February 13, 2024

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: Tris(2-chloroethyl) Phosphate ("TCEP"), Draft Risk Evaluation Under the Toxic Substances Control Act, Docket No. EPA-HQ-OPPT-2023-0265

Dear Assistant Administrator Freedhoff:

The undersigned organizations submit these comments on the Environmental Protection Agency's ("EPA's") Draft Risk Evaluation for Tris(2-chloroethyl) Phosphate ("TCEP") under the Toxic Substances Control Act ("TSCA").[1]

Every day, people are exposed to TCEP and other toxic flame retardants in their homes, workplaces, and communities. TCEP is found in furniture and textiles, insulation and flooring, baby carriers and car seats, and other widely used products. It contaminates indoor and outdoor air, drinking water supplies, and fish and wildlife. When materials containing TCEP are disposed of or recycled, TCEP—and sometimes other highly toxic byproducts—are released from waste incinerators, recycling facilities, and landfills and can leach out of recycled-content products.

TSCA requires EPA to comprehensively evaluate TCEP's exposures and risks, including risks to subpopulations who experience greater risk than the general population because they have greater exposures or are more susceptible to harm from TCEP.[2] Where, as here, EPA finds unreasonable risk, it must regulate the chemical "to the extent necessary so that [it] no longer presents such risk."[3] The draft risk evaluation, while correctly finding that TCEP presents unreasonable risk to human health and the environment, fails to consider the full extent of those risks and deprives EPA of the information it needs to ensure the protection of public health and the environment.

---

[1] EPA, EPA-740-D-23-002, *Draft Risk Evaluation for Tris(2-chloroethyl) Phosphate (TCEP)* (Dec. 2023) ("Draft TCEP Risk Evaluation"), https://www.epa.gov/system/files/documents/2023-12/tcep_draft_risk_evaluation_20231207_hero_public-release.pdf.

[2] 15 U.S.C. § 2605(b)(4)(A) (requiring EPA to evaluate chemicals' risks to "potentially exposed or susceptible subpopulation[s]"); *id.* § 2602(12) (defining "potentially exposed or susceptible subpopulation").

[3] *Id.* § 2605(a).

First, despite EPA's mandate to conduct risk evaluations using the "best available science,"[4] EPA disregards the broad scientific consensus that flame retardants like TCEP should be evaluated and regulated as a class, as expressly authorized by TSCA. While other agencies, states, and scientific bodies are actively pursuing that recommended class-based approach, EPA evaluates TCEP's exposures and risks in isolation, understating the chemical's real-world impacts and inviting the substitution of one toxic flame retardant for another.

Second, EPA unlawfully excludes multiple conditions of use from its TCEP risk determination, claiming that it lacks the information needed to evaluate them. But TSCA requires EPA to assess the risks associated with all of a chemical's conditions of use and to collect or generate the information it needs to do so. Here, not only has EPA failed to use TSCA's information collection authorities to fill asserted data gaps, it also denied a petition seeking additional testing of TCEP by asserting that such testing was not necessary and that EPA could evaluate TCEP's risks adequately using existing data and models. Most problematically, EPA fails to use reasonably available information to calculate the full risks from TCEP disposal, one of the chemical's most significant conditions of use.

Third, for the conditions of use that it does consider, EPA repeatedly understates TCEP's exposures and risks. EPA relies on unsupported assumptions about exposure rates and durations, ignores the impact of background exposures to TCEP, improperly discounts the studies that demonstrate the greatest hazards, and disregards its own guidance concerning the use of uncertainty factors. Compounding those flaws, EPA violates TSCA's mandate to evaluate TCEP's risks to potentially exposed or susceptible subpopulations, including people who are exposed to TCEP from multiple conditions of use and exposure pathways and routes, or who are more susceptible to harm because of their exposures to multiple flame retardants that can exacerbate the risks from TCEP. EPA also underestimates risks to tribal populations who experience increased TCEP exposures not only from the consumption of contaminated fish but also from other subsistence foods and from heightened exposure associated with inadequate waste management infrastructure and open burning of solid waste, among other pathways. EPA substantially understates TCEP's risks to wildlife and fails to consider the chemical's effects on threatened and endangered species and other species of special conservation concern. Finally, EPA relies on vague and underprotective unreasonable risk thresholds that would leave workers, consumers, and fenceline communities exposed to unacceptable harm.

We acknowledge and appreciate the work that went into EPA's draft risk evaluation, which does improve on prior risk evaluations in several respects. EPA correctly identifies tribal populations as a potentially exposed or susceptible subpopulation, recognizes the increased exposures and risks tribal populations often face from fish consumption, and calculates those dietary exposures using both contemporary and heritage tribal fish consumption rates. EPA also considers aggregate risks to certain populations who are exposed from multiple exposure routes, a legally required analysis that EPA has neglected in the past. But EPA cannot adequately evaluate the risks associated with TCEP, or protect the people who are exposed to it, if it persists in ignoring 30 percent of TCEP's conditions of use and systematically understates the risks from

[4] *Id.* § 2625(h).

the other 70 percent. TSCA requires EPA to evaluate the risks from all of TCEP's conditions of use, to all potentially exposed or susceptible subpopulations, so EPA has the information it needs to fully eliminate TCEP's unreasonable risks. We urge EPA to revise its risk evaluation, as set forth in greater detail below, so it complies with those statutory requirements.

I. EPA Cannot Meaningfully Evaluate or Successfully Regulate Individual Flame Retardants in Isolation

Organohalogen flame retardants ("OFRs"), including TCEP, are added to furniture and textiles, furniture foam and vehicle cushioning, building and construction materials, and a broad range of other products.[5] Because they are "mixed into but not chemically bonded to materials, [they] can leach out of products" and into people, wildlife, and the environment.[6] Ninety-seven percent of people in the United States have at least one flame retardant in their blood,[7] and 75 percent of people tested in one study had a TCEP metabolite in their urine.[8]

People are routinely exposed to, and harmed by, combinations of OFRs in their workplaces, homes, and communities. Multiple flame retardants, including TCEP, have been detected in household dust,[9] college dormitories,[10] daycare centers and nurseries,[11] and a range of wildlife species.[12] Multiple OFRs, including TCEP, are also associated with an increased risk of cancer, reproductive harm, and other overlapping health effects.[13] Evaluating the individual

---

[5] *See, e.g.,* Joseph A. Charbonnet et al., *Flammability Standards for Furniture, Building Insulation and Electronics: Benefit and Risk*, 6 Emerging Contaminants 432, 435–38 (2020); Draft TCEP Risk Evaluation at 20–21.
[6] *See* Draft TCEP Risk Evaluation at 19.
[7] Liza Gross, *Flame Retardants in Consumer Products Are Linked to Health and Cognitive Problems*, Wash. Post (Apr. 15, 2013), https://www.washingtonpost.com/national/health-science/flame-retardants-in-consumer-products-are-linked-to-health-and-cognitive-problems/2013/04/15/f5c7b2aa-8b34-11e2-9838-d62f083ba93f_story.html.
[8] Robin E. Dodson et al., *Urinary Biomonitoring of Phosphate Flame Retardants: Levels in California Adults and Recommendations for Future Studies*, 48 Env't Sci. & Tech. 13625, 13627 (2014) (reporting detections of bis(2-chloroethyl) phosphate ("BCEP"), a TCEP metabolite).
[9] Robin E. Dodson et al., *After the PBDE Phase-out: A broad Suite of Flame Retardants in Repeat House Dust Samples from California*, 46 Env't Sci. & Tech. 13056 (2012).
[10] Robin E. Dodson et al., *Flame Retardant Chemicals in College Dormitories: Flammability Standards Influence Dust Concentrations*, 51 Env't Sci. & Tech. 4860, 4864 (2017).
[11] Asa Bradman et al., *Flame Retardant Exposures in California Early Childhood Education Environments*, 116 Chemosphere 61 (2014).
[12] *See infra* Point VII.D.
[13] *See* Letter from David A. Eastmond, Professor & Chair, Dep't of Cell Biology & Neuroscience, Univ. of Cal., Riverside, to Consumer Prod. Safety Comm'n, in Support of Organohalogen Flame Retardants (Sept. 14, 2014), https://greensciencepolicy.org/docs/eastmond-cpsc-statement-14-09-15.pdf; *see also* David A. Eastmond, Supporting Materials in Support of Organohalogen Flame Retardants Petition to the

flame retardants in isolation understates the risks to people and wildlife who are exposed to multiple OFRs and violates TSCA's mandate to consider risks to subpopulations who are more susceptible to harm because of their cumulative exposures.[14]

Flame retardants also have overlapping uses and can be substituted for one another, such that efforts to regulate one flame retardant at a time do not eliminate risk but rather shift the market to other similarly toxic substances. In the 1970s and 1980s, polychlorinated biphenyls ("PCBs") and polybrominated biphenyls ("PBBs") were widely used as flame retardants until they were found to cause cancer and other severe environmental and health impacts.[15] The regulation of PCB and PBB flame retardants resulted in the increased use of polybrominated diphenyl ethers ("PBDEs"), which were later found to cause reproductive, developmental, and neurodevelopmental harm.[16] Even within the PBDE subclass, chemical manufacturers often responded to regulation of a particular chemical by making minor changes to its underlying chemistry and replacing it with a closely related, similarly toxic substitute.[17] As phaseouts of PBDEs began in the 1990s, industry turned to harmful organophosphate ester flame retardants like TCEP, tripentyl phosphate ("TPP"), and tris(2,3-dibromopropyl) phosphate ("TDBPP").[18] Even now, as production of TCEP has decreased in recent years, other organophosphate ester flame retardants like 2-Propanol, 1-chloro-, 2,2',2''-phosphate ("TCPP") and 2-Propanol, 1,3-dichloro-, phosphate (3:1) ("TDCPP") have emerged as replacements.[19] As the United Nations

---

Consumer Product Safety Commission (Sept. 14, 2014), https://greensciencepolicy.org/docs/eastmond-cpsc-supporting-materials-14-09-15.pdf.

[14] *See infra* Point VI.B.

[15] Barbara Hales & Shirra Freeman, Nat'l Collaborating Ctr. for Env't Health, *Regrettable Replacements: The Case of Chemical Flame Retardants* (July 8, 2020), https://ncceh.ca/resources/evidence-briefs/regrettable-replacements-case-chemical-flame-retardants.

[16] *Id.*; Agency for Toxic Substances & Disease Registry ("ATSDR"), *Toxicological Profile for Polybrominated Diphenyl Ethers (PBDEs)* 11–26 (Mar. 2017) ("Tox Profile for PBDEs"), https://www.atsdr.cdc.gov/toxprofiles/tp207.pdf.

[17] Martin Sharkey et al., *Phasing-Out of Legacy Brominated Flame Retardants: The UNEP Stockholm Convention and Other Legislative Action Worldwide*, 144 Env't Int'l 106041, at *3 (2020) ("Penta- and Octa- BDE commercial mixtures were listed in the Stockholm Convention in 2004, while Deca-BDE—used as a replacement for Penta-/Octa-BDEs in several applications—was listed much later, in 2019.").

[18] Arlene Blum et al., *Organophosphate Ester Flame Retardants: Are They a Regrettable Substitution for Polybrominated Diphenyl Ethers?*, 6 Env't Sci. & Tech Letters 638, 639 (2019).

[19] *See* EPA, EPA-740-R1-5001, *TSCA Work Plan Chemical Problem Formulation and Initial Assessment: Chlorinated Phosphate Ester Cluster Flame Retardants* at 11 (Aug. 2015) ("TSCA Problem Formulation"), https://www.epa.gov/sites/default/files/2015-09/documents/cpe_fr_cluster_problem_formulation.pdf ("[A]lthough commercial uses of TCEP as a flame retardant were declining . . . TCPP and TDCPP were structurally similar and increasing as substitutes for TCEP.").

Environment Programme and others have acknowledged, flame retardants present "a classic pattern … of regrettable substitutions: introducing a toxic chemical, ban[ning] it after noticing its harmful impacts, then using a new chemical—probably equally toxic but not yet scrutinized and proven as so—to replace it."[20]

To end this "cynical replacement of one harmful chemical by another,"[21] scientists, policy makers, and EPA itself have called for the evaluation and regulation of classes or subclasses of OFRs. In response to a 2017 petition, the Consumer Product Safety Commission ("CPSC") agreed to initiate rulemaking that would ban the use of OFRs as a class in four categories of consumer products.[22] The CPSC found "overwhelming scientific evidence" "regarding the potential toxicity of OFRs" as a class.[23] This class-based regulatory approach was supported by the National Academies of Sciences, Engineering, and Medicine ("National Academies"), which issued recommendations on how the CPSC could define and assess specific OFR subclasses.[24] The European Union has banned the use of OFRs in various types of products and electronic equipment,[25] and more than a dozen states have regulated flame retardants as a class or

[20] UNEP, *Flame Retardants*, https://www.unep.org/explore-topics/chemicals-waste/what-we-do/persistent-organic-pollutants/flame-retardants (last visited Feb. 13, 2024).
[21] Joseph Allen, Opinion, *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.
[22] *See* Guidance Document on Hazardous Additive, Non-Polymeric Organohalogen Flame Retardants in Certain Consumer Products, 82 Fed. Reg. 45,268, 45,268 (Sep. 28, 2017) ("On June 30, 2015, a coalition of consumer advocates and health professionals petitioned the Commission to declare four categories of consumer products containing OFRs to be 'banned hazardous substances' under the Federal Hazardous Substances Act (''FHSA''). . . . On September 20, 2017, the Commission voted to grant the petition . . .").
[23] *Id.* at 45,269; *see also id.* ("[T]he evidence currently before the Commission suggests OFRs, as a class of chemicals, present a serious public health issue.").
[24] Nat't Acads. of Scis., Eng'g, & Med., *A Class Approach to Hazard Assessment of Organohalogen Flame Retardants* (2019) ("NASEM OFRs Approach"), https://nap.nationalacademies.org/catalog/25412/a-class-approach-to-hazard-assessment-of-organohalogen-flame-retardants.
[25] Commission Regulation 2019/2021of 1 October 2019 Laying Down Ecodesign Requirements for Electronic Displays Pursuant to Directive 2009/125/EC of the European Parliament and of the Council, Amending Commission Regulation (EC) No 1275/2008 and Repealing Commission Regulation (EC) No 642/2009, 2019 O.J. (L 315) (EU), https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32019R2021&rid=5 (banning use of halogenated flame retardants in electronic display enclosures for televisions and other products).

subclass.[26] The Agency for Toxic Substances and Disease Registry ("ATSDR") released a toxicological profile for the subclass of "phosphate ester flame retardants," including TCEP.[27]

TSCA expressly authorizes EPA to conduct risk evaluations for chemical classes or "categories,"[28] and requires EPA to conduct all risk evaluations "in a manner consistent with the best available science."[29] Here, the evaluation of TCEP's risks in isolation is contrary to the best available science for the assessment and regulation of flame retardants. The National Academies have found that a class-based approach would "make regulatory hazard and risk assessment much more efficient" and "begin to . . . address[]" the "problem of regrettable substitution," making it "the only possible practical approach for a set of chemicals as large as the OFRs."[30] A class-based risk evaluation would also facilitate the consideration of cumulative risk, as the National Academies and EPA's Science Advisory Committee on Chemicals ("SACC") have consistently called for.[31] Recognizing the benefits of a multiple-chemical assessment, in 2014 EPA commenced a TSCA risk assessment for TCEP along with two structurally similar phosphate ester flame retardants that were "increasing[ly used] as substitutes for TCEP."[32] And EPA and other governmental authorities have long evaluated other organohalogen chemicals—such as PCBs, organophosphate pesticides ("OPs"), and per- and polyfluoroalkyl substances ("PFAS")—by class because of their shared toxicity and persistence.

There is no legal or scientific basis for EPA to reject this "movement toward a class approach" and to evaluate the risks posed by TCEP in isolation.[33] In addition to violating TSCA's "best available science" requirement, EPA's proposed approach is a poor use of the Agency's limited resources. EPA should not spend years on the evaluation and management of TCEP's risks only to see TCEP replaced by TCPP, TDCPP, and other toxic flame retardants that EPA has not targeted for TSCA regulation. To fully account for TCEP's risks and minimize the likelihood of regrettable substitutions, we urge EPA to: (1) evaluate the cumulative risks from exposures to TCEP and other flame retardants, as set forth in greater detail below,[34] and (2) pursue a class-based evaluation of OFRs or identified OFR subclasses, which include known TCEP substitutes.

---

[26] *See* List of State or Local Laws Banning Organohalogen Flame Retardants in Upholstered Furniture (Sept. 22, 2022) (attached as **Exhibit A**).
[27] ATSDR, *Toxicological Profile for Phosphate Ester Flame Retardants* (Sept. 2012), https://www.atsdr.cdc.gov/toxprofiles/tp202.pdf.
[28] 15 U.S.C. § 2625(c).
[29] *Id.* § 2625(h).
[30] NASEM OFRs Approach at 4, 6.
[31] *See infra* Point VI.B.
[32] TSCA Problem Formulation at 11.
[33] NASEM OFRs Approach at 6.
[34] *See infra* Point VI.B.

II. EPA Appropriately Found That TCEP Presents Unreasonable Risk to Human Health and the Environment

The draft risk evaluation appropriately concludes that "TCEP presents unreasonable risks to human health and the environment."[35] While EPA overlooks and underestimates many of TCEP's risks, its finding that TCEP presents unreasonable risk is well supported by the record.

TCEP is associated with an increased risk of cancer, neurological harm, and reproductive harm, as well as other serious health and environmental effects.[36] According to EPA's own estimates, nearly every occupational condition of use presents unreasonable cancer risks, including risks as high as 6.9-in-100 from workers' dermal exposure to TCEP in paints and coatings alone.[37] Inhalation of TCEP from roofing insulation presents a 4.5-in-100 cancer risk, more than 40,000 times higher than EPA's standard 1-in-1,000,000 unreasonable risk benchmark.[38] TCEP has been widely used in car seats, nursing pillows, and baby toys, and EPA calculated reproductive risks from infants' mouthing of TCEP-containing blocks that are 30 times worse than the Agency's accepted benchmark level.[39] TCEP presents particularly severe risks to tribal communities, including a greater than 1-in-10 cancer risk from the consumption of TCEP-contaminated fish alone.[40] Finally, EPA also calculated unreasonable risks to aquatic life from multiple uses of TCEP, some of which were up to 30 times greater than EPA's benchmark Risk Quotient ("RQ") of 1.0.[41]

While those calculations fail to capture the full extent of TCEP's risks, the draft risk evaluation does contain several important improvements from EPA's prior TSCA risk evaluations. Among them:

- EPA made a risk determination for TCEP as a whole chemical, as required by TSCA's mandate "to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment."[42]
- EPA calculated the aggregate risks to consumers who are exposed to TCEP from multiple exposure routes,[43] although it failed to consider aggregate risks to workers, to the general population, and to people who were exposed from multiple conditions of use.[44]
- EPA evaluated TCEP's risks to fenceline communities, a legally required analysis that EPA nonetheless excluded from its first ten TSCA risk evaluations.[45]

---

[35] Draft TCEP Risk Evaluation at 21.
[36] *Id.* at 250–85.
[37] *Id.* at 302.
[38] *Id.* at 310.
[39] *Id.* at 308.
[40] *Id.* at 321.
[41] *Id.* at 132.
[42] 15 U.S.C. § 2605(b)(4)(A).
[43] Draft TCEP Risk Evaluation at 338–40.
[44] *See infra* Point VI.A.
[45] *See* Draft TCEP Risk Evaluation at 205–06.

- EPA correctly identified tribal populations as a "potentially exposed or susceptible subpopulation"[46] whose risks EPA must specifically consider, acknowledged that tribal populations' distinctive cultures and lifeways give rise to many unique exposure scenarios and increased exposures to chemicals such as TCEP, and calculated exposure and risk associated with one such scenario—fish consumption.

III. EPA Violates TSCA's Mandate to Evaluate All of TCEP's Conditions of Use

A. EPA's Risk Calculations and Unreasonable Risk Determination Exclude Six of TCEP's Twenty Identified Conditions of Use

While the draft risk evaluation identifies 20 conditions of use for TCEP, EPA only determines the risks associated with 14 of them. For the remaining six conditions of use—commercial use of fabric and textile products, commercial use of foam seating and bedding products, commercial use of wood resin composites, commercial use of insulation, consumer use of paints and coatings, and disposal (collectively, the "Unassessed Conditions of Use")—EPA claims that it "does not have sufficient information to determine whether they contribute to TCEP's unreasonable risks."[47]

EPA's failure to evaluate the risks associated with those conditions of use violates multiple provisions of TSCA. First and foremost, TSCA section 6(b) requires EPA to "conduct risk evaluations . . . to determine whether a chemical substance presents an unreasonable risk . . . under the conditions of use."[48] 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."[49] TSCA therefore requires EPA to "determine" the risks associated with a chemical under 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," which EPA concedes it did not do for the Unassessed Conditions of Use.[50] As EPA and the U.S. Court of Appeals for the Ninth Circuit have both recognized, the plain text of TSCA and of EPA's implementing regulations "unambiguously do not grant EPA the discretion" to exclude conditions of use from a

---

[46] 15 U.S.C. §§ 2602(12), 2605(b)(4)(A), (F).

[47] Draft TCEP Risk Evaluation at 21. In addition to the Unassessed Conditions of Use, EPA failed to measure the risks associated with other conditions of use, such as recycling, but nonetheless asserted that those uses would not contribute to TCEP's unreasonable risks. As described below, those conclusory determinations also violate TSCA. *See infra* Point IV.E.

[48] 15 U.S.C. § 2605(b)(4)(A). TSCA defines "conditions of use" as "the circumstances . . . under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of." *Id.* § 2602(4).

[49] *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).

[50] 15 U.S.C. §§ 2602(4), 2605(b)(4)(A).

risk evaluation.[51] But EPA's failure to evaluate the risks associated with the Unassessed Conditions of Use and to determine whether they contribute to unreasonable risk has the exact same effect as excluding those conditions of use from the risk evaluation.

Second, TSCA section 6(a) provides that, "if the Administrator determines" through a risk evaluation under TSCA section 6(b) "that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or mixture, or that any combination of such activities, presents an unreasonable risk of injury to health or the environment," EPA "shall" regulate the chemical "to the extent necessary so that the chemical substance or mixture no longer presents such risk."[52] EPA cannot comply with that mandate to eliminate TCEP's unreasonable risks if EPA has not determined the extent to which each condition of use, individually and in "combination," contributes to such risks. The draft risk evaluation thus deprives EPA of the information and analysis that it needs to satisfy TSCA's risk management requirements. Even if risks from certain Unassessed Conditions of Use "are expected to be lower than those associated with [conditions of use] already quantified,"[53] as EPA claims, EPA would still need to evaluate those conditions of use to address the risks presented by "any combination of" TCEP's uses.[54] TSCA's mandate to "determine whether a chemical substance presents an unreasonable risk . . . under the conditions of use" does not permit EPA to stop looking as soon as it identifies some unreasonable risk from some condition of use.[55] Instead, EPA must evaluate the full extent of a chemical's risks under all its conditions of use, individually and in combination.

Third, EPA's failure to evaluate the Unassessed Conditions of Use violates TSCA's requirement to "take into consideration information . . . that is reasonably available to the Administrator" when conducting risk evaluations.[56] EPA's regulations define "reasonably available information" to include not only information in EPA's possession but also "information that EPA . . . can reasonably generate, obtain, and synthesize for use in risk evaluations, considering the deadlines specified in TSCA."[57] Congress provided EPA up to three-and-a-half years to complete a TSCA risk evaluation, following a year-long prioritization process, precisely

---

[51] *Safer Chems., Healthy Fams. v. EPA,* 943 F.3d 397, 419 (9th Cir. 2019) (explaining why TSCA's text does not authorize EPA to exclude conditions of use); Procedures for Chemical Risk Evaluation Under the Toxic Substances Control Act (TSCA), 88 Fed. Reg. 74,292, 74,297 (proposed Oct. 30, 2023) (stating, in proposed revisions to TSCA risk evaluation rule, that "[i]n the absence of comprehensive risk evaluations on chemical substances (i.e., an approach that considered only a subset of a chemical's uses), the unevaluated uses would create uncertainty as to whether EPA had fully addressed a chemical's unreasonable risk and further delay progress on the backlog of existing chemicals").
[52] 15 U.S.C. § 2605(a).
[53] *See, e.g.,* Draft TCEP Risk Evaluation at 364.
[54] 15 U.S.C. § 2605(a).
[55] *Id.* § 2605(b)(4)(A).
[56] *Id.* § 2625(k).
[57] 40 C.F.R. § 702.33 (defining "reasonably available information").

so EPA would have sufficient time to collect or generate the information it needs to fully evaluate a chemical's conditions of use.[58] Congress also authorized EPA to order testing related to chemical hazards and exposures, to promulgate rules requiring the submission of existing studies and information, and to "subpoena . . . the production of reports, papers, documents, answers to questions, and other information that the Administrator deems necessary" to conduct a risk evaluation.[59] Yet EPA never used any of that authority to fill long-acknowledged data gaps with respect to TCEP. EPA also failed to add TCEP to the Toxics Release Inventory ("TRI") until 2023—too late to generate release information for the draft risk evaluation—and to lower the reporting threshold for the Chemical Data Reporting ("CDR") rule and eliminate reporting loopholes that allow TCEP manufacturers and importers to avoid reporting. EPA's failure to collect information that it claims is needed to evaluate TCEP "stands in the face of its significant statutory authority to require that this information be reported . . . and runs contrary to its obligation to collect reasonably available information to inform and facilitate its regulatory obligations under TSCA."[60]

While TSCA's prioritization and risk evaluation deadlines provided ample time for EPA to collect the information it needs to fully evaluate TCEP, in this case EPA has known of TCEP's likely risks and data gaps for far longer. EPA added TCEP to the TSCA Work Plan—a list of chemicals that EPA has identified for future assessment—in 2012.[61] In 2014, EPA initiated a risk assessment for TCEP and two other chlorinated phosphate ester flame retardants.[62] The following year, EPA released a Problem Formulation and Initial Assessment for that flame retardant cluster, which identified several "data gap[s]" that are "necessary to evaluate" the full scope of TCEP's risks.[63] To fill those identified gaps, in 2017 Earthjustice, the Natural Resources Defense Council, and other public interest organizations petitioned EPA to require additional testing of TCEP.[64] Of relevance here, the petition sought (1) "testing . . . to estimate . . . exposures from disposal facilities in the U.S.," including environmental monitoring around municipal landfills, (2) "testing . . . to estimate . . . exposures from recycling facilities in the U.S.," including

---

[58] 15 U.S.C. § 2605(b)(4)(G).
[59] *Id.* § 2610(c); *see also id.* §§ 2603(a), 2607(b).
[60] *Asbestos Disease Awareness Org. v. Wheeler*, 508 F. Supp. 3d 707 (N.D. Cal. 2020) (holding that EPA's denial of a petition seeking expanded CDR reporting for asbestos violated EPA's obligation to collect "reasonably available information" for use in TSCA risk evaluation).
[61] EPA, *TSCA Work Plan Chemicals* (June 2012), https://www.epa.gov/sites/default/files/2014-02/documents/work_plan_chemicals_web_final.pdf.
[62] *See* EPA, *Assessments Conducted on TSCA Work Plan Chemicals Prior to June 22, 2016*, https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/assessments-conducted-tsca-work-plan-chemicals-prior#process (last updated Feb. 19, 2021).
[63] TSCA Problem Formulation at 9, 36–40.
[64] Petition from Earthjustice & Nat. Res. Def. Council, to EPA, to Order Testing of the Chlorinated Phosphate Ester Cluster Flame Retardants (TCEP, TCPP And TDCPP) Under Section 4(A) of the Toxic Substances Control Act (January 6, 2017), https://www.epa.gov/sites/default/files/2017-01/documents/cpe_test_petition_appx_final_0.pdf.

environmental monitoring in the vicinity of such facilities, and (3) "testing . . . to generate toxicity data for terrestrial organisms."[65]

EPA denied that petition, finding that the petitioners had not "demonstrate[d] that there is insufficient information upon which the effects of the [Chlorinated Phosphate Ester Cluster] chemicals," including TCEP, "can reasonably be determined or predicted."[66] EPA repeatedly asserted that "the approaches requested by the petitioners . . . may not be needed" and suggested that EPA could use "modeling (ChemSTEER, E–FAST and AERMOD) along with existing data to estimate" releases and exposures to TCEP, without additional testing.[67] In announcing the petition denial, EPA committed that it "*will evaluate all conditions of use* and will apply a broad range of scientifically defensible approaches—using data, predictive models, or other methods . . . to characterize risk and enable the Administrator to make a determination of whether the chemical substance presents an unreasonable risk."[68]

After studying TCEP for nearly a decade and refusing to conduct additional testing, EPA now pleads ignorance about the very exposures and risks that EPA previously declined to investigate. But TSCA requires EPA to use "reasonably available information" to evaluate all of TCEP's conditions of use, as EPA promised to do in 2017. To the extent that EPA lacks chemical-specific exposure data for certain conditions of use, EPA can use data from other flame retardants with similar uses or, if needed, model exposures based on reasonable and health protective assumptions.[69] EPA cannot, however, rely on its own inaction over the last decade to excuse its failure to conduct the risk evaluation required by TSCA.

B. EPA Has Not Adequately Assessed the Risks to Health and the Environment from TCEP Disposal

TSCA requires EPA to comprehensively evaluate the risks to health and the environment from TCEP disposal and determine whether disposal contributes to the chemical's unreasonable risks. As discussed above, the statute is clear that a risk evaluation must address *all* of a chemical's "conditions of use,"[70] which include the "circumstances . . . under which a chemical substance is intended, known, or reasonably foreseen to be . . . disposed of."[71] Contrary to this statutory mandate, EPA asserts in the draft risk evaluation that it "does not have sufficient

---

[65] *Id.* at 15–17.
[66] Chlorinated Phosphate Ester (CPE) Cluster; TSCA Section 21 Petition; Reasons for Agency Response, 82 Fed. Reg. 17,601, 17,604–05, 17,607–08 (Apr. 12, 2017).
[67] *Id.* at 17,606–07 (citations omitted)
[68] *Id.* at 17,603 (emphasis added).
[69] EPA, EPA-740-R-20-009, *Final Scope of the Risk Evaluation for Tris(2-chloroethyl) Phosphate* 36 (Aug. 2020), https://www.epa.gov/sites/default/files/2020-09/documents/casrn_115-96-8_tris2-chloroethyl_phosphate_tcep_final_scope.pdf ("EPA plans to review literature sources identified and if surrogate data are found, these data will be matched to applicable conditions of use for potentially filling data gaps.").
[70] 15 U.S.C. § 2605(b)(4)(A).
[71] *Id.* § 2602(4).

information to determine whether [disposal] contribute[s] to TCEP's unreasonable risks."[72] EPA's assertion that it partially assessed disposal-related risks by considering some landfill- and incineration-related risks "in each [condition of use]/[occupational exposure scenario] as opposed to a separate [condition of use]" for disposal does not fill this gap.[73]

This failure is particularly concerning given EPA's own findings indicating that disposal is and will be a primary source of TCEP releases, exposures, and risks for the foreseeable future. As EPA acknowledges in the draft risk evaluation, TCEP has been used in a variety of consumer and commercial products, many of which have long service lives and will continue to enter the waste stream over a long time horizon.[74] Further, as EPA acknowledges, "TCEP is added to manufactured materials via physical mixing rather than chemical bonding."[75] "Consequently, it is highly likely that TCEP will be released from the solid wastes [disposed in landfills] and enter the leachate."[76] Compounding this threat, "TCEP is persistent in the environment," "is anticipated to persist in groundwater for substantially longer than in other media," and is capable of "long-range transport" once it is released into the environment.[77] Thus, the disposal-related releases of TCEP that will continue for many years to come will add to a toxic reservoir of TCEP that will persist and disperse in the environment, perpetuating risks to people and wildlife.

To the limited extent that EPA does consider exposures associated with TCEP disposal, it substantially understates them. As noted, EPA asserts that "waste disposal (landfill or incineration, [is] covered in each [condition of use/occupational exposure scenario]" addressed in the risk evaluation, "as opposed to a separate [condition of use]."[78] This approach is flawed, first, because it inherently fails to capture the full extent of disposal-related exposures for people working in disposal facilities and people living near those facilities. Facilities such as landfills and incinerators likely receive TCEP-containing wastes generated through multiple conditions of use. Accordingly, people who work in, or live near, a facility processing or holding TCEP-containing wastes will not just experience exposure associated with a single use of TCEP. It is irrational for EPA to "consider" disposal-related releases and exposures in the context of single conditions of use as this is not how relevant populations will actually be exposed. In addition, EPA's approach is flawed because it omits major categories of TCEP disposal, including disposal via wastewater discharges and disposal of imported articles.[79] Further, for many of the conditions

---

[72] Draft TCEP Risk Evaluation at 21.
[73] *Id.* at 47.
[74] *See id.* at 22, 147, 175–76 (discussing use of TCEP in aerospace equipment and products, paints, construction materials, building insulation, mattresses, and furniture).
[75] *Id.* at 42.
[76] *Id.* at 436; *see also id.* at 42 ("When used as an additive, TCEP is added to manufactured materials via physical mixing rather than chemical bonding and as a result, TCEP can easily leach or diffuse into its surrounding environment.").
[77] *Id.* at 19, 39, 84.
[78] *Id.* at 47.
[79] *See id.* at 46–47 (indicating limited subset of conditions of use for which associated disposals were assessed).

of use for which EPA purported to consider associated disposals, EPA made no attempt to quantify disposal-related releases or exposures and there is no indication of whether or how EPA actually incorporated any "qualitative" assessment of these releases and exposures into its risk determinations.[80]

EPA's failure to quantify releases of TCEP associated with wastewater discharges is especially concerning. EPA acknowledges that TCEP is widely detected in surface and groundwater samples, is not effectively removed by conventional drinking water or wastewater treatment, and is released into the environment through wastewater effluent and landfill leachate.[81] EPA observes that "TCEP was among the 10 most frequently found compounds in a study that collected wastewater from multiple sites in the Research Triangle Park area of North Carolina between 2002 and 2005," and that TCEP and other flame retardants "were measured primarily at sites downstream from municipal wastewater discharges."[82] EPA further notes that "[l]aundry wastewater may be the primary source of TCEP to wastewater treatment plant influent and subsequently to the aquatic environment."[83] Yet EPA fails to utilize readily available data to estimate the volume of these releases. These data include multiple sampling studies that measured TCEP concentrations in wastewater treatment plant discharges in Los Angeles—studies that EPA itself, as well as the National Marine Fisheries Service ("NMFS") previously utilized to assess risks to wildlife protected under the Endangered Species Act ("ESA").[84] In addition, the Washington Department of Ecology recently measured high concentrations of TCEP in wastewater discharges from aerospace/aircraft modification, industrial laundry, shipbuilding, and food processing facilities, as well as in landfill leachate.[85]

---

[80] *See id.* at 46–47 (indicating that EPA did not quantify releases or exposures from disposals associated with numerous commercial uses of TCEP); *id.* at 49 (acknowledging that "there may be TCEP releases to the environment via the demolition and disposal of consumer articles, as well as to wastewater via domestic laundry," but claiming that "EPA did not have enough information to assess [these] environmental releases quantitatively"); *id.* at 51–52.

[81] *Id.* at 39, 42, 45.

[82] *Id.* at 149, 188.

[83] *Id.* at 75.

[84] *See* Nat'l Marine Fisheries Serv., *Endangered Species Act (ESA) Section 7(a)(2) Biological Opinion and Magnuson-Stevens Fishery Consultation and Management Act Essential Fish Habitat Response* 80 (Mar. 2022), https://repository.library.noaa.gov/view/noaa/37544; EPA Region 9, *Biological Evaluation and Essential Fish Habitat Assessment for Discharges to the Pacific Ocean from Outfalls Associated with the City of Los Angeles Hyperion Water Reclamation Plant and Wastewater Collection Systems* at 7, 21 (Jan. 2023), https://repository.library.noaa.gov/view/noaa/49053 (scroll to p.38 of PDF); Los Angeles Sanitation, Hyperion Treatment Plant and Terminal Island Water Reclamation Plant *Special Study Final Report, Constituents of Emerging Concern (CECs) Special Study* at 5, 7–8 (Apr. 2020), https://repository.library.noaa.gov/view/noaa/49053 (scroll to p.161 of PDF).

[85] Siana Wong, Wash. State Dep't Ecology, *Chemicals of Emerging Concern in Pretreated Industrial Wastewater in Northwestern Washington State: Screening Study Results, 2021* at 30–31 (2021), https://apps.ecology.wa.gov/publications/documents/2203013.pdf. The study also

It is unclear why EPA failed to utilize these data, in combination with information that is referenced in the draft risk evaluation, to estimate TCEP releases associated with municipal wastewater treatment plant discharges and direct industrial discharges. It is similarly unclear why EPA could not quantify releases from landfills and incinerators. As to landfills, EPA claims it is impossible to produce such estimates "[w]ithout a full characterization of non-hazardous landfill . . . conditions and historical wastes . . . around the country."[86] But EPA modeled TCEP releases from landfills,[87] and more recent data on organophosphate flame retardants in landfill leachate are available and could be combined with the data cited in the draft risk evaluation to better characterize environmental releases of TCEP in landfill leachate.[88] EPA's assertion that "[s]ource attribution of the consumer uses to the leaching concentration exhibited . . . [in the risk evaluation] are not available," purportedly precluding a determination of whether "these concentrations are the result of consumer and/or commercial disposal," is irrelevant.[89] EPA must assess all "circumstances . . . under which [TCEP] is intended, known, or reasonably foreseen to be . . . disposed of,"[90] and in prior risk evaluations it has characterized disposal as a condition of use, without attempting to allocate disposal-related exposures between commercial and consumer uses.[91] Here, too, quantifying the proportion of landfill leaching attributable to consumer versus commercial disposal is not required.

Moreover, for the limited disposal-related releases that EPA did attempt to quantify, it utilized loading rates that substantially understate the quantity of TCEP that is currently in, or will foreseeably be entering, the waste phase. Specifically, EPA calculated disposal-related releases based on estimated domestic production volumes of 2,500 pounds per year or 25,000 pounds per year.[92] Even assuming for the sake of argument that those estimates were accurate with respect to *current* TCEP production volume, EPA acknowledges that U.S. production volume for TCEP was nearly 100 percent greater just ten years ago.[93] That figure—which does

---

detected V6—a flame retardant that includes TCEP as an impurity—in wastewater from many of those same source categories.

[86] Draft TCEP Risk Evaluation at 149.

[87] *Id.* at 84–85.

[88] *See, e.g.*, Trine Eggen et al., *Municipal Landfill Leachates: A Significant Source for New and Emerging Pollutants*, 408 Sci. Total Env't 5147 (2010).

[89] Draft TCEP Risk Evaluation at 149.

[90] 15 U.S.C. § 2602(4); *see id.* § 2605(b)(4)(A).

[91] *See, e.g.*, Mem. from Kevin Vuilleumier, Env't Eng'r, Risk Assessment Branch 1, Existing Chem. Risk Assessment Div., EPA, to Ana Corado, Chief, Risk Mgmt. Branch 3, Existing Chem. Risk Mgmt. Div., EPA, Re: Carbon Tetrachloride: Fenceline Technical Support – Ambient Air Pathway at 6, 8, 11, 16–18 (Oct. 21, 2022), https://www.regulations.gov/document/EPA-HQ-OPPT-2020-0592-0050; EPA, EPA-740R18008, *Risk Evaluation for Trichloroethylene* 43, 458–59 (Nov. 2020), https://www.epa.gov/sites/default/files/2020-11/documents/1._risk_evaluation_for_trichloroethylene_tce_casrn_79-01-6.pdf.

[92] *See, e.g.*, Draft TCEP Risk Evaluation at 85 (explaining that EPA utilized these production volume estimates "as potential loading rates" for calculating releases from landfills).

[93] *Id.* at 19; *see also id.* at 23–25.

not even account for imported articles containing TCEP that have been and will be disposed of domestically—makes plain that current production volume does not rationally capture the volume of TCEP in articles that currently are in use and will continue entering the waste stream for many years to come.[94] Nor does it reflect the volume of TCEP in articles that were previously landfilled and continue generating ongoing TCEP releases via leachate.[95] Indeed, EPA acknowledges in the draft risk evaluation that, although "EPA expects environmental releases of TCEP from industrial facilities to be declining," "environmental releases from landfills may remain (*or increase*)."[96] The same is true for releases via waste incineration and, perhaps to a lesser extent, wastewater discharges. Yet EPA's analysis fails to account for this reality.

It is critical for EPA to characterize these releases accurately given, among other factors, the "potential for TCEP to migrate to groundwater and domestic wells from nearby non-hazardous waste landfills . . . or historic waste sites."[97] Indeed, older landfills holding TCEP-containing articles are especially likely to leach TCEP, as they "are more likely to lack the infrastructure of modern landfills, such as liners, leachate collection systems, and reactive barriers, which would prevent leachate from entering the groundwater system."[98] In revising the draft risk evaluation, EPA must incorporate accurate loading rates for TCEP-containing waste disposed via landfilling, incineration, and wastewater to avoid substantially understating disposal-related exposures and risks.

EPA also must correct additional flaws in its analysis of TCEP releases from waste incineration. First, EPA must evaluate exposure and risk associated with the toxic byproducts that result from incineration of TCEP-containing wastes. In the draft risk evaluation, EPA states that "thermal treatment and open burning are not favorable options for the disposal of TCEP" because they generate significant TCEP releases and also "produce numerous toxic byproducts,

---

[94] *See* Draft TCEP Risk Evaluation at 22 ("In the past, TCEP was processed in many products made in the United States, including fabrics and textiles, some types of foam, and construction materials—some of which may still be in use today."); William A. Stubbings et al., *Flame Retardants and Plasticizers in a Canadian Waste Electrical and Electronic Equipment (WEEE) Dismantling Facility*, 675 Sci. Total Env't 594, 600 (2019) (explaining that levels of organophosphate ester flame retardants such as TCEP measured in Canadian e-waste recycling facility in 2017 were within the range reported in studies from Scandinavian countries in the early 2000s, which "suggests that the usage of OPEs in [electrical and electronic equipment] consumed within the Western markets has not changed in the past 20 years").

[95] EPA is required to consider these ongoing releases from past acts of disposal. *See Safer Chems., Healthy Fams. v. EPA*, 943 F.3d 397, 424–26 (9th Cir. 2019) (holding that TSCA "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," and likewise requires EPA to consider as "*independent* disposals" the ongoing leaking or other uncontrolled discharge of a chemical substance that was previously placed in a landfill).

[96] Draft TCEP Risk Evaluation at 84 (emphasis added).

[97] *Id.* at 82.

[98] *Id.* at 436.

including 1,2-dichloroethane ($C_2H_4CL_2$), vinyl chloride (C_2H_3Cl), hydrogen chloride (HCl), carbon monoxide (CO), and acetaldehyde (C_2H_4O), among others."[99] Yet EPA does not account for the risks associated with these byproducts in its risk calculations. EPA must do so in the final risk evaluation, utilizing waste-volume estimates that reflect real world conditions. Second, in so doing, EPA must consider the specific risks associated with treatment of TCEP-containing wastes in nonhazardous solid waste incinerators versus open burning, as these approaches will differ substantially in the extent of TCEP releases and releases of toxic products of incomplete combustion. As explained below, these differences must be accounted for in analyzing risks to potentially exposed or susceptible subpopulations such as tribal populations.

C. EPA Fails to Evaluate Many of TCEP's Conditions of Use

Like other OFRs, TCEP is used as a plasticizer and a flame retardant in a range of plastic products. For instance, TCEP is "used as an additive plasticiser . . . for polyurethane, polyesters, polyvinyl chloride and other polymers."[100] TCEP has also been detected in high-density polyethylene ("HDPE") water pipes,[101] from which it can leach into water supplies and enter the environment.[102] In some products, TCEP is also used "as a secondary plasticiser . . . to suppress the flammability resulting from plasticisers such as phthalates."[103] "When used as an additive, TCEP is added to manufactured materials via physical mixing rather than chemical bonding and as a result, TCEP can easily leach or diffuse into its surrounding environment."[104]

The foregoing plastic uses are all "circumstances . . . under which [TCEP] is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of," and must therefore be considered in the draft risk evaluation.[105] But while EPA considers exposures to TCEP from plastics used in certain aerospace equipment and children's toys, it fails to evaluate the manufacturing, use, and disposal of polyvinyl chloride ("PVC") and HDPE pipes and other plastic materials that are known to contain TCEP.[106] EPA also ignores the

---

[99] *Id.* at 437–38; *see also id.* at 45 ("[T]here is a robust confidence that TCEP . . . produces hazardous byproducts when undergoing thermal degradation . . .").
[100] Nat'l Ctr. for Biotechnology Info., Nat'l Libr. of Med/, PubChem Annotation Record for TRIS(2-CHLOROETHYL) PHOSPHATE § 8.1, PubChem, https://pubchem.ncbi.nlm.nih.gov/compound/8295 (last visited Feb. 6, 2024).
[101] Tomas Diera et al., *A Non-Target Screening Study of High-Density Polyethylene Pipes Revealed Rubber Compounds as Main Contaminant in a Drinking Water Distribution System*, 229 Water Rsch. Art. No. 119480 (2023).
[102] Linhong Xiao et al., *Studies of Emission Processes of Polymer Additives into Water Using Quartz Crystal Microbalance—A Case Study on Organophosphate Esters*, 54 Env't Sci. & Tech. 4876 (2020).
[103] Eur. Comm'n, *Eur. Union Risk Assessment Report, Tris (2-Chloroethyl) Phosphate, TCEP* 18 (July 2009), https://echa.europa.eu/documents/10162/2663989d-1795-44a1-8f50-153a81133258.
[104] Draft TCEP Risk Evaluation at 42.
[105] 15 U.S.C. §§ 2602(4), 2605(b)(4)(A).
[106] *See* Draft TCEP Risk Evaluation at 26, 160, 162, 170, 174–75, 177, 299–302. It is irrelevant whether TCEP is currently being used to make those products, since TSCA requires EPA to

presence of TCEP in microplastics that form from the breakdown of larger plastics containing TCEP, or that adsorb and spread TCEP in the environment.[107] This omission is particularly concerning since studies have found that microplastic co-exposures can exacerbate TCEP's neurotoxicity.[108] Microplastics containing TCEP can be ingested by fish, other wildlife, and people, resulting in aggregate and cumulative risks that EPA unlawfully failed to address.[109] To fully evaluate TCEP's risks "under the conditions of use," EPA must assess a broader range of plastic uses, as well as the presence of TCEP in microplastics, in its final risk evaluation.[110]

Other reported conditions of use, which are not mentioned in the draft risk evaluation, include the use of TCEP in "lubricating oil,"[111] as "an extractant for rare metals,"[112] as a "thermal coolant" for metals,[113] and in "lithium batteries."[114] EPA must look into those uses as well, and either include them in the TCEP risk evaluation or justify its decision to exclude them.

IV. EPA Underestimates Exposures to TCEP

A. The Draft Risk Evaluation Is Predicated on an Unsupported Assumption Concerning TCEP Manufacturing and Import Volumes

EPA's calculations of TCEP's risks to workers, the general population, and the environment are based on an unsupported assumption concerning the amount of TCEP that is presently manufactured or imported. Since EPA has no workplace monitoring or environmental release data for most of TCEP's conditions of use, the Agency instead evaluates TCEP exposures

---

consider a chemical's legacy uses as well as its ongoing ones. *Safer Chems., Healthy Fams. v. EPA*, 943 F.3d 397, 423–25 (9th Cir. 2019).

[107] Haibo Zhang et al., *Occurrences of Organophosphorus Esters and Phthalates in the Microplastics from the Coastal Beaches in North China,* 616 Sci. Total Env't 1505 (2018); Patrik Fauser et al., *Residual Additives in Marine Microplastics and Their Risk Assessment – A Critical Review*, 177 Marine Pollution Bull. Art. No. 113467 (2022); Lina Fu et al., *Adsorption Behavior of Organic Pollutants on Microplastics*, 217 Ecotoxicology & Env't Safety Art. No. 112207, at *1–4 (2021).

[108] Yongfeng Deng et al., *Evidence That Microplastics Aggravate the Toxicity of Organophosphorus Flame Retardants in Mice (*Mus Musculus*)*, 357 J. Hazardous Materials 348 (2018).

[109] *See infra* Points VI.A and VI.B (describing EPA's obligation to evaluate TCEP's aggregate and cumulative risks)

[110] 15 U.S.C. § 2605(b)(4)(A).

[111] Yu Qiao et al., *Ecological Risk Assessment for Tris(2-chloroethyl) Phosphate to Freshwater Organisms*, 10 Frontiers Env't Sci. Art. No. 963918, at *2 (2022).

[112] *Id.*

[113] Longchang Chemical, *Sinoflare® TCEP: CAS 115-96-8*, https://longchangchemical.com/product/sinopszr-tcep-cas-115-96-8/ (last visited Feb. 6, 2024).

[114] *Id.; see also* Ataman Chemicals, TCEP = Tris-2-Chloroethyl-Phosphate, https://www.atamanchemicals.com/tcep-tris-2-chloroethyl-phosphate_u24766/ (last visited Feb. 6, 2024).

and risks based on EPA's assumption that 2,500 pounds of TCEP are manufactured or imported each year.

But EPA acknowledges that it does not know how much TCEP is manufactured or imported, and its 2,500-pounds assumption underestimates total TCEP exposures.[115] Just a decade ago, companies reported nearly 160,000 pounds of annual TCEP manufacturing and imports under the CDR rule.[116] While no companies reported TCEP manufacturing or imports during the latest CDR reporting cycle,[117] the CDR reporting threshold is 25,000 pounds per year *per facility*, meaning up to 25,000 pounds of TCEP could be entering commerce from each manufacturing or importing facility without triggering CDR reporting.[118]

The draft risk evaluation calculates the risks associated with both 25,000 and 2,500 pounds of annual TCEP production, but EPA bases its unreasonable risk determinations on the lower production estimate.[119] EPA does not explain how it derived that value; it merely asserts that it "considers 2,500 [pounds] to be a more realistic production volume" than 25,000 pounds.[120] EPA notes that CDR reporting has been trending downward over the last decade, and that Datamyne— a private database of imports and exports based on U.S. Customs records— reported 593 pounds Of TCEP imports in 2020 "and generally the most recent Datamyne information (2017 to 2020) in the low thousands of pounds or lower."[121] But, according to EPA, "some shipments containing TCEP may be excluded [from Datamyne] due to being categorized under other names," "[t]here also may be errors in the data that prevent shipment records containing the chemical from being located," and "Datamyne does not include articles/products containing the chemical unless the chemical name is included in the description."[122] The CDR also excludes the import of articles containing TCEP, even though such imports contribute to occupational and consumer risks (*e.g.*, from the use of TCEP-containing products) and environmental releases (*e.g.*, from the disposal of those products.)[123] This is a major gap in EPA's

---

[115] 15 U.S.C. § 2618(c)(1)(B)(i)(I) (when reviewing EPA risk management rules and the underlying risk determination, "the court shall hold unlawful and set aside such rule if the court finds that the rule is not supported by substantial evidence in the rulemaking record taken as a whole").
[116] Draft TCEP Risk Evaluation at 25.
[117] *Id.* at 23.
[118] 40 C.F.R. § 711.8(a).
[119] Draft TCEP Risk Evaluation at 25–26.
[120] *Id.* at 25.
[121] *Id.* EPA also states that it "received public comments . . . confirming industry's transition away from the domestic use of TCEP." *Id* (citation omitted). Those unsubstantiated industry comments are limited to particular companies and particular uses of TCEP; EPA cannot rely on them to draw any conclusions about the broader manufacturing, import and use of the chemical.
[122] *Id.* at 24 n.2.
[123] *See* 40 C.F.R. § 711.10(b) (exempting parties that "imported the chemical substance as part of an article" from CDR reporting requirements).

exposure assessment, since TCEP remains widely used overseas and can enter the United States via imported articles.[124]

Given EPA's admission that neither the CDR nor Datamyne provides a complete picture of TCEP manufacturing and imports, the absence of CDR and Datamyne reporting does not justify EPA's reduction to its TCEP production estimates. Indeed, a 2018 study estimated 1,110 kilograms (2,425 pounds) of annual TCEP air emissions in the City of Toronto alone, with a high-end estimate (95% confidence interval) of 26,000 kilograms (57,320 pounds)[125] With a single Canadian city estimated to release nearly 2,500 pounds of TCEP per year, EPA cannot justify calculating national TCEP releases and exposures based on a 2,500-pound production estimate. EPA should instead evaluate risk based on a current production level that is equal to or greater than the CDR reporting threshold of 25,000 pounds, while also accounting for substantially higher domestic production and import of TCEP in the recent past.

EPA's reliance on current production levels to calculate TCEP's risks understates the chronic risks to people who were exposed to far greater amounts of TCEP in earlier life stages.[126] Between 1986 and 2002, the CDR-reported production volume for TCEP was between 1,000,000 and 10,000,000 pounds, and in 2006 it was between 500,000 and 1,000,000 pounds—several orders of magnitude higher than EPA's current 2,500-pound estimate.[127] TCEP presents cancer and other chronic risks that accrue over a lifetime of exposures, and EPA calculates those risks using a "lifetime average daily dose" representing the average amount of TCEP that someone is exposed to each day over the course of their lifetime.[128] For the purpose of determining a Lifetime Average Daily Dose, past exposure levels within a person's lifespan are just as relevant as current ones. As the SACC advised EPA in its report on the draft risk evaluation for perchloroethylene:

> [O]lder data should be used to estimate prior exposure doses, which can then be added to exposures going forward in time. It is unrealistic to only address [those] who start their exposures today (or within the last 10 years only). The [draft risk

[124] *See*, *e.g.*, Qiao et al. 2022 at *2 ("The annual production and use of TCEP in China are tens of thousands of tons.").
[125] Timothy F. M. Rodgers et al., *Organophosphate Ester Transport, Fate, and Emissions in Toronto, Canada, Estimated Using an Updated Multimedia Urban Model*, 52 Env't Sci. & Tech. 12465, 12468 (2018).
[126] Further, as explained *supra* Points III.B and IV.D, it also leads EPA to underestimate the magnitude of TCEP releases associated with recycling and disposal of materials that contain the chemical.
[127] Draft TCEP Risk Evaluation at 24.
[128] EPA, EPA/630/P-03/001F, *Guidelines for Carcinogen Risk Assessment* at 3-26 (2005), https://www.epa.gov/sites/default/files/2013-09/documents/cancer_guidelines_final_3-25-05.pdf ("Unless there is evidence to the contrary in a particular case, the cumulative dose received over a lifetime, expressed as average daily exposure prorated over a lifetime, is recommended as an appropriate measure of exposure to a carcinogen."); *see also* Draft TCEP Risk Evaluation at 520–21.

> evaluation] did not accurately estimate the risks to 40- and 50-year-old individuals who already have accumulated 20+ years of prior exposure. Those older exposures are relevant to today's added risks.[129]

While EPA cannot turn back the clock and undo those prior exposures, it must regulate current TCEP uses and exposure "to the extent necessary" so that the Lifetime Average Daily Dose remains below the level associated with unreasonable risk. Moreover, as described above, EPA must consider prior production and import levels when evaluating the risks from TCEP disposal, because much of the TCEP-containing waste that is currently being disposed of, or that is currently leaching out of landfills, comes from articles and products that were manufactured or imported decades ago.[130] By calculating risk using only an estimate of current production volume—which in itself is unjustifiably low—EPA underestimates the chronic risks to workers, consumers, and others who were exposed to much higher levels of TCEP in earlier decades and violates TSCA's mandate to apply the "best available science."[131]

B. EPA Understates Infants' and Children's Exposures to TCEP

The draft risk evaluation recognizes that "[i]nfants are a potentially susceptible population because of their higher exposure per body weight, immature metabolic systems, and the potential for chemical toxicants to disrupt sensitive developmental processes, among other reasons."[132] Infants are exposed to TCEP from the milk they drink, the toys they play with, the mattresses they sleep on, and other sources. In multiple ways, however, EPA understates those exposures.

First, EPA assumes that infants breastfeed for a maximum of one year, [133] despite evidence and public health recommendations to the contrary. The American Academy of Pediatrics and the World Health Organization recommend the continuation of breastfeeding for at least two years or longer,[134] and CDC data show that more than 17 percent of infants are still breastfed at 18 months of age.[135] EPA's assumption that breastfeeding will end after one year is

---

[129] TSCA Sci. Advisory Comm. on Chems., *Meeting Minutes and Final Report No. 2020-5: Peer Review for EPA Draft Risk Evaluation of Perchloroethylene* at 52 (Aug 18, 2020), https://www.regulations.gov/document/EPA-HQ-OPPT-2019-0502-0055.
[130] *See supra* Point IV.A.
[131] 15 U.S.C. § 2625(h).
[132] Draft TCEP Risk Evaluation at 224.
[133] *Id.* at 295, 494.
[134] WHO, *Infant and Young Child Feeding* (Dec. 20, 2023), https://www.who.int/news-room/fact-sheets/detail/infant-and-young-child-feeding; Am. Ass'n of Pediatrics, *Newborn and Infant Breastfeeding*, https://www.aap.org/en/patient-care/newborn-and-infant-nutrition/newborn-and-infant-breastfeeding (last updated May 31, 2022).
[135] CDC, *Breastfeeding Among U.S. Children Born 2013–2020, CDC National Immunization Survey-Child*, https://www.cdc.gov/breastfeeding/data/nis_data/results.html (last updated Aug. 1, 2023).

contrary to the best available science and unprotective of infants who are breastfed for longer periods.

Second, EPA assumes that infants will mouth toys and products containing TCEP for seven to ten minutes per hour, [136] significantly less than the duration that EPA's *Exposure Factors Handbook* recommends for use in risk assessment. EPA concedes that "[i]nformation on . . . mouthing durations" was "limited,"[137] and the Exposure Factors Handbook recommends 95th percentile mouthing durations ranging from 11 minutes per hour (for children aged two to three years) to 26 minutes per hour (for children aged three to six months.)[138] EPA claims that its mouthing values were taken from EPA's Consumer Exposure Model ("CEM") but it does not say how the model derived those estimates, whereas the recommendations in the *Exposure Factors Handbook* are backed by multiple studies of infants' and children's mouthing behaviors.[139] EPA should use the 95th percentile mouthing durations from the *Exposure Factors Handbook*, or any higher estimates in published literature, to calculate TCEP mouthing exposures.

Third, while EPA separately calculated the risks from infants' breastfeeding and mouthing, it failed to consider the risks to infants who are exposed to TCEP from both breastmilk and the products they mouth, as well as other exposure pathways.[140] Breastfeeding and mouthing are both typical infant behaviors, making it highly likely that a significant number of infants will be exposed from both pathways. Similarly, when calculating the concentrations of TCEP in breastmilk, EPA considered maternal TCEP exposures from individual conditions of use in insolation, but failed to consider aggregate exposures to lactating people who are exposed from multiple conditions of use and thus have greater levels of TCEP in their breastmilk. As described in greater detail below, EPA's failure to consider those aggregate exposures is contrary to TSCA and inconsistent with the best available science.[141]

C. EPA Also Understates Consumer, Worker, and General Population Exposures to TCEP

EPA also understates consumer, worker, and general population exposures to TCEP. First, EPA underestimates the concentrations of TCEP in polyurethane foam products that are used by consumers and workers, including furniture and automobile cushioning. While TCEP has been detected at concentrations up to 19,800 mg/kg (1.98 percent) in such foam, EPA

[136] Draft TCEP Risk Evaluation at 195.
[137] *Id.* at 192.
[138] EPA, EPA/600/R-09/052F, *Exposure Factors Handbook: 2011 Edition*, at 4-3 (Sept. 2011) ("Exposure Factors Handbook"), https://ordspub.epa.gov/ords/eims/eimscomm.getfile?p_download_id=522996 (recommending 95th percentile mouthing duration values of 11-26 minutes per hour, depending on age).
[139] *Compare* Draft TCEP Risk Evaluation at 197, *with* Exposure Factors Handbook at 4-3, 4-12 to 4-14.
[140] *See* Draft TCEP Risk Evaluation at 245.
[141] *See infra* Point VI.A.

disregards that data and assumes TCEP concentrations of less than one percent.[142] EPA asserts that the lower values were "thought to be more current and representative of the U.S. population," presumably because the higher concentrations were taken from a German study published in 2001 (the "Ingerowski study").[143] But TCEP and TCEP-containing products are imported into the United States, and many older vehicles and products containing TCEP foam are either still in use or are being disposed of. Moreover, EPA relies on the Ingerowski study—and other data that predates that study by more than a decade—to calculate other TCEP exposures.[144] EPA should similarly use that study when calculating TCEP exposures from polyurethane foam products.

EPA also ignores workers' incidental ingestion of TCEP-containing dust that settles on their hands and clothing, despite previously "acknowledg[ing] that oral exposures are a potential route for workers and agree[ing] that hand-to-mouth and ingestion of dust particles can be sources of occupational oral exposure."[145] TCEP has been detected in dust samples taken from residential spaces, public spaces, vehicles, and recycling facilities.[146] While EPA considered consumers' ingestion of TCEP-containing dust, it excludes that exposure route from its occupational risk assessment and thus underestimates workers' exposures and risks.[147]

Finally, EPA understates the duration and volume of general population exposures to TCEP. EPA falsely assumes that no one will be exposed to TCEP in the ambient air or surface water for more than 33 years, based on a decades-old study of how long most people remained in a single residence.[148] But as the SACC advised EPA in its recent report on the supplemental 1,4-dioxane risk evaluation, the "homeowner mobility value (33 years) … is inadequate for [potentially exposed or susceptible subpopulation] communities," which TSCA expressly requires EPA to consider, and is "arguably invalid for the general population as well."[149] EPA's assumption understates the risks to people who remain the in same residence for longer than 33 years, as well as to people who move within a given community but remain exposed to the same

---

[142] Draft TCEP Risk Evaluation at 175.
[143] *Id.*
[144] *Id.* (using the Ingerowski study to calculate TCEP exposures from insulation); *id.* at 198 (using data from 1997 to calculate TCEP levels in wood products).
[145] EPA, *Summary of Public Comments Received on the Draft Scopes of the Risk Evaluations for Twenty Chemical Substances Under the Toxic Substances Control Act (TSCA)* 35 (Aug. 2020), https://www.epa.gov/sites/default/files/2020-09/documents/rtc_on_draft_scopes_20_hps.pdf.
[146] Draft TCEP Risk Evaluation at 86; Linh V. Nguyen et al., *Exposure of Canadian Electronic Waste Dismantlers to Flame Retardants*, 129 Env't Int'l 95 (2019).
[147] Draft TCEP Risk Evaluation at 86.; John W. Cherrie et al., *How Important Is Inadvertent Ingestion of Hazardous Substances at Work?*, 50 Annals. Occupational Hygiene 693, 702 (2006).
[148] Draft TCEP Risk Evaluation at 295; Exposure Factors Handbook at 16-8.
[149] TSCA Sci. Advisory Comm. on Chems., *Meeting Minutes and Final Report No. 2023-02, A Set of Scientific Issues Being Considered by the Environmental Protection Agency Regarding: 2023 Draft Supplement to the 1,4-Dioxane Risk Evaluation* at 49 (Nov. 16, 2023), https://www.regulations.gov/document/EPA-HQ-OPPT-2022-0905-0078.

air and water contamination. It is "clearly not representative of tribes [or] diverse socioeconomic communities," who often have lower levels of geographic mobility and stronger connections to the places where they live.[150] The best available science requires EPA to calculate TCEP's risks to impacted communities and the general population over an entire lifetime, as opposed to arbitrarily cutting off its exposure calculations after 33 years.[151]

D. EPA Unlawfully Ignores Most Dietary Exposures to TCEP

EPA further understates risks to exposed populations by ignoring dietary exposures beyond contaminated fish. According to EPA, "[a]n Australian study indicated that more than 75 percent of the estimated daily intake of TCEP came from dietary ingestion."[152]

But EPA excludes the vast majority of those dietary exposures from its draft risk evaluation, improperly attributing them to "non-TSCA" uses.[153] Contrary to EPA's claim, many dietary exposures are subject to regulation under TSCA and must be evaluated and regulated by EPA. While TSCA excludes from the definition of chemical substance "any food," as defined in the Federal Food, Drug, and Cosmetic Act ("FFDCA"), "when manufactured, processed, or distributed in commerce for use as a food," not all foods and methods of food production fall within the scope of that exclusion.[154] For instance, just as subsistence fishing does not constitute the "manufactur[ing], process[ing], or distribut[ion] in commerce" of an FFDCA-regulated food product, neither does the cultivation of crops, gathering of plants, or raising of livestock for personal consumption. Yet the draft risk evaluation does not evaluate whether TCEP's conditions of use may cause soil, water, or biosolids contamination that result in non-excluded dietary exposures (*e.g.*, from personal gardening and farming.)

Moreover, even uses that are not regulated under TSCA still must be considered as background exposures when evaluating the risks posed by TCEP. As EPA has previously acknowledged, "[t]he potential risks of non-TSCA uses may help inform the Agency's risk determination for the exposures from uses that are covered under TSCA."[155] Here, people with greater dietary exposures will have higher levels of TCEP in their bodies, and will thus be more susceptible to harm from additional exposures. EPA cannot comply with TSCA's mandate to

---

[150] *Id.*

[151] For additional information on the flaws in this 33-year exposure duration, *see* Black Women for Wellness et al., Comments on the Draft Supplement to the TSCA Risk Evaluation, at 17–21 (Sept. 8, 2023), https://www.regulations.gov/comment/EPA-HQ-OPPT-2022-0905-0055.

[152] Draft TCEP Risk Evaluation at 228.

[153] *Id.* at 226.

[154] 15 U.S.C. § 2602(2)(B)(vi).

[155] Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act, 82 Fed. Reg. 33,726, 33,735 (July 20, 2017); *see also* EPA, EPA-740-P-23-002, *Draft Proposed Approach for Cumulative Risk Assessment of High-Priority Phthalates and a Manufacturer-Requested Phthalate Under the Toxic Substances Control Act* at 114 (Feb. 2023) (finding that "[c]ertain non-TSCA sources may be major pathways of human exposure, and their exclusion … may lead to an underestimation of risk.")

evaluate risks to "potentially exposed or susceptible subpopulations" if it fails to consider all dietary exposures.[156] Moreover, exposures to TSCA-regulated uses of TCEP are additive to exposures from so-called "non-TSCA" uses, and EPA cannot rationally determine whether the TSCA-regulated uses present unreasonable risks if it ignores the impact of those background exposures.[157]

In other contexts, EPA routinely considers background exposures from products or sources that it does not directly regulate. For example, in its assessment and regulation of the pesticide fumigant sulfuryl fluoride, EPA's Office of Pesticide Programs ("OPP") considered all sources of exposure to fluoride, including ones EPA does not regulate (such as toothpaste). Considering these exposures was critical for accurate risk calculation and decision-making—OPP proposed to terminate pesticidal uses of sulfuryl fluoride because children's total exposure to fluoride (mainly from drinking water and toothpaste) exceeded acceptable exposure levels.[158] EPA's Office of Water similarly routinely accounts for background exposures to contaminants when establishing drinking water standards by applying a default assumption that 80 percent of total contaminant exposures arise from non-water sources, despite those exposures falling outside of the regulatory purview of the Safe Drinking Water Act.[159] Here, too, dietary exposures contribute to TCEP's total risks and exacerbate the risks that people experience from TSCA regulated uses. EPA must consider those exposures in the final risk evaluation.

E. EPA Understates Exposure Associated with Recycling of TCEP-Containing Materials

EPA has not fully or accurately characterized environmental releases, occupational exposures, or consumer exposures associated with the recycling of materials containing TCEP. EPA understates releases and exposures associated with e-waste recycling and fails to consider environmental, occupational, or consumer exposures associated with the recycling of other TCEP-containing products, such as polyurethane foam. EPA must correct the flaws, and fill the gaps, in its analysis of recycling-related exposures in the final risk evaluation.

In the draft risk evaluation, EPA asserts that it "was not able to quantify releases of TCEP that could occur during the recycling of e-waste."[160] Nonetheless, EPA asserts that "total releases are expected to be low since TCEP is not typically used in electronics"[161] and on that basis concludes that the recycling condition of use does not contribute to TCEP's unreasonable

---

[156] *See infra* Point VI.
[157] *See* Nat'l Rsch. Council, *Science and Decisions: Advancing Risk Assessment* at 132 (2009) ("Science and Decisions"), https://nap.nationalacademies.org/catalog/12209/science-and-decisions-advancing-risk-assessment (emphasizing "the need for evaluation of background exposures" to avoid an underestimation of risk (cleaned up)).
[158] Sulfuryl Fluoride; Proposed Order Granting Objections to Tolerances and Denying Request for a Stay, 76 Fed. Reg. 3422-01, 3439–42 (Jan. 19, 2011).
[159] *See* Cong. Rsch. Serv., *Regulating Contaminants Under the Safe Drinking Water Act (SDWA)* at 13 (Jan. 5, 2022), https://crsreports.congress.gov/product/pdf/R/R46652.
[160] Draft TCEP Risk Evaluation at 50.
[161] *Id.* at 146, 364.

risks.[162] It is not clear what EPA means when it asserts that TCEP use in electronics is not "typical," including what time period this comment is intended to characterize and what volume of TCEP-containing electronics may nonetheless exist from "atypical" or historical use. Indeed, the source EPA cites for the proposition that TCEP is not typically used in electronics, Stapleton et al. 2011, concerns detections of TCEP in foam and does not discuss the extent to which TCEP or any other flame retardant is used in electronics.[163] Contrary to EPA's characterization, peer-reviewed literature analyzing TCEP concentrations in e-waste recycling facilities indicates that TCEP releases are strongly associated with e-waste recycling. For example, Gravel et al. 2019 detected TCEP in 100 percent of air samples from Canadian e-waste recycling facilities, compared to 67 percent of control group samples.[164] Along with triphenyl phosphate ("TPhP"), TCEP was measured at the highest concentrations among all organophosphate esters analyzed and was associated with the processing of both older [cathode ray tube] televisions and newer televisions.[165] Nguyen et al. 2019 also detected TCEP and other flame retardants in dust and air samples at Canadian e-waste processing facilities, with TCEP "the most abundant [organophosphate ester flame retardant] in workbench air samples."[166] Further, Nguyen et al. 2019 measured higher dust concentrations at workbenches compared to a central location within the facility, "consistent with the release of contaminated dust during dismantling" of electronics.[167]

Moreover, EPA makes no attempt to characterize releases and exposures associated with the recycling of other TCEP-containing materials, including polyurethane foam, in which EPA asserts TCEP "is predominantly found."[168] Polyurethane foam is recycled through a variety of processes,[169] including mechanical processes that generate substantial amounts of dust during the chopping or shredding of foam.[170] Recycling of polyurethane foam exposes recycling workers, communities, and the environment near recycling facilities; carpet installers; and consumers who purchase recycled-content products such as "rebond" carpet padding or upholstered furniture that contains recycled foam. "Post-consumer foam (old carpet cushion) now returning for recycling may contain up to 12 percent by weight" of TCEP and other halogenated flame retardants, which

---

[162] *Id.* at 355, 364.
[163] Heather M. Stapleton et al., *Identification of Flame Retardants in Polyurethane Foam Collected from Baby Products*, 45 Env't Sci. & Tech. 5323 (2011).
[164] Sabrina Gravel et al., *Halogenated Flame Retardants and Organophosphate Esters in Air of Electronic Waste Recycling Facilities: Evidence of High Concentrations and Multiple Exposures*, 128 Env't Int'l 244, 246 (2019).
[165] *Id.* at 251.
[166] Nguyen et al. (2019) at 98; *see also* Stubbings et al. (2019).
[167] Nguyen et al. (2019) at 95; *see also id.* at 98.
[168] Draft TCEP Risk Evaluation at 146.
[169] Aleksandra Kemona & Malgorzata Piotrowska, *Polyurethane Recycling and Disposal: Methods and Prospects*, 12 Polymers Art. No. 1752 (2020).
[170] Jim Vallette et al., *Eliminating Toxics in Carpet: Lessons for the Future of Recycling*, Healthy Building Network, at 25 (2017), https://healthybuilding.net/uploads/files/eliminating-toxics-in-carpet-lessons-for-the-future-of-recycling.pdf.

will leach out of recycled-content carpet pads over the course of their service life.[171] EPA cannot ignore these releases and exposures, which are part of the recycling condition of use. Its conclusion in the draft risk evaluation that recycling does not contribute to TCEP's unreasonable risks fails to consider these important recycling-related exposures and is not rationally supported.

V. EPA Underestimates TCEP's Hazards

A. EPA Overlooks and Misapplies Necessary Uncertainty Factors

When calculating TCEP's hazards and risks, EPA disregarded the best available science, as well as EPA's own risk assessment guidance, concerning the use of uncertainty factors. Uncertainty factors are "very important . . . to determining the safety of [chemicals] . . . to humans,"[172] since they account for gaps and uncertainties in the risk assessment process that could otherwise "result [in] an incomplete characterization of the chemical's toxicity" and an "underprotective" risk calculation.[173] The use of appropriate uncertainty factors is necessary to conduct risk evaluations "in a manner consistent with the best available science."[174] In its draft risk evaluation, however, EPA failed to apply two critical uncertainty factors and misapplied another.

First, when calculating TCEP's chronic reproductive toxicity, EPA relied on a subchronic duration study without applying the recommended "subchronic-to-chronic-duration" uncertainty factor.[175] In the draft risk evaluation, EPA explains that it chose "a study with a shorter exposure duration" to assess "chronic exposure scenarios because it resulted in a[] [human equivalent dose] that is more sensitive . . . than most longer-term results."[176] The problem is not that EPA selected the wrong study to calculate reproductive risks, but rather that EPA misapplied the results of that study. When determining chronic risks from a sub-chronic duration study, EPA

---

[171] *Id.*
[172] *Nat. Res. Def. Council v. EPA*, 658 F.3d 200, 209 (2d Cir. 2011).
[173] EPA, EPA/630/P-02/002F, *A Review of the Reference Dose and Reference Concentration Processes* at 4-44 (Dec. 2002) ("EPA Review of Ref. Dose"), https://www.epa.gov/sites/default/files/2014-12/documents/rfd-final.pdf (describing database uncertainty factor); *see also* EPA, *Determination of the Appropriate FQPA Safety Factor(s) in Tolerance Assessment* at A-3 (Feb. 2002) https://www.epa.gov/sites/default/files/2015-07/documents/determ.pdf, ("For almost 30 years, EPA, as well as others in the scientific and regulatory community, has routinely been using . . . uncertainty factors when relying on animal testing to assess the potential for human hazard . . . .").
[174] 15 U.S.C. § 2625(h).
[175] EPA Review of Ref. Dose at 4-45 to 4-46; *see also* TSCA Sci. Advisory Comm. on Chems., *Meeting Minutes and Final Report No. 2019-01, A Set of Scientific Issues Being Considered by the Environmental Protection Agency Regarding: Peer Review for EPA Draft Risk Evaluation of C.I. Pigment Violet 29* at 43 (Sept. 19, 2019), https://www.regulations.gov/document/EPA-HQ-OPPT-2018-0604-0088 (criticizing EPA's failure to apply a subchronic-to-chronic uncertainty factor in the draft risk evaluation for Pigment Violet 29).
[176] Draft TCEP Risk Evaluation at 283.

recommends a default uncertainty factor of ten to compensate for the absence of chronic exposure information.[177] EPA admits that its reliance on a subchronic study "does lend uncertainty to the risk evaluation because . . . it is uncertain whether the [point of departure] would be lower if [the subchronic study] extended the exposure duration."[178] But EPA failed to follow its own guidance for addressing that uncertainty, resulting in a ten-fold underestimate of TCEP's chronic reproductive risks.[179]

EPA also failed to apply the recommended uncertainty factor for "database deficiencies," despite acknowledging significant gaps in EPA's understanding of TCEP's exposures and hazards. As described above, EPA claims that it lacks sufficient data to evaluate several of TCEP's conditions of use.[180] EPA also asserts that "the currently available evidence is inadequate to assess whether TCEP may cause endocrine changes," "thyroid changes," "lung or respiratory effects in humans," or "immunological or hematological effects in humans."[181] Those asserted gaps do not excuse EPA from evaluating all of TCEP's conditions of use and health effects, and EPA has an established approach for addressing precisely those sorts of database deficiencies. "[T]o account for the potential for deriving an underprotective [risk estimate] as a result of an incomplete characterization of the chemical's toxicity," EPA guidance recommends the use of an additional "database deficiency" uncertainty factor.[182] In light of EPA's own claims of inadequate data, EPA must apply that uncertainty factor here.

Finally, EPA misapplies the "intraspecies" uncertainty factor, which is intended to "account for variations in susceptibility" within the general population.[183] The intraspecies uncertainty factor is designed to cover the myriad sources of variations within the general population, not the increased risks faced by discrete potentially exposed or susceptible subpopulations. EPA has applied that ten-fold uncertainty factor even in circumstances where it found "no evidence of increased susceptibility for any single group relative to the general population,"[184] while acknowledging that "a 10-fold factor may . . . be too small" to account for

---

[177] EPA Review of Ref. Dose at 4-45 to 4-46.
[178] Draft TCEP Risk Evaluation at 283.
[179] *Id.* at 282 tbl.5-49 (applying a "total [uncertainty factor]" of 30 to EPA's reproductive toxicity risk calculation). Had EPA applied the recommended subchronic-to-chronic uncertainty factor, the total uncertainty factor would have been 300 and EPA's reproductive risk estimates would have been ten-fold higher.
[180] *Id.* at 21.
[181] *Id.* at 265–66.
[182] EPA Review of Ref. Dose at 4-44 to 4-45.
[183] *Id.* at 4-42.
[184] EPA, EPA-740-R-18-015, *Final Risk Evaluation for C.I. Pigment Violet 29 (Anthra[2,1,9-def:6,5,10-d'e'f']diisoquinoline- 1,3,8,10(2H,9H)-tetrone)* 76, 83 (Jan. 2021), https://www.epa.gov/sites/default/files/2021-01/documents/1_final_risk_evaluation_for_c.i._pigment_violet_29.pdf.

risk to those who are particularly susceptible because of genetic polymorphisms and other factors.[185]

In the draft risk evaluation, EPA improperly relies on that intraspecies uncertainty factor to avoid TSCA's required analysis of TCEP's risks to several potentially exposed or susceptible subpopulations. Instead of calculating the risks to those subpopulations—such as people who are more susceptible to TCEP's risks because of genetic conditions like Klinefelter's syndrome, Y-chromosome microdeletion, and myotonic dystrophy—EPA asserts that their increased susceptibility is "[a]ddressed" through the "[u]se of [the] default [intraspecies uncertainty factor]."[186] But that uncertainty factor is intended to address unspecified variations in susceptibility across the general population, not the heighted risks faced by identified potentially exposed or susceptible subpopulations. Indeed, if a ten-fold intraspecies uncertainty factor is used to account for general population variation even in the absence of a potentially exposed or susceptible subpopulation,[187] the same adjustment plainly cannot account for those who are known to experience increased susceptibility, and EPA offers no evidence that its default uncertainty factor would adequately capture the risks to all potentially exposed or susceptible subpopulations. When EPA identifies potentially exposed or susceptible subpopulations, EPA must calculate their risks separately from those of the general population, as opposed to relying on a default uncertainty factor that—by EPA's own admission—may not be up to the task.[188]

B. EPA Understates TCEP's Neurotoxicity Risks

Contrary to typical agency practice and the best available science, EPA failed to use the most sensitive study when calculating TCEP's neurotoxic effects (the "Tilson study"). EPA acknowledges that the Tilson study was the "most sensitive" neurotoxicity study after accounting for uncertainty factors, resulting in risk estimates that are far greater than those that EPA calculated in the draft risk evaluation.[189] But EPA did not use that study because "the authors

[185] EPA Review of Ref. Dose at 4-44.
[186] Draft TCEP Risk Evaluation at 423.
[187] *See supra* note 184.
[188] Draft TCEP Risk Evaluation at 330 tbl.5-69 ("The magnitude of differences in toxicokinetics and toxicodynamics for some individuals may be greater than accounted for by the [intraspecies uncertainty factor] of 10."). Indeed, were EPA to maintain a single uncertainty factor to account for all sources of intraspecies variability, the best available science indicates that the uncertainty factor would have to be far greater than 10. *See* Comments from Scientists, Academics, & Clinicians on Revisions to EPA's Risk Evaluation Framework Rule, Docket ID EPA-HQ-OPPT-2023-0496, at 10 (Dec. 14, 2023), https://prhe.ucsf.edu/sites/g/files/tkssra341/f/resources/2023.12.14_Risk%20Evaluation%20Framework%20Rule_UCSF%20PRHE%20Comments.pdf.
[189] Draft TCEP Risk Evaluation at 276. In particular, the ratio of the benchmark margin of exposure (expressed as "total UF") to the point of departure (expressed as human equivalent dose or HED) is approximately 4.6 for the Tilson study and approximately 3.2 for the study selected by EPA, indicating that the Tilson study is more sensitive and would result in higher risk calculations than those calculated in the draft risk evaluation. *Id.* at 276–77.

tested only a single dose level, which did not allow a full understanding of the dose-response for TCEP" and "only a [Lowest Observed Adverse Effect Level, or "LOAEL"] was identified," as opposed to a No Observed Adverse Effect Level ("NOAEL").[190]

None of those arguments justifies the decision to understate TCEP's neurotoxicity risks. While the Tilson study did involve only one dose, nothing precludes EPA from relying on a single-dose study when it is the most sensitive, and EPA does not need "a full understanding of the dose-response" in order to establish a point of departure and calculate risks from that study.[191] Indeed, the Tilson study has been favorably cited in an analysis conducted for the CPSC,[192] by Environment Canada and Health Canada,[193] and, previously, by EPA itself.[194] Similarly, the fact that the Tilson study did not identify a NOAEL does not support disregarding the study. EPA frequently calculates risks based on LOAELs, using a ten-fold uncertainty factor to account for the absence of a NOAEL.[195] To capture all of TCEP's potential risks, it is critical that EPA use the most sensitive study for each endpoint, including the Tilson study for neurotoxicity.

C. EPA Understates TCEP's Cancer Risks

When calculating TCEP's cancer risks, EPA relied exclusively on kidney tumor data even though TCEP exposures have been associated with other cancer sites as well.[196] In addition to kidney cancer, studies have linked TCEP to leukemia and thyroid cancer.[197] EPA admits that "[u]se of tumor data for only one target organ (*i.e.*, not combining incidence with other target organ tumors) may result in some underestimation of risk."[198] But EPA made no effort to address that concern by calculating total cancer risks.

EPA must consider all known cancer sites in its dose-response analysis and its determination of whether TCEP presents unreasonable cancer risks. As set forth in EPA's *Guidelines for Carcinogen Risk Assessment*: "Because an agent may induce multiple tumor types, the dose-response assessment includes an analysis of all tumor types, followed by an

---

[190] *Id.* at 275.
[191] *Id.*
[192] *See* Toxicology Excellence for Risk Assessment & The Lifeline Grp., *Toxicity Review of Tris(2-chloroethyl) Phosphate (TCEP)* 18–19, 23 (Dec. 2013) ("Toxicity Review of TCEP"), https://www.cpsc.gov/s3fs-public/pdfs/TCEP-contract-report-with-cover-letter.pdf (prepared pursuant to contract with the Consumer Product Safety Commission).
[193] Env't Can. & Health Can., *Screening Assessment for the Challenge Ethanol, 2-chloro-, phosphate (3:1) (Tris(2-chloroethyl) Phosphate [TCEP]* (Aug. 2009), https://www.ec.gc.ca/ese-ees/default.asp?lang=En&n=AE75E117-1.
[194] TSCA Problem Formulation at 26.
[195] EPA Review of Ref. Dose at 4-44.
[196] Draft TCEP Risk Evaluation at 291.
[197] *Id.* at 269–70.
[198] *Id.* at 291.

overall synthesis that includes a characterization of the risk estimates across tumor types . . . ."[199] Instead of knowingly "underestimat[ing]" TCEP's risks, we urge EPA to add non-kidney cancers associated with TCEP exposure to its analysis of cancer risk.[200]

VI. EPA Violates TSCA's Mandate to Evaluate TCEP's Risks to Potentially Exposed or Susceptible Subpopulations

The draft risk evaluation also violates TSCA's mandate to 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 TCEP.[201] As set forth below, EPA fails to consider several potentially exposed or susceptible subpopulations—including people who have "greater exposure" to TCEP from multiple conditions of use or exposure pathways or who have "greater susceptibility" to harm because of their cumulative exposures to other flame retardants and toxic chemicals in addition to TCEP. Additionally, EPA understates the risks to the potentially exposed or susceptible subpopulations that it did identify.

A. EPA Fails to Consider the Increased Exposures and Risks to People Who Are Exposed to TCEP From Multiple Conditions of Use and Exposure Pathways

TSCA requires EPA to evaluate risks to those who are exposed to a chemical from multiple conditions of use or from multiple exposure routes and pathways. First, such populations experience "greater exposure" and "greater risk" than the general population because of those aggregate exposures, and thus constitute a "potentially exposed or susceptible subpopulation" that EPA must evaluate under TSCA section 6(b).[202] In addition, TSCA section 6(a) directs EPA to eliminate the unreasonable risks from "any combination of" a chemical's conditions of use, which is only possible if EPA first evaluates the risks from such combinations of exposures and determines whether they are unreasonable.[203] Finally, TSCA's "best available science" mandate compels the consideration of aggregate exposures and risks.[204] The National Academies have acknowledged the "need for" risk assessment to cover "aggregate exposure . . .

---

[199] *Guidelines for Carcinogen Risk Assessment* at 1-12 to 1-13; *see also* EPA, EPA-740-R1-8012, *Risk Evaluation for Asbestos Part I: Chrysotile Asbestos* 173–175 (Dec. 2020), https://www.epa.gov/sites/default/files/2020-12/documents/1_risk_evaluation_for_asbestos_part_1_chrysotile_asbestos.pdf (adding the risks associated with multiple types of cancer associated with chrysotile asbestos to determine the overall cancer risk).
[200] Draft TCEP Risk Evaluation at 291.
[201] 15 U.S.C. §§ 2602(12), 2605(b)(4)(A).
[202] *Id.* §§ 2602(12), 2605(b)(4)(A).
[203] *Id.* § 2605(a).
[204] *Id.* § 2625(h).

[from] all routes, pathways, and sources of exposure to a given agent,"[205] and EPA's SACC has specifically advised EPA to aggregate exposures from multiple conditions of use under TSCA.[206]

EPA itself has recognized that "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."[207] In its recently proposed revisions to the TSCA risk evaluation rule, EPA states that it "will consider aggregate exposures to the chemical substance."[208]

In the draft TCEP risk evaluation, however, EPA ignores all aggregate exposures from combinations of conditions of use and most aggregate exposures from combinations of exposure pathways and routes.[209] While EPA claims to "lack . . . reasonably available data indicating co-exposures of multiple TCEP containing activities or products in the occupational and indoor environment," EPA cannot disregard aggregate exposures merely because it failed to gather information on them.[210] TSCA requires EPA to evaluate the risks posed by TCEP through the "circumstances . . . under which [the] chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of."[211] TCEP's uses are neither rare nor unforeseen; the chemical has been widely used as a flame retardant and plasticizer in home insulation, furniture, rugs, and other common products. It is thus virtually inevitable, and certainly "reasonably foreseen," that some of the people whose roof contains TCEP insulation also own a rug or a vehicle with TCEP as well, and that some of the people who are exposed to TCEP on the job also have TCEP-containing products and materials in their homes.[212] EPA must evaluate those reasonably foreseen combinations of exposures, and the risk evaluation contains all of the information that EPA needs to do so. Since EPA has calculated the exposures from those conditions of use individually, it can add them to calculate risks to the people who are exposed from reasonably foreseen combinations of conditions of use. As further support for those aggregate exposure calculations, EPA should consider studies of

---

[205] Science and Decisions at 266.
[206] TSCA Sci. Advisory Comm. on Chems., *Meeting Minutes and Final Report No. 2022-01, 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 58 (May 16, 2022) ("SACC Report on Fenceline Screening Approach"), https://www.regulations.gov/document/EPA-HQ-OPPT-2021-0415-0095.
[207] 88 Fed. Reg. at 74,305.
[208] *Id.* at 74,322. While those revisions are not yet final, they are anticipated to be finalized before the completion of the TCEP risk evaluation, and EPA has said that it plans to apply them to pending risk evaluations like TCEP's "to the extent practicable." *Id.* at 74,295.
[209] Draft TCEP Risk Evaluation at 243–45.
[210] *Id.* at 244.
[211] 15 U.S.C. § 2602(4) (defining "conditions of use"); *see id.* § 2605(b)(4)(A) (requiring EPA to evaluate the risks presented by chemicals "under the conditions of use").
[212] *See* Draft TCEP Risk Evaluation at 244 (acknowledging that "[c]onsumers may have multiple articles at home that contain TCEP").

total indoor air and dust concentrations of TCEP, which would reflect contributions from all TCEP-containing products and materials within the home.

EPA also "did not aggregate exposure estimates to the general population" across multiple exposure pathways (such as outdoor air and drinking water), claiming that those individual "exposure estimates were based on release estimates assuming a production volume of 2,500 [pounds] per [exposure scenario], and an aggregation would double count the production volume."[213] This explanation fails for multiple reasons. First, as described above, EPA has not supported its total production volume estimate of 2,500 pounds per year.[214] Second, even if that estimate were supported and all production-related releases were attributed to a single pathway, the public would still experience aggregate exposures that EPA has not accounted for. In addition to production-related releases of TCEP, people are also exposed to TCEP from landfill leachate (which is the result of historic as well as ongoing TCEP use), the consumption of contaminated fish and wildlife (which does not depend on current production volumes alone), and from other exposure routes and pathways. Rather than "double count[ing]" exposures, the consideration of risks across exposure routes and pathways—many of which are not tied to TCEP's current production volume—would more accurately reflect real-world exposures and risks.

EPA also claims that when a single exposure pathway or condition of use is sufficient to establish unreasonable risk, the consideration of additional, aggregate exposures is unnecessary.[215] This argument misunderstands the central purpose of a risk evaluation, which is not only to determine the need for risk management (*i.e.*, whether an unreasonable risk exists) but also to determine the extent of the risk management needed. TSCA requires EPA to regulate chemicals "to the extent necessary so that [they] no longer present[] [unreasonable] risk."[216] If EPA has not considered aggregate exposures to determine the full extent of a chemical's unreasonable risks, then it will not have the information it needs during risk management to ensure that such risks are eliminated. For instance, someone may be exposed to unreasonable cancer risk from both the ingestion of TCEP-contaminated fish and the inhalation of TCEP from their home insulation. According to EPA, there is no need to consider their aggregate exposures and risks because either condition of use and exposure pathway alone is sufficient to support an

---

[213] *Id.*

[214] *See supra* Point IV.A.

[215] Draft TCEP Risk Evaluation at 340 ("There were no instances of aggregate lifetime risk for any [condition of use] where there was not already risk to the [condition of use] from an individual route . . . . Indeed, infant cancer risk estimates exceeded 1 in 1,000,000 for all [conditions of use and exposure scenarios] based on maternal fish ingestion (high BAF). Aggregating other exposure scenarios will not further inform risk characterization."); *id.* at 341 ("Furthermore, since the general population and subsistence fisher estimates result in chronic risk for all [conditions of use], aggregating additional exposure scenarios (*e.g.*, consumer, occupational) with the general exposure scenarios (fish ingestion) is uninformative in characterizing risks.").

[216] 15 U.S.C. § 2605(a).

unreasonable risk determination for TCEP.[217] But if EPA's risk management rule reduces the risks from each pathway to a level that EPA deems acceptable (*i.e.*, less than 1-in-1,000,000), that person could still experience unreasonable risks because of their aggregate exposures. To fully address their risks, and to comply with its TSCA obligations, EPA must evaluate the risks from known, intended, and reasonably foreseen combinations of conditions of use, exposure routes, and exposure pathways.

B. EPA Fails to Consider the Increased Susceptibility of People Who Are Exposed to TCEP and Other Toxic Chemicals That Contribute to Cumulative Health Risks

EPA also fails to evaluate as potentially exposed or susceptible subpopulations people who experience "greater susceptibility" to harm from TCEP exposures because of their cumulative exposures to multiple chemicals and non-chemical stressors.[218] Like the failure to consider aggregate exposures, this omission violates not only TSCA's mandate to evaluate risks to potentially exposed or susceptible subpopulations but also the requirement to conduct risk evaluations using the "best available science."[219] The National Academies have 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."[220] More recently, the National Academies 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" and economically insecure communities.[221] Similarly, the SACC has characterized cumulative exposure assessment as "a necessary step" in the TSCA risk evaluation process.[222] EPA itself admits that "without considering the cumulative risk of chemicals, the Agency's risk mitigation may not fully be able to consider the public-health implications of various risk management options for reducing exposure."[223]

Yet EPA makes no effort to address cumulative exposures and risks in the draft TCEP risk evaluation, despite available evidence of such risks. For example, scientific studies have

---

[217] Draft TCEP Risk Evaluation at 341.
[218] 15 U.S.C. § 2602(12). As explained *infra* Point VII.D, EPA also fails to consider aggregate and cumulative exposures to wildlife.
[219] *Id.* § 2625(h).
[220] Science and Decisions at 219.
[221] 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-andtomorrows-challenges.
[222] SACC Report on Fenceline Screening Approach at 49.
[223] 88 Fed. Reg. at 74,306.

established the potential for cumulative effects from exposures to TCEP and benzo-a-pyrene, a polycyclic aromatic hydrocarbon found in cigarette smoke, food, and the environment.[224] These co-exposures are also likely to occur, since "[s]everal recent studies showed that TCEP coexists with [benzo-a-pyrene] in the atmosphere, surface water and fish."[225] But EPA did not model or otherwise assess the extent of those co-exposures. Similarly, studies have shown cumulative risks from co-exposures to TCEP and microplastics, which exceed the risks associated with TCEP alone.[226] EPA did not consider those cumulative exposures and the resulting increase in susceptibility and risk.

Nor did EPA evaluate cumulative risks from exposures to TCEP and other flame retardants. For instance, TCEP is an impurity in the flame-retardant mixture V6, and the two flame retardants are frequently detected in the same products and environmental media.[227] While EPA considered exposures to TCEP from the use of products containing V6, it never assessed the cumulative effects of those flame retardants together. TCEP also is found alongside other flame retardants—including PBDEs and other organophosphate ester flame retardants like TCPP and TDCPP—in household dust, water, and other environmental media.[228] Many of those flame retardants are associated with the same types of harm as TCEP,[229] meaning people who are exposed to other flame retardants will be more susceptible to harm from their TCEP exposures. EPA has acknowledged the cumulative effects from other organophosphate chemicals, such as organophosphate pesticides.[230] Organophosphate ester flame retardants are "structurally similar"

---

[224] Draft TCEP Risk Evaluation at 333 ("*In vitro* data on co-exposure with benzo-a-pyrene showed increased impacts on inflammation and proliferation pathways.").
[225] Youjian Zhang et al., *Combined Effect of Tris(2-chloroethyl)phosphate and Benzo (a) pyrene on the Release of IL-6 and IL-8 from HepG2 Cells Via the EGFR-ERK1/2 Signaling Pathway*, 7 Royal Soc'y Chem. Advances 54,281 (2017) (footnotes omitted).
[226] Deng et al. (2018).
[227] Toxicity Review of TCEP at 93, 95 (noting that "V6 was detected along with TCEP in 15 of the 16 [baby product] samples" and that "V6 and TCEP were found in [household] dust samples and were highly correlated").
[228] *See, e.g.,* Erika D. Schreder et al., *Flame Retardant Transfers from U.S. Households (Dust and Laundry Wastewater) to the Aquatic Environment*, 48 Env't Sci. & Tech. 11575 (2014); Dodson et al. (2012); *see also* Stubbings et al. (2019).
[229] *E.g.*, Tiantian Xu et al., *Tris(2-chloroethyl) Phosphate (TCEP) and Tris(2-chloropropyl) phosphate (TCPP) Induce Locomotor Deficits and Dopaminergic Degeneration in Caenorhabditis Elegans*, 6 Toxicology Rsch. 63, 71 (2017).
[230] *See generally* EPA, *Organophosphorus Cumulative Risk Assessment* 3 (July 31, 2006) ("OPs share the ability to bind to and phosphorylate the enzyme acetylcholinesterase in both the central (brain) and peripheral nervous systems."), https://www.regulations.gov/document/EPA-HQ-OPP-2006-0618-0002; *see also* Eur. Comm'n, *EFSA-SANTE Action Plan on Cumulative Risk Assessment for Pesticides Residues* 5 (Feb. 2, 2021), https://food.ec.europa.eu/system/files/2021-03/pesticides_mrl_cum-risk-ass_action-plan.pdf ("Previous [cumulative risk assessment] for acute effects on the nervous system revealed that organophosphorus insecticides are the main risk drivers of acute brain and/or erythrocyte AChE inhibition .").

to organophosphate pesticides, and both classes are associated with neurotoxicity and other shared harms.[231] At a minimum, therefore, EPA must evaluate any increased susceptibility from co-exposures to TCEP and other organophosphate flame retardants or organophosphate pesticides.

C. EPA Understates TCEP Exposures and Risks to Tribal Populations

We strongly support EPA's identification of tribal populations as a "potentially exposed or susceptible subpopulation" for purposes of the TCEP risk evaluation.[232] As reflected in the draft risk evaluation and elaborated below, TSCA's definition of "potentially exposed or susceptible subpopulation" indisputably includes tribal populations, who consistently face "greater risk than the general population of adverse health effects from exposure to a chemical substance or mixture" because of both "greater exposure" and "greater susceptibility."[233] Yet, until now, EPA failed to identify tribal populations as a potentially exposed or susceptible subpopulation requiring particularized consideration in risk evaluation and risk management. In taking the critical step of identifying tribal populations as a higher-risk subpopulation, EPA correctly recognizes that tribal populations' "intricate connection to the land and . . . distinctive lifeways and cultures . . . create many unique exposure scenarios that can expose tribal members to higher doses of contaminants in the environment."[234]

However, in the draft risk evaluation for TCEP, EPA failed to follow through on this insight by comprehensively assessing the factors that increase tribal populations' exposure to—and susceptibility to harm from—TCEP. Indeed, "EPA did not evaluate" the heightened exposures associated with "activities that are unique to tribal populations" and "quantitatively evaluated only the tribal fish ingestion pathway for TCEP because of data limitations."[235] As EPA acknowledges, this approach "overlooks many other unique exposure scenarios"[236] and ultimately understates the risks TCEP presents to tribal populations. To satisfy TSCA, in the final TCEP risk evaluation EPA must utilize all readily available information to characterize tribal populations' exposures and susceptibilities, as well as appropriately conservative assumptions and uncertainty factors where data are limited.

Among other factors that increase TCEP exposures in tribal populations, EPA must account for the impact of solid waste disposal practices in tribal communities. As described *supra* Point III.B, EPA's failure to adequately characterize TCEP releases and exposures associated with disposal led EPA to broadly understate exposure and risks to human and wildlife

---

[231] Jiawen Yang et al., *A Review of a Class of Emerging Contaminants: The Classification, Distribution, Intensity of Consumption, Synthesis Routes, Environmental Effects and Expectation of Pollution Abatement to Organophosphate Flame Retardants (OPFRs)*, 20 Int'l J. Molecular Sci. 2874 at 21 (2019).
[232] Draft TCEP Risk Evaluation at 34, 331.
[233] 15 U.S.C. § 2602(12).
[234] Draft TCEP Risk Evaluation at 219.
[235] *Id.* at 219, 332.
[236] *Id.* at 219.

populations. This concern is particularly acute with respect to tribal populations. Substandard landfill infrastructure, open dumps, and open burning of solid waste in many rural tribal communities increase those communities' exposures to TCEP as well as to the highly toxic byproducts that result from incomplete combustion of TCEP-containing wastes.[237] In addition, many members of tribal populations—whether in the lower-48 or Alaskan Arctic—live in regions with very cold, long winters that lead them to spend more time indoors, often in residential environments with older furniture, carpeting, and building materials that are associated with higher releases of TCEP and other toxic chemicals to the indoor environment.[238]

Several additional factors that EPA overlooked particularly increase TCEP exposures and risks among Arctic Indigenous People. "Indigenous peoples in the far north are disproportionately exposed to contaminants as a result of global atmospheric transport" as well as "traditional subsistence diets rich in marine mammals which are known to contain high levels

---

[237] *See, e.g.*, Ian L. Moran et al., *Diffusive Fluxes of Persistent Organic Pollutants Between Arctic Atmosphere, Surface Waters and Sediments*, 892 Sci. Total Env't Art No. 164566, at 8 (2023) (hypothesizing that "[l]ocal waste disposal practices and a nearby open-air landfill may represent an important source of atmospheric TCEP concentrations" in the Yupik community of Sivuqaq, and noting that "[w]aste management practices in the Arctic are the product of unique logistic and socioeconomic constraints" and "[i]n some cases, landfill conditions have resulted in hazardous emissions to residents of other Arctic communities"); Letter from Terry Rambler, Chairman, San Carlos Apache Tribe, to Irina Myers, EPA, Re: Response to Tribal Consultation, Aug. 27, 2015, Notification of Consultation and Coordination on TSCA Work Plan Chemical Problem Formulation and Initial Assessment and Data Needs Assessment for Flame Retardants (FR) Clusters, at 3 (Dec. 10, 2015), https://www.regulations.gov/document/EPA-HQ-OPPT-2015-0068-0025 (explaining that "[t]he main sources for pollutants on [the San Carlos Apache] Reservation" include "open dumps [and] backyard open burning (burn barrels)," and describing concerns over releases of toxic flame retardants from household waste in sixty open dumps on reservation); Suzanne Fluharty & Kathleen Sloan, *Understanding the Cumulative Effects of Environmental and Psycho-Social Stressors that Threaten the Pohlik-lah and Ner-er-ner Lifeway: The Yurok Tribe's Approach* 36 (2014) (describing open burning of household waste on Yurok Reservation); Alaska Dep't of Env't Conservation, *Burning Waste in Class III Landfills* (promoting open burning of waste in rural Alaskan communities), https://dec.alaska.gov/eh/solid-waste/waste-in-rural-alaska/burning-in-class-3-landfills/ (last visited Jan. 29, 2024).

[238] *See, e.g.*, Letter from Chief Brenda Commander, Houlton Band of Maliseet Indians, to Irina Myers, EPA, Re: Response to Tribal Consultation, Aug. 17, 2015, Notification of Consultation and Coordination on TSCA Work Plan Chemical Problem Formulation and Initial Assessment and Data Needs Assessment for Flame Retardants (FR) Clusters (Dec. 10, 2015), https://www.regulations.gov/document/EPA-HQ-OPPT-2015-0068-0021 (describing tribal members' tendency to spend substantial amounts of time indoors during winters in northern Maine); Draft TCEP Risk Evaluation at 331 ("Monitoring literature indicates TCEP levels in dust are significantly associated with the presence of extremely worn carpets. This may be relevant for lower socioeconomic status families.").

of many [persistent organic pollutants] due to biomagnification."[239] Although EPA acknowledges in the draft risk evaluation that "TCEP can be carried long distances via air and water and has been detected in the Arctic,"[240] it did not utilize the available literature on TCEP concentrations in the Arctic environment to characterize Arctic Indigenous Peoples' exposure from contaminated air and other environmental media that contain significant concentrations of TCEP as well as other organophosphate flame retardants, brominated flame retardants, and other persistent organic pollutants.[241] This literature includes a recent study, Moran et al. 2023, which reported vapor phase TCEP concentrations in ambient air in the Yupik community of Sivuqaq that are significantly higher than the levels reported in literature cited in the draft risk evaluation and are approximately the same as the ambient air concentrations EPA modeled for locations within ten meters of a facility engaged in spray application of TCEP-containing paints and coatings[242]—a condition of use that EPA determined presents unreasonable risk to the general population through inhalation exposure.[243] EPA also did not consider TCEP exposures to Arctic Indigenous People from subsistence foods beyond fish that can contain high concentrations of TCEP, such as marine mammals, seabirds, and seabird eggs. In the final risk evaluation, EPA must address these factors to develop an assessment of TCEP exposures in tribal populations that reflects real-world conditions.

Regarding tribal fish consumption, we strongly support EPA's recognition that fish consumption rates in many tribal communities can significantly increase exposure to TCEP.[244] Further, EPA correctly recognized that "current fish consumption rates [in tribal communities] are suppressed by contamination, degradation, or loss of access" to subsistence species and appropriately utilized available data on "heritage rates" of fish consumption within tribal communities, as well as current rates, to characterize exposure.[245]

At the same time, there are several flaws in EPA's assessment of TCEP exposures from fish consumption in tribal communities that EPA should correct in the final risk evaluation. First,

---

[239] Moran et al. (2023), at 2; *see also* Arctic Monitoring & Assessment Programme, *AMAP Assessment 2016: Chemicals of Emerging Concern* 107–08 (2017) ("AMAP Assessment"), https://www.amap.no/documents/download/3003/inline.

[240] Draft TCEP Risk Evaluation at 19; *see also id.* at 43.

[241] *See, e.g.*, Moran et al. (2023); AMAP Assessment; Amina Salamova et al., *Organophosphate and Halogenated Flame Retardants in Atmospheric Particles from a European Arctic Site*, 48 Env't Sci. & Tech. 6133 (2014).

[242] *Compare* Moran et al. (2023), at 6–7 (reporting 2.8 ng/m^3 TCEP in ambient air), *with* Draft TCEP Risk Evaluation at 60–63 (projecting "a maximum ambient air concentration of 2.55 ng/m^3 at 10 m from [a] facility" engaged in the spraying of TCEP-containing paints and coatings); *see also* Draft TCEP Risk Evaluation at 323 (calculating cancer risks exceeding 2-in-100,000 from exposure to ambient air 10 meters from a facility engaged in the spraying of TCEP-containing paints and coatings); *id.* at 360–61.

[243] Draft TCEP Risk Evaluation at 365.

[244] *Id.* at 331.

[245] *Id.* at 220.

EPA has not justified its exclusive reliance on mean fish ingestion rates to calculate TCEP exposures in tribal populations. Elsewhere in the risk evaluation, EPA consistently utilizes both 50th and 95th percentile exposure values to estimate TCEP exposures to the general population and to workers who, like tribal populations, experience heightened exposure.[246] And there are readily available data reflecting 95th percentile fish ingestion rates in tribal populations. For example, Harper et al. 2007 cites a 95th percentile fish ingestion rate of 798 g/day for the Suquamish Tribe.[247] Second, even if it were appropriate to utilize only mean fish ingestion rates, the value EPA utilized to characterize mean current/suppressed tribal fish consumption rates—216 g/day—is too low. EPA's *Exposure Factors Handbook* provides a mean fish ingestion rate for an Alaska Native Nation of 770 g/day.[248] A 1999 study by Walker and Pritchard reports an ingestion rate of 650 g/day for subsistence fishers in the Yakama Tribe, based on actual use between 1950 to 1971.[249] EPA provides no basis for disregarding these substantially higher reported rates. Third, as discussed above, EPA underestimates environmental releases of TCEP and resulting concentrations of TCEP in fish, which leads EPA to further understate TCEP exposures from fish consumption in tribal communities.[250] Fourth, although EPA calculated TCEP exposures from fish consumption using a high and low bioaccumulation factor ("BAF") of 2,198 L/kg and 109 L/kg, respectively,[251] EPA only utilized the low BAF "to determine unreasonable risk."[252] EPA offers no explanation for discarding the higher BAF at the risk characterization stage, which generated significantly less severe risk calculations.[253]

Finally, EPA did not consider aggregate or cumulative chemical exposures affecting tribal populations nor account for increased susceptibility to harm from TCEP exposures among tribal populations due to psychosocial stressors such as poverty, crowded and/or substandard housing conditions, health care inequity, and discrimination.[254] Further, while EPA acknowledged that tribal populations' access to subsistence fish species is severely constrained, EPA did not consider the effect that reduced access to fish and other traditional foods has on nutrition, health,

---

[246] *See, e.g.*, Draft TCEP Risk Evaluation at 170, 221, 232.
[247] Harper et al. (2007), at 202; *see also* Wash. Dep't of Ecology, *Fish Consumption Rates Technical Support Document, A Review of Data and Information About Fish Consumption in Washington Version 2.0*, at 55–56 (2013) (reporting 95th percentile current ingestion rates of 268 g/day for the Tulalip Tribe and 280 g/day for the Squaxin Island Tribe), https://apps.ecology.wa.gov/publications/documents/1209058.pdf.
[248] Exposure Factors Handbook at 10-3 tbl.10-6.
[249] D.E. Walker & L.W. Pritchard, *Estimated Radiation Doses to Yakama Tribal Fishermen: An Application of the Columbia River Dosimetry Model for the Hanford Environmental Dose Reconstruction Project* (1999), *summarized in* Barbara L. Harper et al., *Traditional Tribal Subsistence Exposure Scenario and Risk Assessment Guidance Manual* at 211 app. A (Or. State Univ. 2007).
[250] *See supra* Point VI.C.
[251] Draft TCEP Risk Evaluation at 218–220.
[252] *Id.* at 360.
[253] *See id.* at 319, 321.
[254] *See, e.g.*, Fluharty & Sloan (2014), at 52–53.

and susceptibility to disease associated with toxic chemical exposures in tribal communities. These omissions, particularly in combination with the multiple ways EPA understated tribal populations' exposures to TCEP, led EPA to understate their risks. EPA must correct these deficiencies in the final risk evaluation to accurately characterize exposures and risks in tribal populations and ensure that EPA's forthcoming risk management rule for TCEP will include all measures that are necessary to eliminate the unreasonable risks tribal populations face.

D. EPA Fails to Calculate TCEP's Increased Risks to Truck Drivers, Students Residing in Dormitories, and Firefighters.

EPA also overlooks increased TCEP exposures of several other potentially exposed or susceptible subpopulations.

First, TCEP is used in automotive foam,[255] posing increased risks to long-haul truck drivers and others who spend more time in vehicles than the general population. TCEP is also used in mattresses and carpets, with greater exposures from "extremely worn carpets."[256] Long-haul truck drivers spend far more time inside vehicles than the general population, and they are more likely to sleep in their vehicle cabs.[257]

But EPA never considered the increased risks that truck drivers—a potentially exposed or susceptible subpopulation—experience from their "greater exposure" to TCEP.[258] Instead, EPA solely evaluates the risks that TCEP in automotive and furniture foam presents to the general public, who EPA assumes will be exposed for no more than one hour per day and no more than 73 days per year.[259] Those assumptions underestimate risks to the general population (including people who have long, daily commutes in their cars), and are plainly inapplicable to truckers who can exceed EPA's annual exposure estimate in a span of one to two weeks.

EPA also fails to calculate TCEP's risks to firefighters, despite identifying them as a potentially exposed or susceptible subpopulation. EPA acknowledges that "firefighters have elevated TCEP exposures as a result of firefighting activities,"[260] including the inhalation of TCEP that is aerosolized from products and building materials when they burn. A TCEP metabolite was detected in the urine of 10 percent of the general population but 90 percent of

---

[255] *See* Draft TCEP Risk Evaluation at 175.
[256] *Id.* at 416.
[257] *See* U.S. Bureau of Labor Statistics, *Heavy and Tractor-Trailer Truck Drivers*, in *Occupational Outlook Handbook*, https://www.bls.gov/ooh/transportation-and-material-moving/heavy-and-tractor-trailer-truck-drivers.htm#tab-9 (last updated Sept. 6, 2023); *see also* Felipe P. Rocha et al., *Evaluation of Truck Driver Rest Locations and Sleep Quality*, 15 Sleep Sci. 55 (2022).
[258] *See* 15 U.S.C. § 2602(12).
[259] EPA, Draft TCEP Risk Evaluation: Supplemental Information File – Consumer Exposure Model Scenario, Inputs and Assumptions and Sensitivity Analysis (Dec. 2023), https://www.epa.gov/system/files/documents/2023-12/tcep-draft-re-consumer-exposure-modeling-inputs-dec-2023.xlsx ("furniture, auto foam" tab).
[260] Draft TCEP Risk Evaluation at 335.

firefighters, who also had higher levels of that biomarker in their bodies.[261] High levels of TCEP and other flame retardants have also been detected in dust collected from fire stations and firefighting equipment.[262]

EPA claims that it "conducted a qualitative assessment for firefighters," which is embodied in a single paragraph of the draft risk evaluation.[263] But EPA never determines whether firefighters are exposed to unreasonable risk, much less calculates the extent of such risks. Without that analysis, EPA will not have the information it needs to ensure that any upcoming risk management rule regulates TCEP "to the extent necessary so that [it] no longer presents [unreasonable] risk" to firefighters.[264] EPA has sufficient information to quantify firefighters' exposures to TCEP, including extensive biomonitoring data, fire station dust levels, and information about the levels of TCEP in the products and materials that can be combusted during a building fire. Using that information, EPA should calculate TCEP's risks to firefighters.

Finally, EPA must consider TCEP's risks to students in dormitories and other student housing, which are more likely to contain older or second-hand furniture and less likely to have vacuum cleaners that limit the accumulation of dust. High levels of TCEP have been detected in dust in student dorms and common areas, with measurements up to 32,000 ng/g.[265] TCEP levels in one dorm room exceeded California's risk-based soil screening standards, indicating potential risk.[266] Yet EPA fails to consider that data in the draft risk evaluation, and it does not evaluate students' increased exposures to and risks from TCEP.

VII. EPA Has Not Adequately Assessed the Risks TCEP Poses to Wildlife

As EPA acknowledges, it has coequal obligations under TSCA to determine whether TCEP "presents an unreasonable risk of injury to health *or the environment.*"[267] Yet in multiple respects, EPA's assessment of the risks TCEP poses to wildlife is incomplete, does not consistently incorporate and reflect the best available science, and violates TSCA. We urge EPA to correct the deficiencies outlined below in the final risk evaluation.

A. EPA Unlawfully Omitted Conditions of Use, Exposure Pathways, and Exposure Sources from Its Assessment of Wildlife Exposures to TCEP

At the outset, EPA's assessment of TCEP's environmental risks does not satisfy TSCA because EPA failed to determine the environmental risks associated with multiple conditions of use[268] and, for many others, provided only a cursory discussion that dismissed environmental

[261] *Id.*
[262] *Id.*
[263] *Id.*
[264] 15 U.S.C. § 2605(a).
[265] Dodson et al. (2017), at 4864.
[266] *Id.* at 4866–67.
[267] 15 U.S.C. § 2605(b)(4)(A) (emphasis added); *see* Draft TCEP Risk Evaluation at 33.
[268] *See, e.g.*, Draft TCEP Risk Evaluation at 146–47 (stating that "EPA has not made any conclusions regarding [environmental] risk" for the recycling and distribution in commerce

risk without any risk calculation.[269] While we agree with EPA's conclusion that TCEP, as a whole chemical, presents unreasonable risk to the environment, as explained *supra* Point III, EPA cannot fully evaluate TCEP's risks unless it addresses all conditions of use, and it will not be able to develop a TSCA-compliant risk management rule for TCEP if it does not know the risks associated with many of the chemical's conditions of use.

The partial justifications EPA offers for failing to determine the environmental risks from all conditions of use do not pass muster. For example, to justify its failure to determine the environmental risks associated with TCEP releases from consumer products, EPA asserts that "[c]onsumer releases to the environment are anticipated to be less than occupational releases, and wastewater concentrations from manufacturing, commercial and processing [conditions of use] were shown to be significantly lower than acute and chronic [concentrations of concern]" calculated in the draft risk evaluation.[270] It is difficult to understand how EPA can make this claim about the magnitude of TCEP releases from consumer products since it failed to estimate those releases. Indeed, EPA's observation elsewhere in the draft risk evaluation that "[l]aundry wastewater may be the primary source of TCEP to wastewater treatment plant influent and subsequently to the aquatic environment" appears to contradict the Agency's justification for writing off consumer product releases.[271] Further, even if EPA were correct that environmental releases from consumer products are less than releases from other conditions of use, that would not excuse EPA from fully characterizing and accounting for those releases. As discussed above, in the context of assessing human health risks EPA has recognized that "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."[272] This conclusion applies equally to EPA's assessments of environmental risk and underscores that EPA may not write off exposures associated with a specific condition of use on the basis that they may be less than those associated with another.

As EPA recently acknowledged in its proposed amendments to the regulations governing TSCA risk evaluations, it also lacks discretion to disregard known pathways of TCEP exposure

---

condition of use "separately from the risks already estimated for other relevant [conditions of use]"); *id.* at 364 ("EPA is unable to determine if disposal contributes to TCEP's unreasonable risk.").

[269] *See, e.g., id.* at 147 (explaining that EPA failed to quantify environmental exposures to TCEP associated with industrial and commercial use of aerospace equipment and products but "expect[s]" these conditions of use "to have lower risk than the quantified scenarios"); *id.* at 148 (explaining that EPA failed to quantify environmental exposures associated with consumer use and disposal of articles containing TCEP but stating without support that these releases are "anticipated to be less than occupational releases"); *id*. at 363 (asserting that, for most conditions of use, "the Agency had limited data available and was not able to fully quantify risks to the environment").

[270] *Id.* at 148.

[271] *Id.* at 75.

[272] 88 Fed. Reg. at 74,305.

to wildlife.[273] Nonetheless, EPA states in the draft risk evaluation that it did not quantify inhalation exposure to TCEP among wildlife because "dietary exposure was determined to be the driver of exposure to wildlife."[274] But if the same species is exposed to TCEP via diet and inhalation, the inhalation exposures will contribute to overall risks and must be considered even if dietary exposures are greater. Similarly, "[d]irect exposure of TCEP to aquatic receptors via biosolids was not assessed quantitatively."[275] These omissions violate TSCA, which does not give EPA discretion to write off exposure pathways that it judges—here, without even conducting a complete analysis—contribute relatively less to overall risk. Further, EPA will not be able to determine what measures are needed at the risk management stage to eliminate TCEP's environmental risks if it has ignored important segments of exposure and risk at the evaluation stage. Wildlife exposure to TCEP via biosolids application is undoubtedly important; as EPA found, "[d]ue to its persistence, it is likely that dissolved TCEP will eventually reach surface water via runoff after the land application of biosolids."[276]

It also appears that EPA's analysis of wildlife ingestion exposure did not consider the contribution of ingested plastic debris and microplastics. Many wildlife species, including loggerhead sea turtles protected by the ESA,[277] are chronically exposed to organophosphate flame retardants such as TCEP and other toxic chemicals through ingestion of plastic.[278] "Sea birds also ingest microplastics voluntarily," and peer-reviewed research indicates that "ingested plastic debris [i]s a major source of plastic additives for sea birds."[279] Further, in recent studies "[t]he concentration of plastic additives in surface waters and the abundance of microplastic particles were not correlated, implying that they are not necessarily good indicators for each other in this compartment."[280] Accordingly, EPA's consideration of TCEP concentrations in surface water and prey species does not substitute for analyzing wildlife exposures to TCEP from ingested plastic. EPA must address this source of ingestion exposure in the final risk evaluation.

---

[273] *See id.* at 74,294 (stating that "exclud[ing] certain exposure pathways" from a risk evaluation "conflict[s] with the plain language of the law to evaluate chemical substances under the known, intended or reasonably foreseen circumstances associated with the full lifecycle of the chemical substance" and "prevent[s] consideration of relevant exposure information . . . in spite of statutory requirements that the Agency base its decisions on the best available science").
[274] Draft TCEP Risk Evaluation at 94; *see also id.* at 119, 138.
[275] *Id.* at 138.
[276] *Id.*
[277] *See* NOAA Fisheries, *Loggerhead Turtle*, https://www.fisheries.noaa.gov/species/loggerhead-turtle (last visited Jan. 25, 2024) (identifying distinct population segments listed as threatened or endangered under the Endangered Species Act).
[278] Berta Sala et al., *First Study on the Presence of Plastic Additives in Loggerhead Sea Turtles (*Caretta caretta*) from the Mediterranean Sea*, 283 Env't Pollution Art No. 117108, at 1–2, 4–6 (2021); *see also* Fauser et al. (2022), at 17 (discussing literature documenting "strong leaching" of TCEP and other chemicals from microplastics into bird stomach oils).
[279] Sala et al (2021), at 6.
[280] *Id.*

B. EPA's Environmental Hazard Thresholds Are Not Sufficiently Protective of Aquatic Species

EPA's environmental hazard thresholds are insufficiently protective of aquatic life. EPA calculated a concentration of concern of 55.9 parts-per-billion ("ppb") for chronic TCEP exposure among aquatic species, based on a 14-day study of growth and development effects in Japanese medaka, a fish species.[281] However, a 2021 peer reviewed study (Zhao et al. 2021) documented adverse effects on juvenile yellow catfish exposed to substantially lower concentrations of TCEP over 30 days, including significant adverse effects on growth, histological changes to gills, and altered gene expression.[282] Histological changes to gill cells occurred at doses as low as 1 μg/L, equivalent to 1 ppb, while adverse effects on growth and body weight occurred at doses as low as 10 ppb.[283] And at 100 ppb TCEP exposure, "the survival rate of juvenile yellow catfish . . . was significantly decreased compared with the control after 30-day exposure, which implied that high environmental concentrations of TCEP could threaten the survival of juvenile yellow catfish."[284] Based on this study and utilizing the assessment factor of ten that EPA applied to calculate its concentration of concern, Zhao et al. would support a concentration of concern as low as 0.1 ppb (based on histological changes to gill cells) or 1 ppb (based on growth effects). It does not appear that EPA considered this study in developing the draft risk evaluation, and it must do so in revising the draft and appropriately strengthen its hazard thresholds to protect aquatic life—including the most sensitive species.

C. EPA Has Not Adequately Evaluated the Risks TCEP Presents to Birds, Marine Mammals, Threatened and Endangered Species, and Other Species of Special Concern

The draft risk evaluation indicates that EPA's assessment of TCEP's hazards to aquatic organisms and mammals rests on studies in fish (for aquatic organisms) and mice and rats (for mammals),[285] and that its risk characterization for terrestrial vertebrates is based on an analysis of trophic transfer exposures to American mink.[286] EPA has not justified its failure to assess hazards and risks to other species in characterizing TCEP's risks to wildlife. EPA also failed to incorporate available literature and data in the draft risk evaluation that are relevant to assessing risks to birds, marine mammals, and threatened and endangered species. EPA must correct these omissions in the final risk evaluation to satisfy TSCA and ensure that its risk determinations and

[281] Draft TCEP Risk Evaluation at 104, 107.
[282] Yixin Zhao et al., *Effects of Tris (2-chloroethyl) Phosphate (TCEP) on Survival, Growth, Histological Changes and Gene Expressions in Juvenile Yellow Catfish* Pelteobagrus fulvidraco, 87 Env't Toxicology & Pharmacology Art No. 103699 (2021).
[283] *Id.* 7; *see also id.* at 1, 3–4 (describing adverse effects on growth at 10 ppb TCEP exposure).
[284] *Id.* at 5.
[285] Draft TCEP Risk Evaluation at 104–06.
[286] *Id.* at 144.

subsequent risk management rule will protect wildlife species whose life histories and/or vulnerable conservation status place them at greater risk from exposure to TCEP.[287]

At the outset, EPA has not justified its reliance on such a narrow set of wildlife species to characterize TCEP's environmental hazards. EPA's ecological risk assessment guidance directs the Agency to consider multiple criteria in selecting "assessment endpoints" for ecological risk assessment, including a species' "(1) ecological relevance, (2) susceptibility to known or potential stressors, and (3) relevance to management goals."[288] "Of these, ecological relevance and susceptibility are essential for selecting assessment endpoints that are scientifically defensible."[289] EPA has not justified its exclusive reliance on fish and mouse/rat studies under these criteria.

Further, EPA has not considered all reasonably available information that is relevant to evaluating TCEP's risks to species of special ecological and conservation concern—including but not limited to marine mammals. Aside from citing three studies reporting lipid concentrations of TCEP in aquatic mammals,[290] the draft risk evaluation does not discuss exposure or risks to these species. This omission must be addressed in the final risk evaluation. TCEP and other organophosphates are widely detected in marine mammals,[291] and a recent study documented significant biomagnification of the TCEP metabolite bis(2-chloroethyl) phosphate ("BCEP") in marine mammals.[292] Further, "[m]arine mammals, such as cetaceans and pinnipeds, are widely acknowledged as sentinel species to assess marine contamination status and health of marine ecosystem[s] due to being long-term inhabitants and long-lived apex predators at high trophic levels in the marine ecosystem."[293] As a result of their long life spans, high trophic position in aquatic food webs; and "thick subcutaneous lipid layer (i.e. blubber)," in which persistent pollutants can accumulate, their exposure to and risks from persistent pollutants such as TCEP

---

[287] 15 U.S.C. § 2605(b)(4)(F)(i) (requiring EPA to "integrate and assess available information on hazards and exposures . . . that is relevant to specific risks of injury to . . . the environment").
[288] EPA, EPA/630/R-95/002F, *Guidelines for Ecological Risk Assessment* 30 (Apr. 1998) ("Guidelines for Ecological Risk Assessment"), https://www.epa.gov/sites/default/files/2014-11/documents/eco_risk_assessment1998.pdf.
[289] *Id.*
[290] Draft TCEP Risk Evaluation at 96.
[291] *See*, *e.g.*, Mengqin Chen et al., *Tissue Distribution and Trophic Transfer of Organophosphate Triesters and Diesters in Three Marine Mammals of the Liaodong Bay and the Northern Yellow Sea*, 461 J. Hazardous Materials Art. No. 132694 (2024).
[292] *Id.* at 5 (advising that "BCEP . . . should be taken seriously as [it] may be accumulated in predators with continuously increasing concentration along the food chains/webs").
[293] *Id.* at 2; *see also* Nat'l Marine Fisheries Serv., *Endangered Species Act (ESA) Section 7(a)(2) Biological Opinion and Magnuson-Stevens Fishery Conservation and Management Act Fish Habitat Response, Reissuance of Nat'l Pollution Discharge Elimination Sys. (NPDES) Permit (#CA0107409) for the Point Loma Wastewater Treatment Plant and Ocean Outfall* 74 (2022) ("Point Loma BiOp") (discussing recent study, Bekele et al. 2019, which "demonstrated both bioaccumulation and biomagnification of organophosphate flame retardants in the marine food webs").

are distinct from fish or terrestrial mammals and require specific evaluation.[294] Indeed, NMFS—the federal resource agency with primary responsibility for and expertise in the conservation and recovery of threatened and endangered marine species—has concluded that "marine mammals in particular, and likely sea turtles as well, are susceptible to endocrine disruption and harmful effects from . . . organophosphate flame retardants."[295]

In addition, EPA has not evaluated TCEP exposures and risks in a sufficient diversity of bird species and life stages. In its avian exposure assessment, EPA discusses only two studies measuring TCEP concentrations in bird eggs,[296] disregarding a recent study, Choo et al. 2022, that reported high concentrations of TCEP in black gull eggs and a 377 percent increase in measured TCEP concentrations between 2012 to 2018.[297] Further, it does not appear that EPA integrated the available data on TCEP concentrations in bird eggs into its risk characterization.[298] This is problematic because the sensitivity of wildlife to chemical stressors "can be related to the life stage of an organism when exposed to a stressor," and "[f]requently, young animals are more sensitive to stressors than adults."[299]

Regarding hazards to avian species, EPA asserts that "only a single high-quality study was available for the American kestrel with no hazard value for the avian insectivore within [the] analysis."[300] This approach is not adequate to accurately characterize TCEP exposures and risks to birds. The high TCEP concentrations in black gull eggs reported in Choo et al. 2022 may reflect the study's assessment of birds that feed primarily on fish since, as EPA acknowledges, "TCEP has the ability to quickly bioaccumulate in fish tissue if it is exposed to high TCEP concentration[s] in the surrounding water for a period of time."[301] In the final risk evaluation, EPA should consider exposure and risk to fish-eating birds. EPA recognized the need to fill a similar gap in response to public comments on its draft risk evaluation for the flame retardant HBCD.[302] In addition, EPA should consider additional data on TCEP concentrations in insects to

---

[294] Berta Sala et al., *Transplacental Transfer of Plasticizers and Flame Retardants in Fin Whales (*Balaenoptera physalus*) from the North Atlantic Ocean*, 313 Env't Pollution Art. No. 120168, at *2 (2022).
[295] Point Loma BiOp at 89.
[296] Draft TCEP Risk Evaluation at 98.
[297] Gyojin Choo et al., *Temporal and Spatial Trends of Chlorinated Paraffins and Organophosphate Flame Retardants in Black-Tailed Gull (*Larus crassirostris*) Eggs*, 803 Sci. Total Env't Art. No. 150137, at *4–5 (2022).
[298] *See* Draft TCEP Risk Evaluation at 144, 466–68.
[299] Guidelines for Ecological Risk Assessment at 33.
[300] Draft TCEP Risk Evaluation at 151.
[301] *Id.* at 442.
[302] EPA, *Summary of External Peer Review and Public Comments and Disposition for Cyclic Aliphatic Bromide Cluster (HBCD)* 106–07 (Sept. 2020), https://www.epa.gov/sites/default/files/2020-09/documents/2._summary_of_external_peer_review_and_public_comments_and_disposition_for_cyclic_aliphatic_bromide_cluster.pdf.

better characterize exposure and risk to avian insectivores. TCEP has been widely detected in insect species, with significant variation among species and even individual species' life stages, which indicates that their avian predators are likely to experience significant differences in TCEP exposures depending on the particular insect species they consume and the life stage of their prey.[303]

EPA also failed to consider risks to wildlife species that are listed as threatened or endangered under the ESA or other species of special conservation concern. As noted above, this is contrary to EPA's own ecological risk assessment guidelines as well as its statutory obligations under the ESA to "seek to conserve endangered species and threatened species" and "utilize [its] authorities in furtherance of the purposes [of the ESA]."[304] In this regard, NMFS has noted that chlorinated organophosphates such as TCEP "may have similar toxic effects on ESA-listed species" as the PBDEs for which they are often substitutes.[305] These effects include, but are not limited to, "endocrine disruption and neurotoxicity that can negatively impact fish nervous systems, thyroid and liver functions, and endocrine and reproductive systems,"[306] as well as impaired immune response, which is "of particular concern for salmonids because a properly functioning immune system is vital for both individual survival and population productivity."[307] NMFS has determined that "data from toxicity testing, epidemiological studies, and risk assessments all suggest that there are health concerns" for wildlife "at current exposure levels for organophosphate flame retardants,"[308] and has expressed "particular concern" regarding the effects of TCEP, TCPP, and TDCPP on threatened and endangered wildlife.[309] At a minimum, in light of the readily available evidence indicating heightened exposures and risks, the final risk

---

[303] *See, e.g.,* Yin-E Liu et al., *Bioaccumulation of Legacy and Emerging Organophosphorous Flame Retardants and Plasticizers in Insects During Metamorphosis*, 406 J. Hazardous Materials Art. No. 124688, at *3 (2021).
[304] 16 U.S.C. § 1531(c).
[305] Point Loma BiOp at 73–74.
[306] *Id.* at 125.
[307] Sandra M. O'Neill et al., *Chemical Tracers Guide Identification of the Location and Source of Persistent Organic Pollutants in Juvenile Chinook Salmon (*Oncorhynchus tshawytscha*), Migrating Seaward Through an Estuary With Multiple Contaminant Inputs*, 712 Sci. Total Env't Art No. 135516, at *12 (2020); *see also* Mary R. Arkoosh et al., *Disease Susceptibility of Salmon Exposed to Polybrominated Diphenyl Ethers (PBDEs)*, 98 Aquatic Toxicology 51 (2010); Teresa M. Mongillo et al., *Exposure to a Mixture of Toxic Chemicals: Implications for the Health of Endangered Southern Resident Killer Whales,* Nat'l Marine Fisheries Serv., at 4, 8–10 (2016) (discussing PBDE exposures and effects); Moira A. McKernan et al., *Toxicity of Polybrominated Diphenyl Ethers (DE-71) in Chicken (*Gallus gallus*), Mallard (*Anas platyrhynchos*), and American Kestrel (*Falco sparverius*) Embryos and Hatchlings*, 28 Env't Toxicology Chem. (2009).
[308] Point Loma BiOp at 77.
[309] *Id.* at 74.

evaluation must consider TCEP's effects on ESA-listed salmon, marine mammals, and loggerhead sea turtles.[310]

D. EPA Must Assess Aggregate and Cumulative Risks to Wildlife

Finally, to satisfy its statutory mandate to utilize the best available science, EPA's final risk evaluation for TCEP must consider aggregate and cumulative exposures and risks to wildlife.[311] It is axiomatic that "organisms do not live in single-stress situations. Rather they are constantly exposed to a series of different stressors, both chemical and non-chemical."[312] EPA's risk evaluation cannot ignore this reality.

Regarding aggregate exposures to TCEP among wildlife, EPA acknowledged but refused to consider them.[313] This leads EPA to underestimate wildlife exposures and risks and must be corrected in the final risk evaluation.

EPA likewise must correct its failure to consider cumulative exposures and risks among wildlife. As NMFS has observed, "[m]ixture effects case studies that have examined effects from the interaction of [persistent organic pollutants] . . . demonstrate that the interaction of pollutants is primarily synergistic and toxicity is enhanced, especially when the exposure to the chemical mixture is at a critical developmental growth period."[314] Accordingly, NMFS has criticized ecological risk assessments that focus on "high doses of [single] contaminants," which "may underestimate risk . . . because some contaminants can interact at doses below the no observed effect concentrations (NOECs) and produce significant effects."[315] Consideration of additive and synergistic effects is particularly important in the risk evaluation at hand given the extensive literature documenting wildlife species' co-exposures to TCEP along with other organophosphates, PBDEs, PCBs, phthalates, and additional contaminants that are known to exert common adverse health effects on animals.[316] Further, there are established methods and

---

[310] *See* Sala et al. (2021), at 1, 4 (reporting TCEP detections in 85–86 percent of sampled loggerheads and total levels of organophosphate ester flame retardants "much higher than the values reported previously for teleost fishes and marine mammals from the western Mediterranean"—indeed, "the highest levels reported to date" among marine wildlife, indicating that fish studies are not adequate for assessing exposure and risk in loggerheads).
[311] 15 U.S.C. § 2625(h).
[312] Benoit Goussen et al., *Integrated Presentation of Ecological Risk from Multiple Stressors*, 6 Sci. Reps. Art. No. 36004, at *1 (2016).
[313] Draft TCEP Risk Evaluation at 145–46.
[314] Point Loma BiOp at 79.
[315] *Id.*
[316] *See, e.g.*, Sala et al. (2022); Anna Lippold et al., *Occurrence of Emerging Brominated Flame Retardants and Organophosphate Esters in Marine Wildlife from the Norwegian Arctic*, 315 Env't Pollution Art. No.120395 (2022); Rui Hou et al., *Accumulation and Distribution of Organophosphate Flame Retardants (PFRs) and their Di-alkyl Phosphates (DAPs) Metabolites in Different Freshwater Fish from Locations Around Beijing, China*, 229 Env't Pollution 548 (2017); Mongillo et al. (2016).

many templates for conducting a cumulative wildlife risk assessment for TCEP.[317] Indeed, "unlike health risk assessment, ecological risk assessment incorporated the concept of cumulative impacts from its inception in the 1990s."[318] EPA must draw from this well-established body of science to account for cumulative exposures and risk to wildlife in the final TCEP risk evaluation.

VIII. EPA's Unreasonable Risk Thresholds Are Unsupported and Underprotective

EPA's thresholds for determining whether TCEP presents unreasonable cancer risk are unsupported, vague, and inconsistently applied. EPA has historically supported the use of a 1-in-1,000,000 cancer risk threshold under TSCA, consistent with the level used in other EPA programs.[319] In the draft TCEP risk evaluation, however, EPA replaces that clear benchmark with "a range of extra cancer risk from 1×10^{-4} [1-in-10,000] to 1×10^{-6} [1-in-1,000,000]."[320] There is no legal or scientific justification for that change.

EPA sets the threshold for unreasonable occupational cancer risks at the less protective end of that range, claiming that, "[c]onsistent with [National Institute for Occupational Safety and Health ("NIOSH")] guidance, under TSCA EPA typically applies a 1×10^{-4} [1-in-10,000] benchmark for occupational scenarios in industrial and commercial work environments subject to [Occupational Safety and Health Administration] requirements."[321] This justification misinterprets NIOSH guidelines, which describe 1-in-10,000 not as a target cancer risk level but rather "a starting point for continually reducing exposures in order to reduce the remaining risk."[322] NIOSH goes on to say that "for most carcinogens, there is no known safe level of exposure" and NIOSH will continue to recommend that employers reduce worker exposure to occupational carcinogens as much as possible through the hierarchy of controls, most

---

[317] *See* Alianza Nacional de Campesinas, Inc. et al., Comments on Draft Proposed Principles of Cumulative Risk Assessment Under the Toxic Substances Control Act, at 29–30 (Apr. 28, 2023), https://www.regulations.gov/comment/EPA-HQ-OPPT-2022-0918-0035 (collecting examples).
[318] Gina Solomon et al., *Integrating Environmental Justice into Public Health: Approaches for Understanding Cumulative Impacts*, 5 Frontiers Pub. Health Servs. & Sys. Rsch. 9, 11 (2016).
[319] *See, e.g.,* Charles W. Schmidt, *TSCA 2.0: A New Era in Chemical Risk Management*, 124 Env't Health Persp. 182, 184 (2016) ("Asked what constitutes 'unreasonable risk' under the new TSCA . . . [Office of Pollution Prevention and Toxics Director Wendy] Cleland-Hamnett cites the EPA's cancer risk benchmark of no more than 1 case out of 1 million people exposed to a given carcinogen."); EPA, EPA-744-D-22-001, *Draft TSCA Screening Level Approach for Assessing Ambient Air and Water Exposures to Fenceline Communities: Version 1.0*, at 54 (Jan. 2022) ("Fenceline Assessment Approach"), https://www.epa.gov/system/files/documents/2022-01/draft-fenceline-report_sacc.pdf (adopting a 1-in-1,000,000 cancer risk benchmark "for cancer risk in fenceline communities" "consistent with the cancer benchmark used for general population cancer risk in several other EPA programs and in previous risk evaluations").
[320] Draft TCEP Risk Evaluation at 296.
[321] *Id.* (citation omitted).
[322] NIOSH, *Current Intelligence Bulletin 68: NIOSH Chemical Carcinogen Policy* 20 (July 2017), https://www.cdc.gov/niosh/docs/2017-100/pdf/2017-100.pdf.

importantly elimination or substitution of other chemicals that are known to be less hazardous."[323] By accepting occupational cancer risks of 1-in-10,000—risks up to100 times greater than "acceptable" consumer and general population risks—EPA eliminates any incentive for employers to exceed that benchmark, misconstruing NIOSH policy and leaving workers exposed to excessive cancer risks.[324]

For consumers, the general public, and fenceline communities, EPA claims that it "typically considers the . . . benchmark for cancer risk to be within the range of 1×10^{-6} [1-in-1,000,000] and 1×10^{-4} [1-in-10,000]."[325] That is a substantial, and unexplained, departure from the approach set forth in EPA's *Draft TSCA Screening Level Approach for Assessing Ambient Air and Water Exposures to Fenceline Communities*, which affirmed that "EPA used [1-in-1,000,000] as the benchmark for cancer risk in fenceline communities."[326] Similarly, in the first ten TSCA risk evaluations EPA used a 1-in-1,000,000 cancer risk benchmark to characterize unreasonable consumer risks.[327] Not only is EPA's "range" of supposedly permissible risk levels up to 100 times less protective than EPA's prior approach, it also is far less transparent and invites arbitrary decision making, since EPA has not explained how it will determine whether a risk that falls within that range is reasonable or unreasonable. EPA vaguely states that "[e]xposure-related considerations (*e.g.*, duration, magnitude, population exposed) can affect" the reasonableness of cancer risk, but it does not explain how it will apply and weigh those considerations, opening the door to arbitrary and unprincipled risk determinations.[328]

Finally, the draft risk evaluation does not even adhere to EPA's own, weakened cancer risk thresholds. EPA states that five conditions of use "were preliminary [sic] determined not to contribute to the unreasonable risk," including consumer uses of "building/construction materials – insulation."[329] But according to EPA's risk calculations, "[i]nhalation from insulation presents the highest lifetime cancer risk (4.50×10^{-2})" to consumers.[330] This calculated cancer risk of 4.5-in-100 is more than 450 times greater than the EPA's least protective, 1-in-10,000 unreasonable

---

[323] *Id.*
[324] *Id.*; *see also* TSCA Sci. Advisory Comm. on Chems., *Meeting Minutes and Final Report No. 2020-02: Peer Review for EPA Draft Risk Evaluation for N-Methylpyrrolidone (NMP)* 91 (Mar. 5, 2020), https://www.regulations.gov/document/EPA-HQ-OPPT-2019-0236-0066 (criticizing EPA's "[d]ecision that assumes the target cancer risk of less than [1-in-10,000] is an acceptable risk for occupational users when other programs['] threshold risks [are] at [1-in-100,000 or 1-in-1,000,000]").
[325] Draft TCEP Risk Evaluation at 296.
[326] Fenceline Assessment Approach at 54.
[327] *See, e.g.,* EPA, EPA-740-R1-8013, *Risk Evaluation for 1-Bromopropane (*n-*Propyl Bromide)*, at 321 (Aug. 2020), https://www.epa.gov/sites/default/files/2020-08/documents/risk_evaluation_for_1-bromopropane_n-propyl_bromide.pdf ("EPA used $1x10^{-6}$ as the benchmark for the cancer risk to consumers and bystanders . . . .").
[328] Draft TCEP Risk Evaluation at 297.
[329] *Id.* at 20–21.
[330] *Id.* at 306.

risk benchmark, and *45,000 times greater* than the appropriate benchmark of 1-in-1,000,000, yet EPA still did not find unreasonable risk. EPA offers no explanation for this discrepancy. We urge EPA to affirm and consistently apply a cancer risk threshold of 1-in-1,000,000.

IX. EPA Should Not Calculate Existing Chemical Exposure Limits During the Risk Evaluation

The purpose of a TSCA risk evaluation is to determine whether a chemical presents unreasonable risk that triggers the need for regulation, not to prejudge potential regulatory options. Congress separated EPA's decisions about how to manage unreasonable risk into a distinct regulatory process that follows the completion of a risk evaluation.[331] Indeed, TSCA section 6(c) enumerates factors that EPA "shall consider" during the risk management process,[332] which include "costs [and] other nonrisk factors" that EPA is expressly precluded from considering in a TSCA risk evaluation.[333]

Yet EPA blurs the line between risk evaluation and risk management by improperly calculating Existing Chemical Exposure Limits ("ECELs")—a risk management tool—in its draft TCEP risk evaluation. Appendix N of the draft risk evaluation contains a "Draft [ECEL]" that "may be used to support risk management efforts for TCEP under TSCA section 6(a)."[334] EPA even evaluates whether TCEP would be detectable at the draft ECEL value using existing air sampling methods, a "nonrisk factor[]" that EPA is barred from considering at this stage.[335] Notably, EPA does not discuss any other risk management approach in its risk evaluation. For instance, it does not consider whether engineering controls would eliminate TCEP's unreasonable risks to workers; whether pretreatment requirements or other disposal regulations would address TCEP's disposal related risks; or whether a ban on the manufacturing, processing, and commercial distribution of TCEP would be more effective than EPA's draft ECEL. The analysis of potential ECELs in the draft risk evaluation suggests that EPA has impermissibly prejudged potential risk management measures, well before the risk management process has even begun.

In addition to being premature, EPA's draft ECELs are underprotective and inconsistent with TSCA's requirement to regulate TCEP "to the extent necessary so that [it] no longer presents [unreasonable] risk."[336] EPA's draft ECEL of 0.09 mg/m^3 TCEP, measured over an eight-hour time-weighted average,[337] falls short of that statutory requirement. EPA determined the draft ECEL based on the level of TCEP exposures that are estimated to keep occupational

---

[331] 15 U.S.C. § 2605(a)–(b).
[332] *Id*. § 2605(c)(2).
[333] *Id*. § 2604(b)(4)(A) (prohibiting EPA from considering "costs or other nonrisk factors" during the risk evaluation stage); *id.* § 2605(c)(2)(A)(iv)(II) (requiring EPA to consider "the costs and benefits of the proposed and final regulatory action" during the risk management stage).
[334] Draft TCEP Risk Evaluation at 568.
[335] 15 U.S.C. § 2604(b)(4)(A).
[336] *Id*. § 2605(a).
[337] Draft TCEP Risk Evaluation at 568.

cancer risks at or below 1-in-10,000,[338] a benchmark that accepts far greater occupational cancer risks than EPA has found acceptable for consumers or the general public. Further, in calculating that level, EPA assumes that workers would be exposed to TCEP from a single exposure route (inhalation), via a single condition of use, without any out-of-work exposures from TCEP in their homes or environment.[339] EPA's draft ECEL would thus fail to eliminate unreasonable risks to workers who are exposed to TCEP on and off the job, or, for example, from dermal contact as well as inhalation. EPA also fails to address how it plans to implement and enforce an ECEL when, by its own account, EPA has no idea where TCEP is manufactured and used. However, those questions and others should be addressed during the TSCA risk management process, when a proposed ECEL can be compared to other risk management options. In the meantime, draft ECELs have no place in the TCEP risk evaluation.

X. EPA Should Publish a Non-Technical Summary of the Draft TCEP Risk Evaluation That Adheres to EPA Guidance and Best Practices on Risk Communication

The TSCA risk evaluation rule requires "EPA . . . to provide public access to . . . [a] nontechnical summary of the risk evaluation."[340] The non-technical summary must allow people who are adversely impacted by the chemical undergoing evaluation, such as workers, consumers, and residents of fenceline communities, to readily identify what potential risks they face and how EPA calculated those risks. However, EPA did not provide a non-technical summary alongside the draft TCEP risk evaluation. The closest that EPA comes to such a summary is an overview of key points at the beginning of a select number of chapters.[341] Even then, these chapter summaries use technical jargon and are difficult for the general public to understand, and do not suffice as a substitute for the non-technical summary required by TSCA's implementing regulations.[342]

EPA should have published a non-technical summary alongside the draft TCEP risk evaluation. Doing so would allow workers, consumers, and communities impacted by TCEP exposures to not only better understand the results of the TCEP risk evaluation, but also to better engage in the comment period, which is the only formal opportunity to express their views on the TCEP risk evaluation. By foregoing a non-technical summary at the draft risk evaluation stage, EPA fails to effectively communicate the results of the draft TCEP risk evaluation to people exposed to the chemical and facilitate their engagement in the public comment process.

In addition to publishing a non-technical summary, EPA should have conducted meaningful outreach to tribes, fenceline communities, labor unions, and other exposed

---

[338] *Id.* at 569.
[339] *Id.*
[340] 40 C.F.R. § 702.51(d).
[341] *See, e.g.,* Draft TCEP Risk Evaluation at 39.
[342] *See, e.g., id.* at 157 ("For OESs that do not have data, EPA used relevant generic scenario and/or emission scenario documents to identify worker activities and exposure routes that are reasonably expected to occur. Exposure distributions were then created using Monte Carlo simulation with 100,000 iterations and the Latin Hypercube sampling method.").

populations to better understand their communication preferences and needs.[343] EPA must tailor its communication strategy to each target audience. In order to achieve effective risk communication, EPA must engage multiple impacted groups early in the risk evaluation process, as opposed to the end, and solicit their feedback on what information should be included in the non-technical summaries, as well as the preferred form and manner in which the information is delivered.[344]

Furthermore, we advise EPA to, at a minimum, adhere to the following risk communication principles recommended by EPA in the past and by the Interstate Technology and Regulatory Council ("ITRC").[345] 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. As mentioned above, in the chapter summaries included in the draft TCEP risk evaluation, EPA uses scientific, legal, and technical terms with which a layperson may be unfamiliar.[346] 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."[347] Similarly, the ITRC published guidance regarding risk communication advises that writing for fact sheets should be at "a sixth-grade comprehension level."[348] EPA should do the same in its non-technical summary of the risk evaluation.

EPA should also organize its summaries in a way that is easy for readers to process information. EPA should consider organizing its non-technical summaries in more reader-

---

[343] The recommended outreach to tribes to support effective risk communication is distinct from, and not a substitute for, EPA's obligation to engage in meaningful government-to-government consultation with tribes concerning the TCEP risk evaluation.

[344] *See* Mem. from Richard L. Revesz, Adm'r, Off. of Info. & Regul. Affs., to Heads of Exec. Dep'ts & Agencies at 10 (July 19, 2023), 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 . . . .").

[345] *See* Interstate Tech. Regul. Council, *Risk Communication Toolkit*, https://rct-1.itrcweb.org/ (last visited Feb. 8, 2024).

[346] *See, e.g.*, Draft TCEP Risk Evaluation at 157, 171 (using jargon when describing "key points" in the risk evaluation findings regarding occupational, consumer, and general population exposures).

[347] 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.

[348] Interstate Tech. Regul. Council, *14.3.6.2 Fact Sheets and Frequently Asked Questions (FAQs)*, *Risk Communication* in *PFAS* ("ITRC FAQs"), https://pfas-1.itrcweb.org/14-risk-communication/ (last visited Feb. 8, 2024).

friendly structures, such as using visual elements or detailed headings.[349] A good example of this is the EPA Office of Water's fact sheet regarding 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.[350]

Additionally, EPA should make non-technical summaries more accessible by "providing materials in multiple languages for nonnative English speakers."[351] EPA should use demographic information to ensure that communities in which English is not the predominant language have access to information regarding their risks of exposure. As mentioned *supra*, EPA does not have information on *where* TCEP is being released despite having had more than sufficient time to collect this data. We urge EPA to collect this information and adopt this practice for any future risk evaluations. If EPA lacks this information, such as is the case here, it should still provide non-technical summaries in languages other than English based on national statistics, such as from the U.S. Census Bureau, on languages spoken across the United States.

Lastly, the information that EPA conveys through its non-technical summaries should include the results that are most relevant to impacted groups. EPA must provide a plain-language 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, as opposed to vaguely defined categories. For instance, the draft risk evaluation says that TCEP is used in "fabric and textile products" and "foam seating and bedding products,"[352] but it fails to specify that TCEP has been detected in nursing pillows, crib mattresses, yoga mats, and other products that people use on a daily basis. We recommend that EPA describe the products in which TCEP is found in more accessible and relevant terms, and also provide a clear and digestible illustration or infographic to help the general public more easily understand their sources of exposure. 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.

We urge EPA to, at a minimum, publish a non-technical summary that adheres to the best practices laid forth above alongside the publishing of the final TCEP risk evaluation, and going forward, to publish a non-technical summary that adheres to best practices for any future draft risk evaluations in order to increase meaningful engagement with impacted groups and communities.

---

[349] *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.").
[350] 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.
[351] ITRC FAQs.
[352] Draft TCEP Risk Evaluation at 27.

XI. The SACC Should Have the Opportunity to Review the Draft Risk Evaluation in a Panel Peer Review Process With a Broadened Charge

Instead of a full panel review of the draft TCEP risk evaluation, EPA intends to conduct a "letter peer review" in which a small number of SACC members individually review EPA's draft.[353] A letter review involves no public peer review meeting, no deliberation between the reviewers, and thus no opportunity for experts from different backgrounds and disciplines to debate points of disagreement and coalesce around common recommendations. For all those reasons, letter review is disfavored by EPA and by the SACC itself and should not be used for the draft TCEP risk evaluation.

EPA's *Peer Review Handbook* advises against the use of letter peer review for "influential scientific information" like draft TSCA risk evaluations.[354] The *Handbook* defines "influential scientific information" ("ISI") as "scientific information the agency reasonably can determine will have or does have a clear and substantial impact on important public policies or private-sector decisions."[355] "Highly influential scientific assessment" ("HISA"), a subset of ISI, is defined as "a scientific assessment that: (i) could have a potential impact of more than $500 million in any year, or (ii) is novel, controversial, or precedent-setting or has significant interagency interest."[356] TSCA risk evaluations—which are intended to inform regulatory decisions and which frequently involve "novel" scientific issues with "significant interagency interest" —are both ISI and HISA.[357] The *Handbook* thus recommends that such risk evaluations undergo full panel review:

> [P]anels 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. Panel peer review meetings may be open to the public, with opportunities for public comment.[358]

Members of the SACC have reached the same conclusion. The peer reviewers of EPA's *Quantitative Human Health Approach to be Applied in the Risk Evaluation for Asbestos Part 2* were highly critical of EPA's decision to use a letter review process, which they found "entirely inconsistent with the 40-year history of EPA Science Advisory Panels" and contrary to the "legal

---

[353] Tris(2-chloroethyl) Phosphate; Draft Risk Evaluation Under the Toxic Substances Control Act (TSCA); Letter Peer Review; Notice of Availability, Public Meeting and Request for Comment, 88 Fed. Reg. 86,894-02 (Dec. 15, 2023).
[354] *See* EPA, *Peer Review Handbook* at 42–43, 57 (4th ed. 2015), https://www.epa.gov/sites/default/files/2016-03/documents/epa_peer_review_handbook_4th_edition.pdf.
[355] *Id.* at 42.
[356] *Id.* at 43; *see also id.* (listing "safety or ecological risk assessments" as an example of highly influential scientific assessment).
[357] *Id.* (quotation omitted).
[358] *Id.* at 57.

expectations of a 'SACC review.'"[359] In particular, reviewers complained that they were "specifically . . . told that we are not to talk with one another" and "that there will be no conference calls among members," precluding open communication and deliberation.[360] As one reviewer concluded: "The design of this 'letter peer review' process seems to be intended to avoid having the Agency receive a proper evaluation of their work."[361]

In more than seven years since the 2016 TSCA amendments, EPA has never issued a risk evaluation without at least one opportunity for a full panel SACC review. TCEP should not be the first. According to EPA, there are several "novel" aspects of the draft TCEP risk evaluation—including EPA's approach to estimating aerial deposition of TCEP, exposures to TCEP in breastmilk, and drinking water contamination from landfill leachate—that EPA is using "for the first time" under TSCA.[362] Those issues and others would benefit from the consideration and input of the full SACC. EPA has ample time to schedule and conduct a panel review of the draft TCEP risk evaluation, which can be held virtually consistent with EPA's post-2020 practice. We urge EPA to do so.

We are also concerned by the narrow charge that EPA provided to prospective peer reviewers.[363] EPA seeks input on discrete aspects of its risk evaluation, such as "the approach that EPA/OPPT took . . . to estimate anaerobic degradation" and "how EPA/OPPT calculated the HC_{05},"[364] while ignoring the major uncertainties and data gaps that EPA itself identified in its evaluation. For instance, EPA claims that it "does not have sufficient information to determine whether [six conditions of use] contribute to TCEP's unreasonable risks," but it has not solicited the SACC's advice on how it could fill those gaps or otherwise calculate those risks.[365] EPA also says that it "was not able to quantify releases of TCEP that could occur during the recycling of e-waste,"[366] but it has not asked whether the SACC is aware of any data or methods that could address that exposure pathway. Wherever EPA has identified uncertainties or data gaps, it should seek the SACC's advice on how to address them, along with a broader solicitation of feedback on the strengths and weaknesses of the draft risk evaluation that extends beyond the narrowly tailored questions in the draft charge.

---

[359] EPA, *Peer Reviewer Comments on the White Paper: Quantitative Human Health Approach to be Applied in the Risk Evaluation for Asbestos Part 2— Supplemental Evaluation including Legacy Uses and Associated Disposals of Asbestos* 15, 34 (Dec. 26, 2023), https://www.regulations.gov/document/EPA-HQ-OPPT-2023-0309-0020.
[360] *Id.* at 34.
[361] *Id.* at 15; *see also id.* at 34 (explaining that "it is particularly critical that true experts, who have spent one, two or three decades evaluating the 16 or more relevant epidemiology studies, meet with one another to discuss the strengths and weaknesses of each study").
[362] 88 Fed. Reg. at 86,895–96.
[363] *See* EPA, *Charge Questions for the Draft Risk Evaluation for Tris(2-chloroethyl) Phosphate (TCEP)* (Dec. 2023), https://www.regulations.gov/document/EPA-HQ-OPPT-2023-0265-0007.
[364] *Id.* at 1–2.
[365] Draft TCEP Risk Evaluation at 21.
[366] *Id.* at 50.

* * *

If you have any questions about these comments, please contact Jonathan Kalmuss-Katz (jkalmusskatz@earthjustice.org) or Katherine O'Brien (kobrien@earthjustice.org) at Earthjustice.

Respectfully submitted,

Alaska Community Action on Toxics
Ecology Center (Michigan)
Earthjustice
Healthy Babies Bright Futures
Natural Resources Defense Council
Sierra Club
Toxic-Free Future