IN THE UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

Docket No. 17-72260
Consolidated with Docket Nos. 17-72501, 17-72968,
17-73290, 17-73383, 17-73390

SAFER CHEMICALS, HEALTHY FAMILIES et al.,

Petitioners,

v.

U.S. ENVIRONMENTAL PROTECTION AGENCY et al.,

Respondents.

IPC INTERNATIONAL, INC. et al.,

Respondents-Intervenors.

On Petition for Review of Final Rules of the U.S. Environmental Protection Agency

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SUPPLEMENTAL BRIEF OF PETITIONERS:

ALASKA COMMUNITY ACTION ON TOXICS; ALLIANCE OF NURSES FOR HEALTHY ENVIRONMENTS; ASBESTOS DISEASE AWARENESS ORGANIZATION; CAPE FEAR RIVER WATCH; ENVIRONMENTAL DEFENSE FUND; ENVIRONMENTAL HEALTH STRATEGY CENTER; ENVIRONMENTAL WORKING GROUP; LEARNING DISABILITIES ASSOCIATION OF AMERICA; NATURAL RESOURCES DEFENSE COUNCIL; SAFER CHEMICALS, HEALTHY FAMILIES; SIERRA CLUB; UNION OF CONCERNED SCIENTISTS; UNITED STEEL, PAPER AND FORESTRY, RUBBER, MANUFACTURING, ENERGY, ALLIED INDUSTRIAL AND SERVICE WORKERS INTERNATIONAL UNION, AFL-CIO/CLC; VERMONT PUBLIC INTEREST RESEARCH GROUP; and WE ACT FOR ENVIRONMENTAL JUSTICE

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INTRODUCTION

Petitioners have demonstrated standing for all of their claims. By unlawfully warping TSCA's requirements for risk evaluation and prioritization, EPA's Framework Rules injure Petitioners in two ways. First, the Rules ensure that EPA will systematically understate risk, making it more likely that EPA will fail to identify and regulate unsafe chemicals as Congress intended. This creates a material risk of harm to Petitioners' members' concrete interests in minimizing exposure to harmful chemicals. Second, the Rules will deprive Petitioners of information about chemical risks to which they are entitled under TSCA and need to reduce exposures to toxic chemicals.

Both injuries are imminent. Petitioners' members are exposed to asbestos, 1,4-dioxane, and HBCD, whose ongoing risk evaluations have already been infected by EPA's illegal Rules.

Petitioners' claims are also ripe: Congress authorized immediate review, and this is Petitioners' only opportunity to bring a facial challenge to the Rules. Delaying review of the purely legal issues presented until as-applied challenges would harm Petitioners by deferring the comprehensive risk evaluations Congress required and the resulting regulations addressing unreasonable risks faced by Petitioners' members exposed to toxic chemicals.

ARGUMENT

I. Petitioners have standing because the Framework Rules threaten their members' concrete interests in minimizing toxic chemical exposures

A. Legal Standards

Article III standing requires Petitioners to have "suffered an injury in fact" that is "fairly traceable" to the challenged action and "likely to be redressed by a favorable judicial decision." *Spokeo, Inc. v. Robins* (*Spokeo I*), 136 S. Ct. 1540, 1547 (2016). The injury must be both "concrete and particularized" and "actual and imminent." *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560 (1992) (internal quotation marks omitted).

Congress has the power to define injuries and articulate chains of causation that will give rise to a case or controversy. *Spokeo I*, 136 S. Ct. at 1549. Accordingly, statutory violations result in concrete injury where (1) the requirements "were established to protect [petitioners'] concrete interests," and (2) the specific violations alleged "present a material risk of harm" to those interests. *Robins v. Spokeo, Inc.* (*Spokeo II*), 867 F.3d 1108, 1113 (9th Cir. 2017). This analysis of whether the injury is concrete is not "fundamentally changed" by whether the statutory requirements are deemed "substantive" or "procedural." *City of Sausalito v. O'Neil*, 386 F.3d 1186, 1197 (9th Cir. 2004); *see Bassett v. ABM Parking Servs., Inc.*, 883 F.3d 776, 782 n.2 (9th Cir. 2018); *compare California v. Azar*, 911 F.3d 558, 570-71 (9th Cir. 2018) (asking whether procedural violation

presents "reasonably probable" threat to plaintiff's concrete interests), *with NRDC v. EPA*, 735 F.3d 873, 878 (9th Cir. 2013) (asking whether agency action presents "credible threat" of future harm to petitioner's members).

Where agency action causes injuries by illegally altering processes required by statute, those injuries are redressable where "the relief requested—that the agency follow the correct procedures—may influence the agency's ultimate decision." *WildEarth Guardians v. U.S. Dep't of Agric.*, 795 F.3d 1148, 1156 (9th Cir. 2015) (quoting *Salmon Spawning & Recovery All. v. Gutierrez*, 545 F.3d 1220, 1226 (9th Cir. 2008)).

For purposes of standing (and ripeness), the Court can consider affidavits and other extra-record evidence. *Nw. Envtl. Def. Ctr. v. Bonneville Power Admin.*, 117 F.3d 1520, 1528 (9th Cir. 1997); *Util. Workers Union of Am. Local 464 v. FERC*, 896 F.3d 573, 577 (D.C. Cir. 2018). Additionally, the Court "must … assume" Petitioners would be successful on the legal merits of their claims. *City of Waukesha v. EPA*, 320 F.3d 228, 235 (D.C. Cir. 2003); *e.g.*, *Legal Aid Soc'y of Alameda Cty. v. Brennan*, 608 F.2d 1319, 1333 n.27 (9th Cir. 1979).

B. Petitioners' members suffer a concrete injury from the Rules

The Framework Rules injure Petitioners because they contravene TSCA's requirements for the prioritization and risk evaluation processes Congress designed

to protect Petitioners' members' health from toxic chemicals.[1] These statutory violations result in processes that necessarily underestimate risk, because the Rules exclude from consideration activities that contribute to risk and information required for accurate risk determinations. *See infra* pp. 7-16. Because EPA is already applying, and will continue to apply, these risk-excluding methods to chemicals to which Petitioners' members are exposed, the Rules create a current material risk of harm to those members. *See Spokeo I,* 136 S. Ct. at 1549-50.

Accurately assessing risk is central to TSCA's objectives. Congress commanded EPA to protect people and the environment from "unreasonable risk[s]" of injury from chemicals, 15 U.S.C. §§ 2601(b)(2), 2605(a), and defined the steps EPA must follow to do so, *see generally id.* § 2605(b). Risk evaluations are critical to that scheme, because their outcomes dictate whether and how EPA must regulate each chemical. *Id.* § 2605(b)(4)(A) (evaluation "determine[s]" whether chemical poses "unreasonable risk"), (a) (requiring regulation to eliminate "unreasonable risk" from chemical).

A chemical's risk is determined by combining how harmful it is (hazard) with how much contact individuals have with it (exposure). *See id.* § 2605(b)(1)(B)(i), (b)(4)(F)(i); Pet'rs' Br. 1-2. Risk can thus be represented

[1] Petitioners undisputedly meet the second and third prongs required for associational standing under *Hunt v. Washington State Apple Advertising Commission*, 432 U.S. 333 (1977). *See* Pet'rs' Br. 62; EPA Br. 39 n.9.

through the simplified equation *Risk = Hazard x Exposure*. PA871. TSCA requires EPA to examine all known, intended, and reasonably foreseen sources of exposure to the chemical throughout its lifecycle (i.e., all conditions of use), and to assess those exposures in combination. Pet'rs' Br. 21-31, 39-49. Eliminating any of these sources from the equation *necessarily* deflates the calculation of risk, preventing EPA from properly determining whether TSCA requires health-protective regulation of the chemical.

The Rules' provisions (1) removing "legacy activities" from consideration, (2) allowing EPA to cherry-pick conditions of use, and (3) authorizing EPA to exonerate isolated uses have the same effect: greenlighting EPA to consider fewer exposures than Congress mandated and thereby underestimate each chemical's risks. *See infra* pp. 7-15. The Rules thus create a material risk that EPA's ultimate regulatory decisions will not protect Petitioners' members against unreasonable chemical risks, the "real harm[] that [TSCA] is designed to prevent." *Spokeo II*, 867 F.3d at 1116; *see Salmon River Concerned Citizens v. Robertson*, 32 F.3d 1346, 1355 (9th Cir. 1994) (finding concrete injury where "consequences might be overlooked" because of "deficien[t]" government analysis (quotation omitted)). Congress also required EPA to consider all "reasonably available information" to ensure accurate, reasoned decisionmaking, 15 U.S.C. § 2625(k), and the

challenged provisions permitting EPA to ignore such information similarly create a material risk of inaccurate decisions, *see* Pet'rs' Br. 51-61.

Congress's express authorization for swift review of the Rules is "instructive" and confirms that Petitioners' injuries are concrete. *See Spokeo I*, 136 S. Ct. at 1549. By defining requirements for EPA to prioritize chemicals, evaluate their risks, and regulate unreasonable risks; instructing EPA to promulgate rules governing prioritization decisions and risk evaluations, 15 U.S.C. § 2605(b)(1)(A), (b)(4)(B); and authorizing pre-implementation review of those rules in this Court, *id.* § 2618(a)(1)(A), Congress has defined a causal chain connecting EPA's Rules to Petitioners' concrete interests in avoiding harmful chemical exposures. *See Massachusetts v. EPA*, 549 U.S. 497, 516 (2007).

Indeed, where Congress authorizes immediate review, courts routinely hear facial challenges to rules governing future agency decision-making, including challenges to regulations affecting petitioners' exposure to pollutants. *See, e.g.*, *Sierra Club v. EPA*, 129 F.3d 137, 139 (D.C. Cir. 1997) (finding standing to challenge rule establishing "criteria and procedures" for future determinations of whether transportation projects conform to pollution-control plans); *Elec. Power Supply Ass'n v. FERC*, 391 F.3d 1255, 1261-62 (D.C. Cir. 2004); *NRDC v. EPA*, 643 F.3d 311, 317-18 (D.C. Cir. 2011); *cf. NRDC v. EPA*, 638 F.3d 1183, 1189 n.3 (9th Cir. 2011) (finding standing to challenge EPA rulemaking approving state

plan controlling future decisions on transportation projects, where petitioners had been and would be exposed to resulting emissions).

Moreover, the threat to Petitioners' concrete interests is not speculative. As Petitioners have shown, EPA is currently applying, and will continue to apply, the unlawful procedures dictated by the Rules to chemicals to which Petitioners' members are exposed.

1. EPA's unlawful "legacy" exclusions present a material risk to members' interests in minimizing exposure to chemicals, including asbestos and lead

EPA's binding statutory interpretation that so-called "legacy activities" are not conditions of use presents a material risk of harm to Petitioners' members' concrete interests because it necessarily results in an underestimation of risk for chemicals EPA is currently evaluating and will put through the prioritization process. TSCA mandates that EPA evaluate chemicals' "conditions of use," including all known and reasonably foreseen circumstances of their use and disposal. *See* 15 U.S.C. §§ 2602(4), 2605(b)(4)(A). Under Petitioners' reading, which the Court must assume is correct in assessing standing, these conditions of use encompass what EPA terms legacy activities. Pet'rs' Br. 40-44. EPA's interpretation is "definitional," requiring EPA to ignore ongoing exposures from "legacy activities" in *every* risk evaluation and prioritization decision. EPA Br. 32 n.6. Excluding these ongoing exposures from consideration, and thereby

understating a chemical's health risks, violates Petitioners' members' right to risk evaluations and prioritization decisions that comply with TSCA, and threatens their concrete interests in receiving the full health protections the statute affords. *See supra* pp. 3-6. Indeed, EPA conceded that Petitioners have standing on this claim. Oral Arg. Recording, at 40:38–40:53.

The injury to Petitioners' members, who are currently exposed to asbestos from ongoing "legacy" uses and disposals, is not speculative. Asbestos is well known to cause mesothelioma and other cancers. PA652-54. And although the manufacture of many asbestos-containing products has been discontinued, these products remain in use in factories, gaskets, and commercial and residential buildings. PA650, MA114-15. Members of Petitioners including United Steelworkers are exposed to asbestos through these "legacy" activities. PA389, 650-51; *see also* PA401-02 (Petitioner Vermont PIRG's members also exposed); MA115 (describing excluded legacy uses as "present[ing] the potential for human exposure").

But EPA is excluding these uses from the risk evaluation, as the Rules require. MA114-15 (scope document clearly excluding "[l]egacy uses"). As a result, EPA cannot account for the ongoing exposures these excluded uses cause when determining whether asbestos's risks are "unreasonable" and thus require regulation. *See* 40 C.F.R. §§ 702.43(a)(4), 702.47. These failures violate TSCA

and pose a material risk of harm to the interests of United Steelworkers' and other Petitioners' members who are exposed to asbestos.

Likewise, the concrete interests of Petitioners' members who are exposed to lead, which is highly toxic, are threatened by EPA's exclusions under the Prioritization Rule of well-known "legacy" sources of exposure (like lead paint and water pipes). *See* PA38-39, 72-74, 254-58, 325-29, 390-91, 423-34, 437-41, 446-47.[2]

Respondents' suggestion that EPA may consider legacy activities as "background exposures" neither cures EPA's unlawful approach nor mitigates the threat to Petitioners' interests in fully protective decision-making under TSCA. If "legacy activities" are not conditions of use, EPA has no authority to address the risks they pose. *See* Reply Br. 11 n.3. Nor does this suggestion defeat Petitioners' standing: Assessing the sufficiency of this purported alternative to TSCA's requirements "goes not to standing, but to the substantive validity of the [] regulations." *See Nat'l Wildlife Fed'n v. Hodel*, 839 F.2d 694, 713 (D.C. Cir. 1988); *Sierra Club*, 129 F.3d at 139.

[2] EPA must put lead through the prioritization process, because lead is on the 2014 EPA Workplan for Chemical Assessments, ER371, and EPA must prioritize all chemicals on the Workplan, *see* 15 U.S.C. § 2605(b)(2)(B).

2. The Risk Evaluation Rule unlawfully permits EPA to exclude conditions of use, threatening members' interests in minimizing exposure to chemicals, including 1,4-dioxane

Petitioners are injured by the Risk Evaluation Rule's unlawful grant of authority to exclude conditions of use from consideration. This injury is not hypothetical: Numerous provisions authorize such exclusions, and EPA cannot deny that those provisions codify its "final" interpretation of TSCA. *See* ER3-4, Reply Br. 36-40. Moreover, EPA is exercising this asserted authority to Petitioners' detriment in the 1,4-dioxane evaluation, creating a material risk of harm to members' interests in avoiding further exposure.

1. As with EPA's "legacy" exclusions, once EPA excludes conditions of use from a risk evaluation, EPA cannot analyze all exposures to the chemical and will necessarily underestimate risk. *See supra* pp. 3-6. This is not a "mere technical violation[]"; it threatens "the real-world interests that Congress chose to protect." *Spokeo II*, 867 F.3d at 1117 (internal quotation omitted).

EPA's assertion, EPA Br. 35-37, 40-41, that it will use this authority only on a "case-by-case basis" is irrelevant. *See NRDC*, 643 F.3d at 317-19 (finding standing for facial challenge to rule authorizing EPA to make future determinations "on a case-by-case basis"). In evaluating standing, the Court must assume Petitioners will succeed on the merits, and thus that EPA never has authority to exclude conditions of use. Therefore, because the Rule authorizes such

exclusions—even if it does not require them in any particular evaluation—Petitioners may challenge the Rule now. *See NRDC*, 643 F.3d at 317-19 (rejecting identical EPA argument).

2. Indeed, EPA's exercise of the Risk Evaluation Rule's pick-and-choose authority is not hypothetical; EPA is using this unlawful authority *now* to exclude known sources of 1,4-dioxane to which Petitioners' members are exposed.

1,4-Dioxane is a likely carcinogen. PA616-19. It is used intentionally in manufacturing, PA539-40, and is a known byproduct of some manufacturing processes, PA540. 1,4-Dioxane also appears as a byproduct in thousands of consumer products, including detergents, paints, and antifreeze. PA226-27, 612; MA170. Importantly, 1,4-dioxane's hazards "are identical whether it is produced intentionally or as a byproduct." PA611.

Members of Petitioners Cape Fear River Watch, Sierra Club, and NRDC are exposed to high levels of 1,4-dioxane in their drinking water, to which byproduct uses of 1,4-dioxane contribute. PA62-65, 69, 74-75, 294-97, 332-34; *see* PA226-27, 229, 542-46. These members must spend additional money on bottled water and filters, and worry that they cannot completely avoid exposures. PA63, 74, 295-96, 333.

In EPA's current evaluation of 1,4-dioxane, its byproduct form "is excluded from the scope," notwithstanding EPA's recognition that production and use of the

byproduct constitute "conditions of use." MA168, 170, 180.[3] Under the Risk Evaluation Rule, EPA will evaluate only those conditions of use "within the scope of the risk evaluation." 40 C.F.R. § 702.41(a), (c).

EPA's exclusions from the 1,4-dioxane evaluation will "necessarily lead to an incomplete analysis of risk," preventing EPA from accurately determining whether the chemical poses an unreasonable risk, and precluding EPA from regulating any byproduct that contributes to unreasonable risk. PA229; *see supra* pp. 3-6. Petitioners have thus linked the application of EPA's illegal statutory interpretation to a specific, material risk to their concrete interests in minimizing exposure to 1,4-dioxane. *Cf. Summers v. Earth Island Inst.*, 555 U.S. 488, 495-97 (2009) (explaining that showing threat of harm from specific applications of facially challenged rules would have been sufficient for standing). Thus, application of EPA's authority is not "uncertain[]," *contra Habeas Corpus Research Ctr. v. U.S. Dep't of Justice*, 816 F.3d 1241, 1250 (9th Cir. 2016), nor is Petitioners' injury premised on a series of speculative "if[s]," *contra LEAN v. Browner*, 87 F.3d 1379, 1383 (D.C. Cir. 1996). EPA must conduct this risk evaluation, 15 U.S.C. § 2605(b)(2), the Rules grant authority to exclude conditions of use, and EPA has already made exclusions in the 1,4-dioxane evaluation.

[3] The scope document is relevant evidence that EPA is already implementing the Rule's unlawful grant of discretion to exclude conditions of use.

3. EPA cannot justify this failure by suggesting it "may" consider the byproduct form of 1,4-dioxane in some unspecified future risk evaluation. EPA Br. 38. The "delay" in evaluating and potentially regulating byproducts is itself an injury. *NRDC*, 643 F.3d at 318-19. Moreover, under EPA's interpretation, EPA may *never* evaluate any chemicals of which 1,4-dioxane is a byproduct. *See* MA170 (identifying several such classes of chemicals). Finally, this alternative to the statutory mandate (to evaluate all uses of 1,4-dioxane in this evaluation) cannot defeat Petitioners' standing. *See Hodel*, 839 F.2d at 713.

3. The Risk Evaluation Rule's use-by-use approach threatens members' interests in avoiding harmful exposures from the combined uses of each chemical, such as HBCD

The Risk Evaluation Rule's use-by-use approach will lead EPA to underestimate risk where exposure results from multiple activities involving a chemical. This threatens members' concrete interests in avoiding harmful exposures to chemicals, like the flame retardant HBCD, which EPA is currently evaluating.

The Rule states that, in every evaluation, EPA "*will* determine whether [a] chemical substance presents an unreasonable risk … under *each* condition of use[]." 40 C.F.R. § 702.47 (emphases added); *see id.* § 702.41(a)(9) (authorizing early single-use risk determinations). Consequently, the Rule creates a material

risk that EPA will determine that individual chemical uses do not present unreasonable risk, even where the uses, in combination, do. Reply Br. 28.

For example, HBCD is toxic; it is associated with reproductive and developmental harm to humans, particularly children. PA859-62. HBCD is used in multiple products—e.g., electronics, furniture, insulation—and released into the environment from multiple activities—e.g., manufacturing, use, disposal. PA862-65. Once emitted, HBCD travels far, persists in the environment, and accumulates in larger animals. PA861-66; MA236-41.

Members of Alaska Community Action on Toxics (ACAT) are exposed to HBCD when they use HBCD-containing products and when it travels to the Arctic and accumulates in animals and plants they eat for subsistence. PA2-3, 16-18, 27-29, 33-36, 865-69. Household dust and subsistence fish may each be contaminated by multiple conditions of use. Thus, to accurately assess risk to ACAT members, EPA must analyze the combined exposures resulting from all conditions of use. PA862-74; Pet'rs' Br. 30-32.

But, under the Rule, when EPA assesses risk from each condition of use in isolation, and fails to evaluate the combined risk from all conditions of use, it will underestimate ACAT members' actual exposure and associated risk. PA868-69, 871-74; *see also* PA19-21. This presents a material risk that EPA will fail to

accurately determine whether HBCD as a whole presents an unreasonable risk of harm, particularly to vulnerable groups, such as Arctic residents. Reply Br. 27-28.

4. The Rules' violation of TSCA's mandate to consider all reasonably available information threatens members' interests in receiving TSCA's full health protections

Petitioners challenged four provisions in the Framework Rules that, on Petitioners' reading, will prevent EPA from considering all "reasonably available information" in prioritization decisions and risk evaluations, as Congress required. Pet'rs' Br. 55-61; *see* 15 U.S.C. § 2625(k). Evaluations based on incomplete information mean that some chemical risks "might be overlooked," including in the ongoing evaluations of asbestos and 1,4-dioxane. *See Salmon River*, 32 F.3d at 1355 (internal quotation marks omitted). This creates a material risk to Petitioners' members' interests in accurate priority designations and risk evaluations that comply with TSCA and thereby fully protect their health.

For instance, section 702.37(b)(4) allows manufacturers to submit information only for conditions of use they want evaluated. It is "a hardly-speculative exercise in naked capitalism" to predict that manufacturers will not submit more information than required by EPA's unlawfully narrowed regulation, for which manufacturers themselves lobbied. *See Sierra Club v. EPA*, 755 F.3d 968, 975 (D.C. Cir. 2014) (internal quotation marks omitted); ER170-71. Thus, it is reasonably probable that EPA (and the public) will never obtain information

about some conditions of use and attendant exposures that may be harmful—and that could influence EPA's evaluations—but that manufacturers withhold as not "relevant" to their requested evaluations. *See* 40 C.F.R. § 702.37(b)(4).

Similarly, the Rules create unlawful information screens, allowing EPA to ignore risk-related studies and data. Pet'rs' Br. 55-58, Reply Br. 34-35. The screens mean that EPA need never notify the public that the information exists, preventing the public from assessing it and commenting on its significance. And the flaws in section 702.5(e) mean that EPA may fail to generate and thus consider required risk-related information. Pet'rs' Br. 60-61.

These failures constitute a quintessential procedural injury. The information EPA considers will plainly influence its assessment of risks, and thus the failure to obtain and consider all required information presents a material risk of harm to Petitioners' members' health. *See Idaho Conservation League v. Mumma*, 956 F.2d 1508, 1516 (9th Cir. 1992) (connecting statutorily mandated procedural safeguards to subsequent agency decisions).

C. Petitioners have shown causation and redressability

The Rules cause Petitioners' injuries, and those injuries would be redressed by declaring unlawful and vacating the challenged provisions.

Although the violations here do not involve a failure to prepare an Environmental Impact Statement or follow notice-and-comment protocol, EPA's

disregard of TSCA's requirements governing the *processes* for risk evaluations and prioritization causes an injury that is considered "procedural." *New Mexico v. Dep't of Interior*, 854 F.3d 1207, 1215 (10th Cir. 2017); *see Sierra Club*, 129 F.3d at 138-39 (analyzing challenge to "procedural rule" that established unlawful "criteria and procedures" for making future determinations under "procedural-rights" standing doctrine); *Elec. Power Supply Ass'n*, 391 F.3d at 1262 (similar). TSCA grants Petitioners a right to risk evaluations and prioritization decisions that comply with TSCA's requirements. *Cf. Salmon Spawning*, 545 F.3d at 1225-26 (statutory requirements for inter-agency consultation created "right" to "procedurally sound consultation"). Because the Rules deviate from TSCA's requirements, they deprive Petitioners of "procedural protections or benefits conferred by [the statute]." *New Mexico*, 854 F.3d at 1215.

Absent the Rules, there would be no authority for EPA to exclude legacy uses, pick and choose among conditions of use, conduct use-by-use risk evaluations, or constrain information EPA will consider. Thus, the Rules cause Petitioners' injury by illegally modifying requirements designed to protect Petitioners' members from toxic chemical exposures. *See Sierra Club*, 129 F.3d at 139.

EPA's argument that the Risk Evaluation Rule is not the cause of defective scoping decisions for asbestos and 1,4-dioxane, EPA Br. 40, is meritless. Those

evaluations must follow the Rule to the "maximum extent practicable," 40 C.F.R. § 702.35(a), and EPA's scope documents expressly cite the Rule as the legal basis for EPA's unlawful exclusions in those evaluations. MA101-02, 160-61. Indeed, EPA specifically "aligned" the scope documents with the Rule. Notice of Availability, 82 Fed. Reg. 31,592, 31,593 (July 7, 2017).

Nor is standing defeated because there are steps between the Rules and the final harm caused by the Rules' illegal provisions. *Azar*, 911 F.3d at 571. Petitioners have shown the connection between each link in the chain: from the unlawful Rules, to EPA's exercise of its authority under the Rules, to the threat to Petitioners' concrete interests, in particular relating to asbestos, 1,4-dioxane, and HBCD. *See supra* pp. 3-16.

Petitioners' injuries would be redressed by vacating the unlawful provisions. Requiring EPA to assess exposures in combination from all conditions of use and to consider all reasonably available information would necessarily yield more accurate and complete risk determinations, which could result in more protection from, e.g., asbestos, 1,4-dioxane, and lead. *See WildEarth Guardians*, 795 F.3d at 1156. That connection between "the procedural step" and the "substantive result" is "[a]ll that is necessary for standing." *EDF v. EPA*, 922 F.3d 446, 453 (D.C. Cir. 2019) (internal quotation marks omitted); *Massachusetts*, 549 U.S. at 518.

In any event, the distinction between substantive and procedural violations can be "murky." *Bassett*, 883 F.3d at 782 n.2. And, even under the standards for non-procedural violations, Petitioners have shown causation and redressability. The Rules necessarily "cause" EPA to underestimate chemical risks, *supra* pp. 3-15; this "increases the threat" of insufficiently protective regulations and consequent "future harm" to members currently exposed to chemicals EPA is evaluating. *NRDC*, 735 F.3d at 878. This injury can be redressed by vacating the challenged provisions and requiring EPA to follow TSCA's requirements. *See Renee v. Duncan*, 686 F.3d 1002, 1013 (9th Cir. 2012).

II. Petitioners have informational standing for each of their challenges to the Framework Rules

Petitioners suffer injury-in-fact when agency action deprives them of "information which must be publicly disclosed pursuant to a statute" and would help them. *FEC v. Akins*, 524 U.S. 11, 21 (1998). *Spokeo I* reaffirmed this principle. 136 S. Ct. at 1549-50 (citing *Akins*, 524 U.S. at 20-25; *Pub. Citizen v. Dep't of Justice,* 491 U.S. 440, 449 (1989)). Accordingly, the D.C. Circuit recently held that when TSCA requires publication of information that would help petitioners, they have standing to challenge regulations affecting the information's publication. *See EDF*, 922 F.3d at 452.

In addition to requiring EPA to publish risk evaluations, 15 U.S.C. § 2605(b)(4)(C), (b)(4)(H), TSCA mandates that EPA "shall make available to the

public" "a nontechnical summary of each risk evaluation," including "a list of the studies" (and their "results") considered by EPA, and "each [prioritization] designation … along with … the information, analysis, and basis" supporting the designations, *id.* § 2625(j)(3)-(5). Congress included these requirements to "improve[] public access" to information about chemicals. *See* S. Rep. No. 114-67, at 9, 21 (2015); H.R. Rep. No. 114-176, at 16 (2015). Indeed, developing "adequate information" about "the effect of chemical[s] … on health and the environment" is one of TSCA's primary purposes. 15 U.S.C. § 2601(b)(1). These required disclosures serve important purposes separate from any regulation that may flow from EPA's evaluations; they enable Petitioners and their members to make informed decisions about how to protect themselves and their constituencies against harmful exposures to toxic chemicals. *E.g.*, PA52-54, 59-60, 77-78, 220-31, 300-01, 339-40, 344-46.[4]

Here, "[t]here is no reason to doubt [Petitioners'] claim that the information [disclosed under TSCA] would help them." *Akins*, 524 U.S. at 21; *see also Friends of Animals v. Jewell*, 824 F.3d 1033, 1040-41 (D.C. Cir. 2016). Ample evidence shows that information from comprehensive prioritization designations

[4] In TSCA, unlike some statutes, Congress required publication of the final products of prioritization and risk evaluation, not just draft versions. This serves independent informational purposes beyond allowing public notice and comment. *Cf. Wilderness Soc'y, Inc. v. Rey*, 622 F.3d 1251, 1259-60 (9th Cir. 2010).

and risk evaluations would assist Petitioners in performing their missions, which include providing their constituencies with complete and accurate information about hazardous chemicals. PA11-13, 21-22, 52-54, 59-60, 218-31, 263-64, 318-19, 336-46, 385; *see* Pet'rs' Br. 68. These groups and their members rely extensively on government information, including information TSCA requires EPA to release. PA220-25, 230-31, 281-82, 343-47.

The flaws in EPA's Rules directly hamper these groups' missions. For example, Petitioner Asbestos Disease Awareness Organization (ADAO) has a primary mission to provide information about sources of exposure to and health effects of asbestos, PA52-54, including exposures from asbestos previously installed in buildings, PA642-47; *see supra* p. 8. But EPA's illegal, blanket exclusion of "legacy activities" guarantees that EPA will not publish vital information about the risks presented by those conditions of use. This will frustrate ADAO's mission to educate public officials, researchers, and others in its efforts to prevent deadly asbestos exposures. PA56-60.

Similarly, a core mission of Petitioner Environmental Working Group (EWG) is to provide consumers with accurate information about hazardous chemicals in everyday items so they can make informed health decisions. PA220, 229. EPA's illegal decision to ignore byproduct uses of 1,4-dioxane in consumer products and drinking water, *see supra* p. 11, will harm EWG's educational

mission by depriving it of information about the risks those uses present. PA226-31; *see also* PA358, 364-65 (explaining how lack of complete risk information will frustrate Union of Concerned Scientists' mission). Moreover, EPA's unlawful use-by-use approach will deprive Petitioners of information disclosing combined risks from a chemical. *See* PA300-01, 318-19, 401; *supra* pp. 13-15.

Finally, each of EPA's flawed informational provisions will prevent EPA from obtaining, considering, and disclosing information as required by TSCA, including information about the full risks posed by chemicals like asbestos and 1,4-dioxane. *See* Pet'rs' Br. 55-61; *supra* pp. 15-16; *see also Am. Canoe Ass'n v. City of Louisa Water & Sewer Comm'n*, 389 F.3d 536, 543 (6th Cir. 2004). Vacating those provisions will redress Petitioners' injury by requiring disclosure of those risks. *EDF*, 922 F.3d at 452-53. Moreover, now is the time for review; Petitioners need not wait for a chemical-specific application of the Rules. *See id.* at 452.

III. Petitioners' claims are ripe

Petitioners' challenges to the Framework Rules are constitutionally and prudentially ripe.

Petitioners' claims are ripe under Article III because Petitioners have demonstrated injury-in-fact. *See Bishop Paiute Tribe v. Inyo Cty.*, 863 F.3d 1144, 1153-54 (9th Cir. 2017); *supra* pp. 3-16, 19-22. Indeed, "[c]onstitutional ripeness

… coincides squarely with standing's injury in fact prong." *Bishop*, 863 F.3d at 1153 (internal quotation marks omitted); *see also Susan B. Anthony List v. Driehaus*, 573 U.S. 149, 157 n.5 (2014).

Although this Court has "discretion[]" to consider whether Petitioners' claims are also prudentially ripe, *Bishop*, 863 F.3d at 1154, it has called prudential ripeness a "disfavored judge-made doctrine that 'is in some tension with [the Supreme Court's] recent reaffirmation … that a federal court's obligation to hear and decide cases within its jurisdiction is virtually unflagging.'" *Fowler v. Guerin*, 899 F.3d 1112, 1116 n.1 (9th Cir. 2018) (quoting *Susan B. Anthony List*, 573 U.S. at 167) (alteration in original); *see also Clark v. City of Seattle*, 899 F.3d 802, 809 n.4 (9th Cir. 2018) (similar). In any event, Petitioners satisfy the three prudential ripeness factors set forth in *Abbott Laboratories v. Gardner*, 387 U.S. 136, 149-52 (1967), and *Ohio Forestry Ass'n v. Sierra Club*, 523 U.S. 726, 733 (1998).[5]

First, this Court's review of Petitioners' claims would not "benefit from further factual development," *Ohio Forestry*, 523 U.S. at 733, because Petitioners' challenges are "purely legal," *Assiniboine & Sioux Tribes v. Bd. of Oil & Gas Conservation*, 792 F.2d 782, 789 (9th Cir. 1986). Petitioners' claims—that the

[5] The Court in *Ohio Forestry* applied the prudential ripeness test from *Abbott Laboratories*, 523 U.S. at 732-33; *see Bishop*, 863 F.3d at 1154 (test in *Abbott Laboratories* concerns prudential ripeness). This Court applied the same test in *Habeas Corpus*, 816 F.3d at 1252.

Rules contravene TSCA as a matter of law—involve questions of statutory interpretation and will be based only on the now-closed administrative record.

The purely legal nature of this case distinguishes it from *Habeas Corpus*, where petitioners alleged that "vagueness" in the challenged regulations prevented them "from making reasonable predictions as to whether and how the Attorney General" would conduct the certification process at issue. 816 F.3d at 1246.[6] Here, by contrast, the Rules on their face violate TSCA by impermissibly authorizing EPA to narrow the scope of prioritizations and risk evaluations, thereby pre-ordaining illegal applications (which have already begun). The error is "complete" because EPA has "rendered its last word on the matter." *Cottonwood Envtl. Law Ctr. v. U.S. Forest Serv.*, 789 F.3d 1075, 1084 (9th Cir. 2015) (internal quotation marks omitted).

Second, this Court's review will not "inappropriately interfere with future administrative action." *Ohio Forestry*, 523 U.S. at 733. Congress expressly authorized pre-implementation review of the Rules. 15 U.S.C. § 2618(a)(1)(A). This "constitutes compelling evidence that Congress has, in effect, decided that the interest of the EPA in effectuating [the statute's] purposes will generally be furthered by review during the statutory period and … hindered by postponing

[6] *Habeas Corpus* is also distinguishable because Congress in that case did not authorize immediate judicial review, as it did under TSCA.

review." *Eagle-Picher Indus., Inc. v. EPA*, 759 F.2d 905, 916 (D.C. Cir. 1985) (analyzing similar language). Indeed, in *Ohio Forestry*, the Court explicitly distinguished the forest plan at issue there from TSCA rules "that Congress has specifically instructed the courts to review 'preenforcement.'" 523 U.S. at 737.

EPA's suggestion that it intends to refine its policies through specific risk evaluations misses the mark. Any "refinement" by EPA during individual risk evaluations could not alter the final legal interpretations codified in the challenged Rules. *Cf. Cottonwood*, 789 F.3d at 1084 (rejecting argument "that judicial intervention would preclude [agency] from refining its policies" because that refinement "would apply only at the project-specific level, not the programmatic level in dispute"). Because EPA has made a final determination that it can, e.g., ignore so-called "legacy activities" and exclude conditions of use when prioritizing chemicals and conducting risk evaluations, that decision is "at an administrative resting place," *Citizens for Better Forestry v. U.S. Dep't of Agric.*, 341 F.3d 961, 977 (9th Cir. 2003), and is ripe for review.

Third, the parties will suffer hardship if this Court delays review. *See Ohio Forestry*, 523 U.S. at 733-34. If Petitioners cannot challenge the Rules until EPA completes individual risk evaluations, EPA's under-protective evaluations will result in irreparable harm to Petitioners' members' health before those future legal disputes are resolved. *See Ctr. for Biological Diversity v. Kempthorne*, 588 F.3d

701, 709 (9th Cir. 2009) (finding that "inherent delay of litigation and the irreparable nature of environmental impact" constituted hardship to petitioner of withholding immediate review). EPA would spend years conducting risk evaluations that will have to be redone if the Court later determines they were based on illegal regulations, derailing the systematic process and deadlines Congress established in amending TSCA. This would cause hardship to Petitioners, whose members are already exposed to toxic chemicals and will continue to face harm from that exposure until EPA issues adequate risk evaluations and resulting regulations to eliminate unreasonable risks. That EPA is already "actively applying" the Rules to specific risk evaluations further shows that "delayed review would cause hardship" to Petitioners and their members. *Cottonwood*, 789 F.3d at 1084. Moreover, review now could forestall a parade of individual challenges in various courts that might result in inconsistent rulings.

Here, Petitioners "are taking advantage of … their only opportunity to challenge [the Rules] on a nationwide … basis," rendering the dispute "ripe for adjudication." *California ex rel. Lockyer v. U.S. Dep't of Agric.*, 575 F.3d 999, 1011 (9th Cir. 2009).

CONCLUSION

This Court has jurisdiction to reach the merits of these Petitions for Review.

June 3, 2019

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FOR THE NINTH CIRCUIT

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