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UNITED STATES DISTRICT COURT	
NORTHERN DISTRICT OF CALIFORNIA	١

ASBESTOS DISEASE AWARENESS ORGANIZATION, et al.,

Plaintiffs,

v.

ANDREW WHEELER, et al.,

Defendants.

STATE OF CALIFORNIA, et al.,

Plaintiffs,

v.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY, et al.,

Defendants.

Case No. 19-cv-00871-EMC

ORDER GRANTING PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT AND DENYING **DEFENDANT'S CROSS-MOTION FOR** SUMMARY JUDGMENT

Docket Nos. 49, 52

Case No. 19-cv-03807-EMC

Docket Nos. 60, 63

Plaintiffs in Case No. 19-0871 are a group of nonprofit public health and environmental organizations that promote awareness about the health risks associated with asbestos. The lead plaintiff is the Asbestos Disease Awareness Organization ("ADAO") (collectively, "Plaintiffs"). In Case No. 19-3807, 10 states (led by California) and the District of Columbia (collectively, "the States") bring suit. Plaintiffs and the States filed suit against the Environmental Protection Agency ("EPA") and its Administrator, Andrew Wheeler, challenging the EPA's denial of their

¹ Asbestos Disease Awareness Organization ("ADAO"), American Public Health Association ("APHA"), Center for Environmental Health ("CEH"), Environmental Working Group ("EWG"), Environmental Health Strategy Center ("EHSC"), and Safer Chemicals Healthy Families ("SCHF") (collectively, "Plaintiffs"). ADAO FAC at 1.

petitions to initiate rulemaking under Section 21 of the Toxic Substances Control Act ("TSCA").
The petitions requested EPA to initiate rulemaking to expand its information-gathering process
regarding asbestos-related health risks. In particular, the petitions asked EPA to use its significant
enforcement authority to mandate that companies report information in their possession
concerning the risks posed by asbestos to human health and the environment.

EPA moved to dismiss ADAO's First Amended Complaint for lack of subject matter jurisdiction. Docket No. 16. The Court denied the motion, finding that Plaintiffs' claims were proper under Section 706 of the Administrative Procedure Act ("APA"). Docket No. 43. Because Plaintiffs' petition sought an amendment to the existing Chemical Data Reporting rule under TSCA (40 C.F.R. Part 711), the Court found that APA review under 5 U.S.C. § 706 is appropriate, and that *de novo* review under Section 21(b)(4)(B) of TSCA does not apply. Order at 12.

Plaintiffs and the States now move for summary judgment under the APA, arguing that the EPA's denial of their rulemaking petitions was arbitrary and capricious as a matter of law. Docket Nos. 49, 60. EPA has filed an identical Cross-Motion for Summary Judgment in both cases, asserting that it possesses the requisite information concerning asbestos-related health risks to inform its rulemaking efforts, and that the information requested by Plaintiffs and the States would be duplicative and unnecessary. Docket Nos. 52, 63 (collectively "DMSJ").

I. FACTUAL AND PROCEDURAL BACKGROUND

A. Regulatory Background (TSCA)

Congress enacted TSCA in 1976 as a national program for assessing and managing the risks of chemicals to human health and the environment. Section 2(b) of the Act espouses the following policies: (1) "adequate information should be developed with respect to the effect of chemical substances and mixtures on health and the environment and ... the development of such information should be the responsibility of those who manufacture and those who process such chemical substances and mixtures" and (2) "adequate authority should exist to regulate chemical substances and mixtures which present an unreasonable risk of injury to health or the environment, and to take action with respect to chemical substances and mixtures which are imminent hazards." 15 U.S.C. § 2601(b)(1)-(2).

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TSCA provides the EPA with the authority to regulate such chemicals. Section 6(a) provides that EPA "shall" regulate the "manufacture, processing, distribution in commerce, use, or disposal" of a chemical substance or mixture when EPA determines that it presents an unreasonable risk of injury to health or the environment. See 15 U.S.C. § 2605(a). If it finds an unreasonable risk, the EPA may take a number of measures, including prohibiting the manufacturing, processing, or distribution in commerce of a substance or mixture. 15 U.S.C. § 2605(a)(1).

In fulfilling Section 2(b)'s instruction to develop "adequate information," TSCA empowers the EPA to gather information to enable it to perform its regulatory obligations. Section 8(a)(1) of TSCA provides that the EPA "shall promulgate rules" that require each person who manufactures or processes a chemical substance to submit a report as the Administrator "may reasonably require." 15 U.S.C. § 2607(a)(1)(A). However, Section 8(a)(5)(A) prohibits the EPA, to the extent feasible, from requiring reporting that is "unnecessary or duplicative." 15 U.S.C. § 2607(a)(5)(A). Further, EPA must only apply the reporting obligations under Section 8(a) to "persons likely to have information relevant to the effective implementation [of TSCA]". 15 U.S.C. § 2607(a)(5)(C).

In 2011, EPA used its section 8(a) authority to promulgate the comprehensive Chemical Data Reporting ("CDR") rule. 40 C.F.R. pt. 711. This rule was intended to support EPA's risk assessment and reduction efforts by "providing basic information about the manufacturing, use and exposure profiles of a wide cross-section of chemicals in commerce." MSJ at 4. Reporting requirements apply to all chemicals manufactured or imported at a site in amounts of 25,000 pounds or more in a given reporting year. 40 C.F.R. § 711.8(a). For chemicals like asbestos, which are already regulated under certain other TSCA provisions, the reporting threshold is set at 2,500 pounds per reporting year. 40 C.F.R. § 711.8(b). EPA develops a list of chemical substances on a "Master Inventory File," and all individuals or companies who manufacture or import substances covered by the file, in amounts greater than 25,000 or 2,500 pounds (depending on the applicable standard), must report during a "submission period." See 40 C.F.R. § 711.5; 40 C.F.R. § 711.8. In November 2020, EPA extended the 2020 CDR submission period to January

29, 2021, but maintained that subsequent submission periods will be in four-year intervals. 40 C.F.R. § 711.20; *see also* 85 Fed. Reg. 75,235 ("EPA is issuing this amendment to extend the deadline for 2020 CDR submission reports until January 29, 2021. This is an extension for the 2020 submission period only: Subsequent submission periods (recurring every four years, next in 2024) are not being amended").

In 2016, Congress amended TSCA with the Frank R. Lautenberg Chemical Safety for the 21st Century Act ("LCSA"). The LCSA directed EPA to establish a risk-based process for determining which chemicals it will prioritize for assessment, identifying chemicals as "high" or "low" priority substances. Chemicals deemed high-priority are those "that the [EPA] Administrator concludes, without consideration of costs or other nonrisk factors, may present an unreasonable risk of injury to health or the environment because of a potential hazard and a potential route of exposure under the conditions of use, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by the Administrator." Pub. L. No. 114-182, 130 Stat. 448 (2016). A high-priority designation triggers a requirement and deadline for EPA to complete a risk evaluation: LSCA provides that within 180 days of its enactment, the EPA must have ongoing risk evaluations for 10 chemical substances. 15 U.S.C. § 2605(b)(2)(A). EPA must publish a final rule not later than two years after the date on which the final risk evaluation regarding a high-priority chemical substance is published. 15 U.S.C. § 2605(c)(1)(B). However, EPA may extend the deadline for publication of the final rule for a period of up to two years. 15 U.S.C. § 2605(c)(1)(C).

B. <u>Procedural Background</u>

Asbestos was identified by EPA as one of the ten chemicals selected for initial risk evaluations under LSCA. In May 2017, Plaintiffs notified the EPA that Occidental Chemical Corporation had failed to report its asbestos imports (totaling several hundred tons), which violated its reporting obligations under the CDR. FAC ¶ 34. In response to Plaintiffs' notice, the EPA wrote a letter to Occidental on July 28, 2017, informing it that its asbestos imports were not subject to reporting because they fell under the "naturally occurring chemical substances" exception to the CDR. *Id.* ¶ 35; *see also* 40 C.F.R. § 711.6(a)(3) (discussed *infra*). This letter led

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to Plaintiffs' petition under Section 21 of TSCA, which was filed on September 25, 2018. Section
21 of TSCA provides that "[a]ny person may petition the [EPA] Administrator to initiate a
proceeding for the issuance, amendment, or repeal of a rule under section 4, 6, or 8 [of TSCA]."
15 U.S.C. § 2620(a). Plaintiffs' petition requested that EPA initiate rulemaking under Section
8(a)(1) to expand the CDR reporting requirements in the following ways:

- (1) eliminate the asbestos exemption in the current rule and designate asbestos as a reportable substance, thereby triggering requiring reporting on importation and use of asbestos in the US;
- (2) lower the reporting threshold, eliminate exemptions for impurities and articles, and require reporting by processors in order to assure that EPA has the information on asbestos use and exposure necessary for its TSCA risk evaluation;
- (3) require immediate submission of reports on asbestos for the 2016 reporting cycle, thereby maximizing EPA's ability to use the information reported to conduct the ongoing asbestos risk evaluation and the subsequent risk management rulemaking under TSCA section 6(a); and
- (4) determine that reports submitted on asbestos are not subject to protection as confidential business information (CBI), enabling the public to submit informed comments on the asbestos risk evaluation and assuring full public awareness of asbestos uses and exposure that present a significant risk to health

FAC ¶ 36.

The EPA denied Plaintiffs' petition on December 21, 2018. EPA asserted the following grounds for the denial:

- (1) The asbestos loophole in the CDR rule only "applied under the specific circumstances described in the letter [to Occidental Chemical]. EPA did not find that the exemption applied for all 'manufacturers or importers of asbestos or asbestos-containing products' as claimed by petitioners." (Petition Denial, at 17)
- (2) "EPA does not believe that the requested amendments would result in the reporting of any information that is not already known to EPA... After more than a year of research and stakeholder outreach, EPA believes that the Agency is aware of all ongoing uses of asbestos and already has the information that EPA would receive if EPA were to amend the CDR requirements" (Petition Denial, at 13)
- (3) [A]mending the CDR rule would [not] be helpful in collecting additional import information on articles . . . [EPA] has sufficient information on imported articles containing asbestos to

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conduct the risk evaluation." (Petition Denial at 19)

- (4) [E]ven if EPA believed that the requested amendments would collect information on any new ongoing uses, EPA would not be able to finalize such amendments in time to inform the ongoing risk evaluation or, if needed, any subsequent risk management decision(s)..." (Petition Denial at 13–14)
- (5) With regard to the impurity exemption, the petitioners requested that these exemptions be made inapplicable to asbestos 'since the low levels of asbestos that have been found in makeup and crayons may be unintended contaminants that comprise byproducts and impurities' . . . [P]etitioners make no attempt to explain why they believe these findings are the result of the manufacture of asbestos as a byproduct or impurity Thus, it is unlikely that EPA would receive new information that would change its understanding of the conditions of use for asbestos that can be addressed under TSCA." (Petition Denial at 22)
- (6) Petitioners' request [for disclosure of reported information containing CBI] is not appropriate for a TSCA section 21 petition EPA believes that disclosure of CBI would have no practical relevance to the risk evaluation or risk determination as the CBI claims are limited and EPA retains the ability to characterize the information without revealing the actual protected data." (Petition Denial at 25–26)

FAC ¶ 43.

Plaintiffs subsequently filed the operative first amended complaint, which included claims for relief under Section 21 of TSCA and Section 706 of the APA. Section 21 of TSCA provides that the EPA Administrator must either grant or deny a petition within 90 days, and that the grounds for denial must be published in the Federal Register. 15 U.S.C. § 2620(b)(3). After such a denial, the petitioner may initiate a civil action in U.S. district court within 60 days, which is reviewed under a *de novo* standard of review. 15 U.S.C. § 2620(b)(4)(A)-(B).

The Government moved to dismiss Plaintiffs' APA claim for lack of subject matter jurisdiction, arguing that the APA only granted the Court with jurisdiction in the absence of an adequate alternative remedy. The Government argued that Congress had enacted an adequate remedy at law through Section 21's grant of *de novo* judicial review. *Id.* In its ruling on the motion to dismiss, the Court first noted that, for petitions which seek issuance of a *new* rule, Section 21(b)(4)(B) provides for *de novo* review. 15 U.S.C. § 2620(b)(4)(B). Section 21 does not govern the standard of review for denials of petitions seeking *amendment* of existing rules. In

denying EPA's motion to dismiss, the Court held that Plaintiffs' rulemaking petition expressly requested EPA to modify its existing asbestos rules under TSCA, and thus, as the petition sought to amend existing rules, *de novo* review under Section 21(b)(4)(B) did not apply. Order at 11 (Docket No. 43). Instead, EPA's denial of Plaintiffs' petition is governed by the more deferential standard of review provided by Section 706 of the APA. The Court therefore denied EPA's motion to dismiss the APA claim.

II. STANDING

A. <u>Organizational Plaintiffs</u>

The EPA stipulates to the ADAO's standing. Plaintiffs' Reply at 3. But it has not stipulated to the standing of the other Plaintiff organizations (*i.e.*, APHA, CEH, EWG, EHSC, and SCHF).

Standing is an "irreducible constitutional minimum" which contains three elements. *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560 (1992). First, the plaintiff must have suffered an injury-infact, meaning "an invasion of a legally protected interest which is (a) concrete and particularized and (b) actual or imminent, not conjectural or hypothetical." *Id.* (internal citations and quotation marks omitted). *See also Spokeo v. Robins*, 136 S. Ct. 1540, 1548 (2016) (finding that, in order to demonstrate Article III standing, a plaintiff must show, *inter alia*, that they have "suffered an invasion of a legally protected interest that is concrete and particularized and actual or imminent, not conjectural or hypothetical") (internal citations omitted). Second, there must be a causal connection between the plaintiff's injury and the conduct complained of – the injury is "fairly traceable to the challenged action of the defendant" rather than some third party not before the court. *Id.* at 561-62 (internal quotation marks omitted). Third, it must be likely that the injury will be redressed by a favorable court decision. *Id.* at 562.

Organizations can assert standing on their members' behalf or in their own right. *E. Bay Sanctuary Covenant v. Trump*, 950 F.3d 1242, 1265 (9th Cir. 2020). Here, the Plaintiff organizations are asserting standing in their own right. Under *Havens Realty Corp. v. Coleman*, 455 U.S. 363 (1982), to demonstrate injury, an organization must show "concrete and demonstrable injury to [its] activities [and] the consequent drain on [its] resources." *Id.* at 379.

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The Ninth Circuit has also held that "an organization suing on its own behalf can establish an injury when it suffered both a diversion of its resources and a frustration of its mission." La Asociacion de Trabajadores de Lake v. City of Lake Forest, 624 F.3d 1083, 1088 (9th Cir. 2010).

Denial of access to information can constitute an injury-in-fact where a statute requires that the information be publicly disclosed. Federal Election Comm'n v. Atkins, 524 U.S. 11, 21 (1998)) ("[t]he 'injury in fact' that respondents have suffered consists of their inability to obtain information – lists of AIPAC donors ... and campaign-related contributions and expenditures ... [and] [t]here is no reason to doubt their claim that the information would help them"); see also Envtl. Def. Fund v. EPA, 922 F.3d 446, 452 (D.C. Cir. 2019) ("[t]he law is settled that a denial of access to information qualifies as an injury in fact where a statute (on the claimants' reading) requires that the information be publicly disclosed and there is no reason to doubt their claim that the information would help them") (internal quotation marks omitted).

Plaintiffs have demonstrated (1) the requisite injury-in-fact for informational standing under Atkins and (2) the requisite injury-in-fact for organizational standing under Havens. Plaintiffs are non-profit public health and environmental organizations dedicated to reducing the health risks of asbestos. MSJ at 1. The requested information (i.e., more accurate reporting, under an enhanced CDR rule, about the quantities of asbestos in the U.S. chain of commerce) sought herein would be disclosed to the general public. 15 U.S.C. § 2605(c)(2)(A) ("[i]n proposing and promulgating a rule ... with respect to a chemical substance or mixture, the Administrator shall consider and publish a statement based on reasonably available information with respect to ... the effects of the chemical substance or mixture on health and the magnitude of the exposure of human beings to the chemical substance or mixture ... [and] the effects of the chemical substance or mixture on the environment and the magnitude of the exposure of the environment to such substance or mixture") (emphasis added). While certain information may be withheld from public disclosure as Confidential Business Information, all information, confidential or not, would assist Plaintiffs in fulfilling their objectives. ² For instance, Plaintiffs state that it will "use

² TSCA protects the public disclosure of certain information deemed "Confidential Business Information" ("CBI"). 15 U.S.C. § 2613(a). However, Section 14(d)(3) of TSCA provides that

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enhanced CDR reporting to support future advocacy on asbestos" and to further "understand[] the risks of asbestos and assist the many APHA members whose day-to-day job [and] public health responsibilities involve prevention and mitigation of asbestos exposure and treating asbestos disease." Benjamin Decl. ¶ 19-20; ADAO argued in its petition that enhanced CDR reporting will help the general public because "[k]nowledge of which entities are importing and using asbestos, where and how these activities occur and the quantities of asbestos involved is critical to identifying exposed populations and pathways of exposure and taking steps to reduce risks." MSJ at 19 n.47.

Moreover, if Plaintiffs lack access to accurate information, they would be hindered in their advocacy efforts for asbestos-related legislation and in their efforts to educate the public about the dangers posed by asbestos. Plaintiffs must spend more time petitioning EPA to obtain this information and less time pursuing their stated mission of reducing asbestos-related health risks and advocating for asbestos-related legislation. See Benjamin Decl. ¶ 14 (Georges C. Benjamin, the Executive Director of the APHA, states that APHA "adopt[s] policy statements and communicate[s] [its] views to Congress and federal and state agencies [on asbestos health risks] through comments on bills or regulatory proposals, testimony at hearings and public meetings and

information shall be disclosed "if the Administrator determines that disclosure is necessary to protect health or the environment against an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by the Administrator under the conditions of use." 15 U.S.C. § 2613(d)(3). Plaintiffs' petition asked EPA to determine that CDR reports on asbestos are not subject to protections as CBI. MSJ at 6. As Plaintiffs note, LSCA narrowed the scope of CBI protections by excepting from disclosure "a general description of a process used in the manufacture or processing and industrial, commercial, or consumer functions and uses of a chemical substance." 15 U.S.C. § 2613(b)(3)(B). And, as discussed *infra*, the CBI label has no bearing on whether information is deemed reasonably available. 40 C.F.R. § 702.33(5) ("[i]nformation that meets the terms of the preceding sentence is reasonably available information whether or not the information is confidential business information, that is protected from public disclosure under TSCA section 14"). Given that (1) the CBI provision has been significantly narrowed by LSCA, and (2) information which companies claim as CBI must still inform EPA's asbestos rulemaking efforts if it is reasonably available, Plaintiffs have made an adequate showing that a favorable court decision would redress their harm to some extent. Cf. New York v. Trump, No. 20-CV-5770 (RCW) (PWH) (JMF), 2020 U.S. Dist. LEXIS 165827, at *86 (S.D.N.Y. Sep. 10, 2020) ("[b]ut Plaintiffs' burden is not to show that a favorable court ruling would fully remedy the injuries that they have suffered or will suffer. Instead, they need show only that the 'risk [of harm] would be reduced to some extent if [they] receive[] the relief they seek'") (citing Massachusetts v. EPA, 549 U.S. 497, 526 (2007)).

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conadoration with other stakeholders who share our views. In appropriate cases, we engage in
litigation"); Benjamin Decl. ¶ 15 ("[i]n November 2019, APHA reiterate[d] its call for Congress
to pass legislation to ban the import, manufacture, processing, and distribution of asbestos and
asbestos-containing products" and subsequently describes numerous lobbying efforts by APHA
for asbestos legislation); Benjamin Decl. ¶ 19 (APHA will use increased CDR reporting "to
support its advocacy in several ways, including providing our views on further work EPA
conducts on the DRE [Draft Risk Evaluations] in response to the [SACC] [Scientific Advisory
Committee on Chemicals] recommendations [and] continuing to work with Congress and other
stakeholders to advance asbestos ban legislation"); Benjamin Decl. ¶ 20 ("[1]ack of reporting of
the detailed use and exposure information called for by the petition will also harm APHA's
education, public communication, and scientific mission"). Cf. City of San Jose v. Trump, No. 20-
CV-05167-RRC-LHK-EMC, 2020 U.S. Dist. LEXIS 196733, at *43 (N.D. Cal. Oct. 22, 2020)
(diversion of resources could constitute an injury-in-fact in City of San Jose v. Trump, where the
Black Alliance for Just Immigration ("BAJI") was forced to "divert its essential and limited
resources, including staff time and money, from other priorities and programs in order to
counteract the harmful effects of the Apportionment Presidential Memorandum.") (internal
citation omitted). Plaintiff organizations like APHA are diverting resources from their lobbying
and advocacy efforts in order to counteract the potentially harmful effects which occur when EPA
conducts its asbestos-related rulemaking efforts with inadequate information.

Plaintiffs have also demonstrated causation: EPA is the Agency tasked with making risk assessments and issuing a final rule under TSCA. The challenged exceptions to and limitations in EPA's CDR reporting rule is what prevents Plaintiffs from obtaining the information they seek.

Finally, a favorable court decision will redress Plaintiffs' harms. The 2020 CDR submission period is from June 1, 2020, to January 29, 2021. See 40 C.F.R. § 711.20. Should the Court issue an order expanding the scope of the CDR rule, companies will have until January 29 to report that additional information; however, the EPA could extend the CDR reporting period to allow for adequate time to collect new information. In fact, EPA has already extended the CDR reporting deadline twice this year. See 85 Fed. Reg. 75,235 (notice in the Federal Register

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informing the public that, on April 9th, 2020, EPA extended the CDR submission period deadline from September 30, 2020 to November 30, 2020 and that that the reporting deadline was once again being extended to January 29, 2021). And, as discussed supra, LSCA provides that the EPA must publish a final rule not later than two years after the date on which the final risk evaluation regarding a high-priority chemical substance is published (and even then, EPA may extend the deadline for publication of the final rule for a period of up to two years). EPA has not yet completed its final risk evaluation, and this two-year deadline has therefore not begun yet. Given the flexibility which EPA has already demonstrated in extending the CDR reporting deadline, and given the vast amounts of information which EPA could collect under a more robust CDR rule (discussed infra), Plaintiffs have demonstrated redressability.

В. State Plaintiffs

The States argue that they satisfy the criteria for (1) traditional Article III standing, and (2) informational standing. At the summary judgment stage, the States can no longer rest on mere factual allegations in the complaint, but "must set forth by affidavit or other evidence specific facts, [under] Fed. Rule Civ. Proc. 56(e), which for purposes of the summary judgment motion will be taken to be true." Lujan, 504 U.S. at 561.

The declarations submitted by the States demonstrate the requisite elements for traditional Article III standing. The States argue that EPA's unwillingness to capture the full range of reasonably available information under the CDR has harmed them in the following ways.

Hazard Evaluation System and Information Service ("HESIS"). HESIS is part of the California Department of Public Health and serves as a repository of current data regarding toxic materials and harmful physical agents in use (or potentially in use) in places of employment throughout the state. Cummings Decl. ¶ 3. HESIS is charged with "providing reliable information to members of the public (employers and employees) on possible workplace hazards as well as recommendations to the California Division of Occupational Safety and Health (Cal/OSHA) for regulation of toxic substances in the workplace." Cummings Decl. ¶ 5. It uses the data which EPA compiles under the CDR rule to "prioritize chemicals for educational fact sheets and hazard alerts for workers and

employers based on manufactured and imported volumes; to prioritize chemicals for public health outreach and interventions to control exposures in California workplaces based on volumes produced; to learn how chemicals are used in the workplace (e.g., as solvents, adhesives, or cleaning agents); to understand the types of companies and specific companies that manufacture or import specific toxic chemicals; and to estimate the number of industrial workers likely exposed to chemicals of interest." Cummings Decl. ¶ 9. If data compiled by EPA under the CDR rule is not as complete and accurate as possible, this will adversely affect HESIS in several ways: (1) it will undermine the agency's ability to assess the extent to which high-priority chemicals are used in the workplace, as well as the extent of occupational exposure to those chemicals; (2) increased reporting exemptions will limit information for sites within the state of California, particularly because some of the information which EPA collects under the CDR rule is not available elsewhere; and (3) this will, in turn, affect the agency's ability to identify those chemicals that have the greatest potential to adversely affect the health of California workers. Cummings Decl. ¶ 10.

California Environmental Health Hazard Assessment ("OEHHA"): OEHHA is part of the California Environmental Protection Agency ("CalEPA"). Several programs administered by OEHHA, including Proposition 65 (which protects the state's drinking water sources from being contaminated with chemicals known to cause cancer, birth defects, or other reproductive harm, and requires businesses to inform Californians about exposures to such chemicals) rely on data compiled and reported under the CDR rule regarding the manufacture, import, processing, and use of high-risk chemicals. Cogliano Decl. ¶ 8. If EPA does not obtain complete information under the CDR rule, this will "impair [OEHHA's] ability to assess the extent and magnitude of use and potential exposure to particular chemicals of concern." Cogliano Decl. ¶ 9. For instance, the Biomonitoring California program (which measures the amount of chemicals in a person's body and traces the sources of those chemicals) relies upon CDR data, and it has the following criterion for recommending a designated chemical to the program: the extent to which the

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public (or a specific subgroup) is exposed or potentially exposed to the chemical. Cogliano Decl. ¶ 9. This is precisely the information which the CDR rule is supposed to collect. Thus, if TSCA data reported by EPA is inaccurate, unreliable, or incomplete, this will impair Biomonitoring California's ability to accurately assess the extent of human exposure to the chemicals it monitors.

Oregon Health Authority ("OHA"): OHA administers the state's All Payer All Claims Database (APAC), which measures "health care costs, quality, and utilization as an integral component of the state's ongoing health care improvement efforts." De Jung Decl. ¶¶ 4-5. One tool for identifying medical costs is the International Classification of Diseases ("ICD") code system, which is currently in its Tenth Revision ("ICD-10"). De Jung Decl. \P 6. APAC data for fiscal years 2016 through 2019 show that Oregon incurred the following expenses for illnesses attributable to asbestos exposure, as identified through ICD-10 codes: the state spent \$172,813.60 on medical care related to asbestosis and \$1,025,532.79 for mesothelioma-related care. De Jung Decl. ¶ 7. If EPA collects incomplete data under the CDR rule, OHA is hindered in its efforts to identify the costs which the state incurs from asbestos-related health conditions.

Thus, Plaintiff states like California suffer an injury-in-fact when EPA collects incomplete information on asbestos risks via CDR reporting, because state agencies (e.g., HESIS and CalEPA) are not provided with the information they need for their own risk evaluation assessments and for the implementation of State environmental safety programs (which rely upon accurate reporting data about asbestos risks). This injury is fairly traceable to EPA, because EPA is the agency conducting these risk assessments under TSCA. And a favorable court decision will redress the injury—if EPA is directed to revamp the CDR rule to collect complete information (i.e., without the asbestos loopholes discussed infra), then these agencies will receive the information they need to protect their citizens.

The States have also shown a specific injury-in-fact relative to informational standing. TSCA contemplates the grant of complementary authority to the States to address toxic substances where the EPA administrator is unwilling or unable to take action. See 15 USCS § 2627(a) ("[f]or

the purpose of complementing (but not reducing) the authority of, or actions taken by, the Administrator under this Act ... the Administrator may make grants to States for the establishment and operation of programs to prevent or eliminate unreasonable risks within the States to health or the environment which are associated with a chemical substance or mixture and with respect to which the Administrator is unable or is not likely to take action under this Act ... for their prevention or elimination"). To receive a grant, States must demonstrate a "priority need," as determined by the rules set by the EPA Administrator; these rules must "take into consideration the seriousness of the health effects in a State which are associated with chemical substances or mixtures, including cancer, birth defects, and gene mutations, the extent of the exposure in a State of human beings and the environment to chemical substances and mixtures, and the extent to which chemical substances and mixtures are manufactured, processed, used, and disposed of in a State." 15 USCS § 2627(b)(2).

In other words, TSCA contemplates a complementary grant of authority to states like California based on the "extent of the exposure" in the state to chemical substances like asbestos. If EPA does not gather all available data under CDR, states will be inhibited in meeting this prerequisite showing of a "priority need" to receive grants from EPA for programs which eliminate the unreasonable risks posed by asbestos. TSCA contemplates public disclosure of the information for the Plaintiff States' benefit. This provides the requisite injury-in-fact for informational standing under *Atkins* and *Envtl. Def. Fund*.

III. <u>EPA'S DUTY TO GATHER INFORMATION AT</u> <u>THE RISK EVALUATION STAGE</u>

At the risk evaluation stage, EPA requires persons and companies subject to the CDR Rule to report reasonably available information about the quantities and uses of asbestos they import or manufacture. The purpose of this reporting is to provide EPA with the baseline information it needs to determine whether certain "conditions of use" of asbestos pose an unreasonable risk to human health or the environment. EPA's statutory authority is significant, and it must consider information from a wide variety of sources to make a holistic final risk assessment which informs its rulemaking efforts under Section 6 of TSCA.

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Δ	FPA's Duty to	Obtain "reason	ahly ayailah	le information"	Under TSCA § 26(k)
Α.	EPA S Duly to	Obtain reason	adiv availad	ie information	Under ISCA 9 ZOIK

As discussed *supra*, Section 6(b)(2)(A) requires EPA to initiate risk evaluations on 10 chemical substances within 180 days of the enactment of the LSCA. In December 2016, EPA selected asbestos as one of these 10 substances. Under Section 6(b)(4)(A), EPA risk evaluations must determine whether a substance presents an unreasonable risk under "conditions of use." See 15 USCS § 2605(b)(4)(A) ("[t]he Administrator shall conduct risk evaluations pursuant to this paragraph to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant to the risk evaluation by the Administrator, under the conditions of use").

The term "conditions of use" is defined as the "circumstances, as determined by the [EPA] Administrator, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of." 40 CFR § 702.33. The term "potentially exposed or susceptible subpopulation" means "a group of individuals within the general population identified by the Agency who, due to either greater susceptibility or greater exposure, may be at greater risk than the general population of adverse health effects from exposure to a chemical substance or mixture, such as infants, children, pregnant women, workers, or the elderly." 40 CFR § 702.33.

EPA identified the following conditions of use associated with asbestos: imported raw bulk chrysotile asbestos for the fabrication of diaphragms for use in chlorine and sodium hydroxide production; several imported chrysotile asbestos-containing materials, including sheet gaskets for production of titanium dioxide, brake blocks for oil drilling, aftermarket automotive brakes/linings, and other vehicle friction products; other gaskets and packing; cement products; and woven products. DMSJ at 9.

TSCA requires EPA to consider "reasonably available information" when conducting risk evaluations on conditions of use. See 15 U.S.C. § 2625(k) ("[i]n carrying out sections 4, 5, and 6 [of TSCA], the Administrator shall take into consideration information relating to a chemical substance or mixture, including hazard and exposure information, under the conditions of use, that Northern District of California

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is reasonably available to the Administrator"). EPA has implemented this statutory mandate in its risk evaluation process: "EPA will base each risk evaluation on reasonably available information." 40 C.F.R. § 702.41(b)(1). These two provisions implement the overarching policy embodied by Section 2(b) of TSCA. See 15 U.S.C. § 2601(b)(1) ("[i]t is the policy of the United States that ... adequate information should be developed with respect to the effect of chemical substances and mixtures on health and the environment and that the development of such information should be the responsibility of those who manufacture and those who process such chemical substances and mixtures").

TSCA defines reasonably available information to mean "information that EPA possesses or can reasonably generate, obtain, and synthesize for use in risk evaluations," considering the deadlines for completing the evaluation. 40 C.F.R. § 702.33. Reasonably available information may include "information, models, and screening methodologies, as appropriate." See 40 C.F.R. § 702.41(b)(4). Information which meets the requirements of 40 CFR § 702.33 is "reasonably available information whether or not the information is confidential business information, that is protected from public disclosure under TSCA section 14." See 40 C.F.R. § 702.33. The approaches EPA will use in the risk evaluation are "determined by the quality of the information, the deadlines . . . for completing the risk evaluation, and the extent to which the information reduces uncertainty." Id. Individuals and companies which report information under the CDR rule are also required to report information which is either known or which is "reasonably ascertainable" to them. See 40 CFR § 711.15 ("[a] submitter of information under this part must report information as described in this section to the extent that such information is known to or reasonably ascertainable by that person"). In this regard, the term "known to or reasonably ascertainable" is defined as "all information in a person's possession or control, plus all information that a reasonable person similarly situated might be expected to possess, control, or know." 40 CFR § 720.3(p).

EPA's powers under the CDR rule are extensive. It is unlawful for any person or company to refuse or fail to submit information under the CDR rule. See 15 U.S.C § 2614(3) (providing that it is unlawful for any person to "fail or refuse to (A) establish or maintain records, (B) submit

reports, notices, or other information, or (C) permit access to or copying of records, as required by

this Act or a rule thereunder"). Failure to report may result in a civil fine or criminal prosecution for willful violations. See 15 USCS § 2615(a)(1); see also 15 USCS § 2615(b)(1). Further, EPA may seek judicial relief to compel submission of information required under Section 8(a) (i.e., information required to be reported under the CDR rule, which was promulgated under EPA's Section 8(a) authority). See 15 USCS § 2616(a)(1)(C). TSCA also allows the EPA administrator to inspect facilities to ensure compliance with the statute, and the Administrator may even subpoena witnesses and any reports, papers, documents, or other information he deems necessary. See 15 USCS § 2610(a); see also 15 USCS § 2610(c).

In sum, EPA has significant enforcement power to compel companies and persons to submit information which is known to them, or which is reasonably ascertainable, under the CDR rule. There are a number of tools which the agency can use to glean the full spectrum of information concerning the risks posed by asbestos conditions of use in the U.S. chain of commerce. It is obvious that the complete and adequate information is necessary to an effective assessment of risk and regulation thereof. *See* 15 U.S.C. § 2601(b)(1).

IV. INFORMATION GAPS

Despite the strong enforcement powers at its disposal and the importance of complete and adequate information, the EPA, in this instance, has declined to collect all reasonably available information concerning the risks posed by asbestos conditions of use. The loopholes in the statutory scheme which exempt certain data from the reporting requirements of the CDR rule are significant. EPA asserts that closing them would not lead to additional information and instead lead to the collection of duplicative information (*i.e.*, information which it already possesses through current CDR reporting data). *See* 15 U.S.C. § 2607(a)(5) ("[i]n carrying out this section, the Administrator shall, to the extent feasible—(A) not require reporting which is unnecessary or duplicative"). As demonstrated herein, it is evident that the EPA does not know what it does not know, and its conclusion that closing the loopholes would yield nothing useful is not an informed one. EPA currently lacks possession of all reasonably available information because: (1) it has declined to eliminate the current loopholes in the CDR reporting rule and (2) its modeling cannot

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adequately capture the full range of asbestos-related risks because EPA lacks reliable and sufficiently comprehensive raw data inputs.

Under the APA, agency action may be set aside if it is arbitrary or capricious. *See* 5 U.S.C. § 706(2)(A). "[A] court is not to substitute its judgment for that of the agency" and "should uphold a decision of less than ideal clarity if the agency's path may reasonably be discerned." *F.C.C. v. Fox Television Stations, Inc.*, 556 U.S. 502, 513-14 (2009) (citation and quotation omitted). However, an agency must "examine the relevant data and articulate a satisfactory explanation for its action." *Motor Vehicle Mfrs. Ass'n of United States, Inc. v. State Farm Mut. Automobile Ins. Co.*, 463 U.S. 29, 43 (1983).

As discussed *infra*, EPA has not articulated a satisfactory explanation for its decision not to use its significant enforcement powers to collect information from companies concerning asbestos-related health risks. EPA cannot know what information is "reasonably ascertainable" to submitters, and thereby "reasonably available" to EPA, without knowing the full range of potentially available information to be reported. Further, EPA's excuse that it need not seek to acquire the requested information because it would be duplicative is not rational. First, there is not a categorical bar on the collection of duplicative information. TSCA merely provides that the Administrator "shall, to the extent feasible ... not require reporting which is unnecessary or duplicative." See 15 U.S.C. § 2607(a)(5)(A) (emphasis added). Second, EPA's assertion that certain information is "duplicative" is premised on the notion that it knows the full range of reasonably available information in the first place. As discussed *infra*, this is not the case. The current CDR reporting scheme contains several reporting "loopholes" which prevent EPA from collecting the full scope of information which is reasonably ascertainable for submitters. These loopholes are large and cannot be cured by EPA's modeling efforts without sufficiently reliable and comprehensive raw data inputs. The EPA has not demonstrated it has a sufficient grasp of the universe of available information to determine it need do nothing further. In light of these deficiencies, EPA has "failed to articulate a satisfactory explanation" for its action, and its action is therefore arbitrary and capricious under the APA. State Farm, 463 U.S. at 43. The Court begins by examining the loopholes in EPA's information gathering process.

A. **Current Loopholes**

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The following loopholes in the CDR reporting scheme prevent EPA from receiving reasonably available information: (1) the asbestos-containing articles exemption; (2) the impurities exemption; and (3) the processors exemption.

1. **Asbestos-Containing Articles**

The importation of a chemical substance "as part of an article" is not subject to reporting under the CDR rule. See 40 C.F.R. § 711.10(b) ("[a] person described in § 711.8 is not subject to the requirements of this part [the CDR reporting rule] ... when ... (b) The person imported the chemical substance as part of an article"). Plaintiffs' petition asked EPA to amend the CDR rule so that the article exemption is inapplicable to asbestos. MSJ at 20 (citing Petition at 11).³

An article means "a manufactured item (1) which is formed to a specific shape or design during manufacture, (2) which has end use function(s) dependent in whole or in part upon its shape or design during end use, and (3) which has either no change of chemical composition during its end use or only those changes of composition which have no commercial purpose separate from that of the article, and that result from a chemical reaction that occurs upon end use of other chemical substances, mixtures, or articles; except that fluids and particles are not considered articles regardless of shape or design." 40 C.F.R. § 704.3. In plain terms, a chemical substance is considered to be "part of an article" if it is not intended to be removed from that article and has no end use or commercial purpose separate from the article of which it is a part. DMSJ at 6 (citing 84 Fed. Reg. 3,396, 3,401 (Feb. 12, 2019)); see also TSCA Chemical Data Report, Fact Sheet: Articles (Aug. 3, 2012).

Based on "significant research and outreach," EPA claims that it obtained all reasonably available information on imported articles containing asbestos for the risk evaluation. DMSJ at 24. It identified the following asbestos-containing articles imported in the U.S.: asbestoscontaining sheet gaskets, other gaskets, aftermarket automotive brakes/linings, other vehicle friction products, and brake blocks. DMSJ at 25. It requested this information throughout the risk

³ The States' petition pointed to the same deficiencies in the CDR rule as ADAO's petition. See Docket No. 1, Ex. 1. For ease of reference, this order cites solely to the ADAO petition.

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evaluation process by "open[ing] public dockets for the submission of such information, and conduct[ing] outreach to manufacturers, processors, users and other stakeholders." Id. EPA also reviewed "reasonably available information from other federal agencies, the peer-reviewed literature, industries using asbestos or asbestos-containing products, and trade associations that represent this industry to identify relevant exposure data" and promulgated the Significant New Use rule to require notification of any new asbestos-containing articles which it had not previously identified. Id.

However, the EPA has missed substantial reasonably available information. First, the asbestos-containing articles which EPA identified appear to be only the tip of the iceberg. The United States Geological Survey identifies, in its 2015 and 2017 Minerals Yearbook for asbestos, a number of asbestos-containing articles which EPA does not account for in its 2017 DRE Scoping Document or its 2019 Problem Formulation: cement products; clothing; compressed asbestos fiber jointing paper; millboard; felt; yarn and thread; cords and string; woven or knitted fabric; asbestos articles for use in civil aircraft; crocidolite footwear; accessories and headgear; asbestos paper; compressed asbestos fiber jointing in sheets or rolls; asbestos woven or knitted fabric; wallboard and floor tiles; window caulking; recycled asphalt shingle scrap; adhesive mastic; gaskets for motorcycles and pads for ATV's and scooters. See U.S. Geological Survey Minerals Yearbook 2015, Table 6 in Adkins Decl., Ex. 1 (Docket No. 52-1); U.S. Geological Survey Minerals Yearbook 2017, Table 6.4 For many of the categories of asbestos-containing articles in Table 6 of the 2015 and 2017 Minerals Yearbooks, USGS is unable to determine the quantity of asbestoscontaining articles entering the country. See id. These findings by USGS indicate that EPA is not accounting for certain asbestos-containing articles that are imported into the U.S., for which quantity information is unknown. In fact, EPA explicitly admits in its 2018 Problem Formulation that "the import volume of products containing asbestos is not known." EPA, Problem Formulation of the Risk Evaluation for Asbestos, No. EPA-740-R1-7018 (May 2018) at 22 ("Problem Formulation"). EPA could mitigate this uncertainty if it elected to require submitters to

⁴ Available at https://prd-wret.s3.us-west-

^{2.}amazonaws.com/assets/palladium/production/atoms/files/myb1-2017-asbes.pdf.

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report this information under the CDR rule.

EPA counters that its 2017 Scoping Document adequately captured all intended, known, or reasonably foreseeable imports of asbestos-containing articles. See 15 U.S.C. § 2602(4) (defining conditions of use as the circumstances under which a chemical substance is "intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of"). EPA cites Table 2-2 of the Scoping Document:

Table 2-2. Current Known and Assumed Conditions of Use of Asbestos

Use				
Status*	Product Category	Use Example	Reference	
Known Use	Asbestos Diaphragms	Chlor-alkali Industry	U.S. EPA (2017c); Comment ID EPA-HQ-OPPT 2016-0736-0041; Comment ID EPA-HQ-OPPT 2016-0736-0063	
	Sheet Gaskets	Chemical Manufacturing	Comment ID <u>EPA-HQ-OPPT-2016-0736-0067</u>	
Evidence of Use	Industrial Friction Products	Brake Blocks in Oil Industry		
	Aftermarket Automotive Brakes	Passenger Vehicles	Preliminary Use Information EPA-HQ-OPPT-2016-0736-0005	
	Other Vehicle Friction Products	Non-passenger Vehicles		
	Adhesive and Sealants	Mirror adhesive; tile cement		
	Roof and Non-roof Coatings	Roofs/Foundations; Mastics		
	Other Gaskets and Packing	Washers		
Reasonably	Building Materials	Imported Cement		
Foreseen Use	Woven Products	Imported Textiles	Preliminary Use Information EPA-HQ-OPPT-2016-0736-0005	
	Other	Articles not specified	<u>LFA-11Q-GFF 1-2010-0730-0003</u>	

cycle diagram.

The table lists eight conditions of use in the "Known Use" and "Evidence of Use" categories. The Table refers generally to, e.g., "Building Materials," "Adhesive and Sealants," and gives limited examples of use. But it does not list all known or reasonably foreseeable uses, per 15 U.S.C. § 2602(4) ("[t]he term 'conditions of use' means the circumstances, as determined by the Administrator, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of"). It does not expressly capture with any specificity the multitude of building materials containing asbestos (e.g., wallboard and floor tiles, window caulking, recycled asphalt shingle scrap, adhesive mastic). As to the "Woven Products" category, the "Use Example" for Woven Products ("Imported

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Textiles") does specifically capture the consumer products which Plaintiff organizations identified (e.g., yarn, thread, and woven/knitted fabric). Nor is there any information about the *downstream* use of asbestos-containing yarn and fabric by, e.g., retail distributors who sell these products to the general public

More fundamentally, as noted above, EPA has not attempted to quantify the volume of asbestos-containing articles imported into the U.S. Indeed, after listing only eight known categories of use, EPA acknowledges in its Problem Formulation that "the import volume of products containing asbestos is not known." Problem Formulation at 22. In their Section 21 petition, Plaintiffs pointed to this tacit acknowledgement by EPA, contending that EPA lacked basic information about the volumes in which asbestos-containing products are produced or imported, the sites where they are used, and the number of exposed individuals. MSJ at 11.

This lack of information is particularly significant given the EPA's unwillingness to capture and quantify downstream uses of asbestos-containing articles. The EPA explicitly acknowledges in its Problem Formulation that "[c]onsumer exposures will be difficult to evaluate since the quantities of these products that still might be imported into the United States is not known." Problem Formulation at 39. In one significant example, the EPA fails to measure the extent of consumer exposure which occurs when mechanics change asbestos-containing brake linings, or when consumers use asbestos-containing woven products. MSJ at 12 (citing Plaintiffs' Section 21 petition at 7-8). This despite the fact that EPA anticipates that consumers are likely to be exposed to asbestos while changing asbestos-containing brake linings, and that the most likely route of exposure is inhalation of asbestos fibers. Problem Formulation at 39. Dr. Barry Castleman, a member of ADAO's Science Advisory Board, wrote a paper advising EPA on the factors it should consider in its asbestos risk assessments. Dr. Castleman estimated that there at least 900,000 U.S. mechanics, who regularly do car and truck repairs, who may be exposed to asbestos in imported brake linings and in asbestos engine and exhaust gaskets. Dr. Barry Castleman, Continuing Public Asbestos Exposure in the US, EPA-HQ-OPPT-2016-0736-0122 at 6 (2018). These mechanics may be exposed to airborne asbestos dust which is hundreds of times higher than the current OSHA permissible exposure limit for asbestos. *Id.*

Finally, the basis for EPA's conclusion that it already has sufficient information rests on a thin reed. For instance, as ADAO discussed in its Section 21 petition, the Problem Formulation states that EPA "had originally identified an asbestos-containing adhesive for use as a mirror adhesive but later determined after contacting the supplier that it is no longer sold." Petition at 8 (citing Problem Formulation at 19). But as ADAO correctly notes, the comment of a single supplier does not mean that there are no other suppliers manufacturing or selling this adhesive. Moreover, ADAO notes that a "voluntary oral statement made in a telephone call with EPA does not carry the same indicia of accuracy and completeness as a formal written submission in compliance with an EPA rule." MSJ at 14 n.24.

EPA has significant enforcement powers under TSCA, including the power to subpoena documents and compel the submission of information required under the CDR rule from a federal court. See 15 USCS § 2616(a)(1)(C); 15 USCS § 2610(c). EPA's refusal to exercise that power and instead to rely, e.g., on voluntary statements from an evidently insufficient sample size implies the EPA is not capturing all reasonably available information. The EPA lacks information, inter alia, on the quantity of asbestos-containing articles being imported and the extent of their downstream use in the chain of commerce. It also does not know the amount of additional information it could gain if it used its significant enforcement powers to collect the full spectrum of information via the CDR rule. In short, the EPA does not know what it does not know.

2. <u>Impurities</u>

TSCA provides that reporting under the CDR rule is not required when a person manufactured a chemical substance in the manner described in 40 C.F.R § 720.30(g) or (h). 40 CFR § 711.10(c). Thus, the manufacture or import of a substance as an impurity, which is not used for commercial purposes, is exempt from the CDR rule's reporting requirements. *See* § 720.30(h)(1)-(2) (exempting from the notification requirements "[a]ny impurity" and "[a]ny byproduct which is not used for commercial purposes"). TSCA defines an impurity as "a chemical substance which is unintentionally present with another chemical substance." 40 CFR § 720.3(m). ADAO's petition asked EPA to amend the CDR rule so that the impurities exemption

is inapplicable to asbestos. MSJ at 22. The petition cited several studies demonstrating the presence of asbestos contamination in makeup, crayons and other children's toys made from talc (a mineral often found in deposits also containing asbestos) raising the possibility that thousands of asbestos-contaminated talc-based consumer products may be entering the US. *Id*.

EPA states that it is aware of press reports of studies that found low levels of asbestos in makeup and crayons. After considering these studies, EPA claims that it would not receive additional information if it eliminated the impurities exemption because all currently available data on impurities is from independent laboratory testing (DMSJ at 28-29) and that because testing for impurities was not done by the submitters themselves, this information is not "reasonably ascertainable" within the meaning of 40 CFR § 720.3(p). DMSJ at 29. At oral argument, EPA again represented that companies are not performing testing on their products, but rather are obtaining such testing through third parties.

However, EPA does not know what information regarding asbestos impurities is reasonably ascertainable for submitting companies unless it requires that information to be reported under the CDR rule.⁵ It might be that submitters have, for instance, a ready access to information from third-party testing for their products. Either way, EPA cannot know until it mandates this information. For instance, EPA might find that large companies like Johnson & Johnson could use their considerable resources to obtain testing on the asbestos impurities present in their products. EPA's definition of "reasonably ascertainable" includes "all information that a reasonable person similarly situated might be expected to possess, control, or know." 40 CFR § 720.3(p). EPA cannot know what submitters are "expected to possess, control, or know" unless and until it requests that they submit their test results on asbestos impurities. By enacting a "one-size-fits-all" approach that categorically declined to require *any* submitters to submit information on asbestos impurities, EPA was unable to determine for which companies this information was

⁵ EPA's Problem Formulation makes one passing reference to talc, and otherwise does not discuss it. *See* Problem Formulation at 16 (noting that tremolite, a type of asbestos fiber, may be found as a contaminant in industrial minerals such as silk). Its 2020 DRE does not mention or discuss asbestos contamination in talc in any way whatsoever. *See generally* EPA, Draft Risk Evaluation for Asbestos, No. EPA-740-R1-8012 (2020).

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reasonably ascertainable in the first place.⁶ There is no evidence that EPA has sufficiently surveyed the field to know what information might be reasonable ascertainable to submitters if the CDR were applied with full force.

3. **Processors**

TSCA unambiguously requires processors to report their data to EPA. See 15 USCS § 2607(a)(1)(A) ("[t]he Administrator shall promulgate rules under which—(A) each person (other than a small manufacturer or processor) who manufactures or processes or proposes to manufacture or process a chemical substance (other than a chemical substance described in subparagraph (B)(ii) shall maintain such records, and shall submit to the Administrator such reports, as the Administrator may reasonably require..."). The term "process" means "the preparation of a chemical substance or mixture, after its manufacture, for distribution in commerce—(A) in the same form or physical state as, or in a different form or physical state from, that in which it was received by the person so preparing such substance or mixture, or (B) as part of an article containing the chemical substance or mixture." 15 USCS § 2602(13). But EPA has not required processors to report this information since 2011. DMSJ at 31. It claims that this information is already reported under the existing regulatory scheme, because "if a manufacturer is required to report for a chemical substance under the CDR Rule, it must also report processing and use information for the chemical substance unless an exemption applies." DMSJ at 31-32 (citing 40 C.F.R. §§ 711.6(b), 711.15(b)(4)).

In its petition, ADAO asked EPA to expand the scope of reporting to "processors" of asbestos-containing articles because "[i]n many cases, importers will be unable to provide the detailed information about use and exposure" in the possession of the companies that use these products. MSJ at 21 (citing Petition at 11).

EPA claimed at the motion hearing that there are only two conditions of use which constitute reportable "processing": (1) diaphragms, and (2) sheet gaskets. See also DMSJ at 34

⁶ At oral argument, counsel for ADAO stated that suppliers of talc-based products conduct testing for trace amounts of asbestos. If even a small fraction of importers have access to that industry data from suppliers, there is no question that it would aid in EPA's risk evaluation methodologies.

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("[b]ased on this extensive research, EPA identified only two conditions of use of asbestos that constitute processing: (1) the processing of raw asbestos into diaphragms and (2) the fabrication of gaskets from imported asbestos-containing sheet gaskets."). Thus, EPA argues that other conditions of use (e.g., installation of car brakes) are not "processing," and that the exemption is defined in a very narrow way. The Agency therefore denied ADAO's petition to close the processors loophole because it "does not believe that requiring processors of asbestos [to report] under the CDR rule will provide useful information not already in the Agency's possession." 84 Fed. Reg. 3402.

ADAO counters that the exemption is much broader than the EPA suggests and leads to information gaps. For instance, if a retailer purchases large quantities of asbestos-containing brake linings and then re-packages them to be sold, that would constitute a form of processing and should be reported. The States' similarly argue that voluntary reporting cannot adequately capture the extent of asbestos processing that is ongoing in the U.S. States' MSJ at 18.

EPA's argument that it already captures all reasonably available information is not reasonable. The information which EPA currently acquires regarding the processing of asbestos comes from importers. DMSJ at 31-32. As Plaintiffs emphasized in their petition, importers will often be relatively uninformed about the downstream uses of their products by their customers, and in many cases will be unable to provide detailed information about the use and exposure which occurs with asbestos processing. Petition at 11. In fact, the CDR reporting form calls for relatively vague information concerning the downstream processing activities that are not in the control of the reporting company. See 40 C.F.R. § 711.15(b)(4)(i) (requiring submitters to select "[a] designation indicating the type of industrial processing or use operation(s) at each site that receives a reportable chemical substance from the submitter site directly or indirectly (whether the recipient site(s) are controlled by the submitter site or not)"). The CDR rule allows importers to select from five processing designations, each of which indicates a separate processing "operation": (1) "Processing as a reactant" ("PC"); (2) "Processing—incorporation into formulation, mixture, or reaction product" ("PF"); (3) ("Processing—incorporation into article" ("PA"); (4) "Processing—repackaging" ("PK"); and (5) "Use—non-incorporative activities"

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("U"). See id. EPA merely requires that importers select one of these five designations to denote the downstream asbestos processing that occurs with their products. EPA does not require submitters to specify what these designations mean in practice, e.g., what kind of a "reactant" is being used; the type of "formulation" or "mixture" in which asbestos is processed; the type of "article" that is used; or the other "non-incorporative activities" which involve asbestos processing.

Instead, EPA relies on limited voluntary reporting, rather than systematic mandatory reporting through the CDR rule, to collect information on asbestos processing. For instance, EPA states that, during a 2017 meeting, industry representatives confirmed that there are only three companies in the United States (Olin Corporation, Occidental Chemical and Axial/Westlake Corporation) who own a total of fifteen chlor-alkali plants which continue to fabricate and use asbestos-containing diaphragms on-site. Problem Formulation at 25. Through direct communication with these processors, EPA claims that it obtained robust information on the use, processes, and disposal methods relating to the fabrication of asbestos-containing diaphragms. DMSJ at 34. Additionally, the fabrication of sheet gaskets was identified as a condition of use during the public comment period, during which one chemical production company (Chemours) notified EPA that it currently uses imported gaskets from China. See Problem Formulation at 25. The problem with this method is that EPA is obtaining information from a limited universe. It has not used its enforcement authority to mandate that companies provide this processing information as part of the CDR reporting rule. See 15 USCS § 2607(a)(1)(A) ("[t]he Administrator shall promulgate rules under which ... each person ... who ... processes ... a chemical substance ... shall maintain such records, and shall submit to the Administrator such reports, as the Administrator may reasonably require") (emphasis added). Thus, EPA only acquires information from companies which choose to reach out and voluntarily report this information. There may be other companies which fabricate sheet gaskets not being picked up by the EPA, which it could easily obtain by tightening up the reporting requirements.

Although the EPA has *some* useful information for its risk assessments through voluntary meetings with industry representatives, its sole reliance on those meetings does not assure it has

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sufficiently complete information.⁷

In sum, EPA's current CDR reporting requirements for processors are insufficient to capture the full range of information, especially that regarding downstream processing of asbestos. EPA instead relies on voluntary reporting from companies regarding the current state of asbestos processing in the U.S. EPA could mandate that this information be reported as part of the CDR rule. It has not articulated a rational decision as to why it has not done so.

B. Inadequacy of EPA's Modeling Assessments

TSCA contemplates that EPA may use models as a means of obtaining reasonably available information. *See* 40 CFR § 702.41(b)(4) ("[i]n conducting risk evaluations, EPA will utilize reasonably available information including information, models, and screening methodologies, as appropriate"). EPA claims that it uses modeling to close certain data gaps where there is uncertainty. For asbestos, EPA proceeded the following way:

"EPA relied on quantitative data obtained through systematic review to build appropriate exposure scenarios when monitoring data were not reasonably available to develop exposure estimates. For conditions of use with limited exposure data, EPA used similar occupational data and its best professional judgment to estimate exposures and evaluate risk. In all cases, EPA synthesized the reasonably available information, considered limitations associated with the data set for each condition of use, and determined that it had sufficient information to complete the asbestos risk evaluation using a weight of scientific evidence approach."

⁷ The petition also asked EPA to eliminate the "naturally occurring substances" ("NOCS") exemption to the CDR rule. See 40 C.F.R. § 711.6(a)(3). And it asked EPA to lower the reporting threshold for asbestos from 2,500 pounds to 10 pounds. See 40 C.F.R. § 711.8(b). EPA defines a NOCS as a substance which is "(i) unprocessed or (ii) processed only by manual, mechanical, or gravitational means; by dissolution in water; by flotation; or by heating solely to remove water." 40 C.F.R. § 710.4(b)(i). This means that **raw asbestos is a NOCS**. EPA denied the request to eliminate the NOCS exemption because the purpose of importing raw asbestos into the U.S. is to make asbestos diaphragms (for the chlor-alkali industry), for which EPA already has use and exposure information, and removing the NOCS exemption would therefore not provide any additional data. MSJ at 10. But Plaintiffs note that the 2015 USGS Minerals Yearbook, which EPA relies on in its Problem Formulation and DRE, reveals imports of raw asbestos (in 2014 and 2015) that are not used by the chlor-alkali industry. Plaintiffs' Reply at 15. Thus, Plaintiffs argue that there may be "reasonably foreseen" conditions of use for asbestos which EPA might not capture under the current CDR rule (e.g., imports of raw asbestos outside the chlor-alkali industry in quantities below 2,500 pounds). Id. at 15 n.14 (citing 40 CFR § 702.33). But unlike the other loopholes (i.e., articles, impurities, and processors) Plaintiffs do not give specific examples of asbestos imports of NOCS which EPA misses. However, the Court need not rest its decision on the NOCS loophole in light of its ruling on the other loopholes discussed *supra*.

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DMSJ at 25. When considering the appropriateness of its assumptions and its analytical approaches, EPA "relies on agency guidelines and professional judgment." DMSJ at 26.

The Court does not dispute that EPA may use occupational data and its best professional judgment to build models that close certain data gaps where there is uncertainty surrounding asbestos-related health risks. However, the predictive efficacy of these models is conditioned upon reliable and sufficiently comprehensive raw data inputs. In light of the informational gaps for certain conditions of use (*i.e.*, the asbestos-containing articles, asbestos impurities, and asbestos processors exemptions), EPA's models do not have the comprehensive raw data necessary to make accurate assessments that capture all "reasonably available" data.

The Report of EPA's Science Advisory Committee on Chemicals ("SACC"), discussed further infra, points to the specific inadequacies of EPA's modeling. For instance, SACC points to the inadequacy of EPA's modeling with respect to certain consumer exposure scenarios to airborne emission of asbestos, e.g., exposures from contaminated work clothing and automotive brake pads. TSCA Science Advisory Committee on Chemicals Meeting Minutes and Final Report, No. 2020-6 at 49 ("SACC Report"). SACC finds, in its report: "[o]verall, [EPA's] risk evaluation is a classic case of having to provide an analysis given relatively meager and imperfect information. Research has not occurred that renders source rates for the airborne emission of asbestos from articles during exposure scenarios; thus, physical modeling of these scenarios is not possible. The relatively meager concentration and exposure data available allows the DRE [Draft Risk Evaluation] to use only a reasonable worst-case analysis." *Id.* (emphasis added). Thus, SACC recommends that EPA *collect additional raw data* to fill these occupational exposure gaps: "Recommendation 26: Use statutory authority granted under TSCA to request additional data on occupational exposures to fill knowledge gaps." SACC Report at 37. SACC's recommendation establishes that certain knowledge gaps cannot be filled with predictive modeling. Importantly, SACC notes that EPA has the statutory authority (indeed, the mandate) to fill these knowledge gaps, which would allow it to build more accurate and reliable models (e.g., with both best-case and worst-case exposure scenarios). Id.

C. The SACC Report and the DRE

EPA's failure to adequately gather all reasonably available information regarding the risk of exposure to asbestos is underscored by the Draft Risk Evaluation ("DRE") and, as noted above, the advice of the SACC.

To understand the role of the DRE and SACC, it is important to set forth the risk assessment process which occurs in several stages. EPA first completes a "scope" of the risk evaluation, identifying the hazards, exposures, conditions of use, and potentially exposed or susceptible populations it expects to consider. EPA, *Risk Evaluations for Existing Chemicals under TSCA*, https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/risk-evaluations-existing-chemicals-under-tsca#determination; *see also* 40 C.F.R. § 702.41(a)(1). As part of the scope, EPA develops "a Conceptual Model that describes actual or predicted relationships between the chemical substance, the conditions of use within the scope of the evaluation and human and environmental receptors." 40 C.F.R. § 702.41(c)(4)(i). This model "identif[ies] human and ecological health hazards the EPA plans to evaluate for the exposure scenarios EPA plans to evaluate." 40 C.F.R. § 702.41(c)(4)(ii). After publication of a Draft Risk Evaluation ("DRE") and public comment, the process culminates with EPA issuing its final determination as to whether a chemical substance presents unreasonable risk to health or the environment under its identified conditions of use. 40 C.F.R. § 702.41(a)(9).

Throughout the risk assessment process, EPA is directed by TSCA to consider the information and advice of the Science Advisory Committee on Chemicals ("SACC"), which provides independent scientific advice and recommendations to EPA on its risk assessments and methodologies for the chemicals it regulates under TSCA. *See* 40 CFR § 702.41(b)(3) ("[a]mong other sources of information, the Agency will consider information and advice provided by the Science Advisory Committee on Chemicals established pursuant to 15 U.S.C. 2625").

⁸ Normally, EPA takes public comment on its draft risk evaluation scope document after publication in the federal register. *See* 40 C.F.R. § 702.41(7). However, EPA states that TSCA's deadlines did not leave it with sufficient time to take public comment on a draft of the scope document after publication. DMSJ at 9. Instead, EPA took public comment on a Problem Formulation, wherein it further refined the conditions of use that were included in the scoping document (removing the conditions of use it did not expect to include in its risk evaluation). *Id*.

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ADAO points to significant deficiencies in EPA's knowledge base and cites two documents outside the Administrative Record: (1) a report by the SACC (an independent scientific advisory body created to advise EPA on its TSCA risk assessments) and (2) EPA's DRE, discussed supra.

In its report, the SACC's central conclusion was that "[o]verall, EPA's environmental and human health risk evaluation for asbestos was not considered adequate and resulted in low confidence in the conclusions." MSJ at 8 (citing TSCA Science Advisory Committee on Chemicals Meeting Minutes and Final Report, No. 2020-6 at 17 ("SACC Report")). For instance, the SACC specifically faulted EPA for relying on voluntary submissions instead of its authority to mandate reporting under TSCA: "[t]he approach of "voluntary report of importing asbestos" seems like a low bar. There should be an attempt to collect more extensive data on the topic. Recommendation 67: Actively collect more data on imported products suspected of containing asbestos instead of relying exclusively on voluntary reporting." SACC Report at 66 (emphasis in original). The SACC also faulted EPA for its unwillingness to mitigate the uncertainty surrounding occupational exposure for downstream uses of asbestos: "The Committee was unclear why the number of potentially exposed workers was uncertain. This is something that certainly EPA in its full authority can require and request. Recommendation 68: Require reporting of numbers of potentially exposed workers from industrial facilities that process asbestos." SACC Report at 67 (emphasis in original).

ADAO asks the Court to take judicial notice of this extra-record document because it shows that "EPA's science advisors raised numerous concerns about the sufficiency of the available use and exposure information and recommended mandatory reporting under TSCA, contradicting the rationale for EPA's petition denial." Plaintiffs' Reply at 8 n.5. In typical APA actions, the Court is limited to the administrative record consisting of all materials the agency decision-maker(s) relied upon directly or indirectly in making the challenged decision. Ramos v. Wolf, 975 F.3d 872, 900 (9th Cir. 2020). However, extra-record evidence may be considered in limited circumstances. In Great Basin Mine Watch v. Hankins, 456 F.3d 955 (9th Cir. 2006), the Ninth Circuit held that "[i]n limited circumstances, district courts are permitted to admit extra-

record evidence: (1) if admission is necessary to determine whether the agency has considered all relevant factors and has explained its decision, (2) if the agency has relied on documents not in the record, (3) when supplementing the record is necessary to explain technical terms or complex subject matter, or (4) when plaintiffs make a showing of agency bad faith." *Id.* at 975; *see also Portland Audubon Soc'y v. Endangered Species Comm.*, 984 F.2d 1534, 1548 (9th Cir. 1993) ("[w]hen it appears the agency has relied on documents or materials not included in the record, supplementation is appropriate"). The Ninth Circuit has also found that "[i]t will often be impossible, especially when highly technical matters are involved, for the court to determine whether the agency took into consideration all relevant factors unless it looks outside the record to determine what matters the agency should have considered but did not." *See Asarco, Inc. v. U.S. EPA*, 616 F.2d 1153, 1160 (9th Cir. 1980); *see also California v. Ross*, 358 F. Supp. 3d 965, 1009 (N.D. Cal. 2019) (electing to consider extra-record evidence because the case involved "complex technical issues related to survey methodology and census-related practices" and "meaningfully evaluating whether Defendants considered all relevant factors or irrationally departed from settled policy would be difficult on the Administrative Record alone."). 9

Likewise, the issue here is what information, if any, the EPA "should have considered but did not." *Asarco, Inc.*, 616 F.2d at 1160. Whether EPA has adequately assembled all reasonably available information, and what kinds of information the EPA did not possess, is at the crux of this case. The information provided by the DRE and the SACC Report is highly probative to those questions because they shed light on the information which EPA *does not have*. The conventional administrative record alone is not likely to fully expose whether the EPA's body of information

⁹ To be clear, the Ninth Circuit struck a careful balance in *Asarco, Inc.*, finding that, if the reviewing court goes outside the Administrative Record, "it should consider evidence relevant to the substantive merits of the agency action only for background information ... or for the limited purposes of ascertaining whether the agency considered all the relevant factors or fully explicated its course of conduct or grounds of decision ... [and] [c]onsideration of the evidence to determine the correctness or wisdom of the agency's decision is not permitted." *Asarco, Inc.*, 616 F.2d at 1160 (emphasis added). The Court strikes that careful balance here. It does not evaluate the correctness or wisdom of EPA's final rulemaking on asbestos health risks (this process is not at issue in the case at bar because EPA is still in the information gathering stage). Instead, the Court

considers these extra-record materials only for the purpose of ascertaining whether EPA has considered all the relevant factors throughout its information gathering process, as TSCA requires.

(which it has collected under TSCA) is inadequate—the very point of this suit. *Cf. Bunker Hill Co. v. Envtl. Prot. Agency*, 572 F.2d 1286, 1292 (9th Cir. 1977) ("[b]ut in the often difficult task of reviewing administrative regulations, the courts are not straightjacketed to the original record in trying to make sense of complex technical testimony, which is often presented in administrative proceedings without ultimate review by nonexpert judges in mind"). Thus, because the DRE and SACC Report are probative to that central question, they inform "what matters [EPA] should have considered but did not," and are properly considered herein. *Asarco, Inc.*, 616 F.2d at 1160. It is especially noteworthy that the SACC Report, in particular, provides an independent, third-party perspective which EPA is *required* by TSCA to consider. *See* 40 CFR § 702.41(b)(3) ("[a]mong other sources of information, the Agency will consider information and advice provided by the Science Advisory Committee on Chemicals established pursuant to 15 U.S.C. 2625").

V. WHETHER EPA'S PETITION DENIAL WAS ARBITRARYAND CAPRICIOUS IN LIGHT OF THESE INFORMATION GAPS

A. Summary Judgment

Federal Rule of Civil Procedure 56 provides that a "court shall grant summary judgment [to a moving party] if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). An issue of fact is genuine only if there is sufficient evidence for a reasonable jury to find for the nonmoving party. See Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248-49 (1986). The mere existence "of a scintilla of evidence . . . will be insufficient; there must be evidence on which the jury could reasonably find for the [nonmoving party]." Id. at 252. At the summary judgment stage, evidence must be viewed in the light most favorable to the nonmoving party and all justifiable inferences are to be drawn in the nonmovant's favor. See id. at 255.

Where a plaintiff moves for summary judgment on claims that it has brought (*i.e.*, for which it has the burden of proof), it "must prove each element essential of the claims . . . by undisputed facts." *Cabo Distrib. Co. v. Brady*, 821 F. Supp. 601, 607 (N.D. Cal. 1992). Where a defendant moves for summary judgment based on a claim for which the plaintiff bears the burden of proof, the defendant need only by pointing to the plaintiff's failure "to make a showing

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sufficient to establish the existence of an element essential to [the plaintiff's] case." Celotex Corp. v. Catrett, 477 U.S. 317, 322, 106 S. Ct. 2548, 91 L. Ed. 2d 265 (1986); see also Fontenot v. Upjohn Co., 780 F.2d 1190, 1194 (5th Cir. 1986) (stating that, "if the movant bears the burden of proof on an issue, either because he is the plaintiff or as a defendant he is asserting an affirmative defense, he must establish beyond peradventure all of the essential elements of the claim or defense to warrant judgment in his favor") (emphasis omitted).

B. Administrative Procedure Act

While the Court "is not to substitute its judgment for that of the agency" and "should uphold a decision of less than ideal clarity if the agency's path may reasonably be discerned," F.C.C., 556 U.S. at 513-14, "courts should not automatically defer to the agency's express reliance on an interest in finality without carefully reviewing the record and satisfying themselves that the agency has made a reasoned decision based on its evaluation of the significance -- or lack of significance -- of the new information." Marsh v. Oregon Natural Resources Council, 490 U.S. 360, 378 (1989). A federal agency "ha[s] a duty to take a hard look at the proffered evidence." Id. at 385 (emphasis added); see also Norton v. S. Utah Wilderness All., 542 U.S. 55, 72-73 (2004).

EPA's decision not to collect the information which the Plaintiffs contend should be collected via the elimination of the CDR exceptions did not come after taking a "hard look" at the value and availability of the additional information the EPA has forsaken. As noted above, EPA declined the petition's request to collect more information about asbestos-containing articles even though the petition accurately described how little information EPA has about the quantities of asbestos-containing products in the U.S. chain of commerce and the overall consumer and occupational exposure for downstream uses of asbestos. EPA declined to collect more information about asbestos impurities without seriously analyzing whether companies had access to reasonably ascertainable third-party testing from suppliers. And EPA declined to collect more information about asbestos processors, instead relying on the type of voluntary reporting that its scientific advisors deem inadequate in the SACC Report.

EPA is not incapable of collecting this information; instead, it is *unwilling* to do so. EPA's

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unwillingness to act stands in the face of its significant statutory authority to require that this information be reported via the CDR rule and runs contrary to its obligation to collect reasonably available information to inform and facilitate its regulatory obligations under TSCA. By failing to do so, the EPA has not acted in accordance with law. See 15 U.S.C. § 2625(k); 40 CFR 702.33(5). By failing to consider all "relevant factors" in its information-gathering efforts, the EPA has also acted arbitrarily and capriciously. Citizens to Pres. Overton Park, Inc. v. Volpe, 401 U.S. 402, 416 (1971). See 5 U.S.C. § 706(2).

VI. <u>CONCLUSION</u>

For the reasons stated here, Plaintiffs' Motion for Summary Judgment is **GRANTED** and Defendant's Cross-Motion for Summary Judgment is **DENIED**. The Court remands to the EPA with instructions to proceed consistent with this order. The EPA is directed to amend its CDR reporting rule pursuant to its authority under 15 U.S.C. § 2607(a)(1)(A) (i.e., under Section 8(a) of TSCA), to address the information-gathering deficiencies identified herein. Cmty. Voice v. United States EPA (In re Cmty. Voice), 878 F.3d 779, 788 (9th Cir. 2017) (after EPA granted a petition from several organizations asking for a rulemaking to update lead-based and dust-lead hazard standards, the Ninth Circuit found that TSCA imposed a clear duty on EPA to conclude a rulemaking proceeding within a reasonable time, and it "order[ed] ... that EPA issue a proposed rule within ninety days of the date that th[e] decision bec[ame] final ... [and] retain[ed] jurisdiction for purposes of ensuring compliance"); NRDC v. United States EPA (In re NRDC), 956 F.3d 1134, 1143 (9th Cir. 2020) (finding that EPA's delay in responding to an environmental organization's administrative petition, which requested that it cancel the registration of a /// /// /// /// /// ///

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dangerous pesticide used in household pet products, merited mandamus relief because it delayed the performance of its statutory duties on a crucial matter of public health). This Court retains jurisdiction for purposes of ensuring compliance.

This order disposes of Docket Nos. 49 and 52 in C-19-0871 and Docket Nos. 60 and 63 in C-19-3807.

IT IS SO ORDERED.

Dated: December 22, 2020

EDWARD M. CHEN United States District Judge