No. 17-72260 (and consolidated cases)

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

BRIEF OF INTERVENORS IN SUPPORT OF RESPONDENT UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

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September 19, 2018

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CORPORATE DISCLOSURE STATEMENTS

Pursuant to Rule 26.1 of the Federal Rules of Appellate Procedure, the American Chemistry Council, American Coatings Association, American Coke and Coal Chemicals Institute, American Forest & Paper Association, American Fuel & Petrochemicals Manufacturers, American Petroleum Institute, Battery Council International, Chamber of Commerce of the United States of America, EPS Industry Alliance, IPC International, Inc., National Association of Chemical Distributors, National Mining Association, Polyurethane Manufacturers Association, Silver Nanotechnology Working Group, Society of Chemical Manufacturers and Affiliates, Styrene Information and Research Center, Inc., and Utility Solid Waste Activities Group respectfully submit this Corporate Disclosure Statement and state as follows:

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13. The Polyurethane Manufacturers Association states that it has no parent corporation and does not issue stock to the public, and thus no publicly held corporation owns 10% or more of its stock.

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17. The Utility Solid Waste Activities Group states that it has no parent corporation and does not issue stock to the public, and thus no publicly held corporation owns 10% or more of its stock.

INTRODUCTION

In 2016, Congress amended the Toxic Substances Control Act ("TSCA" or "Act"). In these Amendments, Congress created a framework for the Environmental Protection Agency ("EPA" or "Agency") to conduct a sequenced review of tens of thousands of chemicals in U.S. commerce. Essential to its framework, Congress expressly imposed aggressive timelines and metrics to ensure EPA sustains a continuous "throughput" of chemical reviews. In so doing, Congress sought to improve the public's confidence in EPA's regulation of chemicals in commerce, protect the public from unreasonable risks to human health and the environment, encourage innovation in the chemical industry, and discourage the growing patchwork of inconsistent state regulations.

This is an ambitious undertaking. To accomplish it, Congress directed EPA to adopt a three-step process of (1) prioritization, (2) risk evaluation, and if an unreasonable risk is determined, (3) risk management. The two EPA rules at issue here—the Prioritization Rule and the Risk Evaluation Rule—lay out the first two steps. *See* "Procedures for Prioritization of Chemicals for Risk Evaluation Under the Toxic Substances Control Act," 82 FR 33,753 (July 20, 2017) ("Prioritization Rule") and Procedures for Chemical Risk Evaluation Under the Toxic Substances Control Act," 82 FR 33,726 (July 20, 2017) ("Risk Evaluation Rule") (collectively, the "Rules").

Intervenors represent regulated entities whose products supply diverse markets, including aerospace, agriculture, automotive, building and construction materials, chemical and raw material production, consumer and industrial goods, distribution electronics, energy, medical technology, information technology, paper products, and plastics.[1] Intervenors encouraged Congress to update TSCA to keep pace with scientific advancements and ensure that chemical products are safe for their intended uses, while encouraging innovation.

EPA's Rules create a process that achieves the balance Congress envisioned. Drawing from the tens of thousands of chemicals on EPA's inventory, EPA will screen and prioritize chemicals for evaluation (Prioritization Rule), evaluate chemicals by assessing the potential hazards from potential exposures to chemicals under conditions of use using rigorous standards subject to peer review (Risk Evaluation Rule), and then, as appropriate, initiate a separate rulemaking to decide whether to regulate further any chemical that presents an unreasonable risk under "conditions of use" for that chemical. The Rules include the aggressive deadlines and requirements for continuous chemical reviews mandated by Congress, while allowing for extensive public participation and judicial review.

[1] *See* Michael Walls Decl., Mot. for Leave to Intervene of American Chemistry Council, *et al.*, ECF No. 10579428 (Sept. 13, 2017).

To manage this effort and make it achievable on the rapid schedule Congress has demanded, EPA has reasonably focused its risk evaluations on the "conditions of use" arising from the ongoing manufacturing, processing and distribution of chemicals as they are available to be used in commerce today, while reserving the discretion to further focus the conditions of use it will consider on a case-by-case basis. Petitioners challenge this approach. According to Petitioners, EPA must consider "all" conditions of use and can never exclude any past "legacy" activities or exercise any discretion whatsoever in defining the scope of the circumstances it will review in a risk evaluation.

Petitioners' challenge should be rejected. Nowhere did Congress require EPA to consider "all" conditions of use. Rather, Congress required the Agency to continuously complete chemical reviews on aggressive timelines, while affording EPA substantial discretion to determine and define the conditions of use it will consider in its evaluations. Moreover, Petitioners' assertion—that every intended, known or foreseeable circumstance in which a chemical has ever been or could be used or disposed of—merits a full-blown risk evaluation would not be sound policy. Petitioners' interpretation would waste significant resources, as EPA would be required to investigate circumstances or conditions of use that do not present a real risk of exposure. Rather than providing the review that Congress envisioned,

Petitioners' approach would grind the process to a halt and thwart Congress' clear goals in amending TSCA.

STATEMENT OF THE CASE

A. The Business of Chemistry

Petitioners' assertion that Congress intended to require EPA to evaluate every conceivable way in which a chemical has been or could be manufactured, processed, distributed in commerce, used, or disposed of, must be considered in context. Chemicals are fundamental building blocks of modern life.[2] Chemistry is essential to the fabrics we produce for the clothes we wear, the energy we need to power our homes and businesses and to transport us, the smartphones and electronic devices on which we rely, the appliances we use every day, the medicines we need to keep us healthy, and the food we eat.[3] Quite literally, virtually every aspect of our daily life in some way involves chemicals and the products created from them.

Moreover, the types of chemicals—and their uses—are extraordinarily diverse. These include: (1) basic "building block" chemicals, such as inorganic chemicals, bulk petrochemicals, intermediates, plastic resins, synthetic rubber, manufactured fibers,

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[2] *See generally,* American Chemistry Council ("ACC"), 2017 Elements of the Business of Chemistry (2017), https://www.americanchemistry.com/2017-Elements-of-the-Business-of-Chemistry.pdf.

[3] *E.g.*, the National Association of Manufacturers, Risk Evaluation Rule Comments ("RE Comments") 1 ("Chemicals are the building blocks of lifesaving products, the newest technologies and everyday products that make life better.") (SER946).

dyes, pigments and inks, which are used to make other chemicals, incorporated into manufactured goods, or aid processing of other materials; (2) specialty chemicals, such as adhesives and sealants, catalysts, coatings, flavors, fragrances, food additives, fuel and lubricants, cleaners, oilfield chemicals, paper additives, plastics compounding, and many others; (3) agricultural chemicals, such as fertilizers and crop protection products; (4) pharmaceuticals; and (5) chemicals used to make consumer products, including soaps, detergents, laundry aids, toothpaste, hair and skin care products.[4] Just the basic building block chemicals have *hundreds of thousands* of discrete uses.[5]

For EPA to conduct a risk evaluation on thousands of chemicals will be an extraordinarily complex undertaking, as a risk evaluation will be founded on integrating a hazard assessment (based upon data, research and studies) and an

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[4] *See* 2017 Elements of the Business of Chemistry at 14-26; Dow Chemical, RE Comments 1 ("Dow's … specialty chemical, advanced materials, agrosciences and plastics businesses delivers a broad range of technology-based products and solutions to customers in approximately 180 countries and in high-growth sectors such as packaging, electronics, water, coatings and agriculture.") (SER915); Society of Chemical Manufacturers Association ("SOCMA") RE Comments 1 ("From pharmaceuticals to cosmetics, soaps to plastics and all manner of industrial and construction products, SOCMA members make materials that save lives, make our food supply safe and abundant, and enable the manufacture of literally thousands of other products.") (SER960); American Composite Manufacturers Association, Prioritization Rule Comments ("PR Comments") 1 (chemicals used in "a broad variety of products ... including turbine blades and nacelles for the generation of electricity from wind, rust proof reinforcing bars for highway bridges, corrosion resistant tanks for underground storage of gasoline") (SER861).

[5] *E.g.,* ACC RE Comments 9 (ER142).

exposure assessment (requiring exposure information and scientific models) for each condition of use EPA identifies in its scope. As chemicals can perform many thousands of functions under each of many disparate conditions of use, EPA must separately examine the pathways of potential exposure for humans (oral, inhalation, dermal) and for the environment (via air, water or soil). Hence, to conduct a risk evaluation under "all" conditions of use as Petitioners assert TSCA requires—including every known legacy use or disposal of these chemicals—would be an almost infinite exercise calculated to frustrate, rather than inform, the analysis of chemicals in commerce.

B. The TSCA Amendments

Congress enacted TSCA in 1976 to authorize EPA to identify, and, if necessary, regulate, chemicals that present an unreasonable risk of injury to health or the environment. 15 U.S.C. § 2601(b)(2). Congress directed EPA to exercise this authority in a "reasonable and prudent manner" that did not impede unduly the technical innovation essential to our economy. 15 U.S.C. § 2601(b)(3),(c).

Forty years later, however, Congress found that the original TSCA had not fully accomplished its goals and needed reform. S. Rep. 114-67 at 2 (June 18, 2015) (Environment and Public Works Committee) ("effective implementation of TSCA … had been challenged by shortcomings in the statute itself, and by several key decisions of Federal Courts and the Agency's interpretation of those decisions."). These

limitations left thousands "of unassessed chemicals in commerce," S. Rep. 114-67 at 13, as TSCA had "grandfathered in tens of thousands of chemicals to the inventory" without a sequenced and methodical review, 162 Cong. Rec. S3516 (June 7, 2016) (Detailed Analysis and Additional Views of Democratic Members); *see also* H.R. Rep. 114-176 at 12-13 (June 23, 2015) (noting "persistent concerns about the pace of EPA's work under TSCA").

Congress also recognized that in the absence of federal action, states had enacted their own rules. The resulting patchwork of "different State requirements will create confusion for the general public, and significantly increase the cost and burden of regulatory compliance for chemical manufacturers, importers and users while failing to apply any protections to more than a relatively small number of citizens." S. Rep. 114-67 at 6. Congress understood that effective regulation of interstate commerce would require regulation of intrastate commerce for chemical substances and mixtures. 15 U.S.C. § 2601(a)(3). Moreover, "[b]ecause TSCA regulates products manufactured for national and international commercial use," Congress "strongly intend[ed] … to establish a robust, nationally uniform program for the effective regulation of chemicals…" S. Rep. 114-67 at 24.

With that backdrop, Congress amended TSCA to provide EPA with improved federal tools to prioritize, evaluate, and, if necessary, regulate under federal law chemicals in today's marketplace that present unreasonable risks. The Prioritization

and Risk Evaluation Rules implement that direction, as well as Congress' grant to EPA of the reasonable discretion to determine the conditions of use it would evaluate. EPA has outlined the framework in detail. EPA Br. 5-11. In summary:

Prioritization. EPA must screen and prioritize chemicals as "high priority" or "low-priority" for "risk evaluation" under a number of factors, including the "conditions of use" for the chemical "as determined by" EPA. 15 U.S.C. § 2605(b)(1), (b)(3)(C)(ii); 40 C.F.R. § 702.7(a)-(e); 15 U.S.C. § 2602(4); 40 C.F.R. § 702.33. The screening process, 40 C.F.R. § 702.9, is to ensure chemicals "in commerce" are "subject to a systematic review." S. Rep. 114-67 at 11. The public will have multiple opportunities to participate in the process, *e.g.*, 40 C.F.R. § 702.7(d)-(e) (initial listing of chemicals for prioritization); 40 C.F.R. § 702.9(g) (proposed designation), as well as to obtain judicial review of an EPA low-priority designation, 15 U.S.C. § 2618(a)(1)(C)(i).

Risk Evaluation. EPA must conduct ongoing "risk evaluations" of chemicals under the conditions of use. 15 U.S.C. § 2605(b)(4)(A). The first 10 risk evaluations, selected from a pre-identified set, are now underway. 15 U.S.C. § 2605(b)(2) (2014 "TSCA Work Plan").[6] EPA must then conduct reviews of chemicals that manufacturers ask EPA to evaluate, 15 U.S.C. § 2605(b)(4)(C)(ii); and chemicals EPA

[6] The TSCA Chemical Work Plan is available at https://www.epa.gov/sites/production/files/2015-01/documents/tsca_work_plan_chemicals_2014_update-final.pdf.

designates as high-priority through the Prioritization Rule process. 15 U.S.C. § 2605(b)(3)-(4). Each risk evaluation must be under a defined scope, and Congress granted EPA the discretion to define the "scope … including the … conditions of use" that EPA "expects to consider" in the evaluation. 15 U.S.C. § 2605(b)(4)(D); 40 C.F.R. § 702.41(c)(1). The scoping allows EPA to focus its evaluation on the potential hazards and exposures under conditions of use that present the greatest risk potential. As with the screening process in the Prioritization Rule, the public will have ample opportunities to comment. In particular, EPA will take public comment on the draft scope of each discrete risk evaluation, 40 C.F.R. § 702.41(c)(7)(iii). Throughout this process, EPA must meet TSCA's aggressive throughput requirements. *See* 15 U.S.C. § 2605(b)(2)(B)-(C), (b)(3)(C).

Each risk evaluation is a complex examination of a chemical that will assess potential hazards and exposures of a chemical under the conditions of use based on best available science, 15 U.S.C. § 2605(b)(4)(F)(i); 40 C.F.R. § 702.41(d)-(e), integrate hazard and exposure assessments, and consider uncertainty and variability, data quality, and environmental risks. 15 U.S.C. § 2625(h), (i), (j); 40 C.F.R. § 702.43. Each draft evaluation will be peer reviewed, 15 U.S.C. § 2625(h)(5); 40 C.F.R. § 702.45, and will be subject to public comment. 15 U.S.C. § 2605(b)(4)(H); 40 C.F.R. § 702.49(a). Then, based on the weight of the scientific evidence, EPA will issue a final risk evaluation. 15 U.S.C. § 2605(b)(4)(H); 40 C.F.R. § 702.49(b). When the final risk

evaluation is completed, EPA will make its final determination of unreasonable risk, 40 C.F.R. § 702.49(c), or no unreasonable risk, 40 C.F.R. § 702.49(d).

Risk management. If EPA determines a chemical poses an unreasonable risk under one or more conditions of use, EPA must initiate a separate risk management rulemaking to address the unreasonable risk. 15 U.S.C. § 2605(a)(1) (referencing § 2605(b)(4)(A)); 40 C.F.R. § 702.49(c). EPA has substantial discretion in formulating this rule, and the Agency may consider a number of factors ranging from the "effects" of the chemical to the "reasonably ascertainable economic consequences of the rule." 15 U.S.C. § 2605(c)(A)(i)-(iv). A final risk management rule (and underlying risk determination) is final action subject to judicial review, as is a final determination of "does not present an unreasonable risk" following the completion of the risk evaluation step. 15 U.S.C. § 2605(i)(1)-(2); 40 C.F.R. § 702.49(d).

Deadlines. Congress set strict deadlines and metrics to structure EPA's approach to the monumental task of addressing tens of thousands of chemicals. Once it starts to review a chemical, EPA must make its prioritization decision in 9-12 months. 15 U.S.C. § 2605(b)(1)(C). EPA was required to begin action on the initial 10 chemicals promptly (within six months of the Amendments), 15 U.S.C. § 2605(b)(2)(A), must have at least 20 risk evaluations underway on high-priority chemicals and designated at least 20 chemicals as low-priority by the end of 2019, 15 U.S.C. § 2605(b)(2)(B), and must continue on at least that pace if not more quickly

"consistent with [EPA's] ability…to complete risk evaluations," generally completing evaluations within three years of designation as a high priority chemical. 15 U.S.C. § 2605(b)(1)(C), (b)(2)(C), and (b)(4)(G). EPA must complete a final risk management rule, if any, not more than two years thereafter. 15 U.S.C. § 2605(c)(1)(B).

Thus, through multiple comment periods, the public will have substantial opportunity to engage with EPA, while the Agency ensures it meets statutorily set pacing and deadlines. Each decision must be based on a record and is subject to judicial review at times specified by Congress. 15 U.S.C. §§ 2605(i), 2618(a)(1)(C)(i), 2618(c).

SUMMARY OF THE ARGUMENT

EPA's Rules appropriately balance Congress' goals of continuously evaluating on a meaningful timeline those priority chemicals that may present unreasonable risks. Petitioners' claim that this carefully constructed process improperly interprets the "conditions of use" under which the Agency will prioritize and evaluate chemicals under the Rules. Petitioners' rigid interpretation, however, is flawed and should be rejected.

First, EPA properly exercised its discretion to determine that legacy activities are not circumstances of a condition of use of a chemical that should be prioritized and evaluated under TSCA. Congress expressly provided EPA with this discretion, by authorizing EPA to identify those circumstances "as determined by the

Administrator" in defining the conditions of use. Petitioners' claims not only ignore this statutory language, but are contrary to the legislative history of the Amendments and the overall structure of TSCA. Indeed, the inherent delays that would result from Petitioners' approach would defeat Congress' mandate to move forward promptly at the pace set by the Amendments with a robust, uniform federal program to address the deficiencies in the original TSCA framework and the resulting patchwork of state laws.

Second, as expressly authorized by TSCA, EPA likewise has properly reserved its ability, on a case-by-case basis, to identify in the "scope" for its risk evaluation the conditions of use that the Agency "expects to consider" in its risk characterization. Petitioners' argument that EPA must consider "all" conditions of use in each and every risk evaluation has no basis in the statute, is inconsistent with the statutory structure, and contrary to Congress' intent. EPA took only the limited step of determining that it would, on fact-specific basis, consider whether some conditions of use might be excluded from the scope of a risk evaluation on the grounds that specific uses presumptively did not raise material risks or could be more appropriately addressed in other contexts. Allowing EPA discretion, applied in context-specific basis, to focus its resources on those circumstances of exposure that present the greatest potential concern is a wholly reasonable approach—and will ensure EPA

moves ahead to meet the statutory deadlines established by Congress and avoid bringing the process to a grinding halt.

Third, EPA's determination to allow for an iterative process under which EPA may evaluate specific circumstances of conditions of use separately is consistent with the statute and legislative history. Indeed, Congress specifically granted EPA the discretion to consider a range of potential circumstances or conditions of exposures in the course of its evaluations—including whether it may choose to consider "aggregate" exposures or some other approach. Nowhere does TSCA demand the "holistic" process Petitioners seek.

Fourth, EPA has moved to remand without vacatur certain provisions of the Risk Evaluation Rule, including two provisions that specify the information manufacturers will provide to EPA when asking EPA to evaluate a particular chemical. If the Court does not grant EPA's request, it should reject Petitioners' challenge to these provisions. TSCA grants EPA discretion to create the process, including to promulgate a rule setting the "form and manner" and "criteria" for considering manufacturer requests, and EPA's approach in the Rules is reasonable. EPA has ensured that manufacturers provide complete information that meets Congress' standards for sound scientific information, while reserving to EPA the ability to consider additional information in a transparent process.

Finally, even if the Court were to find EPA's Rules inadequate in some respect, the proper remedy would be a remand for additional explanation, rather than a vacatur that would frustrate Congress' purpose for timely EPA action under TSCA.

ARGUMENT

I. EPA properly exercised its discretion to determine how to address legacy activities when prioritizing and evaluating chemicals.

EPA properly exercised its discretion in the Rules to focus on those chemicals that are currently being manufactured, processed, and distributed in commerce, but to exclude "legacy" chemicals and associated activities—legacy uses (activities that do not reflect ongoing or prospective manufacturing, processing, or distribution), associated disposal (the future disposals from legacy uses), and legacy disposal (disposals that have already occurred). 82 FR 33,729 (ER4). EPA will still consider background exposures from legacy activities as may be relevant to its overall analysis. 82 FR 33,730 (ER5); EPA Br. 30.

Petitioners wrongly contend that TSCA *compels* a reading that EPA *must* address *all* legacy activities of *all* chemicals as "conditions of use" in each and every risk evaluation. Pet'rs Br. 40-51. Petitioners' reading would mean that EPA must undertake the immense task of attempting to evaluate every legacy use of a chemical no longer being produced, every potential disposal associated with each such legacy use, and every past disposal of a chemical, including how and where individual chemicals were historically disposed of at the thousands of disposal sites around the

country over the course of the past 40 years. The time, information gathering efforts, and other resources EPA would require to accomplish this approach is staggering. Meanwhile, the extraordinary delays that would necessarily result would mean that EPA could not undertake risk evaluations at the pace Congress expects, thus defeating one of Congress' central reasons for enacting the Amendments.

As EPA explains, and as explained below, Congress did not mandate such a burdensome and self-defeating inquiry. Petitioners' argument is contrary to TSCA's text, its legislative history, and the structure of TSCA as a whole.

A. TSCA granted EPA the discretion to determine the circumstances that constitute conditions of use.

TSCA expressly grants EPA discretion to determine the circumstances under which a chemical will be prioritized and evaluated under the Act in the definition of "conditions of use": "the circumstances, *as determined by the Administrator*, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of." 15 U.S.C. § 2602(4) (emphasis added). All EPA has done here is memorialize the plain language of the statute in its regulations, 40 C.F.R. § 702.33 (regulatory definition of "conditions of use" matches statutory definition), and reasonably exercise that discretion in promulgating the Rules.

Notwithstanding this statutory language, Petitioners claim that EPA has absolutely no discretion in determining the "conditions of use," asserting that the

phrase "as determined by the Administrator" envisions merely ministerial fact-finding. Pet'rs Br. 33-34. Petitioner EDF did not take that extreme position before the Agency in the rule development process, recognizing its implausibility. To the contrary, in comments before EPA, EDF agreed that EPA has discretion and that not "all conceivable use[s]" must be considered. EDF RE Comments 13 (SER811); *see also id.* (incorporating by reference prior EDF Comments 6 ("we also recognize that not all conceivable use, misuse or abuse of a chemical is reasonable to consider" and identifying intentional misuse as an example)).[7]

Regardless, Petitioners' position here does not square with the plain meaning of the provision. *E.g.*, *Pioneer Inv. Servs. Co. v. Brunswick Assocs. Ltd. P'ship,* 507 U.S. 380, 388 (1993) (when a term is not defined, courts look to common meaning). The verb "determine" does not mean ministerial fact gathering, but is a discretionary process "to settle or decide by choice of alternatives or possibilities." *E.g.*, Merriam-Webster, https://www.merriam-webster.com/dictionary/determine. This Court accordingly has construed similar language to authorize the exercise of discretionary judgment by the assigned agency. *See Hagood v. Sonoma Cty. Water Agency*, 81 F.3d 1465, 1477 (9th Cir. 1996) ("*as determined by the Secretary of the Army*" conferred "fairly wide discretion") (emphasis in original); *San Bernardino Mountains Cmty. Hosp. Dist. v. Sec'y of Health &*

[7] The additional comments that EDF incorporated by reference are available at https://www.regulations.gov/contentStreamer?documentId=EPA-HQ-OPPT-2016-0400-0026&attachmentNumber=1&contentType=pdf.

Human Servs., 63 F.3d 882, 886 (9th Cir. 1995) (phrase "'as determined by the Secretary' [was part of a] broad grant of discretionary authority"); *see also Nat'l Mall Tours of Wash., Inc. v. U.S. Dep't of the Interior,* 862 F.3d 35, 38 (D.C. Cir. 2017) ("as determined by the Secretary" "affords the agency discretion"); *Transitional Hosp. Corp. of Louisiana, Inc. v. Shalala*, 222 F.3d 1019, 1027 (D.C. Cir. 2000) ("as determined by the Secretary" gives agency discretion); EPA Br. 19-21 (citing cases).[8]

Petitioners' interpretation would strip the phrase "as determined by the Administrator" of any meaning, contrary to the Supreme Court's long-established direction to "give effect, if possible, to every clause and word of a statute." *Duncan v. Walker*, 533 U.S. 167, 174 (2001), *citing United States v. Menasche*, 348 U. S. 528, 538-539 (1955). If Congress meant for EPA to have no discretion, it could have and would have omitted this language entirely.[9]

Moreover, Petitioners' reading is contrary to TSCA's legislative history, which confirms that Congress intended to grant EPA appropriate discretion to determine

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[8] Petitioners' citation to a D.C. Circuit ruling in *U.S. Sugar Corp. v. EPA,* 830 F.3d 579 (D.C. Cir. 2016) is not to the contrary. Pet'rs Br. 34. There, the court *upheld* EPA's discretion to set emission control standards "as determined by the Administrator." 830 F.3d at 610-11. Where the court found EPA's discretion constrained, it did so because the Clean Air Act required EPA to determine "the best controlled source" but EPA had adopted a rule that excluded units that fell within that category. *Id.* at 631. By contrast, there is no similar textual limitation in TSCA.

[9] Reading this language as Petitioners propose—merely directing EPA to engage in a ministerial determination—is functionally no different than if this language was not included. EPA would have the same (merely ministerial) authority.

the conditions of use. Where, as here, Congress did not prepare a conference report, the statements by sponsors of the legislation and its drafting history are instructive. *E.g., Begier v. IRS,* 496 U.S. 53, 64 n.5 (1990) (in the "absence of a conference" and in view of "key roles played by" floor managers, court "treated their floor statements … as persuasive evidence of congressional intent"); *North Haven Bd. of Educ. v. Bell*, 456 U.S. 512 (1982) (statements by sponsor were "authoritative guide to the statute's construction"); *Doe v. Chao*, 540 U.S. 614, 622 (2004) (statutory interpretation "underscored by drafting history showing that Congress cut out the very language in the bill that would have authorized" claim).

Here, the sponsors were clear they intended to grant EPA discretion to determine the conditions of use. In a colloquy entitled "Congressional Intent Behind Specific Provisions of the Bill," the Amendments' Senate co-sponsor, Senator Vitter, stated that "the Agency is *given the discretion to determine the conditions of use* that the Agency will address in its evaluation of the priority chemical." 162 Cong. Rec. S3519 (emphasis added); *id.* ("EPA's understanding of a chemical's conditions of use—and importantly, it is the circumstances 'the Administrator' determines—will be critical" to EPA's risk evaluation process.). Indeed, "without this discretion" EPA could not meet the goals of the Amendments. 162 Cong. Rec. S3519.

The drafting history of the Amendments bolsters these floor statements. *INS v. Cardoza–Fonseca*, 480 U.S. 421, 442-43 (1987) ("Few principles of statutory

construction are more compelling than the proposition that Congress does not intend *sub silentio* to enact statutory language that it has earlier discarded in favor of other language."). The predecessor Senate bill had granted EPA the discretion to determine the "conditions of use," while the bill reported out by the House did not. *Compare* S. Rep. 114-67 at 41 ("'conditions of use' means the intended, known, or reasonably foreseeable *circumstances the Administrator determines* a chemical substance is manufactured, processed, distributed in commerce, used, or disposed of.") (emphasis added), *with* H.R. Rep. 114-176 at 2 ("'intended conditions of use' means the circumstances under which a chemical substance is intended, known, or reasonably foreseeable to be manufactured, processed, distributed in commerce, used, and disposed of.") *and id.* at 22 ("the Agency will generally interpret this term to mean intended by the manufacturer, known by the manufacturer or the public, or reasonably foreseeable by the manufacturer or the Administrator"). Here, in reconciling these bills, Congress considered the conflicting options and chose to leave the determination to EPA.

B. In view of TSCA's language, legislative history, structure and purpose, EPA's interpretation of the statute to generally exclude legacy and associated uses and disposal is reasonable and an appropriate exercise of EPA's discretion.

Beyond the express grant of discretion to EPA to "determine" conditions of use, EPA's decision to focus on the prospective flow of chemicals into the market while generally excluding legacy activities draws additional support from the definition

of "conditions of use," as well as the broader structure and purpose of TSCA. 15 U.S.C. § 2601(c) ("It is the intent of Congress that the Administrator shall carry out this chapter in a reasonable and prudent manner").

Foremost, in its definition of "conditions of use," Congress used only the present and future tense in the definition and only provided three circumstances, all of which are forward-looking: (i) Those in which the chemical "*is intended … to be* manufactured, processed, distributed in commerce, used, or disposed of," (ii) those in which the chemical "*is … known … to be* manufactured, processed, distributed in commerce, used, or disposed of," and (iii) those in which the chemical "*is … reasonably foreseen to be* manufactured, processed, distributed in commerce, used, or disposed of." 15 U.S.C. § 2602(4). Merriam-Webster defines "is" as the "present tense third-person singular of be" and "to be" as "that is to be: future." https://www.merriam-webster.com/dictionary/is; https://www.merriam-webster.com/dictionary/to-be.

The legislative history likewise repeatedly confirms the Amendments are forward looking—designed to focus on those chemicals that are "in commerce" and being actively manufactured, processed, and distributed into the market—and not looking backwards at legacy activities. S. Rep. 114-67 at 2 ("while TSCA is one of many statutes that regulate chemicals; its unique focus is on industrial chemicals in commerce"); *id.* at 4 (concern was TSCA had no mechanism for "EPA [to] systematically assess existing chemicals in commerce" or how to decide which

chemicals to assess). Hence, Congress sought to create "a process that assures every chemical in commerce is subject to a systematic review by EPA…" *Id.* at 11. Indeed, "the goal of the legislation is to ensure that all chemicals on the market get such a review." 162 Cong. Rec. S3516 (Detailed Analysis and Additional Views of Democratic Members). *See also* EPA Br. 29-30 (citing legislative history). Nowhere did Congress express a desire for EPA to investigate uses that have been discontinued.

EPA's reading is supported further by the overall structure and purposes of the Amendments. "Reasonable statutory interpretation must account for both 'the specific context … in which language is used' and the 'broader context of the statute as a whole.'" *Utility Air Regulatory Grp. v. EPA*, 134 S. Ct. 2427, 2442 (2014). Here, EPA's approach to legacy activities fits Congress' carefully constructed mandate that EPA move forward expeditiously to prioritize and review chemicals, and manage any risk determined unreasonable. With tens of thousands of chemicals presenting literally hundreds of thousands of uses, Congress recognized the need for EPA to have discretion to define the universe of its overall review and the conditions of use of each discrete chemical review. The review of even a single chemical can be a very complex undertaking, due to the extensive data analysis, review of scientific literature, testing, and the consideration of public input and peer review for a risk evaluation.

See 40 C.F.R. §§ 702.41 (evaluation requirements), 702.43 (risk characterization), 702.45 (peer review).[10]

To expand the process to encompass also a review of every past disposal, every past use and associated disposal, and the range of potential exposures and potential hazards associated with each one of those legacy activities would impose massive additional burdens on the Agency. This is because there are typically numerous past "legacy" uses—*i.e.*, past uses for a given chemical that have ceased and are no longer being introduced into commerce—which, under Petitioners' interpretation, EPA would be required to consider.[11]

Petitioners' backwards-looking interpretation would also raise retroactivity concerns. *Landgraf v. USI Film Prods.*, 511 U.S. 244, 267-68 (1994) (presumption against applying a statute retroactively absent clear direction from Congress). If the

[10] For example, just during the scoping phase, EPA will identify the conditions of use it expects to consider in the risk evaluation, and for *each* of those conditions of use it will evaluate the potentially exposed populations, identify the reasonably available scientific information, develop a conceptual model with actual and predicted relationships between the condition of use and human and environmental receptors, undertake an analysis plan for use during the risk evaluations, analyze hypotheses and alternative hypotheses about the relationships identified in the conceptual model, and identify the Agency's plan for peer review. 40 C.F.R. § 702.41(c).

[11] Examples include flame retardants no longer used to make insulation for buildings; plasticizers formerly used to make plastic flooring flexible, or a fragrance additive no longer used in warehoused candles manufactured decades ago. Requiring EPA to consider each of these legacy uses—and literally many tens of thousands others—and the potential exposure scenarios for each—would overwhelm the process Congress created.

inquiry into decades of legacy use and legacy disposal that Petitioners claim Congress *required* is to have any meaning, then the Amendments must impair settled rights and impose new duties on those past activities, *Landgraf*, *supra*, 511 U.S. at 280, in the form of a future risk management regulation. Otherwise, Petitioners' argument concerning legacy use and disposal is a pointless one.

Moreover, as Petitioners acknowledge (Pet'rs Br. 7-8), Congress adopted the Amendments to address deficiencies in the previous statutory framework. S. Rep. 114-67 at 13. Congress therefore structured TSCA to "assure that the Agency can effectively assess and control priority chemicals *and* meet the new law's strict deadlines." 162 Cong. Rec. S3519 (emphasis added). It created a stepwise process of prioritization, risk evaluation, and, if necessary, risk management, designed to ensure EPA increasingly focuses on the highest priorities, 15 U.S.C. § 2605(a), (b)(1)(B), (b)(4)(D), while imposing specific, strict deadlines with identified metrics to ensure the Agency moved forward expeditiously. 15 U.S.C. § 2605(b)(1)(C) (prioritization must be complete within 9-12 months), (b)(4)(D) (scoping must be completed 3-12 months after initiating a risk evaluation), (b)(4)(G) (risk evaluation generally completed within 3 years); 15 U.S.C. § 2605(b)(2)(A)-(B) (by the end of 2019, 20 high-priority chemicals undergoing risk evaluations and 20 designated as low-priority). Congress reinforced its intention for expeditious action by directing EPA to select

and start risk evaluations on 10 chemicals almost immediately—even before these Rules were finalized. 15 U.S.C. § 2605(b)(2)(A).

Congress viewed meeting these deadlines as critical to effective implementation of the Amendments. *E.g.*, S. Rep. 114-67 at 16 ("Importantly, the section [requiring assessments] establishes strict, enforceable deadlines for EPA action."). Congress was also clear that it wanted to ensure that EPA "undertake a minimum number of reviews and increase 'through-put'" of its reviews. S. Rep. 114-67 at 11; *id.* at 17 (expressing concern with fact that "EPA has been able to regulate only a handful of existing chemicals"). As such, it gave EPA no discretion to ignore these specific mandates, *see Biodiversity Legal Found. v. Badgley*, 309 F.3d 1166, 1175 (9th Cir. 2002) (Congress enacted statutory deadline for "purpose of curtailing the process"), and thus any reasonable interpretation of the "conditions of use" must recognize this overall statutory structure. Absent providing the Administrator some reasonable discretion to determine the circumstances under which a chemical is "used" or "disposed of" when prioritizing and evaluating chemicals, EPA cannot be expected to meet the aggressive schedule Congress imposed. Indeed, it would be antithetical to the process Congress envisioned, let alone unreasonable and impractical, to compel

EPA to devote its limited resources towards evaluating legacy uses of chemicals no longer being manufactured, processed or distributed for that purpose.[12]

Moreover, the Amendments did not alter EPA's ability to consider its other statutory authorities in determining what it would address under TSCA. Hence, if a risk "could be eliminated or reduced to a sufficient extent by actions taken under other authorities contained in … other Federal laws … administered in whole or in part by" EPA, the Agency "shall use such other authorities to protect against such risks" unless EPA determines, in its discretion, that the public interest requires action under TSCA. *Id.* § 2608(b)(1).[13] Congress never intended to transform TSCA into a sweeping statute that reached into every conceivable legacy use—and Petitioners advance no reason why TSCA should be interpreted to address a particular legacy use when extensive rules under other statutes already manage risks.[14]

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[12] As discussed *infra*, Congress also granted discretion to EPA to define the conditions of use that the Agency "expects to consider." That provides a separate legal basis for EPA's determination to exclude legacy activities. 82 FR 33,730 (EPA could also exclude legacy activities through the discretion granted in § 2605(b)(4)(D)) (ER5).

[13] EPA may also refer identified risks to other agencies (*e.g.*, OSHA) where that agency may be able to address that risk under authorities it administers.

[14] For example, Petitioners focus on asbestos, for which there is already extensive regulation. *E.g.*, 40 C.F.R. § 61.145 (Clean Air Act demolition and renovation work practices); 29 C.F.R. § 1910.1001 (OSHA general standards, including permissible exposure limits, engineering controls, worker training, labeling, respiratory protection) and § 1926.1101 (OSHA construction standards, including work practices during demolition and renovation, worker training, disposal of asbestos waste, and specification of permissible exposure limits).

This is especially true for associated disposal, the only potentially "future" action associated with legacy use about which Petitioners have asserted a concern. Comprehensive federal and state laws are already in place to address the associated disposal of any legacy uses. The disposal of all solid and hazardous waste materials is highly regulated under the federal Resource Conservation and Recovery Act ("RCRA"), 42 U.S.C. § 6901 *et seq*., under which EPA has established a detailed body of regulatory requirements. *See, e.g.*, 40 C.F.R. Parts 260-265. State and local governments across the country have their own rules to implement RCRA and many impose additional requirements beyond the minimum federal standards. 42 U.S.C. § 6926(b) (States may be authorized to implement RCRA hazardous waste requirements); § 6941 (States implement programs under EPA direction to manage disposal of solid waste). Municipal governments often have their own additional requirements to manage solid waste. Petitioners would seek to have EPA create yet another federal layer on top of these extant programs.[15] Petitioners have proffered no reasons from the record why EPA should do so.

Likewise, the Comprehensive Environmental Response Compensation and Liability Act ("CERCLA") is a comprehensive statute designed to address the historic,

[15] Again, Petitioners focus on asbestos. Pet'rs Br. 42-43. The disposal of asbestos is also already regulated. *E.g.,* 40 C.F.R. § 61.150 (Clean Air Act waste disposal requirements for manufacturing, fabricating, demolition, renovation and spraying operations); 40 C.F.R. Part 763, Subpt. E, Appx. D (certain disposal requirements for asbestos containing materials); 29 C.F.R. § 1926.1101 (disposal requirements).

legacy disposal of hazardous substances. 42 U.S.C. § 9601 *et seq.* CERCLA provides broad powers to EPA to identify, evaluate, study the risks of, and respond to potential threats to human health and the environment from legacy disposal sites. *E.g.*, 42 U.S.C. §§ 9604-9607. It establishes standards for evaluating risks, making decisions and taking response actions in order to protect human health and potential damages to natural resources from releases from such sites. *E.g.*, 42 U.S.C. §§ 9617, 9621. EPA has adopted extensive regulations and guidance to implement these requirements. 40 C.F.R. § 300 *et seq.* (EPA's National Contingency Plan). Also, many states have their own state-CERCLA programs to provide additional response authority.[16] There is no indication that Congress mandated that EPA must impose another set of requirements on top of CERCLA for legacy activities—and Petitioners again have offered no reasons from the record why EPA should do so.

Finally, EPA has made clear that it will consider legacy activities in risk evaluations where relevant, but not as conditions of use. EPA explained that "in a particular risk evaluation, EPA may consider background exposures from [legacy activities] as part of an assessment of aggregate exposure or as a tool to evaluate the risk of exposures resulting from non-legacy uses." 82 FR 33,730 (ER5); *see* EPA Br. 30. As noted above, with multiple comment opportunities—from the initiation of

[16] *E.g.,* Environmental Law Institute, An Analysis of State Superfund Programs: 50-State Study, 2001 Update (2002), https://www.eli.org/sites/default/files/eli-pubs/d12-10a.pdf.

prioritization through scoping, risk determination, and, if necessary, a risk management rule under § 2605(a)—Petitioners and all stakeholders have ample opportunity to present information on legacy activities, including the impact of legacy activities on the potential risks of high priority chemicals. Such information will become part of the record for EPA's risk decisions.

II. TSCA authorizes EPA to refine the scope of its risk evaluations to focus on the conditions of use that potentially present the greatest risks.

Once a chemical has been selected for risk evaluation, EPA must then prepare a "scope" for the evaluation. 15 U.S.C. § 2605(b)(4)(D). Contrary to Petitioners' hyperbole, EPA's regulatory actions here were quite modest. EPA *rejected* comments seeking to exclude additional specific categories of conditions of use by regulation. 82 FR 33,730 ("EPA believes that it would be premature to definitively exclude a priori specific conditions of use from risk evaluation.") (ER5). Instead, in the course of developing the scope for a particular chemical, EPA reserved the right, "on a case-by-case basis," to "exclude certain activities that EPA has determined to be conditions of use in order to focus its analytical efforts on those exposures that are likely to present the greatest concern, and consequently merit an unreasonable risk determination." 82 FR 33,729 (ER4). Thus, EPA may exclude uses that present de minimis exposures or conditions already adequately addressed under other regulatory frameworks. *Id.*

Petitioners contest EPA's approach. Pet'rs Br. 21-38. Petitioners claim EPA violated TSCA by not committing up front to considering "all" conditions of use in

every risk evaluation and that EPA has allegedly improperly retained "unfettered discretion" to exclude conditions of use from a risk evaluation. That, Petitioners claim, would frustrate Congress' intent to address unreasonable risks to the public.

Petitioners' claims fail. As EPA explains, the actual regulation hews closely to the statutory language governing the risk evaluation process, and thus there is no legal basis for Petitioners' challenge—or their wholly speculative assertions of injury. EPA Br. 32-42; *compare* 15 U.S.C. § 2605(b)(4)(D) (scope of risk evaluation) *with* 40 C.F.R. § 702.41(c)(1) (scope of the risk evaluation). The text of the Amendments, their purpose, and sound policy support EPA's reasonable and prudent approach. Moreover, EPA's discretion in deciding whether or not a chemical presents an unreasonable risk that requires regulation is not unfettered. Quite the opposite; throughout the prioritization, evaluation and risk management of chemicals EPA's decisions are subject to an extensive public process that Congress has mandated, as well as judicial review, 15 U.S.C. § 2618, to ensure the Agency's choices reflect reasoned decisionmaking consistent with the statutory goals.

A. TSCA authorizes EPA to establish the scope of its risk evaluation, including the conditions of use it will consider.

1. Section 2605(b)(4) expressly authorizes EPA to define the conditions of use that it "expects to consider" in a risk evaluation.

That EPA has discretion to determine what conditions of use to consider in a risk evaluation is clear on the face of the statute. TSCA provides that EPA must

"conduct risk evaluations *pursuant to this paragraph* to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment … under the conditions of use." 15 U.S.C. § 2605(b)(4)(A) (emphasis added). In subparagraph (4) of "this paragraph," TSCA requires EPA to define the scope of the risk evaluations in a scope document, in which EPA will identify "*the* hazards, exposures, *conditions of use* …" that the Agency "*expects to consider*" in the risk evaluation. 15 U.S.C. § 2605(b)(4)(D)(emphases added).

Nowhere does this language command EPA to conduct a risk evaluation for "all" conditions of use, as Petitioners assert (Pet'rs Br. 21).[17] On the contrary, by directing EPA to prepare a scope for the risk evaluation based on those conditions of use that the Agency "expects to consider," Congress necessarily authorized EPA to consider something less than "all" conditions of use in the scope of its risk evaluation. Petitioners' argument would effectively read out the phrase "expects to consider," contrary to a cardinal rule of statutory construction. *Duncan*, 533 U.S. at 174 (courts "give effect, if possible, to every clause and word of a statute").[18]

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[17] Indeed, as EPA noted, Petitioner EDF in fact acknowledged that EPA has "authority to exclude certain conditions of use from a risk evaluation scope." EDF RE Comments 15 (SER813).

[18] Petitioners claim that "expects to consider" is merely a provision that directs EPA to provide the results of a fact-finding effort, Pet'rs Br. 34-35, but they offer no plausible explanation as to why "expects to consider" cannot reasonably be read as conferring room for discretion by EPA. Petitioners also claim that "expects to consider" only modifies "the potentially exposed or susceptible subpopulations" and not "conditions of use." This argument is waived as Petitioners have only presented

Again, as outlined, *supra*, the legislative history confirms that Congress intended to give EPA discretion to define the scope of the "conditions of use that the Agency will address in its [risk] evaluation." 162 Cong. Rec. S3519 (statement of co-sponsor Sen. Vitter). Congress gave this discretion to EPA so "that the Agency can effectively assess and control priority chemicals and meet the new law's strict deadlines." *Id.* With this discretion, EPA can focus on "conditions of use that raise the greatest potential for risk." *Id.* Indeed, Congress recognized that "[w]ithout this discretion to focus on chemical risk assessments on certain conditions of use, the Agency's job would be more difficult." *Id.* Hence, Congress clearly did not intend to require EPA to conduct full-blown risk evaluations for all conditions of use.

Nonetheless, Petitioners raise three arguments as to why they contend EPA has no discretion to determine the conditions of use the Agency will consider in a risk evaluation. None has merit.

First, Petitioners argue that TSCA requires the evaluation to be on the "chemical substance" as a "whole," and thus, the evaluation must address all conditions of use. Pet'rs Br. 23-24. This argument begs the question. There is no doubt that the final risk evaluation will address the "whole" chemical. 82 FR 33,729

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it in a conclusory footnote. *See, e.g.*, *Hilao v. Estate of Marcos*, 103 F.3d 767, 777 n. 4 (9th Cir. 1996) ("[t]he summary mention of an issue in a footnote, without reasoning in support of the appellant's argument, is insufficient to raise the issue on appeal"). It is also meritless for the reasons stated by EPA. EPA Br. 33.

(ER4). However, that says nothing about the *scope* of the risk evaluation for that chemical, including the conditions of use that will be evaluated, which Congress expressly limited to those conditions of use that EPA "expects to consider." 15 U.S.C. § 2605(b)(4)(A), (D) (authorizes EPA to publish the "scope" of the risk evaluation).

Second, Petitioners insist that by including the word "the" before "conditions of use" in § 2605(b)(4)(A), Congress meant that EPA must consider "all" conditions of use. Pet'rs Br. 25-26. In this context, Petitioners' argument is simply an attempt to insert the word "all" into the statute where Congress chose not to do so. *See, e.g.*, *In re Meruelo Maddux Props., Inc.*, 667 F.3d 1072, 1077 (9th Cir. 2012) (Congress could amend statute to include "the whole business enterprise" exception but it did not, so the Court would "apply the statute as it is written."). Indeed, Congress uses "all" in other instances in TSCA. Elsewhere in Section 2605, TSCA requires that "at least 50 percent of *all* chemical substances on which risk evaluations are being conducted" come from the TSCA Work Plan. 15 U.S.C. § 2605(b)(2)(B) (emphasis added). It requires EPA to consider "*all* relevant factors" in considering reimbursements under its testing authority. 15 U.S.C. § 2603(c)(3)(A) (emphasis added). Congress also required EPA to make publicly available "*all*" submissions of written comments to a risk management rule proposed under Section 2605(a). 15 U.S.C. § 2605(d)(1)(B) (emphasis added). Had Congress intended to require "all" conditions of use to be

considered, it would have said so. Instead, Congress expressly authorized EPA to define the scope of the risk evaluation to include those conditions of use EPA "expects to consider," and not "all" conditions of use.

In re Cardelucci, 285 F.3d 1231 (9th Cir. 2002) does not support Petitioners' argument that "the" actually means "all." *See* Pet'rs Br. 25. *Cardalucci* merely explained that the "definite article 'the' particularizes the subject which it precedes." As the Court subsequently observed in *Hernandez v. Williams, Zinman & Parham*, 829 F. 3d 1068, 1074 (9th Cir. 2016), the meaning of "the" in any specific instance depends on the surrounding statutory language and context. Here, the statutory text in the same paragraph of TSCA establishes how the conditions of use are "particularized," by making clear that "*the* conditions of use" in 2605(b)(4)(A) are the conditions of use that EPA "expects to consider," as provided in 2605(b)(4)(D).

Third, Petitioners assert that because Congress used the word "specific" condition of use in directions to EPA elsewhere in the Amendments, *see* 15 U.S.C. §§ 2605(c)(2)(C) (alternative uses), (g)(1)(exemption) and (h)(test marketing), but did not refer to "specific" conditions of use in § 2605(b)(4), this Court should infer that Congress intended to require EPA to conduct risk evaluations for "all" conditions of use. Pet'rs Br. 25-26. No such inference is warranted. Congress did in fact express its intent to explicitly qualify conditions of use in § 2605(b)(4)—only instead of a "specific" condition, it referred to those conditions of use EPA "expects to consider."

Congress quite logically chose a different approach when establishing the discretion afforded EPA for scoping a risk evaluation—as opposed to when authorizing an exemption or other use.

Finally, all three of Petitioners' arguments as to why EPA must consider 'all' conditions of use are contrary to the general rule that agencies have the inherent authority to make exceptions to avoid undue burdens. *See Committee for a Better Arvin v. EPA*, 786 F.3d 1169, 1178 (9th Cir. 2015) (finding Clean Air Act "allows EPA to ignore trifling emission control measures when EPA evaluates [state implementation plans]" because this Court "applie[s] in statutory interpretation the ancient principle that the law does not care about trifles."); *see also Ala. Power Co. v. Costle*, 636 F.2d 323, 360-61 (D.C. Cir. 1979) ("[u]nless Congress has been extraordinarily rigid," an agency has implied "*de minimis* authority to provide exemption"); *Ass'n of Admin. Law Judges v. FLRA*, 397 F.3d 957, 962 (D.C. Cir. 2005) (courts have "repeatedly recognized that a de minimis exception is generally not express; rather, it is inherent in most statutory schemes, by implication"). EPA stated it would focus its case-by-case review on uses that present "only '*de minimis*' exposures" as well as its obligation under TSCA to avoid duplicative and unnecessary regulation. 82 FR 33,729 (ER4). To the extent EPA may in the future go beyond these limited exclusions and ignores uses that might "merit an unreasonable risk determination," *id.*, Petitioners will be able to challenge such action, 15 U.S.C. §§ 2605(i)(1), (2).

2. TSCA as a whole confirms that EPA may choose to define the conditions of use to consider in a risk evaluation.

Beyond the language of § 2605(b)(4), the overall framework of TSCA and the Amendments confirms that EPA has discretion to consider fewer than all conditions of use in the risk evaluation. *See Hernandez, supra*, 829 F.3d at 1073 (court does not look to words in isolation, but in context and in light of whole statute).

1. The Amendments' preemption provision confirms that Congress expected EPA may consider fewer than "all" conditions of use. *See* 15 U.S.C. § 2617. After extensive negotiations,[19] Congress provided that during a risk evaluation and after EPA takes final action on a chemical certain state actions will be preempted. 15 U.S.C. § 2617(c)(2)-(3). In each case, Congress drafted the preemption narrowly: state law is preempted "only to" the extent that "the hazards, exposures, risks, and uses or *conditions of use* of such chemical substances" are covered by the risk evaluation or final EPA action. *Id.* (emphasis added). By limiting preemption to "only" those "conditions of use" that EPA addresses in its risk evaluation, Congress must have authorized EPA to exclude some conditions of use. The legislative history of TSCA reinforces that intent. *E.g.*, S. Rep. 114-67 at 25 (EPA "action preempts state restrictions on that substance only for the uses and/or conditions of use included in

[19] 162 Cong. Rec. S3521 ("the preemption section of this bill was the most contentious issue of the negotiations as well as the most important linchpin in the final deal.") (Senator Inhofe).

the EPA review."); H.R. Rep. 114-176 at 31 (preemption only applies to "conditions of use considered by the Administrator in the risk evaluation"). Petitioners themselves have recognized that the scope of the risk evaluation dictates the scope of preemption. EDF RE Comments 14 (SER812). But under the reading Petitioners now advocate, all conditions of use would have to be included—turning the limitation on preemption into surplusage. *E.g., Dunn v. Commodity Futures Trading Comm'n,* 519 U.S. 465, 472 (1997) ("legislative enactments should not be construed to render their provisions mere surplusage.")

2. TSCA's direction that EPA consider other federal regulations also confirms EPA's discretion to exclude ongoing, well-regulated conditions of use from a risk evaluation. Section 2608(b) directs EPA to consider its regulations under other statutes the Agency administers in determining whether to regulate under TSCA. 15 U.S.C. § 2608(b) ("The Administrator shall coordinate actions taken under this chapter with actions taken under other Federal laws administered in whole or in part by the Administrator."); *id.* (giving Administrator "discretion" to rely on other laws it administers to address obligations under TSCA); *see supra* Section I.B. (discussing EPA regulations under RCRA and CERCLA designed to protect human health and the environment). On this point, Petitioners agree EPA has discretion. *See* Pet'rs Br. 27 (citing to § 2608(b) as example of where "Congress intended EPA to exercise discretion under TSCA").

TSCA relatedly directs EPA to consider other agencies' regulations before it makes a risk determination. Under Section 2608(d), EPA "shall consult and coordinate" with other federal agencies and instrumentalities "[i]n administering [TSCA]" to reduce "duplicative requirements." 15 U.S.C. § 2608(d). Such consultation should occur before EPA makes a risk determination, because TSCA only authorizes EPA to regulate the manufacture, processing, distribution in commerce, use, or disposal of chemical that "presents" an "unreasonable" risk. 15 U.S.C. § 2605(a).

These provisions reinforce EPA's discretion to consider fewer than all conditions of use, because effective regulation by another agency may mean a condition of use does not merit a further TSCA risk evaluation. *See* Risk Evaluation Response to Comments ("RE RTC") 8-9 ("During the scoping phase of a risk evaluation, EPA may determine that there are appropriate regulatory safeguards in place for a particular use") (ER183-84); American Petroleum Institute ("API") PR Comments 4 ("The entire gasoline lifecycle—from manufacture, through distribution, to end-use—is subject to detailed, complex, and overlapping regulatory schemes intended to protect both human health and the environment.") (SER882). EPA has no authority to regulate risks already addressed sufficiently by existing regulations, and the statute directs EPA to avoid duplicate regulation under TSCA. In contrast,

Petitioners provide no reason why Congress would want EPA to conduct a full-blown risk evaluation on a condition of use that is known to already be effectively regulated.

Nonetheless, Petitioners assert EPA cannot exclude conditions of use where other agencies "hold jurisdiction." Pet'rs Br. 27. This argument is a red herring. In fact, while EPA noted this as a commenter request, EPA stated it *would not* take that position. 82 FR 33,730 (ER5). Instead, EPA stated it would on a case-by-case basis look to determine whether "a condition of use that has been adequately assessed by another regulatory agency, particularly where the other agency has effectively managed the risk." 82 FR 33,729 (ER4).

Petitioners further argue that because Congress defined "chemical substance" to exclude certain chemical uses regulated by other agencies, 15 U.S.C. § 2602(2)(B), Congress must not have granted EPA discretion to exclude conditions of use that other agencies regulate. Pet'rs Br. 28. That argument also fails. The fact that Congress excluded certain defined chemicals for regulation under TSCA cannot be read to suggest that EPA has no discretion in determining the scope of the conditions of use for which it will conduct a risk evaluation. It is not plausible to believe Congress in Section 2602(2)(B) intended to list every chemical use already effectively regulated by another agency and forbid EPA from taking into account where such effective regulation exists. Instead, in Section 2602(2)(B), Congress merely defined EPA's jurisdiction for chemical uses it can consider, and, in Section 2605(b)(4)(D),

Congress gave EPA discretion when exercising that jurisdiction to determine on a case-by-case basis whether to exclude a particular condition of use from a full risk evaluation because of existing regulation.

Petitioners also argue (Pet'rs Br. 28) that EPA can only consult with an agency regarding whether a particular condition of use is already effectively regulated until *after* EPA goes through the intensive process of making a risk determination on the chemical—including uses that are already effectively regulated. Petitioners point to Section 2608(a), which directs EPA to refer to other agencies an "unreasonable risk" that EPA has already determined through a risk evaluation "may be prevented" through another agency's actions. 15 U.S.C. § 2608(a). It makes no sense to read this provision, as Petitioners suggest, as the mechanism EPA must invoke even where it finds an existing regulation is already effective in addressing a particular unreasonable risk. Petitioners' reading ignores Congress' express direction that EPA can only regulate a chemical substance to the extent a condition of use "presents" an "unreasonable" risk. *See* 15 U.S.C. § 2605(a). EPA may find another regulation has already reduced or removed a risk so that the condition of use does not "present[]" an "unreasonable" risk. *E.g.*, American Fuel & Petrochemical Manufacturers ("AFPM") RE Comments 14 (describing existing OSHA and EPA "[personal protective equipment] requirements, engineering and pollution controls, permit limits" to prevent and mitigate exposures for workers and fence line communities) (SER878). If

a condition of use does not "present" an "unreasonable risk" because it is already effectively regulated, then there is no need to invoke the § 2608(a) process.

This is reinforced by language in § 2608(a)(1) itself, which emphasizes the consulting process is to be used when a risk "*may* be prevented or reduced" after a finding by the Administrator that a use "presents an unreasonable risk." Moreover, as noted, Section 2608(d) directs EPA to consult with other agencies to avoid *duplicative* requirements. Limiting EPA to considering existing regulation until after it conducts a full-blown risk evaluation does not fully avoid "duplicative requirements" but instead would result in unnecessary costs and burdens that Congress could not have intended.

In all events, EPA's determination to consider all or fewer than all conditions of use based on existing regulations will be subject to notice and comment and judicial review. EPA will first identify the conditions of use it expects to consider in a proposed scope, which will be open to public comment for 45 days, and will then finalize the scope. 40 C.F.R. § 702.41(b)(7)-(8). EPA's final determinations of no unreasonable risk, or its risk management determinations in response to unreasonable risks, will be subject to judicial review. 15 U.S.C. § 2605(i).

3. The new data collection process Congress delegated to EPA also confirms the Agency has discretion to consider less than "all" conditions of use in its risk evaluation. The Amendments gave EPA discretion to gather additional information,

including for prioritization and a risk evaluation for a chemical. 15 U.S.C. § 2605(a)(2). As part of its new information-gathering authorities, EPA is now authorized to adopt a "tiered screening … process" for assessing the determinants of risk under the statute, *id.* § 2603(a)(4), including "protocols and methodologies … for the assessment of exposure or exposure potential to humans or the environment," *id.* § 2603(b)(2)(A). If EPA is authorized to "screen out" particular exposures as not warranting further data collection for prioritization or risk evaluation, it necessarily must have discretion to choose not to consider the conditions of use that give rise to those exposures when conducting a risk evaluation.

4. As noted, Congress set strict deadlines and specific metrics to ensure EPA acts expeditiously—and stays on track to complete reviews. *See supra* Section I.B. Yet, under Petitioners' theory, with absolutely no ability to exclude any conditions of use, EPA would risk becoming bogged down gathering data and preparing a full-fledged risk evaluation for every conceivable condition of use, no matter how immaterial. *E.g.,* API RE Comments 4-5 (devoting "undue time and limited resources to consideration of low hazard or low exposure conditions of use" would "slow down the risk evaluation process and result in the evaluation of fewer chemicals") (SER895-96); Independent Lubricant Manufacturers Association ("ILMA"), PR Comments 4 ("The Agency must not get bogged down in a 'fishing excursion' and scour for every possible use of a substance—no matter how unlikely it may be.") (SER920). This

would impede rather than further "Congress's legislative objective of achieving uniform, risk-based chemical management nationally in a manner that supports robust national commerce" in place of the pre-Amendments patchwork of "different interpretations on a state-by-state or locality-by-locality basis." 162 Cong. Rec. S3521; S. Rep. 114-67 at 23 (Congress "strongly intends … to establish a robust, nationally uniform program for the effective regulation of chemicals").

Petitioners' structural arguments are not to the contrary. Petitioners claim because Congress provided "detailed directions" to EPA in deciding how to prioritize and evaluate chemicals, it did not intend to allow EPA to exclude any conditions of use, and that had Congress intended to confer discretion on EPA it would have used the word "discretion." Pet'rs Br. 26-27. These arguments miss the mark.

For one, Petitioners' assertion that Congress gave EPA a "detailed" set of instructions on how to prioritize and evaluate chemicals is misplaced. Congress did provide EPA with a framework the Agency must satisfy, but delegated substantial authority to the Agency to build out the details of its screening and risk evaluation process. 15 U.S.C. § 2605(b)(1), (b)(4). Regardless, the fact that Congress gave EPA guidance in how and when to prioritize and evaluate chemicals, 15 U.S.C. § 2605(b)(1), (b)(4), in no way changes the explicit discretion it *also* gave EPA to determine the scope of that evaluation "including the … conditions of use … the Administrator expects to consider." 15 U.S.C. § 2605(b)(4)(D). Rather, the directions

from Congress complement one another, with EPA being afforded the discretion to set the scope within the framework Congress provided.

Moreover, Congress does not have to set a particular standard or incant the magic word "discretion" in order to provide discretion to an agency. *E.g.*, *Hagood, supra* (discretion conferred by "as determined by"); *San Bernardino Mountains* (same); *cf. Sebelius v. Auburn Reg'l Med. Ctr.*, 133 S. Ct. 817, 824 (2013) (in determining whether a requirement was jurisdictional, Congress did not have to "incant magic words in order to speak clearly"); *see also* EPA Br. 45 (citing case law). Indeed, in the Amendments, Congress clearly gave EPA substantial discretion to make a number of judgments regarding chemicals under TSCA without ever using the word "discretion." *E.g.*, 15 U.S.C. § 2605(a) ("If the Administrator determines…"); § 2605(b)(1)(B)(ii) ("The Administrator shall designate … if the Administrator concludes…"). Congress' delegation to EPA here to define the conditions of use it "expects to consider" is no different.

B. EPA's interpretation that allows it to consider on a case-by-case basis whether to exclude certain conditions of use is reasonable.

In all events, EPA's interpretation of § 2605(b)(4) is reasonable. Contrary to Petitioners' exaggerated allegations, (Pet'rs Br. 21-22), EPA has not claimed "unfettered discretion" to "pick and choose" and exercise "*carte blanche*" over which conditions of use it expects to consider in a risk evaluation. Instead, EPA has taken a reasonable approach to enable it to "triage" through a potentially massive amount of

information regarding thousands of chemicals and identify for study those conditions of use that actually merit close scrutiny. *E.g.*, EPA Br. 4. There is nothing "unfettered" about the process, as the statute and EPA's Rules provide opportunities for public comment and judicial review.

1. EPA's approach is not "unfettered" and will consider public input in finalizing the scope of risk evaluations.

Petitioners' concerns about "unfettered discretion" and EPA excepting a "smorgasbord" of pathways are wholly without foundation. Pet'rs Br. 22. As EPA has made clear, aside from excluded legacy activities, EPA rejected any categorical exclusions. Instead, it will determine the conditions of use for each chemical on a case-by-case basis—excluding "de minimis" exposures or where EPA foresees an "otherwise insignificant" risk. 82 FR 33,729-730 (ER4-5). In doing so, it has committed to take a limited, "conservative approach[]" when developing scopes for risk evaluations. RE RTC 10 (ER185). Moreover, EPA's actions will be framed by the input from multiple comment periods and subject to judicial review at various points prescribed by Congress. 40 C.F.R. § 702.41(c)(7); *see* 82 FR 33,729 (ER4). There is absolutely no indication that EPA's approach would provide the Agency with "unfettered discretion" to ignore uses that pose unreasonable risks.

Petitioners' assertions that EPA's determination as to which conditions of use it would choose to exclude lacks adequate criteria are equally baseless. Pet'rs Br. 26. TSCA does provide a standard to frame EPA's discretion, as Congress directs EPA to

base its decisions under § 2605 on best available science. 15 U.S.C. § 2625(h) ("In carrying out sections 2603, 2604, and 2605 of this title, to the extent that the Administrator makes a decision based on science, the Administrator shall use scientific information, technical procedures, measures, methods, protocols, methodologies, or models, employed in a manner consistent with the best available science.") The Agency's regulations incorporate those standards—and EPA has committed to clearly describe the data used and assumptions made in carrying out its responsibilities under the Amendments. 40 C.F.R. § 702.41 (evaluation requirements); 40 C.F.R. § 702.43(b) (carry out obligations to use best science); 40 C.F.R. § 702.45 (peer review); RE RTC 2-3 (ER177-78).

Further, EPA has defined how it will exercise its discretion when establishing the scope for its evaluations: EPA will "make reasonable, technically sound scoping decisions in light of the overall objective of determining whether chemicals in commerce present an unreasonable risk." 82 FR 33,730 (ER5). Additionally, the draft and final scope for each risk evaluation will be open for comment. 40 C.F.R. § 702.41(c)(7); *see* 82 FR 33,729 (draft scope will include "basis for EPA's preliminary determination to provide the public with an opportunity to comment on the exclusions" and final scope "will also identify whether particular conditions of use have been excluded as a result of this process, along with the Agency's rationale") (ER4); RE RTC 35-36 (ER210-11). Thus, EPA will have a record for the conditions

of use it may exclude, and at the points prescribed by Congress, EPA's determinations will be subject to judicial review based on substantial evidence. 15 U.S.C. § 2618(c); *see* RE RTC 8 (As a tenet of administrative law, "EPA must have a rational basis for each 'condition of use' determination;" its decisions must be reasonable based on its record.) (ER183).

2. EPA's interpretation allows it to reach more reasonable determinations that will provide clarity to consumers, the regulated community, and states.

At the same time, EPA's decision to allow for some flexibility to exclude presumptively low risk uses is entirely reasonable. *See Compassion over Killing v. U.S. Food & Drug Admin.*, 849 F.3d 849, 856 (9th Cir. 2017) (implementing agency has broad discretion to choose how to marshal its resources to carry out its statutory responsibilities). EPA reasonably concluded that it should not devote its limited resources to studying conditions of use that present no unreasonable risk or are already well-controlled under existing regulations. Doing so would be contrary to the risk-based approach taken by Congress in the Amendments that recognize the importance of prioritizing the allocation of finite agency capacity.

Yet, Petitioners' reading of the Act would have EPA undertake a massive effort to perform hazard assessments, exposure assessments, and risk characterizations, under statutorily mandated scientific standards and peer review, for "all" conditions of use for thousands of chemicals without any exclusions—including those uses EPA

already knows are "*de minimis*" or "adequately addressed by another regulatory agency," and thus either present no real risk or are otherwise well-controlled. 82 FR 33,729 (ER4). Given the tens of thousands of chemicals on EPA's Inventory—presenting hundreds of thousands of discrete uses—that would be a wholly unworkable process if there were not some reasonable ability to define the scope of the conditions of use EPA expects to consider in a risk evaluation. *See* National Association of Chemical Distributors ("NACD") RE Comments 1-2 ("it will be virtually impossible for EPA to evaluate efficiently and thoroughly all the conditions of use for every chemical prioritized for evaluation, particularly given the high number of chemicals to be evaluated and the agency's limited resources.") (SER942-43); Aluminum Association RE Comments 3 (to "assess each condition of use will result in collapse of the process") (SER853).

Indeed, as noted, commodity chemicals and building block chemicals collectively have hundreds of thousands of discrete uses. ACC RE Comments 9 (ER142). If EPA could not conduct reasonable triage in determining potential "conditions of use," it would be required to invest enormous resources to consider even the most anecdotal examples for full-fledged risk evaluations, without any demonstrable benefit. *Id.*; ILMA PR Comments 4 ("a passing reference to an off-label use, perhaps one expressly disapproved by the manufacturer, by an online commenter" does not merit full risk evaluation) (SER920); ILMA RE Comments 3

("Analysis of remote or highly improbable conditions of use does nothing but add to Agency's workload for an individual chemical evaluation without a corresponding health benefit.") (SER924).

Congress recognized that EPA may already possess sufficient information to exclude certain uses and exposures before it conducts a full-fledged risk evaluation. "[T]he Agency is well aware that some categories of uses pose greater potential for exposure than others and that the risks from many categories are deemed negligible or already controlled." 162 Cong. Rec. S3519; *see* International Fragrance Ass'n N. Am. ("IFRANA") RE Comments 8 ("Most existing chemicals have been in commerce since before TSCA was enacted; many for a century or more. In many cases, chemicals' uses in the United States have been quite well-established for long periods of time[], potentially many decades.") (SER935). If, for example, a chemical is known to pose risks from inhalation, but not from dermal contact, it makes sense for EPA to focus its limited resources during the risk evaluation on the inhalation risk, rather than also conducting a study to evaluate the known non-risk. National Mining Association RE Comments 4 (SER952); Utility Solid Waste Activities Group RE Comments 4 (SER985).

Similarly, as EPA observed in its rulemaking, many chemicals are used in entirely enclosed ("closed-loop") systems for which it is well known that there is very low, if any, exposure level. 82 FR 33,729 (ER4); U.S. Chamber of Commerce RE

Comments 4 (SER980). This may include, for example, an intermediate chemical manufacturing site, where worker exposure is well-documented and controlled. ACC RE Comments 8 (ER148). Similarly, chemicals in articles of consumer products that are designed not to be released or are in an interior component of a product pose extremely low exposure potential. Alliance of Automobile Manufacturers ("Alliance") RE Comments 2 (average vehicle has over 30,000 unique components that do not change in design after manufacture and are specifically engineered to limit consumer exposure) (SER842). It would be entirely reasonable to screen out these conditions of use from a full risk evaluation.

Finally, and in all events, Congress created a path for judicial review if a particular circumstance arises where a party believes that EPA incorrectly excluded a condition of use. *E.g.*, 15 U.S.C. §§ 2605(i), 2618. The mere *possibility* that EPA may, at some unknown future date, incorrectly exclude a condition of use does not render EPA's approach unreasonable. *See, e.g.*, *Cruzan by Cruzan v. Dir., Mo. Dep't of Health*, 497 U.S. 261, 354 (1990) (Stevens, J. concurring) (rejecting argument that "the mere possibility of error in *any* case suffices" to allow one party's interests to override others' interests "in *every* case") (emphases in original).

C. EPA's process for manufacturers to request risk evaluation of a chemical on certain conditions of use, and for gathering information on additional conditions of use, is reasonable.

In a single sentence, Petitioners make the off-handed assertion that questions the process EPA established for handling a manufacturer's request to EPA to prepare an evaluation on a particular chemical. Pet'rs Br. 22. Petitioners note the Risk Evaluation Rule provides that a manufacturer may limit its request to specified "conditions of use," but offer no specific argument for why EPA's approach to manufacturer-initiated requests is invalid. As such, this argument is waived, *Dilley v. Gunn*, 64 F.3d 1365, 1367-68 (9th Cir.1995), and Petitioners should not be allowed to provide their reasoning on reply. In any event, EPA has merely applied the discretion the statute affords the Agency to establish that process.

TSCA authorizes a manufacturer to ask EPA to conduct a risk evaluation on a particular chemical. 15 U.S.C. § 2605(b)(4)(C)(ii). That provision grants EPA broad discretion to establish the process for conducting that review: EPA "shall conduct and publish risk evaluations … that a manufacturer of the chemical substance has requested, *in a form and manner and using the criteria prescribed by the Administrator in*" its risk evaluation rule. *Id.* (emphasis added). Congress also viewed the manufacturer-initiated request process as a way to leverage resources outside of EPA and increase the pace of chemical risk evaluations, requiring EPA to "ensure" manufacturer-initiated evaluations are 25-50% of all EPA risk evaluations. 15 U.S.C. §

2605(b)(4)(E)(i) (setting percentage requirements) and (E)(ii)(requiring payment of fees).

Following that direction, under EPA's Rules, a manufacturer may ask EPA to conduct a risk evaluation on a particular chemical. 40 C.F.R. § 702.37 (setting the rules for "submission of manufacturer requests for risk evaluation"). The Rules provide that a manufacturer must specify the circumstances of the conditions of use for which it is seeking the evaluation, justify those circumstances as the proper scope, and provide relevant information. 40 C.F.R. § 702.37(b). EPA will decide if the request is complete and then determine the conditions of use it expects to consider, just as it would for a chemical evaluation EPA initiates. 40 C.F.R. § 702.37(e)(3). EPA will complete this review in 60 days, 40 C.F.R. § 702.37(e)(4), provide 45 days for public comment on its proposal, and then decide whether to prepare a scope for a risk evaluation of the chemical, as it would for any high-priority chemical. 40 C.F.R. § 702.37(e)(6), (e)(8).[20]

Petitioners offer no statutory basis for questioning this process that authorizes manufacturers to seek evaluations based on less than all conditions of use, which is well within EPA's discretion. Indeed, as certain Petitioners conceded in comments, TSCA granted EPA "significant discretion" to design the process for manufacturer-

[20] Manufacturer-requested evaluations receive "no preferential treatment." 40 C.F.R. §702.35(e)(9)-(10).

initiated requests. *See* Environmental Working Group ("EWG") RE Comments 6 (ER519). That is all EPA has done here.

Moreover, EPA's approach is reasonable. Congress created this option consistent with its objective of providing more certainty to regulated manufacturers through a federal evaluation process that will ensure the percentage requirements for manufacturer-initiated evaluations can be achieved, 162 Cong. Rec. S3516, while addressing key health and environmental concerns and increasing public confidence. S. Rep. 114-67 at 13; *see* 15 U.S.C. § 2605(b)(4)(E)(i). EPA will, as appropriate, gather information on other circumstances in which a chemical may be used, as it does for every other chemical it may choose to prioritize, and is *not* restricted to considering only those conditions of use identified by the manufacturer. *See* 40 C.F.R. § 702.37(e)(3) (in addition to those conditions identified by the manufacturer, "EPA will also assess what, if any, additional conditions of use [] warrant inclusion within the scope of a risk evaluation for the chemical substance. EPA will conduct these assessments and make proposed determinations based on the same considerations applied in the same manner as it would for a risk evaluation for a high-priority substance").

III. EPA chose a reasonable method for calibrating its evaluations for each condition of use identified in the scope.

Under the Risk Evaluation Rule, EPA has reserved the ability to conduct a more iterative or "use by use" approach to risk evaluation. If EPA has adequate

information to complete its evaluation for a particular condition (or multiple conditions) of use, the Agency has retained the flexibility to complete an early risk evaluation for that condition or those conditions of use, rather than wait until it finishes the entire risk evaluation for that chemical. 82 FR 33,740 (ER15); 40 C.F.R. § 702.47. In this early determination EPA may find that the chemical does or does not present an unreasonable risk for the particular conditions of use evaluated. *Id.*

Petitioners, however, argue that this should only be a one-way ratchet. Pet'rs Br. 39-40. According to Petitioners, EPA can follow an iterative approach and consider conditions of use separately, but can only make an early determination if it finds the conditions of use evaluated pose an unreasonable risk. If, on the other hand, EPA determines that specific conditions of use do not pose an unreasonable risk, the Agency could not consider those condition of use separately. Rather, Petitioners argue, TSCA requires a "holistic risk determination for each chemical." Petitioners' position is not well founded.

EPA's interpretation that it has authority to employ an iterative approach is supported by the statute. *See* EPA Br. 51-52. Congress directed EPA to conduct "risk evaluations" on a chemical under the conditions of use and to generally complete its work in three years. 15 U.S.C. § 2605(b)(4)(A). Whether EPA conducts a single risk evaluation for all conditions of use at once or follows an iterative approach that makes an early risk determination for one or more condition of use,

"the Agency will still complete a risk evaluation on all conditions of use identified in the final scope, within the statutory 3-year deadline." 82 FR 33,740 (ER15). TSCA § 2605(b) requires nothing more—and does not impose the one-way ratchet, which Petitioners created out of whole cloth. On the contrary, Congress expressly allowed EPA to exercise its considered judgement over whether or not to conduct an "aggregate" risk evaluation for a particular chemical. 15 U.S.C. § 2605(b)(4)(F)(ii) ("In conducting risk evaluation" EPA is to describe "whether" it chose to conduct an "aggregate" exposure analysis). This contrasts with other statutes where Congress required aggregate exposure assessments. *See* 21 U.S.C. § 346a(b)(2)(A)(ii), (b)(2)(D)(vi) (Food and Drug law requires consideration of aggregate exposures to pesticides).

Moreover, EPA's interpretation is confirmed by the legislative history of the Amendments. As Senate co-sponsors explained, Congress clearly understood that EPA's "determinations are made on a use-by-use basis" and that "EPA will make decisions based on conditions of use, and must consider various conditions of use, so there could be circumstances where EPA determines that a chemical does not present an unreasonable risk in certain uses, but does in others." 162 Cong. Rec. S3521. Hence, EPA clearly was given this discretion—subject ultimately to judicial review. 15 U.S.C. § 2618.

Petitioners nonetheless argue that EPA's decision to reserve the right to make early determinations on certain conditions of use cannot be squared with EPA's discretion to issue a risk management rule under § 2605(a) if EPA determines based on a risk evaluation that "any combination" of activities presents an unreasonable risk. Pet'rs Br. 25. Petitioners' claim misses the mark, as EPA's approach to risk evaluation is fully consistent with the discretion the Agency has to issue a risk management rule. All EPA has decided is that there may be some conditions of use where the overall risk evaluation does not turn materially on other conditions of use. In those circumstances, there is no logical reason why EPA cannot determine the risk of those conditions of use separately and before completing its evaluation of other conditions of use.

EPA's approach is also a reasonable means of achieving Congress' goals of identifying and addressing unreasonable risk of injury to health or the environment and providing clarity to consumers and regulated entities. The sooner EPA identifies that a condition of use poses no unreasonable risk, the sooner it can devote its resources to evaluating the relevant circumstances associated with other conditions of use. RE RTC 47-48 (ER222-23). Efficiently identifying which uses of chemical substances do not present unreasonable risk also provides the public information in a clear and timely manner. Rubber Manufacturers Association RE Comments 2 (SER957). This can reduce confusion on the risks associated with different

conditions of use for a chemical substance. *See* American Water Works Association RE Comments 3 (SER914); RE RTC 10 (ER185). It also furthers Congress' goal of providing clarity to the regulated community to encourage innovation. *See* NACD RE Comments 2 (separate determinations on conditions of use will "reduce confusion and provide the public and industry assurance") (SER943). EPA's approach best achieves Congress' goals, is reasonable, and should be upheld.

IV. EPA's Rules follow TSCA's direction for considering reasonably available information in manufacturer-initiated risk evaluations.

Petitioners also challenge five information-gathering provisions of the Rules. Pet'rs Br. § IV at 51-61. EPA has briefed its position on the merits for two of the provisions, EPA Br. 55-58, and moved to remand the other three. *See* EPA Motion for Voluntary Remand. Two of the three provisions on which EPA seeks remand without vacatur—40 C.F.R. § 702.37(b)(4), (6)—relate to the scope and scientific quality of the information a manufacturer submits when it asks EPA to conduct a risk evaluation on a chemical the manufacturer produces. Intervenors do not object to EPA's request for remand without vacatur, but if the Court reaches the merits on these two specific challenges, it should reject them.

A. Allowing manufacturers to provide information related to the conditions of use specified by the manufacturer is reasonable and does not in any way limit EPA's risk evaluation.

As detailed, *supra*, TSCA authorizes a manufacturer to ask EPA to conduct a risk evaluation on a particular chemical. 15 U.S.C. § 2605(b)(4)(C)(ii). It also directs

EPA to establish procedures for manufacturers to submit requests and for EPA to evaluate them. 15 U.S.C. § 2605(b)(4)(C)(ii) (directing EPA to adopt rules setting "form and manner" of and "criteria" for evaluating manufacturer requests).

Following Congress' direction, EPA has included rules for "submission of manufacturer requests for risk evaluation." 40 C.F.R. § 702.37. Among other directions, in 40 C.F.R. § 702.37(b)(4) EPA provides an expansive list of the types of information a manufacturer must provide related to the conditions of use for which the manufacturer is requesting a risk evaluation. In 40 C.F.R. § 702.37(b)(6) EPA specifies that the "[s]cientific information submitted" by the manufacturer "must be consistent with the scientific standards in 15 U.S.C. § 2625(h)."

Petitioners argue that these information requirements for manufacturer-requested risk evaluations violate TSCA by directing manufacturers to submit information related to the conditions of use it is asking EPA to evaluate, as opposed to "all" information about "all' conditions of use. Pet'rs Br. 58-59. Petitioners claim EPA's focused information gathering is inconsistent with TSCA's direction that EPA consider "information relating to a chemical substance or mixture, including hazard and exposure information, under the conditions of use, that is reasonably available to the Administrator." 15 U.S.C. § 2625(k).

This argument is a red herring. First, EPA affirmatively requires manufacturers to submit "all of the information necessary for EPA to conduct the evaluation for the

requested conditions of use." 82 FR 33,736 (ER11); 40 C.F.R. § 702.37(b)(4). This includes a requirement to certify that information is accurate and complete along with a certification statement: "I am aware it is unlawful to knowingly submit incomplete, false and/or misleading information in this request and there are significant criminal penalties for such unlawful conduct, including the possibility of fine and imprisonment." 40 C.F.R. § 702.37(b)(7).

Second, EPA will obtain any other necessary information it needs for the risk evaluation, as it does for its evaluation of any other chemicals. As EPA makes clear, while the Agency will accept requests from manufacturers to evaluate a chemical based on specified circumstances of conditions of use, it will nonetheless conduct the risk evaluation in the same manner as any other risk evaluation. 82 FR 33,736 (ER11). Hence, EPA will "conduct a full risk evaluation that encompasses both the conditions of use that formed the basis of the request, and any additional conditions of use that EPA identifies." *Id.* The only difference here is that some of the information will be provided by the manufacturer with its request. However, instead of requiring the manufacturer to try to discern what other circumstances EPA chooses also to evaluate, EPA will gather that information itself, "in the same manner as it would for" any chemical it evaluates. 40 C.F.R. § 702.37(e)(3); 82 FR 33,736 (ER11). Moreover, EPA will also hold a public comment period to gather more information on whether additional conditions of use should be evaluated. 40 C.F.R. § 702.37(e)(4).

In addition, EPA's determination to require submission of information for the conditions requested is eminently reasonable. "[M]anufacturers are not always privy to every downstream use, and therefore would find it very difficult to obtain all the required information" and to submit complete, compliant requests. 82 FR 33,735-736 (ER10-11). Indeed, the supply chain in the chemical manufacturing and processing industry is complex, NACD RE Comments 3 (SER944), and a manufacturer may not know or have access to information held by another private entity. RE RTC 26 (ER201); American Coatings Association ("ACA") RE Comments 3 (downstream entities may not have access to all information) (SER857). Unlike EPA, a manufacturer cannot compel information from a private entity, RE RTC 26 (ER201); ACC RE Comments 21 (ER154), and entities down the supply chain may not have any requirement to provide information on uses to the upstream manufacturer. API RE Comments 11 (SER902). Some information may be confidential or proprietary. *Id.*; Alliance RE Comments 7 (SER847); *see* AFPM RE Comments 6 ("EPA should not assume that manufacturers are privy to all end uses of a substance.") (SER870).

EPA's approach facilitates manufactures' participation, which helps EPA "ensure" it meets Congress' expressed intent that 25-50% of all risk evaluations are initiated by manufacturer requests. API RE Comments 11 (SER902); ACA RE Comments 3 (requirement to provide information on all conditions of use would be a "deterrent" for manufacturer requests) (SER857).

B. Requiring that manufacturers submit scientific information consistent with the scientific standards adopted in TSCA is unquestionably reasonable.

Petitioners further assert (Pet'rs Br. 55-57) that because EPA is to consider information "reasonably available to the Administrator," 15 U.S.C. § 2625(k), EPA improperly limited the information the manufacturer submits to EPA as part of its risk evaluation request, by directing that the information "be consistent with scientific standards in 15 U.S.C. § 2625(h)." 40 C.F.R. § 702.37(b)(6). This, too, is groundless. EPA is directing manufacturers to provide information that comports with scientific standards as directed by TSCA. There can be nothing unreasonable about that.

As summarized, *supra*, TSCA requires in the circumstances in which EPA makes a decision based on science that EPA (i) "use scientific information, technical procedures, measures, methods, protocols, methodologies, or models, employed in a manner consistent with the best available science," and (ii) "consider as applicable" five factors to evaluate the quality of the information. 15 U.S.C. § 2625(h). EPA must then "make decisions … based on the weight of the scientific evidence." 15 U.S.C. § 2625(i).

With that framework, it is entirely reasonable for EPA to require that information it receives in the manufacturer-initiated process meet the requirements EPA must satisfy in making decisions under TSCA. 40 C.F.R. § 702.37(b)(6). In this way, EPA will receive quality information on which it can more likely rely when

making a decision on a manufacturer's request. 82 FR 33,736 ("holding the requester to the statutory standard helps to ensure that if EPA grants the request, the Agency can effectively utilize the information") (ER11). Indeed, Petitioners advocated that EPA apply these types of criteria to information being submitted to it by third parties. EDF RE Comments 23 ("[T]he [Risk Evaluation R]ule should make it clear that the scientific standards established in the statute, including those in sections 26(h) and (i), fully apply to third party risk evaluations.") (SER821); EWG RE Comments 14 (third party draft risk evaluations "must, at minimum, meet all the same criteria as EPA's risk evaluations") (ER527).

Petitioners baldly assert (Pet'rs Br. 56) that this requirement will mean that manufacturers will "screen" and withhold data from EPA. In fact, industry encouraged EPA to adopt "rigorous frameworks and objective criteria" in EPA's Rules. SOCMA RE Comments 5 (SER964). Manufacturers must merely follow requirements that it "use" scientific information and other measures consistent with best available science, and "consider" factors such as the extent of uncertainty in the information it submits. The statutory factors are objective descriptors of the scientific information submitted, not tools for withholding information.

In any event, EPA provides the public, including Petitioners, ample opportunity during the comment period to add other information that EPA should consider. Because EPA's interpretation is consistent with the statutory language,

allows EPA to gather reasonably available information through a variety of tools, and achieves Congress' goal of allowing EPA to make science-based decisions, Petitioners' argument here should be rejected.

V. Petitioners' Request for Vacatur Should Be Rejected.

As the foregoing demonstrates, EPA's action is well-supported by the statute and is reasonable. If, however, the Court finds against EPA on any of Petitioners' challenges, the Court should remand the matter back to EPA for further proceedings without vacatur.

First, Petitioners inappropriately seek vacatur of the entirety of 40 C.F.R. § 702.37 (governing manufacturer risk evaluation requests) and the related preamble, *see* Risk Evaluation, III.G, 82 FR 33,735-38 (ER10-13), even though they challenge only selected subjections (40 C.F.R. § 702.37(b)(3) and (e)(3) (regarding conditions of use) and (b)(4), (6) (information gathering)). As EPA points out, Petitioners offer no basis for this broader request to vacate the entire subsection. *See* EPA Br. 58-61. For that reason, the broad contention is waived. *United States v. Kama*, 394 F.3d 1236, 1238 (9th Cir. 2005). Even if the argument had not been waived, as detailed, Congress granted EPA discretion to adopt rules setting the "form and manner" of and "criteria" for evaluating manufacturer requests to designate chemicals for risk evaluation. 15 U.S.C. § 2605(b)(4)(C)(ii). EPA has done so, and Petitioners provide no basis for vacating the remainder of that provision.

Second, were the Court to find for Petitioners on any one argument here, the proper remedy in this matter would be to remand the relevant provision(s) back to EPA for further proceedings. Remand is the favored remedy where vacating the rule would be unduly disruptive. As this Court has explained, a finding that EPA's final rule was invalid "is not the end of the analysis." *Cal. Cmtys. Against Toxics v. EPA*, 688 F.3d 989, 993 (9th Cir. 2012). Rather, a regulation should be left in place "when equity demands," and the Court should balance agency errors against the "disruptive consequences" of a vacatur. *Id.* at 992-93.

As outlined, Congress has made plain that the chemical review process needs to move forward with dispatch, and it enacted the Amendments to accomplish that goal. For that reason, Congress included explicit deadlines and metrics, along with the required review procedures. *E.g.*, 15 U.S.C. § 2605(b)(2) (deadlines for prioritization) and (b)(3)-(4) (ongoing risk evaluation). Vacating the Rules as broadly as Petitioners request would disrupt the entire process and defeat Congress' clear intent for EPA to make significant progress where it was unable to do so before Congress enacted the Amendments.

Further, there is no need for the disruption vacatur would cause. Even if the Court were to make an adverse finding based on Petitioners' challenges, during a remand, EPA should be able to move forward to prioritize and evaluate chemicals—and, if necessary, consider any uses that were not initially considered. 15 U.S.C. §

2605(a). Any gaps in the review process that may require additional analysis for a particular chemical and that may or may not result in additional restrictions can be completed after such a remand. There is no need to halt the entire process to await that additional review, if any is required, merely because of Petitioners' speculation that EPA might choose not to consider a particular use or disposal practice that Petitioners believe EPA should restrict.

CONCLUSION

For the foregoing reasons, the Court should deny the Petition.

Respectfully submitted,

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September 19, 2018

STATEMENT OF RELATED CASES

Pursuant to Ninth Circuit Rule 28-2.6, Intervenors state that they are not aware of any related cases other than those that have been consolidated here.

CERTIFICATE OF COMPLIANCE

Pursuant to Rules 32(a)(5), 32(a)(6), 32(a)(7)(B), and 32(g) of the Federal Rules of Appellate Procedure, and Ninth Circuit Rule 32-1, I certify that the attached brief is in 14-point proportionally spaced Century Schoolbook font, and contains 15,240 words, as counted by my word processing program, exclusive of the portions of the brief excepted by Rule 32(f). Pursuant to Ninth Circuit Rule 32-1(e), a signed Form 8 also accompanies the attached brief.

Dated: September 19, 2018

/S/ PETER D. KEISLER
PETER D. KEISLER

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.*

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Signature of Attorney or Unrepresented Litigant [/s/ Peter D. Keisler] Date [Sep 19, 2018]

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

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 September 19, 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.

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