December 14, 2023

Submitted via Regulations.gov
Dr. Michal Freedhoff
Assistant Administrator, Environmental Protection Agency
Office of Chemical Safety and Pollution Prevention
1200 Pennsylvania Ave, NW
Washington, DC 20460-0001

Re: Procedures for Chemical Risk Evaluation under the Toxic Substances Control Act, Docket No. EPA-HQ-OPPT-2023-0496

Dear Assistant Administrator Freedhoff:

The undersigned organizations submit these comments on the Environmental Protection Agency's ("EPA's" or the "Agency's") proposed revisions to its framework rule for conducting risk evaluations under the Toxic Substances Control Act (the "Proposed Rule").[1]

Every day, in communities across the country, people are exposed to and harmed by toxic chemicals in their workplaces, their air and water, and the products in their homes. The Toxic Substances Control Act ("TSCA") requires EPA to evaluate and then eliminate those chemicals' unreasonable risks to health and the environment. EPA cannot comply with that requirement, or achieve TSCA's "overarching purpose . . . to protect the public from chemicals that pose an unreasonable risk to health and the environment,"[2] unless its risk evaluations reflect chemicals' real-world impacts on fenceline communities, Indigenous peoples, and other exposed populations.

Yet EPA's risk evaluation practices—and the current TSCA risk evaluation rule—are fundamentally flawed, understating chemicals' risks and undermining efforts to regulate substances that are known to cause cancer, developmental and reproductive harm, and other severe health effects. This rulemaking provides an opportunity for EPA to address those deficiencies and to finally require the comprehensive risk evaluations that TSCA demands and that impacted communities need.[3]

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[1] Procedures for Chemical Risk Evaluation Under the Toxic Substances Control Act (TSCA), 88 Fed. Reg. 74,292 (proposed Oct. 30, 2023).
[2] *Food & Water Watch, Inc. v. EPA*, 302 F. Supp. 3d 1058, 1066 (N.D. Cal. 2018); *see also* S. Rep. No. 94-698, at 1 (1976) (expressing intent of TSCA to "prevent unreasonable risks of injury to health or the environment associated with the manufacture, processing, distribution in commerce, use, or disposal of chemical substances").
[3] Nothing in these comments should be interpreted as an endorsement of TSCA's risk-based decision-making regime. As EPA itself recently acknowledged, "the technical complexity of [human health risk assessment] can . . . lead to a lack of transparency and accountability," and risk assessment typically "does not quantify factors such as fairness, voluntariness, responsibility, [and] control … or incorporate community insights and priorities around sources of risk." EPA, Draft Revision, *Technical Guidance for Assessing Environmental Justice in Regulatory Analysis* 29, 29 n.46 (2023), https://www.epa.gov/system/files/documents/2023-

When it amended TSCA in 2016, Congress directed EPA to improve its risk assessment and risk management practices. Under the amended law, EPA must apply the "best available science" to evaluate chemicals' risks to "potentially exposed or susceptible subpopulation[s]" who have "greater exposure[s]" to toxic chemicals or "greater susceptibility" to harm from those exposures.[4] TSCA thus requires EPA to consider risks to those with "greater exposure[s]" because they are exposed to a chemical from multiple sources or in multiple ways, or with "greater susceptibility" because they are exposed to multiple chemicals and non-chemical stressors that pose cumulative risks to their health. EPA must also consider all the "circumstances . . . under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of," including facility start-up and shutdown conditions, chemical spills and accidents, and other excess emission events that occur on an almost daily basis.[5]

EPA's current risk evaluation rule, and the first ten risk evaluations conducted under the amended TSCA, violate each of those statutory requirements. Crafted by the chemical industry and signed by the Trump Administration, that rule purports to allow EPA to exclude conditions of use and entire exposure pathways from its TSCA risk evaluations. The risk evaluations EPA conducted under that rule failed to consider the chemicals' impacts on fenceline communities or others who breathe contaminated air, drink contaminated water, and are otherwise exposed to the chemicals in the environment. They also understated worker exposures, ignored known and foreseen combinations of chemical exposures, and relegated ecological risk to an afterthought.

While the Proposed Rule corrects several of the worst flaws in the existing rule, it falls short of requiring science-based, TSCA-compliant risk evaluations. We support EPA's recognition that TSCA does not permit the Agency to exclude exposure routes, pathways, or conditions of use from a risk evaluation. We also support proposed procedural improvements to the scoping and risk evaluation process, as well as the expansion of the "potentially exposed or susceptible subpopulation" definition to expressly reference "overburdened communities."[6]

But the Proposed Rule continues to ignore the lived experiences of people in those communities by failing to require the consideration of aggregate and cumulative chemical exposures, the effects of which are exacerbated by stressors such as food insecurity, racial

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11/ejtg_revision_110823_508compliant_0.pdf. To overcome those and other limitations, we encourage EPA to pursue non-risk-based chemical regulations where it has ability to do so. *See* Alaska Cmty. Action on Toxics et al., Comments on EPA's Cumulative Risk Assessment Guidelines for Planning and Problem Formulation 4–5 (Aug. 30, 2023), https://www.regulations.gov/comment/EPA-HQ-ORD-2013-0292-0198. For statutes like TSCA that mandate the consideration of risk, however, EPA must at a minimum ensure that its risk evaluations reflect the lived experiences of all exposed populations and the full extent of chemicals' impacts.

[4] 15 U.S.C. § 2602(12) (defining "potentially exposed or susceptible subpopulation"); *id.* §§ 2605(b)(4), 2625(h).

[5] *Id.* § 2602(4).

[6] 88 Fed. Reg. at 74,320 (defining "potentially exposed or susceptible subpopulation").

discrimination, and limited access to health care. EPA also permits the continued exclusion of reasonably foreseen but unplanned chemical releases, in violation of TSCA's plain text. Finally, we oppose provisions of the Proposed Rule that could curtail the peer review process for TSCA risk evaluations, unlawfully consider personal protective equipment ("PPE") when calculating worker risks, and allow EPA to write off potentially significant chemical uses and exposures based on undefined "fit-for-purpose" criteria.[7]

TSCA simply does not work, and it will not achieve its core purpose, unless EPA's risk evaluations consider all sources of exposure, susceptibility, and risk. We know that in the real world chemical facilities leak, catch fire, and experience other foreseeable but unplanned releases.[8] We know that people are exposed to multiple chemicals from multiple sources, and that certain communities and populations are more susceptible to harm because of their cumulative exposures to chemicals and other stressors.[9] And we know the people who experience the greatest harms from toxic chemicals, and who have suffered the greatest impacts from the flaws in EPA's risk evaluations, are often communities of color, low-wealth communities, Indigenous peoples, and other overburdened populations.[10] TSCA requires EPA to evaluate and address those risks, and we urge EPA to revise its Proposed Rule—along the lines set forth below—to align its TSCA risk evaluations with the best available science and TSCA's statutory mandates.

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[7] *Id.* at 74,321.

[8] *See, e.g.*, Carey Gillam, *US Faces Almost Daily Hazardous Chemical Accidents, Research Suggests*, Guardian (Nov. 9, 2023), https://www.theguardian.com/us-news/2023/nov/09/how-many-chemical-accidents-spills-explosion ("Hazardous chemical accidents are occurring almost daily, on average, in the United States, exposing people to dangerous toxins through fires, explosions, leaks, spills and other releases, according to a new analysis by non-profit researchers.").

[9] *See, e.g.,* EPA, EPA/600/R-22/014a, *Cumulative Impacts Research: Recommendations for EPA's Office of Research and Development* 1 (Sept. 30, 2022), https://www.epa.gov/system/files/documents/2022-09/Cumulative%20Impacts%20Research%20Final%20Report_FINAL-EPA%20600-R-22-014a.pdf ("For EPA to fulfill its mission to protect human health and the environment, the Agency needs to address the cumulative impacts of exposure to multiple chemical and non-chemical stressors using the best available science.") (footnotes omitted); Phasedown of Hydrofluorocarbons: Allowance Allocation Methodology for 2024 and Later Years, 87 Fed. Reg. 66,372, 66,404 (proposed Nov. 3, 2022) ("EPA finds evidence of environmental justice concerns near HFC production facilities from cumulative exposure to existing environmental hazards in these communities.").

[10] Robert D. Bullard et al., *Toxic Wastes and Race at Twenty 1987—2007: A Report Prepared for the United Church of Christ Justice & Witness Ministries* 54, United Church of Christ (2007), https://www.ucc.org/wp-content/uploads/2021/03/toxic-wastes-and-race-at-twenty-1987-2007.pdf; Ronald White et al., *Life at the Fenceline: Understanding Cumulative Health Hazards in Environmental Justice Communities* 2, 6, 9–10 (Sept. 2018), https://ej4all.org/assets/media/documents/Life%20at%20the%20Fenceline%20-%20English%20-%20Public.pdf.

I. TSCA REQUIRES EPA TO CONDUCT COMPREHENSIVE EVALUATIONS OF CHEMICALS' REAL-WORLD EXPOSURES AND RISKS

A. The Current Risk Evaluation Rule Violates TSCA

When it amended TSCA in 2016, Congress overhauled the way that EPA evaluates and regulates toxic chemicals. Whereas the prior law contained no requirement for EPA to evaluate existing chemicals' risks, resulting in few risk evaluations and even fewer regulations, the amended law directs EPA to "conduct risk evaluations . . . to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment."[11] Congress further specified that such evaluations must: (1) be based the "best available science," without any consideration of "costs or other nonrisk factors";[12] (2) evaluate risks to "potentially exposed or susceptible subpopulation[s]" who "due to either greater susceptibility or greater exposure, may be at greater risk than the general population of adverse health effects from exposure to a chemical substance or mixture";[13] and (3) consider all of a chemical's "conditions of use," or "the circumstances . . . under which [the] chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of."[14] If EPA finds that a chemical presents "unreasonable risk of injury to health or the environment," "including an unreasonable risk to a potentially exposed or susceptible subpopulation," then EPA must regulate the chemical "to the extent necessary so that the chemical substance or mixture no longer presents such risk."[15] The results of EPA's risk evaluations therefore determine whether and the extent to which EPA must regulate toxic chemicals; flawed or incomplete evaluations lead to unprotective regulations and continued harm to fenceline communities, workers, and the environment.

To aid in the implementation of the amended law, Congress directed EPA to "establish, by rule, a process to conduct risk evaluations."[16] However, EPA's initial risk evaluation rule violated core TSCA requirements. As initially proposed in January 2017, that rule had significant omissions, but it would have at least required the consideration of all conditions of use and exposure pathways.[17] The Trump Administration eliminated those requirements upon taking office, rewriting key parts of the proposed rule to align with recommendations from the American Chemistry Council and other industry associations.[18]

As finalized in June 2017, the current risk evaluation rule violates core principles of TSCA. EPA asserted the discretion to make piecemeal risk determinations for individual

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[11] 15 U.S.C. § 2605(b)(4)(A).
[12] *Id.*; *id.* § 2625(h).
[13] *Id.* §§ 2602(12), 2605(b)(4)(A).
[14] *Id.* § 2602(4).
[15] *Id.* § 2605(a),(b)(4)(A).
[16] *Id.* § 2605(b)(4)(B).
[17] *See generally* Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act, 82 Fed. Reg. 7,562 (proposed Jan. 19, 2017).
[18] A table showing how the proposed rule was revised to accommodate industry comments, in several places verbatim, is attached to these comments as **Exhibit A**.

conditions of use, despite TSCA's requirement for EPA to evaluate the risks associated with "a chemical substance" as a whole.[19] EPA also claimed that it could exclude entire conditions of use and exposure pathways from consideration, in violation of TSCA's mandate to evaluate the exposures and risks associated with all conditions of use.[20] EPA rewrote the statutory definition of "conditions of use" to exclude so-called "legacy uses" and "associated disposals" of chemicals that remain in use after manufacturing for that use has ceased, including the use of asbestos in insulation.[21] And EPA failed to require necessary information from chemical manufacturers who requested risk evaluations, while subjecting members of the public who voluntarily submit relevant but "incomplete" information to criminal liability.[22]

In August 2017, labor unions, community organizations, national environmental and public health organizations, and others filed petitions for review challenging the Trump Administration's risk evaluation rule. While those suits were pending, EPA sought voluntary remand of certain challenged provisions governing manufacturer-requested risk evaluations, explaining that "after reviewing [Petitioners'] arguments and taking a closer look at the provisions, the Agency has decided to revisit the provisions and take further administrative action."[23]

On November 14, 2019, the Ninth Circuit Court of Appeals granted that remand request and partially granted the petitions for review. The Court held that "EPA's exclusion of legacy uses and associated disposals contradicts TSCA's plain language," because "TSCA's 'conditions of use' definition plainly addresses conditions of use of chemical substances that will be used or disposed of in the future, regardless of whether the substances are still manufactured for the particular use."[24] Without reaching the merits, the Court ruled that Petitioners' challenge to the authorization of use-by-use risk determinations was not ripe "because it is not clear, due to the

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[19] *Compare* 40 C.F.R. § 702.47 (authorizing separate unreasonable risk determinations for "each condition of use[]"), *with* 15 U.S.C. § 2605(b)(4)(A) (requiring EPA to "conduct risk evaluations . . . to determine whether *a chemical substance* presents an unreasonable risk" (emphasis added)).

[20] *Compare* Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act, 82 Fed. Reg. 33,726, 33,729 (July 20, 2017) (asserting that "EPA may, on a case-by-case basis, exclude certain activities that EPA has determined to be conditions of use"), *with* 15 U.S.C. § 2605(b)(4)(A) (requiring EPA to "conduct risk evaluations . . . to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment . . . under the conditions of use").

[21] *Safer Chems., Healthy Fams. V. EPA,* 943 F.3d 397, 425 (9th Cir. 2019) (holding that "TSCA's definition of 'conditions of use' clearly includes uses and future disposals of chemicals even if those chemicals were only historically manufactured for those uses" and that "EPA's exclusion of legacy uses and associated disposals from the definition of 'conditions of use' is therefore unlawful").

[22] Petitioners' Opening Brief at 52–60, *Safer Chems., Healthy Fams. V. EPA*, 945 F.3d 397 (9th. Cir. 2019) (No. 17-72260) (attached as **Exhibit B**).

[23] Respondents' Motion for Partial Voluntary Remand at 6, *Safer Chems., Healthy Fams. V. EPA*, 945 F.3d 397 (9th. Cir. 2019) (No. 17-72260) (attached as **Exhibit C**).

[24] *Safer Chems., Healthy Fams*, 945 F.3d at 424.

ambiguous text of the Risk Evaluation Rule, whether the Agency will actually conduct risk evaluations in the manner Petitioners fear."[25] Finally, with respect to EPA's alleged discretion to pick and choose which conditions of use to evaluate, the Court ruled that the current risk evaluation rule "unambiguously do[es] not grant EPA the discretion" to select which conditions of use and exposure pathways to include in a risk evaluation.[26]

The flaws in the Trump Administration's risk evaluation rule have impacted every risk evaluation that EPA conducted under the 2016 TSCA amendments, as well as EPA's proposed risk management rules for highly toxic chemicals like methylene chloride, perchloroethylene, and carbon tetrachloride. As described below, the Proposed Rule corrects certain of those flaws while leaving other key shortcomings unaddressed.

B. The Proposed Rule Contains Several Important and Legally Required Changes

i. EPA correctly interprets TSCA to require a risk determination for the "chemical substance" as a whole

We fully support the Proposed Rule's affirmation that, as a matter of law, "the risk determination [under TSCA] is on the chemical substance—not individual conditions of use."[27] While EPA correctly interprets TSCA to require a risk determination for a chemical substance as a whole (or a mixture or category of chemical substances), we are concerned that the Proposed Rule remains silent on the corollary requirement that EPA evaluate risks across a chemical's conditions of use. EPA cannot determine the risks posed by a chemical substance unless it considers the chemical's impacts on people who are exposed from multiple conditions of use, and we urge EPA to affirm that requirement as well in the Proposed Rule.

TSCA's mandate is clear; EPA "shall conduct risk evaluations . . . to determine whether *a chemical substance* presents an unreasonable risk of injury to health or the environment."[28] Despite that unambiguous text, the first ten risk evaluations that EPA conducted under the amended TSCA contained hundreds of use-specific risk determinations without any assessment of the risks posed by the chemical substance as a whole. While the Biden Administration reversed that policy and issued "whole chemical" unreasonable risk determinations covering nine

[25] *Id.* at 413; *see also id.* at 415 ("If EPA does, in the future, fail to consider all conditions of use together in completing a risk evaluation, and if Petitioners are harmed by that failure, then Petitioners may, under TSCA, seek review of EPA's "no unreasonable risk" determination.").
[26] *Id.* at 419.
[27] 88 Fed. Reg. at 74,302; *see also id.* ("Although the Agency indicated in its June 2021 announcement that it would make a single risk determination on a chemical when it was 'clear that majority of conditions of use warrant one determination,' EPA now believes a better understanding of the statute is that a single determination on the chemical substance is required in every instance, and is proposing to make this clear in this procedural rule.").
[28] 15 U.S.C. § 2605(b)(4)(A) (emphasis added).

of those chemicals,[29] when doing so, EPA still asserted the discretion to decide between whole chemical and use-by-use risk determinations on a case-by-case basis.[30]

The Proposed Rule appropriately revisits that position and clarifies that a risk determination "on *the chemical substance* is required in every instance."[31] We agree. The decision of "whether" a chemical substance does or does not present unreasonable risk "indicates a binary choice."[32] TSCA's requirement that EPA evaluate chemicals "under the conditions of use" merely defines the range of circumstances that EPA must consider in making its risk determination for the chemical substance.[33] It does not—as industry has argued—permit EPA to consider each condition of use in isolation and forego the required determination for the chemical as a whole.

Other provisions of TSCA reinforce the statutory requirement for whole chemical risk determinations.[34] For example, when prioritizing chemicals for evaluation under TSCA, "[t]he Administrator shall designate as a high-priority substance a chemical substance that the Administrator concludes . . . may present an unreasonable risk of injury to health or the environment because of a potential hazard and a potential route of exposure under the conditions of use."[35] The process of considering a whole chemical's potential risks during the prioritization stage would not make sense if EPA could ignore those risks during the ensuing risk evaluation and focus instead only on the risks from individual conditions of use.[36] TSCA section 6(a) also directs EPA to eliminate unreasonable risks caused by "any combination of" conditions of use,[37] which is not possible if EPA solely determines the risks posed by individual conditions of use in isolation.

While the Proposed Rule would correctly require whole chemical risk determinations, it fails to require the holistic analysis that is needed to support those determinations. In particular, EPA's mandate to determine whether "a chemical substance" presents unreasonable risk and address the unreasonable risks presented by "any combination" of the chemical's uses requires

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[29] *See* 88 Fed. Reg. at 74,302; EPA, *EPA Announces Path Forward for TSCA Chemical Risk Evaluations* (June 20, 2021), https://www.epa.gov/newsreleases/epa-announces-path-forward-tsca-chemical-risk-evaluations.
[30] *See e.g.*, Methylene Chloride; Revision to Toxic Substances Control Act (TSCA) Risk Determination; Notice of Availability, 87 Fed. Reg. 67,901, 67,904 (Nov. 10, 2022) ("Therefore, notwithstanding EPA's choice to issue condition-of-use-specific risk determinations to date, EPA interprets its risk evaluation regulation to also allow the Agency to issue whole-chemical risk determinations. Either approach is permissible . . . .").
[31] 88 Fed. Reg. at 74,302 (emphasis added).
[32] *See SAS Inst. Inc. v. Iancu*, 138 S. Ct. 1348, 1355 (2018).
[33] 15 U.S.C. § 2605(b)(4)(A).
[34] *See id.* § 2605(b)(1)–(4), (i).
[35] *Id.* § 2605(b)(1)(B)(i).
[36] *See* 40 C.F.R. § 702.1(b) ("EPA will make priority designations pursuant to these procedures for a chemical substance, not for a specific condition or conditions of uses of a chemical substance.").
[37] 15 U.S.C. § 2605(a).

EPA to evaluate the chemical's risks across its conditions of use.[38] It is precisely that consideration that distinguishes the risks posed by "a chemical substance" from the risks posed by its discrete conditions of use.

To date, however, none of EPA's TSCA risk evaluations have considered the risks to people who are exposed to a chemical from multiple conditions of use, and the Proposed Rule does not expressly mandate such analysis. EPA's revised unreasonable risk determinations for the first ten risk evaluation chemicals relied exclusively on EPA's prior calculations of those chemicals' use-specific risks, resulting in "whole chemical" risk determinations in name only.[39] The Proposed Rule continues that approach, emphasizing that "EPA generally expects every risk determination to identify which conditions of use are—or are not—significant contributors to EPA's determination that the risk presented is unreasonable."[40] This emphasis on the risk contributions from individual conditions of use raises the question of whether EPA intends to evaluate risks from conditions of use in combination. This is not an academic concern; EPA has identified multiple conditions of use within a single facility, or within multiple facilities in the same neighborhood, but it has yet to calculate the risks to workers and residents who are exposed from those combinations of uses.[41] We urge EPA to clarify that the evaluation of risks posed by "a chemical substance" requires the consideration of total exposures from multiple conditions of use.

Finally, the requirement to determine the risks posed by a chemical as a whole does not prevent EPA from making early determinations that a chemical presents unreasonable risk due to particular conditions of use and moving those uses into risk management while the broader risk evaluation is ongoing. Rather, as EPA explains in the Proposed Rule, "if a specific use of a chemical—in isolation—presented an unreasonable risk under TSCA, that chemical itself would necessarily present an unreasonable risk irrespective of risks posed by other uses."[42] However, "[t]he converse may not be true," since, as noted above, even if a condition of use does not present unreasonable risk on its own, it may still contribute to unreasonable risks when combined

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[38] 15 U.S.C. § 2605(a), (b)(4)(A).

[39] *See, e.g.*, EPA, Final Revised Unreasonable Risk Determination for Methylene Chloride 5 (Oct. 2022), https://www.epa.gov/system/files/documents/2022-11/MC_Final%20Revised%20RD_10.26.22-final%20%281%29.pdf.
(explaining that "the revisions to the [methylene chloride] unreasonable risk determination are based on the existing risk characterization section of this Risk Evaluation (Section 4), and do not involve additional technical or scientific analysis").

[40] 88 Fed. Reg. at 74,302–03.

[41] *See, e.g.,* EPA, *Final Risk Evaluation for Methylene Chloride, Supplemental File: Supplemental Information on Releases and Occupational Exposure Assessment* 31, 42 (June 2020), https://www.epa.gov/sites/default/files/2020-06/documents/15_mecl_supplemental_information_on_releases_and_occupational_exposure_assessment_public.pdf (identifying multiple conditions of use for methylene chloride—namely, manufacturing and repackaging—at Dow Chemical facility in Pittsburg, California and Occidental Chemical facility in Geismar, Louisiana).

[42] 88 Fed. Reg. at 74,301.

with others.[43] Therefore, while EPA cannot make use-specific "no unreasonable risk" determinations, EPA can make an unreasonable risk determination based on a single use and begin to develop regulations for that use while it "complete[s] a full risk evaluation of the chemical substance."[44]

While the 2017 proposed risk evaluation rule expressly acknowledged EPA's authority to make early unreasonable risk determinations, EPA declined to include a similar provision in the Proposed Rule. In defense of that omission, EPA wrote that "the notion of early, use-specific risk determinations is not practical or realistic within [TSCA's] statutory deadlines," and "[t]he theoretical benefit of such an approach—enabling the early start of risk management efforts for the subset of uses that are clearly of highest risk—is outweighed by the burdens of managing the completion of multiple risk evaluation processes on a single chemical followed by potentially multiple rulemakings."[45] EPA also stated "[i]n the event that there is a known, imminent and unreasonable risk of serious or widespread injury to health or the environment (*i.e.*, imminent hazard) associated with a use or chemical that the Agency needs to address immediately, TSCA section 7 provides EPA the authority to take such immediate action."[46]

Neither of those reasons justify EPA's abandonment of its prior proposal to permit early unreasonable risk determinations. If such determinations would overtax the Agency's resources in a given instance, nothing in TSCA requires EPA to make an early unreasonable risk determinations in that case. Instead, the prior proposal merely affirmed EPA's discretion to take expedited action on specific conditions of use, leaving the door open to such determinations in circumstances where EPA has sufficient information about a particular condition of use and waiting three-plus years for the completion of the full risk evaluation would result in serious harm to health or the environment. Moreover, to the extent EPA is concerned about the feasibility of managing multiple simultaneous rulemakings, relying on TSCA section 7 would pose a far greater burden on EPA than an early unreasonable risk determination. Section 7, which applies only where a chemical presents "an imminent and unreasonable risk of serious or widespread injury to health or the environment,"[47] requires the federal government to prosecute "a civil action" against the parties responsible for such risk—who could be numerous—in a U.S. District Court, which may be unable or unwilling to provide relief that would be comparable to what EPA could achieve through regulation.[48] While TSCA section 7(d) authorizes EPA to "initiate a proceeding for the promulgation of a [risk management] rule" at the time it pursues judicial relief,[49] an early unreasonable risk determination and prompt risk management rule under TSCA section 6 would typically be faster and more efficient than the relief available under section 7. We urge EPA to include language in the Proposed Rule affirming EPA's authority to make early unreasonable risk determinations for particular conditions of use.

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[43] *Id.*
[44] 82 Fed. Reg. at 7578.
[45] 88 Fed. Reg. at 74,303.
[46] *Id.*
[47] 15 U.S.C. § 2606(f).
[48] *Id.* § 2606(a).
[49] *Id.* § 2606(d).

ii. EPA correctly interprets TSCA to preclude the exclusion of conditions of use and exposure pathways from a risk evaluation

The Proposed Rule correctly acknowledges that EPA must consider all conditions of use, exposure routes, and exposure pathways when conducting risk evaluations.[50] This acknowledgment—which is compelled by the text, history, and judicial interpretation of TSCA—corrects one of the biggest flaws in the existing risk evaluation rule, which resulted in the unlawful exclusion of key conditions of use and exposure pathways from the first ten TSCA risk evaluations.

a. TSCA prohibits EPA from excluding conditions of use from the scope of a risk evaluation

TSCA requires EPA to "determine whether a chemical substance presents an unreasonable risk of injury to health or the environment . . . under the conditions of use."[51] As described above, the required risk determination is for "a chemical substance,"[52] and EPA cannot determine the risks presented by a chemical substance unless it considers all conditions of use, individually and in combination.[53] Further, it is well established that when the word "the" precedes a collective or plural noun, such as "conditions of use," it is equivalent to "all."[54] TSCA thus compels the evaluation of a chemical substance (or a mixture or category of substances) as a whole, taking into account all conditions of use.

TSCA broadly defines "conditions of use" to encompass 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."[55] As EPA has recognized and the Ninth Circuit Court of Appeals has held, EPA's authority to "determine" the conditions of use for a chemical does not permit EPA to exclude circumstances that fall within the scope of that statutory definition.[56] Rather, that language merely establishes EPA's obligation to determine how a given chemical is manufactured, processed, distributed in commerce, used, and disposed of. As the Ninth Circuit explained in rejecting EPA's exclusion of certain "legacy" uses from the scope of TSCA risk evaluations:

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[50] 88 Fed. Reg. at 74,321–22.
[51] 15 U.S.C. § 2605(b)(4)(A).
[52] *Id.*
[53] *See supra* pp. 7–8; *see also* 88 Fed. Reg. at 74,298 ("Exclusion of conditions of use from risk evaluations—irrespective of the Agency's intention in so doing—deprives the public of a complete picture of the chemical's risk, and may leave significant risk to human health or the environment unaccounted for and ultimately unaddressed.").
[54] *See, e.g., Dutcher v. Matheson*, 840 F.3d 1183, 1194 (10th Cir. 2016); *Kaufman v. Allstate N.J. Ins. Co*., 561 F.3d 144, 155 (3d Cir. 2009); *Frazier v. Pioneer Ams. LLC*, 455 F.3d 542, 546 (5th Cir. 2006).
[55] 15 U.S.C. § 2602(4).
[56] *Safer Chems., Healthy Fams.*, 943 F.3d at 425.

> We agree that the statute grants EPA discretion to determine the conditions of use for each chemical substance, but that discretion may only be exercised within the bounds of the statutory definition itself. *See Massachusetts v. EPA*, 549 U.S. 497, 533, 127 S.Ct. 1438, 167 L.Ed.2d 248 (2007) (explaining that a statute directing an agency to use its "judgment" did not grant the agency "a roving license to ignore the statutory text," but rather directed the agency to "exercise discretion within defined statutory limits"). Where Congress has explicitly provided a definition for a term, and that definition is clear, an agency must follow it.[57]

In TSCA, Congress provided a clear definition of "conditions of use," and EPA cannot circumvent that definition by excluding uses that fall within the boundaries set by Congress. We support the provisions of the Proposed Rule that "make clear that the scope of TSCA risk evaluations will not exclude any 'conditions of use' (*i.e.*, any circumstance, based on reasonably available information, under which a chemical substance is known, intended or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of)."[58]

b. <u>TSCA prohibits EPA from excluding exposure routes and pathways from the scope of a risk evaluation</u>

The directive to consider all conditions of use when evaluating a chemical substance's risks also requires EPA to evaluate all exposure routes and pathways associated with those conditions of use. EPA appropriately acknowledges that mandate in the Proposed Rule, which states that "EPA will assess all exposure routes and pathways relevant to the chemical substance under the conditions of use, including those that are regulated under other Federal statutes."[59]

That provision corrects a major flaw in the existing risk evaluation rule, under which EPA unlawfully asserted the discretion to exclude from consideration under TSCA all chemical exposures that are, or could be, regulated under the Clean Air Act, the Safe Drinking Water Act, and other environmental laws. Relying on that asserted discretion, EPA excluded all ambient air or drinking water exposures from the first ten TSCA risk evaluations, regardless of whether the chemical being evaluated was in fact regulated under those others laws.[60] For instance, EPA's

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[57] *Id.*

[58] 88 Fed. Reg. at 74,296; *see also id.* at 74,321 (requiring EPA to "determine whether a chemical substance does or does not present an unreasonable risk after considering the risks posed under all of the conditions of use").

[59] *Id.* at 74,322.

[60] *See e.g.*, Carbon Tetrachloride (CTC); Regulation Under the Toxic Substances Control Act (TSCA), 88 Fed. Reg. 49,180, 49,188 (proposed July 28, 2023). While the Biden Administration has conducted "screening level" analyses of those chemicals' risks to fenceline communities, it has cited "uncertainties associated with the fenceline analys[es]" to avoid TSCA regulation even when the analyses identified elevated cancer risks to fenceline communities. *See, e.g.*, *id.* at 49,211.

initial risk evaluation for 1,4-dioxane failed to consider drinking water exposures,[61] even though 1,4-dioxane is not currently regulated under the Safe Drinking Water Act, and "[t]he most common way people come in contact with 1,4-dioxane is by drinking 1,4-dioxane-contaminated tap water."[62] EPA also failed to consider exposures to 1-bromopropane in the air, even though, at the time of the evaluation, 1-bromopropane was not regulated as a hazardous air pollutant, and it is still not subject to any Clean Air Act National Emission Standards for Hazardous Air Pollutants.[63]

EPA offered two justifications for those exclusions, neither of which has any legal basis. First, EPA claimed that it could pick which exposure pathways to exclude from a risk evaluation because TSCA requires the risk evaluation scope to identify "the hazards, exposures, conditions of use, and the potentially exposed or susceptible subpopulations the Administrator expects to consider."[64] But, as the Ninth Circuit explained in rejecting EPA's attempt to exclude conditions of use, that phrase "expects to consider" merely "refers to the Agency's role in determining what the [exposures] are for a particular substance;" the Court agreed with Petitioners that such language "*does not* grant EPA discretion to exclude" exposures.[65] Congress used the word "expects" to "acknowledg[e] that the Agency's expectations at the scoping phase may not always align perfectly with the . . . draft and final risk evaluations," such that additional information received after a final scope may result in the identification of new exposure routes and pathways.[66]

Second, EPA claimed that it could exclude exposure pathways because TSCA section 9 permits EPA to rely on other environmental laws to address the risks posed by a chemical or mixture "if the Administrator determines that a risk to health or the environment associated with a chemical substance or mixture could be eliminated or reduced to a sufficient extent by actions taken under the authorities contained in such other [environmental] laws."[67] As is plain from the text of that provision, section 9 applies only during TSCA's risk management phase, after EPA has already completed a risk evaluation and determined a chemical presents unreasonable risk. "If exposure pathways covered by other laws are not assessed in TSCA risk evaluations, it is unclear how the Administrator would have sufficient information to determine under TSCA

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[61] EPA, *Final Risk Evaluation for 1,4-Dioxane* 272 (Dec. 2020), https://www.epa.gov/sites/default/files/2020-12/documents/1._risk_evaluation_for_14-dioxane_casrn_123-91-1.pdf.
[62] Fla. Dep't of Health, *1,4-Dioxane* (Dec. 2, 2021), https://www.floridahealth.gov/environmental-health/hazardous-waste-sites/contaminant-facts/_documents/final-faq-14dx.pdf.
[63] EPA, 740-R1-8013, *Risk Evaluation for 1-Bromopropane (n-Propyl Bromide)* 377 (Aug. 2020), https://www.epa.gov/sites/default/files/2020-08/documents/risk_evaluation_for_1-bromopropane_n-propyl_bromide.pdf ("Since 1-BP is not a HAP, currently, there are no National Emissions Standards for Hazardous Air Pollutants (NESHAPs).").
[64] 15 U.S.C. § 2605(b)(4)(D); 82 Fed. Reg. at 33,729.
[65] *Safer Chems., Healthy Fams. v. EPA*, 943 F.3d at 419.
[66] 88 Fed. Reg. at 74,297.
[67] 15 U.S.C. § 2608(b)(1); 88 Fed. Reg. at 74,299 (describing EPA's prior reliance on TSCA section 9).

section 9(b) that a risk to health or the environment associated with a chemical substance could be eliminated or reduced to a sufficient extent under another Federal law, or whether it is in the public interest to protect against such risk by actions taken under TSCA . . . ."[68] In short, TSCA never gave EPA the discretion that it asserted in the initial risk evaluation rule, and we support the Proposed Rule's affirmation that TSCA mandates the consideration of all exposure routes and pathways.

iii. EPA correctly interprets TSCA to require the evaluation of risks from the presence of chemicals as byproducts or impurities

As EPA explains in the preamble to the Proposed Rule, "[t]he known, intended, and reasonably foreseen production of a chemical as a byproduct or the known presence of a chemical as an impurity or within an article, for example, are squarely 'conditions of use'" within the meaning of TSCA.[69] EPA is correct that risk evaluations must consider the risks posed by the presence of these chemicals as byproducts or impurities.

TSCA's plain language and EPA past practice make clear that EPA is expected to evaluate byproducts and impurities in deciding whether and how to regulate a chemical substance. TSCA requires EPA to consider risks posed by a chemical substance "under the conditions of use,"[70] defined to be the circumstances "under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of."[71] Nothing in TSCA limits conditions of use to those chemical substances that are intentionally created rather than incidentally created, and "manufacture" is defined in TSCA to broadly include "produce" without reference to the intentionality of production.[72] Indeed, EPA has long recognized that references in TSCA to manufacturing and processing include manufacturing and processing byproducts and impurities.[73]

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[68] 88 Fed. Reg. at 74,299.

[69] *Id.* at 74,298. While the terms byproduct and impurity are not defined in TSCA or in the Proposed Rule, we urge EPA to interpret those terms broadly to cover the production of a chemical during the manufacture, processing, use, or disposal of another chemical, including as a contaminant or residual in other chemicals, articles, and products.

[70] 15 U.S.C. § 2605(b)(4)(A).

[71] *Id.* § 2602(4).

[72] *Id.* § 2602(9).

[73] *See, e.g.*, 40 C.F.R. § 710.3 ("The term [manufacture for commercial purposes] also applies to substances that are produced coincidentally during the manufacture, processing, use, or disposal of another substance or mixture, including byproducts that are separated from that other substance or mixture and impurities that remain in that substance or mixture."); 40 C.F.R. § 716.3 ("Manufacture for commercial purposes also applies to substances that are produced coincidentally during the manufacture, processing, use, or disposal of another substance or mixture, including byproducts and impurities."); *id.* ("If a chemical substance or mixture containing impurities is processed for commercial purposes, then those impurities are also processed for commercial purposes.").

A risk evaluation that fails to account for the risks associated with the unintended production or presence of a chemical substance—either as a byproduct or an impurity—would run afoul of TSCA's express directive to consider not only the "intended" but also the "known[] or reasonably foreseen" circumstances under which a chemical is manufactured or used.[74] Such a risk evaluation would undermine the purpose of TSCA to protect people and the environment from unreasonable risks posed by a chemical, as it would understate the human and environmental exposures to a chemical present as a byproduct or impurity. These exposures can be significant—in the case of 1,4-dioxane, for example, EPA has recognized that 1,4-dioxane produced as a byproduct can be found in a wide array of commercial and consumer products, such as soaps, detergents, cleaning products, antifreeze, textiles, dyes, and paints and lacquers, as well as in drinking water due to releases from, and disposal of, these products.[75]

In order for EPA to comply with TSCA and conduct risk evaluations that capture a chemical's real-world exposures to people and the environment, it must consider all of the chemical's conditions of use. As the known or reasonably foreseeable manufacture, processing, distribution, use, or disposal of a chemical as a byproduct or impurity fits squarely within the definition of "condition of use," EPA must consider the risks associated with these activities.

C. EPA Must Expand the Proposed Rule to Ensure Compliance with TSCA's Risk Evaluation Requirements

i. EPA must revise the Proposed Rule to require the consideration of risks to all potentially exposed or susceptible subpopulations, including groups that are experiencing aggregate and cumulative exposures and risks

TSCA's directive that EPA consider the risks faced by "potentially exposed or susceptible subpopulation[s]" mandates consideration of those groups that are at greater risk of harm than the general population due to aggregate or cumulative exposures to toxic chemicals.[76] In the Proposed Rule, EPA correctly recognizes that overburdened communities constitute "potentially exposed or susceptible subpopulation," and in the preamble, it acknowledges that aggregate and cumulative exposures can render a community overburdened.[77] At the same time, however, EPA fails to mandate that risk evaluations assess aggregate and cumulative exposures to accurately account for the risks faced by these exposures and to identify such overburdened groups. EPA should retain the reference to overburdened communities in the final rule. But in its final rule, EPA must specify that such communities may be overburdened, and thus a potentially exposed or susceptible subpopulation, because of aggregate or cumulative exposures. EPA must also commit to including aggregate exposure and cumulative risk assessments in all of its risk evaluations, as TSCA requires.

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[74] 15 U.S.C. § 2602(4).
[75] *See* EPA, *1,4-Dioxane Draft Revised Unreasonable Risk Determination* 7–8 (July 2023), https://www.epa.gov/system/files/documents/2023-07/Draft%20Revised%20Risk%20Determination%2014-Dioxane-2023.pdf.
[76] 15 U.S.C. § 2605(b)(4)(A).
[77] 88 Fed. Reg. at 74,304–05.

In proposing to include "overburdened communities" as an example in the regulatory definition of "potentially exposed or susceptible subpopulation," EPA correctly acknowledges that certain communities experience disproportionate harms from chemical exposures due to environmental factors like aggregate or cumulative chemical exposures, as well as due to socio-economic stressors.[78] We appreciate EPA finally recognizing that such factors may render a group at higher risk of harm from a chemical, which EPA is statutorily required to consider under TSCA's risk evaluation regime. However, to remove any doubt about the scope of that obligation, we urge EPA to expressly define "overburdened communities" in the regulatory text to include those groups who are potentially exposed or susceptible due to aggregate exposures and cumulative risks associated with chemical exposures.

TSCA defines a potentially exposed or susceptible subpopulation as "a group of individuals . . . who, due to either greater susceptibility or greater exposure, may be at greater risk than the general population of adverse health effects from exposure to a chemical substance or mixture."[79] As many of the undersigned commenters have repeatedly explained in comments submitted to EPA,[80] this definition includes those who face greater exposures to a chemical because of exposures from multiple sources or who are more susceptible to the effects of a chemical because they face exposures to multiple chemicals that cause similar health effects or non-chemical stressors that worsen the impacts of chemical exposures. Because TSCA requires consideration of a chemical's risks to a "potentially exposed or susceptible subpopulation," EPA must evaluate those risks to populations whose aggregate and cumulative exposures place them at greater risk than the general population.

In the preamble of its Proposed Rule, EPA appears to recognize the importance of taking into account aggregate exposures to a chemical in assessing the risks faced by potentially exposed or susceptible subpopulations. In particular, EPA explains that:

> If a community is exposed to a chemical substance through multiple routes and/or pathways . . . and/or from multiple sources . . . , the Agency has the authority to aggregate those exposures, subject to the best available science standard, per TSCA section 26(h). Not only does the Agency have the authority, but *in developing a comprehensive risk estimate for a chemical substance, it is the Agency's responsibility to consider the aggregation* of what may be lower individual exposures from individual conditions of use and routes of exposure.[81]

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[78] *Id.*
[79] 15 U.S.C. § 2602(12).
[80] *See, e.g.*, Alianza Nacional de Campesinas, Inc. et al., Comments on EPA's Draft Proposed Principles of Cumulative Risk Assessment under the Toxic Substances Control Act, Docket No. EPA-HQ-OPPT-2022-0918-0035 (Apr. 28, 2023), https://www.regulations.gov/comment/EPA-HQ-OPPT-2022-0918-0035; Alaska Cmty. Action on Toxics et al., Comments on EPA's Cumulative Risk Assessment Guidelines for Planning and Problem Formulation, Docket No. EPA-HQ-OPPT-2022-0292-0198, at 5–6 (Aug. 30, 2023), https://www.regulations.gov/comment/EPA-HQ-ORD-2013-0292-0198.
[81] 88 Fed. Reg. at 74,305 (emphasis added).

In the preamble, EPA goes on to say that it "is committed to conducting an aggregate assessment, as supported by the science, in future TSCA risk evaluations."[82] However, EPA appears to walk back this commitment in the actual proposed text of the regulation by attaching a number of qualifications to the circumstances under which it will conduct an exposure assessment. There, EPA explains that it "will consider aggregate exposures to the chemical substance, and, *when supported by reasonably available information, consistent with the best available science and based on the weight of scientific evidence*, include an aggregate exposure assessment in the risk evaluation, or will otherwise explain in the risk evaluation the basis for not including such an assessment."[83]

To the extent that EPA views its decision to include an aggregate exposure assessment in a risk evaluation for a chemical as discretionary or only appropriate in certain situations,[84] it is wrong. First, as explained above, EPA cannot determine whether a chemical substance poses an unreasonable risk to a potentially exposed or susceptible subpopulation if it does not consider the risks faced by those who are more exposed to a chemical substance because of exposures from multiple routes and multiple pathways. Second, as noted above, TSCA requires EPA to regulate when it finds there are unreasonable risks posed by "the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance . . . or . . . *any combination of such activities*,"[85] which, by its own terms, requires EPA to consider the aggregate exposures to a chemical from multiple sources and exposure pathways. And third, TSCA requires EPA to evaluate and regulate chemicals "in a manner consistent with the best available science."[86] Aggregate exposure assessments represent the best available science that EPA is required to use.[87] It is never "consistent with the best available science" to ignore aggregate exposures, and EPA's attempt to make aggregate exposure assessment discretionary violates TSCA's unambiguous mandate for such analysis.[88]

TSCA similarly requires the consideration of those who experience increased susceptibility and risks because of their cumulative chemical exposures, including but not limited to fenceline communities who are exposed to multiple chemicals with similar health effects. In the preamble to the Proposed Rule, EPA explains that it has authority to consider cumulative

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[82] *Id.*
[83] *Id.* at 74,322 (emphasis added).
[84] *See, e.g.*, *id.* at 74,305 ("While there is no mandate to conduct aggregate exposure analyses, EPA may conduct aggregate exposure analyses at its discretion.").
[85] 15 U.S.C. § 2605(a) (emphasis added).
[86] *Id.* § 2625(h).
[87] *See* Swati D.G. Rayasam et al., *Toxic Substances Control Act (TSCA) Implementation: How the Amended Law Has Failed to Protect Vulnerable Populations from Toxic Chemicals in the United States*, 56 Env't Sci. & Tech. 11969, 11973 (2022), https://doi.org/10.1021/acs.est.2c02079 ("Using the best available science, as required by TSCA, means EPA must quantify the aggregate exposures and cumulative risks.").
[88] To the extent that EPA believes it lacks information required to conduct an aggregate exposure assessment, it can gather such information using the authority granted to it pursuant to sections 4, 8, and 11 of TSCA. *See* 15 U.S.C. §§ 2603, 2607, 2610. It should not, however, use a purported lack of information as an excuse to avoid conducting an aggregate exposure assessment.

risks posed by multiple chemical substances and asserts that, "for some chemical substances undergoing risk evaluation, the best available science may indicate" that a cumulative risk assessment is appropriate.[89] But the regulatory text fails to mention cumulative exposures and risks, much less to mandate their evaluation.

While we agree that EPA has authority to consider cumulative impacts, we submit that such consideration—like consideration of aggregate exposures—is mandated by several provisions of TSCA. First, as explained above, people who are exposed to multiple chemicals that cause the same health effects, or to nonchemical stressors that worsen the impacts of chemical exposures, are more likely to experience harm than they would be without those cumulative exposures and thus have "greater susceptibility" to the effects of each chemical.[90] Thus, TSCA's directive that EPA consider risks to a potentially exposed or susceptible subpopulation requires it to consider those who are susceptible due to other chemical exposures or nonchemical stressors.

Second, just as TSCA's "best available science mandate" requires EPA to consider aggregate exposures in a risk evaluation, so too does it require consideration of cumulative exposures. The National Academy of Sciences, Engineering, and Medicine ("NASEM") has repeatedly called for the consideration of cumulative exposures in chemical risk evaluations, explaining that "it is difficult to imagine any risk assessment in which it would not be important to understand the effects of coexposures to agents or stressors that have similar [modes of action] or to identify characteristics of the affected populations that could contribute to vulnerability to a given exposure."[91] More recently, NASEM called on agencies to "move beyond source-by-source and pollutant-by-pollutant . . . risk assessment and toward a fuller characterization of the cumulative and potentially synergistic health risks from multiple environmental and social stressors that disproportionately impact communities of color."[92] EPA's designated TSCA scientific review panel, the Scientific Advisory Committee on Chemicals ("SACC"), has affirmed that "aggregate and cumulative exposures should be considered" and has described

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[89] 88 Fed. Reg. at 74,305.

[90] *See* Nat'l Rsch. Council, *Science and Decisions: Advancing Risk Assessment* 147 (2009) ("Science & Decisions"), https://nap.nationalacademies.org/catalog/12209/science-and-decisions-advancing-risk-assessment; *id.* at 214 ("Ignoring numerous agents or stressors that affect the same toxic process as the chemical of interest and omitting background processes could lead to risk assessments that, for example, assume population thresholds in circumstances when such thresholds may not exist."); *see also* Kristi P. Fedinick, et al., *A Cumulative Framework for Identifying Overburdened Populations Under the Toxic Substances Control Act: Formaldehyde Case Study*, 18 Int'l J. Env't Rsch. & Pub. Health Art. No. 6002 (2021), https://www.mdpi.com/1660-4601/18/11/6002 EPA, EPA/630/P-02/001F; EPA, *Framework for Cumulative Risk Assessment* 51 (May 2003), https://www.epa.gov/sites/default/files/2014-11/documents/frmwrk_cum_risk_assmnt.pdf.

[91] Science & Decisions at 219.

[92] Nat'l Acads. of Sci., Eng'g, & Med., *Transforming EPA Science to Meet Today's and Tomorrow's Challenge*s 35 (2023), https://nap.nationalacademies.org/catalog/26602/transforming-epa-science-to-meet-todays-and-tomorrows-challenges.

cumulative exposure assessment as "a necessary step" in a risk assessment process.[93] The World Health Organization's International Programme on Chemical Safety has acknowledged "a need . . . for assessing the combined risk from exposure to multiple chemicals via all relevant routes and pathways."[94]

In light of the above and other scientific recommendations, it would be inconsistent with the "best available science," and thus contrary to TSCA, for EPA to conduct risk evaluations that disregard cumulative risks. Nor would EPA be able to adequately consider the risks faced by potentially exposed or susceptible subpopulations if it does not consider the cumulative risks that make such a group susceptible. EPA must commit to conducting a cumulative risk assessment—and must include such commitment in its final rule—any time reasonably available information indicates that a group is exposed to a chemical with similar health effects as the chemical undergoing evaluation or faces nonchemical stressors that render them more susceptible to harm from that chemical.

ii. EPA must revise the Proposed Rule to affirm that reasonably foreseen spills, fires, and other excess emission events must be considered in a risk evaluation

As described above, TCSA requires EPA to consider all of the "circumstances . . . under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of" when conducting risk evaluations.[95] Those circumstances include not only "intended" chemical releases associated with routine facility operations, but also releases that are "known" or "reasonably foreseen" to occur as a result of spills and leaks, facility malfunctions, and other foreseeable but unintended chemical incidents.[96] Yet EPA ignored those excess emission events in each of the first ten risk evaluations, and the Proposed Rule fails to ensure their consideration moving forward.

In the first ten risk evaluations, EPA claimed that "even if accidental releases . . . could be considered part of [a chemical's conditions of use] . . . EPA is . . . exercising its discretionary authority to exclude releases from accidents from the scope of the . . . risk evaluation."[97] But, as

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[93] Sci. Advisory Comm. on Chems., Meeting Minutes and Final Report on *A Set of Scientific Issues Being Considered by the Environmental Protection Agency Regarding: Draft TSCA Screening Level Approach for Assessing Ambient Air and Water Exposures to Fenceline Communities Version 1.0*, at 47–49 (May 16, 2022), https://www.regulations.gov/document/EPA-HQ-OPPT-2021-0415-0095.

[94] WHO, *Assessment of Combined Exposures to Multiple Chemicals: Report of a WHO/IPCS International Workshop* 18 (2009), https://inchem.org/documents/harmproj/harmproj/harmproj7.pdf.

[95] 15 U.S.C. § 2602(4); *see also id.* § 2605(b)(4)(A).

[96] *Id.* § 2602(4).

[97] *See, e.g.*, EPA, *Summary of External Peer Review and Public Comments and Disposition for Methylene Chloride* 61–62 (June 2020), https://www.epa.gov/sites/default/files/2020-06/documents/2_mecl_peer_review_and_public_comment_response_final.pdf; EPA, *Summary of External Peer Review and Public Comments and Disposition for 1-Brompropane (n-Propyl*

acknowledged elsewhere in Proposed Rule, EPA has no discretion to exclude releases associated with a chemical's conditions of use.[98] Instead, "[o]ne of the defining features of the 2016 amendments to TSCA was the mandate for EPA to systematically prioritize those thousands of existing chemicals for review, and then to evaluate their risks, holistically, under the chemical's 'conditions of use'—a phrase that Congress defined to capture a chemical's full lifecycle."[99]

Unable to rely on its prior justification for excluding unplanned chemical releases, the Proposed Rule improperly dismisses their foreseeability, asserting that "one-time accident[s]" and "exposures associated with future extreme weather events (*e.g.*, hurricanes and wildfires)" are not "reasonably foreseen" and "would generally not be assessed as part of a risk evaluation."[100] That explanation misreads TSCA and ignores the recurring nature of chemical incidents and natural disasters. Because the subject of a TSCA risk evaluation is the "chemical substance," foreseeability must be assessed with respect to the chemical as a whole and not any particular facility. A series of "one-time accidents" and other excess emission events—even if they occur at different facilities and at unpredictable intervals—is evidence that unplanned releases are "reasonably foreseen" to occur and must be considered under TSCA.

There is overwhelming evidence that facility malfunctions, fires, spills, and other unplanned incidents are reasonably foreseen but distressingly common. EPA has multiple regulatory programs—including the Clean Air Act's Risk Management Program;[101] the Clean Air Act's Start-up, Shutdown, and Malfunction regulations;[102] the Emergency Planning and Community Right to Know Act's ("ECPRA") Tier I and Tier II reporting requirements;[103] emergency release reporting requirements under EPCRA and the Comprehensive Environmental Response, Compensation, and Liability Act;[104] the proposed Hazardous Substance Worst Case Discharge Planning rule under section 311(j)(5) of the Clean Water Act;[105] and more— that are predicated on the expectation that unplanned releases will occur and must be prepared for and regulated. Studies covering only a subset of total chemical facilities have found that "[h]azardous chemical accidents . . . occur[] almost daily, on average, in the United States, exposing people to dangerous toxins through fires, explosions, leaks, spills and other releases."[106] Those releases are

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Bromide) 22–23 (Aug. 2020), https://www.epa.gov/sites/default/files/2020-08/documents/summary_of_external_peer_review_and_public_comments_and_disposition_for_1-bromopropane_n-propyl_bromide.pdf.

[98] 88 Fed. Reg. at 74,297.

[99] *Id.* at 74,296.

[100] *Id.* at 74,298.

[101] 40 C.F.R. Part 68.

[102] *Id.* § 65.6.

[103] *Id*. §§ 370.40–370.45.

[104] 42 U.S.C. §§ 9603, 11004.

[105] 33 U.S.C. §1321(j)(5).

[106] Carey Gillam, *U.S. Faces Almost Daily Hazardous Chemical Accidents, Research Suggests*, Guardian (Nov. 9, 2023), https://www.theguardian.com/us-news/2023/nov/09/how-many-chemical-accidents-spills-explosion.

most common in states with heavy concentrations of chemical manufacturers, refineries, and other industrial facilities, such as Texas and Louisiana.[107]

These foreseeable incidents are often the source of significant exposures and risks. For instance, a May 5, 2023 fire at a Shell Chemicals refinery in Deer Park, Texas released approximately 820,500 pounds of air contaminants, including approximately 16,000 pounds of 1,3-butadiene, into the surrounding community.[108] That incident alone would represent approximately 45 percent of the total 1,3-butadiene releases that the facility reported to the Toxics Release Inventory in all of 2021 and approximately 40 percent of the total reported releases in 2022.[109] And, far from a "one-time accident,"[110] the May 5 fire is one of more than five hundred excess emission events that facility self-reported to the Texas Department of Environmental Quality during the past twenty years.[111] Similarly, a fire at the Dow Chemical facility in Plaquemine, Louisiana, on July 14, 2023, released 31,525 pounds of the potent carcinogen ethylene oxide—approximately the same volume of ethylene oxide that the Dow facility reported releasing during the entire nine-year period spanning from 2013 to 2021.[112] And that incident was just one of ten emergency incidents over the past four years from that facility that resulted in unauthorized releases of toxic chemicals.[113] The same people are exposed, time and time again, because of the recurring nature of chemical incidents in fenceline communities. That is the very definition of a "reasonably foreseen" circumstance.[114]

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[107] Coming Clean & Env't Just. Health All. for Chem. Pol'y Reform, *Key Findings: Chemical Incident Tracking 2021-2023*, at 6 (Nov. 9, 2023), https://comingcleaninc.org/assets/media/images/Chemical%20Disaster%20Prevention/Key%20Findings%202021-2023%20FINAL.pdf.

[108] Tex. Comm'n on Env't Quality, *Air Emission Event Report Database Incident 400010*, https://www2.tceq.texas.gov/oce/eer/index.cfm?fuseaction=main.getDetails&target=400010 (last visited Dec. 14, 2023).

[109] According to EPA's Toxics Tracker, Shell Chemical LP in Deer Park released 35,000 pounds of 1,3-butadiene into the air in 2021 and 40,900 pounds in 2022. *See TRI Explorer*, EPA, https://enviro.epa.gov/triexplorer/tri_release.chemical (last visited December 14, 2023) (under the "Release Reports" tab, select "Chemical," "User Selected Chemical(s)," "1,3-Butadiene," and then search under "Year of Data" for 2022 and 2021).

[110] 88 Fed. Reg. at 74,298.

[111] Dylan Baddour, *Shell Refinery Unit in Deer Park Had History of Malfunctions Before Fire*, Tex. Tribune (May 10, 2023), https://www.texastribune.org/2023/05/10/texas-shell-refinery-fire-problems-tceq/ (citing TCEQ reports).

[112] David J. Mitchell, *Dow Explosion Released Years' Worth of Cancer-Causing Chemical; Cause Still Not Clear*, Baton Rouge Advoc. (Sept. 7, 2023), https://www.theadvocate.com/baton_rouge/news/business/years-worth-of-potent-carcinogen-released-in-dow-blaze/article_c4ae8260-4cef-11ee-acb7-1b90d126db53.html.

[113] Wesley Muller, *LDEQ Records Show Frequent Emergencies at Dow Plaquemine Facility*, La. Illuminator (July 27, 2023), https://lailluminator.com/2023/07/27/ldeq-records-show-frequent-emergencies-at-dow-plaquemine-facility/.

[114] *Cf. Foreseeability*, Black's Law Dictionary (11th ed. 2019) (defining "foreseeability" as "the quality of being reasonably anticipatable").

EPA must also evaluate chemical releases associated with reasonably foreseen, and increasingly common, natural disasters like hurricanes and wildfire. The Proposed Rule distinguishes between "regular and predictable changes in exposures" associated with "rising sea levels or extreme temperatures made worse by climate change" (which EPA "expects" to consider) and "a future one-time accident involving the chemical substance" or "exposures associated with future extreme weather events (*e.g.*, hurricanes and wildfires)" (which "would generally not be assessed as part of a risk evaluation").[115] In addition to being legally and factually unsupported, the line that EPA is attempting to draw is impossible to apply in practice. Just as "rising sea levels" and "extreme temperatures" are scientifically established and reasonably foreseen consequences of climate change, so is an increase in the frequency and severity of hurricanes, wildfires, and other extreme weather events.[116] The Government Accountability Office has warned that 3,219 of 10,420 facilities that use or store hazardous chemicals in levels exceeding the Clean Air Act's Risk Management Plan threshold "are located in areas with one or more . . . natural hazards that may be exacerbated by climate change," including a high concentration of facilities along the Gulf coast.[117] Many of those facilities experience increased risks of chemical releases precisely because of the combination of rising sea levels and more extreme weather events.[118] Following a major storm, there is no way to separate the portion of a chemical release that is attributable to rising sea levels from the portion attributable to the increased likelihood and severity of extreme weather events.

Chemical spills, facility malfunctions, fires, and other excess emission events are a reasonably foreseen and significant source of fenceline community risks. Even if EPA cannot predict the time or location of the next such incident, it can evaluate the impacts of such releases using readily available information. Resources such as the Texas Commission on Environmental Quality's ("TCEQ's") Air Emission Event Report Database,[119] the Coast Guard's National

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[115] 88 Fed. Reg. at 74,298.

[116] U.S. Global Change Rsch. Program, *Fifth National Climate Assessment: Report-in-Brief*35 (Nov. 2023), https://nca2023.globalchange.gov/downloads/NCA5_Report-In-Brief.pdf ("As the world's climate has shifted toward warmer conditions . . . heavy precipitation, drought, flooding, wildfire, and hurricanes, are becoming more frequent and/or severe, with a cascade of effects in every part of the country.").

[117] GAO, GAO-22-104494, *Chemical Accident Prevention: EPA Should Ensure Regulated Facilities Consider Risks from Climate Change* 19 (Feb. 2022), https://www.gao.gov/assets/gao-22-104494.pdf; *see also* Ctr. for Progressive Reform et al., *Preventing "Double Disasters": How the U.S. Environmental Protection Agency Can Protect the Public from Hazardous Chemical Releases Worsened by Natural Disasters* (July 2021), https://www.ucsusa.org/sites/default/files/2021-07/preventing-double-disasters%20FINAL.pdf.

[118] Ctr. for Progressive Reform et al., *Preventing "Double Disasters": How the U.S. Environmental Protection Agency Can Protect the Public from Hazardous Chemical Releases Worsened by Natural Disasters* (July 2021), https://www.ucsusa.org/sites/default/files/2021-07/preventing-double-disasters%20FINAL.pdf.

[119] Tex. Comm'n on Env't Quality, *Reports of Air Emission Events*, https://www.tceq.texas.gov/airquality/emission-events/eventreporting (last visited Dec. 14, 2023).

Response Center reports,[120] and the Agency for Toxic Substances and Disease Registry's ("ATSDR") former National Toxic Substance Incidents Program[121] provide data about prior chemical incidents and spills. Risk Management Plans submitted under the Clean Air Act and Tier I and Tier II forms submitted under EPCRA can help EPA predict the consequences of future releases. Between those sources, EPA has more than enough information to analyze the exposures and risks associated with chemical incidents. We urge EPA to revise its Proposed Rule and clarify that excess emission events and natural disasters are reasonably foreseen and must be considered under TSCA.

iii. EPA must revise the Proposed Rule to consider ongoing releases and exposures from previously disposed chemicals

TSCA defines a chemical's "conditions of use" to include "the circumstances . . . under which [the chemical] is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, *or disposed of*."[122] Chemicals are "known . . . to be . . . disposed of" in contaminated sites across the country, as well as in landfills and other commercial disposal facilities. Many of those disposed chemicals continue to migrate through the soil and groundwater, or to volatilize into the indoor or outdoor air, resulting in ongoing exposures to people and the environment.[123] The plain text of TSCA requires EPA to consider those disposal-related exposures.

However, the Proposed Rule "categorical[ly]" excludes so-called "legacy disposals," or "disposal[s] that ha[ve] already occurred," from consideration under TSCA.[124] EPA claims that "the Ninth Circuit . . . [held] that TSCA unambiguously does not require legacy disposals to be considered as conditions of use."[125] While the Ninth Circuit did uphold the risk evaluation rule's exclusion of legacy disposals, [126] EPA misstates that holding and ignores a key limitation on the exclusion. In particular, EPA claims that "[t]he Court reasoned that a substance that has already been disposed of will not ordinarily be intended, known, or reasonably foreseen to be prospectively manufactured, processed, distributed in commerce, used, or disposed of again."[127] But the Court expressly carved out of the exclusion "spills, leaks, and other uncontrolled discharges" of previously disposed material, explaining that the ongoing migration of such materials would constitute "independent disposals" that fall within TSCA's definition of

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[120] U.S. Coast Guard, *National Response Center*, https://nrc.uscg.mil/ (last visited Dec. 14, 2023).
[121] Agency for Toxic Substances & Disease Registry, *National Toxic Substances Incident Program (NTSIP)*, https://www.atsdr.cdc.gov/ntsip/ (last visited Dec. 14, 2023).
[122] 15 U.S.C. § 2602(4) (emphasis added) (defining "conditions of use").
[123] *See, e.g.,* EPA, *What Is Vapor Intrusion?*, https://www.epa.gov/vaporintrusion/what-vapor-intrusion (last updated Oct. 11, 2023); EPA, *Groundwater Contamination*, at C1 to C2 (2015), https://www.epa.gov/sites/default/files/2015-08/documents/mgwc-gwc1.pdf.
[124] 88 Fed. Reg. at 74,298.
[125] *Id.*
[126] *See Safer Chems., Healthy Fams.*, 943 F.3d at 426.
[127] 88 Fed. Reg. at 74,298.

conditions of use.[128] The Court concluded that "if . . . something is in fact *again* disposed of—even if it was disposed of previously—or when a disposal is *in fact ongoing*, we see no reason why that use is not captured as a prospective disposal."[129]

EPA must revise the Proposed Rule to clarify that TSCA requires the consideration of ongoing releases and exposures from disposed chemicals.[130] EPA ignored those exposures in each of the first ten risk evaluations, leaving a major source of risk unaddressed.[131] Many of those risk evaluation chemicals are known to contaminate drinking water supplies because of spills and disposals that continue to leach through the soil and groundwater.[132] Many chemicals are also known to volatilize from the soil and groundwater and to migrate into overlying residences and businesses.[133] EPA cannot evaluate the risks associated with a chemical substance across its "full lifecycle" unless it considers those ongoing, disposal-related exposures.[134]

iv. EPA must revise the Proposed Rule to ensure full evaluation of chemicals' environmental risks

TSCA requires EPA to consider whether a chemical substance presents an unreasonable risk of injury to health *or the environment* and to regulate the chemical to the extent necessary to eliminate such risk.[135] In order to discharge this statutory duty, EPA must conduct meaningful, robust risk evaluations that assess the risks a chemical poses to the environment—including wildlife—in addition to human health. And EPA must use the best available science, including aggregate and cumulative exposure assessments, in assessing risks to the environment. EPA's past risk evaluations have fallen short of that standard, and its final rule should guard against

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[128] *See Safer Chems., Healthy Fams.*, 943 F.3d at 426 (emphasis omitted) (quoting 40 C.F.R. § 761.3).
[129] *Id.*
[130] *See id.*
[131] *See, e.g.,* EPA, *Summary of External Peer Review and Public Comments and Disposition for Trichloroethylene (TCE)* 35–36 (Nov. 2020), https://www.epa.gov/sites/default/files/2020-11/documents/2._summary_of_external_peer_review_and_public_comments_and_disposition_for_for_trichloroethylene_tce_response_to_support_risk_evaluation__0.pdf.
[132] *See, e.g.*, Agency for Toxic Substances & Disease Registry, *Toxicological Profile for Tetrachloroethylene* 263 (June 2019) ("Tox. Profile for PCE"), https://www.atsdr.cdc.gov/ToxProfiles/tp18.pdf.
[133] *See* N.Y. State Dep't of Env't Conservation, *Site Characterization Soil Vapor Intrusion Data Summary Report February-March 2008* (June 2008), http://newtowncreekalliance.org/docs/MeekerAvePlume_ResidentialAirSampling_Summary.pdf; *see also* Tonia Burk & Gregory Zarus, *Community Exposures to Chemicals Through Vapor Intrusion: A Review of Past ATSDR Public Health Evaluations*, 75 J. Env't Health 36 (2013), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4692377/
(carbon tetrachloride detected in indoor air above screening values at nine contaminated sites).
[134] 88 Fed. Reg. at 74,294.
[135] 15 U.S.C. § 2605(b)(4)(A). TSCA defines the "environment" broadly to mean "water, air, and land and the interrelationship which exists among and between water, air, and land and all living things." *Id.* § 2602(6).

inadequate assessments of environmental risks by expressly stating that it will consider environmental harms and adopt real-world approaches to ecological risk assessment.

In prior risk evaluations, EPA failed to adequately consider the risks associated with a chemical substance to wildlife and the environment, including risks to the climate. For example, in its risk evaluation for carbon tetrachloride, EPA ignored the risks that chemical poses to the ozone layer and the climate, instead citing other statutes that "already account for . . . climate change."[136] It similarly failed to assess carbon tetrachloride exposure to terrestrial organisms through ambient air, reasoning that "this exposure pathway is covered under the jurisdiction of the [Clean Air Act]," or from water, in part because "carbon tetrachloride is identified as a priority pollutant under [the Clean Water Act] regulating releases to water."[137] But, as EPA recognizes in the preamble of its Proposed Rule, "the mere existence of authority to assess or regulate a chemical . . . under a statute other than TSCA does not equate to effective risk management of that chemical, . . . and an assumption that risk will—or could be—managed in the future cannot be used to satisfy the Agency's statutory obligations to evaluate existing chemical substances under TSCA and manage identified risks."[138] EPA should make clear in its final rule that the existence of other regulations or statutes that relate to the climate or environmental media does not relieve it of its obligation to consider such effects in connection with its risk evaluations under TSCA. EPA should also expressly state that it will consider climate effects whenever they are associated with a chemical and that it will assess all exposures to aquatic, amphibian, avian, and terrestrial species regardless of whether the media through which those species are exposed is subject to regulation by another statute.

In past risk evaluations, EPA also gathered insufficient data to adequately consider the risks posed to the environment, including terrestrial and aquatic species, and erroneously concluded that the data it collected did not indicate unreasonable risks of injury to the environment. For example, in multiple prior risk evaluations, EPA failed to consider the risks faced by various types of organisms and real-world exposure scenarios.[139] The Proposed Rule

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[136] EPA, EPA-740-R1-8014, *Summary of External Peer Review and Public Comments and Disposition for Carbon Tetrachloride* 38 (Oct. 2020), https://www.epa.gov/sites/default/files/2020-10/documents/2_ccl4_summary_external_peer_review_public_comments_disposition_for_carbon_tetrachloride.pdf .

[137] EPA, EPA-740-R1-8014, *Risk Evaluation for Carbon Tetrachloride* 124 (Oct. 2020) , https://www.epa.gov/sites/default/files/2020-10/documents/1_ccl4_risk_evaluation_for_carbon_tetrachloride.pdf. .

[138] 88 Fed. Reg. 74,300.

[139] *See, e.g.*, Sci. Advisory Comm. on Chems., Meeting Minutes and Final Report on *Peer Review for EPA Draft Risk Evaluation for Trichloroethylene (TCE)* 18 (June 1, 2020), https://www.regulations.gov/document/EPA-HQ-OPPT-2019-0500-0111("An inadequate rationale is provided for not examining hazards to other organisms, including sediment-dwelling organisms, aquatic birds, and burrowing animals including mammals in functionally confined spaces exposed to trichloroethylene from vapor intrusion."); Sci. Advisory Comm. on Chems., Meeting Minutes and Final Report on *Peer Review for EPA Draft Risk Evaluations for*

lacks the requisite specificity to prevent such errors from being repeated, particularly with respect to how EPA will evaluate risks to the environment in a manner that accounts for exposures to all types of organisms—including terrestrial, aquatic, amphibian, or avian—as well as real-world exposures to wildlife and when EPA will conclude the risk faced by a species is unreasonable. For example, the Proposed Rule does not expressly mandate the consideration of risks facing multiple types of organisms or even sublethal risks a species faces from the chemical undergoing evaluation. Nor does it require use of tools and consideration of literature concerning a chemical's impacts on terrestrial or aquatic species in the natural environment, rather than consideration solely of laboratory studies, instead simply listing "ecological field data" as a type of information that *may* be evaluated during a hazard assessment.[140] It should do so, and it should further mandate consideration of a chemical's effects on species designated as threatened, endangered, or of concern by federal, state, or tribal authorities; their habitats; and the effect of the chemical on species they consume, in order to account for the harm associated with a loss of biodiversity that may be associated with a chemical's conditions of use.[141] Moreover, in the past EPA has inappropriately concluded that injury to the environment does not drive a finding of unreasonable risk even when EPA has calculated an acute risk quotient ("RQ") above 1.0, which indicates unreasonable risks.[142] The Proposed Rule should guard against such irrational conclusions and explain that RQs above 1.0 are unreasonable.

TSCA's requirement to use the "best available science" to evaluate risks extends to its consideration of risks to the environment. In order to comply with this directive, EPA must incorporate aggregate and cumulative exposure assessments for ecological receptors into its risk evaluations. Indeed, "[t]he holy grail of ecological risk assessment is the understanding of the effects of multiple stressors on individuals, populations, and, ultimately, groups of interacting species at different spatial scales."[143] Just as humans are not exposed to chemicals in isolation, wildlife face exposures to a chemical from multiple sources or exposures to various chemicals

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1,4-Dioxane and Cyclic Aliphatic Bromide Cluster (HBCD) 129 (Aug. 2, 2019), https://www.regulations.gov/document/EPA-HQ-OPPT-2019-0238-0063 ("Amphibians are an important interface between terrestrial and aquatic ecosystems. Amphibians are currently not mentioned in the [HBCD Risk] Evaluation but should be discussed and justification for exclusion provided."); Sci. Advisory Comm. on Chems., Meeting Minutes and Final Report on *Peer Review for the United States Environmental Protection Agency (EPA) Draft Risk Evaluation for Carbon Tetrachloride* 30 (May 1, 2020), https://www.regulations.gov/document/EPA-HQ-OPPT-2019-0499-0046 ("Terrestrial receptors should have been assessed . . . . There is also no assessment of threatened or endangered species in the Evaluation . . . .").

[140] 88 Fed. Reg. at 74,322.

[141] EPA can and should utilize facility-specific information as well as its Exposure and Fate Assessment Screening Tool to identify areas where such species are facing exposures to chemicals undergoing evaluation.

[142] *See* Carbon Tetrachloride Final Risk Evaluation at 250–51, 309 tbl.E-2.

[143] Paul J. Van den Brink et al., *New Approaches to the Ecological Risk Assessment of Multiple Stressors*, 67 Marine & Freshwater Rsch. 429, 431 (2016), https://doi.org/10.1071/MF15111.

and non-chemical stressors simultaneously.[144] Climate change and habitat loss are just two of these non-chemical stressors that EPA must take into account.[145]

TSCA requires EPA to protect both human health and the environment, and its final rule must take seriously this dual mandate by including provisions designed to promote risk evaluations that capture the real-world effects a chemical has on the environment and nonhuman species.

II. IN ADDITION TO THE PRECEDING CHANGES, EPA HAS PROPOSED OTHER IMPORTANT IMPROVEMENTS TO THE TSCA RISK EVALUATION PROCESS

A. EPA Appropriately Acknowledges Its Authority to Regulate Chemical Categories Under TSCA

TSCA section 26(c) provides that "[a]ny action authorized or required to be taken by the Administrator . . . with respect to a chemical substance or mixture may be taken by the Administrator . . . with respect to a category of chemical substances or mixtures."[146] Despite that longstanding authority to evaluate and regulate chemical categories, virtually every TSCA risk evaluation has been conducted either on a single chemical substance or a small group of structurally related substances.[147] This chemical-by-chemical approach is inefficient and often counterproductive, since chemicals that are ultimately regulated under TSCA may be replaced by equally or more toxic substitutes from the same chemical class.[148] For instance, after concerns emerged about polybrominated biphenyl flame retardants' developmental harms, they were

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[144] *See* OECD, *Considerations for Assessing the Risks of Combined Exposure to Multiple Chemicals* 13 (2018) ("There is a general recognition that the assessment of chemicals on an individual basis does not reflect conditions in the environment or in humans, where a target site is typically exposed to various chemicals at the same time. This includes natural and anthropogenic chemicals. Therefore, emphasis has been shifting from the traditional single-chemical risk assessment approach used historically, to consideration of risk scenarios that integrate multiple sources, stressors, pathways and effects on a community-relevant scale, in order to provide a more realistic, and possibly, a more protective approach."); Van den Brink et al., *supra* note 144, at 429 (2016) ("Ecosystems are highly complex and interconnected, with many interactions among multiple stressors, multiple-exposure pathways and multiple receptors.").

[145] *See* Van den Brink et al., *supra* note 144, at 430 ("Habitat modification can . . . increase the accumulation of contaminants.").

[146] 15 U.S.C. § 2625(c).

[147] *See, e.g.,* EPA, 740-R1-8006, *Risk Evaluation for Cyclic Aliphatic Bromide Cluster (HBCD)* (Sept. 2020), https://www.epa.gov/sites/default/files/2020-09/documents/1._risk_evaluation_for_cyclic_aliphatic_bromide_cluster_hbcd_casrn25637-99-4_casrn_3194-5_casrn_3194-57-8.pdf (evaluating a cluster of three related chemicals).

[148] *See* Joseph Allen, *Stop Playing Whack-a-mole with Hazardous Chemicals*, Wash. Post. (Dec. 15, 2016), https://www.washingtonpost.com/opinions/stop-playing-whack-a-mole-with-hazardous-chemicals/2016/12/15/9a357090-bb36-11e6-91ee-1adddfe36cbe_story.html.

largely replaced with structurally similar and equally toxic polybrominated diphenyl ether ("PBDE") flame retardants.[149] And when PBDEs were found to cause decreased sperm counts and other endocrine-related harms, they were replaced in part with flame retardants like tris(2-chloroethyl) phosphate, a carcinogen that is currently undergoing risk evaluation under TSCA.[150] To prevent those regrettable substitutions and to fully protect the public from toxic chemicals while using its limited resources efficiently, EPA must evaluate and regulate more chemical categories.

We thus support the provisions of the Proposed Rule that clarify that "all references . . . to 'chemical' or 'chemical substance' shall also apply to 'a category of chemical substances.'"[151] While that regulation is not needed to grant EPA the authority to regulate chemical categories, it is a useful clarification that will harmonize EPA's risk evaluation rule with the text of TSCA. We also support the deletion of "single" from the phrase "a single chemical substance" from the definitions of "aggregate exposure" and "sentinel exposure," in recognition of the fact that aggregate and sentinel exposure assessments may consider multiple chemicals or a chemical category.[152] We urge EPA to use its authority under TSCA section 26(c) and the revised risk evaluation rule to prioritize, evaluate, and regulate chemical categories.

B. EPA Proposes Important Changes to the TSCA Scoping Process

We also support EPA's proposed changes to the risk evaluation scoping process, which would result in clearer scopes and more efficient risk evaluations. The scoping process establishes a roadmap for TSCA risk evaluations, setting forth "the hazards, exposures, conditions of use, and the potentially exposed or susceptible subpopulations the Administrator expects to consider."[153] The scope also determines the extent of potential preemption of state laws, since TSCA section 18 provides that TSCA risk management rules may only preempt state laws regulating "the hazards, exposures, risks, and uses . . . included in the scope of the risk evaluation."[154] To avoid confusion about the scope of a risk evaluation and its potentially preemptive effects, it is critical that the scoping process be open and transparent.

For each of the first ten risk evaluations, EPA rewrote, and in many instances narrowed, the final scopes in a series of "problem formulation" documents.[155] The "problem formulation" documents effectively superseded the scopes for those evaluations, despite the fact that neither

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[149] *Id.*
[150] *Id.*
[151] 88 Fed. Reg. at 74,320.
[152] *Id.*
[153] 15 U.S.C. § 2605(b)(4)(D).
[154] *Id.* § 2617(c).
[155] Problem Formulations for the Risk Evaluations to be Conducted Under the Toxic Substances Control Act, and General Guiding Principles to Apply Systematic Review in TSCA Risk Evaluations; Notice of Availability, 83 Fed. Reg. 26,998, 26,988 (June 11, 2018) ("The 10 problem formulation documents announced in this document refine the scope documents published in June 2017.").

TSCA nor its implementing regulations reference problem formulation documents.[156] Moreover, while EPA solicited comment on its draft problem formulation documents, the absence of any procedural requirements governing that process creates a risk of EPA cutting the public out of future scope revisions.

EPA eliminates that risk in its Proposed Rule by requiring all changes to a final scope to be described (1) "in the draft risk evaluation" (at which point they will be subject to review and comment) or (2) in "a notice of availability . . . in the Federal Register" prior to the release of the draft risk evaluation.[157] These procedures would allow EPA to respond to new information that arises after the scoping process while ensuring that any changes to the scope are announced through an established, public process. We urge EPA to provide a mandatory comment period of at least forty-five days on any "notice of availability" announcing changes to a final scope, consistent with the requirements governing the original scoping process.

The Proposed Rule would also move up the timing of the scoping process, with the stated goal of "publish[ing] the draft scope during the prioritization process concurrent with publication of a proposed designation as a High-Priority Substance."[158] TSCA requires a final scope to be published "not later than 6 months after the initiation of a risk evaluation,"[159] but it does not dictate when EPA begins the scoping process with the publication of a draft scope. Historically, EPA has waited until the close of the TSCA prioritization process to publish draft scopes. At that point, the three-year period for EPA to complete the risk evaluation is already running, making it harder for EPA to incorporate substantive revisions to the draft scope without delaying the underlying risk evaluation.[160] Beginning the scoping process during prioritization would allow the public to submit scoping comments at a time when they are more likely to be taken into account and would allow EPA to finalize the scope earlier in the risk evaluation process, making it easier for the Agency to meet its statutory deadlines for the completion of risk evaluations.

C. EPA Has Proposed Appropriate Limits on Revisions to Final Risk Evaluations

Neither the text of TSCA nor the risk evaluation rule establish a clear process for revising final risk evaluations. While we acknowledge that certain circumstances may warrant risk evaluation revisions, we believe that EPA must do so sparingly and with guardrails that shield EPA's science-based risk evaluations from political interference. Risk evaluations are merely the second step in a three-step TSCA process that begins with prioritization and ends, for all chemicals that present unreasonable risk, with risk management. Revisions to final risk evaluations threaten to disrupt the risk management process and delay needed chemical regulations.[161] Moreover, since TSCA requires independent analyses of "the effects of the

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[156] *See generally* 15 U.S.C. § 2601 *et. seq.;* 40 C.F.R. Parts 700–99.
[157] 88 Fed. Reg. at 74,323.
[158] *Id.*
[159] 15 U.S.C. § 2605(b)(4)(D).
[160] *See id.* § 2605(b)(4)(G).
[161] *See* 88 Fed. Reg. at 74,311 ("Continuously revisiting final risk evaluations would drain the Agency's already limited resources and divert attention from other chemicals actively in the prioritization, risk evaluation or risk management phases.").

chemical substance or mixture on health . . . [and] the environment" and "the magnitude of the exposure of human beings . . . [and] the environment" during risk management,[162] EPA has the ability—and often the obligation—to consider new information and conduct new analyses as part of the risk management process. We believe that revisions to a final risk evaluation should be limited to those rare circumstances that cannot be addressed through risk management, such as where EPA finds new information or errors in a final risk evaluation that cast doubt upon a determination that a chemical does not present unreasonable risk.

The Proposed Rule's provisions governing risk evaluation changes are appropriately limited. Under that rule, EPA "will generally not revise, supplement, or reissue a final risk evaluation without first undergoing the procedures . . . to re-initiate the prioritization process for that chemical substance, *except where EPA has determined it to be in the interest of protecting human health and the environment to do so, considering the statutory responsibilities and deadlines under 15 U.S.C. 2605*."[163] Short of restarting the prioritization process entirely, final risk evaluations may only be revised or supplemented where doing so would "protect[] human health and the environment," such as circumstances where new or additional information identified risks that EPA had not accounted for in its risk evaluation.[164] We support that limitation, and urge EPA to replace the conjunctive "and" in the foregoing quote with a disjunctive "or" to clarify that the protection of either human health or the environment can warrant changes to a final risk evaluation.

D. EPA Does Not Need a Regulatory Definition of "Best Available Science"

TSCA requires risk evaluations, and all other science-based decisions, to be made "in a manner consistent with the best available science."[165] While the statute provides a broad range of factors that the Agency "shall consider as applicable" when assessing the best available science,[166] Congress declined to provide a more specific definition, and EPA left the term undefined in its 2017 proposed risk evaluation rule. At the time, EPA correctly explained that "[c]odifying specific definitions . . . may inhibit the flexibility of the Agency to quickly adapt and implement changing science."[167] The Trump Administration, however, inserted a regulatory definition when finalizing that rule, including a requirement that the "best available science" reflect, "when available, peer reviewed science and supporting studies and data collected by accepted methods or best available methods."[168] This definition is redundant at best and confining at worst; there is no need or basis for EPA to limit the broad statutory description of the "best available science" through regulation.[169]

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[162] 15 U.S.C. § 2605(c)(2)(A)(i)–(ii).
[163] 88 Fed. Reg. at 74,323 (emphasis added).
[164] *Id.*
[165] 15 U.S.C. § 2625(h).
[166] *Id.*
[167] 82 Fed. Reg. at 7572.
[168] 40 C.F.R. § 702.33.
[169] For instance, EPA's emphasis on "peer reviewed science" and "best available methods" could be used to justify prioritizing industry-funded exposure studies over incident reporting and other community-based, participatory science.

We therefore support the proposed elimination of that regulatory definition. The text of TSCA, as well as the interpretation of "best available science" in other contexts, provide sufficient guidance for EPA to apply TSCA's best available science mandate while leaving EPA with the flexibility to incorporate emerging scientific developments.

E. EPA Has Proposed Necessary Improvements to the Process Governing Manufacturer-Requested Risk Evaluations

The Proposed Rule includes several improvements to the regulations governing manufacturer-requested risk evaluations under TSCA section 6(b)(4)(C)(ii).[170]

First, EPA proposes the elimination of three unlawful provisions in the current risk evaluation rule that were previously challenged in litigation and voluntarily remanded back to EPA for reconsideration.[171] One of those provisions made it a criminal offense to "submit[] . . . inaccurate, incomplete, or misleading information pursuant to a [manufacturer-requested] risk evaluation."[172] Regardless of its intent, that provision threatened public commenters with criminal liability for the submission of accurate but "incomplete" information on a chemical substance, depriving EPA of reasonably available information and chilling public participation in the risk evaluation process. Two other provisions limited the information that manufacturers must provide when requesting a risk evaluation by: (1) requiring the manufacturer to submit information only about certain, self-selected conditions of use,[173] and (2) allowing the manufacturer to withhold information based on the manufacturer's opinion of its scientific merit.[174] In its motion for remand, EPA stated that "after reviewing [Petitioners'] arguments and taking a closer look at [those] provisions, the Agency has decided to revisit the provisions and take further administrative action."[175] Five years later, EPA has appropriately proposed the deletion of all three provisions.

In addition to the elimination of those provisions, the Proposed Rule would enhance EPA's ability to conduct complete and TSCA-compliant risk evaluations in response to manufacturers' requests. The proposal clarifies that manufacturers may "only . . . make requests for evaluations of entire chemical substances—not individual conditions of use or subsets of conditions of use."[176] This change is compelled by TSCA's requirement that all risk evaluations, whether requested by a manufacturer or initiated through the prioritization process, "determine

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[170] 15 U.S.C. § 2605(b)(4)(C)(ii).
[171] *See Safer Chems., Healthy Fams. v. EPA*, 791 F. App'x 653 (9th Cir. 2019).
[172] 40 C.F.R. § 702.31(d).
[173] *Id.* § 702.37(b)(4) (requiring the submission of information about the risks presented by a chemical substance under "the circumstances identified by the manufacturer(s)").
[174] *Id.* § 702.37(b)(6) (requiring manufacturers to determine whether information is "consistent with the scientific standards in 15 U.S.C. 2625(h)" and to submit only information that is deemed consistent with those standards).
[175] Respondents' Motion for Partial Voluntary Remand at 6, *Safer Chems., Healthy Fams. v. EPA*, 945 F.3d 397 (9th. Cir. 2019) (No. 17-72260).
[176] 88 Fed. Reg. at 74,313.

whether *a chemical substance* presents an unreasonable risk of injury to health or the environment."[177] The Proposed Rule further provides that, as a general matter, "it is the burden of the requesting manufacturer to provide EPA with the information necessary to carry out the risk evaluation" and that "the requesting manufacturer agrees to provide, or develop and provide, EPA with information EPA deems necessary to carry out the risk evaluation."[178] These provisions ensure that EPA will have the information it needs to conduct manufacturer-requested risk evaluations, without undue burden or delay. The Proposed Rule also appropriately clarifies that "[i]n circumstances where there have been additional data needs identified . . . but the requesting manufacturer(s) is unable or unwilling to fulfill those needs in a timely manner, [or] has produced information that is insufficient . . . , EPA may deem the request to be constructively withdrawn."[179]

The Proposed Rule would enhance public participation in the review of manufacturers' risk evaluation requests. Currently, the risk evaluation rule provides a single comment period of at least forty-five days on a manufacturer's (often heavily redacted) risk evaluation request.[180] Under the Proposed Rule, EPA would provide: (1) an initial sixty-day comment period on the risk evaluation request and all supporting information, during which time the public can identify any gaps in the request or propose additional conditions of use for evaluation, and (2) an additional sixty-day comment period on the draft conditions of use for the requested risk evaluation.[181] These additional comment opportunities will provide EPA with more information that it can use to determine the scope of the risk evaluation and identify data gaps that must be filled before EPA grants a risk evaluation request.

We support the foregoing changes to the manufacturer-requested risk evaluation process, and we urge EPA to build upon them in its final rule. For instance, the Proposed Rule requires manufacturers to submit, along with their risk evaluation request, information about "[t]he chemical substance's exposure potential, including occupational, general population and consumer exposures, and facility release information."[182] For the reasons set forth above, EPA should also demand information about exposures to the chemical in overburdened communities, and should specify that the required "facility release information" includes information about chemical spills and other unintended releases. If the chemical is intended to be used in products or industrial processes, EPA should require the manufacturer to provide information about other chemicals contained in those products or used in those processes, so EPA can evaluate the potential for such co-exposures to result in increased susceptibility and risk.

[177] 15 U.S.C. § 2605(b)(4)(A) (emphasis added).
[178] 88 Fed. Reg. at 74,323.
[179] *Id.* at 74,325.
[180] 40 C.F.R. § 702.37(e)(4).
[181] 88 Fed. Reg. at 74,324.
[182] *Id.*

III. OTHER PROVISIONS OF THE PROPOSED RULE MUST BE REVISED OR STRENGTHENED

A. The Proposed Rule Should Not Permit the Consideration of Respirators and Other PPE When Calculating Occupational Exposures and Risks

For the reasons set forth in the comments from the American Federation of Labor-Congress of Industrial Organizations ("AFL-CIO") and other labor unions, we strongly oppose the provisions of the Proposed Rule that would permit EPA, in any circumstance, to rely on the use of respirators and other PPE in its calculations of worker risks. In the first ten TSCA risk evaluations, EPA reduced workers' chemical exposures by a factor of up to 1,000 based on the presumed use of PPE. As described in the AFL-CIO comments, EPA's reliance on PPE when calculating worker risks ignores the recommendations of the Occupational Safety and Health Administration ("OSHA") and the National Institute for Occupational Safety and Health, disregards longstanding occupational risk assessment practices, and violates TSCA's mandate to evaluate worker risks in a manner consistent with the best available science. To its credit, the Biden Administration revised those prior risk determinations to eliminate the assumption of PPE use, and the Proposed Rule states that "EPA will not consider exposure reduction based on assumed use of personal protective equipment as part of [a] risk determination."[183] But EPA also "distinguish[es] between an 'assumed' use of PPE and a use that is supported by the reasonably available information" and states that "where EPA has reasonably available information that substantiates use and effectiveness of PPE . . . EPA generally expects to take that information into account in the risk determination."[184]

We agree with the AFL-CIO that any consideration of PPE in a TSCA risk evaluation is unlawful and unacceptable. As EPA has acknowledged, PPE is a *risk management* tool of "last resort."[185] It therefore may be considered, if at all, only during the TSCA risk management process that follows a finding of unreasonable risk, when it can be compared to other, more effective risk management options. By incorporating PPE use into its risk evaluations, EPA erases TSCA's distinction between risk evaluation and risk management, disregards the "best available science" for assessing and controlling occupational risks, and accepts the use of equipment that is "uncomfortable to wear, cumbersome to use, and interfere[s] with communication in the workplace, which can often be critical to maintaining safety and health."[186] Reliance on PPE in a risk evaluation also understates risks to workers who "may be physically unable to wear a respirator."[187] For those reasons and others, OSHA regulations

[183] *Id.* at 74,322–23.
[184] *Id.* at 74,305.
[185] Significant New Use Rules on Certain Chemical Substances, 78 Fed. Reg. 38,210, 38,214 (June 26, 2013).
[186] Occupational Exposure to Methylene Chloride, 62 Fed. Reg. 1494, 1583 (Jan. 10, 1997).
[187] Methylene Chloride and N-Methylpyrrolidone; Regulation of Certain Uses Under TSCA Section 6(a), 82 Fed. Reg. 7464, 7481 (proposed Jan. 19, 2017).

require the measurement of chemical exposures and risks without regard to respiratory protection.[188] We urge EPA to do the same.

B. The Proposed Rule Should Not Authorize Open-ended, "Fit-for-purpose" Risk Evaluations

The Proposed Rule authorizes EPA to adopt "a fit-for-purpose approach" to risk evaluations that "may result in varying types and levels of analysis and supporting information for certain conditions of use."[189] The term "fit-for-purpose" does not appear in TSCA or in the regulatory text of the current risk evaluation rule, and it is not defined in EPA's proposal. Instead, the term appears to give EPA blanket authority to scale back its risk evaluations whenever EPA decides, based on unstated criteria, "to focus more detailed—and therefore more time and resource intensive—quantitative efforts on the conditions of use that pose the greatest potential for exposure and therefore risk."[190] But EPA does not explain how it will determine which conditions of use present the greatest potential exposure without a quantitative analysis, or how it will determine the risks to those who are exposed from multiple conditions of use if not all conditions of use are quantified. Similarly, EPA writes that "the Agency will decide the level of analysis warranted" in an exposure assessment "based on a number of factors, including but not limited to: the substance's physical-chemical properties; environmental fate and transport properties; the likely duration, intensity, frequency, and number of exposures under the condition of use; reasonably available information about the release; and other relevant considerations."[191] This list of factors is so expansive that it does not provide any limitation at all; instead, EPA appears to assert the authority to reduce the "level of analysis" used to evaluate any condition of use or exposure pathway, for any reason whatsoever.

EPA's prior invocations of "fit-for-purpose" analysis heighten the concerns about the Proposed Rule. For instance, EPA has justified its rejection of pre-established and peer-reviewed systematic review methodologies by citing the need for its "fit-for-purpose" approach.[192] But that "fit-for-purpose" TSCA systematic review was fundamentally flawed, and the NASEM found that "the specific and general problems in TSCA risk evaluations are partially due to the decision to develop a largely de novo [systematic review] approach" that "does not meet the criteria of 'comprehensive, workable, objective, and transparent.'"[193] Similarly, in response to

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[188] *See* 29 C.F.R. § 1910.1052 (defining "employee exposure" to methylene chloride as "exposure . . . which occurs or would occur if the employee were not using respiratory protection").
[189] 88 Fed. Reg. at 74,321.
[190] *Id.* at 74,299.
[191] *Id.* at 74,298.
[192] *See* EPA, *Summary of External Peer Review and Public Comments and Disposition for Trichloroethylene (TCE)* 387 (Nov. 2020), https://www.epa.gov/sites/default/files/2020-11/documents/2._summary_of_external_peer_review_and_public_comments_and_disposition_for_for_trichloroethylene_tce_response_to_support_risk_evaluation__0.pdf.
[193] Nat'l Acads. of Scis., Eng'g, & Med., *The Use of Systematic Review in EPA's Toxic Substances Control Act Risk Evaluations* 7 (2021) ("NASEM Systematic Review"), https://doi.org/10.17226/25952.

comments raising concerns about the lack of exposure and toxicity information underlying EPA's designation of twenty low-priority chemicals under TSCA, EPA replied that it "developed a fit-for-purpose screening process appropriate for the designation of Low-Priority Substances."[194] Without clear limits, which are wholly absent in the Proposed Rule, the "fit-for-purpose" label can be used to excuse compliance with established risk evaluation procedures and to justify shortcuts that leave people and the environment exposed to serious, but unstudied, risks.

We agree with EPA that "[r]isk evaluations under TSCA should not be so complex or procedurally cumbersome that they cannot reliably be completed within the timeframes required by the statute."[195] We also agree that EPA need not use the exact same methods and procedures to all of a chemical's conditions of use and exposure pathways, and there may be instances where EPA can find unreasonable risk based on a chemical's release information, hazards, and physical chemical characteristics, without a detailed risk evaluation.[196] But we are opposed to an open-ended "fit for purpose" review standard without clear limits on how or when that authority will be used. To the extent that EPA intends to vary the scope or depth of its analysis, it must provide clear criteria that will ensure that the risk evaluation adheres to the best available science and that all components of the evaluation are robust enough to determine the real-world aggregate and cumulative risks experienced by the most vulnerable populations. We urge EPA to eliminate the Proposed Rule's references to open-ended "fit for purpose" risk evaluations.

C. The Proposed Rule Should Not Reduce the Scope of Peer Review for TSCA Risk Evaluations

The current Risk Evaluation Rule requires "each risk evaluation conducted on chemicals identified pursuant to TSCA section 6(b)(4)(A)" to undergo peer review.[197] As EPA has found, "one important element in ensuring that decisions are based on sound and defensible science is to have an open and transparent peer review process."[198] The SACC's peer reviews of the first ten TCSA risk evaluations provided invaluable feedback to EPA, identifying specific flaws in each

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[194] Final Designation of Low-Priority Substances Under the Toxic Substances Control Act (TSCA); Notice of Availability, 85 Fed. Reg. 11,069, 11,076 (Feb. 26, 2020).
[195] 88 Fed. Reg. at 74,300.
[196] *See, e.g.*, Memorandum on Risk Assessment of the Per- and Polyfluoroalkyl Substances (PFAS) in SN-23-0002-0006 and SN-23-0008-0011, from Risk Assessment Branches/Industrial Chem. Branch, New Chems. Div., Off. of Pollution Prevention & Toxics, EPA, to Risk Mgmt. Branch 1, New Chems. Div., Off. of Pollution Prevention & Toxics, EPA (Nov. 30, 2023), https://www.epa.gov/system/files/documents/2023-12/11-30-23-final-clean-inhance-risk-assessment-of-9-pfas-snuns_marked_redacted.pdf (finding unreasonable risk based on the known release of persistent, bioaccumulative, and toxic PFAS).
[197] 82 Fed. Reg. at 33,743; *see also* 40 C.F.R. § 702.45 ("Peer review will be conducted on the risk evaluations for the chemical substances identified pursuant to 15 U.S.C. 2605(b)(4)(A).").
[198] EPA, *Peer Review Handbook*, at xiii (Oct. 2015) ("Peer Review Handbook"), https://www.epa.gov/sites/default/files/2020-08/documents/epa_peer_review_handbook_4th_edition.pdf.

of those evaluations and recommending ways that EPA could address them.[199] That independent, expert perspective will be no less important for EPA's upcoming risk evaluations.

We therefore strongly oppose provisions of the Proposed Rule that would weaken those existing peer review requirements. Instead of the existing commitment that "peer review will be conducted" on all TSCA risk evaluations for high priority chemicals,[200] the Proposed Rule states that "EPA expects that peer review activities on risk evaluations . . . or portions thereof, will be consistent with . . . applicable peer review policies, procedures, guidance documents, and methods."[201] The rule would allow EPA to withhold risk evaluations from peer review and to limit peer review to select "portions" of an evaluation, meaning EPA could shield the portions that present the greatest concerns from the peer review process. EPA also asserts discretion over "the type of peer review that EPA can conduct" and suggests that it may use "letter peer review" in lieu of full SACC panel review.[202] But only a full panel review provides for public deliberation, including the opportunity for oral comment from the public and open discussion between committee members. EPA's Peer Review Handbook thus provides that panel reviews are "preferable for influential products because they tend to be more deliberative than individual letter reviews and the reviewers can help inform one another. Panels are valuable when the work product is complex and multidisciplinary."[203] EPA's Handbook identifies "health, safety or ecological risk assessments" as "highly influential scientific material," which presumptively require not only peer review but full panel review.[204]

EPA asserts that its Peer Review Handbook allows EPA to forego panel review, and potentially to skip the peer review process altogether, in circumstances where "specific approaches may be used repeatedly" in multiple risk evaluations or where a risk evaluation incorporates "work that has been previously [peer] reviewed."[205] But those are among the circumstances where peer review is most necessary, since it enables the SACC to track EPA's responses to prior recommendations and to weigh in on the development of EPA's risk evaluation procedures over time. Moreover, many TSCA risk evaluations are based at least in part on Integrated Risk Information System ("IRIS") assessments and other analyses that have undergone some prior peer review. If EPA could shield from the SACC all risk evaluation components that are based on previously reviewed approaches or methodologies, it would

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[199] *See* 88 Fed. Reg. at 74,307 ("Reports from those peer review committees proved extremely instructive and resulted in more robust and scientifically defensible products and improvements to EPA methods used in the risk evaluation process.").
[200] 40 C.F.R. § 702.45.
[201] 88 Fed. Reg. at 74,323.
[202] *Id* at 74,307.
[203] Peer Review Handbook at 56.
[204] *Id.* at 43. While EPA notes that certain Highly Influential Scientific Materials may forego peer review if they "have had adequate prior peer review," none of the upcoming risk evaluations have been previously reviewed and all of them are likely to present novel questions and issues for the peer review panel. *See* 88 Fed. Reg. at 74,308.
[205] 88 Fed. Reg. at 74,308 ("EPA believes this provides the needed flexibility to conserve agency resources and avoid redundant peer review.").

significantly diminish the SACC's vital role under TSCA and reduce EPA's incentive to meaningfully engage with and address the SACC's recommendations.

We urge EPA to abandon its proposed changes to the risk evaluation rule's peer review provision and to maintain the existing requirement that all risk evaluations undergo peer review. Further, panel review should remain the norm for TSCA risk evaluations. The opportunities for greater collaboration among reviewers, public participation, and transparency associated with panel reviews are worth the added time and administrative burden associated with full panel reviews. Moreover, with its continuity of membership, the SACC can provide oversight of cross-cutting issues that arise across multiple evaluations, a role that is undermined by letter reviews involving selected SACC members and no open deliberation. While we understand the peer review process can be resource-intensive, EPA can address those concerns by holding virtual SACC meetings (as EPA has done since 2020) or by grouping related risk evaluations for consideration during a single peer review meeting. EPA need not, and should not, sacrifice the independent scientific oversight that panel reviews provide.

D. The Proposed Rule Should Retain and Strengthen the Current Rule's Systematic Review Requirement

The current risk evaluation rule requires EPA to apply a "systematic review method . . . that uses a pre-established protocol to comprehensively, objectively, transparently, and consistently, identify and evaluate each stream of evidence, including strengths, limitations, and relevance of each study and to integrate evidence as necessary and appropriate based upon strengths, limitations, and relevance."[206] Systematic review is a critical step in the risk evaluation process, in that it provides structure for EPA's collection and analysis of different type of data. When conducted pursuant to an accepted, peer-review methodology, systematic review can reduce the risk of bias and guide the consideration of all reasonably available information, as required by TSCA.[207]

EPA's Office of Research and Development; the National Toxicology Program; and the University of California, San Francisco have all developed widely used, peer-reviewed systematic review methods that can be readily adapted for use under TSCA. Instead of doing so, however, the Trump Administration created its own TSCA-specific systematic review method that the NASEM rejected as "confusing," "not transparent," and contrary to accepted "standards of systematic review methodology."[208] In particular, the NASEM found that "the specific and general problems in TSCA risk evaluations are partially due to the decision to develop a largely de novo approach [to systematic review], rather than starting with the foundation offered by approaches that were extant in 2016."[209] They recommended EPA "step back from the approach that it has taken and consider what components of the [Office of Health Assessment and

[206] 40 C.F.R. § 702.33.
[207] *See* NASEM Systematic Review at 10 ("Well-conducted systematic reviews methodically identify, select, assess, and synthesize the relevant body of research, and clarify what is known and not known about the potential benefits and harms of the exposure being researched.").
[208] *Id.* at 7, 26.
[209] *Id.* at 7.

Translation], IRIS, or Navigation Guide methods could be incorporated directly . . . [or] modified for" use under TSCA.[210]

Instead of following that recommendation and strengthening the current rule's systematic review requirements, the Proposed Rule would weaken them. EPA proposes to replace the existing systematic review mandate with a vague reference to "systematic review and/or systematic approaches."[211] The proposal does not define "systematic approaches," and, unlike "systematic review," there is no broadly accepted scientific definition of that term. The proposal thus opens the door to risk evaluations that are not governed by accepted systematic review principles, but rather an undefined alternative that may be used to exclude or dismiss relevant data. As explained in greater detail in the accompanying comments from the University of California, San Francisco's Program on Reproductive Health and the Environment, we urge EPA to preserve and strengthen the risk evaluation rule's existing systematic review requirements.[212]

E. EPA Should Establish Minimum Risk Communication Requirements to Ensure the Results of Its Risk Evaluations Are Accessible to Impacted Populations

The current risk evaluation rule requires "EPA . . . to provide public access to . . . [a] nontechnical summary of the risk evaluation."[213] But the rule currently provides no direction on what information is contained in these nontechnical summaries and does not identify their intended audience. The non-technical summaries must allow groups that are adversely impacted by chemicals, such as workers, consumers, and residents of fenceline communities, to readily identify what potential risks they face from the risk evaluation chemicals. In order to accomplish this, EPA must establish minimum standards of risk communication in the Proposed Rule.

First and foremost, EPA must ensure that the results of risk evaluations are effectively communicated to groups that are exposed to these chemicals. EPA must conduct meaningful outreach to communities, labor unions, and other exposed populations to better understand their preferences and needs and tailor its communication strategy to each target audience, rather than employing a "one-size-fits-all" approach. In its Proposed Rule, EPA "seek[s] comment on how to improve its outreach to the stakeholder community, including education on the TSCA risk evaluation process for small entities."[214] However, EPA only mentions "early engagement with and feedback from all those who manufacture, process, distribute, use or dispose of a chemical."[215] EPA must expand the scope of their engagement beyond representatives from industry. EPA fails to mention any early engagement with groups such as fenceline communities

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[210] *Id.* at 54.
[211] 88 Fed. Reg. at 74,321.
[212] EPA states that, by embedding the systematic review requirement within the regulatory definition of "weight of evidence," the current risk evaluation rule "conflates [weight of scientific evidence] . . . and systematic review." 88 Fed. Reg. at 74,311. We have no objection to separating the systematic review requirement from the "weight of evidence" definition as long as the current requirement is maintained.
[213] 40 C.F.R. § 702.51(d).
[214] 88 Fed. Reg. at 74,316.
[215] *Id.*

and labor unions, despite the fact that these groups often face the most harm from chemical exposures. In order to achieve effective risk communication, EPA must engage multiple impacted groups early in the risk evaluation process and solicit their feedback on what information should be included in the summaries, as well as the preferred form and manner in which the information is delivered.[216]

We also advise EPA to, at a minimum, adhere to the following risk communication principles recommended by EPA in the past and the Interstate Technology and Regulatory Council ("ITRC").[217] EPA should simplify its language in order to make non-technical summaries more digestible, and it should refrain from using any legal or scientific jargon. For example, in its non-technical summary for the methylene chloride risk evaluation, EPA references sections of TSCA without providing context as to what they dictate, and it also uses scientific and technical terms that a layperson would be unfamiliar with.[218] An EPA guidance from 2007 on risk communication advises "translat[ing] technical terms . . . into everyday language the public can easily understand," "avoid[ing] . . . jargon," and "writ[ing] short sentences."[219] Similarly, the ITRC published guidance regarding risk communication and advises that writing for fact sheets should be at "a sixth-grade comprehension level."[220]

EPA should also organize its fact sheets in a way that is easy for readers to process information. For example, in its methylene chloride summary, the information is divided into blocks of text with generic section titles. EPA should consider organizing fact sheets in more reader-friendly structures, such as using visual elements or detailed headings.[221]A good example

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[216] *See* Memorandum from Richard L. Revesz, OMB, to Heads of Exec. Dep'ts & Agencies, https://www.whitehouse.gov/wp-content/uploads/2023/07/Broadening-Public-Participation-and-Community-Engagement-in-the-Regulatory-Process.pdf ("In many cases, it will be most effective to prioritize early engagement with communities, when agencies are still defining regulatory priorities and establishing an overall regulatory program . . . [The White House Office of Information and Regulatory Affairs] encourages agencies to consider how they can prioritize early engagement with affected communities")

[217] *See* Interstate Tech. Regul. Council, *Risk Communication Toolkit*, https://rct-1.itrcweb.org/ (last visited Dec. 14, 2023).

[218] EPA, 740-S-22-003, *Non-Technical Summary of the Risk Evaluation for Methylene Chloride* 2, 4–5 (Oct. 2022), https://www.epa.gov/system/files/documents/2022-11/MC_Non-Technical_Summary_10.31.22.pdf. (using "conditions of use" and other terminology that is not familiar to a broader audience).

[219] EPA, EPA/625/R-05/003, *Risk Communication in Action: The Risk Communication Workbook* 8 (Aug. 2007) ("Risk Commc'n Workbook"), https://www.epa.gov/sites/default/files/2020-12/documents/risk-communication-risk-communication-workbook.pdf.

[220] Interstate Tech. Regul. Council, *14.3.6.2 Fact Sheets and Frequently Asked Questions (FAQs)*, *Risk Communication* in *PFAS*, https://pfas-1.itrcweb.org/14-risk-communication/ (last visited Dec. 14, 2023).

[221] *See* Risk Commc'n Workbook at 8 ("Use headings and other formatting techniques to provide a clear and organized structure."); *id.* at 31 ("Make fact sheets visually interesting by using pictures, graphs, or diagrams to accompany textual information.").

of this is EPA's fact sheet in its proposal to limit PFAS in drinking water, which uses a question-and-answer format to organize its information, allowing a reader to easily grasp the most salient points.[222] Additionally, EPA should make non-technical summaries more accessible by "providing materials in multiple languages for nonnative speakers."[223] We urge EPA to pull demographic information on impacted communities who face risks from facilities that manufacture, process, use, or dispose of chemicals and publish fact sheets in their native languages.[224]

Lastly, the information that EPA conveys through its non-technical summaries should include the results that are most relevant to impacted groups. In its past non-technical summaries, EPA failed to include geographic information pertaining to which facilities' releases present unreasonable risks to surrounding communities, rendering impacted groups unable to readily identify if they are at risk. This information is often buried in technical support documents and multi-tab spreadsheets within the rulemaking docket but is not readily accessible or mentioned anywhere in the non-technical summary.[225] Furthermore, EPA must provide a plain-text summary of each "condition of use" so that fenceline residents, workers, and consumers can easily understand what processes or products can expose them to risk. Finally, EPA should also strive to convey the results of its risk calculations in a simple manner, so impacted groups can better understand the degree of risk that they face.

CONCLUSION

The current risk evaluation rule violates TSCA, resulting in flawed risk evaluations and under-protective risk management rules. While we support EPA's decision to revise that rule, further changes are needed to ensure that EPA's risk evaluations comply with TSCA and reflect chemicals' real-world exposures and impacts. The recommendations set forth above can be readily incorporated into the Proposed Rule, as summarized below:

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[222] EPA, Fact Sheet, *EPA's Proposal to Limit PFAS in Drinking Water* (Mar. 2023), https://www.epa.gov/system/files/documents/2023-04/Fact%20Sheet_PFAS_NPWDR_Final_4.4.23.pdf.

[223] Interstate Tech. Regul. Council, *14.3.6.2 Fact Sheets and Frequently Asked Questions (FAQs)*, *Risk Communication* in *PFAS*, https://pfas-1.itrcweb.org/14-risk-communication/ (last visited Dec. 14, 2023).

[224] *See* Enforcement of Title VI of the Civil Rights Act of 1964—National Origin Discrimination Against Persons With Limited English Proficiency; Policy Guidance, 65 Fed. Reg. 50,123, 50,123 (Aug. 16, 2000)
(acknowledging that "failure to assure that people who are not proficient in English can effectively participate in and benefit from programs and activities may constitute national origin discrimination prohibited by Title VI").

[225] *See, e.g.*, EPA, *1,4-Dioxane Draft RE – Air Exposures and Risk Estimates for Single Year Analysis* (July 10, 2023), https://www.regulations.gov/document/EPA-HQ-OPPT-2022-0905-0029; EPA, *1,4-Dioxane Draft RE – Drinking Water Exposure and Risk Estimates for 1,4-Dioxane Release to Surface Water from Individual Facilities* (July 10, 2023), https://www.regulations.gov/document/EPA-HQ-OPPT-2022-0905-0026.

- 40 C.F.R. § 702.31(c): EPA states that it "will seek" to apply the rule's requirements to its twenty-three pending risk evaluations "to the extent practicable." Given EPA's acknowledgment of the shortcomings in the current risk evaluation rule, EPA should, at a minimum, commit to applying the revised rule in those evaluations to the extent practicable.
- 40 C.F.R. § 702.33: We urge EPA to clarify that people with "greater exposure" because of their aggregate exposures to the same chemical and/or "greater susceptibility" because of their cumulative exposures to multiple chemicals and stressors are potentially exposed or susceptible subpopulations.[226] EPA can incorporate that clarification by adding a definition of "overburdened community" that encompasses aggregate and cumulative exposures or by otherwise expanding its regulatory definition of "potentially exposed or susceptible subpopulation."[227] We also urge EPA to revise the definition of "variability" to acknowledge that the variability can result from extrinsic, human-created factors as well as "inherent natural variation."[228]
- 40 C.F.R. § 702.37(a): In the rule's summary of "evaluation requirements," we urge EPA to eliminate the reference to "fit-for-purpose" risk evaluations and to clarify that, at a minimum, all risk evaluations will consider aggregate exposures, cumulative exposures, and unintended but reasonably foreseen exposures associated with fires and spills, facility malfunctions, natural disasters, and other excess emission events.[229]
- 40 C.F.R. § 702.37(b)(2): EPA should commit to the use of systematic review and delete the Proposed Rule's vague reference to other "systematic approaches."[230]
- 40 C.F.R. § 702.37(b)(4): EPA states that "where appropriate, to the extent practicable, and scientifically justified, EPA will require the development of information generated without the use of new testing on vertebrates." But TSCA also requires non-animal test methods to "provide information of equivalent or better scientific quality and relevance for assessing risks of injury to health or the environment" than traditional animal tests.[231] We urge EPA to revise the risk evaluation rule to reflect that requirement as well.
- 40 C.F.R. § 702.39(b)(3): In addition to identifying "the ecological receptors that EPA plans to evaluate," the risk evaluation scope should identify any endangered species, threatened species, species of special concern, or critical habitat that may be impacted by the chemical's releases.[232]
- 40 C.F.R. § 702.39(b)(4): The conceptual model for a risk evaluation should include the analysis of co-exposures to chemical and non-stressors that worsen the chemical's impacts.[233]

[226] 15 U.S.C. § 2602(12).
[227] *See supra* pp. 14–18.
[228] 88 Fed. Reg. at 74,320.
[229] *See supra* pp. 18–21.
[230] *See supra* pp. 36–37.
[231] 15 U.S.C. § 2603(h)(2)(A).
[232] *See supra* p. 25.
[233] *See supra* pp. 16–18.

- 40 C.F.R. § 702.39(c): EPA should require hazard assessments to consider, in addition to the elements currently listed in the Proposed Rule, all relevant human health and ecological endpoints, including developmental neurotoxicity and endocrine disrupting effects in humans and sublethal effects on wildlife and plants.[234]
- 40 C.F.R. § 702.39(d)(3): EPA should require exposure assessments to consider, in addition to the data sources current listed in the Proposed Rule, information about co-exposures to other chemicals that are manufactured, processed, used, distributed, disposed of, or otherwise detected along with the chemical substance and which may contribute to cumulative effects. EPA should also consider information about excess emission events and unplanned releases, including information about prior chemical incidents; risk management plans; and EPCRA Tier I and Tier II forms. Finally, EPA must evaluate aggregate exposures to a chemical substance whenever such exposures are known, intended, or reasonably foreseen to occur.[235]
- 40 C.F.R. § 702.39(f)(1): Instead of requiring a "single determination as to whether the chemical substance presents an unreasonable risk," EPA should require a determination as to whether a chemical substance, as a whole, presents unreasonable risk across its conditions of use. As EPA proposed in 2017, EPA should also affirm its authority to make an early unreasonable risk determination for the chemical substance based on certain conditions of use and to begin risk management for those conditions of use while it completes its risk evaluation.[236]
- 40 C.F.R. § 702.39(f)(2): EPA should revise this provision to clarify that TSCA does not permit the consideration of personal protective equipment when evaluating occupational exposures and risks.[237]
- 40 C.F.R. § 702.41: EPA should maintain the requirement in the current risk evaluation rule that all TSCA risk evaluations undergo panel peer review.[238]
- 40 C.F.R. § 702.49: EPA should establish minimum requirements for the contents and distribution of its non-technical risk evaluation summaries, to ensure the most impacted communities and populations are informed of those summaries and are able to understand the risks they face.[239]

If you have any questions about these comments, please contact Jonathan Kalmuss-Katz at jkalmusskatz@earthjustice.org or Kelly Lester at klester@earthjustice.org.

Respectfully submitted,

Alaska Community Action on Toxics
Center for Environmental Health
Earthjustice
Natural Resources Defense Council

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[234] *See supra* p. 24-25.
[235] *See supra* pp. 18–21.
[236] *See supra* pp. 6–9.
[237] *See supra* pp. 32.
[238] *See supra* pp. 34–36.
[239] *See supra* pp. 37–39.

Sierra Club
Toxic-Free Future
Union of Concerned Scientists