Comptroller of Currency*, 156 F.3d 1279, 1279-80 (D.C. Cir. 1998) (*denial of*

[7] Petitioners make no attempt to explain why memoranda regarding the Risk Evaluation Rule should be included in the record for the Prioritization Rule as well. Petrs.' Mot. at 10-13, Marks Exs. 4-5).

[8] Setting aside the deliberative nature of this document, Petitioners do not explain how an internal review of *chemical scoping documents*, which are themselves outside the records, *see infra* Section V, could have been considered by EPA decision-makers in forming the Prioritization and Risk Evaluation Rules.

*reh'g en banc*) ("[T]he actual subjective motivation of agency decisionmakers is immaterial as a matter of law" to APA review) (citing *Overton Park*, 401 U.S. at 420; *Camp*, 411 U.S. at 138; *United States v. Morgan*, 313 U.S. 409, 409 (1941)); *Portland Audubon Soc'y*, 984 F.2d 1534 (distinguishing purely internal deliberations from improper ex parte contacts with outside parties, indicating that deliberative materials are not part of record for APA review). Therefore, a "'strong showing of bad faith or improper behavior'" would be necessary before the court would be "warranted in examining the deliberative proceedings." *In San Luis Obispo*, 789 F.2d at 44-45 (quoting *Overton Park*, 401 U.S. at 420).

Ignoring this precedent, Petitioners argue that this Court "routinely" relies on internal memoranda in reviewing agency actions. Petrs.' Mot. at 12-13. But the opinions cited do not involve attempts to expand certified records with deliberative materials, and they are not in conflict with *In San Luis Obispo*. In *Reno-Sparks Indian Colony v. EPA*, 336 F.3d 899, 906 (9th Cir. 2003), for example, nothing in the opinion suggests that the "internal agency memorandum" at issue was deliberative rather than, say, a memorandum to the docket. The Court simply describes it as adopting a particular state classification and then cites to the Federal Register. *Id*. Likewise, in *Earth Island Institute v. Hogarth*, 494 F.3d 757, 768-69 (9th Cir. 2007), there is no discussion of an attempt to supplement a certified record, and in any case, that case *did* involve a finding of improper

behavior on the part of the Secretary of Commerce. The opinion in *NRDC v. Pritzker*, 828 F.3d 1125, 1136 (9th Cir. 2016), discussed a white paper authored by scientists who worked at the National Marine Fisheries Services, but nothing in the opinion indicates that this was internal or deliberative. And in *Western Watersheds Project v. Kraayenbrink*, 632 F.3d 472, 479, 497-98 (9th Cir. 2011), nothing in the opinion indicates that the interdisciplinary report under the Endangered Species Act ("ESA") Section 7 consultation process were deliberative rather than normal public ESA consultations.

Here, the documents are plainly deliberative, and Petitioners have made no showing of bad faith. They argue that the memoranda reflect various issues raised during the review process, Petrs.' Mot. at 10-12, but that is the whole point of internal deliberations. The agency *should* seek out and consider all issues and viewpoints related to a decision. That is not a sign of bad faith but of a functioning deliberative process. These documents were properly excluded.

## III. Petitioners' late-filed comment letter (Marks Ex. 7) was not considered by EPA in forming the Rules.

Petitioners also seek to include in both records their own comment letter, which was filed over two months after the close of the comment period, plus attachments including another late-filed letter dated a few weeks earlier. Petrs.' Mot. at 14-17, Marks Ex. 7. This document and its attachments were properly excluded from the administrative records because they were submitted one week

before the Rules were signed, far too late in the process for EPA to have considered it either directly or indirectly. *See* Petrs.' Mot. at Marks Ex. 7; *Thompson*, 885 F.2d at 555. Indeed, Petitioners do not even claim that EPA actually "considered" the letter. *See id*. And this, too, is not even cited in Petitioners' merits brief to support any argument about the Rules' validity; it is cited only in the background section. *See* Petrs.' Br. at 14-15.

EPA did not consider this (or any) late-filed comments in forming either Rule. EPA was under a statutory deadline to issue these Rules by June 22, 2017, so it would have been nearly impossible to consider comments submitted in June. *See* 15 U.S.C. § 2605(b)(1)(A), (b)(4)(B). This process was consistent with EPA's normal practice, as reflected in EPA's guidance on compiling administrative records. EPA, Administrative Records Guidance 10 (Sept. 2011), *available at* http://www3.epa.gov/ogc/adminrecordsguidance09-00-11.pdf (last visited Apr. 23, ("EPA Guidance").

Moreover, the letter is not relevant to the issues before the Court, i.e. whether the Rules are valid exercises of EPA's discretion under TSCA and the APA. The letter, which reflects Petitioners' beliefs about one of the many EPA employees who worked on the Rules, is not going to help the Court evaluate the Rules. This letter is not part of either record.

## IV. An ethics opinion from an EPA employee's personnel file (Marks Ex. 8), which Petitioners misconstrue, is not part of either administrative record.

Petitioners next ask the Court to supplement both records with an EPA ethics opinion concerning the permissible activities of Dr. Nancy Beck, a former ACC employee. Petrs.' Mot. at 9-10, 17, Marks Ex. 8. Petitioners claim that the opinion created "constraints" on Dr. Beck's participation in the rulemaking and that whether she "complied with those constraints" is relevant to whether the Rules should be upheld. *See id*. at 17. They are wrong on both accounts.

It is true that Dr. Beck is a former ACC employee and that, after coming to work for EPA, she received an ethics opinion about permissible activities related to her prior employer. *See* Petrs.' Mot. at Marks Ex. 8. However, Petitioners misconstrue the opinion. *See* Petrs.' Mot. at 17. The language quoted by Petitioners appears in a discussion of Dr. Beck's temporary prohibition from participation in "specific party matters" involving ACC (which do not include rulemaking), and states that "*you have been advised—and understand*—that you cannot participate in any meetings, discussions or decisions that relate to any individual ACC comment nor attend any meeting in which ACC is present." *See* Petrs.' Mot. at Marks Ex. 8 at 2 (emphasis added). But the opinion then goes on to confirm that Dr. Beck is allowed "to participate fully in matters of general

applicability, including rulemaking, including consideration of any comments that were made by ACC." *See* Petrs.' Mot. Marks Ex. 8 at 2.

Even more importantly, this ethics opinion is in the nature of a personnel record and was not considered by EPA in forming the Rules. Of course EPA would have considered it when making *staffing* decisions. But administrative records are not so expansive as to include every time-card and personnel file; they cover documents considered by the Agency "on which the *administrative decision was based*." *Thompson*, 885 F.2d at 555 (emphasis added).

As with several of the other categories of documents, Petitioners effectively admit that the ethics opinion is not relevant to whether the Rules may withstand APA review. They argue in their Motion that the opinion is relevant to whether the Rules were the result of "reasoned decision-making," Petrs.' Mot. at 17, but then they do not actually assert in their merits brief arguments that Dr. Beck's involvement had anything to do with Rules' outcome or validity, *see generally* Petrs.' Br. Instead, they cite the opinion in their merits brief only in a background section making insinuations about Dr. Beck's participation in the rulemaking, *see* Petrs.' Br. at 14-15, apparently in an attempt to color the Court's impression of this particular EPA employees, who was not even the ultimate decision-maker. It is unsurprising that the new administration has hired people with expertise and views that reflect its policies or that these new hires would work on matters that pertain to

their expertise. But this will not help the Court resolve whether the Rules are a lawful and reasonable exercise of Agency discretion under the APA. This document is simply not part of either administrative record.

## V. Documents setting forth the scope of risk evaluations for specific chemicals pursuant to the Risk Evaluation Rule (Marks Exs. 9-14) are not part of that record.

Petitioners also ask the Court to supplement the record for the Risk Evaluation Rule with, or to take judicial notice of, ten "scope documents" that were published for public comment on June 22, 2017, the same day that EPA signed the Rules. *See* Petrs.' Mot. at 18-22, Marks Exs. 9-14. These documents identify the expected scopes of risk evaluations that will be performed on specific chemicals pursuant to the Risk Evaluation Rule. *See* Petrs.' Mot. at 18-22, Marks Exs. 9-14. Despite referring to "ten scope documents," Petrs.' Mot. at 18, Petitioners only attached 6 such documents to their Motion, Marks Exs. 9-14, and only cite three of these in their merits brief arguments, Petrs.' Br. at 37, 42, 46-48. It is not clear which of these Petitioners are seeking to include in the Risk Evaluation Rule record. Nevertheless, none of them are part of the administrative record because they were not considered in forming that Rule.

Petitioners' basis for claiming the scope documents are part of the Risk Evaluation Rule record is that they were influenced by and developed to be consistent with the Rule. *See* Petrs.' Mot. at 18-20. In fact, this shows why these

documents are not part of the record for the Risk Evaluation Rule. The Risk Evaluation Rule lays out procedures for conducting risk evaluations. 82 Fed. Reg. 33,753. The scope documents are the first step in conducting those evaluations. *See*, *e.g.*, Marks Ex. 10. Of course, it would be important for EPA to bear in mind the Risk Evaluation Rule then in development when creating the scope documents. *See* 82 Fed. Reg. at 33,726 ("This process will be used for the first ten chemical substances undergoing evaluation."). But as EPA did not "consider" these documents, which had not been published before the Rule, EPA properly excluded them from the administrative record. *See Thompson*, 885 F.2d at 555.

## VI. Internal EPA emails and a press release (Marks Exs. 15-24) are not part of either record.

Petitioners attach to their Motion nine internal EPA emails (Marks Exs. 15-23) and a press release (Marks Ex. 24). Petrs.' Mot. at 18-22. Petitioners make no argument in support of including these documents in the administrative records, do not cite the documents in their merits brief, and did not confer with EPA counsel about including these specific documents, *see* Cir. R. 27-1(5); Exs. A-B. They mention five of the emails and the press release in their Motion only in support of their argument that the *scope documents* should be part of the Risk Evaluation Record. *See* Petrs.' Mot. at 18-19. Because Petitioners include no support for including these, the Court should not consider them. In any event, they are not part of the administrative records.

The EPA emails are internal deliberative communications and therefore not part of the administrative record. *See supra* at 10-11. The press release is clearly outside of the records as it is dated the same day the Rules were signed. *See* Petrs.' Mot. at Marks Ex. 24 (stating that EPA "has completed" the Rules); *see also Overton Park*, 401 U.S. at 420 (judicial review based on record before agency "at the time" agency made the decision); EPA Guidance at 5-6, 10.

Insofar as Petitioners rely on these documents to support their argument that the scope documents should be included, they are wrong. Petitioners argue that the emails show that the scope documents were delayed in order to make them consistent with the Risk Evaluation Rule and that EPA reviewers who commented on the Risk Evaluation Rule also commented on the scope documents. *See* Petrs.' Mot. at 18-19. Even accepting Petitioners' reading of these ancillary documents, they are not evidence that EPA considered the scope documents in formulating the Risk Evaluation Rule. Rather, they show that the scope documents were developed to be consistent with the Risk Evaluation Rule.

## VII. Petitioners provide no basis for supplementing the record with the documents in the Gartner Exhibit (Gartner Ex. 1-3).

Petitioners attach three additional documents to their Motion: a chart prepared by Petitioners *after* the Rules were issued (Gartner Ex. 1) (comparing language in final Rules to proposed versions); an email from EPA's Office of Congressional and Intergovernmental Relations to a Congressperson's staff during

the development of the TSCA amendments (Gartner Ex. 2); and an approximately 200-page article on toxicity testing (Gartner Ex. 3). Petrs.' Mot. at Gartner Exs. 1-3. Again, Petitioners make no argument as to why these documents should be included in either administrative record, and Petitioners never conferred with EPA about including these in the records. *See* Cir. R. 27-1(5). However, these documents are each cited in Petitioners' merits brief. *See* Petrs.' Merits Br. at 15, 29, 61. Because Petitioners' fail to advance any argument in support of including these documents in the records, the Court should deny the Motion with respect to these documents and should not consider them in its evaluation of the merits.

There is no arguable basis for including Petitioners' chart in the administrative record as it was never provided to EPA or "considered" in forming the Rules. Petitioners' inclusion of this document and citation to in their merits brief appears to be an attempt to circumvent the word limit in their brief. *Compare* Cir. R. 32-1, 32-2(b) (principal briefs of separately represented parties must contain no more than 15,400 words), *with* Petrs.' Br. at 74 (certifying that brief contains 15,332 words), *and* Petrs.' Mot. at Gartner Ex. 1 (containing 3,964 additional words). More importantly, the chart, which purports to show similarities between the Rules and ACC's public comments, is irrelevant. Whether or not EPA adopted the positions of some commenters, the question before this

Court is whether the final Rules are permissible under TSCA and reflect judgments that are supported by the records.

Nor is there any basis for including the email from an EPA congressional liaison to a Congressperson during the drafting of the TSCA amendments. This email reflects an opinion of a single person at EPA before the new TSCA language was even finalized. No evidence shows that it was considered by the EPA decisionmakers who finalized the Rules, and it plainly does not reflect the views of EPA decisionmakers who approved the final Rules.

Finally, the Court should exclude consideration of the article on toxicity testing, which Petitioners cite in their merits brief in support of a scientific statement. *See* Petrs.' Br. at 61. This article, authored by the National Research Council, is in the nature of general reference material. *See* Petrs.' Mot. at Gartner Ex. 3. Its existence is not in dispute. But Petitioners' opportunity to draw EPA's attention to any particular information in the article for consideration in forming the Rules was during the public comment period. They cannot now create a new record for judicial review before this Court. *See Camp*, 411 U.S. at 142.

## CONCLUSION

The Court should therefore deny Petitioners' Motion in its entirety and review the Rules based solely on the records as compiled and certified by EPA.

Dated: April 26, 2018

Respectfully submitted,

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**CERTIFICATE OF SERVICE**

I hereby certify that on April 26, 2018, I caused a true and correct copy of the above Opposition to be served via the court's CM/ECF system on all registered counsel.

*/s/ Samara M. Spence*
Samara M. Spence
United States Department of Justice

# Exhibit A

**From:** Eve C. Gartner
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**Cc:** Tallman, Sarah (stallman@nrdc.org); Rob Stockman (rstockman@edf.org); Bob Sussman (bobsussman1@comcast.net); Randy Oshlaw (randy@oshlaw.org); Tosh Sagar
**Subject:** Request for position on motion in Safer Chem Healthy Families, et al. v. USEPA, No. 17-72260
**Date:** Tuesday, April 3, 2018 12:10:06 PM
**Attachments:** Motion to Complete - Documents shared.docx
Motion to Complete - Documents shared.docx

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Dear Counsel,

I am writing on behalf of all counsel in this case. We do not believe that the Certified Indices to the Administrative Records that EPA filed in this consolidated case are complete. We are planning to file a Motion to Complete the Record or, in the Alternative, to Take Judicial Notice of documents that should have been included in the Records or, alternatively, that the Court should nonetheless consider.

After careful review, we have determined that the certified Records improperly omit six categories of documents that were before EPA when it finalized the rules: (1) pre-proposal public comments; (2) materials from a meeting EPA had with industry representatives; (3) late-filed comments regarding Dr. Nancy Beck's conflicts of interest; (4) intra-agency memoranda raising serious concerns regarding EPA's last-minute changes to the rules; (5) a memorandum regarding conflicts posed by Dr. Beck's prior employment and conditions for her participation in agency business, including rulemaking; and (6) "scope documents" considered by Agency decision-makers in developing the rules at issue.

A list of the documents that we have identified and believe should be included is attached. In addition, we will be moving to have any additional Final Agency Review memos from other EPA offices added to the Record.

Pursuant to local rule 27-1(5), we are seeking your position on our motion to complete and/or to take judicial notice. We would appreciate your response by noon on Thursday, April 5.

Thank you.
Eve

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EARTHJUSTICE

Motion to Complete - Documents

## I. 2016 Pre-Proposal Comments

1. Comment submitted by Nancy B. Beck, PhD, DABT, Senior Director, Regulatory and Technical Affairs, American Chemistry Council (ACC), to the pre-proposal public docket for the Risk Evaluation Rule as EPA-HQ-OPPT-2016-0400-0028. NRDC downloaded this comment from regulations.gov on March 22, 2018.

2. Comment submitted by Sarah Brozena, Senior Director, Regulatory & Technical Affairs, American Chemistry Council (ACC), to the pre-proposal docket for the Prioritization Rule as EPA-HQ-OPPT-2016-0399-0020. NRDC downloaded this comment from regulations.gov on March 22, 2018.

3. Comment submitted by Andy Igrejas, Executive Director, Safer Chemicals Healthy Families, et al. to the public dockets for the pre-proposal Risk Evaluation and Prioritization Rules as EPA-HQ-OPPT-2016-0400-0019 and EPA-HQ-OPPT-2016-0399-0033, respectively. NRDC downloaded this comment from regulations.gov on March 22, 2018.

4. Comment submitted by Daniel Rosenberg, Senior Attorney, Natural Resources Defense Council, to the public docket for the pre-proposal Risk Evaluation Rule as EPA-HQ-OPPT-2016-0400-0024. NRDC downloaded this comment from regulations.gov on March 22, 2018.

5. Comment submitted by Daniel Rosenberg, Senior Attorney, Natural Resources Defense Council to the public docket for the pre-proposal Prioritization Rule as EPA-HQ-OPPT-2016-0399-0030. NRDC downloaded this comment from regulations.gov on March 22, 2018.

6. Comment submitted by Pamela Miller, Executive Director, Alaska Community Action on Toxics, to the public dockets for the pre-proposal Risk Evaluation and Prioritization Rules as EPA-HQ-OPPT-2016-0400-0036 and EPA-HQ-OPPT-2016-0399-0041, respectively. NRDC downloaded this comment from regulations.gov on March 23, 2018.

7. Comment submitted by Eve Gartner, Staff Attorney, Earthjustice et al. to the public dockets for the pre-proposal Risk Evaluation and Prioritization

Rules as EPA-HQ-OPPT-2016-0400-0067 and EPA-HQ-OPPT-2016-0399-0050, respectively. NRDC downloaded this comment from regulations.gov on March 23, 2018.

8. Comment submitted by Gina M. Solomon, M.D., M.P.H., Deputy Secretary for Science and Health, California Environmental Protection Agency, to the public docket for the Risk Evaluation Rule as EPA-HQ-OPPT-2016-0400-0023. NRDC downloaded this comment from regulations.gov on March 23, 2018.

9. Comment submitted by Gina M. Solomon, M.D., M.P.H., Deputy Secretary for Science and Health, California Environmental Protection Agency, to the public docket for the Prioritization Rule as EPA-HQ-OPPT-2016-0399-0032. NRDC downloaded this comment from regulations.gov on March 23, 2018.

10. Comment submitted by U. S. Academic Scientists to the public docket for the Risk Evaluation Rule as EPA-HQ-OPPT-2016-0400-0071. NRDC downloaded this comment from regulations.gov on March 23, 2018.

11. Comment submitted by U. S. Academic Scientists to the public docket for the Prioritization Rule as EPA-HQ-OPPT-2016-0399-0052. NRDC downloaded this comment from regulations.gov on March 23, 2018.

12. Comment submitted by Asbestos Disease Awareness Organization to the public docket for the Risk Evaluation Rule as EPA-HQ-OPPT-2016-0400-0032. NRDC downloaded this comment from regulations.gov on March 23, 2018.

13. Comment submitted by Thomas M. Gellhaus, MD, FACOG, President, American Congress of Obstetricians and Gynecologists, to the public docket for the Risk Evaluation Rule as EPA-HQ-OPPT-2016-0400-0005. NRDC downloaded this comment from regulations.gov on March 23, 2018.

## II. OMB Meeting Materials

14. Office of Management and Budget (OMB) log for EO 12866 Meeting 2070-AK23 ("the OMB Meeting), on November 30, 2016, requested by the American Chemistry Council and attended by staff from OMB, EPA,

and industry. NRDC downloaded this log on March 23, 2018 from https://www.reginfo.gov/public/do/viewEO12866Meeting?viewRule=true&rin=2070-AK23&meetingId=2487&acronym=2070-EPA/OCSPP;%20supp%20ltr%20ex%20

15. "ACC Comments to Inform the EPA Risk Evaluation Proposed Rule," attached as a handout to the log for the OMB meeting, and downloaded by NRDC on March 23, 2018 from https://www.reginfo.gov/public/do/eoDownloadDocument?pubId=&eodoc=true&documentID=2793

16. "Summary of ACC's Comments to Inform the EPA's Prioritization Process Rule under the LCSA,"" attached as a handout to the log for the OMB meeting, and downloaded by NRDC on March 23, 2018 from https://www.reginfo.gov/public/do/eoDownloadDocument?pubId=&eodoc=true&documentID=2792"

## III. Supplemental Comment Letter

17. Letter from Earthjustice, NRDC, and SCHF, to Susanna Blair & Ryan Schmit, Immediate Office, Office of Pollution Prevention & Toxics, EPA (June 13, 2017) with selected exhibits.

## IV. Concur With Memos including

18. Memorandum from Gregory Sullivan, Director, Waste and Chemical Enforcement Division, Office of Enforcement and Compliance Assurance, to Angela F. Hofmann, Director, Regulatory Coordination Staff, Office of Assistant Administrator, Office of Chemical Safety and Pollution Prevention. NRDC downloaded this document from a repository the New York Times released with Eric Lipton, "Why Has the EPA Shifted on Toxic Chemicals? An Industry Insider Helps Call the Shots," New York Times, Oct. 21, 2017, available at https://www.documentcloud.org/documents/4113586-EPA-and-Toxic-Chemical-Rules.html#document/p15/a382932

19. Memorandum from Michael Shapiro, Acting Assistant Administrator, Office of Water, to Wendy Cleland-Hamnett, Acting Assistant Administrator, Office of Chemical Safety and Pollution Prevention (May

30, 2017). NRDC downloaded this document from a repository the New York Times released, https://www.documentcloud.org/documents/4113586-EPA-and-Toxic-Chemical-Rules.html#document/p11/a382932

## V. Minoli Memorandum

20. Memorandum from Kevin Minoli, Designated Agency Ethics Official and Acting General Counsel, to Nancy Beck, Ph.D., OABT, Deputy Assistant Administrator Office of Chemical Safety and Pollution Prevention, dated June 8, 2017, with the subject "Participation in Specific Party Matters Involving Your Former Employer, the American Chemistry Council. NRDC downloaded this document from a repository the New York Times released, https://www.documentcloud.org/documents/4113586-EPA-and-Toxic-Chemical-Rules.html#document/p1/a382932

## VI. All 10 Scoping Documents

21. Scope of the Risk Evaluation for Asbestos (June 2017), EPA Doc. No. EPA-740-R1-7008, which NRDC downloaded on March 23, 2028 from https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/asbestos-scope-document-and-supplemental-files.
22. Scope of the Risk Evaluation for 1-Bromopropane (June 2017), EPA Doc. No. EPA- 740-R1-7009, which NRDC downloaded on March 23, 2018 from https://www.epa.gov/sites/production/files/2017-06/documents/bp_scope_06-22-17.pdf"
23. Scope of the Risk Evaluation for Carbon Tetrachloride (Methane, Tetrachloro-) (June 2017), EPA Doc. No. EPA-740-R1-7010, which NRDC downloaded March 23, 2018 from https://www.epa.gov/sites/production/files/2017-06/documents/ccl4_scope_06-22-17.pdf"
24. Scope of the Risk Evaluation for 1,4-Dioxane (June 2017), EPA Doc. No. EPA-740-R1-7003, which NRDC downloaded March 23, 2018 from https://www.epa.gov/sites/production/files/2017-06/documents/dioxane_scope_06-22-2017.pdf"
25. Scope of the Risk Evaluation for Cyclic Aliphatic Bromides Cluster (June 2017), EPA Doc. No. EPA-740-R1-7002, which NRDC downloaded March 23, 2018 from https://www.epa.gov/sites/production/files/2017-06/documents/hbcd_scope_06-22-17_0.pdf"

26. Scope of the Risk Evaluation for Methylene Chloride (Dichloromethane, DCM) (June 2017), EPA Doc. No. EPA 740-R1-7006, which NRDC downloaded March 23, 2018 from https://www.epa.gov/sites/production/files/2017-06/documents/mecl_scope_06-22-17.pdf"
27. Scope of the Risk Evaluation for N-Methylpyrrolidone (2-Pyrrolidinone, 1-Methyl-) (June 2017), EPA Doc. No. EPA-740-R1-7005, which NRDC downloaded March 23, 2018 from https://www.epa.gov/sites/production/files/2017-06/documents/nmp_scope_6-22-17_0.pdf"
28. Scope of the Risk Evaluation for Perchloroethylene (Ethene, 1,1,2,2-Tetrachloro) (June 2017), EPA Doc. No. EPA-740-R1-7007, which NRDC downloaded March 23, 2018 from https://www.epa.gov/sites/production/files/2017-06/documents/perc_scope_06-22-17.pdf"
29. Scope of the Risk Evaluation for Pigment Violet 29 (Anthra[2,1,9-def:6,5,10-d'e'f']diisoquinoline-1,3,8,10(2H,9H)-tetrone) (June 2017), EPA Doc. No. 740-R1-7011, which NRDC downloaded March 23, 2018 from https://www.epa.gov/sites/production/files/2017-06/documents/pv29_scope_06-22-17.pdf"
30. Scope of the Risk Evaluation for Trichloroethylene (June 2007), EPA Doc. No. EPA-740-R1-7004, which NRDC downloaded March 23, 2018 from https://www.epa.gov/sites/production/files/2017-06/documents/tce_scope_06-22-17.pdf"

# Exhibit B

| | |
|---|---|
| **From:** | Eve C. Gartner |
| **To:** | Zilioli, Erica (ENRD); Spence, Samara (ENRD); "Boxerman, Samuel B. (sboxerman@sidley.com)" |
| **Cc:** | Tallman, Sarah (stallman@nrdc.org); Rob Stockman (rstockman@edf.org); Bob Sussman (bobsussman1@comcast.net); Randy Oshlaw (randy@oshlaw.org); Tosh Sagar |
| **Subject:** | RE: Request for position on motion in Safer Chem Healthy Families, et al. v. USEPA, No. 17-72260 |
| **Date:** | Tuesday, April 10, 2018 8:40:53 PM |
| **Attachments:** | NRDCvEPA_17cv05928_0003903-21 EPA resp. to interagency comments SCOPES (002).pdf |

Dear Erica and Sam –

Sorry for this last minute request but we have identified an additional document that we believe are part of the administrative records as it was before the agency and considered by agency decision-makers in conjunction with the development of the Risk Evaluation Rule and relate to how EPA's new approach would affect its risk evaluations.

The document, which was recently released to NRDC via a FOIA request, is attached here. Since EPA was not able to reach a decision on whether the scope documents are part of the records, we expect that it will not be able to agree that this document is part of the records. However, we wanted to give EPA and intervenors the opportunity to provide their position for the record.

Thank you very much for your prompt response.

Eve

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**From:** Zilioli, Erica (ENRD) [mailto:Erica.Zilioli@usdoj.gov]
**Sent:** Tuesday, April 10, 2018 5:00 PM