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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REPLY 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

In amending TSCA, Congress directed EPA in unequivocal terms to ensure comprehensive protection of public health from toxic chemicals. To achieve this goal, the statute prescribes precisely how EPA must prioritize and evaluate chemical risks.

EPA defied these statutory directives by promulgating Framework Rules designed to narrow its chemical evaluations, minimizing the chance EPA will identify unreasonable risks that would compel regulation. EPA asserts broad discretion to exclude from its evaluations some circumstances under which chemicals are manufactured, processed, distributed, used, and disposed of—such as from so-called legacy activities or the presence of the chemical as a byproduct—even if they imperil public health. It claims authority to evaluate and exonerate individual uses one by one, even if unreasonable risk may not become evident until all uses are considered together. And it gives itself the option to ignore relevant, available information about each chemical and allows manufacturers to do the same. EPA's slicing and dicing will prevent the Agency from understanding the full risk posed by each "chemical substance"—the core question TSCA section 6

requires EPA to evaluate.

EPA's approach is fundamentally at odds with TSCA's purpose: to protect the public, and especially vulnerable subpopulations like children, the elderly, and workers, from harmful chemical exposures. Notwithstanding that these groups are defined by their greater susceptibility or exposure to chemicals, including from low doses or multiple pathways of exposure, the Framework Rules allow EPA to forego analyzing these very sources of risk, compromising the special protection TSCA affords to those groups. Respondents offer *no* defense for leaving these groups unprotected.

Instead of focusing on TSCA's health-protective aims, Respondents refer repeatedly to the law's risk-evaluation process as a "triage scheme," in which EPA may limit the scope of risk evaluations so that it can "quickly" prioritize and evaluate "thousands of chemicals" in commerce. This is not how Congress intended the law would work. To the contrary, Congress mandated that EPA concentrate its efforts on a small number of chemicals (20 at any given time). Congress also gave EPA at least three years to complete each evaluation, along with additional tools to manage the Agency's workload to ensure timely and comprehensive evaluations. The Framework Rules' exclusionary, piecemeal approach to risk evaluations is an attempt to rewrite TSCA based on unlawful policy considerations divorced from the statutory text and legislative intent.

The Court must also reject EPA's attempts to evade or postpone judicial review of what is plainly final rulemaking. EPA's repeated refrain that the Court should wait to resolve the legality of EPA's foundational approaches until future lawsuits over individual risk evaluations is contrary to settled administrative law and could put the public at risk for years from unprotective evaluations. Petitioners have standing, and the regulations are ripe for review.

ARGUMENT

I. TSCA requires EPA to consider so-called "legacy activities" in risk evaluations

EPA's justifications for eliminating legacy use, associated disposal, and legacy disposal from TSCA's "conditions of use" definition are "divorced from the statutory text," and thus must be rejected. *Massachusetts v. EPA*, 549 U.S. 497, 532 (2007).

A. EPA fails to square removing "legacy activities" from the definition of conditions of use with TSCA's text and structure

EPA fails to rebut that TSCA's definition of "conditions of use" unambiguously includes "legacy activities." First, EPA's assertion that the term "conditions of use" "focus[es] on the continuing flow" of chemicals through the "stages of their lifecycle, … not … [on] potential risks associated with chemicals already in the environment," EPA Br. 25, ECF No. 67, is contradicted by the definition's plain text, *see* Pet'rs' Br. 41-42, ECF No. 44-1. TSCA defines

conditions of use as the circumstances under which a chemical "is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of." 15 U.S.C. § 2602(4). EPA ignores that its interpretation fails to give independent meaning to each of these five circumstances, as required by the definition's disjunctive list. *See Reiter v. Sonotone Corp.*, 442 U.S. 330, 338-39 (1979). EPA likewise cannot explain how it comports with TSCA's plain text to treat identical uses and disposal activities as conditions of use for some chemicals, but not for others, based only on the happenstance of whether the chemical's manufacturing, processing, or distribution are ongoing. Pet'rs' Br. 46.[1]

EPA's authority to "determine[]" the circumstances that constitute a chemical's conditions of use, 15 U.S.C. § 2602(4), does not confer unfettered discretion to write out of the statute circumstances that plainly fall within TSCA's definition. A grant of authority to an agency to "determine" is "a direction to exercise discretion *within defined statutory limits*." *See Massachusetts*, 549 U.S. at 533 (emphasis added). Thus, the scope of EPA's authority to "determine" what activities constitute "conditions of use" must be understood based on statutory

[1] EPA also contends that miscellaneous legislative-history references to "chemicals in commerce" show that Congress intended EPA to ignore "legacy activities." EPA Br. 29-30. But such general and scattered references "can't override statutory text" defining conditions of use. *Am. Rivers v. FERC*, 201 F.3d 1186, 1204 (9th Cir. 1999) (internal quotation marks omitted).

context. *See King v. Burwell*, 135 S. Ct. 2480, 2489 (2015). EPA cannot exclude activities falling within the definition's language based on rationales "divorced from the statutory text," as explained *infra* pp. 7-14. *Massachusetts*, 549 U.S. at 532.

None of Respondents' cases support their reliance on the clause "as determined by the Administrator" as a "roving license to ignore the statutory text." *Id.* at 532-33. Instead, in each of those cases, the agency's asserted discretion arose not only from the word "determine," but from *other*, plainly discretionary statutory criteria. The statutes at issue directed agencies to "determine," for example, how to allocate costs so that parties "share[d] *equitably*" in the benefits, *see Hagood v. Sonoma Cty. Water Agency*, 81 F.3d 1465, 1477 (9th Cir. 1996); which concession vendor submitted the "best proposal," *Nat'l Mall Tours of Wash., Inc. v. U.S. Dep't of the Interior*, 862 F.3d 35, 37 (D.C. Cir. 2017); and whether to create exemptions the agency "deems appropriate," *San Bernardino Mountains Cmty. Hosp. Dist. v. Sec'y of Health & Human Servs.*, 63 F.3d 882, 886-87 & n.6 (9th Cir. 1995). The courts in those cases found that a determination of whether something is "equitable," "best," or "appropriate" entails a judgment call. TSCA's "conditions of use" definition includes no such discretionary language.

Transitional Hospitals Corp. of Louisiana v. Shalala, 222 F.3d 1019 (D.C. Cir. 2000), relied on by EPA and Intervenors (together, Respondents), confirms that authority to make a determination is not an automatic grant of discretion untethered to statutory language. There, the court concluded that a statute that based hospital reimbursements on whether the "average inpatient length of stay (as determined by the Secretary)" was longer than 25 days authorized the agency to select the methodology for calculating that average. *Id.* at 1024-25. EPA cannot seriously argue that such discretion would have permitted the agency to, e.g., ignore Mondays when calculating the average stay. But that is exactly what EPA is attempting here: claiming discretion to eliminate conditions of use falling squarely within the statutory definition, based on rationales that have nothing to do with TSCA's text or context.

Further, EPA does not dispute that Congress consciously decided to subject "inactive substances" to prioritization and risk evaluation under section 6. *See* EPA Br. 27. Since "inactive substances" are those that have not been manufactured or processed since 2006, 15 U.S.C. § 2607(b)(4)(A), their inclusion under section 6 makes sense only if their continuing use and disposal, standing alone, comprise "conditions of use." *See* Pet'rs' Br. 45-46. EPA tries to avoid this conclusion by arguing that it is "impossible" to "harmoniz[e]" section 6(b) with section 8(b)(4)-(6)'s inventory reporting requirements. EPA Br. 27. But the

statute is perfectly consistent if inactive chemicals' continuing uses and disposal ("legacy activities") constitute "conditions of use." *See FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 133 (2000) (holding that where terms can fit "into an harmonious whole," the Court must so interpret them (internal quotation marks omitted)).

Finally, EPA erroneously asserts, unsupported by statutory text, that TSCA has an exclusively "prospective focus." EPA Br. 28. That Congress purposefully subjected "inactive chemicals" to risk evaluations shows otherwise. Congress's authorization to EPA to evaluate and regulate so-called "legacy activities" makes sense, given TSCA's objective of protecting human health and the environment from harmful chemical exposures, *see* 15 U.S.C. § 2601, which often result from "legacy activities," *see infra* pp. 8-10.[2]

For instance, EPA has previously regulated so-called legacy uses of asbestos under TSCA. *See* 40 C.F.R. §§ 763.120-.123 (imposing safety requirements relating to management of asbestos *in situ*). And Congress instructed EPA to regulate "disposal" of a harmful class of chemicals called polychlorinated biphenyls (PCBs) under TSCA section 6 *after* banning their manufacture,

[2] Indeed, TSCA's definition of "distribution in commerce," which includes not only chemical sale and resale, but also the "holding of[] the substance … after its introduction into commerce," 15 U.S.C. § 2602(5), shows that Congress was not concerned only about newly manufactured and processed chemicals.

processing, and distribution. 15 U.S.C. § 2605(e)(1)(A), (2)(A). Thus, EPA's contention that TSCA's risk-evaluation process is focused only on the prospective "flow [of chemicals] from manufacture into use," EPA Br. 10, is meritless. *Cf.* Cong. Rec. H3026 (May 24, 2016) (statement by Rep. Pallone) (TSCA amendments intended to enable EPA to "get[] dangerous chemicals like lead, mercury, and asbestos … out of the environment"); Lautenberg Chemical Safety for the 21st Century Act (S. 697): Hearing Before S. Comm. on Env't & Pub. Works, 114th Cong. 78 (2015) (assurance from EPA official that proposed amendments would enable EPA to make asbestos a "high priority").

In sum, none of Respondents' arguments provide any basis for ignoring TSCA's plain text or structure, which show that Congress intended legacy use, associated disposal, and legacy disposal to constitute "conditions of use."

B. Contrary to EPA's contentions, so-called "legacy activities" comprise ongoing and future use and disposal of chemicals

Even if TSCA were focused on "current and future activities," EPA Br. 17-18, that would not justify excluding "legacy activities" from the "conditions of use" definition. Petitioners do not contend that TSCA requires EPA to consider "historical activities" or "reach back in time" to evaluate former chemical risks. *Id.* at 2, 17. Rather, what EPA dismisses as "legacy activities" unambiguously fall within the "conditions of use" definition because they consist of *ongoing and*

future "use" and "disposal" that create continuing exposures. 15 U.S.C. § 2602(4); Pet'rs' Br. 41-44.

First, courts have recognized that the word "use" has an expansive meaning encompassing "'to employ' or 'to derive service from.'" *Smith v. United States*, 508 U.S. 223, 228-29 (1993) (quoting *Astor v. Merritt*, 111 U.S. 202, 213 (1884)). Under these definitions, chemicals are still "used" when they are *in situ*, and indeed, EPA has long interpreted "use" in accord with this ordinary meaning. Asbestos is a clear example. Asbestos-containing insulation, pipes, and wallboard already installed in buildings are still in use and perform ongoing functions that benefit building occupants. As EPA has made plain: "Management of asbestos in place is use" under TSCA. 65 Fed. Reg. 24,806, 24,821 (Apr. 27, 2000); *see* 65 Fed. Reg. 69,210 (Nov. 15, 2000) (Asbestos Worker Protection Rule) (codified at 40 C.F.R. § 763.120 et seq.); *see also* MA 229 (insulation *in situ* is a "use" of HBCD). EPA does not explain why it has abandoned its long-standing interpretation of "use" under TSCA. *See Cal. Pub. Utils. Comm'n v. FERC*, 879 F.3d 966, 977 (9th Cir. 2018) (agency's departure from prior policy "without acknowledgment or explanation" was invalid).

So too, EPA concedes that "associated disposal" is the "future disposal" of a chemical. EPA Br. 10. Nothing in the definition of "disposal" excludes future disposal of a product—such as of asbestos-containing debris from building

demolition or renovation—merely because the product being disposed is no longer manufactured. EPA cannot "exclude from coverage certain items that clearly fall within the plain meaning of a statutory term" where, as here, there is no "strong structural or contextual evidence" to support such an exclusion. *U.S. Telecom Ass'n v. FCC*, 359 F.3d 554, 592 (D.C. Cir. 2004).

As with "use," EPA's own prior interpretation of "disposal" in TSCA undermines its new claim in the Framework Rules that "legacy disposal" is "past" activity. *See* Pet'rs' Br. 43-44. EPA's attempt to disclaim its long-held interpretation of "disposal," *see* EPA Br. 22, only highlights that its new, narrowed interpretation is arbitrary and has no basis in statutory text or legislative history. EPA's operative TSCA regulations cover "legacy disposal" of PCBs and define disposal broadly to include "spills, leaks, and other uncontrolled discharges," and "actions related to containing, … or confining PCBs[.]" 40 C.F.R. § 761.3. EPA recognized that a narrower meaning "would subvert the environmental protection goals of [TSCA]." *Newell Recycling Co. v. EPA*, 231 F.3d 204, 208 (5th Cir. 2000). EPA provides no basis for defining the term "disposal" in two different ways within a single statutory section. *See Boise Cascade Corp. v. EPA*, 942 F.2d 1427, 1432 (9th Cir. 1991) (presuming "that words used more than once in the same statute have the same meaning" throughout).

In sum, the Court should reject EPA's "interpretive gerrymander[]" that eliminates known and reasonably foreseen use and disposal from TSCA's definition. *Michigan v. EPA*, 135 S. Ct. 2699, 2708 (2015).[3]

C. EPA's feigned powerlessness to regulate "legacy activities" is contradicted by the text and history of TSCA

EPA's claim that it has "only limited tools for regulating legacy activities," and that therefore Congress did not intend it to evaluate such activities, EPA Br. 23, 25, is completely at odds with TSCA sections 6(a) and 9.

First, section 6 gives EPA a wide array of tools to address risks posed by "legacy uses," i.e., ongoing *in situ* chemical uses. EPA can prohibit or otherwise regulate "any manner or method of commercial use" of a chemical. 15 U.S.C. § 2605(a)(5). This expansive authority allows EPA to require, for example: surveys of the presence of substances in buildings; work-practice requirements to minimize exposure for workers and bystanders during maintenance and repair; and inspection and monitoring requirements to detect contamination in indoor or outdoor air.

[3] EPA cannot save its unlawful legacy exclusions through a vague suggestion that it "*may* consider background exposures" from legacy activities "as a tool" to assess a chemical's risks. EPA Br. 30 (quoting ER 5) (emphasis added). If legacy activities are not conditions of use, then they cannot be included in the scope of EPA's determination of unreasonable risk, and thus cannot be addressed through a risk-management rule.

Similarly, TSCA authorizes EPA to regulate "any manner or method of" commercial disposal, *id.* § 2605(a)(6)(A), including future disposal of a chemical or product that is no longer manufactured (associated disposal). This broad authority enables EPA to impose requirements that mitigate risk during waste removal, transport, containment, or treatment, or in the cleanup of contaminated sites. This includes the authority to regulate waste management of chemicals already placed in facilities (legacy disposal), such as through chemical-specific monitoring and abatement requirements.

Accordingly, section 6(a) allows EPA to address a broad span of industrial, commercial, and residential "legacy" activities, and EPA's contention to the contrary is inaccurate.[4]

Finally, EPA's exclusion of legacy activities ignores that TSCA was enacted to enable comprehensive evaluation of chemical risks that could be addressed only in piecemeal form under other laws. *See* H.R. Rep. No. 94-1341, at 6 (1976). Thus, in TSCA section 9(a), Congress directed EPA to consider whether actions taken under other federal laws would sufficiently manage risks that EPA has

[4] EPA's hypothetical couch example does not show otherwise. EPA has several options to address risks posed by flame retardants in couches. *Contra* EPA Br. 23. EPA could require companies to provide notice of the unreasonable risk to the "public" or "persons in possession" of the sofa, or could require companies "to replace or repurchase" it. 15 U.S.C. § 2605(a)(7). EPA could also refer the issue to the Consumer Product Safety Commission, which has tools to reduce the risk through, e.g., public notification or recalls. 15 U.S.C. § 2064(c); *id.* § 1274(a)-(b).

identified *through a TSCA risk evaluation*, and if so to submit a report to the other agency. 15 U.S.C. § 2608(a). Congress's instruction that EPA consider using EPA-administered laws other than TSCA, *id.* § 2608(b), at the risk-management stage, *after* EPA determines through a risk evaluation that a chemical poses an unreasonable risk, underscores that any limit on EPA's authority under TSCA to regulate "legacy activities" is not a basis for excluding them from risk evaluations. *See* Pet'rs' Br. 50. Indeed, section 9(b)(2) expressly requires EPA to "compar[e]" the costs and efficiencies of addressing the risk using TSCA versus other laws, a requirement EPA cannot implement without first evaluating a chemical's full risks, without regard to which laws may be most appropriate for managing those risks. 15 U.S.C. § 2608(b)(2). Respondents' reading would render this provision "meaningless, or superfluous." *See Boise Cascade Corp.*, 942 F.2d at 1432.

D. EPA's overblown concerns about the manageability of evaluating "legacy activities" are devoid of textual or record support

Respondents exaggerate the burdens of risk evaluation as an excuse to constrict the "conditions of use" definition. Petitioners do not ask that EPA "evaluate every circumstance wherein chemicals exist in the environment in some way." EPA Br. 18-19. Rather, the statute already circumscribes the activities EPA must evaluate, to those circumstances wherein a chemical is "intended, known, or reasonably foreseen to be … used, or disposed of." 15 U.S.C. § 2602(4).

Nor is there anything in the record to support Intervenors' claims about the "massive additional burdens," Intervenors' Br. 22, ECF No. 76, of conducting evaluations that consider legacy activities. Congress carefully set a modest minimum number of chemicals to be evaluated under TSCA at any given time. *See* 15 U.S.C. § 2605(b)(2)(B), (b)(3)(C). Intervenors cite nothing to support their suggestion that the limited number of chemicals under review at a particular time will have "literally hundreds of thousands of uses." Intervenors' Br. 21. In any event, given the serious dangers of chemicals like asbestos, any additional effort to evaluate the chemical's uses in "legacy activities" that continue to pose exposure risks will be offset by the potential gains in health protection.

II. EPA fails to show how excluding conditions of use from risk evaluations comports with TSCA's text, structure, and purposes

Petitioners established that TSCA unambiguously requires EPA to evaluate a "chemical substance" in its entirety, under all of its "conditions of use." Pet'rs' Br. 23-26. Respondents offer no response to this plain-text argument. Instead, EPA attempts to distract the Court with (a) an erroneous reading of an isolated phrase from a provision requiring EPA to publish a document; (b) a contrived "triage scheme," *e.g.*, EPA Br. 46, unmentioned in TSCA's text, legislative history, or the administrative record; and (c) a promise to use its unbounded discretion to focus on "greatest risk," ignoring that vulnerable subpopulations face unreasonable risk

even from low exposures, and that greatest risk will often not be apparent at the scoping stage.

A. EPA fails to respond to Petitioners' arguments showing that risk evaluations must cover all conditions of use

Respondents have no answer for Petitioners' argument that TSCA requires EPA to conduct risk evaluations of the "chemical substance" as a whole. *See* Pet'rs' Br. 23-24. Moreover, Respondents fail to identify any authority to counter Petitioners' argument that requiring EPA to evaluate the substance "under *the* conditions of use" unambiguously mandates that EPA consider *all* conditions of use. *Id.* at 23-26. The only case Intervenors cite relating to the construction of "the" is inapposite.[5]

Instead, Respondents argue that Congress could have said "all" conditions of use if that is what it meant. EPA Br. 43-44; Intervenors' Br. 32-33. But "[t]his is perhaps the weakest of all statutory construction arguments, particularly where, as here … [the] alternative language … has substantially the same meaning as the language which Congress did employ." *Ass'n of Am. R.R.s v. Costle*, 562 F.2d 1310, 1316 (D.C. Cir. 1977) (rejecting EPA's argument that if Congress had meant

[5] Unlike "conditions of use," which is a collective noun, that case involved a singular noun and, consequently, it would have contravened the plain meaning for the court to interpret "the initial communication" with a consumer to mean all initial communication with a consumer. *Hernandez v. Williams, Zinman & Parham PC*, 829 F.3d 1068, 1074 (9th Cir. 2016).

"all," it could easily have said so by using the word 'all' rather than the word 'the'"). Because here, construing "the" to mean "all" is "the right and fair reading of the statute," the Court does not ask whether Congress could have indicated its intent "in more crystalline fashion." *Torres v. Lynch*, 136 S. Ct. 1619, 1633-34 (2016).

Respondents do not attempt to rebut Petitioners' arguments that excluding conditions of use at the outset of a risk evaluation will undermine TSCA's overriding purpose of eliminating unreasonable risks posed by "chemical substances," particularly to vulnerable subpopulations, such as children and workers, who are given special consideration. *Compare* EPA Br. 42-50 *with* Pet'rs' Br. 30-32; *see King*, 135 S. Ct. at 2493 ("We cannot interpret federal statutes to negate their own stated purposes." (internal quotation marks omitted)). These groups can be harmed by even low-level exposures to a chemical, either in isolation or in combination, and they may have more extensive exposures than the general population. *See* Pet'rs' Br. 31-32. In light of these characteristics, EPA cannot determine whether these subpopulations face an unreasonable risk from the chemical—as TSCA expressly requires, 15 U.S.C. § 2605(b)(4)(A)—without evaluating risk from all conditions of use. *See* Pet'rs' Br. 31-32. Respondents simply ignore this fundamental problem with EPA's approach. *See* EPA Br. 42-50. The Court "must reject" EPA's interpretation as it "frustrate[s] the policy that

Congress sought to implement." *Brower v. Evans*, 257 F.3d 1058, 1065 (9th Cir. 2001).

B. EPA cannot rely on the isolated phrase "expects to consider," or TSCA's preemption provision, to claim discretion to exclude conditions of use

To justify its purported right to exclude conditions of use from risk evaluations, EPA relies heavily on the sub-provision requiring EPA to publish an interim scope document that "includ[es] the hazards, exposures, conditions of use, and the potentially exposed or susceptible subpopulations the Administrator expects to consider." 15 U.S.C. § 2605(b)(4)(D). But this publication requirement does not change the fundamental structure of TSCA risk evaluations, which requires consideration of all conditions of use. Indeed, at every step of the risk-evaluation process, EPA must evaluate the "chemical substance," not *some of* its conditions of use. *Id*. § 2605(b)(1)(B) (prioritization), 2605(b)(4)(D) (scoping), 2605(b)(4)(F)(i) (risk evaluation), 2605(b)(4)(A) (risk determination). Read in context, the three words "expects to consider" do not bear the weight Respondents place on them. *See King*, 135 S. Ct. at 2489 ("[T]he meaning … of certain words or phrases may only become evident when placed in context." (internal quotation marks omitted)).

Regardless of whether the phrase "expects to consider" modifies "conditions of use," the phrase does not grant EPA discretion to exclude conditions of use.

Contra EPA Br. 43-46; Intervenors' Br. 29-30. Read in context, Congress's use of the word "expects" reflects the interim nature of the scope document. Congress required EPA to "publish" at the six-month mark, 15 U.S.C. § 2605(b)(4)(D), an outline of the analysis EPA "expects"—i.e., anticipates—it will conduct over the next two-and-a-half years. *See* Pet'rs' Br. 34-35; *cf.* ER 64 (recognizing that EPA might learn of additional or new conditions of use after completing scoping). The purpose of the scope document is to publish the contours of the evaluation EPA expects to complete in the future, thus enhancing public transparency. Accordingly, EPA must include in the scope an "analysis plan that identifies the approaches, methods, and/or metrics" EPA anticipates using in the evaluation, and a description of EPA's "[h]ypotheses" about the health and environmental effects of the chemical. 40 C.F.R. § 702.41(c)(4)-(5). Nothing about this ordinary meaning of "expects to consider" in a provision outlining what EPA must publish implies a broad grant of discretion to EPA to pick and choose among a chemical's uses, hazards, or exposures.

In any event, as Petitioners previously described, under ordinary rules of grammar, "expects to consider" modifies only the phrase "the potentially exposed or susceptible subpopulations," not "conditions of use." Pet'rs' Br. 35 n.7. The last-antecedent rule is the default rule of statutory interpretation because it comports with ordinary usage, and Respondents fail to identify any indicia of

meaning to "overcome" its application here. *Barnhart v. Thomas*, 540 U.S. 20, 26 (2003). Because the qualifying phrase "expects to consider" appears at the end of the list, and the determiner "the" is used before the final list entry, the qualifying phrase applies only to the final entry. *See, e.g.*, *FTC v. Mandel Bros., Inc.*, 359 U.S. 385, 389-90 (1959) (applying the last-antecedent rule where statutory list was broken up by two determiners); *see also* Antonin Scalia & Bryan A. Garner, *Reading Law* 149-50 (2012).

EPA argues that the last-antecedent rule does not apply, *see* EPA Br. 33, but unlike the cases EPA cites, here there are no "special reasons" that counsel against applying the rule. *Porto Rico Ry., Light & Power v. Mor*, 253 U.S. 345, 348-49 (1920) (rejecting reading where applying last-antecedent rule would be "inconsistent" with treaty obligations); *see also Paroline v. United States*, 572 U.S. 434, 447 (2014) (rejecting application of the last-antecedent rule to a "catchall" clause, i.e., a clause that is a summary of the enumerated items).

Respondents also cannot justify EPA's asserted discretion to exclude conditions of use based on TSCA section 18(c)(3), which provides that any state-law preemption arising from an unreasonable-risk determination is limited to the conditions of use "included" in the final risk evaluation. EPA Br. 43-44 (citing 15 U.S.C. § 2617(c)(3)); Intervenors' Br. 35 (same). New conditions of use may emerge or be identified after the risk evaluation is complete that EPA could not

have "included" and assessed, and, consequently, there would be no basis for preempting state regulation of them. *See supra* pp. 17-18.

Accordingly, EPA's reliance on the phrase "expects to consider" fails.

C. EPA's reliance on floor statements by a single senator is misplaced

Respondents cannot rely on floor statements by a single senator, even a co-sponsor, "'to cloud [] statutory text that is clear.'" *J & G Sales Ltd. v. Truscott*, 473 F.3d 1043, 1050 (9th Cir. 2007) (quoting *Ratzlaf v. United States*, 510 U.S. 135, 147-48 (1994)); *accord Consumer Prod. Safety Comm'n v. GTE Sylvania, Inc.*, 447 U.S. 102, 118 (1980). Moreover, EPA's discussion of legislative history ignores that EPA itself represented to congressional drafters that the TSCA amendments would require EPA to consider all conditions of use. Pet'rs' Br. 29-30. For example, EPA told congressional drafters that "the scope of assessments under the Senate bill would include *all* uses of a chemical." SA 3 (March 21, 2016 Technical Assistance email from EPA to Sen. Markey's Office) (emphasis added).

* * *

As the text, structure, and purposes of TSCA require EPA to consider all conditions of use, EPA's contrary interpretation fails at *Chevron* Step One.

D. EPA's policy justifications for excluding conditions of use are contrary to TSCA

Claiming that EPA will focus on the greatest risks as an excuse to exclude others, Respondents invent three justifications that conflict with the statute. First, they argue discretion to exclude so-called *de minimis* risks prior to evaluating those risks, though the Risk Evaluation Rule and preamble do not limit exclusions to the *de minimis* category. Second, they invoke congressional deadlines as an excuse to truncate the evaluation process. Third, they rely on other agencies to do the job Congress delegated to EPA. All three justifications fail.

The Court should reject EPA's promise that it will exclude conditions of use "consistent[ly] with the statutory scheme and congressional intent," EPA Br. 49, as it is simply a claim to exercise discretion "without reference to the provisions of the Act." *Comcast Corp. v. FCC*, 600 F.3d 642, 655 (D.C. Cir. 2010) (quoting *FCC v. Midwest Video Corp.*, 440 U.S. 689, 702 (1979)); *see also Midwest Video Corp.*, 440 U.S. at 702 (rejecting agency's claim it could exercise discretion "so long as the rules promote statutory objectives"). As EPA itself recognized in the proposed rule, TSCA "provides no criteria for EPA to apply in making [exclusions]," ER 64; Pet'rs' Br. 26-27, and Respondents have identified none here. Indeed, the only limit EPA acknowledges is that exclusions made with "no explanation" are prohibited. EPA Br. 49. EPA's approach, which is not based on

any limits found in TSCA's text, is unlawful, as it "would virtually free [EPA] from its congressional tether." *Comcast Corp.*, 600 F.3d at 655.

1. The Risk Evaluation Rule does not limit exclusions to *de minimis* risks, and in any event such exclusions are inconsistent with EPA's statutory obligation to assess risks to vulnerable subpopulations

Respondents suggest that EPA will limit exclusions to conditions of use it "believe[s]" are "not likely to pose an unreasonable risk," or present only *de minimis* or insignificant risks or exposures. EPA Br. 11, 46; *see* Intervenors' Br. 3, 44. First, neither the regulatory text nor preamble codified these purported limitations on EPA's asserted discretionary authority. Rather, the Risk Evaluation Rule authorizes exclusions unrelated to risk, belying any suggestion that EPA's exclusions will be limited to the *de minimis* category. *See* Pet'rs' Br. 28; Intervenors' Br. 34.

In any event, TSCA does not permit EPA to exclude *de minimis* exposures before conducting the risk evaluation. EPA does not explain how it can determine, at the outset of a risk evaluation, without assessing both hazard and exposure, whether a condition of use is likely to pose or contribute to an unreasonable risk. Indeed, that assessment is the very purpose of a risk evaluation. *See* Pet'rs' Br. 37.

Moreover, EPA never explains how it can square excluding conditions of use based on supposed *de minimis* exposure with TSCA's requirement to protect

vulnerable subpopulations who may face unreasonable risks from even low-level exposures. *See* EPA Br. 42-50; *supra* pp. 16-17.

2. EPA's unfounded concerns about meeting TSCA's deadlines do not permit EPA to "focus" on only some conditions of use

EPA seeks to justify its pick-and-choose approach based on vague allusions to TSCA's deadlines and managing agency resources, *see, e.g.*, ER 3; EPA Br. 46-48, 50-51; Intervenors' Br. 31, 46, but these justifications are contrary to the statute and lack record support. EPA cannot invoke the specter of those deadlines—which it does not claim, let alone demonstrate, it cannot meet—to rewrite the statute. *Ala. Power Co. v. Costle*, 636 F.2d 323, 357 (D.C. Cir. 1979) (observing that "there exists no general administrative power to create exemptions to statutory requirements based upon the agency's perceptions of costs and benefits"); *Util. Air Regulatory Grp. v. EPA*, 134 S. Ct. 2427, 2445 (2014) (holding that agency may not rewrite statute to suit its "policy goals").

Congress prohibited EPA from considering "nonrisk factors" when conducting risk evaluations, 15 U.S.C. § 2605(b)(4)(A), (b)(4)(F)(iii), because Congress intended that risk determinations would be "based solely on risk to human health and the environment—the integration of hazard and exposure information." S. Rep. No. 114-67, at 17 (2015). To ensure EPA could fulfill this mandate to accurately assess risk, Congress crafted the deadlines to give EPA

sufficient time to complete comprehensive risk evaluations. During the legislative drafting process, EPA represented to Congress that three years would be sufficient to complete a risk evaluation of "all" conditions of use. *See* SA 3. Congress mandated that EPA complete risk evaluations within three years, 15 U.S.C. § 2605(b)(4)(G)(i), and gave EPA tools to ensure it could do so. Congress authorized EPA to set the number of chemicals undergoing prioritization and risk evaluation to ensure that it can meet the deadlines for ongoing risk evaluations, *id.* § 2605(b)(2)(C), and permitted EPA to extend deadlines for completing risk evaluations by six months, *id.* § 2625(b)(4)(G)(ii). *See also id.* § 2625(b)(1) (authorizing EPA to set fees "sufficient" to defray the costs of risk evaluations). In relying on concerns about deadlines and resources—plainly nonrisk factors—to justify the pick-and-choose approach, the Risk Evaluation Rule contravenes the statutory scheme and fails at *Chevron* Step One.

Moreover, EPA maintained in the proposed rule its conclusion that three years was a "manageable" timeframe to conduct comprehensive risk evaluations. ER 64, 66. In doing so, EPA identified tools to both meet the deadlines *and* consider all conditions of use. For example, EPA recognized it could adjust the "level of evaluation" such that "lower-volume or less dispersive uses" received less quantitative evaluation. ER 64. In reversing course in the Risk Evaluation Rule, EPA did not explain what new information it had obtained or considered that

rendered inaccurate its earlier conclusion that three years was sufficient. *See* ER 3-4. Its new pick-and-choose approach must be rejected as an unreasonable and arbitrary "post-hoc rationalization[]" with no support in the record. *Council for Urological Interests v. Burwell*, 790 F.3d 212, 222 (D.C. Cir. 2015) (at *Chevron* Step Two, courts look only to what the agency said during the rulemaking).[6]

EPA's unsupported concerns about "administrative difficulties" are "mere predictions" that cannot justify its unlawful approach. *Sierra Club v. EPA*, 719 F.2d 436, 463 (D.C. Cir. 1983).

3. EPA cannot shirk its duty to eliminate unreasonable risk based on the potential actions of other agencies

Nothing in TSCA gives EPA discretion to constrict a risk evaluation because another agency has assessed or issued a regulation addressing the chemical under evaluation. Intervenors' Br. 37-38; EPA Br. 46. Even if another agency has regulated a condition of use, it does not follow that the use will not result in exposure or present or contribute to an unreasonable risk. Indeed, many statutes authorize regulation of chemicals based on standards that do not require consideration of "unreasonable risk," or are based on feasibility rather than risk. For example, the Occupational Safety and Health Administration has analyzed and

[6] Intervenors seek to supply the rationales EPA failed to provide, *see* Intervenors' Br. 46-47, but these are unavailing, as EPA did not adopt these unsupported claims in the Risk Evaluation Rule.

regulated occupational exposures to methylene chloride—a chemical EPA is now evaluating under TSCA—and concluded that even when its exposure limit is fully implemented, workers will still face a "significant risk" from exposure. 62 Fed. Reg. 1494, 1516 (Jan. 10, 1997). Thus, even if another agency has issued a regulation, there may be ongoing exposure that presents or contributes to an unreasonable risk, particularly where the other statute is not risk-based or does not require the same level of protection as TSCA, e.g., for vulnerable subpopulations.[7] Such regulation therefore cannot constrict the risk evaluation TSCA requires.

Intervenors err in claiming that TSCA section 9(d)'s general requirement that EPA "consult and coordinate" with other federal agencies, 15 U.S.C. § 2608(d), authorizes EPA to exclude conditions of use that are regulated—even if inadequately—by another agency, Intervenors' Br. 37, 39-40. Section 9(d)'s general language cannot override the specific requirements in TSCA section 9(a), which require EPA to refer findings of concern to other agencies *after* completing a risk evaluation. *See supra* pp. 12-13.

[7] Therefore, to the extent Respondents imply that EPA will exclude conditions of use only where another agency has reduced the risk to a reasonable or *de minimis* level, *see* EPA Br. 46, that misrepresents EPA's approach.

III. EPA fails to show how use-by-use "no unreasonable risk" determinations can be squared with the text or health-protective purpose of TSCA

Respondents' insistence that EPA can slice and dice its risk determination for a chemical substance into piecemeal findings that isolated uses of the substance pose "no unreasonable risk," EPA Br. 50-52; *see* Intervenors' Br. 52-55, is an unlawful and pernicious attempt to minimize the total risk posed by a chemical substance and avoid regulation. Respondents concede that risk evaluations must cover "the 'whole' chemical," Intervenors' Br. 31; *see also* EPA Br. 44, but then negate this concession by arguing for use-by-use risk determinations that would ignore the risks presented by the whole chemical, EPA Br. 50-52. Contrary to EPA's assertion, TSCA is not silent on *how many* "no unreasonable risk" findings EPA can make per chemical substance. *Id.* at 50-51. Rather, TSCA commands EPA to determine "whether" "a chemical substance"—not particular uses of a chemical substance—presents an unreasonable risk in a single, comprehensive determination. 15 U.S.C. § 2605(b)(4)(A); *see also id.* § 2605(a) (requiring risk-management rule if "any combination of" a chemical's conditions of use presents "*an* unreasonable risk" (emphasis added)); S. Rep. No. 94-698, at 1-2 (1976) (explaining that TSCA was designed to "look comprehensively" at a chemical's hazards "in total").

TSCA section 6(b)'s requirement that EPA determine "whether" the substance poses an unreasonable risk "indicates a binary choice." *SAS Inst. Inc. v. Iancu*, 138 S. Ct. 1348, 1355-56 (2018). Accordingly, piecemeal determinations that isolated conditions of use pose "no unreasonable risk" violate TSCA's plain text.[8]

Moreover, if EPA fails to analyze the chemical holistically, it cannot satisfy its mandate to "integrate and assess available information on hazards and exposures" from "the conditions of use." 15 U.S.C. § 2605(b)(4)(F)(i). Such integration is necessary because any single use of a chemical may be the proverbial "straw that breaks the camel's back," converting an otherwise reasonable risk into an unreasonable one. This is particularly true for vulnerable subpopulations that are more susceptible to harm from even low-level exposures, or may have more extensive exposures than the general population. *See* Pet'rs' Br. 30-32. Indeed, EPA "does not deny" that it "might determine that a chemical poses no risk under multiple minor uses when it might pose a risk in totality." EPA Br. 53; *see also* Pet'rs' Br. 31 (citing ER 63-64).

[8] On the other hand, all parties agree that where a single condition of use, in isolation, presents an unreasonable risk, TSCA requires EPA to make a finding that the *chemical substance* presents an unreasonable risk. Pet'rs' Br. 39; EPA Br. 51. It is only logical that if a single use of a substance poses unreasonable risk, then the substance as a whole poses unreasonable risk.

Rather than respond to these textual arguments, Respondents complain that Petitioners are demanding that EPA conduct an "aggregate" exposure assessment in every risk evaluation. EPA Br. 52-54. This is not the case. Exposure assessment is the step in the risk evaluation process where "exposures will be estimated (usually quantitatively) *for the identified conditions of use*." ER 17 (emphasis added). This assessment can be accomplished through multiple methods, including "aggregate" or "sentinel" exposure assessments. *Cf.* 15 U.S.C. § 2605(b)(4)(F)(ii). Both are methods of measuring exposures for the "conditions of use" that are being evaluated. Petitioners' position does not require EPA to use any specific exposure assessment methodology, and is compatible with either an aggregate *or* sentinel exposure assessment; either approach can be used to measure exposures stemming from all conditions of use (i.e., all the circumstances under which the chemical is manufactured, processed, distributed, used or disposed of).[9]

Moreover, section 6(b)(4)(F)(ii) merely requires EPA to "describe" and explain "the basis" for its exposure assessment methodology. 15 U.S.C. § 2605(b)(4)(F)(ii). It does not state or imply that EPA has discretion to assess

[9] Like aggregate exposure assessment, sentinel exposure assessment methodology can be used, when appropriate, for accounting for exposures from all conditions of use. *Contra* EPA Br. 54. According to EPA, sentinel exposures "represent upper bound exposures" within "broad use categories." ER 8. The sentinel exposures for these broad use categories can then be combined to account for exposure from the full range of conditions of use.

exposures from each individual condition of use in isolation, or to ignore the combined risks from multiple routes or pathways of exposure. Thus, regardless of the methodology EPA uses for its exposure assessment, it must conduct that assessment based on "the" conditions of use, taking into account that unreasonable risk resulting from "any combination" of such conditions requires risk management. *Compare* 15 U.S.C. § 2605(a), (b)(4)(a), *with id.* § 2605(b)(4)(F)(ii); *see Russello v. United States*, 464 U.S. 16, 23 (1983) (different words have different meanings). Hence, EPA cannot determine that a subset of uses poses no unreasonable risk until it considers all uses in "combination." 15 U.S.C. § 2605(a).

In addition to violating the statutory text, the issuance of use-specific no-unreasonable-risk determinations is irrational, as it will lead to piecemeal litigation over each use of a disputed chemical. EPA concedes that each early no-unreasonable-risk determination is final agency action, subject to judicial review. EPA Br. 12, 54. As any challenge to such a determination must be made within 60 days, 15 U.S.C. § 2618(a)(1)(A), the courts of appeals could be inundated with cases challenging multiple no-unreasonable-risk determinations of the same substance. As the scope of review would be the same in each case—whether the "chemical substance" presents an unreasonable risk—different courts could issue conflicting rulings on similar issues in the context of different uses. *Id.*

§ 2605(i)(1). It strains credulity that Congress intended this inefficient, potentially inconsistent, use of judicial resources.

For these reasons, determinations that single uses present no unreasonable risk are unlawful at either *Chevron* Step One or Two.

IV. Respondents fail to justify aspects of the Framework Rules that will deny EPA "reasonably available information"

Petitioners challenged five provisions that will prevent EPA from obtaining and developing the "reasonably available information" it needs—and is required to consider—to conduct sound, comprehensive risk evaluations. 15 U.S.C. § 2625(k). The challenged provision that criminalizes the public's submission of "incomplete" information to EPA—40 C.F.R. § 702.31(d)—is no longer at issue after EPA's uncontested motion for remand with vacatur. Resp'ts' Mot. for Partial Voluntary Remand (Remand Mot.), ECF No. 66.

EPA has also effectively conceded the illegality of the two other challenged Risk Evaluation Rule provisions relating to information-gathering: 40 C.F.R. §§ 702.37(b)(4) and (b)(6). First, EPA asked the Court to remand these provisions so it could "revisit" them (though *without* vacatur). Remand Mot. 1-2. Second, EPA forfeited defense of these provisions by failing to mention them in its

Response Brief.[10] *See Clem v. Lomeli*, 566 F.3d 1177, 1182 (9th Cir. 2009). Intervenors' defense of these provisions, which allow them to withhold meaningful information from EPA when they request risk evaluations of their chemicals, fails.

In addition, EPA's attempt to defend the two Prioritization Rule provisions that will illegally limit the information the Agency can rely on also fails.

A. TSCA does not permit manufacturers to withhold available information about chemicals for which they request risk evaluations

Intervenors cannot show how 40 C.F.R. § 702.37(b)(4) is consistent with TSCA section 26(k) or reasonable. Intervenors concede that if a manufacturer seeks a risk evaluation of a subset of conditions of use, EPA can nonetheless conduct the risk evaluation on a broader set of conditions of use. Intervenors' Br. 58. Moreover, if the Court agrees that risk evaluations must cover all conditions of use, *see supra* Part II, EPA will have to conduct comprehensive risk evaluations regardless of the scope of a manufacturer's request. Pet'rs' Br. 58-59. Under either of these circumstances, section 702.37(b)(4) would permit the manufacturer to withhold from EPA information about the potential risk of its chemical, claiming it has provided what it deems "relevant" to its chosen conditions of use. EPA will thus be denied information about the full set of conditions of use within

[10] EPA's Brief references only the two Prioritization Rule provisions as "Still at Issue," confirming that EPA is not defending the three provisions subject to its remand motion. *See* EPA Br. 55.

the scope of its risk evaluation, contrary to TSCA's command that EPA consider all "reasonably available information." 15 U.S.C. § 2625(k).

Intervenors engage in circular reasoning by arguing that this withholding is permissible because manufacturers must certify that the limited information they provide EPA complies with section 702.37(b)(4). Intervenors' Br. 58. A manufacturer could certify that its submission complies with that section even if it withholds relevant information about its chemical, exactly because the provision does not require the submission of all reasonably available information about the substance.

Similarly, Intervenors' argument that manufacturers may lack complete information about their substance is a strawman. Intervenors' Br. 59. No one asserts that manufacturers must turn over information they do not have or cannot reasonably obtain.

Intervenors' final argument—that EPA can get from other sources information manufacturers withhold—is irrational. *Id*. Even if EPA could find alternative sources of the information, why should it have to undertake this effort? And if the withheld information is unavailable elsewhere, EPA will be denied the information. It is no wonder EPA is not defending this provision. *See Nw. Ecosystem All. v. U.S. Fish & Wildlife Serv.*, 475 F.3d 1136, 1140 (9th Cir. 2007)

(agency's decision must have "a reasonable basis" (internal quotation marks omitted)).

B. EPA's conversion of the section 26(h) considerations into threshold screening requirements contravenes TSCA

Section 702.37(b)(6) creates another loophole allowing manufacturers to withhold information relevant to risk evaluations they request, violating TSCA section 26(k). The TSCA section 26(h) factors are *not* "objective descriptors of the scientific information submitted." *Contra* Intervenors' Br. 61. Rather, by their terms, the section 26(h) factors are relative criteria for placing information along a spectrum of reliability, not "objective descriptors" to exclude that information from consideration. *See* Pet'rs' Br. 56-57. Each section 26(h) factor involves a judgment about the weight EPA is to give to scientific information. 15 U.S.C. § 2625(h). By contrast, section 702.37(b)(6) gives manufacturers authority to determine in the first instance whether some information falls below a threshold the manufacturer self-selects, enabling it to withhold the information from EPA and preventing EPA from assessing its weight as required under section 26(h). This gives manufacturers ample opportunity to screen out relevant, but unfavorable, information.

Intervenors also err in arguing that any information manufacturers withhold based on section 702.37(b)(6) can be submitted by the public during a comment

period. Intervenors' Br. 61-62. Obviously, the public often lacks access to this information.

While EPA does not address section 702.37(b)(6), it defends a parallel provision in the Prioritization Rule, 40 C.F.R. § 702.9(b), claiming that the provision "does not screen out information but rather explains how EPA will assess the quality of information." EPA Br. 56. However, implicit in this provision—which states that EPA "expects to consider sources of information … consistent with [TSCA section 26(h)]," 40 C.F.R. § 702.9(b)—is its obverse: EPA will *not consider* sources of information that are *not consistent* with TSCA section 26(h). EPA's assertion that invalidating section 702.9(b) would render section 26(h) surplusage is also misguided. EPA can rely on the section 26(h) criteria to *assess the weight* to give scientific evidence without using them as screens for exclusion. For this reason, Petitioners did not challenge EPA's incorporation of section 26(h) criteria when they were not invoked as a "screen" for excluding information. *See* 40 C.F.R. § 702.43(b).

C. EPA fails to ensure it has adequate information for risk evaluations

None of EPA's rationales for how 40 C.F.R. § 702.5(e) comports with TSCA addresses Petitioners' core argument: if EPA commences prioritization before it has adequate information to conduct a risk evaluation, as section 702.5(e) allows, it will, in some cases, fail to obtain often-vital information that can be

generated only through longer-term testing. Such information may be "reasonably available" because EPA "can reasonably generate" it "considering the deadlines" for *both* prioritization and risk evaluation. 40 C.F.R. § 702.3. In these instances, EPA's risk evaluation would be based on less than all the information that would be "reasonably available" had EPA considered its information needs before prioritization.

EPA's main argument is that section 702.5(e) sets only a "floor" of the minimum information required to start prioritization, and that it has the *option* to obtain more information than section 702.5(e) requires. EPA Br. 57. However, TSCA section 26(k)'s mandate to rely on "reasonably available information" is not optional. Moreover, EPA's recitation of ways it *might* gather information during prioritization or risk evaluation, EPA Br. 58, does not respond to Petitioners' argument that the statutory deadlines may be too short for EPA to obtain needed, "reasonably available information" if it does not start gathering it before prioritization. Section 702.5(e) therefore violates TSCA.

V. EPA's attempts to evade review of the Risk Evaluation Rule fail

Petitioners challenge multiple aspects of EPA's final Framework Rules, issued through notice and comment rulemaking, which Congress directed this Court to hear. Nonetheless, EPA argues that this Court lacks jurisdiction over a single issue presented in this challenge: whether the Risk Evaluation Rule

unlawfully authorizes EPA to exclude conditions of use from consideration in risk evaluations. Because all of EPA's arguments regarding finality, standing, and ripeness misstate the relevant jurisdictional standards, the Court should reject EPA's attempt to avoid judicial review.

A. The Rule's interpretation of TSCA is final agency action

EPA's claim that there has been no final agency action because EPA has not yet excluded conditions of use from any particular risk evaluation, *see* EPA Br. 34, 36-37, misunderstands the legal question presented. Petitioners challenge the Risk Evaluation Rule as unlawfully authorizing EPA to exclude conditions of use from risk evaluations. Pet'rs' Br. 21-23. "[F]or the purposes of finality, it is irrelevant how th[at] interpretation will apply to any individual" risk evaluation. *NRDC v. EPA*, 643 F.3d 311, 320 (D.C. Cir. 2011).

The promulgation of the Risk Evaluation Rule represents the "consummation of the agency's decisionmaking process" as to whether EPA has authority to exclude conditions of use, and "legal consequences will flow" from that decision. *U.S. Army Corps of Eng'rs v. Hawkes Co.*, 136 S. Ct. 1807, 1813 (2016) (internal quotation marks omitted). During the rulemaking, EPA fully considered whether TSCA required it to include all conditions of use in risk evaluations, and purported to resolve the question. Pet'rs' Br. 12-17. Though the proposed rule required EPA to consider "all" conditions of use, *see id.*, EPA

"reevaluated" its proposal and, in the final Rule, set out a "final approach" in which EPA will have "discretion to determine the conditions of use that the Agency will address," ER 3; *see also* ER 63-64, 180. EPA consummated its decisionmaking process when it "'reconsidered [its] interpretation' and settled on a new one," following notice and comment. *Whitman v. Am. Trucking Ass'n*, 531 U.S. 457, 477-79 (2001) (quoting preamble). In addition, the Rule has legal consequences because it codifies a binding framework that "alter[s] the legal regime" for all future risk evaluations. *See NRDC,* 643 F.3d at 319-20. The final Rule, if left intact, would unlawfully alter TSCA's requirement that EPA consider all conditions of use.

EPA implies that Petitioners are contesting preamble language, EPA Br. 31-37, but Petitioners challenge regulatory provisions that codify this change. These provisions expressly state that some conditions of use will be "within the scope of the evaluation" and thus, that some will be left out and necessarily ignored. Pet'rs' Br. 22 (citing 40 C.F.R. § 702.41(a) and (c), among other provisions). Additionally, where the proposed rule required the scope to include "all circumstances" constituting the conditions of use, ER 76, the final Rule allows EPA to include only "[t]he condition(s) of use … that the EPA plans to consider," 40 C.F.R. § 702.41(c)(1). EPA changed that language for a reason—to give itself the discretion to exclude conditions of use.

Further, despite EPA's arguments, EPA Br. 32 n.6, 35-37, the Court may review the Rule's preamble statements because they confirm that this is EPA's binding and "final" interpretation. ER 3; *cf. City of Las Vegas v. FAA*, 570 F.3d 1109, 1117 (9th Cir. 2009) (looking at preamble to determine the "intent of the agency promulgating the regulations"). Thus, the preamble states the "final scope … *will* also identify whether particular conditions of use have been excluded." ER 4 (emphasis added); *see McLouth Steel Prod. Corp. v. Thomas*, 838 F.2d 1317, 1320-21 (D.C. Cir. 1988) ("[T]he word 'will' suggests the rigor of a rule"). Just as EPA concedes that its approach to legacy activities is binding because it "*intends* to apply [it] going forward," EPA Br. 32 n.6 (emphasis added), its interpretation that it may exclude conditions of use is also binding because EPA likewise stated it "intends" to make exclusions during risk evaluations, *see, e.g.*, ER 4, 5.

These unequivocal statements prove that EPA has made a "final" decision—that it has discretion to exclude conditions of use. *Compare* ER 3-4 *with* EPA Br. 32 n.6, 35-37. EPA's final decision here is thus unlike *NRDC v. EPA*, 559 F.3d 561 (D.C. Cir. 2009), which concerned EPA's statements about whether particular "examples" "may" constitute "exceptional events" within the meaning of the statute. *Id.* at 565. *Contra* EPA Br. 32 n.6, 35-37. Regardless of whether EPA has firmly decided *which* specific exclusions it will make in any particular risk evaluation, its final determination that it has authority to make such exclusions in

the first instance is reviewable.

Finally, EPA argues this Court lacks jurisdiction because one provision of the many regulations Petitioners challenged as codifying the "pick-and-choose" approach, *see supra* p. 38, is similar to the statutory text. EPA Br. 32-35 (citing 40 C.F.R. § 702.41(c)(1)). But that provision diverges from TSCA's text, and those differences are presumed to make a legal difference, a presumption borne out by EPA's preamble statements. *Cf. Russello*, 464 U.S. at 23. Whether those differences are unlawful is a question for the merits. In any event, it is EPA's *interpretation* of TSCA's text as embodied in its regulations, regardless of similarities between the statutory and regulatory text, that is subject to this Court's review. *Cf. Gonzales v. Oregon*, 546 U.S. 243, 257 (2006) (reviewing agency interpretation of regulation that parroted statutory text).

In short, EPA cannot avoid judicial review because its determination that it may exclude conditions of use is part of "a regulatory scheme, fully explained and defended in the text setting out the regulations." *Maine v. Thomas*, 874 F.2d 883, 887 (1st Cir. 1989).

B. EPA's limited challenge to Petitioners' standing fails

Respondents do not contest that several Petitioner-groups have organizational and informational standing. Pet'rs' Br. 67-69. As one Petitioner's standing is sufficient to confer jurisdiction, the Court need not evaluate EPA's

arguments questioning Petitioners' members' standing. *See Massachusetts*, 549 U.S. at 518.

EPA's challenge to Petitioners' members' standing fails, EPA Br. 42, because the Risk Evaluation Rule's "unlawful evaluation process," Pet'rs' Br. 64, threatens members' concrete interests in avoiding exposure to toxic chemicals, *see Friends of Santa Clara River v. U.S. Army Corps of Eng'rs*, 887 F.3d 906, 918 (9th Cir. 2018) (explaining elements to show standing for procedural injuries). The Rule unlawfully authorizes EPA to exclude conditions of use, such as the presence of a chemical as an impurity or byproduct, from consideration. *See* ER 5. A failure to account for all sources and uses of a chemical will "underestimate[]" risks to populations including workers, children, and infants. PA 874; *see* PA 62-65, 620-21 (noting that health effects of 1,4 dioxane exposure are identical whether present by design or as byproduct). As a result, EPA will understate the risks presented by chemicals that undergo risk evaluation, depriving Petitioners' members of the protections they would have received, and increasing their risk of exposure. *See* Pet'rs' Br. 30-32, 64. It is therefore reasonably probable that the Risk Evaluation Rule threatens members' health interests that Congress intended to protect through TSCA.[11]

[11] EPA's arguments misapprehend the relevant inquiry for a procedural injury. *See* EPA Br. 42. Members have a concrete interest in avoiding additional exposure to toxic chemicals, and Congress mandated TSCA's risk evaluation procedures to

This Court's precedents foreclose EPA's argument that the members' threatened injury is too speculative to be cognizable for purposes of standing. *See, e.g.*, *Citizens for Better Forestry v. U.S. Dep't of Agric.*, 341 F.3d 961, 973-74 (9th Cir. 2003). Members' "asserted injury is that [health] consequences might be overlooked, as a result of deficiencies in the government's analysis" under TSCA. *Salmon River Concerned Citizens v. Robertson*, 32 F.3d 1346, 1355 (9th Cir. 1994) (internal quotation marks omitted). EPA's "[s]peculation" that its pick-and-choose risk evaluations may not always result in less-protective risk determinations or risk-management rules "is irrelevant." *Id.*; *contra* EPA Br. 40-41. "[S]hort of assuming that Congress impose[s] useless procedural safeguards," EPA's failure to follow those safeguards must "play[] some … part in subsequent decisions." *Idaho Conservation League v. Mumma*, 956 F.2d 1508, 1516 (9th Cir. 1992).

Indeed, this Court has roundly rejected EPA's argument that a court should wait and see if a flawed agency policy "might be … mitigated" when applied. *Citizens for Better Forestry*, 341 F.3d at 973-74 (quoting *Idaho Conservation League*, 956 F.2d at 1515). Requiring Petitioners to wait to bring an "as-applied challenge" would mean that "no one would have standing to challenge EPA's authority to [exclude uses] in the first place" and would allow EPA to "effectively

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protect that interest. *See* Pet'rs' Br. 6, 8. By unlawfully modifying the procedures for risk evaluation, EPA has threatened that concrete interest. *See Friends of Santa Clara River*, 887 F.3d at 918.

maintain th[e] very discretion" the statute prohibits. *See NRDC*, 643 F.3d at 319. EPA's regulatory decision to ignore TSCA's directive to consider all conditions of use is itself "a concrete injury that plaintiffs must, at some point, have standing to challenge. That point is now, or it is never." *Idaho Conservation League*, 956 F.3d at 1516.

Nor can EPA escape review by suggesting that it might ultimately consider all conditions of use in its risk evaluations. EPA Br. 40. It "strains credulity" that EPA would not utilize the provisions that give it authority to exclude uses. *See Nat'l Wildlife Fed'n v. Hodel*, 839 F.2d 694, 708 (D.C. Cir. 1988) (rejecting argument that it was uncertain whether elimination of minimum standard for state regulations would result in states reducing their standards). Indeed, using this authority, EPA has already excluded conditions of use from ongoing risk evaluations for chemicals to which members are exposed. *See* MA 170 (1,4-dioxane produced as a by-product "is excluded" from evaluation's scope); Pet'rs' Br. 63 (discussing members' exposure to 1,4-dioxane); EPA Br. 40-41 (confirming EPA is excluding conditions of use from risk evaluations underway).

Consequently, EPA cannot argue that Petitioners' members are not injured by chemicals currently being evaluated because it is not "bound" to follow the Risk Evaluation Rule for those evaluations. EPA Br. 40. The very regulation EPA cites, 40 C.F.R. § 702.35(a), states EPA "will" follow the Framework Rules "to the

maximum extent practicable."[12]

EPA also misunderstands the requirements for redressability, *see* EPA Br. 41, as Petitioners need show only that "the relief requested … *may* influence the agency's ultimate decision," *WildEarth Guardians v. U.S. Dep't of Agric.*, 795 F.3d 1148, 1156 (9th Cir. 2015) (emphasis added) (internal quotation marks omitted); *Massachusetts*, 549 U.S. at 518 (litigant asserting procedural injury "never has to prove that if he had received the procedure the substantive result would have been altered" (internal quotation marks omitted)). Members' injuries are redressable because by requiring EPA to consider all conditions of use, EPA would more accurately estimate risks posed by chemicals under review, potentially leading to different risk determinations and risk management regulations.

C. Petitioners' challenge is ripe

Because Petitioners have standing, they also satisfy the constitutional ripeness requirement. *See Thomas v. Anchorage Equal Rights Comm'n*, 220 F.3d 1134, 1138 (9th Cir. 2000) (en banc) ("[I]n many cases, ripeness coincides squarely with standing's injury in fact prong."); *Nat'l Treasury Emps. Union v. United States*, 101 F.3d 1423, 1427 (D.C. Cir. 1996) (finding they are the same).

EPA nonetheless contends that Petitioners' claim is unripe under the

[12] Regardless, Petitioners' injuries are not based only on the chemicals currently undergoing risk evaluations. *See* PA 38-41 (lead); PA 72-75 (lead and GenX); PA 80-85 (PBDE); PA 255-58 (lead).

prudential ripeness test, a discretionary and possibly obsolete doctrine. *Bishop Paiute Tribe v. Inyo Cty.*, 863 F.3d 1144, 1154 (9th Cir. 2017); *see Susan B. Anthony List v. Driehaus*, 134 S. Ct. 2334, 2347 (2014) (noting "tension" between prudential ripeness doctrine and courts' "unflagging" duty to exercise jurisdiction). Delaying review here would be particularly inappropriate given that "Congress has emphatically declared a preference for immediate review" by setting a 60-day deadline to challenge TSCA rules, 15 U.S.C. § 2618(a)(1)(A). *See Cement Kiln Recycling Coal. v. EPA*, 493 F.3d 207, 215 (D.C. Cir. 2007) (internal quotation marks omitted) (analyzing similarly-worded judicial-review provision); *NRDC*, 643 F.3d at 320. TSCA's judicial-review provision required Petitioners to challenge the Framework Rules now and "specifically instruct[s] the courts to review" the rules immediately, rather than waiting for their application. *See Ohio Forestry Ass'n, Inc. v. Sierra Club*, 523 U.S. 726, 737 (1998).

Even if the two-prong prudential ripeness test applied, Petitioners satisfy it. First, Petitioners' claim is fit for decision because it raises a purely legal question of statutory interpretation—whether TSCA allows EPA to exclude conditions of use. *Supra* pp. 37-39; *see Wolfson v. Brammer*, 616 F.3d 1045, 1060 (9th Cir. 2010). Contrary to EPA's argument, EPA Br. 37-38, no factual development is required to resolve that question because Petitioners do not challenge any particular exclusion of a condition of use. *See Appalachian Power Co. v. EPA*,

208 F.3d 1015, 1023 n.18 (D.C. Cir. 2000) (factual development unnecessary when validity of agency's legal determination "will not turn on the specifics of any particular [implementing decision]").

Second, Petitioners' members will face hardship if the Court delays review. Waiting for EPA's final risk evaluations would place an undue burden on Petitioners' members who face exposure to toxic chemicals as long as TSCA's lawful implementation is delayed. *See* Pet'rs' Br. 63-64. Given the substantial resources needed to prepare risk evaluations, it is in both the public and EPA's interest to ensure their accuracy the first time around.

VI. Petitioners' requested remedy is appropriate

EPA's argument that "Petitioners do not adequately make a case for vacatur as to any provision" flips the standard on its head. EPA Br. 62. Vacatur is the presumptive remedy when a court holds agency action unlawful. *E.g.*, *All. for the Wild Rockies v. U.S. Forest Serv.*, No. 16-35829, -- F.3d --, 2018 WL 5316129, at *11 (9th Cir. Oct. 25, 2018); *Wood v. Burwell*, 837 F.3d 969, 976 (9th Cir. 2016). Indeed, vacatur is the remedy expressly contemplated by TSCA. 15 U.S.C. § 2618(c) (incorporating 5 U.S.C. § 706, which provides that reviewing courts "shall … set aside" unlawful agency action). Requiring Petitioners to separately justify each sub-provision of a regulation they seek to vacate runs against this well-established rule, and EPA cites no contrary precedent. Consequently, Petitioners

were not required to provide such justifications in their Opening Brief and have not waived any right to vacatur.

Petitioners requested that the Court vacate an enumerated set of provisions because the flaws in the Framework Rules are pervasive but discrete. Pet'rs' Br. 70. EPA itself "intends that the provisions of th[e] rule be severable" so that "any individual provisions that can continue to operate will be left in place." ER 3; *accord* ER 30. Accordingly, Petitioners tailored their request for vacatur to the specific provisions corresponding to the violations asserted in their petitions, even though they are entitled to a broader remedy.[13] *See NRDC v. EPA*, 489 F.3d 1364, 1375 (D.C. Cir. 2007) (vacating parts of rule that used challenged language).

EPA's contention that Petitioners "raise no argument as to the invalidity of the[] provisions" in its remedy request, EPA Br. 58-60, is flatly contradicted by Petitioners' Brief. For example, many of the provisions codify EPA's unlawful assertion of authority to exclude conditions of use from risk evaluations by using the phrase "the conditions of use within the scope of the risk evaluation."[14] *See* Pet'rs' Br. 22. Similarly, section 702.41(a)(7) refers to a determination by EPA

[13] If the Court finds in favor of Petitioners but that the challenged provisions are not severable, full vacatur of the Framework Rules would be the presumptive remedy.

[14] *See* 40 C.F.R. §§ 702.41(a)(5), (a)(8), (a)(9), (c)(1), (c)(4)(i), (c)(4)(iii), (d)(2); 702.43(a)(1); 702.47; 702.49(b)-(d).

that it may "complete its risk evaluation of the condition(s) of use" in a use-by-use fashion. *See* Pet'rs' Br. 39-40 (challenging use-by-use risk determinations). So too for each of the provisions for which Petitioners requested vacatur. *Compare* 40 C.F.R. § 702.9(b)-(c) (referring to review of information "consistent with" 15 U.S.C. § 2625(h)) *with* Pet'rs' Br. 58; *compare* 40 C.F.R. § 702.7(a) (EPA will initiate prioritization when it has information sufficient for prioritization alone) *with* Pet'rs' Br. 60-61.

Although in "rare circumstances" it may be appropriate to leave an unlawful agency rule in place during remand, *see Humane Soc'y of U.S. v. Locke*, 626 F.3d 1040, 1053 n.7 (9th Cir. 2010), EPA states only that vacatur "could be" disruptive, without any explanation, EPA Br. 62. That cursory and equivocal statement cannot rebut the "presumption of vacatur." *See All. for the Wild Rockies*, 2018 WL 5316129, at *12. Regardless, no disruption will occur: TSCA contains detailed directions for how EPA is to conduct risk evaluations that EPA could follow during remand, and indeed EPA began risk evaluations prior to issuing the Framework Rules.

CONCLUSION

For these reasons, this Court should grant the petitions for review.

November 9, 2018

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that I electronically filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the Ninth Circuit by using the appellate CM/ECF system on November 9, 2018.

I certify that all participants in the case are registered CM/ECF users and that service will be accomplished by the appellate CM/ECF system.

Dated: November 9, 2018

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Form 8. Certificate of Compliance Pursuant to 9th Circuit Rules 28.1-1(f), 29-2(c)(2) and (3), 32-1, 32-2 or 32-4 for Case Number 17-72260

Note: This form must be signed by the attorney or unrepresented litigant *and attached to the end of the brief.*

I certify that (*check appropriate option*):

☐ This brief complies with the length limits permitted by Ninth Circuit Rule 28.1-1.
The brief is [ ] words or [ ] pages, excluding the portions exempted by Fed. R. App. P. 32(f), if applicable. The brief's type size and type face comply with Fed. R. App. P. 32(a)(5) and (6).

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☐ This brief complies with the longer length limit authorized by court order dated [ ]
The brief's type size and type face comply with Fed. R. App. P. 32(a)(5) and (6). The brief is [ ] words or [ ] pages, excluding the portions exempted by Fed. R. App. P. 32(f), if applicable.

☒ This brief is accompanied by a motion for leave to file a longer brief pursuant to Ninth Circuit Rule 32-2 (a) and is [10,893] words or [ ] pages, excluding the portions exempted by Fed. R. App. P. 32 (f), if applicable. The brief's type size and type face comply with Fed. R .App. P. 32(a)(5) and (6).

☐ This brief is accompanied by a motion for leave to file a longer brief pursuant to Ninth Circuit Rule 29-2 (c)(2) or (3) and is [ ] words or [ ] pages, excluding the portions exempted by Fed. R. App. P. 32(f), if applicable. The brief's type size and type face comply with Fed. R. App. P. 32(a)(5) and (6).

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The brief is [ ] words or [ ] pages, excluding the portions exempted by Fed. R. App. P. 32(f), if applicable. The brief's type size and type face comply with Fed. R. App. P. 32(a)(5) and (6).

Signature of Attorney or Unrepresented Litigant [/s/ Sarah C. Tallman] Date [11/9/2018]

("s/" plus typed name is acceptable for electronically-filed documents)

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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PETITIONERS' SUPPLEMENTAL STATUTORY ADDENDUM

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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SUPPLEMENTAL ADDENDUM TABLE OF CONTENTS

Except for the following, all applicable statutes, etc., are contained in the brief or addenda of Petitioners or Respondents.

[1] The Technical Assistance email was made public pursuant to a FOIA request by a non-party and is publicly available on the U.S. Government's FOIA online website (https://www.foiaonline.gov/foiaonline/action/public/submissionDetails?trackingNumber=EPA-HQ-2016-005210&type=request), and may be downloaded by clicking the hyperlink entitled "TSCA 5" under the heading "Released Records." It is located at page 60 of the document and is provided here for the convenience of the Court.

Sinai School of Medicine of the City University of New York, New York, New York.
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21. E. Occella and G. Maddalon, X-ray diffraction characteristics of some types of asbestos in relation to different techniques of comminution, *Med. Lavoro*, *54*(10):628–636, 1963.
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27. J. A. Leroux, B. C. Davey, and A. Paillard, *Am. Ind. Hyg. Assoc. J.*, *34*:409, 1973.

[47 FR 23369, May 27, 1982; 47 FR 38535, Sept. 1, 1982; Redesignated at 60 FR 31922, June 19, 1995]

Subpart F [Reserved]

Subpart G—Asbestos Worker Protection

SOURCE: 65 FR 69216, Nov. 15, 2000, unless otherwise noted.

§ 763.120 What is the purpose of this subpart?

This subpart protects certain State and local government employees who are not protected by the Asbestos Standards of the Occupational Safety and Health Administration (OSHA). This subpart applies the OSHA Asbestos Standards in 29 CFR 1910.1001 and 29 CFR 1926.1101 to these employees.

§ 763.121 Does this subpart apply to me?

If you are a State or local government employer and you are not subject to a State asbestos standard that OSHA has approved under section 18 of the Occupational Safety and Health Act or a State asbestos plan that EPA has exempted from the requirements of this subpart under § 763.123, you must follow the requirements of this subpart to protect your employees from occupational exposure to asbestos.

§ 763.122 What does this subpart require me to do?

If you are a State or local government employer whose employees perform:

(a) Construction activities identified in 29 CFR 1926.1101(a), you must:

(1) Comply with the OSHA standards in 29 CFR 1926.1101.

(2) Submit notifications required for alternative control methods to the Director, National Program Chemicals Division (7404), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

(b) Custodial activities not associated with the construction activities identified in 29 CFR 1926.1101(a), you must comply with the OSHA standards in 29 CFR 1910.1001.

(c) Repair, cleaning, or replacement of asbestos-containing clutch plates and brake pads, shoes, and linings, or removal of asbestos-containing residue from brake drums or clutch housings, you must comply with the OSHA standards in 29 CFR 1910.1001.

§ 763.123 May a State implement its own asbestos worker protection plan?

This section describes the process under which a State may be exempted from the requirements of this subpart.

(a) *States seeking an exemption.* If your State wishes to implement its own asbestos worker protection plan, rather than complying with the requirements of this subpart, your State must apply for and receive an exemption from EPA.

(1) *What must my State do to apply for an exemption?* To apply for an exemption from the requirements of this subpart, your State must send to the Director of EPA's Office of Pollution Prevention and Toxics (OPPT) a copy of its asbestos worker protection regulations and a detailed explanation of how your State's asbestos worker protection plan meets the requirements of TSCA section 18 (15 U.S.C. 2617).

(2) *What action will EPA take on my State's application for an exemption?* EPA will review your State's application and make a preliminary determination whether your State's asbestos worker protection plan meets the requirements of TSCA section 18.

(i) If EPA's preliminary determination is that your State's plan does meet the requirements of TSCA section 18, EPA will initiate a rulemaking, including an opportunity for public comment, to exempt your State from the requirements of this subpart. After considering any comments, EPA will issue a final rule granting or denying the exemption.

(ii) If EPA's preliminary determination is that the State plan does not meet the requirements of TSCA section 18, EPA will notify your State in writing and will give your State a reasonable opportunity to respond to that determination.

(iii) If EPA does not grant your State an exemption, then the State and local government employers in your State are subject to the requirements of this subpart.

(b) *States that have been granted an exemption.* If EPA has exempted your State from the requirements of this subpart, your State must update its asbestos worker protection regulations as necessary to implement changes to meet the requirements of this subpart, and must apply to EPA for an amendment to its exemption.

(1) *What must my State do to apply for an amendment to its exemption?* To apply for an amendment to its exemption, your State must send to the Director of OPPT a copy of its updated asbestos worker protection regulations and a detailed explanation of how your State's updated asbestos worker protection plan meets the requirements of TSCA section 18. Your State must submit its application for an amendment within 6 months of the effective date of any changes to the requirements of this subpart, or within a reasonable time agreed upon by your State and OPPT.

(2) *What action will EPA take on my State's application for an amendment?* EPA will review your State's application for an amendment and make a preliminary determination whether your State's updated asbestos worker protection plan meets the requirements of TSCA section 18.

(i) If EPA determines that the updated State plan does meet the requirements of TSCA section 18, EPA will issue your State an amended exemption.

(ii) If EPA determines that the updated State plan does not meet the requirements of TSCA section 18, EPA will notify your State in writing and will give your State a reasonable opportunity to respond to that determination.

(iii) If EPA does not grant your State an amended exemption, or if your State does not submit a timely request for amended exemption, then the State and local government employers in your State are subject to the requirements of this subpart.

Subpart H [Reserved]

Subpart I—Prohibition of the Manufacture, Importation, Processing, and Distribution in Commerce of Certain Asbestos-Containing Products; Labeling Requirements

SOURCE: 54 FR 29507, July 12, 1989, unless otherwise noted.

§763.160 Scope.

This subpart prohibits the manufacture, importation, processing, and distribution in commerce of the asbestos-containing products identified and at the dates indicated in §§763.165, 763.167, and 763.169. This subpart requires that products subject to this rule's bans, but not yet subject to a ban on distribution in commerce, be labeled. This subpart also includes general exemptions and procedures for requesting exemptions from the provisions of this subpart.

§763.163 Definitions.

For purposes of this subpart:

Act means the Toxic Substances Control Act, 15 U.S.C. 2601 *et seq.*

Agency means the United States Environmental Protection Agency.

Tillery, Loreto

From: Kaiser, Sven-Erik
Sent: Monday, March 21, 2016 1:54 PM
To: 'Freedhoff, Michal (Markey)'
Subject: Sen. Markey TSCA TA request - timeframes

Michal,
This TA responds to your request on timeframes.

I was not involved when the various timeframes for EPA activities were selected and don't know what their basis was. Where did a 3 year risk evaluation timeframe come from? Could it be shorter without straining EPA's ability to meet its deadlines? How much shorter? What about 1 year to complete a priority designation given what that entails in the Senate offer?

Response: The three year timeline for risk evaluation developed from EPA's experience with conducting risk assessments under current TSCA. Given that the scope of assessments under the Senate bill would include all uses of a chemical – and that our current assessments are more limited in scope – reducing the timeframe would likely endanger EPA's ability to meet the timeline.

EPA does think that the one year timeline for designating a priority chemical, as described in section 6(b)(3), is achievable.

Please let me know if any additional questions. Thanks,
Sven

Sven-Erik Kaiser
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From: "Freedhoff, Michal (Markey)" <Michal_Freedhoff@markey.senate.gov>
Date: March 19, 2016 at 1:18:39 PM EDT
To: "Kaiser, Sven-Erik" <Kaiser.Sven-Erik@epa.gov>
Subject: TA request - risk evaluations

Sven

This is for Monday anytime (and if you need longer that's fine, just let me know - don't mess w anyone's weekend).

I was not involved when the various timeframes for EPA activities were selected and don't know what their basis was. Where did a 3 year risk evaluation timeframe come from? Could it be shorter without straining EPA's ability to meet its deadlines? How much shorter? What about 1 year to complete a priority designation given what that entails in the Senate offer?

Thanks
Michal

Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)