No. 17-72260 (and consolidated Case Nos. 17-72501, 17-72968, 17-73290, 17-73383, 17-73390)

IN THE UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

SAFER CHEMICALS HEALTHY FAMILIES, et al.,

Petitioners,

v.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY, ET AL.,

Respondents.

ON PETITION FOR JUDICIAL REVIEW OF ACTIONS BY THE UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

RESPONDENT EPA'S RESPONSE TO PETITIONERS' SUPPLEMENTAL BRIEF ADDRESSING ARTICLE III JUSTICIABILITY

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TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases

Statutes

Regulations

Other Authorities

INTRODUCTION

The Rules under review are process rules. They establish certain steps EPA will take when evaluating risks of existing chemicals and interpret the phrase "conditions of use" to generally exclude legacy activities. These Rules do not establish the scope of future risk evaluations. They do not determine whether or when EPA will issue one or multiple risk determinations for a single chemical or cabin EPA's discretion to conduct aggregate evaluations. Nor do they require EPA to ignore statutory provisions when reviewing chemical information. Any such decision would occur in the context of chemical-specific evaluations, which will themselves be judicially reviewable. 15 U.S.C. §§ 2605(i)(1)-(2), 2618(a)(1)(C)(i).

Petitioners have plausibly alleged standing to challenge only the definitional interpretation of "conditions of use" and the two provisions still subject to EPA's motion for voluntary remand. As to the remainder of their claims, Petitioners do not allege harm from any decision in the two Rules at issue. The allegations are based on hypotheticals and other non-final agency actions currently being considered by the agency. Under *Habeas Corpus Resources Center v. Department of Justice*, there is no concrete, particularized, and ripe injury sufficient to challenge process rules when the rules themselves do not include a "concrete application" making the specific alleged harm imminent. 816 F.3d 1241, 1250 (9th Cir. 2016).

The Court should therefore dismiss Petitioners' challenges to (1) EPA's preamble statements about the potential scope of future risk evaluations, Pet'rs Br.,

Doc. No. 10839027, 21-38; (2) EPA's regulatory provisions leaving the door open to issue early risk determinations, *id.* 39-40; and (3) the remaining information-gathering provisions still at issue, *id.* 58, 60-61. If EPA ever takes final agency actions based on the decisions Petitioners hypothesize, those would be the proper actions for Petitioners' challenges.

APPLICABLE STANDARD

I. Standing Requires a Concrete, Particularized, and Non-Hypothetical Injury That Is Caused by the Agency Decision Being Challenged.

TSCA authorizes judicial review of rules promulgated under the Act, including the Rules under review here, and places jurisdiction in the Courts of Appeals. 15 U.S.C. § 2618(a)(1)(A). That provision, however, does not fully resolve this Court's jurisdiction because Petitioners must still meet the normal requirements of standing and ripeness for each claim. *See Spokeo, Inc. v. Robins*, 136 S. Ct. 1540, 1547-48, 1549 (2016); *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 572-73 (1992).

The standing elements are well-known. A petitioner wishing to avail itself of this Court's jurisdiction bears the burden to establish (1) an "injury-in-fact," (2) caused by or "fairly traceable" to the challenged action, (3) that would "likely" be "redressed by a favorable decision." *Lujan*, 504 U.S. at 560–61. The Supreme Court has admonished that an alleged injury must be "concrete," meaning it is real rather than abstract; "particularized," meaning it affects the petitioner in a personal and individualized way; and "actual or imminent, not conjectural or hypothetical." *Spokeo*,

136 S. Ct. at 1548-49. Petitioners asserting associational standing, as Petitioners do here, bear the burden to explain and substantiate their claims of standing by showing that their members meet all three requirements for individual standing. *Util. Workers Union v. Fed. Energy Regulatory Comm'n*, 896 F.3d 573, 577 (D.C. Cir. 2018).

Injuries can be substantive (i.e., a tangible harm), procedural, or informational. Petitioners here allege only procedural and informational injury. *See* Pet'rs Suppl. Br., Doc. No. 11318085, 1, 4.

Procedural injury means the petitioner has been denied a procedural right (such as a right to a hearing prior to denial of a license or a right to an environmental impact statement prior to major federal actions). *See Lujan*, 504 U.S. at 572. Procedural rights do not exist in the abstract; they must be found in law. *Spokeo*, 136 S. Ct. at 1549 ("[V]iolation of a procedural right granted by statute can be sufficient in some circumstances."); *Massachusetts v. EPA*, 549 U.S. 497, 516 (2007) ("Congress must at the very least identify the injury it seeks to vindicate."). Parties seeking to vindicate procedural injuries must still "show that the action injures [them] in a concrete and personal way." *Id.* at 517.

Informational injuries arise when agencies fail to disclose or provide access to information mandated by law. *Pub. Citizen v. U.S. Dep't of Justice*, 491 U.S. 440, 450 (1989); *Wilderness Soc'y, Inc. v. Rey*, 622 F.3d 1251, 1258-60 (9th Cir. 2010) (no injury where statute created no right to the information). Informational injury cannot exist if the petitioner has not been denied or deprived of any information. *See, e.g.*, *Pub.*

Citizen, 491 U.S. at 450 (discussing denials of requests for information that gave rise to informational injury).

Regardless of the type of injury, the causation element requires that the agency action being challenged contain the agency's decision that allegedly causes harm. *See Lujan*, 504 U.S. at 560. If the alleged injury is caused not by the challenged action, but by an "independent action" not before the Court, then there can be no Article III jurisdiction. *Id.*; *see also*, *e.g.*, *California v. Azar*, 911 F.3d 558, 571 (9th Cir. 2018) (procedural injury was agency's failure to follow notice-and-comment requirements in promulgating the challenged rule). When the challenged rule regulates someone other than the petitioner (even the agency itself), proving causation is more difficult because it involves presuming choices not before the Court that cannot be predicted. *Lujan*, 504 U.S. at 562.

Petitioners also must prove their claims are ripe. The ripeness doctrine has both Article III and prudential elements, both of which may be raised on the Court's own motion. *Nat'l Park Hosp. Ass'n v. Dep't of Interior*, 538 U.S. 803, 808 (2003). Constitutional ripeness bars the Court from issuing advisory opinions where the issues are hypothetical or abstract. *Bishop Paiute Tribe v. Inyo Cty.*, 863 F.3d 1144, 1153-54 (9th Cir. 2017) (claims were ripe because statute had already been enforced against plaintiff). It overlaps squarely with the injury prong of standing doctrine. *Id.* at 1153.

The question of whether agency actions are ripe typically falls under prudential ripeness.[1] *See*, *e.g.*, *Habeas Corpus*, 816 F.3d at 1252-53*; Eagle-Picher Indus., Inc. v. EPA*, 759 F.2d 905, 186-87 (D.C. Cir. 1985); *Fowler v. Guerin*, 899 F.3d 1112 (9th Cir. 2018). The doctrine examines the "fitness" of the matter for judicial review and the "hardship" to the parties of waiting for later review. *Bishop Paiute*, 863 F.3d at 1154. Agency actions are not "fit" for review, even for pure legal challenges, if the "administrative decision has [not] been formalized" or if the Court would benefit from deferring review until there is a further factual record. *Eagle-Picher*, 759 F.2d at 913, 915-16. In other words, if the agency decision that would allegedly cause harm is not contained in the challenged action but would come in some later action, the matter is not yet fit for review. *Id.* at 919 (challenged agency action was ripe during initial review period because the challenge raised a pure legal issue and the rule "represented the agency's 'final position'"). If the agency would have to take additional steps to implement the policy, the action is not ripe. *Habeas Corpus*, 816 F.3d at 1253; *Fowler*, 899 F.3d at 1116-17 (takings claim unripe until "the government entity charged with implementing the regulations has reached a final decision regarding [its] application").

[1] EPA acknowledges the Court's Order seeking supplemental briefing on Article III justiciability. Order, Doc No. 11300583 (May 16, 2019). While prudential ripeness does not fall under Article III, the caselaw does not always distinguish it from constitutional ripeness. To assist the Court, this brief addresses both.

While the Court may look outside the record for purposes of establishing its own jurisdiction, *Util. Workers Union*, 896 F.3d at 578, this does not eviscerate the requirement that only final agency actions are reviewable. 5 U.S.C. § 704; *Or. Nat. Desert Ass'n v. U.S. Forest Serv.*, 465 F.3d 977, 982 (9th Cir. 2006) (finality requirement treated as jurisdictional in Ninth Circuit). Preamble statements to rulemakings only constitute final agency action when the language indicates an agency's intent to bind itself. *Kennecott Utah Copper Corp. v. U.S. Dep't of Interior*, 88 F.3d 1191, 1223 (D.C. Cir. 1996).

II. *Habeas Corpus Resources* Controls Because It Involved Similar Challenges to Process Rules.

Out of the many cases cited by Petitioners, one is most relevant on the facts: *Habeas Corpus Resources*, 816 F.3d at 1248.[2] There, this Court reviewed a Department of Justice process rule for certifying state post-conviction review programs for capital prisoners. Like here, the rule in *Habeas Corpus Resources* established steps the Department would take, such as reviewing state requests for certification, and certain substantive requirements for certification, such as a court of record to appoint counsel. *Id.* at 1245-46. And there, like here, representative organizations not themselves subject to the government action asserted injury from the possibility of

[2] Most of the cases cited by Petitioners involve challenges to substantive or non-agency actions rather than to process rules. *E.g.*, *City of Sausalito v. O'Neil*, 386 F.3d 1186 (9th Cir, 2004) (alleging substantive environmental harms from a National Park Service plan to develop a military base).

later harmful Department actions rather than from any final substantive decision contained in the action. *Id.* at 1248-49.

This Court held that the organizations did not have a sufficiently concrete and particularized injury based on the "bare uncertainty" over whether or how the Department would review and certify state post-conviction mechanisms. *Id.* at 1249-50. Without a "concrete application [of the process rule] that threatens imminent harm to [the plaintiff's] interests," the petitioners could not prove that the harm alleged was "certainly impending." *Id.* at 1250-51. And the challenges were not ripe because the challenged rule does not "command anyone to do anything" and the petitioner will have "ample opportunity later to bring its legal challenge at a time when harm is more imminent and more certain." *Id.* at 1253.

ARGUMENT

The only claim the Court should reach on the merits is the challenge to EPA's interpretation of "conditions of use." Of the four categories of claims still at issue, only this one is based on an alleged injury from a final decision that EPA made in these Rules. As to the others, Petitioners allege only hypothetical injuries arising from other, future agency actions that are either speculative or non-final.

I. Petitioners Sufficiently Alleged a Concrete and Particularized Injury from EPA's Interpretation of "Conditions of Use."

Petitioners have adequately alleged standing to challenge EPA's definitional interpretation of the phrase "conditions of use" to generally exclude legacy activities.

Under Section 2605 of the Toxic Substances Control Act ("TSCA"), EPA prioritizes and evaluates existing chemicals for unreasonable risks under their "conditions of use." 15 U.S.C. §§ 2605(b)(1)(A), (b)(4). In the preamble to the Risk Evaluation Rule, EPA interpreted that phrase to be focused on uses for which a chemical is still on the market.[3] 82 Fed. Reg. 33,726, 33,729-30 (July 20, 2017) (ER4-5). Going forward, therefore, EPA will prioritize specific chemicals and make unreasonable risk findings under the chemicals' conditions of use, but this will generally exclude legacy activities. *See id.* (creating a general "exclusion").

Petitioners allege they are harmed by the Rules because EPA will not make unreasonable risk determinations on any chemical's legacy activities. *See* Pet'rs Suppl. Br. 7-9. They tie this alleged harm to risks some of their members allegedly face from certain chemicals that remain in the environment from historical activities. *Id.* (citing standing declarations). While EPA does not concede Petitioners' members will be harmed, this is a sufficient allegation for standing purposes.

[3] As explained in EPA's answering brief, EPA reasonably interpreted this phrase under *Chevron* step two because of the express discretion conferred on the EPA Administrator to determine which "uses" and "disposals" EPA should review for existing chemicals; indications in 15 U.S.C. § 2605(a) that EPA's best tools for regulating risks apply to uses for which chemicals are on the market; and legislative history expressly stating that EPA was given authority to decide what uses to evaluate. EPA. Br., Doc. No. 10967460, 17-30. EPA concedes only that the Court has jurisdiction to review Petitioners' claim.

The informational harm alleged is concrete, particularized, and ripe because in these Rules, EPA created a general presumption that it will not prioritize and evaluate existing chemicals under their legacy uses and disposals. *See*, *e.g.*, *Habeas Corpus*, 816 F.3d at 1248-53; *Eagle-Picher*, 759 F.2d 905 at 913-14, 919. Unless and until EPA changes its rule,[4] EPA intends to apply it prospectively to all ensuing chemical-specific evaluations. No other agency action is required to know what is being excluded (legacy uses for which a chemical is no longer on the market) or where (chemical-specific risk evaluations). There will be no later opportunity to challenge this policy because EPA does not intend to further develop it as it is applied. Petitioners therefore have standing to assert this claim.

II. The Court Lacks Jurisdiction Over Petitioners' "Scope" Claim Because the Rules Being Challenged Contain No Decision on If or When EPA May Exclude a Particular Condition of Use from the Scope of a Risk Evaluation.

Petitioners have not alleged a concrete, particularized, or ripe injury from EPA's preamble discussion of possibly excluding certain conditions of use from the scope of chemical-specific risk evaluations, nor have they shown that the alleged injury is caused by the Rules being challenged.

[4] For example, as noted at oral argument, EPA could at some future time apply the statute through its discretion under *Chevron* step two to create a carve-out to the general exclusion (such as for outlier chemicals or to address certain legacy activities once the most significant uses on the market are addressed). *See FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 514-16 (2009) (agencies may change policies based on reasoned explanation).

In the preamble to the Risk Evaluation Rule, EPA stated that it "may" "on a case-by-case basis" exclude certain conditions of use (such as de minimis uses) from consideration "in order to focus its analytical efforts on those exposures that are likely to present the greatest concern." 82 Fed. Reg. at 33,729 (ER4). However, EPA expressly declined to decide in this Rule whether it would ever exclude any conditions of use or what conditions of use would be excluded. *Id.* at 33,730 (ER5) (it would "be premature to definitively exclude a priori specific conditions of use from risk evaluations" at this time). And the regulations promulgated do not require EPA to ever exclude any condition of use, but instead simply track the statutory requirement for EPA to state the conditions of use that will be evaluated in a scope document. *Compare* 40 C.F.R. § 702.41(c)(1) (scope of a risk evaluation will include "the conditions of use, as determined by the Administrator, that the EPA plans to consider") *to* 15 U.S.C. § 2605(b)(4)(D) (EPA shall publish a scope document that includes the "conditions of use . . . the Administrator expects to consider.").

Petitioners' alleged injury from EPA's preamble discussion is that if EPA excludes a condition of use from the scope of a risk evaluation, EPA might underestimate risks of the chemical being evaluated. Pet'rs Suppl. Br. 10.

Petitioners do not establish a concrete or particularized injury caused by the Rule because the harm they allege does not arise from this agency action. It would arise, if at all, from evaluations excluding particular conditions of use from the scope of evaluations for particular chemicals that harm Petitioners' members. EPA did not

decide in this Rule whether *any* conditions of use would be excluded from future risk evaluations, making the claimed injury too abstract and hypothetical to be concrete here. *See Spokeo*, 136 S. Ct. at 1548-49. Rather, EPA generally discussed the sort of conditions of use that *might* be excluded (such as those already sufficiently regulated) but did not decide the matter in this Rule, undermining particularity. *See id.* The injury alleged is akin to that alleged in *Habeas Corpus Resources*; Petitioners assume that EPA will later take an allegedly harmful action but are really challenging the "bare uncertainty" about how EPA will apply this process rule in later chemical-specific applications. 816 F.3d at 1250-51. That is simply not sufficient to give rise to an injury-in-fact.

The matter is also not ripe. The injury alleged is too hypothetical to be constitutionally ripe because EPA did not decide here to take the action Petitioners claim will harm them. *See Bishop Paiute*, 863 F.3d at 1153-54. And because the administrative decision over whether or what condition of use to exclude has not been formalized, the matter is not fit for review and the Court "should stay its hand until agency policy has crystallized." *Eagle-Picher*, 759 F.2d at 915.

Petitioners attempt to support the claim that some of their members are imminently harmed by the risk of underestimation by pointing to another non-final agency action—EPA's ongoing evaluation of 1,4-dioxane. Pet'rs Suppl. Br. 11-12 (citing non-record "expert declarations," standing declarations claiming harm from 1,4-dioxane, and proposed scope document). In the scope for that risk evaluation,

EPA proposed to not address circumstances in which that chemical appears as a byproduct in the context of the evaluation for the remaining conditions of use of 1,4-dioxane. Proposed Scope for Risk Evaluation of 1,4-Dioxane (MA 150 at 170). Instead, EPA will address it elsewhere, in the context of evaluations for chemical substances the byproduct appears in. *Id.*

The fact that Petitioners need to point to another agency action to show even a risk of harm undermines rather than supports their claim. First, the scope document for 1,4-dioxane is a non-final document in the context of a risk evaluation that EPA has not yet completed. (MA 150 at 157-58) (inviting comment on scope); *see also* https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/risk-evaluations-existing-chemicals-under-tsca#ten (risk evaluation for 1,4-dioxane not final). It is hypothetical at this time to say what EPA's final risk evaluation of that chemical will contain. Thus, neither this chemical-specific proceeding nor EPA's statements in this Rule about what it *might* do in a future proceeding is "final." And Petitioners cannot manufacture a "final" reviewable action through the alchemy of melding a non-final past action with a non-final pending action. *See Nat. Desert Ass'n*, 465 F.3d at 982.

Second, it is the chemical-specific risk evaluation for 1,4-dioxane, not this Rule, that will eventually constitute a "concrete application" of the process rules and could potentially result in an imminent risk to Petitioners. *Habeas Corpus*, 816 F.3d at 1250-51. An alleged injury from that other "independent action" not before this Court

does not satisfy the causation prong of standing to challenge the Rules at issue. *See Lujan*, 504 U.S. at 560.

Third, to even know what type of condition of use has been excluded and why, the Court would have to look at this other pending agency action, but that is not part of the administrative record in this case. *Fla. Power & Light Co. v. Lorion*, 470 U.S. 729, 743-44 (1985). The Court's review on the merits would still be limited to the conditional, equivocal preamble language in this Rule, which is exactly the kind of hypothetical review that ripeness doctrine is designed to avoid. If the 1,4-dioxane risk evaluation ultimately includes no risk determination on the instances when that chemical presents as a byproduct, that hypothetical decision would be reviewable when final. 15 U.S.C. §§ 2605(i)(1)-(2), 2618(a)(1)(A). Petitioners' claim would be more fit for review in the context of that agency action and that administrative record because waiting would "significantly advance[e the Court's] ability to deal with the legal issue presented." *Eagle-Picher*, 759 F.2d at 917.

And fourth, Petitioners still cannot point to any EPA action making other kinds of exclusions Petitioners challenge in their brief, such as conditions of use that have already been sufficiently regulated. *See* Pet'rs Br. 22. In short, this Court does not have jurisdiction to entertain challenges to EPA's nonbinding and equivocal statements about actions EPA may or may not take in the future.

It is no answer that Petitioners have now narrowed their claim to a facial challenge to EPA's legal interpretation that it potentially has authority to exclude

conditions of use when there is a good reason to do so. *See* Pet'rs Suppl. Br. 10. There is still no concrete or particularized injury because EPA has not decided if or where to act on that authority. And even in the case of pure legal challenges, Petitioners must still meet the causation element of standing by showing that the action being challenged actually contains the decision that allegedly causes harm. *See Lujan*, 504 U.S. at 560. EPA's preamble discussion here merely leaves the door open for EPA to take the action that Petitioners allege would harm them in a later "independent action" not currently before the Court. *Id.*

Moreover, under *Habeas Corpus Resources*, the issue is not prudentially ripe because the Rules do not "command anyone to do anything"—including EPA—and Petitioners will have "ample opportunity later to bring [their] legal challenge at a time when harm is more imminent and more certain." 816 F.3d at 1253; *see also Assiniboine & Sioux Tribes v. Bd. of Oil & Gas Conservation*, 792 F.2d 782, 789 (9th Cir. 1986) (ripeness question for pure legal challenges involves consideration of "whether the action represents a definitive statement of the agency"). Petitioners' cited case, *NRDC v. EPA*, 643 F.3d 311 (D.C. Cir. 2011), is consistent with this basic proposition. *See* Pet'rs Suppl. Br. 10. There, petitioners challenged an EPA guidance document directing regional EPA air directors to implement the ozone air quality standards in a particular way. *NRDC*, 643 F.3d at 316-17 (directors must give states one of two substantive options for how to implement air quality standards). That decision was found to be ripe because, unlike here, it was a substantive change in law

authorizing approval of state air quality plans containing specific substantive provisions. *Id.* at 319. Here, EPA's legal interpretation does nothing more than preserve a substantive decision for a later time.

III. Petitioners Have Not Alleged a Concrete Injury From EPA's Regulation Permitting Risk Determinations to Be Issued in Multiple Documents Because EPA Did Not Here Decide If It Will Ever Issue an Early Risk Determination Under the Circumstances Petitioners Worry About.

Petitioners have similarly not alleged a concrete or particularized injury from the Rule's promulgation of 40 C.F.R. § 702.47 or Petitioners' hypotheses about how EPA may apply it in the future. Petitioners allege only speculative, "some day" harms that would occur—if at all—in other reviewable agency actions.

40 C.F.R. § 702.47 states that EPA will issue a risk determination for "each condition of uses" within the scope of a chemical-specific risk evaluation, "either in a single decision document or in multiple decision documents." Petitioners' claim seeks an additional requirement that EPA must conduct an aggregate risk assessment of all conditions of use for every chemical.[5] Pet'rs Br. 39; Pet'rs Suppl. Br. 14 (asserting that EPA must "evaluate the combined risk from all conditions of use"—i.e., conduct an aggregate assessment). Petitioners further object to the possibility that EPA may issue an early risk determination finding that certain conditions of use for a chemical

[5] An "aggregate" assessment means EPA considers the combined effects of multiple exposures to a chemical on a person likely to be exposed in multiple ways. A "sentinel" assessment means EPA uses the most dangerous type of exposure as a proxy to represent all exposures.

present no "unreasonable risk." Pet'rs Br. 40. Petitioners' claimed injury is that the regulation "creates a material risk" that EPA—in a future agency action itself reviewable—could choose the multiple-document approach in a circumstance where the different approaches would lead to different conclusions regarding risk. Pet'rs Suppl. Br. 13-14. Petitioners claim personal injury to their members because they believe this might occur in the future final risk evaluation for a chemical known as "HBCD," which they allege harms their members when it accumulates from multiple sources. *Id.* at 14 (citing standing declarations).

First, the Court lacks jurisdiction over this claim because Petitioners' alleged procedural right cannot be found in the statute. *See Spokeo*, 136 S. Ct. at 1549. The Act expressly gives EPA authority to *choose* whether to use an aggregate approach for each chemical, 15 U.S.C. § 2605(b)(4)(F)(ii), and nothing in TSCA gives Petitioners the right to a single risk determination document for each chemical. *Id.* § 2606(b)(4) (EPA conducts risk evaluations on chemicals "under the conditions of use.").

Moreover, this is precisely the kind of challenge to process rules that this Court found insufficient to confer standing in *Habeas Corpus Resources*. 816 F.3d at 1245-49. Like there, the alleged injury arises from Petitioners' assumption that EPA might apply the regulation in a manner they believe will harm them rather than from anything the regulation actually requires. *Id.* at 1248-50. In case there is any doubt of this, Petitioners themselves do not disagree that EPA may use the multiple-document approach as the regulation permits when the early risk determination concludes that

particular conditions of use do present an unreasonable risk. Pet'rs Br. 40. Instead they object to a particular hypothetical "concrete application" of the Rule not now "certainly impending." *Habeas Corpus*, 816 F.3d at 1250-51.

Petitioners also allege nothing that could give rise to a concrete, non-conjectural risk of their members being harmed simply because EPA could potentially decline to use aggregate risk assessments in a future risk evaluation. The regulation does not prevent EPA from aggregating exposures where appropriate. *See, e.g.*, 15 U.S.C. § 2605(b)(4)(F)(ii). EPA very well may determine that aggregating exposures makes sense for some chemicals or a subset of exposures (even for the chemicals that Petitioners' members claim harm them) but not for others. For instance, aggregating exposures may be appropriate where a chemical is used in multiple ways in the same industrial process and the same worker can be exposed in multiple ways. By contrast, where a chemical poses risks only from dermal exposure and does not pose any significant risks when used in an industrial "closed system" where dermal exposure is unlikely, an early risk determination may be appropriate for the industrial use. The precise approach suitable for any given chemical depends entirely on the nature of the chemical and the particular condition of use.

It is pure speculation at this point to say that EPA will choose the approach Petitioners fear in the context of HBCD at all, let alone that the agency will do so in a way that deprives Petitioners' members of information. EPA has not yet issued any final risk determinations for HBCD or any other chemical. Additionally, any harm to

Petitioners from how EPA completes a chemical-specific evaluation will be caused by the specific decisions made there, not by these process rules.

In short, there is no final EPA decision doing what Petitioners say EPA might do and no record explaining why such an action was (or was not) appropriate in any particular setting. The Court should decline Petitioners' invitation to issue an advisory opinion.

IV. Petitioners Have Not Shown Standing As to the Two Information-Gathering Provisions that Remain at Issue.

The challenged information-gathering provisions fall into three categories relevant for this Court's jurisdiction. For the two provisions not subject to EPA's pending motion for voluntary remand, this Court lacks jurisdiction. For the two provisions for which EPA has requested voluntary remand, the Court has authority to grant EPA's motion. *See* EPA Mot. for Remand 1-2, Doc. No. 10967428 ("Remand Mot."). The Court need not address the criminal penalty provision because it was vacated and remanded upon EPA's motion. *See* Order, Doc. No. 11124328.

A. The Court lacks jurisdiction over the remaining information-gathering claims because Petitioners allege harm from hypothetical future illegal action, which the Rules do not require.

Only two of Petitioners' challenges to the Rules' information-gathering provisions are not included in EPA's voluntary remand motion and therefore truly remain at issue: (1) the challenge to 40 C.F.R. § 702.9(b), and (2) the challenge to 40

C.F.R. § 702.5(e). Petitioners have not alleged a concrete and particularized injury that is fairly traceable to the provisions challenged in these claims.

40 C.F.R. § 702.9(b) says that in prioritizing chemicals, "EPA expects to consider sources of information relevant to the listed criteria [in subsection (a)] and consistent with the scientific standard provisions in 15 U.S.C. § 2625(h)." *See also* 15 U.S.C. § 2625(h) (EPA "shall" use information and scientific methodologies "consistent with the best available science."). Petitioners' claim is not that they object to EPA following the requirements of 15 U.S.C. § 2625(h), but that EPA should have also explicitly incorporated 15 U.S.C. § 2625(k), which says that EPA shall take into consideration information "reasonably available to the Administrator." Pet'rs Br. 51-52. Petitioners' claimed injury is that this regulation "will prevent EPA from considering all 'reasonably available information.'" Pet'rs Suppl. Br. 15.

This is merely a hypothetical speculation that EPA may violate the Act in the future, not a concrete injury, and Petitioners have not shown any chain of causation between the claimed injury and this agency action. *See Lujan*, 504 U.S. at 560, 564. The regulation itself does not require EPA to violate § 2625(k) and does not indicate that EPA will do so. In fact, the immediately preceding subsection shows the opposite: EPA "will generally use reasonably available information" to prioritize chemicals. 40 C.F.R. § 702.9(a). Nor is the claimed injury particularized with a showing of personal harm to Petitioners. Petitioner fails to show that EPA is actually or imminently ignoring any reasonably available information.

40 C.F.R. § 702.5(e) says that "EPA generally expects to obtain the information necessary to inform prioritization prior to initiating the" prioritization process for that chemical. Petitioners claim that EPA should have also stated that it will obtain information necessary to complete risk evaluation (the second step in chemical-specific review) for a particular chemical before starting prioritization (the first step) for that chemical. Pet'rs Br. 60. The alleged injury is that the regulation creates an information "screen" and allows EPA to ignore information. Pet'rs Suppl. Br. 16.

Setting aside that the alleged injury does not appear to be tied even to the claim, Petitioners fail to show how the alleged injury is non-speculative and "fairly traceable" to the challenged regulation. Petitioners are presuming that EPA will not consider the information reasonably available for risk evaluations. Critically, however, Petitioners do not, and cannot, show that EPA's regulations actually prevent it from doing so. *See* EPA Br. 57-58. The regulation does not include any language suggesting EPA will screen information or that EPA will not consider whether it expects to have enough information to complete a risk evaluation. Moreover, this alleged injury is not particularized. *See Spokeo*, 136 S. Ct. at 1548. The Court is not told what chemical Petitioners think EPA is prioritizing or will prioritize without having—or without having the ability to gain—sufficient information to complete risk evaluations.

Petitioners do not even point to any suggestion by EPA that it will read the regulations as Petitioners presume. Nor do they explain how their conjecture is

sufficiently non-hypothetical to confer constitutional ripeness. If EPA ever does the things Petitioners speculate about in future prioritizations, the alleged injury would then be ripe, and Petitioners would have an opportunity to challenge the resulting final agency action.

B. The Court should grant the remaining portions of EPA's pending motion for voluntary remand.

EPA has moved for voluntary remand of two provisions in the Risk Evaluation Rule: (1) 40 C.F.R. § 702.37(b)(4), and (2) 40 C.F.R. § 702.27(b)(6). Order, Doc. No. 11124328; Remand Mot. 6 (seeking remand because EPA intends to modify these provisions in light of Petitioners' concerns). These provisions govern requirements that manufacturers must follow when requesting that EPA conduct risk evaluations of specified chemicals. 40 C.F.R. § 702.37(b)(4) (manufacturer requests must include a list of all existing information "relevant to whether the chemical substance, under the circumstances identified by the manufacturer(s), presents an unreasonable risk"); 40 C.F.R. § 702.37(b)(6) ("Scientific information submitted must be consistent with the scientific standards in 15 U.S.C. 2625(h).").

Here, Petitioners allege an informational injury. Petitioners claim that these provisions create a loophole, allowing manufacturers to be the judge of what is relevant and consistent with the scientific standard in § 2625(h) and to potentially withhold plausibly relevant information. Pet'rs Br. 56-59. Petitioners point to a D.C. Circuit decision holding that petitioners had standing to challenge a substantive

exemption from the Resource Conservation and Recovery Act because it was reasonable to predict that facilities would rely on the exemption. *See* Pet'rs Suppl. Br. 15 (citing *Sierra Club v. EPA*, 755 F.3d 968, 972, 975 (D.C. Cir. 2014)).

Petitioners do not raise a concrete injury traceable to the regulations here because the Rules create no substantive exemption and there is no reason to predict that manufacturers will ultimately withhold information, particularly in light of EPA's independent authority to collect information. *See, e.g.*, 40 C.F.R. § 702.41(b)(2), (b)(5). Nor do Petitioners allege with any particularity when or where they believe manufacturers have withheld or will withhold information.

However, the Court need not reach this issue because EPA seeks a voluntary remand of these provisions. *See* Remand Mot. 5-9. Should the Court decline to issue a remand, EPA nonetheless has the ability to modify its own regulations even without a remand.

CONCLUSION

The Court can reach the merits of the legacy exclusion claim. The Court should dismiss the following claims for lack of standing and ripeness: the "scope" claim; the challenge to EPA's regulation regarding the potential number of risk determinations; and the information-gathering claims not subject to EPA's motion for voluntary remand. The Court should grant EPA's pending motion for remand of the remaining two information-gathering claims.

Respectfully submitted,

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UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

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