UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

BLUE RIDGE ENVIRONMENTAL DEFENSE LEAGUE, CLEAN WISCONSIN, MIDWEST ENVIRONMENTAL DEFENSE CENTER, and SIERRA CLUB, Plaintiffs, v. MICHAEL S. REGAN, in his official capacity as Administrator,[1] U.S. Environmental Protection Agency, Defendant.	Case No. 1:16-cv-364-CRC

Joint Motion to Extend Deadlines Under Court Order

After conferral regarding the issues discussed in prior status reports, the parties jointly move the Court for an extension of EPA's deadlines under the Court's March 22, 2017 Order, ECF No. 38, to take final action to control hazardous air pollution in light of *Louisiana Environmental Action Network v. EPA*, 955 F.3d 1088 (D.C. Cir. 2020) (*LEAN*).

EPA earlier explained that it had finalized six actions in response to that order. Those actions include hazardous air pollution rules required under sections 112(d) and 112(f) of the Clean Air Act, 42 U.S.C. § 7412(d), (f). *See* Order (Mar. 22, 2017) (requiring that EPA "complete its 'Risk and Technology Review' ("RTR") rulemakings" for six source categories by June 30, 2020). The actions cover six source categories: Lime Manufacturing Plants,

[1] Michael S. Regan is substituted for his predecessor Jane Nishida under Fed. R. Civ. P. 25(d).

Rubber Tire Manufacturing, Miscellaneous Coating Manufacturing, Plywood and Composite Wood Products, Taconite Iron Ore Processing, and Iron and Steel Foundries. ECF No. 55.

As EPA was preparing those actions for signature, the D.C. Circuit decided *LEAN* on April 21, 2020. In a case concerning the national emission standards for pulp mill sources, the court held that EPA must set limits on uncontrolled hazardous air pollutant ("HAP") emissions when it conducts rulemakings under section 112(d)(6) of the Act, 42 U.S.C. § 7412(d)(6). EPA then reported that it was evaluating whether *LEAN* affects the scope of its obligations under this Court's order. *See, e.g.*, ECF No. 55.

Since then, EPA has concluded that *LEAN* does not affect the scope of its obligations for the risk and technology review of the Iron and Steel Foundries category.[2] But for the other five of the source categories—Lime Manufacturing Plants, Miscellaneous Coating Manufacturing, Rubber Tire Manufacturing, Plywood and Composite Wood Products, and Taconite Iron Ore Processing[3]—EPA has concluded that, in finalizing its actions, it did not (or for the source category italicized in the list below, may not have) set all necessary emission limits for HAP emissions as part of its final rules as required by *LEAN*. To allow EPA to fill these regulatory gaps in accordance with *LEAN* and without the need for further litigation on new deadlines, the parties ask the Court to extend the deadlines to take final action on these five source categories as follows:

[2] 85 Fed. Reg. 56,080 (Sept. 10, 2020).
[3] *See* 85 Fed. Reg. 44,960 (July 24, 2020) (Lime Manufacturing Plants); 85 Fed. Reg. 49,724 (Aug. 14, 2020) (Miscellaneous Coating Manufacturing); 85 Fed. Reg. 44,752 (July 24, 2020) (Rubber Tire Manufacturing); 85 Fed. Reg. 49,434 (Aug. 13, 2020) (Plywood and Composite Wood Products); 85 Fed. Reg. 45,476 (July 28, 2020) (Taconite Iron Ore Processing).

Source category	**New deadline for signature of Final Rule**
Rubber Tire Manufacturing	October 27, 2022
Miscellaneous Coating Manufacturing	*February 16, 2023*
Lime Manufacturing Plants	February 23, 2023
Plywood and Composite Wood Products	November 16, 2023
Taconite Iron Ore Processing	November 16, 2023

EPA believes that these deadlines would give it time to collect and analyze any additional information needed to address *LEAN*, as well as provide meaningful public participation in the rulemaking process.

Plaintiffs state that they have agreed to these dates to allow time for EPA to meet its obligations under *LEAN*. Plaintiffs also have agreed to allow this additional time due to the change in Administrations and the time needed for EPA to comply with the directive from President Biden to "review . . . agency actions taken between January 20, 2017 and January 20, 2021 . . . that are or may be inconsistent with, or present obstacles to," the Administration's policy "of protecting public health and the environment" and "advanc[ing] environmental justice." E.O. 13,990 (Jan. 20, 2021), 86 Fed. Reg. 7037 (Jan. 25, 2021).

After submission of any signed notice of an information collection request, or notice of a proposed rule to the Federal Register for publication for these source categories, EPA will make its best efforts to notify Plaintiffs within 10 days of each such action. No later than 30 days after publication of each final rule for these source categories, EPA shall notify this Court of that action.

A proposed order accompanies this motion.

Submitted on April 13, 2021.

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Certificate of Service

I certify that on April 13, 2021, I filed the foregoing with the Court's CMS/ECF system, which will notify each party.

/s/ Sue Chen
Sue Chen

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

BLUE RIDGE ENVIRONMENTAL DEFENSE LEAGUE, CLEAN WISCONSIN, MIDWEST ENVIRONMENTAL DEFENSE CENTER, and SIERRA CLUB, Plaintiffs, v. MICHAEL S. REGAN, in his official capacity as Administrator, U.S. Environmental Protection Agency, Defendant.	Case No. 1:16-cv-364-CRC

EPA's Unopposed Motion to Extend Deadline

EPA moves for an extension of its deadline to take final action. Plaintiffs do not oppose EPA's requested relief.

Earlier this Court ordered EPA to complete risk and technology review rulemakings for certain source categories, including Lime Manufacturing Plants, under section 112(d) and (f) of the Clean Air Act, 42 U.S.C. § 7412(d), (f). ECF No. 38 (setting deadline at June 30, 2020). The Court later extended the deadline for Lime Manufacturing Plants to February 23, 2023. *See* ECF No. 61 (extending deadline); ECF No. 60 (joint motion for extension).

EPA's analysis here took longer than expected and the proposed rule for this action was published in the Federal Register on January 5, 2023. 88 Fed. Reg. 805. The comment period is open until February 21, 2023. As a result, EPA will need more time to complete final action.

The agency thus asks the Court to extend its deadline for Lime Manufacturing Plants until August 1, 2023.

Submitted on January 23, 2023

/s/ Sue Chen

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Certificate of Service

I certify that on January 23, 2023, I filed the foregoing with the Court's CMS/ECF system, which will notify each party.

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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

BLUE RIDGE ENVIRONMENTAL DEFENSE LEAGUE, CLEAN WISCONSIN, MIDWEST ENVIRONMENTAL DEFENSE CENTER, and SIERRA CLUB, Plaintiffs, v. MICHAEL S. REGAN, in his official capacity as Administrator, U.S. Environmental Protection Agency, Defendant.	Case No. 1:16-cv-364-CRC

EPA's Unopposed Motion to Extend Deadline

EPA moves for an extension of its deadline to take final action until June 30, 2024. Plaintiffs do not oppose EPA's requested relief.

Earlier this Court ordered EPA to complete risk and technology review rulemakings for certain source categories, including Lime Manufacturing Plants, under section 112(d) and (f) of the Clean Air Act, 42 U.S.C. § 7412(d), (f). ECF No. 38 (setting deadline at June 30, 2020). The Court later extended the deadline for Lime Manufacturing Plants to August 1, 2023. Minute Order (Jan. 24, 2023) (extending deadline to August 1, 2023); *see* ECF No. 61 (extending deadline to February 23, 2023).

In January, EPA's proposal for this action was published in the Federal Register. 88 Fed. Reg. 805 (Jan. 5, 2023). The comment period closed on February 21, 2023. Some

comments challenged underlying assumptions that EPA had made when it decided, under the Regulatory Flexibility Act, that the proposal would not have "a significant economic impact on a substantial number of small entities." 5 U.S.C. § 605(b). Because EPA can no longer certify that the proposal would not have such effects, the agency now plans to convene a review panel under 5 U.S.C. § 609(b), invite public comments on an initial regulatory flexibility analysis, and issue a final regulatory flexibility analysis to accompany the final rule. *See id.* §§ 603-04.

As a result, EPA will need more time to take final action. The agency thus asks that the Court extend the deadline for Lime Manufacturing Plants to June 30, 2024.

Submitted on July 20, 2023

/s/ Sue Chen

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Certificate of Service

I certify that on July 20, 2023, I filed the foregoing with the Court's CMS/ECF system, which will notify each party.

/s/ Sue Chen

Sue Chen

ORAL ARGUMENT NOT YET SCHEDULED

IN THE UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

No. 15-1487 (and consolidated cases)

SIERRA CLUB, et al.,

Petitioners,

v.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY, et al.,

Respondents.

On Petition for Review of Final Action of the
United States Environmental Protection Agency

BRIEF FOR RESPONDENT UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

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DATED: January 19, 2017
FINAL FORM: April 28, 2017

CERTIFICATE AS TO PARTIES, RULINGS, AND RELATED CASES

A. Parties and Amici

All parties and intervenors appearing in these consolidated cases are listed in the Brief for Environmental Petitioners and the Brief for Industry Petitioners.

B. Rulings Under Review

These petitions challenge EPA's final action entitled "NESHAP for Brick and Structural Clay Products Manufacturing; and NESHAP for Clay Ceramics Manufacturing," published at 80 Fed. Reg. 65,470 (Oct. 26, 2015). Petitioner Brick Industry Association also challenges EPA's final action entitled "NESHAP for Brick and Structural Clay Products Manufacturing; and NESHAP for Clay Ceramics Manufacturing," published at 81 Fed. Reg. 31,234 (May 18, 2016).

C. Related Cases

Case No. 15-1487 is consolidated with Case Nos. 15-1492, 15-1493, 15-1496, and 16-1179.

s/ Kate R. Bowers
KATE R. BOWERS

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* Authorities chiefly relied upon are marked with an asterisk.

CODE OF FEDERAL REGULATIONS

FEDERAL REGISTER

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* Authorities chiefly relied upon are marked with an asterisk.

LEGISLATIVE MATERIALS

* Authorities chiefly relied upon are marked with an asterisk.

GLOSSARY

ATSDR	Agency for Toxic Substances and Disease Registry
BIA	Petitioner Brick Industry Association
Brick/Clay Rule	NESHAP for Brick and Structural Clay Products Manufacturing; and NESHAP for Clay Ceramics Manufacturing, published at 80 Fed. Reg. 65,470 (Oct. 26, 2015)
Brick Rule	NESHAP for Brick and Structural Clay Products Manufacturing
CAA	Clean Air Act
Clay Rule	NESHAP for Clay Ceramics Manufacturing
EPA	United States Environmental Protection Agency
HAP	Hazardous Air Pollutant
MACT	Maximum Achievable Control Technology
NESHAP	National Emission Standards for Hazardous Air Pollutants
PM	Particulate Matter
RTC	Responses to Comments
TCNA	Petitioner Tile Council of North America
UPL	Upper Prediction Limit
2003 Rule	NESHAP for Brick and Structural Clay Products Manufacturing; and NESHAP for Clay Ceramics Manufacturing, published at 68 Fed. Reg. 26,690 (May 16, 2003)

STATEMENT OF JURISDICTION

This Court has jurisdiction pursuant to 42 U.S.C. § 7607(b)(1), except that, as set forth below, Petitioner Tile Council of North America ("TCNA") has failed to meet its burden to demonstrate Article III standing to challenge the tile industry standards.

STATEMENT OF THE ISSUES

Petitioners challenge emission standards established by Respondent Environmental Protection Agency ("EPA") under section 112 of the Clean Air Act ("CAA" or "the Act"), 42 U.S.C. § 7412, for hazardous air pollutants ("HAPs") emitted by brick and structural clay products and clay ceramics manufacturing facilities. EPA promulgated these regulations through the final agency action titled "NESHAP for Brick and Structural Clay Products Manufacturing; and NESHAP for Clay Ceramics Manufacturing" ("Brick/Clay Rule"), 80 Fed. Reg. 65,470 (Oct. 26, 2015). Petitioner Brick Industry Association ("BIA") also challenges EPA's final action on reconsideration of the Brick/Clay Rule, 81 Fed. Reg. 31,234 (May 18, 2016).

The issues raised by Environmental Petitioners are:

1. Is EPA's decision to establish health-based standards for acid gas emissions consistent with the CAA and reasonable?

2. Did EPA reasonably use the Upper Prediction Limit ("UPL") methodology to calculate emission standards for sources for which EPA had limited emissions data?

3. Is EPA's creation of alternative emission standards for brick kilns consistent with the CAA and reasonable, where the alternative standards are each expressed in a different unit of measurement and calculated based on the best-performing sources according to that unit of measurement?

The issues raised by Industry Petitioners are:

4. Is BIA barred from challenging EPA's inclusion of synthetic area source data in MACT floor calculations? And if reviewable, did EPA reasonably include emissions information from synthetic area sources in calculating the MACT floors to set standards for major sources?

5. Did EPA adequately justify the MACT floors for particulate matter ("PM") and non-mercury metals for brick industry sources and reasonably estimate the emissions from the best-performing 12 percent of sources?

6. Did EPA comply with the CAA in setting mercury standards for sources in the brick industry, and in declining to subcategorize based on the mercury content of raw materials?

7. Does Petitioner TCNA lack standing to challenge the tile industry standards and EPA's decision to list a major source category which includes the tile industry, where TCNA has not shown that any of its members would be injured by the standards for that category?

8. Does EPA have authority to set standards for major sources in the tile industry when, at the time the standards are proposed and issued, there are no sources in the category that would be subject to the standards?

9. Is TCNA barred from challenging EPA's decision to list a major source category including ceramic tile sources? And if reviewable, did EPA adequately support the listing of a major source category that includes tile sources?

10. Did EPA reasonably rely on reported emission levels that were measured using an established test method to set standards for dioxin/furan for tile industry sources?

11. Did EPA reasonably decline to include malfunction data in setting standards for the tile industry?

12. Are EPA's standards for ceramic tile sources reasonable where such standards are set at MACT floor levels and where EPA has neither required the use of a specific control technology nor set standards based on a beyond-the-floor analysis?

13. Did EPA reasonably base its MACT floor calculations for sanitaryware sources in part on emissions information from a source operating with emission controls that the source is not required to use?

PERTINENT STATUTES AND REGULATIONS

Pertinent statutes and regulations appear in Petitioners' briefs and Addendums thereto. Additional statutes are included in a separate addendum.

STATEMENT OF THE CASE

A. Statutory Background

The Brick/Clay Rule regulates the emissions of hazardous air pollutants ("HAPs") pursuant to CAA section 112, 42 U.S.C. § 7412. As amended in 1990, section 7412 directs EPA to regulate HAP emissions utilizing technology-based standards. *Sierra Club v. EPA*, 353 F.3d 976, 979 (D.C. Cir. 2004). In the 1990 amendments, Congress designated 189 HAPs that it deemed to be hazardous and therefore subject to regulation. *See* 42 U.S.C. § 7412(b)(1). Congress also required EPA to identify the categories of sources of each HAP, *id.* § 7412(c), and to set emission limits for each major stationary source, *id.* § 7412(d)(1). The statute defines major sources as those that emit or have the potential to emit considering controls more than ten tons per year of any covered HAP, or more than twenty-five tons per year of any combination of HAPs. *Id.* § 7412(a)(1). Sources that emit lower levels of HAPs are classified as "area sources." *Id.* § 7412(a)(2).

For major sources, section 7412 requires EPA to establish national emission standards for listed categories for both new and existing major sources. These standards are ordinarily promulgated under section 7412(d) and "require the maximum degree of reduction in emissions of the hazardous air pollutants subject to this section (including a prohibition on such emissions, where achievable)" that the Administrator determines is achievable based on existing technology, taking into consideration cost and other specific factors. 42 U.S.C. § 7412(d)(2). These emission

standards are referred to as "maximum achievable control technology" or "MACT" standards.

To establish MACT standards, EPA follows a two-step process. *U.S. Sugar Corp. v. EPA*, 830 F.3d 579, 594 (D.C. Cir. 2016). First, EPA establishes a "MACT floor," which is the absolute minimum level of emissions reductions covered sources must achieve. *Mossville Envtl. Action Now v. EPA*, 370 F.3d 1232, 1235 (D.C. Cir. 2004). The MACT floor is based on what level of emissions limitation has been achieved within the source category. For new sources, the MACT floor is "the emission control that is achieved in practice by the best controlled similar source, as determined by the Administrator." 42 U.S.C. § 7412(d)(3). The MACT floor for existing sources in categories or subcategories with 30 or more sources is "the average emission limitation achieved by the best performing 12 percent of the existing sources (for which the Administrator has emissions information)." *Id.* Where there are fewer than 30 sources in a category of subcategory, the MACT floor is determined based on the best-performing 5 sources. *Id.* Second, EPA has the discretion to set standards that are more stringent than the MACT floor (known as beyond-the-floor standards) that EPA determines are achievable "taking into consideration the cost of achieving such emissions reduction, and any non-air quality health and environmental impacts and energy requirements." *Id.* § 7412(d)(2); *see U.S. Sugar*, 830 F.3d at 594-95.

EPA has extensive discretion to determine whether and how to collect data and to decide how to identify and assess relevant data when establishing emission

standards. *Cement Kiln Recycling Coal. v. EPA*, 255 F.3d 855, 867 (D.C. Cir. 2001). EPA may use estimates of emission levels that have been achieved or are achievable, and may account for variability of a source's emissions. *Mossville*, 370 F.3d at 1240-42; *U.S. Sugar*, 830 F.3d at 632. "Floors need not be perfect mirrors of the best-performers' emissions . . . [but instead are to] reflect a reasonable estimate of the emissions 'achieved' in practice by the best-performing sources." *Cement Kiln*, 255 F.3d at 871-72 (citations omitted).

Under certain circumstances, section 7412 allows EPA to exercise its discretion to promulgate standards other than numeric MACT emission limitations. First, EPA has discretion to promulgate "health-based" emission limits pursuant to section 7412(d)(4). When section 7412 was first enacted, it required EPA to identify and regulate HAPs when they were found to "cause, or contribute to, an increase in mortality or an increase in serious irreversible [ ] or incapacitating reversible [ ] illness." Pub. L. No. 91-604, § 4(a), 84 Stat. 1676, 1685 (1970), 42 U.S.C. § 7412(a)(1) (1970). Congress amended section 7412 in 1990 to direct the use of technology-based standards because the prior health-based standards proved exceedingly difficult to generate. *NRDC v. EPA*, 529 F.3d 1077, 1079 (D.C. Cir. 2008).

By contrast, section 7412(d)(4) provides, "With respect to pollutants for which a health threshold has been established, the Administrator may consider such threshold level, with an ample margin of safety, when establishing emission standards

under this subsection."[1] 42 U.S.C. § 7412(d)(4). As EPA explained, "This provision is intended to allow the EPA to establish emission standards other than technology-based MACT standards, in cases where an alternative emission standard will still ensure that the health threshold will not be exceeded, with an ample margin of safety." NESHAP for Brick and Structural Clay Products Manufacturing; and NESHAP for Clay Ceramics Manufacturing; Proposed Rules, 79 Fed. Reg. 75,622, 75,638/3 (Dec. 18, 2014).

Second, if EPA determines that it is "not feasible" (as defined in section 7412(h)(2)) to prescribe or enforce a numeric MACT standard, it may instead promulgate a design, equipment, work practice or operational standard. 42 U.S.C. § 7412(h). These alternative standards are referred to as "work practice" standards.

B. Regulatory Background

EPA initially promulgated major source standards for brick and clay sources in 2003. NESHAP for Brick and Structural Clay Products Manufacturing; and NESHAP for Clay Ceramics Manufacturing, 68 Fed. Reg. 26,690 (May 16, 2003) ("2003 Rule"). This Court vacated those standards in 2007. *Sierra Club v. EPA*, 479

[1] EPA describes the "health threshold" as the level "below which no adverse health effects are expected to occur." 80 Fed. Reg. at 65,491/3. Additionally, the Senate report accompanying the 1990 amendments refers to the "no observable effects level" or "health-effects threshold" as a level of exposure "below which human exposure is presumably 'safe.'" S. Rep. No. 101-228, at 171 (1989), *reprinted in* 5 A Legislative History of the Clean Air Act Amendments of 1990 ("1990 Legis. Hist.") at 8511 (Comm. Print 1993).

F.3d 875, 876 (D.C. Cir. 2007). Pursuant to a consent decree establishing deadlines for the proposal and promulgation of standards, EPA issued a proposed rule on December 18, 2014, 79 Fed. Reg. 75,622, and promulgated the final Brick/Clay Rule on October 26, 2015. 80 Fed. Reg. 65,470.

Following publication of the Brick/Clay Rule, the Industry Petitioners each submitted petitions for administrative reconsideration. On May 12, 2016, EPA denied BIA and TCNA's petitions, and granted in part and denied in part Kohler's petition. 81 Fed. Reg. 31,234 (May 18, 2016).

The Brick/Clay Rule establishes emission limitations for two major source categories: brick and structural clay products manufacturing (the "Brick Rule"), and clay ceramics manufacturing (the "Clay Rule"). The brick and structural clay products source category includes manufacturers of brick, clay pipe, roof tile, extruded floor and wall tile, and other extruded, dimensional clay products. 80 Fed. Reg. at 65,473/3. The clay ceramics source category includes manufacturers of pressed tile and sanitaryware (e.g., toilets and sinks). *Id.* at 65,477/3. The HAPs emitted by these sources are primarily acid gases such as hydrogen fluoride, hydrogen chloride, and chlorine. *Id.* at 65,473/2. These sources also emit lesser amounts of metals, including mercury, as well as dioxin/furan. *Id.* Depending on duration and level of the exposure, exposure to these chemicals can cause a variety of chronic and acute effects to the lungs, skin, central nervous system, digestive system, and kidneys. *Id.* at 65,473/2-3.

For each source category, EPA finalized a combination of requirements. In general, EPA set three types of standards: (1) numeric emission limitations at the MACT floor level; (2) health-based numeric emission limitations, pursuant to section 7412(d)(4); and (3) non-numeric work practice standards. The specific requirements challenged in this case are discussed below in the sections of the argument that relate to each requirement.

SUMMARY OF ARGUMENT

This case presents challenges to the Brick/Clay Rule from two sides. On the one hand, Environmental Petitioners argue that the rule is not sufficiently protective of public health. They challenge health-based standards set pursuant to section 7412(d)(4), emission limits calculated using an established statistical methodology, and the flexibility afforded to industry to choose standards that are all calculated based on the best-performing sources. On the other hand, Industry Petitioners argue that the rule is overly stringent for a litany of reasons largely relating to the data EPA considered in setting the standards for brick and clay ceramics manufacturing facilities. Neither side is right.

A. Environmental Petitioners' Claims

1. EPA reasonably promulgated health-based emission limits for acid gases pursuant to section 7412(d)(4). The statute does not specify what it means when a health threshold "has been established," and the concept of an "established" threshold is unique to section 7412(d)(4). The identification of an "established"

health threshold in the same rulemaking in which EPA set health-based emission limits is fully consistent with the plain language of the CAA. EPA was not required to affirmatively conclude that the acid gases were not carcinogens before invoking section 7412(d)(4). Petitioners' argument to the contrary misunderstands the nature of scientific uncertainty and how EPA must address such uncertainty when regulating. Additionally, EPA thoroughly analyzed the best available scientific information, including well-established, peer-reviewed toxicity databases, to determine that the three pollutants all had health thresholds. Furthermore, EPA appropriately considered evidence and classification of carcinogenic risk in considering whether hydrogen chloride, chlorine, and hydrogen fluoride had health thresholds. EPA provided adequate support for the specific health threshold levels it identified, and EPA's technical judgments are entitled to the highest level of deference. Finally, EPA's health-based standards include an "ample margin of safety" as required by section 7412(d)(4) because EPA built a margin of safety into its process for translating the acid gas health thresholds into emission limits by including several conservative assumptions in its emissions modeling. This approach is consistent with the statute, and EPA fully explained why it expected this approach to result in exposure concentrations well below the identified threshold values.

2. EPA's use of the Upper Prediction Limit ("UPL") methodology to account for variability in calculating MACT floors for which the Agency had limited emissions data was reasonable. This Court has affirmed EPA's use of the UPL as a

general matter, and EPA has sufficiently articulated a process for ensuring that the application of the methodology to limited datasets still results in a reasonable estimate of the emissions achieved in practice by the best-performing sources in each subcategory. Moreover, EPA followed that process here, which resulted in adjustments to five of the MACT floors for brick kilns to more accurately account for the distribution of data. EPA adequately explained the basis for all five of those adjustments. Additionally, the upward adjustment of two of those floors was related to the addition of a raw material variability factor, which Petitioners do not challenge and which was not part of the UPL limited dataset analysis. Furthermore EPA may make either upward or downward adjustments to its MACT floor calculations if it determines based on its limited dataset analysis that such adjustments are necessary.

3. EPA's promulgation of alternative emission limits for mercury and non-mercury metals for brick tunnel kilns was both consistent with the statute and reasonable. Nothing in the plain language of section 7412(d) forbids EPA from promulgating multiple alternative MACT standards, so long as those standards require the maximum degree of emission reduction and are based on the best-performing source or sources. Because each floor was determined based on the best-performing sources according to the unit of measurement in which the floor is expressed, the alternative floors are all based on the best-performing sources and satisfy the requirements of section 7412(d)(3). EPA's method for calculating the alternative limits was therefore reasonable.

B. Industry Petitioners' Claims

4. BIA's challenge to EPA's inclusion of synthetic area source data is barred because BIA did not challenge the approach when EPA first used it in the 2003 Rule. In any case, EPA properly included emissions data from synthetic area sources, which would emit HAPs at major source levels but for their federally-enforceable controls, in determining the MACT floors for PM and mercury emissions from brick kilns. EPA's use of such data is consistent with the statutory requirement to determine MACT floors based on emission levels achieved by the "best performing" sources. Inclusion of synthetic area sources in the MACT floor calculations is consistent with the CAA, congressional intent, and longstanding EPA policy.

5. EPA's determination to base the PM and non-mercury HAP metal standards for brick industry sources on the top 12 percent of sources for which it had emissions data was consistent with the statute and reasonable. EPA's other proposed approach, preferred by BIA, would have set standards based on the top 12 percent of the total number of sources in the category. If EPA had used that approach, it would have needed to ensure that it had emissions data from all the best-performing sources in the category. In the final rule, EPA appropriately rejected BIA's preferred approach because EPA had no basis to conclude that it had data from all of the sources comprising the best-performing 12 percent of the entire industry.

6. EPA appropriately set mercury standards for brick kilns at the MACT floor levels based on what the best-performing sources actually achieved. EPA did not and could not consider other factors when calculating the MACT floor. The standards are not based on any specific control method, and leave sources with flexibility as to the methods for achieving compliance. Further, in setting the mercury standards for sources in the brick industry, EPA reasonably declined to subcategorize based on raw material content, and legislative history regarding EPA's ability to consider raw material switching is not applicable here.

7. TCNA has not adequately demonstrated that it has standing to challenge the standards and the major source category listing of tile industry sources. In arguing that EPA impermissibly promulgated standards for a source category that includes no major sources, TCNA fails to allege that any of its members have suffered a cognizable injury.

8. EPA has authority to set standards for tile industry sources, and its promulgation of such standards was proper even in the absence of sources that would be subject to the standards at the time of proposal or promulgation. The tile industry sources are part of a source category listed pursuant to section 7412(c), and EPA is required to set standards for listed source categories. EPA reasonably set major source standards for the tile industry because major sources existed in the industry when the category was listed, and because existing synthetic area sources and area sources could increase emissions to become subject to the major source standards.

9. The CAA provides for judicial review of EPA's listing of a major source category at the time standards are issued for the category. Because EPA issued major source standards for the clay ceramics manufacturing category in 2003, challenges to the listing should have been brought at that time. No challenges to the listing were brought within 60 days of the date the standard was issued, so TCNA's challenge to the listing is now untimely, and the vacatur of the prior standards does not provide another opportunity to challenge the listing. In any case, EPA's listing of the category that includes the tile industry was consistent with the CAA and adequately supported.

10. EPA's reliance on information from tile industry sources collected using an established EPA test method, Method 23, to calculate MACT floors for dioxin/furan is consistent with the CAA's requirement that EPA calculate MACT floors based on the best-performing sources for which it has emissions information. TCNA's argument that Method 23 does not provide reliable "emissions information" is without merit. Whether results from Method 23 are appropriate to use in setting dioxin/furan emission standards is a decision squarely within the Agency's expertise, and EPA reasonably concluded that Method 23 results are reliable and appropriately considered here.

11. EPA reasonably did not include data from periods of malfunction when establishing standards for the tile industry. To estimate emission levels of the best-performing sources, EPA relied on test data collected from those sources and accounted for variability in their actual operations. Because malfunctions are

unpredictable events with unpredictable effects on emissions, EPA reasonably determined that information gathered during malfunctions was not useful in determining the MACT floors or otherwise setting standards.

12. EPA reasonably set standards for tile industry mercury and dioxin/furan emissions based on the MACT floor. TCNA's argument that EPA impermissibly considered the effectiveness of activated carbon injection controls in setting these standards is misplaced. EPA did not set them based on anything other than what tile sources have actually achieved.

13. EPA permissibly calculated the MACT floors for sanitaryware sources based in part on data collected from a source using controls built to comply with the vacated 2003 Rule. Kohler's argument that use of this data in setting standards was impermissible is without merit. Vacatur of the 2003 Rule did not erase the actual emission reductions that sources had achieved. Because the CAA requires that EPA base the MACT floors on emission levels that have been achieved, and emissions data using controls demonstrated the emission levels achieved, EPA reasonably considered this data.

STANDARD OF REVIEW

Challenged portions of the Brick/Clay Rule may not be set aside unless they are "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law." 42 U.S.C. § 7607(d)(9). The "arbitrary and capricious" standard presumes the validity of agency action, and a reviewing court is to uphold an agency action if it

satisfies minimum standards of rationality. *Small Refiner Lead Phase-Down Task Force v. EPA*, 705 F.2d 506, 520-21 (D.C. Cir. 1983); *Ethyl Corp. v. EPA*, 541 F.2d 1, 34-35 (D.C. Cir. 1976) (*en banc*). Where EPA has considered the relevant data and articulated a rational connection between the facts found and the choices made, its regulatory choices must be upheld. *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983).

When reviewing scientific determinations within an agency's special expertise, a reviewing court must be at its most deferential. *Baltimore Gas & Elec. Co. v. NRDC*, 462 U.S. 87, 103 (1983). In reviewing EPA judgments regarding acceptable levels of risk, "EPA, not the court, has the technical expertise to decide what inferences may be drawn from the characteristics of . . . substances and to formulate policy with respect to what risks are acceptable." *NRDC v. EPA*, 824 F.2d 1146, 1163 (D.C. Cir. 1987) (citation and quotation marks omitted). This Court "will not second-guess a determination based on that expertise." *Id.*

Questions of statutory interpretation are governed by the two-step test set forth in *Chevron, U.S.A., Inc. v. NRDC* ("*Chevron*"), 467 U.S. 837, 842-45 (1984). The reviewing court must first determine "whether Congress has directly spoken to the precise question at issue." *Chevron*, 467 U.S. at 842. If the congressional intent is clear from the statutory language, the inquiry ends. *Id.* at 842-43. If the statute is silent or ambiguous, the reviewing court must accept the agency's interpretation if it is

reasonable; the agency's interpretation need not represent the only permissible reading of the statute nor the reading that the court might prefer. *Id.* at 843 & n.11.

ARGUMENT

I. EPA reasonably set health-based emission limits for acid gases pursuant to section 7412(d)(4).

In order for EPA to invoke section 7412(d)(4) and adopt a standard more lenient than the MACT floor for a pollutant, two requirements must be met: (1) there must be an established health threshold; and (2) the health-based standards must provide an ample margin of safety. 42 U.S.C. § 7412(d)(4). In the Brick/Clay Rule, EPA reasonably promulgated health-based emission limits for three acid gases (hydrogen fluoride, hydrogen chloride, and chlorine) for all existing and new brick tunnel kilns and clay ceramics roller and tunnel kilns. 80 Fed. Reg. at 65,471, 65,474, 65,478.

First, *before* deciding to set health-based standards, EPA appropriately determined, based on the best available toxicity information, that each of the three pollutants has a health threshold. 80 Fed. Reg. at 65,488/2. For all three pollutants, EPA: (1) evaluated the carcinogenic and non-cancer health effects based on existing scientific literature; (2) identified a health benchmark below which adverse effects are not expected to occur; and (3) provided a rationale for their designation as threshold pollutants. *See id.* at 65,488/2-89/1; 79 Fed. Reg. at 75,639-41. EPA then assessed the suitability of setting a health-based standard specifically for brick and clay

ceramics facilities, considering whether setting technology-based standards would result in significant reductions in emissions of other pollutants, the potential for environmental impacts, the potential for cumulative adverse health effects in light of other co-located or nearby sources that also emit pollutants, and the availability of industry-specific data to determine a standard. 80 Fed. Reg. at 65,495/3-98/3; 79 Fed. Reg. at 75,641/2-42/3, 75,660/1-61/1. Finally, in determining the appropriate level of the health-based standards, EPA developed risk assessments and used modeling to ensure that the established emission limits would provide an ample margin of safety, and that persons exposed to emissions of the pollutants would not experience the adverse health effects on which the health thresholds are based. 80 Fed. Reg. at 65,498/3-65,505/3; 79 Fed. Reg. at 75,643/1-44/2. This approach is consistent with previous actions in which the Agency promulgated or considered promulgating health-based standards. NESHAP Proposed Standards for Hazardous Air Pollutants from Chemical Recovery Combustion Sources at Kraft, Soda, Sulfite, and Stand-Alone Semichemical Pulp Mills, 63 Fed. Reg. 18,754, 18,765/2-68/2 (Apr. 15, 1998); NESHAP for Lime Manufacturing Plants Proposed Rule, 67 Fed. Reg. 78,046, 78,054/2-57/2 (Dec. 20, 2002); NESHAP for Industrial, Commercial, and Institutional Boilers and Process Heaters,[2] 69 Fed. Reg. 55,218, 55,240/1 (Sept. 13, 2004); NESHAP for Major Sources: Industrial, Commercial, and Institutional Boilers

[2] The 2004 standards for boilers were vacated on other grounds in 2007. *NRDC v. EPA*, 489 F.3d 1250 (D.C. Cir. 2007).

and Process Heaters Proposed Rule, 75 Fed. Reg. 32,006, 32,030/3-31/3 (June 4, 2010); NESHAP for the Portland Cement Manufacturing Industry and Standards of Performance for Portland Cement Plants, 75 Fed. Reg. 54,970, 54,985/3-87/2 (Sept. 9, 2010).

Environmental Petitioners' challenge to the health-based standards should be rejected. Petitioners' interpretation of the requirement that a health threshold "has been established" misreads section 7412(d)(4) and misunderstands how EPA addresses scientific uncertainty in the consideration of the potential health effects of a pollutant. It also disregards the fact that EPA set such standards after thoroughly analyzing the best available scientific information in a highly technical field, basing its determinations on rigorously vetted toxicity assessments of acid gases and adequately supporting both its conclusion that hydrogen chloride, chlorine, and hydrogen fluoride had established health thresholds, and the specific threshold values it identified for each pollutant. Finally, Petitioners' argument fails to account for the method EPA used to translate its identified health threshold values into emission limitations that provide an ample margin of safety.

A. EPA reasonably construed section 7412(d)(4).

Section 7412(d)(4) provides that EPA may establish health-based emission standards "[w]ith respect to pollutants for which a health threshold has been established." The concept of a "health threshold [that] has been established" is unique to section 7412(d)(4). EPA does not make findings under the CAA regarding

the existence of a "health threshold" outside the context of determining whether to set health-based emission limits under this subsection. Nor does the statute explain what constitutes an "established" health threshold, or what EPA must do to determine that a health threshold "has been established." 80 Fed. Reg. at 65,491/3. Additionally, by using the passive voice, the statute does not specify *who* must establish the health threshold. *Id.* Accordingly, the precise meaning of the phrase "has been established" is ambiguous.

Here, EPA reasonably interprets the phrase "has been established" as authorizing EPA to identify a health threshold for a particular pollutant as part of a rulemaking establishing emission standards. As the Agency explained, "[i]n the absence of such specificity in the statute, the EPA reads [section 7412(d)(4)] to authorize the EPA to set health-based limits where, in the EPA's expert judgment, there is a health threshold for the pollutant below which no adverse health effects are expected to occur." 80 Fed. Reg. at 65,491/3. Applying this interpretation, EPA appropriately determined in the Brick/Clay Rule that hydrogen chloride, chlorine, and hydrogen fluoride all had established health thresholds. As further explained *infra* in Section I.B, the analysis supporting the rule includes an evaluation of the available and relevant scientific evidence on the cancer risk and non-cancer health effects of each pollutant. *See id.* at 65,488-89; 79 Fed. Reg. at 75,639-41. That evidence included human health values derived as part of several agencies' toxicity assessments, and which EPA used in identifying health threshold values for each pollutant. *See* 79 Fed.

Reg. at 75,639/3-40. EPA's approach of concluding in the Brick/Clay Rule that hydrogen chloride, chlorine, and hydrogen fluoride were threshold pollutants based on existing toxicity assessments was reasonable. Nothing in section 7412(d)(4) precludes EPA from determining that a health threshold has been established for pollutants as part of the same rulemaking process in which it promulgates a health-based emission standard. *See Chevron*, 467 U.S. at 842-43 (holding that where a statute is "silent or ambiguous with respect to the specific issue," the court must defer to the Agency's interpretation so long as it is "based on a permissible construction of the statute").

The plain meaning of section 7412(d)(4) does not support Petitioners' position that a health threshold must already have been established prior to the rulemaking that promulgates health-based standards. Petitioners' references to case law interpreting statutes using the present perfect tense are inapposite. Environmental Br. 34-35. Neither a statute criminalizing a convicted felon's receipt of a firearm which "has been shipped or transported in interstate . . . commerce," nor a statute requiring a person seeking damages for wrongful imprisonment to show that a conviction "has been reversed or set aside," contemplates an agency taking further regulatory action. Indeed, there would be no logical framework for the identified actions under the statutes at issue in those other cases to be performed if they had not already taken place, and therefore it would be illogical to read either of those statutes as being predicated on an action that had not yet happened. Here, however, the statutory

framework contemplates EPA exercising its discretion to take further action to set health-based standards after it determines that those pollutants have health thresholds.

Furthermore, the fact that an unenacted version of section 7412(d)(4) would have allowed EPA to set health-based standards where a health threshold "*can be* established," Environmental Br. 35-36, does not demonstrate that EPA must make a threshold determination prior to the rulemaking in which it sets health-based standards. The change from "*can be* established" to "*has been* established" is most reasonably read to clarify that it is not sufficient for the establishment of a health threshold to be hypothetically possible. Instead, section 7412(d)(4) provides that a health threshold must actually be established for EPA to set health-based standards. Here, EPA's threshold determination did just that.

Finally, EPA reasonably interpreted section 7412(d) as not requiring consensus on or the resolution of all uncertainty regarding a pollutant's health effects before determining that a health threshold "has been established" for that pollutant. As EPA explained with respect to the identification of a health threshold value, "the phrase 'has been established' [does not mean] that there is universal agreement on the health threshold level." 80 Fed. Reg. at 65,491/2-3. Petitioners also ignore the normal degree of uncertainty that is inherent in the scientific process. Indeed, this Court has recognized that "EPA is not obligated to conclusively resolve every scientific

uncertainty before it issues regulation."[3] *White Stallion Energy Ctr., LLC v. EPA*, 748 F.3d 1222, 1245 (D.C. Cir. 2014) (citing *Coal. For Responsible Regulation, Inc. v. EPA*, 684 F.3d 102, 121 (D.C. Cir. 2012)), *rev'd on other grounds*, *Michigan v. EPA*, 135 S. Ct. 2699 (2015). *See also Weyerhaeuser Co. v. Costle*, 590 F.2d 1011, 1026 (D.C. Cir. 1978) (recognizing the "technological and scientific uncertainty that EPA must overcome as best it can in making the discretionary judgments delegated to it by Congress").

This is particularly salient with respect to EPA's evaluation of a pollutant's carcinogenicity, or likelihood of causing cancer. In order for EPA to promulgate a health-based standard for a pollutant, "the pollutant must have a health threshold and not be carcinogenic." 79 Fed. Reg. at 75,639/1. EPA does not apply section 7412(d)(4) to carcinogenic pollutants because it is assumed that any amount of exposure to carcinogens poses *some* risk. *Id.* at 75,639/1 and n.7. *See also* Air Toxics Risk Assessment Technical Resource Manual at 12-5 (Apr. 2004), EPA-HQ-OAR-2013-0291-0572, JA463. Accordingly, EPA evaluates the evidence and classification of carcinogenic risk when determining whether to establish health-based standards. 79 Fed. Reg. at 75,639/1. Where there is not enough evidence to make a conclusive

[3] EPA's guidance materials include instructions for addressing scientific uncertainty in risk assessments. *See* Air Toxics Risk Assessment Technical Resource Manual at 12-22 to 12-24 (Apr. 2004), EPA-HQ-OAR-2013-0291-0572, JA464-466; Guidelines for Carcinogen Risk Assessment at 3-29 to 3-32 (2005), available at https://www.epa.gov/airtoxics/cancer_guidelines_final_3-25-05.pdf, JA1009-1012.

determination of carcinogenicity, EPA conducts a case-by-case evaluation, which it did for hydrogen chloride, chlorine, and hydrogen fluoride in the Brick/Clay Rule. *Id.*

Contrary to Petitioners' argument, Environmental Br. 26-27, EPA is not required to prove a negative, *i.e.*, to affirmatively conclude that a pollutant does not cause cancer before finding that a health threshold has been established and promulgating standards under section 7412(d)(4). And nothing in the legislative history cited by Petitioners suggests otherwise. The 1990 Senate report, *see id.* at 27, simply indicates that health-based limits could be appropriate "where health thresholds are well-established . . . and the pollutant presents no risk of other adverse health effects, including cancer, for which no threshold can be established." S. Rep. No. 101-228 at 171, 1990 Legis. Hist. at 8511. Citing the Senate report, Petitioners suggest that even if pollutants have not been classified as known, likely, or suspect carcinogens, they are still subject to "study and debate" in the absence of conclusive evidence proving non-carcinogenicity. But the Senate report does *not* state that a pollutant's health effects must no longer be subject to "study and debate." The reference to "study and debate" appears in the context of explaining that EPA's authority to set health-based standards is discretionary, as requiring the Agency to "consider the evidence for a health threshold higher than MACT" in every case would "jeopardize the standard-setting schedule imposed under this section with the kind of lengthy study and debate that has crippled the current program." *Id.*

Furthermore, it is rare to find conclusive determinations as to non-carcinogenicity for *any* chemical. Indeed, the International Agency for Research on Cancer has developed monographs on 998 chemicals and agents, and classified only one of those as "probably not carcinogenic to humans." *See* IARC Monographs on the Evaluation of Carcinogenic Risks to Humans (last updated Dec. 22, 2016), http://monographs.iarc.fr/ENG/Classification/. And EPA has classified only two HAPs as "not likely to be carcinogenic to humans." *See* Prioritized Chronic Dose Response Values (May 29, 2014), available at https://www.epa.gov/sites/production/files/2014-05/documents/table1.pdf, JA1029-1036. In short, EPA reasonably interprets section 7412(d)(4) as authorizing it to determine that a health threshold has been established as part of the same rulemaking process in which it promulgates a health-based emission standard, and to identify a health threshold where not all scientific uncertainty has been resolved with respect to carcinogenicity. *See NRDC v. EPA*, 749 F.3d 1055, 1060 (D.C. Cir. 2014) ("[W]e must defer to [EPA's] reasonable interpretation of any ambiguities in the [CAA]."") (citing *Chevron*, 467 U.S. at 843-44).

B. EPA reasonably found that hydrogen chloride, chlorine, and hydrogen fluoride were threshold pollutants based on existing scientific evidence.

Here, contrary to Petitioners' argument, EPA applied its interpretation of section 7412(d)(4) and reasonably found that a health threshold had "been established" for hydrogen chloride, chlorine, and hydrogen fluoride. This finding, as

well as EPA's identification of a specific threshold value for each pollutant, is based on a robust review of existing scientific literature, including consideration of toxicity databases that identify an exposure level below which adverse health effects are not expected to occur. As part of its review of the health effects of hydrogen chloride, chlorine, and hydrogen fluoride, EPA stated that it considered each to be a threshold pollutant based on a lack of affirmative carcinogenicity data and on the Agency's knowledge of how each pollutant reacts in the body and its likely mechanism of action. 80 Fed. Reg. at 65,488/2; 79 Fed. Reg. at 75,639-41.

1. EPA appropriately considered information regarding carcinogenic risk.

Consistent with its position that it may not promulgate health-based emission standards for carcinogenic pollutants, EPA began its health threshold assessment by evaluating the evidence of carcinogenicity of hydrogen chloride, chlorine, and hydrogen fluoride. In doing so, EPA considered reviews conducted by several existing authoritative bodies. 80 Fed. Reg. at 65,488/2. None of those bodies had classified hydrogen chloride, chlorine, or hydrogen fluoride as carcinogens or "suggestive of the potential to be carcinogenic," either individually or in combination. *Id.* EPA found that there was an absence of evidence of carcinogenic risk, and therefore went on to consider whether a threshold existed for each pollutant below which other adverse health effects are not expected. *Id.*

For hydrogen chloride, EPA noted that there were "limited studies on the carcinogenic potential of [hydrogen chloride] in humans." 80 Fed. Reg. at 65,488/2. One occupational study found no evidence of association between exposure to hydrogen chloride and lung cancer among chemical manufacturing plant employees. *Id.* at 65,488/3. EPA found that other occupational studies were not appropriate for evaluating the carcinogenic potential of hydrogen chloride because they involved exposure to a mixture of acid gases and other chemicals, and failed to separate potential exposure to hydrogen chloride from exposure to other substances shown to have carcinogenic activity. *Id.* For hydrogen fluoride, EPA noted that there are a limited number of studies investigating the pollutant's carcinogenic potential, and that those studies are unreliable on that issue. *Id.* at 65,488/3. EPA cited an ATSDR Public Health Statement document, which concluded that "carcinogenicity via inhalation of fluoride is not considered to be likely by most investigators reporting in the existing literature." 79 Fed. Reg. at 75,641/1. Finally, for chlorine, EPA noted that studies of workers in the chemical industry, as well as studies in rodents and primates, have not found any evidence that chlorine was carcinogenic.[4] 80 Fed. Reg. at 65,489/1.

[4] Although Petitioners complain that EPA did not cite studies regarding the carcinogenicity of chlorine, Environmental Br. 13, citations for the studies and more detailed discussions of them are contained in the ATSDR toxicological profile for chlorine. *See* 80 Fed. Reg. at 65,494/3 n.68; Toxicological Profile for Chlorine, EPA-HQ-OAR-2013-0291-0053 (Nov. 2010), at 74-75, JA475-476.

EPA reasonably concluded based on its review of the available scientific evidence regarding the health effects of hydrogen chloride, chlorine, and hydrogen fluoride that there was not evidence of carcinogenic risk for those three pollutants. As discussed *supra* at 24-25, it was not necessary for EPA to affirmatively determine that conclusive evidence proves that hydrogen chloride, chlorine, and hydrogen fluoride do not cause cancer before promulgating standards under section 7412(d)(4). No authoritative body has classified hydrogen chloride, chlorine, or hydrogen fluoride as known, likely, or suspected carcinogens. 80 Fed. Reg. at 65,488/2. It therefore was reasonable for EPA to conclude, in light of other available evidence discussed below, that hydrogen chloride, chlorine, and hydrogen fluoride were threshold pollutants. That conclusion is entitled to a high degree of deference. *Nat'l Wildlife Fed'n v. EPA*, 286 F.3d 554, 560 (D.C. Cir. 2002) ("[P]articular deference is given by the court to an agency with regard to scientific matters in its area of technical expertise. . . ."). Moreover, Petitioners have pointed to no evidence of ongoing debate in the scientific community regarding the carcinogenicity of hydrogen chloride, chlorine, or hydrogen fluoride.

Finally, Petitioners' concern that EPA's invocation of section 7412(d)(4) opens the door for the Agency to issue health-based standards for any HAPs with unknown cancer risks or deliberately "[stay] ignorant" of the cancer risks of a pollutant, Environmental Br. 28, 30, is unfounded. EPA evaluates chemicals for which there is not enough information to make a conclusive determination of non-carcinogenicity

on a case-by-case basis. 79 Fed. Reg. at 75,639/1. EPA also evaluates a host of other factors, including non-cancer health effects, in determining whether a health threshold exists, and in further determining whether health-based emission limits are appropriate. *See, e.g.*, Boiler Proposed Rule, 75 Fed. Reg. at 32,031/3-32/3; NESHAP for Major Sources: Industrial, Commercial, and Institutional Boilers and Process Heaters, 76 Fed. Reg. 15,608, 15,643/3, 15,644/1 (Mar. 21, 2011). And because EPA's exercise of its section 7412(d)(4) authority is discretionary, EPA may decline to promulgate health-based standards even if it finds that a pollutant has an established health threshold.

2. EPA reasonably identified health thresholds for acid gases that were equivalent to established human health values.

After discussing the available evidence on carcinogenicity, EPA then addressed the non-cancer health effects of chronic and acute exposure to hydrogen chloride, chlorine, and hydrogen fluoride. For each pollutant, EPA identified a human health value that is rooted in well-established, peer-reviewed toxicity databases. Several agencies—including EPA's Integrated Risk Information System Program, the Agency of Toxic Substances and Disease Registry (ATSDR), and the California Environmental Protection Agency—had conducted toxicity assessments of one or more of the three pollutants. 80 Fed. Reg. at 65,488/2. Those assessments resulted in the calculation of reference values at and below which exposure is not expected to result in adverse health effects. EPA considered that those agencies' toxicity

assessments "undergo rigorous peer review processes before they are published" and "are widely vetted through the scientific community," and the Science Advisory Board has endorsed the use of those agencies' reference values for pollutants. *Id.* EPA also noted that those agencies were in agreement about using a reference value for hydrogen chloride, chlorine, and hydrogen fluoride. *Id.*

EPA identified threshold values for each pollutant consistent with its practice of using toxicity assessments from different databases in a specified order of priority. Air Toxics Risk Assessment Technical Resource Manual at App'x C (Table 1), JA467-473; Prioritization of Data Sources for Chronic Exposure (Dec. 30, 2016), https://www.epa.gov/fera/prioritization-data-sources-chronic-exposure. In other words, for each pollutant, EPA based its conclusions on the highest-priority database for which an assessment was available. For hydrogen chloride, EPA relied on an EPA-conducted toxicity assessment of chronic inhalation exposure, which established a reference concentration[5] (RfC) of 20 micrograms per cubic meter. 79 Fed. Reg. at

[5] EPA defines "reference concentration" as "an estimate (with uncertainty spanning perhaps an order of magnitude) of a continuous inhalation exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects during a lifetime." 79 Fed. Reg. at 75,639/3. *See also* Basic Information about the Integrated Risk Information System (May 24, 2016), https://www.epa.gov/iris/basic-information-about-integrated-risk-information-system.

75,639/3. For chlorine, EPA relied on the ATSDR's Minimal Risk Level[6] of 0.00015 micrograms per cubic meter. *Id.* at 75,640/1. For hydrogen fluoride, EPA relied on the California EPA's reference exposure level[7] of 0.014 milligrams per cubic meter. *Id.* at 75,640/3. EPA's identification of health thresholds that were based on well-established values already accepted by the scientific community was consistent with the language and purpose of section 7412(d)(4).[8] EPA relied on widely vetted toxicity assessments from authoritative bodies in considering the carcinogenic and non-carcinogenic health effects of hydrogen chloride, chlorine, and hydrogen fluoride, and in identifying a health threshold level for each pollutant. 80 Fed. Reg. at 65,489/2. These bodies, including EPA's Integrated Risk Information System, ATSDR, and California EPA, have derived "health protective reference values at or below which

[6] The minimal risk level is an estimate of daily human exposure to a hazardous substance that is "likely to be without appreciable risk of adverse non-cancer health effects over a specified duration of exposure." ATSDR Toxic Substances Portal, Minimal Risk Levels (Mar. 8, 2016), https://www.atsdr.cdc.gov/mrls/index.asp.

[7] California EPA's chronic inhalation reference exposure levels (RELs) are concentrations at or below which health effects are not likely to occur in the general human population. 80 Fed. Reg. at 65,491/1; Cal. Office of Envtl. Health Hazard Assessment (OEHHA), OEHHA Acute, 8-Hour and Chronic Reference Exposure Level Summary (June 28, 2016), http://www.oehha.ca.gov/air/Allrels.html.

[8] Moreover, EPA has previously stated that it considers hydrogen chloride, chlorine, and hydrogen fluoride to be threshold pollutants. *See, e.g.*, Portland Cement NESHAP, 75 Fed. Reg. at 54,986/1; Boiler Proposed Rule, 75 Fed. Reg. at 32,030/3.

no adverse effects are expected to occur." *Id.* The EPA Science Advisory Board,[9] which reviews the quality and relevance of the scientific information EPA uses in its regulations, has endorsed this approach in the context of EPA's risk assessments under section 7412(f)(2) of the CAA. *Id.*

The Science Advisory Board has also endorsed EPA's preference for applying its own health benchmark values, where available, in instances where other agencies have also derived benchmarks.[10] 80 Fed. Reg. at 65,490/2, 65,491/3 and n.29. *See also* Risk Assessment to Determine a Health-Based Emission Limitation for Acid Gases for the Brick and Structural Clay Products Manufacturing Source Category at 11-12 (May 19, 2014), EPA-HQ-OAR-2013-0291-0132 ("Brick Risk Assessment"), JA495-496. Consistent with its established preferences, EPA here applied its own reference concentration for hydrogen chloride, which was generated in a 1995 EPA risk assessment, as the most appropriate chronic non-cancer health threshold. 80 Fed.

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[9] The Science Advisory Board is a federal advisory committee that was established in 1978 by the Environmental Research, Development, and Demonstration Authorization Act, 42 U.S.C. § 4365. Members are independent experts that provide scientific advice and peer review to EPA on environmental issues. *See* EPA Science Advisory Board Charter, https://yosemite.epa.gov/sab/sabproduct.nsf/WebBOARD/currentcharter (last viewed Jan. 16, 2017).

[10] Where an EPA reference concentration is unavailable for a pollutant, EPA typically selects the ATSDR minimal risk level (as it did here for chlorine). If the minimal risk level is unavailable, EPA typically selects the California EPA reference exposure level (as it did here for hydrogen fluoride). Prioritization of Data Sources for Chronic Exposure (Dec. 30, 2016), https://www.epa.gov/fera/prioritization-data-sources-chronic-exposure.

Reg. at 65,491/3. Environmental Petitioners contend that EPA should have applied a lower reference exposure level derived by the California EPA. Environmental Br. 40. But EPA provided an extensive and reasonable explanation supporting the application of its own reference concentration to derive the health threshold for hydrogen chloride, and EPA's decision to do so is motivated by its consistent institutional preferences, not because one agency's level is higher or lower than another's. *See* 80 Fed. Reg. at 65,490-91. EPA's use of its own reference concentration as opposed to the California EPA reference exposure level is entitled to deference. *Marsh v. Or. Nat. Res. Council*, 490 U.S. 360, 368 (1989); *Ethyl Corp. v. EPA*, 541 F.2d 1, 36-37 (D.C. Cir. 1976).

Furthermore, although EPA assigned the hydrogen chloride reference concentration a "low confidence" label, Petitioners misunderstand the import of that designation. EPA assigns each of its reference concentrations a confidence label of high, medium, or low based on the completeness of the supporting database. 80 Fed. Reg. at 65,490/2. A "low confidence" designation means that the reference concentration is based on less complete data than those with a "high confidence" or "medium confidence" designation, and therefore the reference concentration is more likely to change with the development of additional data. *Id.* at 65,490/3. But the "low confidence" designation does not mean that EPA believes the reference concentration is unreliable or that the supporting data are inadequate. Indeed, EPA does not calculate a reference concentration for a chemical unless its toxicity

assessment establishes that it *is* possible to quantify a chronic exposure level below which adverse health effects are not expected.[11] *Id.*; Methods for Derivation of Inhalation Reference Concentrations and Application of Inhalation Dosimetry at 4-2 to 4-12 (Oct. 1994), EPA-HQ-OAR-2013-0291-0160, JA422-432. EPA therefore properly considered that "[a]ll [reference concentrations], even those with low confidence, are appropriate for regulatory use." 80 Fed. Reg. at 65,490/3. Moreover, EPA reviewed the 1995 hydrogen chloride reference concentration in 2003 and did not identify any critical studies that would change the conclusions of the earlier assessment. *Id.* at 65,490/1.

EPA also explained why the 1995 reference concentration for hydrogen chloride was the suitable basis for a health threshold value even though the reference concentration was itself based on a study that did not identify an exposure level below which there were no observable adverse health effects (referred to as the "no observable adverse effects level"). 80 Fed. Reg. at 65,489-90. Instead, the study identified the lowest dose that induced a measurable adverse health effect, and EPA extrapolated from that level to calculate a reference concentration below which adverse health effects were not expected to occur. *Id.* As EPA stated, it is not

[11] For example, EPA has declined to calculate a reference concentration for acetone because of the amount of uncertainty in the data on health risks. EPA Integrated Risk Information System Chemical Assessment Summary, Acetone at 12 (last viewed Jan. 16, 2017), available at https://cfpub.epa.gov/ncea/iris/iris_documents/documents/subst/0128_summary.pdf.

necessary for a threshold value to have underlying data on the no observable adverse effects level, and many reference concentrations are derived without such data. *Id.* Instead, EPA may extrapolate an analogous level from available data and then apply uncertainty factors[12] to account for data limitations, including the use of the lowest adverse effects level. *Id.*

This approach is consistent with section 7412(d)(4)'s requirement of a health threshold that "has been established" in order to set health-based emission limits, and is a reasonable exercise of EPA's discretion to determine what constitutes an "established" health threshold. Petitioners are essentially asking this Court to re-weigh the scientific evidence considered by EPA and reach its own independent technical conclusions. But that is beyond the proper scope of judicial review. *See Coal. For Responsible Regulation*, 684 F.3d at 122 ("When EPA evaluates scientific evidence in its bailiwick, we ask only that it take the scientific record into account in a rational manner.") (internal quotation marks and citation omitted), *aff'd in part, rev'd in*

[12] Uncertainty factors may be applied where a reference concentration is derived from data that do not match the assumed human exposure scenario to which the reference concentration is intended to apply (for instance, because data are from animal rather than human studies). To account for the uncertainty inherent in extrapolations, including the extrapolation of a no observable adverse effects level from a study that identified a lowest observable adverse effects level, EPA divides the extrapolated effects level by the uncertainty factor, usually an order of magnitude, in calculating the reference concentration. 80 Fed. Reg. at 65,490/3. *See generally* Methods for Derivation of Inhalation Reference Concentrations and Application of Inhalation Dosimetry at 4-73 to 4-80, JA433-440.

part by Util. Air Regulatory Grp. v. EPA, 134 S. Ct. 2427 (2014). In short, EPA provided substantial support for its conclusion that hydrogen chloride, chlorine, and hydrogen fluoride have established health thresholds, and for its use of specific health benchmarks for each pollutant.[13] EPA's application of section 7412(d)(4) to set health-based emission limits was therefore permissible.

C. EPA provided an ample margin of safety.

Once EPA determined that hydrogen chloride, chlorine, and hydrogen fluoride were threshold pollutants, it prepared risk assessments to determine a level of emissions that would ensure those health thresholds would not be exceeded, with an ample margin of safety, at any facility in the brick or clay source categories. *See* Brick Risk Assessment, JA485; Risk Assessment to Determine a Health-Based Emission Limitation for Acid Gases for the Clay Ceramics Manufacturing Source Category (May 19, 2014), EPA-HQ-OAR-2013-0290-0213 ("Clay Risk Assessment"), JA247. Using emissions information for each facility in both source categories, EPA employed the Human Exposure Model to estimate the maximum ambient chronic concentration associated with unit emissions (one ton per year) of hydrogen chloride from each facility in the source category. Brick Risk Assessment at 6, JA490; Clay

[13] Environmental Petitioners also claim that EPA's health-based standard for hydrogen fluoride did not properly account for acute exposure health risks. Environmental Br. 41-43. Because this argument relates to the method by which EPA set emission limits based on the identified health threshold value, it is addressed in Section I.C.3, *infra* at 43-45. Petitioners do not challenge EPA's use of the ATSDR Minimal Risk Level as the basis for the chlorine health threshold level.

Risk Assessment at 3, JA249. After identifying the facility in each source category with the highest modeled ambient chronic concentration—*i.e.*, the source whose emissions would generate exposure at the highest concentrations—EPA then scaled up the emissions of that facility until the emission level would correspond to a non-cancer hazard quotient[14] of one. *Id.*

For brick facilities, that calculation generated an emission level of 250 tons per year of hydrogen chloride-equivalent emissions, which is equivalent to 175 tons per year of hydrogen fluoride or 1.9 tons per year of chlorine. Brick Risk Assessment at 6, JA490. Because an emission level of 250 tons per year of hydrogen chloride-equivalent per brick facility would result in exposures at or below the threshold level at the facility with the greatest potential for human exposure, EPA concluded that an emission level of 250 tons per year of hydrogen chloride-equivalent per brick facility would be unlikely to result in adverse chronic health effects at any facility in the source category, and would result in exposure concentration levels remaining below the chronic health reference values at all facilities. *Id.* at 17, JA501. For clay ceramics facilities, the same approach led to an emission level of 600 tons per year of hydrogen

[14] EPA expresses health hazards by dividing the chronic exposure level by the reference level. Brick Risk Assessment at 9, JA493. The resulting ratio is referred to as the "hazard quotient." *Id.* Exposures at or below the reference level (HQ≤1) are not likely to cause adverse health effects, and the potential for adverse health effects increases as the hazard quotient grows increasingly greater than one. *Id.*

chloride-equivalent, which is equivalent to 420 tons per year of hydrogen fluoride and 4.5 tons per year of chlorine. Clay Risk Assessment at 3, JA249.

EPA also conducted an acute screening assessment for acid gases. Brick Risk Assessment at 9-10, JA493-494; Clay Risk Assessment at 5-6, JA251-252. The acute screening assessment assumed worst-case exposures for a 1-hour period, and compared those exposures to appropriate acute threshold values to evaluate the risk of significant acute inhalation exposures at each facility. *Id.* While the acute screening indicated that the acute reference value for hydrogen fluoride (but not hydrogen chloride or chlorine) might be exceeded at some facilities, EPA was nevertheless able to conclude that there was low potential for acute health effects, as is further discussed *infra* at 43-45. Brick Risk Assessment at 17, JA501; Clay Risk Assessment at 12-13, JA258-259; 80 Fed. Reg. at 65,503/1.[15]

1. Section 7412(d)(4) allows for a margin of safety to be provided in the emission standard.

The phrase "ample margin of safety" has appeared in multiple sections of the Clean Air Act since the statute was enacted, including in the pre-1990 provision for setting health-based standards, Pub. L. No. 91-604, 84 Stat. 1676, 1685 (1970), but Congress has never defined it. In discussing a similar requirement in the context of setting ambient air standards under section 7409, the 1970 Senate Report explained

[15] EPA also evaluated the potential for environmental effects from annual modeled concentrations. Brick Risk Assessment at 10, JA494; Clay Risk Assessment at 6, JA252. Petitioners have not challenged that aspect of EPA's analysis.

that the purpose of the "margin of safety" is to afford a "reasonable degree of protection . . . against hazards which research has not yet identified." S. Rep. No. 91-1196, at 10 (1970), *reprinted in* 1 Legislative History of the Clean Air Act Amendments of 1970 at 410 (Comm. Print 1974). That view, as this Court has recognized, "comports with the historical use of the term in engineering as a safety factor . . . meant to compensate for uncertainties and variabilities." *NRDC v. EPA*, 824 F.2d at 1152 (citation and internal quotation marks omitted). Similarly, this Court noted in discussing identical language in the Federal Water Pollution Control Act that "Congress used the modifier 'ample' to exhort the Administrator not to allow 'the public [or] the environment . . . to be exposed to anything resembling the maximum risk' and, therefore, to set a margin 'greater than "normal" or "adequate."'" *Id.* at 1153 (quoting *Envtl. Def. Fund v. EPA*, 598 F.2d 62, 81 (D.C. Cir. 1978)). This Court has long recognized the discretion Congress vested in EPA to determine an appropriate margin of safety. *Id.* (noting the "great latitude" Congress afforded EPA).[16]

[16] The phrase "ample margin of safety" is also used in section 7412(f)(2), which requires EPA to review MACT standards and determine whether promulgation of additional standards is necessary to provide an "ample margin of safety" to protect public health. 42 U.S.C. § 7412(f)(2). In making such residual risk determinations, EPA relies on the approach and the interpretation of "ample margin of safety" developed in the Agency's 1989 standards for benzene, 54 Fed. Reg. 38,044 (Sept. 14, 1989), which is explicitly preserved in section 7412(f)(2)(B).

Environmental Petitioners argue that an emission limit that allows exposures up to the threshold level does not provide an ample margin of safety. Environmental Br. 44. This argument fails to acknowledge that the statute does not define *how* EPA must include an ample margin of safety when setting health-based emission limits pursuant to section 7412(d)(4). Such a margin could be provided at multiple points in the process. As Petitioners suggest, EPA could identify an exposure level that is below the established threshold level at which adverse health effects are not anticipated, and then run its modeling to determine an emission level that would result in exposure concentrations at or below that lower health value. But EPA may also reasonably choose to base its emissions modeling on the established threshold, and build a sufficiently health-protective model such that compliance with the emission limits should result in exposures below the established threshold level. Either approach would result in actual exposures that are below the threshold level, and either approach therefore provides an ample margin of safety. EPA's use of the second approach here was reasonable. *See* 79 Fed. Reg. 75,642/3-43/1 (concluding that "it would be reasonable to set any [health-based] emission standard for a pollutant with a health threshold at a level that at least assures that, for the sources in the controlled category or subcategory, persons exposed to emissions of the pollutant would not experience the adverse health effects on which the threshold is based").

2. EPA's method of determining emission levels based on identified health threshold values provided an ample margin of safety.

Once EPA identified health threshold values for hydrogen chloride, chlorine, and hydrogen fluoride below which adverse effects were not expected to occur, it modelled each value to determine an emission level that would result in exposure at or below the threshold level. Risk Assessments at 2, JA248, 486. Importantly, however, EPA built several conservative assumptions into its model that it expected would result in actual exposure levels remaining below the threshold level even if a facility emitted at the limit. 80 Fed. Reg. at 65,501/3. This conservative modeling approach provides the "ample margin of safety" required by section 7412(d)(4).

First, EPA based the limits "on the single facility in the source category with the worst-case combination of meteorology and distance to nearest residential receptor that leads to the highest ambient concentrations." 80 Fed. Reg. at 65,501/3; Brick Risk Assessment at 6, JA490; Clay Risk Assessment at 3, JA249. Because the same level of emissions at all other facilities will result in lower ambient concentrations, for all but one facility in each source category, the model understates the quantity of emissions that would be sufficient to cause exposures at the threshold level. 80 Fed. Reg. at 65,501/3 (explaining that chronic exposures at approximately 90 percent of facilities are estimated to be half the threshold level or less).

Additionally, EPA based the limits on estimated ambient concentrations, which assume that people at the exposure location at all times and do not leave (to go to

work or school, for instance). *Id.* Because a person is unlikely to breathe ambient air around the clock at an exposure location, the model overestimates the average exposure to pollutants over time, and thus the risk of exposure at the threshold level, for a person living at an exposure location.

The ample margin of safety thus rests not on an assumption that sources' emissions will be lower than the permitted level, Environmental Br. 46, but on the likelihood that the conservative assumptions built into EPA's risk modeling approach will mean that ambient chronic exposures for each facility remain below the threshold level even if the sources' emissions are at the maximum permitted level. EPA therefore reasonably concluded that this modeling approach, and the resultant emission levels that were determined, would ensure an ample margin of safety.

Moreover, as discussed *supra* at 32-33, EPA's application of its own reference concentration for hydrogen chloride as the threshold level, rather than the different California EPA reference exposure level, was fully explained and reasonable, and therefore does not undermine EPA's separate provision of an ample margin of safety through its modeling process. Petitioners' argument that EPA's use of its own reference concentration negates the margin of safety provided by its modeling approach, Environmental Br. 46-47, is therefore without merit.

3. EPA's health-based standards provide an ample margin of safety with respect to acute exposures.

Petitioners take issue with EPA's assessment of acute exposure risks for hydrogen fluoride, Environmental Br. 41, but EPA properly assessed these risks. While EPA found that acute exposures at the selected emission limit had the potential to be slightly above the California EPA acute reference exposure level for hydrogen fluoride at some facilities (meaning that, at those facilities, the acute hazard quotient values had the potential to be greater than one), EPA nevertheless reasonably found the potential for acute health effects at those facilities was low. Brick Risk Assessment at 17, JA501; Clay Risk Assessment at 12, JA258. As EPA explained, exceeding the California EPA reference exposure level on which the acute hydrogen fluoride threshold was based does not automatically result in adverse health impacts. Brick Risk Assessment at 13, JA497. EPA considers a wider variety of reference values for its acute risk assessments than for its chronic risk assessments. 80 Fed. Reg. at 65,503/2. Here, EPA considered a range of reference values even though it calculated the hazard quotient for acute risk based on the California EPA acute reference exposure levels. *Id.* In particular, EPA explained that applying the Acute Exposure Guideline Level[17] instead would result in a maximum offsite hazard

[17] Similar to the California EPA acute reference exposure levels, the Acute Exposure Guideline Level is a threshold limit for short-term exposures. *See* Brick Risk Assessment at 13, JA497. The Acute Exposure Guideline Levels "represent threshold exposure limits for the general public and are applicable to emergency exposures ranging from 10 [minutes] to 8 [hours]." *Id.* (internal quotation marks omitted).

quotient for hydrogen fluoride of less than one for all facilities. Brick Risk Assessment at 17, JA501; Clay Risk Assessment at 12, JA258.

Additionally, EPA noted that the highest acute hazard quotient (based on the California EPA reference exposure level) for hydrogen fluoride was two. *Id.* By comparison, EPA has found in section 7412(f) residual risk reviews that an emission standard that would result in exposures with hazard quotients well above two can still provide an ample margin of safety. *See, e.g.*, NESHAP: Generic MACT Standards; and Manufacture of Amino/Phenolic Resins, 79 Fed. Reg. 60,898, 60,909 (Oct. 8, 2014) (finding acute hazard quotient value of ten based on reference exposure level value for formaldehyde). Furthermore, EPA's acute exposure scenario included a conservative assumption that a person would be present at the location of maximum exposure for the single worst hour of the year in terms of emission levels and meteorological conditions. Brick Risk Assessment at 17, JA501.

Finally, EPA found that it was unlikely that a facility would emit only hydrogen fluoride and not other acid gases.[18] Brick Risk Assessment at 17, JA501; Clay Risk Assessment at 12, JA258. The brick emission limits allow facilities to emit either 250 tons per year of hydrogen chloride, or 175 tons per year of hydrogen fluoride, or 1.9

[18] This finding is supported by the test data EPA used to set the emission limits. *See* Cover Sheet, "Test run data showing mercury emissions and emissions of hydrogen fluoride in relation to other gases" (summarizing EPA-HQ-OAR-2013-0291-0657 Appendix B ("Brick Test Data Memo") and EPA-HQ-OAR-2013-0290-0293 Appendix B ("Clay Test Data Memo")), JA923.

tons per year of chlorine; or up to 250 tons per year of hydrogen chloride-equivalent of a combination of those pollutants. EPA's acute exposure risk assessment for each particular pollutant, however, assumed that a facility was emitting *that* pollutant at the maximum permitted level. In reality, because all brick facilities emit a combination of acid gases and not just hydrogen fluoride, a facility would invariably exceed the hydrogen chloride-equivalent emission limit based on emissions from a combination of acid gases before it reached the hydrogen fluoride limit. *See id.* Thus, under actual conditions, for a facility emitting 250 tons per year or less of hydrogen chloride-equivalent, the hydrogen fluoride emissions will be less than those predicted by the model. Accordingly, EPA reasonably considered acute health risks when setting a health-based emission limit for hydrogen fluoride.

In short, Petitioners have presented no basis to conclude that EPA acted contrary to law in identifying health thresholds for hydrogen chloride, chlorine, and hydrogen fluoride, and setting emission limits for these pollutants under section 7412(d)(4).

II. EPA set MACT floors based on data reflecting emission levels and using the Upper Prediction Limit.

A. Introduction

Environmental Petitioners challenge EPA's application of an established statistical methodology known as the "Upper Prediction Limit" ("UPL") to determine MACT floors where EPA had limited emissions information to use in such

calculations. Environmental Br. 49-53. As discussed further below, this Court has upheld EPA's use of the UPL, and the record here demonstrates that EPA provided sufficient explanation of why application of the UPL to limited datasets is appropriate. Additionally, EPA reasonably explained its application of the UPL in setting MACT floors in the Brick/Clay Rule.

The CAA mandates that MACT floor standards must be no less stringent than the level of emission control achieved by the best-controlled source or sources. 42 U.S.C. § 7412(d)(3). While such standards also must ensure continuous regulation of the covered sources, *id.* § 7602(k), as this Court has noted, "no source emits any HAP at a constant level; rather, HAP emissions fluctuate over time and for many reasons." *U.S. Sugar*, 830 F.3d at 598. Most sources "do not measure their HAP emissions at all times and under all conditions," *id.*, so EPA must establish MACT standards based on limited data, generally in the form of "stack tests."[19] Stack tests provide a "snapshot" of a facility's emissions in a limited set of conditions. *Id.*

EPA uses the UPL methodology "[t]o compensate for the lack of adequate emissions data . . . [and] to account for the expected variability in emissions levels." *U.S. Sugar*, 830 F.3d at 598. This Court included an extensive discussion of the

[19] A stack test typically consists of three separate sampling periods of several hours each conducted over one or more days. The concentration of tested pollutants is determined for each sampling event, and the result of the test is the average of the three values for each pollutant. *E.g.*, 40 C.F.R. § 63.8445(e) (incorporating § 63.7(e)(3)).

mechanics of the UPL in *U.S. Sugar*, *id.* at 634-36, and summarized the methodology as follows:

> In layman's terms, the UPL uses an equation that considers (1) the average of the best performing source or sources' stack-test results (*i.e.*, the mean); (2) the pattern the stack-test results create (*i.e.*, the distribution); (3) the variability in the best performing source or sources' stack-test results (*i.e.*, the variance); and (4) the total number of stack tests conducted for the best performing source or sources (*i.e.*, the sample size).

Id. at 635. *See also* Use of the Upper Prediction Limit for Calculating MACT Floors at 4-5, (Sept. 9, 2014) EPA-HQ-OAR-2013-0291-0128 ("UPL Memo"), JA506-507. To establish a MACT floor using the UPL, EPA: (1) ranks all sources in each category based on their stack-test data; (2) determines the HAP emission level of the best-performing source or sources pursuant to section 7412(d)(3); and (3) "applies the UPL methodology to provide the cushion necessary to account for the expected peaks and valleys in HAP emissions not reflected in the three-run stack-test 'snapshots.'" *U.S. Sugar*, 830 F.3d at 598.

EPA used the UPL methodology to determine 22 of the brick and 27 of the clay MACT floors. Final Maximum Achievable Control Technology (MACT) Analysis for Brick and Structural Clay Products Manufacturing at C-5, C-6 (Tables C-4, C-5) (Sept. 24, 2015), EPA-HQ-OAR-2013-0291-0660 ("Brick MACT Floor Memo"), JA851, 852; Final Maximum Achievable Control Technology (MACT) Analysis for Clay Ceramics at C-6, C-7 (Tables C-5, C-6) (Sept. 24, 2015), EPA-HQ-OAR-2013-0290-0294 ("Clay MACT Floor Memo"), JA366, 367. Of those, 16 of the

brick floors and 16 of the clay floors were based on what EPA describes as "limited datasets." *See id.* at B-2 to B-3 (Tables B-1, B-2), JA358-359, 844-845 (identifying number of data points in each MACT floor); Brick MACT Floor Memo at C-5 to C-6 (Tables C-4, C-5), JA851-852; Clay MACT Floor Memo at C-6 to C-7 (Tables C-5, C-6), JA366-367 (identifying basis for determining floors). Petitioners challenge EPA's application of the UPL methodology to limited datasets both in general, and specifically with respect to the emission limits it promulgated in the Brick/Clay Rule. Environmental Br. 49-53. But EPA has provided ample support for its methodology.

B. This Court has upheld EPA's use of the UPL as a general matter.

EPA's use of the UPL was challenged in two recent cases in this Circuit. In *National Association of Clean Water Agencies v. EPA* ("*NACWA*"), which involved EPA's MACT standards for sewage sludge incinerators, this Court remanded certain aspects of the rule for further explanation, including the question of how the UPL represents the MACT floor for new and existing units. 734 F.3d 1115, 1143 (D.C. Cir. 2013). The *NACWA* Court did not invalidate the use of the UPL, but rather held that EPA needed to more fully explain why the UPL was appropriate. *Id.* at 1151. *See also U.S. Sugar*, 830 F.3d at 633.

EPA then provided such explanation in its response to a remand of the record in challenges to rules for boilers and commercial and industrial solid waste incineration units. *U.S. Sugar*, 830 F.3d at 633-34. In that case, the Court found that EPA had "demonstrate[d] with substantial evidence . . . that the UPL 'allows a

reasonable inference as to the performance of the top 12 percent of units,'" which represented "reasoned decision making" and accordingly was entitled to deference. *Id.* at 636. The Court concluded that "the UPL 'reflect[s] a reasonable estimate of the emissions achieved in practice by the best-performing sources,'" and upheld EPA's general use of the methodology. *Id.* at 639 (quoting *Cement Kiln*, 255 F.3d at 871-72).

C. EPA adequately justified the application of the UPL methodology to limited datasets.

The Court's opinion in *U.S. Sugar* expressly left open the question of whether the UPL is an appropriate statistical method for small datasets. 830 F.3d at 633 n.25. EPA addressed that issue in this Rule in a pair of memoranda setting forth its general approach for applying the UPL to limited datasets, and explaining how that approach was followed in determining the brick and clay MACT floors. *See* Approach for Applying the Upper Prediction Limit to Limited Datasets (Sept. 24, 2015), EPA-HQ-OAR-2013-0291-0661 ("Brick Limited Datasets Memo") and EPA-HQ-OAR-2013-0290-0295 ("Clay Limited Datasets Memo") JA857, 370.

As EPA explained, determining the distribution of data is an important component of the UPL approach, and EPA uses well-established tests of kurtosis and skewness[20] to determine distribution. Limited Datasets Memos at 1-2, JA370-371,

[20] The kurtosis statistic characterizes the degree of peakedness or flatness of a given data distribution in comparison to a normal distribution. The skewness statistic characterizes the degree of asymmetry of a given data distribution. Brick MACT Floor Memo at 3-4, JA817-818.

857-858. Previously, EPA used a kurtosis equation that required at least four values in a dataset. *Id.* In further reviewing the application of the UPL to limited datasets, however, EPA identified another kurtosis estimating equation that provides a meaningful result with as few as three values. *Id.* This equation enables EPA to apply the UPL to smaller datasets.

As EPA further explained, to determine sample size thresholds above which use of the UPL does not require further scrutiny, or below which use of the UPL is not appropriate, EPA considers how a diminishing sample size affects the t-score, which is "a value that estimates the uncertainty and variability for a certain confidence level associated with a specific number of data points." Brick Limited Datasets Memo at 2, JA858. As the sample size decreases, the t-score—and the uncertainty of the average that is calculated from the available data points—increases. *Id.* As the sample size increases, the relative changes in the t-score become less dramatic, particularly once the sample size is equal to or greater than three. *Id.* at 3 (Figure 1, Table 1), 5, JA859, 861. EPA thus determined that it may be appropriate to use the UPL to develop emission limits based on as few as three datapoints.[21] *Id.* at 2, JA858.

Even with the use of the alternate kurtosis equation, EPA "recognize[d] that the use of the UPL approach for limited datasets introduces some amount of

[21] Additionally, because emission tests typically include three test runs, the MACT floor dataset size is typically a multiple of three. Brick Limited Datasets Memo at 5, JA861.

uncertainty in the calculation of MACT standards." Limited Datasets Memos at 2, JA371, 858. Accordingly, EPA identified additional steps "to ensure that the level of the MACT standards is reasonable." *Id.* For MACT floors based on between three and six test runs, EPA conducts additional, case-by-case evaluation "to ensure that the uncertainty associated with a limited dataset does not cause the calculated emission limit to be so high that it does not reflect the average performance of the units upon which the limit is based after accounting for variability the emissions of those units." *See id.* at 6-8, JA375-377, 862-864. That evaluation includes some combination of "confirming that the data distribution was selected correctly; after confirming the data distribution, ensuring that we use the most appropriate UPL equation; and, as necessary, comparing UPL equation components for the individual unit upon which a new source floor is based with those of the units in the existing source floor to determine if our identification of the best unit is reasonable." *Id.* EPA thus reasonably explained why MACT floors derived from limited datasets can be considered adequate, and identified a sufficient case-by-case evaluation process to ensure that individual MACT floors based on limited datasets are reasonable.

Petitioners' contention that *NACWA* precludes the application of the UPL to limited datasets, Environmental Br. 49, is incorrect. The *NACWA* Court simply directed EPA to explain "why the [UPL] could still be considered accurate given a small dataset," 734 F.3d at 1144-45. EPA in this rule has done exactly what the *NACWA* Court directed, and what the *U.S. Sugar* Court found EPA had successfully

done on a more general level: EPA demonstrated that the UPL can, when applied to limited datasets, still allow a reasonable inference as to the emissions achieved by the best-performing sources, and EPA has adopted a sound analytical process to follow when it uses the UPL to determine a MACT floor and based on limited data.

EPA "'typically has wide latitude in determining the extent of data-gathering necessary to solve a problem,'" and is entitled to deference "when it determines how best to meet the technical challenges in its area of expertise." *U.S. Sugar*, 830 F.3d at 636 (quoting *NACWA*, 734 F.3d at 1131). Here, EPA's analysis of the acceptable level of uncertainty in the determination of MACT floors, and its development of a process to further evaluate and address that uncertainty, are reasonable. *See NACWA*, 734 F.3d at 1141-42; *Mossville*, 370 F.3d at 1241; *Sierra Club v. EPA*, 167 F.3d 658, 661-63 (D.C. Cir. 1999) (stating that the CAA does not specify how EPA must determine what the best-performing units are achieving, and EPA has considerable discretion in doing so as long as its methodology is reasonable).

D. EPA adequately supported its use of the UPL in the Brick/Clay Rule.

The Limited Datasets Memos apply EPA's evaluative process to brick and clay MACT floors involving limited datasets. *See* Brick Limited Datasets Memo at 8-10, JA864-866; Clay Limited Datasets Memo at 8, JA377. EPA had limited datasets for 18 pollutants and subcategories in the brick source category, and for 21 pollutants and subcategories in the clay ceramics source category. Brick Limited Datasets Memo at

11 (Table 4), JA867; Clay Limited Datasets Memo at 9 (Table 2), JA378. For each dataset, EPA explained that it "ensur[ed] that [it] selected the data distribution that best represents each dataset;" "ensur[ed] that the correct equation for the distribution was then applied to the data;" and "compar[ed] individual components of each limited dataset to determine if the standards based on limited datasets reasonably represent the performance of the units included in the dataset." Limited Datasets Memos at 8, JA377, 864. EPA determined based on its evaluation that no changes to its usual floor calculation procedure were warranted for the clay MACT floors, and that changes were warranted for five of the brick floors. *Id.*

Environmental Petitioners contend that EPA did not adequately explain the adjustments made to five brick floor calculations. Environmental Br. 52. They further assert that EPA improperly made upward adjustments to two of the five floors. *Id.* Both of these arguments fail. First, for each of the five adjusted MACT floors, the Limited Datasets Memo includes an explanation of how and why EPA made these adjustments. *See* Brick Limited Datasets Memo at 8-10, JA864-866.

For the new source MACT floor for PM (in pounds per ton) from large tunnel kilns, EPA found that it could not accurately determine a representative distribution from the best-performing source because there were only two test runs for that kiln, so EPA selected the next best-performing unit and recalculated the UPL based on that unit. Brick Limited Datasets Memo at 8, JA864. For the existing source MACT floor for PM (in grams per dry square cubic foot) from small tunnel kilns, EPA found

that the distribution of the dataset would be better represented by a lognormal template, and determined the MACT floor using that template. *Id.* at 8-9, JA864-865. *See also* UPL Memo at 7-9, JA509-511 (describing characteristics of normal and lognormal distribution curves). Similarly, for the new source MACT floors for mercury (in pounds per ton, micrograms per dry standard cubic meter, and pounds per hour), EPA explained that the datasets would be better represented by a lognormal distribution and template. Brick Limited Datasets Memo at 9-10, JA865-866. EPA therefore adequately explained the basis for the adjustments.

Furthermore, EPA reasonably adjusted upward the floors (in pounds per ton and pounds per hour) for mercury emissions from large new kilns. In arguing that EPA's decision to adjust those floors was arbitrary, Environmental Br. 52-53, Petitioners first fail to note that EPA also made changes to the mercury floors outside the limited dataset analysis. As discussed *infra* at 75-76, EPA added a variability factor to account for variations in the mercury content of raw material used at brick kilns. 80 Fed. Reg. at 65,485/2-3. Because the addition of a raw material variability factor—which Environmental Petitioners do not challenge—introduces more uncertainty into the UPL calculations, it results in a higher MACT floor. *See* Brick MACT Floor Memo at 8-9, JA822-823. *See also* Cover Sheet, "Calculation of Upper Prediction Limit before and after addition of mercury variability factor" (summarizing EPA-HQ-OAR-2013-0291-0660, Appendices B-1, B2), JA925-926. Therefore, the upward adjustment of the mercury floors was due at least in part to the uncontested

application of a raw material variability factor. In any event, while the steps outlined in the Limited Datasets Memos aim to ensure that a MACT floor determined by applying the UPL methodology to a limited dataset is not unreasonably high, *see* Brick Limited Datasets Memo at 6, JA862, the specific facts in the record of a given rule may lead to an adjustment either downward or upward to ensure the floor more accurately represents the average of the best-performing source or sources.

In short, EPA articulated a reasonable method for ensuring that MACT floors based on limited datasets "reflect the average performance of the units upon which the limit is based." Limited Datasets Memos at 6, JA375, 862. EPA then applied that method in the case of the brick and clay MACT floors based on limited datasets. EPA demonstrated that its application of the UPL methodology to limited datasets is reasonable both in general and as applied to the Brick/Clay Rule. EPA has therefore met the requirement identified in *NACWA* and *U.S. Sugar* that it "demonstrate[s] with substantial evidence—not mere assertions—that the UPL allows a *reasonable inference* as to the performance of the top 12 percent of units." *U.S. Sugar*, 830 F.3d at 636 (quoting *NACWA*, 734 F.3d at 1131) (internal quotation marks omitted).

III. EPA's use of alternative emission limits for brick tunnel kilns was reasonable.

In the Brick Rule, rather than promulgating a single numeric MACT limit for each subcategory, EPA gave operators of new and existing tunnel kilns a choice of three alternative emission limits, each expressed in a different unit of measurement,

for both mercury and non-mercury metals. 80 Fed. Reg. at 65,474. To comply with the mercury emission limits, sources could choose one of three numeric emission limits expressed as mass of pollutant emitted per ton of bricks produced, pounds per hour, or concentration (micrograms per dry standard cubic meter). *Id.* at 65,530, Table 1. For non-mercury metals, EPA set a pounds per hour emission limit, and also provided options for limiting PM as a surrogate[22] with limits in pounds per ton or grains per dry standard cubic foot. *Id.* This approach "provides flexibility for the regulated community by allowing a regulated source to choose any control technology or technique to meet the emission limits, rather than requiring each unit to use a prescribed control method that may not be appropriate in each case." 79 Fed. Reg. at 75,633/2.

Consistent with the statutory directive to determine MACT floors based on the "best performing" sources "for which [EPA] has emissions information," EPA determined the MACT floor for each of the alternative limits using a slightly different pool of sources. EPA found that the composition of the group of top-ranked sources varied depending on the unit of measurement that was applied. 80 Fed. Reg. at 65,485/2. EPA therefore ranked sources so that "[e]ach floor [would be] based on the best performing units for that unit of measurement." *Id.* In other words, as EPA

[22] The use of PM as a surrogate for HAP metals in the context of setting MACT floors is well-established and not at issue here. *Sierra Club v. EPA*, 353 F.3d at 982 (quoting *Nat'l Lime Ass'n v. EPA*, 233 F.3d 625, 637 (D.C. Cir. 2000)).

explained, "the concentration floor is based on the ranking of concentration data, and the [pounds-per-hour] floor is based on the ranking of the [pounds-per-hour] data." *Id.*

EPA's decision to set alternative emission limits for mercury and non-mercury metals for brick tunnel kilns is consistent with the statutory language. Section 7412(d) directs EPA to promulgate "[e]missions standards . . . [that] require the maximum degree of reduction in emissions," and requires those standards to be based on the best-performing source or sources for which the Administrator has emissions information. 42 U.S.C. § 7412(d)(2), (d)(3). Nothing in the plain language of the statute forecloses the promulgation of multiple, alternative standards that each independently meets those requirements.

Moreover, the statute does not specify what unit of measurement EPA must use in expressing its emission limitations or identifying the best-performing source or sources to determine the MACT floor. Congress therefore left to EPA's discretion the selection of an appropriate metric by which to measure sources' performance. Inherent in that discretion is the ability to set alternative floors based on different metrics.[23] EPA has considerable discretion in its determination of MACT floors as long as its methodology is reasonable. *NACWA*, 734 F.3d at 1141-42; *Mossville*, 370

[23] EPA has promulgated alternative emission limits pursuant to section 7412(d) in several other rules. *See, e.g.*, 40 C.F.R. pt. 63, Subpt. UUU § 63.1564(a)(1) (setting alternative limitations for metal HAP emissions from catalytic cracking units at petroleum refineries); Subpt. DDDDD § 63.7500(a), Tables 1 and 2 (major boilers).

F.3d at 1241; *Sierra Club*, 167 F.3d at 661-63. EPA's decision to promulgate alternative limits is therefore reviewable under *Chevron* step two, and is entitled to deference so long as it is "based on a permissible construction of the statute." *Chevron*, 467 U.S. at 842-43.

Petitioners argue that because the alternative floors were not based on identical emission levels, they are not equal, and that two of the floors are therefore less stringent. Environmental Br. 54. Petitioners further claim that it is impossible for multiple sources or groups of sources to all be the "best" performing source or group of sources unless their emission levels are identical. *Id.* This argument is rooted in an overly simplistic conception of when emission limits may be said to be based on the "best" performing sources. The alternative floors each reflect the "best" performing sources because each is based on the best-performing sources for the unit of measurement for that floor.

Similarly, Petitioners' contention that the use of alternative floors allows regulated facilities to choose the least stringent floor with which to comply, *see* Environmental Br. 53, mistakenly assumes that one of the alternative floors is the most or least stringent. Instead, the relative stringency of the alternative floors is an apples-to-oranges comparison. By way of analogy, in a comparison of the most talented professional football, basketball, and baseball players, it would be impossible to determine which is the best-performing athlete without establishing a metric for evaluating overall athletic performance. Furthermore, it is impossible to say that the

football player who scores the most touchdowns is a better or worse-performing athlete than the basketball player who makes the most three-point shots, or than the baseball player who hits the most home runs, because those metrics are not directly comparable. Given this, it would be reasonable to set a standard for athleticism that requires an athlete to have either scored at least a certain number of touchdowns, make at least a certain number of three-point shots, or hit at least a certain number of home runs. That athletes could pick the metric that they are most capable of meeting would not make the approach unreasonable.

The same is true when measuring the performance of brick kilns. For instance, a smaller facility with fewer kilns may emit a smaller volume of pollutants overall as measured in pounds per hour, but it may emit more pollutants per ton of bricks produced. By contrast, a larger kiln may emit more pollutants as measured in pounds per hour, but may run more efficiently and therefore have lower emissions as measured in pounds per ton of bricks produced. *See, e.g.*, Brick MACT Floor Memo at A-2 (Table A-1), A-5 (Table A-2), A-9 (Table A-5), JA830, 833, 837 (showing Kiln 514 as the top-ranking large kiln as measured by pounds per ton of PM, Kiln 508 as the top-ranking large kiln as measured by grams of PM per dry square cubic foot, and Kiln 526 as the top-ranking large kiln as measured by pounds per hour of non-mercury metal HAP).

EPA's decision to set alternative emission limitations for brick tunnel kilns was therefore a reasonable exercise of its discretion under section 7412(d). Having

decided to promulgate alternative limits, EPA's method for calculating those limits was also reasonable. EPA explained this method and its rationale for calculating each MACT floor based on its own unit of measure dataset. *See* 80 Fed. Reg. at 65,485/2, 65,507/1. In basing each alternative limit on the best-performing sources for that unit of measurement, EPA satisfied the requirement of section 7412(d)(3) to base its MACT floors on the best-performing sources in a category. 42 U.S.C. § 7412(d)(3).

Finally, Petitioners suggest that it was unnecessary for EPA to promulgate alternative limits because EPA could have divided tunnel kilns into further subcategories (*i.e.*, beyond two subcategories based on size), and then set a single emission limit for each subcategory. Environmental Br. 55. While EPA has the discretion to further subcategorize and considered whether to do so, *see* 79 Fed. Reg. at 75,634/1, the discretion to identify subcategories does not foreclose the Agency's authority to promulgate alternative emission limits where appropriate.

IV. EPA reasonably considered emissions information from synthetic area sources in determining major source MACT floors.

Synthetic area sources (or "synthetic minor sources") are sources that have the potential to emit HAPs in excess of the major source threshold, but whose emissions have been controlled to the extent that they fall below the threshold due to federally-enforceable emission controls. *See* Brick Rule Summary of Public Comments and Responses at 46-47 (Sept. 2015), EPA-HQ-OAR-2013-0291-0685 ("Brick Rule RTC"), JA907-908; 2003 Rule, 68 Fed. Reg. at 26,697/2. Consistent with EPA's

interpretation of section 7412, EPA treats such sources as area sources for determining applicability of emission standards, but as major sources for other purposes. Because the statute directs EPA to identify the level of control achieved in practice by the best-performing sources, 42 U.S.C. § 7412(d)(3), EPA considers emissions information from synthetic area sources when determining which sources are the best-performing sources. EPA continued to use this approach in setting the brick industry standards. Brick MACT Floor Memo at A-2 to A-6, A-9, A-10 to A-12 (Tables A-1, A-2, A-5, A-7, A-8, A-9), JA830-834, 837, 838-840.

BIA challenges EPA's inclusion of emissions information from synthetic area sources in determining existing source MACT floors for the PM and mercury standards for large kilns. Industry Br. 20. Because BIA did not challenge this same approach to determining MACT floors in the 2003 Rule, *see* 68 Fed. Reg. at 26,697/2-98/3, its argument is time-barred. *Med. Waste Inst. v. EPA*, 645 F.3d 420, 427 (D.C. Cir. 2011) (holding that a challenge to EPA's approach not raised within sixty days of EPA's first use of the approach was barred). The argument also fails because EPA's interpretation of the ambiguous statutory text is reasonable and consistent with the statute's structure, congressional intent, and longstanding EPA policy.

A. Synthetic area sources do not fit neatly within the section 7412(a) definition of either a major source or an area source.

Section 7412(a) of the CAA defines a "major source" based on a threshold amount of HAPs that a source "emits or has the potential to emit considering

controls." 42 U.S.C. § 7412(a)(1). A source with the potential to emit at or above the threshold is a major source, and any other source is an area source. *Id.* § 7412(a)(1), (a)(2). Major sources are treated differently from area sources in certain respects. *See, e.g.*, *id.* § 7412(c) (requiring EPA to list all categories of major sources, but only requiring EPA to list area sources in certain circumstances); *id.* § 7412(d)(5) (allowing EPA to set standards for area sources based on "generally available control technologies or management practices" rather than the MACT floor).

Determining whether a source should be considered as a major source or an area source is not always straightforward. The definition of a major source includes the phrase "potential to emit *considering controls*." 42 U.S.C. § 7412(a)(1) (emphasis added). This phrase is not defined in the statute, and its meaning is ambiguous. Although this phrase would not matter for determining whether most sources are major sources, it does matter for synthetic area sources. EPA interprets the phrase to show that consideration of a source's potential to emit before and after controls is relevant to how the source is treated (in both setting and applying standards). *See* 80 Fed. Reg. at 65,509/1-2. This interpretation is entitled to considerable deference, as it is a permissible construction of a complex statute that is within the agency's area of expertise. *See Chevron*, 467 U.S. at 842-43; *United States v. Mead Corp.*, 533 U.S. 218, 227-31 (2001).

B. EPA's consideration of synthetic area source data is consistent with the CAA and longstanding EPA policy.

Section 7412 expresses Congress's intent that emission standards for existing major sources are based on levels that are actually achieved by the "best performing" existing sources. *See* 42 U.S.C. § 7412(d)(3)(A) (basing standards on the "best performing 12 percent of the existing sources"); *id.* § 7412(d)(3)(B) (basing standards on the "best performing 5 sources"). Consistent with this intent, EPA includes emissions information from synthetic area sources when determining the MACT floor for existing major sources. Synthetic area sources demonstrate "emission limitation[s] achieved" by major sources because their controls have effectively reduced their emissions from above major source threshold levels to below major source threshold levels. It would be contrary to congressional intent to exclude synthetic area sources from the MACT floor determination simply because their controls decreased their emissions enough to fall below the major source threshold level. This approach is also consistent with the statute's legislative history. *See* Floor Statement of Sen. Durenberger, 1 1990 Legis. Hist. at 870 (clarifying the intent that EPA collect "data on all of the better-performing sources within each category" and ensure that EPA "does not miss any sources that have superior levels of emissions control"). EPA's inclusion of synthetic area sources for purposes of determining the MACT floor ensures "sources that have superior levels of emissions control" are considered.

Further, section 7412(d)(3) expressly excludes from the MACT floor calculation those sources that meet the lowest achievable emission rate requirements of section 7501. *See* 42 U.S.C. §§ 7412(d)(3)(A), 7501(3). The express exclusion of those sources demonstrates that Congress considered the issue of which sources should be excluded from the MACT floor determination, but did not conclude that synthetic area sources should be excluded. Instead, Congress provided EPA the flexibility to include synthetic area sources.

EPA has consistently treated synthetic area sources as area sources when determining the applicability of particular requirements, but as major sources for determining major source MACT floors. *See* 40 C.F.R. § 63.2 (defining "potential to emit" as the "maximum capacity of a stationary source to emit a pollutant under its physical and operational design," and a limitation on the capacity of the source "shall be treated as part of its design if the limitation or the effect it would have on emissions is federally enforceable"—*i.e.*, a synthetic area source would not be subject to major source standards); Memorandum from John S. Seitz to EPA Regions, Potential to Emit for MACT Standards – Guidance on Timing Issues (May 16, 1995), EPA-HQ-OAR-2013-0291-0569 ("Seitz Memo"), JA441-450 (addressing when a major source can become a synthetic area source). And EPA has included synthetic area sources in MACT floor calculations in prior rulemakings. *E.g.*, NESHAP for Municipal Solid Waste Landfills, 68 Fed. Reg. 2227, 2232/2 (Jan. 16, 2003); NESHAP

for Polyvinyl Chloride and Copolymers Production, 77 Fed. Reg. 22,848, 22,876/3-78/1 (Apr. 17, 2012).

C. The CAA allows EPA to treat synthetic area sources as major or area sources depending on context.

BIA's argument that section 7412(d)(3)(A) requires exclusion of synthetic area sources wrongly assumes that synthetic area sources can never be considered major sources for any purpose. BIA argues that EPA may only use sources "in the category" to determine the MACT floor for that category, thus excluding synthetic area source data from consideration, since they are not subject to major source standards. Industry Br. 19-20. BIA's argument is based on the assumption that a source must be treated as either a major or an area source *for every purpose*. As explained above, that is not how EPA interprets the statutory definition of "major source" in the context of synthetic area sources.

Contrary to BIA's assertion, EPA does not "admit[ ] that synthetic [area] sources are not major sources." Industry Br. 21.[24] EPA has stated that although synthetic area sources "are not subject to the requirements imposed on major sources . . . that does not equate to a conclusion that they are no longer major sources in any respect." 80 Fed. Reg. at 65,509/1. EPA considers synthetic area sources to be major

[24] That the standards' application is "limited to brick plants located at a major source," Industry Br. 20, demonstrates only that EPA does not subject synthetic area sources to major source *standards*, which is consistent with EPA's position. *See* 40 C.F.R. § 63.8385.

sources in certain respects, such as when EPA identifies the best-performing major sources as part of the MACT floor determination. *Id.* Thus, even if, as BIA contends, section 7412(d)(3)(A) requires that all sources considered in determining the MACT floor be "in the category," *see* Industry Br. 21, synthetic area sources *are* major sources that are "in the category" for the purpose of determining the MACT floor. Further, this does not mean that section 7412(d)(3)(A)'s phrase "in the category or subcategory" is meaningless. The phrase limits the sources that EPA considers. Here, for example, when setting standards for brick sources, EPA only looked at the emission limitations achieved by brick sources—not the emission limitations achieved by tile sources or other non-brick sources. The phrase also means that brick sources that are true area sources are excluded from major source MACT floor determinations.

Nowhere does the statute require that once a source is treated as "in" (or out of) a category, it must be treated that way for all purposes. BIA's argument that Congress excluded sources meeting the lowest achievable emission rate requirements from section 7412(d)(3) because they are "in" the major source category while synthetic area sources are excluded by definition because they are not "in" the major source category only continues to rely on BIA's preferred interpretation of the statute. *See* Industry Br. 22. EPA's interpretation of the phrase "potential to emit considering controls" is consistent with Congress's direction to use the "best performing" sources in the category or subcategory and is entitled to deference.

Further, this Court has acknowledged that synthetic area sources should not necessarily be treated the same as area sources. *See U.S. Sugar*, 830 F.3d at 650 (finding that EPA had not adequately explained "why the rationale it used to exempt natural area sources from Title V could be identically applied to synthetic area sources."). And for a major source included in more than one source category, if the source's compliance with major source standards for one source category results in the source's potential to emit falling below the major source threshold, EPA's interpretation allows the source to be treated as a synthetic area source for later-promulgated standards for a different source category. *See* Seitz Memo at 9-10, JA449-450. This Court should therefore defer to EPA's reasonable and longstanding treatment of synthetic area sources as major sources for the purpose of determining the MACT floor.

V. The PM standards are consistent with the statute and rationally developed, and EPA adequately responded to BIA's comments.

A. EPA reasonably determined the MACT floors using the best-performing 12 percent of sources for which it had emissions information.

For a category with 30 or more sources, section 7412(d)(3)(A) requires EPA to determine the existing source MACT floor by calculating the "average emission limitation achieved by the best performing 12 percent of the existing sources (*for which the Administrator has emissions information*)." 42 U.S.C. § 7412(d)(3)(A) (emphasis added).

This is precisely what EPA did in determining the MACT floor for PM from existing brick sources.

EPA initially identified two potential approaches for determining the existing source MACT floor for PM emissions from brick sources, and sought information from the brick industry to use in determining MACT floors. 79 Fed. Reg. at 75,635/1-2, 75,649/1-2. The first proposed approach was based on the possibility that EPA could identify the best-performing 12 percent of sources in the entire category, in which case the MACT floors could be based on a larger number of sources. *See* 80 Fed. Reg. at 65,506/3; 79 Fed. Reg. at 75,635/1-2. At the time of the proposal, EPA assumed that kilns with fabric filters would be the best-performing sources. *See* 79 Fed. Reg. at 75,635/1; Analysis of Potential Subcategories for BSCP Tunnel Kilns at 6-7 (Nov. 6, 2014) EPA-HQ-OAR-2013-0291-0122, JA530-531. EPA explained that *if* kilns with fabric filters were the best-performing sources and *if* it had information from all fabric filter-controlled sources, then EPA could identify the best-performing 12 percent of sources. *See* 79 Fed. Reg. at 75,635/1-2; 80 Fed. Reg. at 65,506/2-3. Because the category contained 225 sources at the time of proposal and 220 when the standards were issued, the best-performing 12 percent of the category would be represented by 27 sources. *See* 79 Fed. Reg. at 75,635/2; Brick MACT Floor Memo at 10 (Table 1), JA824 (showing 122 large kilns and 98 small kilns). EPA expressed concern, however, that although kilns with fabric filters were statistically better-performing as a group, emissions data reflected that some sources

with other or no controls performed better than some of the fabric filter-controlled kilns. 79 Fed. Reg. at 75,635/1-2. EPA therefore requested information on the reliability of data showing low emissions from kilns without fabric filters. *Id.*

The second proposed approach was simply to set emission limits "based on the top 12 percent of the data available in each of the kiln size subcategories." *Id.* at 75,635 n.1; *see id.* at 75,649/1-2; Maximum Achievable Control Technology (MACT) Floor Analysis for Brick and Structural Clay Products at 11-12, A-5 to A-8 (Tables A-4, A-5) (Nov. 6, 2014), EPA-HQ-OAR-2013-0291-0119 ("Proposed Brick MACT Floor Memo"), JA522-523, 525-528.[25] EPA proposed emission limits under this approach, Proposed Brick MACT Floor Memo at 12 (Tables 5, 6), JA523, and requested comment on the method of generating those limits, and on whether the available-data approach should be used instead of the fabric filter-based approach. 79 Fed. Reg. at 75,649/2. EPA noted that the reliability of the data from non-fabric

[25] To determine MACT floors based on the total number of sources in the category (with 30 or more sources), EPA would need sufficient information about all sources in the category to conclude that it had emissions data from the best-performing 12 percent of sources. For example, if a category has 100 sources, EPA could base the MACT floors on 12 sources only if it has information to show that those 12 sources are the best performers in the category. Alternatively, EPA could determine the floor based on 12 percent of the sources for which it has emissions information. For example, if EPA has information for only 50 of 100 sources, the MACT floor could be calculated based on the best-performing 6 sources for which EPA has data, even though some of the sources for which EPA does not have data might be better-performing sources.

filter-controlled kilns was "a key factor" in determining which approach is appropriate. *Id.* at 75,635 n.1.

Between the proposal and the final rule, EPA did not receive information sufficient to explain why some non-fabric filter-controlled sources emitted at levels as low as or lower than some sources with fabric filter controls. 80 Fed. Reg. at 65,485/1. EPA therefore had no basis for excluding data from those lower-emitting non-fabric filter-controlled sources and thus could no longer assume that fabric filter-controlled sources were the best performers. Additionally, EPA did not have emissions data from all the fabric filter-controlled sources, so even if it could have excluded the lower emitting data, it would not necessarily have had information from the best-performing 12 percent of sources in the category. *Id.* at 65,484/3-85/1. For these reasons, EPA determined the final PM MACT floors using the best-performing 12 percent of sources for which it had emissions information. *Id.* at 65,485/1-2. EPA finalized the standards using subcategories based on kiln size, consistent with the second approach it had proposed. *Id.* Because the data showed that some non-fabric filter kilns had lower emissions than fabric filter-controlled kilns, EPA reasonably concluded that it could not assume that fabric filter-controlled kilns were the best-performing kilns, and EPA appropriately set the PM MACT floors based on the best-performing 12 percent of sources for which it had emissions information.

B. The PM MACT standard reasonably represents the best-performing 12 percent of sources.

BIA's contention that the PM MACT floors are unrepresentative because the data were skewed toward the best-performing sources, Industry Br. 24-28, is not supported by the record. *See White Stallion*, 748 F.3d at 1247 (considering similar allegations, and finding that "assertions of a biased or irrational data collection process are not supported by a review of the record"). EPA relied on data from a variety of sources, including responses to EPA surveys, test data compiled during the 2003 rulemaking, and additional data from Petitioner BIA. Test Data Used in BSCP Manufacturing Final Rule at 1-2 (Sept. 24, 2015), EPA-HQ-OAR-2013-0291-0657 ("Brick Test Data Memo"), JA812-813. And BIA could have provided emissions data from more sources. Although data from fabric filter-controlled sources were a large portion of EPA's dataset, these sources were not consistently the best performers. Indeed, EPA included data from non-fabric filter-controlled sources to determine the MACT floors. Brick MACT Floor Memo at A-2 to A-9, JA830-837, (showing non-fabric filter-controlled sources ranked in the top twelve percent). And like the data at issue in *White Stallion*, 748 F.3d at 1248, here, some of the best-performing sources for PM were worse-performing for mercury. *Compare* Brick MACT Floor Memo at A-2 to A-6, JA830-834 *with id.* at A-10 to A-12, JA838-840.

EPA has provided ample support and justification for its method, and had no reason to believe that the lower non-fabric filter emissions data were inaccurate. *See*

80 Fed. Reg. at 65,484/3-85/1; 79 Fed. Reg. at 75,635/1-2, 75,649/1-2. EPA proceeded cautiously in questioning the data that were counter to its expectations and requesting comment, and the industry responses did not show that the data were unreliable. *See* 80 Fed. Reg. at 65,484/3-85/1. Moreover, contrary to BIA's assertion that "EPA made no attempt to reconcile the suspicious data," Industry Br. 25, EPA contacted kiln owners to request information concerning the test results, requested input from BIA, and undertook a technical review of the data. *See, e.g.*, Telephone Contact Summary for Lee Brick (May 2015), EPA-HQ-OAR-2013-0291-0650, JA781; Telephone Contact Summary for Boral Industries (May 2015), EPA-HQ-OAR-2013-0291-0649, JA780; Email from Sharon Nizich to Terry Schimmel and Susan Miller, Re: More Information Needed on Kiln Test Reports for Uncontrolled Kilns at 4-6 (June 8, 2015 at 10:42 am), EPA-HQ-OAR-2013-0291-0607, JA785-787; Brick Test Data Memo at 6, JA814. Therefore, EPA reasonably relied on these data in determining the PM MACT floors.

C. EPA complied with procedural requirements.

BIA's argument that EPA failed to respond to information it provided concerning lower emissions data for some non-fabric filter-controlled sources, Industry Br. 28-29, lacks merit. EPA is only required to respond to *significant* comments. 42 U.S.C. § 7607(d)(6)(B); *Covad Commc'ns Co. v. FCC*, 450 F.3d 528, 550 (D.C. Cir. 2006). Here, the sole "comment" that BIA cites is an email providing a list of kilns with short notes on factors BIA suspected *might* affect the test data, without

explaining *why* the factors might cause the data to be unrepresentative of the kiln's emissions. *See* Email from Susan Miller to Sharon Nizich, DLA/Uncontrolled Kilns (June 25, 2015 at 2:43 pm), EPA-HQ-OAR-2013-0291-0614, JA788 (listing notes such as "[i]nitial MACT compliance test- suspect all new limestone"). This can hardly be considered a legally significant comment. Indeed, BIA's explanation of these factors in its brief provides more explanation than was provided in its email. *See* Industry Br. 28-29.

Furthermore, the information in BIA's email would not have changed how EPA determined the MACT floors. *See* 42 U.S.C. § 7607(d)(8) ("In reviewing alleged procedural errors, the court may invalidate the rule only if the errors were so serious and related to matters of such central relevance to the rule that there is a substantial likelihood that the rule would have been significantly changed if such errors had not been made."). In the absence of additional evidence, BIA's identification of factors that it suspected might potentially indicate unrepresentative emissions data would not have provided sufficient justification for EPA to exclude data from low-emitting sources without fabric filter controls. BIA did not show that the non-fabric filter data were unreliable, nor did it provide additional data so that EPA could conclude that it had information from all best-performing sources. Without such evidence, EPA could not have justified using data from 12 percent of sources in the industry—*i.e.*, from more than the top-performing 12 percent of sources for which it had emissions data—in finalizing the fabric filter-based proposed standards. 80 Fed. Reg. at

65,506/2-3. *See also* Letter Responding to BIA Petition for Reconsideration, Enclosure at 2-3 (May 12, 2016), EPA-HQ-OAR-2013-0291-0689, JA919-920. Therefore, EPA satisfied procedural requirements in setting the PM standards for brick sources.

VI. The mercury standards for the brick industry are consistent with the statute and congressional intent.

Contrary to BIA's argument, Industry Br. 29-39, EPA determined the mercury MACT floor for the brick industry exactly as required by section 7412(d)(3)(A). Legislative history cited by BIA does not negate what the statute and case law require. Further, EPA reasonably found that sources can comply with the standard through means other than switching raw materials (although no such finding is necessary). Finally, EPA reasonably declined to establish subcategories based on raw materials.

A. EPA appropriately determined the MACT floors for mercury and set standards at the floor levels.

As this Court has emphasized, "EPA may not deviate from section 7412(d)(3)'s requirement that floors reflect what the best performers actually achieve." *Sierra Club*, 479 F.3d at 880 (quoting *Cement Kiln*, 255 F.3d at 861) (internal quotation marks omitted). "When setting the MACT floor, [ ] EPA considers *only* the performance of the cleanest sources in a category . . . it does not take into account other factors, including the cost of putting a source in line with its better-performing counterparts." *U.S. Sugar*, 830 F.3d at 594.

In its decision vacating the 2003 Rule, this Court held that where EPA had found that raw material content has an appreciable effect on HAP emissions from brick kilns, EPA could not set MACT floors based solely on the use of pollution control technology. *Sierra Club,* 479 F.3d at 882-83. The Court stated that a purely technology-based approach would satisfy the CAA "if pollution control technology were the *only* factor determining emission levels of that HAP." *Id.* at 882 (quoting *Cement Kiln*, 255 F.3d at 863) (internal quotation marks and further citations omitted). By contrast, if factors other than technology "influence a source's performance, it is not sufficient that EPA consider[ ] sources using only . . . MACT controls." *Id.* (quoting *Cement Kiln*, 255 F.3d at 864-65).

Here, EPA determined the mercury MACT floors for brick kilns by calculating the emissions from the best-performing 12 percent of sources for which it had emissions information, as required by section 7412(d)(3)(A). EPA set standards for two subcategories, small kilns and large kilns, and allowed kilns to use one of three alternative measurements to comply. 80 Fed. Reg. at 65,474/2-3, Table 4. EPA set the mercury standards under section 7412(d)(3) at the MACT floor level because it found that more stringent limits (which would have to be based on a beyond-the-floor analysis under section 7412(d)(2)) were "not reasonable relative to the level of emission reduction achieved" due to the costs of additional controls. 79 Fed. Reg. at 75,638/2. Further, because mercury emissions result from the mercury content in the raw clay used, and mercury content varies by the location where clay is quarried, EPA

developed a variability factor for mercury content in raw clay and incorporated it into the UPL equation used to determine the MACT floors. 80 Fed. Reg. at 65,485/2-3. As a result, the final mercury standards are less stringent than the proposed standards. *Compare* 79 Fed. Reg. at 75,628 Table 4 (proposing mercury standards for large kilns as 0.000022 pounds per ton) *with* 80 Fed. Reg. at 65,474 Table 4 (finalizing mercury standards for large kilns as 0.000041 pounds per ton). EPA also noted that the mercury standards provide flexibility for sources by "allowing a regulated source to choose any control technology or technique to meet the emission limits, rather than requiring each unit to use a prescribed control method." 79 Fed. Reg. at 75,633/2. *See also* Brick Rule RTC at 27, JA901 ("[I]t is up to each facility to determine the type of emission control that works best for their particular situation.").

BIA's arguments that the mercury standards are invalid proceed from the incorrect assumption that EPA must ensure that all sources are able to achieve MACT floor-based standards. But that is not what the CAA requires. Rather, this Court has clarified that the MACT floors must be set regardless of whether all sources can achieve them. *Cement Kiln*, 255 F.3d at 861 (stating that section 7412(d)(3) "limits the scope of the word 'achievable' in section 7412(d)(2)," and that "EPA may not deviate from section 7412(d)(3)'s requirement that floors reflect what the best performers actually achieve by claiming that floors must be achievable by all sources using MACT technology"); *Nat'l Lime Ass'n v. EPA*, 233 F.3d 625, 629 (D.C. Cir. 2000) (stating

that MACT floors "apply without regard to either costs or the other factors and methods listed in section 7412(d)(2)").

B. EPA's finding that sources could install controls or switch raw materials to meet the standards was not a basis for the standards, but was reasonable.

In its response to comments, EPA noted that activated-carbon injection control devices were an available compliance option for brick kilns. *See* Brick Rule RTC at 13, 26-27, JA894, 900-901. BIA argues that because no sources in the industry use such devices to reduce mercury emissions, and EPA has not shown that they would be effective, the controls are not a realistic compliance option, so that EPA has effectively required brick facilities to switch raw materials. Industry Br. 30-32.

In fact, the record fully supports EPA's statements concerning the effectiveness of activated carbon injection controls. *See* Brick Rule RTC at 26-27, JA900-901 (noting proven effectiveness of controls in similar industries and noting lack of evidence that controls would interfere with operation of brick sources). *See also* Methodology and Assumptions Used to Estimate the Model Costs and Impacts of BSCP Air Pollution Control Devices for the Final Rule at 7-9 (Sept. 24, 2015), EPA-HQ-OAR-2013-0291-0662 ("Brick Cost Memo"), JA870-872 (considering activated carbon injection controls in the cost analysis). Activated carbon injection controls have proven effective in controlling mercury emissions from similar sources in other industries. Brick Rule RTC at 13, JA894. EPA has used its technical expertise to

reasonably determine that such controls would be effective for the brick industry as well. That technical determination is entitled to considerable deference. *See White Stallion*, 748 F.3d at 1233. Therefore, there is no basis for BIA's conclusion that "the only available means of controlling mercury emissions is raw material substitution." Industry Br. 32.

In any event, as explained *supra* in Section VI.A, EPA does not need to determine *how* sources can meet the MACT floor, let alone *whether* sources can meet the MACT floor at all. BIA's statement that EPA asserts that brick plants could meet the standard by "switching to clay with lower mercury content," Industry Br. 30, wrongfully assumes that EPA's assertion could have any bearing on the levels at which MACT floor-based standards were set. While EPA noted in its cost analysis that "if significant amounts of mercury are found at one location onsite, material found at another onsite location with a lower mercury content could be used," Brick Cost Memo at 9, JA872, EPA explained elsewhere that it was "not requiring the use of offsite raw materials in this rule." Brick Rule RTC at 26, JA900. Stating that sources may be able to comply if they switched raw materials does not amount to a requirement. But even if EPA had found that switching clays was the only way sources could comply with the standards, that finding would not have allowed EPA to set less stringent standards, because the standards are already at the MACT floor level. *See Sierra Club*, 479 F.3d at 880.

C. The CAA legislative history does not prohibit raw material substitution requirements for brick kilns.

Largely ignoring the statutory text and this Court's decision in *Sierra Club*, BIA argues that legislative history indicates that EPA may not require raw materials substitution for brick kilns. *See* Industry Br. 33-34. As explained *supra* in Sections VI.A and VI.B, this argument proceeds from the flawed premises that EPA must explain how all sources could meet the standards, and that all sources must meet the standards through raw material substitution. Even if BIA's premises were correct, this argument would lack merit.

To support its position, BIA cites an explanatory statement in a Conference Report for the 1990 Amendments, which states that in setting standards for categories of sources "engaged in mining, extraction, beneficiation, and processing of nonferrous ores, concentrates, minerals, metals, and related in-process materials, the Administrator shall not consider the substitution of, or other changes in, metal- or mineral-bearing raw materials that are used as feedstocks or materials inputs, or metal- or mineral-bearing materials processed or derived from such feedstocks or materials." Industry Br. 33 (quoting H.R. Rep. No. 101-952 at 339, 1 1990 Legis. Hist. at 1989). However, the clear language of the statute requires EPA to determine the MACT floor by estimating the emissions actually achieved by the best-performing existing sources. *Cement Kiln*, 255 F.3d at 861 ("EPA may not deviate from section 7412(d)(3)'s requirement that floors reflect what the best performers actually

achieve. . . ."). The statutory language provides no allowance to set the MACT floor at a less stringent level if some sources would otherwise need to switch raw materials. Indeed, *Sierra Club* held that MACT floors could not be justified by the Agency's "concern that floors based on clean clay would be unachievable." 479 F.3d at 883.

BIA's request for *en banc* review of *Sierra Club* or an *Irons* footnote, Industry Br. 38, is unjustified because no prior conflicting holdings are at issue. *See Irons v. Diamond*, 670 F.2d 265, 267-68, n.11 (D.C. Cir. 1981). As in the cases BIA cites, "[t]his case does not present the very rare situation where the legislative history of a statute is more probative of congressional intent than the plain text." *Consumer Elecs. Ass'n v. FCC*, 347 F.3d 291, 298 (D.C. Cir. 2003); *see Engine Mfrs. Ass'n v. EPA*, 88 F.3d 1075, 1088 (D.C. Cir. 1996) (discussing that unless the statute's text "compels an 'odd result'" the statute's plain language "should be conclusive") (citing Supreme Court cases); *id.* at 1093 (finding the statute's plain text reliable). Here, interpreting the legislative history to deviate from the plain text of the CAA's MACT floor requirements would uproot not only the holding of *Sierra Club*, but also this Court's longstanding precedent that MACT floors must be set at the lowest levels achieved.

Finally, while the directive of the statute is clear, the legislative history is not. It is not apparent that the statement even intended to refer to and include the brick industry among industries "engaged in mining, extraction, beneficiation, and processing of nonferrous ores, concentrates, minerals, metals, and related in-process

materials." Although brick facilities could be considered as "processing" clays and shales to produce bricks, it is not clear that these clays and shales are among the types of raw materials identified in the statement.[26] Therefore, the plain language of the statute, not legislative history, controls.

D. EPA's decision not to establish subcategories based on raw materials is rational and entitled to deference.

At the time of proposal, EPA stated that it would consider subcategorizing based on the mercury content of raw materials if data were provided showing "a correlation between raw material content and mercury emissions and . . . sharp disparities in raw material mercury content that readily differentiate among types of sources." 79 Fed. Reg. at 75,650/3-51/1. EPA specifically requested "mercury emissions data coupled with raw materials mercury data." *Id.* at 75,651/1. During the rulemaking, however, although EPA assumed a correlation existed between the mercury content of clay and mercury emissions, EPA did not receive sufficient data to subcategorize on that basis. Brick Rule RTC at 13, JA894. Because emissions data

[26] If the legislative history were to have any controlling weight, it would only be to limit EPA's considerations when setting beyond-the-floor standards for specific industries. This is because section 7412(d)(2) allows EPA to consider ways in which sources could reduce emissions, such as materials substitution, in setting standards more stringent than MACT floors. And contrary to BIA's assertion, Industry Br. 34, this interpretation is consistent with how EPA considered legislative history in a prior rulemaking. *See Sierra Club v. EPA*, 353 F.3d at 988 (discussing EPA's decision not to set *beyond-the-floor* standards for copper smelters based in part on legislative history).

were collected years prior to data on raw material content,[27] and because the mercury content of clay varies even within a quarry, *see* Mercury Content of Oklahoma and Ohio Shale Deposits Supplying the Brick Industry at 6, 9 (Tables 1, 2) (Sept. 23, 2015), EPA-HQ-OAR-2013-0291-0659, JA805, 808, EPA could not demonstrate a correlation between the mercury content in the raw materials and mercury emissions. Accordingly, EPA reasonably concluded that it could not justify subcategorization based on raw material content.

BIA contends that subcategorization would "ensure that MACT floors are truly 'achievable'" and would "avoid the need for raw material substitution." Industry Br. 37. As stated above, however, there is no requirement that MACT floors be achievable by all sources,[28] nor has EPA required material substitution. EPA explained what data it would need to justify subcategories, but then determined that it did not receive enough information to justify that approach. EPA's decision not to subcategorize based on raw materials is rational and entitled to deference. *See White Stallion*, 748 F.3d at 1233.

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[27] While the most recent mercury emission test was conducted in 2011, *see* Cover Sheet, "Test run data showing mercury emissions and emissions of hydrogen fluoride in relation to other gases," JA924, the samples for raw material content were collected between 2013 and 2015. *See* Attachment to Email from Susan Miller to Sharon Nizich, Green Brick Mercury Data (May 4, 2015), EPA-HQ-OAR-2013-0291-0618, SJA1-5.

[28] Indeed, setting a standard based on what is "achievable" rather than on what is "achieved" was one of the bases for the vacatur of the 2003 Rule. *Sierra Club*, 479 F.3d at 880.

VII. TCNA lacks standing to challenge the standards for the tile industry and EPA's decision to list the major source category.

TCNA challenges EPA's promulgation of standards on the grounds that they are for a subcategory that did not include any major sources at the time of promulgation, and argues that the hypothetical possibility of a major source arising in the industry in the future is not enough to support EPA's promulgation of the standards. Industry Br. 41. As discussed in greater detail *infra* at 85-88, although major sources in the tile industry existed when EPA listed the category and were subject to the 2003 Rule, no major sources in the tile industry were subject to the Clay Rule at the time it was promulgated.

In challenging EPA's major source standards for the tile industry and EPA's listing of the major source category including the tile industry, TCNA bears the burden of proving that it has Article III standing. *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 561 (1992). TCNA must show that its members suffer an injury caused by the promulgation of the standards that could likely be redressed by this Court. *Id.* at 560-61; *Sierra v. Morton*, 405 U.S. 727, 738-40 (1972). And TCNA must prove that injury is actual or imminent, not conjectural or hypothetical. *Lujan*, 504 U.S. at 561. TCNA incorrectly claims that "[t]he legitimacy of the promulgation is dependent upon TCNA's right to judicial review challenging it." Industry Br. 18. Rather, TCNA must affirmatively establish its right to seek judicial review before its arguments may be considered. *See Lujan*, 504 U.S. at 560.

To demonstrate that it satisfies Article III requirements, TCNA must show that at least one of its members likely would be subject to the standards. But any such demonstration would undermine TCNA's argument that EPA inappropriately promulgated the standards. Accordingly, TCNA has not identified a single member who is or will be harmed, and has failed to allege specific facts sufficient to prove it has standing. *See* Industry Br. 17-18, Attachment B; *Lujan v. Nat'l Wildlife Fed'n*, 497 U.S. 871, 888 (1990) (holding "conclusory allegations" are insufficient to establish standing); *Sierra Club v. EPA*, 292 F.3d 895, 899 (D.C. Cir. 2002) (finding petitioner's burden to prove standing is the same as a plaintiff's burden at summary judgment). If TCNA views the "hypothetical possibility" of a future source becoming subject to the standards as so remote as to preclude EPA from promulgating the standards, then TCNA lacks standing to challenge them. And as discussed *infra* in Sections VIII-XII, TCNA's arguments fail on the merits even if this Court determines that TCNA has standing.

VIII. EPA complied with the CAA in setting standards for major sources in the tile industry.

TCNA argues that the CAA requires that EPA issue standards under section 7412(d) only if it finds that there are major sources in the category that would be subject to the standards. Industry Br. 39-44. This argument lacks merit. EPA appropriately determined that there were major sources in the listed category at the time of listing, consistent with CAA requirements. After EPA properly listed the

category, the CAA required it to promulgate major source standards for sources in that category. Accordingly, EPA properly issued standards for the tile industry.

A. EPA set standards for major sources in the tile industry consistent with CAA requirements.

In the 1990 CAA amendments, Congress required EPA to publish an initial "list of all categories . . . of major sources," and certain area sources of HAPs. 42 U.S.C. § 7412(c)(1), (c)(3). To supplement its initial list, EPA "may at any time list additional categories . . . according to the same criteria for listing" applicable under section 7412(c)(1) and (c)(3). *Id.* § 7412(c)(3). For major sources, the only "criter[ion] for listing" is that the category contain major sources of HAPs. *See id.* Any person can petition to have a category deleted from the list, and EPA may delete a category only if it makes certain determinations specified in section 7412(c)(9). *Id.* § 7412(c)(9); *New Jersey v. EPA*, 517 F.3d 574, 578-79, 582 (D.C. Cir. 2008). Otherwise, once a category is listed, EPA must establish emission standards for major sources in that category. 42 U.S.C. § 7412(c)(2), (c)(5), (d)(1), (e)(1); *see Sierra Club v. EPA*, 850 F. Supp. 2d 300, 304 (D.D.C. 2012).

EPA promulgated the Clay Rule consistent with those requirements. In 1992, EPA published the initial list of source categories, which included a "clay products manufacturing" source category. Notice of Initial List of Categories of Sources under Section 112(c)(1) of the Clean Air Act Amendments, 57 Fed. Reg. 31,576, 31,591/3 (Table 1) (July 16, 1992). In 2002, in addition to proposing standards, EPA provided

notice that it had replaced the clay products manufacturing source category on the source category list with two source categories: brick and structural clay products manufacturing and clay ceramics manufacturing. NESHAP for Brick and Structural Clay Products Manufacturing; and NESHAP for Clay Ceramics Manufacturing; Proposed Rule, 67 Fed. Reg. 47,894, 47,896/2-3 (July 22, 2002).[29] The "clay ceramics manufacturing source category includes those facilities that manufacture pressed floor tile, pressed wall tile, and other pressed tile; or sanitaryware." *Id.* at 47,913/3. EPA finalized clay ceramics standards in 2003, 68 Fed. Reg. 26,690, and existing major sources in the tile industry were subject to the standards starting in 2006, until this Court vacated the standards in 2007. *See* 68 Fed. Reg. at 26,716/1; *Sierra Club*, 479 F.3d at 876.

The clay ceramics manufacturing category remained a listed source category notwithstanding this Court's vacatur of the 2003 Rule, and therefore, EPA was still required to promulgate standards for major sources in the category. 42 U.S.C. § 7412(c)(2), (e)(1); *See Sierra Club*, 850 F. Supp. 2d at 304. Accordingly, EPA properly promulgated standards for major tile industry sources in the Rule under review.

[29] EPA had provided notice in 1999 that it anticipated reevaluating the clay products manufacturing category and replacing it with four categories, including a clay ceramics manufacturing category. Notice of Revision of Source Category List and Schedule for Standards under Section 112 of the Clean Air Act, 64 Fed. Reg. 63,025, 63,028/1 (Nov. 18, 1999). EPA anticipated that each category would be added to the list "[w]hen each of the standards is proposed." *Id.*

B. EPA had authority to set major source standards for the tile industry even when no sources are subject to the standards.

By August 27, 2014, just months before EPA re-proposed major source standards for the clay ceramics manufacturing category, all sources in the tile industry that would otherwise have been subject to the standards had either closed or become synthetic area sources. *See* Email and Letter from Eric Astrachan to Peter Tsirigotis, TCNA Letter - No MACT Major Sources in Ceramic Tile Industry Segment at 1 (Aug. 29, 2014), EPA-HQ-OAR-2013-0290-0131 ("Astrachan Letter"), JA261.[30] Because no tile industry sources would be subject to the standards, EPA at the time of proposal requested comment on whether it was, in fact, required to finalize standards for the tile industry. 79 Fed. Reg. at 75,665/2-3. In the final rule, EPA responded to comments and appropriately concluded that, because the category contained major sources when it was listed, and because EPA is required to set standards for listed

[30] In 2003, EPA projected that four tile industry sources would be subject to major source standards. *See* Updated Inventory Database and Documentation for Clay Ceramics Proposed Rule at 1-2 (Nov. 6, 2014), EPA-HQ-OAR-2013-0290-0222, JA264-265. Since 2003, several tile industry sources have changed their status: one major source closed; three major sources became synthetic area sources; two area sources "briefly became major sources" before becoming synthetic area sources; and one new major source became a synthetic area source. *Id.* at 2-3, JA265-266. *See also* Final Rule: Economic Inputs for Clay Ceramics Manufacturing at 2-3 (Table 1) (Feb. 26, 2003), A-2000-48, IV-B-5, JA212-213 (showing costs of the rule for existing ceramic tile manufacturing facilities operated by TileCera (Florim USA), Dal-Tile, American Marazzi Tile, and Premark (Florida Tile)). The Brick/Clay rulemaking dockets incorporate the 2003 rulemaking dockets. 79 Fed. Reg. at 75,627/2; Brick Docket Incorporation by Reference (Oct. 21, 2014), EPA-HQ-OAR-2013-0291-0510, JA518; Clay Docket Incorporation by Reference (Oct. 21, 2014), EPA-HQ-OAR-2013-0290-0002, JA263.

categories, EPA must set standards for the tile industry. 80 Fed. Reg. at 65,508/3-09/3; Clay Rule Summary of Public Comments and Responses at 2-4 (Sept. 2015), EPA-HQ-OAR-2013-0290-0314 ("Clay Rule RTC"), JA386-388.

TCNA argues that because there are not currently any major sources in the tile industry that are subject to the standards, EPA's promulgation of the Clay Rule was unlawful. Industry Br. 39. In other words, TCNA interprets subsections 7412(c)(1), (c)(2), and (d) to *prohibit* EPA from setting standards for a listed source category unless major existing sources that will be subject to the standards remain in the listed category at the time of the standards' promulgation. *Id.* at 40. This interpretation is inconsistent with the statute's plain text.

The CAA clearly provides that EPA must promulgate standards for listed categories, 42 U.S.C. § 7412(c)(2), (e)(1), absent a decision to delist (*see* 42 U.S.C. § 7412(c)(9)). Further, it is at the *time of listing* that EPA's determination that there are major sources in the category is relevant. As explained *supra* in Section VIII.A, EPA is required to list categories of major sources, and it is the listing of a category that triggers EPA's obligation to set standards. The CAA does not require EPA to reevaluate its decision to list a category before issuing standards.[31] Indeed, this Court

[31] TCNA's argument that EPA interprets the statute to allow major source "regulations for every existing or imaginable industry, regardless of whether a major source had been or would ever exist in the industry," Industry Br. 42, is incorrect. Rather, EPA interprets the statute to only direct it to list categories of major sources when the categories contain major sources. *See* 57 Fed. Reg. at 31,579/3 (noting that

has considered unlawful EPA's removal of a source category from the list on any basis other than those provided in section 7412(c)(9), which does *not* authorize delisting on the basis of a finding that the source category no longer contains major sources. *New Jersey*, 517 F.3d at 582-83.

Nor is there any reason to doubt that EPA's statutory interpretation is consistent with congressional intent. Congress required EPA to set standards for both existing sources and new sources. *See* 42 U.S.C. § 7412(d). In requiring EPA to set standards for *new* major sources, Congress clearly contemplated that EPA could set standards that might never apply, as it is possible that no new major sources would be built in a source category.

Further, even if no major existing sources are subject to the major source standards when they are promulgated, those standards can still have environmental benefits. 80 Fed. Reg. at 65,508/3-09/3. First, major sources in a given category may choose to become synthetic area sources before major source standards go into effect, *see* Seitz Memo at 5-7, JA445-447, thus reducing those sources' emissions in advance of the reductions required by the standards. Second, having major source standards

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EPA only listed categories of major sources "where there was reasonable certainty that at least one stationary source in the category is a major source or where sources in the category are commonly located on the premises of major sources"). Further, TCNA does not, and cannot, contend that major sources never existed in the tile industry. *See, e.g.*, Updated Inventory Database and Documentation for Clay Ceramics Proposed Rule at 1-3 (Nov. 6, 2014), EPA-HQ-OAR-2013-0290-0222, JA264-266 (describing major tile industry sources); Astrachan Letter at 1, JA261 (stating that former major sources in the tile industry had become synthetic area sources).

in effect may deter natural area sources and synthetic area sources from increasing their emissions to avoid becoming subject to the major source standards. *See* Industry Br. Attachment B ¶¶ 5-7. In the absence of major source standards, area and synthetic area sources might have an incentive to increase emissions to become major sources. And, as EPA explained, this incentive is greater when sources are already subject to area source standards. 80 Fed. Reg. at 65,509/1. Further, if EPA were required to identify a source emitting at major source levels at the time of setting standards, as preferred by TCNA, then it is possible that sources emitting at major source levels could become synthetic area sources during the rulemaking process to head off the promulgation of major source standards. *See id.* Indeed, after EPA listed the clay ceramics manufacturing source category, and while EPA was in the process of setting these standards, the remaining major sources in the tile industry become synthetic area sources. *See* Astrachan Letter, JA260-262; Updated Inventory Database and Documentation for Clay Ceramics Proposed Rule at 2-3 (Nov. 6, 2014), EPA-HQ-OAR-2013-0290-0222, JA265-266 (showing changes in tile industry sources' status).[32] Under TCNA's interpretation, EPA would have to hold off on setting standards for the listed source category until it could again identify a source emitting

[32] Contrary to TCNA's assertion, the distinction between a major source and an area source is not as clear as it may at first seem. *See supra* Section IV.A.

at major source levels, at which point the source could become a synthetic area source and (again) foreclose EPA from setting standards.

In addition to creating a regulatory loophole that would prevent EPA from setting appropriate major source standards,[33] TCNA's interpretation would be incredibly inefficient, as EPA would possibly need to rework or abandon proposed standards every time sources changed their status. In short, even if there were any ambiguity in the statute (and there is not), EPA's statutory interpretation is reasonable, and should be upheld under *Chevron* step two.[34]

C. EPA complied with notice and comment procedures in issuing the standards.

TCNA argues that it "was never afforded the opportunity to comment" on EPA's position that listed sources must be regulated, and that it "had no reasonable notice of this position" from the proposal. Industry Br. 46. TCNA also argues that

[33] TCNA asserts that there is no such loophole because section 7412(j) applies to require case-by-case emission limits when section 7412(d) standards have been vacated, and cites a 2010 proposal to revise EPA's section 7412(j) rule as support. Industry Br. 41 n.6. However, case-by-case standards are intended to be a stopgap for the period of time before EPA promulgates standards for a source category, not a permanent substitute for source category standards. Further, the existence of section 7412(j) does not change EPA's duty to promulgate section 7412 standards for the clay ceramics category. *See Sierra Club*, 850 F. Supp. 2d. at 304.

[34] Additionally, because EPA did not act beyond the scope of the CAA, there is no legitimate constitutional challenge to EPA's actions. *See* Industry Br. 44 (arguing that EPA violated Article II).

EPA's position was not a logical extension of the proposal. *Id.* at 46-47. TCNA is wrong on all counts.

First, when EPA proposed standards in 2014, EPA specifically requested comment on whether it must set major source standards for the tile industry in light of the fact that all of the major sources had become synthetic area sources. 79 Fed. Reg. at 75,665/2-3. But EPA also noted that it was required to set standards for the listed clay ceramics manufacturing source category pursuant to section 7412(c), and that the D.C. District Court had already found EPA's mandatory duty to set standards for this listed source category remained in place after vacatur of the 2003 Rule. *Id.* at 75,627/1-2. Further, EPA's longstanding position, as reflected in its initial 1992 listing notice, is that the CAA requires EPA to set standards for listed sources. *See* 57 Fed. Reg. at 31,577/3. In any event, EPA made clear it was proposing to set standards for major sources in the tile industry, and TCNA had ample opportunity to comment on all aspects of whether such regulation was legally appropriate. *See* 79 Fed. Reg. at 75,657-58 (Tables 10, 11).

IX. TCNA cannot now challenge EPA's listing of the major source category, and its challenge is without merit.

A. TCNA's challenge to the listing is untimely.

TCNA challenges EPA's section 7412(c) listing of the major source category containing the tile industry. EPA agrees that section 7412(e)(4) prohibits legal challenges to EPA's decision to list categories of major sources prior to the issuance

of emission standards.[35] *See* Industry Br. 45. However, TCNA's challenge to the listing decision is untimely. As provided in section 7412(e)(4), the time to challenge the listing of a source category arises "when the Administrator issues emission standards for such . . . category." With respect to the clay ceramics category, that occurred in 2003, when EPA promulgated the initial Brick/Clay Rule. At that time, TCNA had 60 days to challenge the category's listing. 42 U.S.C. § 7607(b)(1). TCNA did not do so. Having waived its arguments concerning the validity of the listing decision after the standards were issued in 2003, TCNA cannot now assert them. The vacatur of the 2003 Rule did not change or affect the prior listing, and does not change TCNA's inability to raise this argument. Petitioners had an opportunity to challenge the listing and failed to pursue any timely challenge.

Further, it would be nonsensical to read Section 7412(e)(4) to allow litigants to reassert challenges to the listing decision every time emission standards are issued, reissued or revised for a category. Section 7412(e)(4) is more reasonably read to allow EPA to list categories of major sources of HAPs and begin the process of setting emission standards for those categories without interruption from protracted litigation. In short, Congress provided an opportunity to challenge listing decisions,

[35] Section 7412(e)(4) states that "no action of the Administrator . . . listing a source category or subcategory under subsection (c) of this section shall be a final agency action subject to judicial review, except that any such action may be reviewed under subsection 7607 of this title when the Administrator issues emission standards for such . . . category." 42 U.S.C. § 7412(e)(4).

even though it delayed judicial review of the listing of a category until after emission standards for that category were issued, but Congress limited the timeframe for challenges to EPA's actions. Therefore, the Court should dismiss TCNA's challenge to the listing decision as untimely, and need not reach the merits of this issue.

B. EPA's listing of the major source category was proper.

Even if TCNA's challenge to the listing were timely, it would fail on the merits. TCNA claims that the listing was not adequately supported, and was unlawfully finalized because EPA failed to provide notice and an opportunity to comment. Industry Br. 44-47. TCNA is wrong on both counts.

1. EPA adequately supported its basis for the listing.

TCNA argues that there must be a "citation in the relevant EPA docket to a major source" in the tile industry before EPA can promulgate section 7412(d) standards for the industry. Industry Br. 46. TCNA cites the initial 1992 listing notice and claims that the docket contains no citation to any sources in the ceramic tile manufacturing industry. *Id.* This argument misses the mark. EPA replaced the 1992 listing of the clay products manufacturing category with the listing of the clay ceramics manufacturing category in 2002, at the same time that it proposed setting standards for the listed category. Because the 2002 listing superseded the 1992 listing, any challenge TCNA would have to the listing would be to EPA's 2002 decision. *See* 67 Fed. Reg. at 47,896/2-3.

When EPA listed the clay ceramics manufacturing category in 2002, it had ample information to conclude that sources in that category, *including tile industry sources*, were major sources. *See supra* note 30; 67 Fed. Reg. at 47,913/3-14/1; Documentation of Database of Responses to the 1997 EPA Information Collection Request for Clay Ceramics Manufacturing at 306-09 (Table 11) (Dec. 6, 2001), A-2000-48; II-B-20, JA205-208 (showing four major sources in the tile industry). And the fact that there were major sources at the time of listing cannot be disputed. Further, prior to the promulgation of the 2003 Rule, EPA received no comments challenging the listing of the category based on the absence of major tile industry sources. *See generally* 2003 Clay Rule Summary of Public Comments and Responses (Feb. 2003), A-2000-48, IV-A-1 ("2003 Clay Rule RTC"), JA214.

Even if TCNA could challenge the initial 1992 listing, whether the docket for the initial list identifies any ceramic tile manufacturing sources has no effect on the validity of the listing, because the listed category at that time was clay products manufacturing.[36] EPA needed only to conclude that there were major sources in the category it listed, 42 U.S.C. § 7412(c)(1), and EPA did just that. *See* 57 Fed. Reg. at 31,591/3 (Table 1), 31,592/3 n.a. EPA's rationale for listing all categories, including clay products manufacturing, was based on "reasonable certainty that at least one

[36] TCNA is careful to describe its challenge to the listing based on a lack of material in the docket—rather than claiming that major sources in the tile industry did not exist at that time—presumably because it could not credibly assert that there were not major tile industry sources at the time.

stationary source in the category is a major source or where sources in the category are commonly located on the premises of major sources." *Id.* at 31,579/3. And EPA explicitly found that it had "information indicating that [the clay products manufacturing] source category contains a major source." Documentation for Developing the Initial Source Category List, Final Report at B-45 (July 1992), A-90-49, IV-A-55/V-B-1, JA928. Although the tile industry would later be described as part of the initially-listed clay products manufacturing category, *see supra* at 85-86, there is no requirement that at the time EPA listed the category, it had to identify major sources of every industry that might later be considered part of that initially-listed category. *See* 42 U.S.C. § 7412(c)(1) (requiring publication, and revision if appropriate, of a list of categories of major sources).[37] Therefore, EPA's 1992 listing of the clay products manufacturing category as a major source category pursuant to section 7412(c)(1) was valid.

[37] EPA explained that in proposing standards for each category, it planned to revise the list and better describe the industries in each category. 57 Fed. Reg. at 31,590/3-91/1. This approach ensured that as EPA accumulated information and developed proposed standards for a category, it could properly describe the sources within the listed category that would be subject to the standards. *See, e.g.*, 67 Fed. Reg. at 47,896/2-3, 47,898/3-99/2, 47,913/3-14/1 (replacing one initially-listed category with two categories and describing sources in those categories).

2. TCNA had ample opportunity to comment on the 2002 listing decision in the rulemaking for the 2003 Rule.

TCNA had notice and an opportunity to comment on the listing in 2002, when EPA proposed standards for the clay ceramics manufacturing category.[38] 67 Fed. Reg. at 47,896/2-3. Providing notice of and opportunity to comment on the listing at the time standards are proposed is consistent with section 7412(e)(4), which provides that the window for judicial review commences when EPA issues emission standards. 42 U.S.C. § 7412(e)(4). This approach is also pragmatic: it allows EPA to better describe the sources within the listed category that will be subject to the standards; and until standards are developed, listing of a category has no actual effect on its sources. *See supra* note 37. In the 2002 proposal preamble, EPA explained that it was replacing the clay products source category with two categories, including the clay ceramics manufacturing category. 67 Fed. Reg. at 47,896/2-3. EPA requested comment on the listing and the sources covered by the listing. *Id.* at 47,896/3. After publication of the 2002 proposal, TCNA could not credibly claim that its members had no notice of the listing and no opportunity to comment on it. In fact, tile companies commented that EPA "should delist ceramic tile roller kilns from the final [standards]." Comments on Proposed Rule Submitted for American Marazzi Tile and Monarch Ceramic Tile at 32 (Comment 4) (Sept. 19, 2002), A-2000-48, IV-D-07,

[38] Although TCNA asserts these claims under the APA, these claims can only be considered, if at all, under CAA section 7607. *See* 42 U.S.C. § 7607(d)(1).

JA209; 2003 Clay Rule RTC at 2-38, JA214. Therefore EPA has satisfied any notice and comment requirements for the listing.

X. EPA reasonably set the dioxin/furan standards and adequately responded to public comment.

In the Clay Rule, EPA issued numeric dioxin/furan MACT emission limits for all new and existing ceramic tile roller kilns, sanitaryware tunnel kilns, floor tile press dryers, and ceramic tile spray dryers. 80 Fed. Reg. at 65,478/3, Table 5. TCNA argues that the dioxin/furan standards are not based on "emissions information" because EPA requested that sources use a flawed test method to report emissions. Industry Br. 48-50. Additionally, TCNA argues that EPA did not comply with notice and comment procedures and that the standards were not a logical outgrowth of the proposal. *Id.* at 51. These arguments lack merit. EPA provided sufficient support for the test method. Additionally, TCNA had ample opportunity to comment on the use of the test method, and EPA responded to TCNA's comments.

A. EPA reasonably determined that Method 23 provided emissions information that could be used in determining MACT floors for ceramic tile sources.

Because each tile industry subcategory contained less than 30 sources, EPA determined the MACT floors based on the lowest-emitting 5 sources for which EPA had emissions information. *See* 42 U.S.C. § 7412(d)(3)(B). In gathering information

for the standards, EPA requested that sources use EPA Test Method 23[39] to report dioxin/furan emissions. *See, e.g.*, 2010 Section 114 Information Collection Request to Dal-Tile Corp., Enclosure 3 at 1-3 (Table 1.1) (Mar. 9, 2010), EPA-HQ-OAR-2013-0290-0023, JA218-220. EPA used the information submitted in response to determine the dioxin/furan MACT floors for the tile industry. *See* Clay MACT Floor Memo at 2, 8-12, JA336, 342-346.

TCNA argues that Method 23 is outdated and does not account for naturally-occurring non-gaseous forms of dioxin/furan contained in raw materials used by the tile industry. Industry Br. 49. For this reason, TCNA argues that Method 23 erroneously reports non-gaseous dioxin/furan as emissions, and therefore the data produced by Method 23 are not "emissions information." TCNA asserts that EPA ignored this problem and unlawfully relied on the Method 23 data. *Id.* These arguments fail.[40]

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[39] Method 23 is a specific sampling method used to determine emissions of dioxin and furan. Determination of Polychlorinated Dibenzo-p-Dioxins and Polychlorinated Dibenzofurans from Stationary Sources, 40 C.F.R. pt. 60, App'x A-7.

[40] TCNA also challenges the dioxin/furan emission standards because they control for a "miniscule volume" of dioxin/furan. Industry Br. 50. But because EPA set the standards at MACT floor levels, EPA could not have made those standards less stringent. *See Nat'l Lime*, 233 F.3d at 640 (holding that the CAA "does not provide for exceptions from emissions standards based on *de minimis* principles where a MACT floor exists") (internal quotation marks omitted).

The CAA requires that EPA base the MACT floors on "emissions information," and as TCNA admits, this phrase is not defined in the statute. *See* Industry Br. 48; 42 U.S.C. § 7412(d)(3). Here, EPA reasonably considered the results of Method 23 tests to provide "emissions information." *See* Clay Rule RTC at 12-19, JA390-397 (explaining Method 23's validity and appropriateness in generating emissions information on dioxin/furan for ceramic tile sources).[41] EPA reviewed the data submitted by the tile industry and determined that "the recovery of labeled dioxin and furan congeners met method requirements" and that the samples generated valid data. Clay Rule RTC at 12, JA390. And although implementation of Method 23 varied, EPA found that the quality control inherent in the method supported the validity and accuracy of the results. *Id.* at 12, 16, 18, JA390, 394, 396. For several categories with sources similar to those in the tile industry, EPA had found that Method 23 produced "valid data for particle bound and gaseous chlorinated dioxin." *Id.* at 16. Furthermore, the fact that EPA is working to revise Method 23, Industry Br. 49-50, does not invalidate the data collected using the method. *See* Clay Rule RTC at 15, JA393. EPA specifically determined that the method produced useful emissions information for ceramic tile sources, and TCNA "failed to demonstrate that EPA's [method] 'bears no rational relationship to the reality it purports to represent.'" *Cement*

[41] Contrary to TCNA's assertion, Industry Br. 48, EPA is not required to make an explicit finding in the rulemaking docket that test data or other sources of information EPA considers are "emissions information."

Kiln, 255 F.3d at 867 (quoting *Columbia Falls Aluminum Co. v. EPA*, 139 F.3d 914, 923 (D.C. Cir. 1998)). EPA's decision to use Method 23 data to determine the MACT floors was within the agency's area of expertise and is entitled to deference. *See Cement Kiln*, 255 F.3d at 867 (noting that the Court will "defer to an agency's decision to proceed on the basis of imperfect scientific information, rather than to invest resources to conduct the perfect study," and finding reasonable EPA's interpretation that "emissions information" in section 7412(d)(3) included compliance data gathered under another statute (quoting *Sierra Club*, 167 F.3d at 662) (internal quotation marks omitted)).

B. EPA provided notice and adequately responded to comments regarding the dioxin/furan standards.

EPA provided sufficient opportunity for TCNA to comment on EPA's use of Method 23, and EPA was not required to describe in the proposal its *justification* for using Method 23. *See* 42 U.S.C. § 7607(d)(3) (requiring a statement of the basis and purpose of a proposed rule, including a summary of the factual data and methodology used). Indeed, as demonstrated by its comments, TCNA had the opportunity to comment on the use of the method, including its concern that the method was unjustified. As required, EPA responded to those comments and provided justification for using Method 23. Clay Rule RTC at 11-19, JA389-397.

Further, EPA considered and rejected TCNA's arguments against using Method 23. EPA explained that "the quality control inherent in the method provides

adequate support for the validity and accuracy of the emission results." Clay Rule RTC at 12, JA390. In responding to TCNA's concern that Method 23 does not account for non-gaseous forms of dioxin/furan contained in raw materials, EPA explained that it had no basis to conclude (and TCNA did not provide any) that TCNA's concern was warranted. *Id.* Method 23 had been successfully implemented to measure dioxin/furan from other source categories, and EPA noted that the same requirements for evaluating the validity of the data still applied. *Id.* at 12, 16, JA390, 394. EPA reviewed the Method 23 data submitted by tile industry sources and found they "met method requirements" and "generated valid data on emission concentration." *Id.* at 12, JA390; *see id.* at 16-18, JA394-396 (describing validation methodology for data collected from tile industry sources).

In characterizing EPA's response to TCNA's comments in the preamble as "a six-sentence non-responsive brush-off," Industry Br. 51, TCNA overlooks (1) EPA's more thorough responses to TCNA's comments in its response-to-comments document, *see* Clay Rule RTC at 12-19, JA390-397; and (2) the fact that the cited statements in the preamble, 80 Fed. Reg. at 65,511/1, *are actually in response to different comments*. *See* 80 Fed. Reg. at 65,471/1 (noting availability of EPA's responses to comments in a separate document in the docket). And with respect to TCNA's argument that EPA's final rule was not a logical outgrowth of the proposal, *see* Industry Br. 51, EPA did not change its position: EPA proposed to and did use Method 23. Thus, the question of logical outgrowth does not even arise here.

XI. EPA's decision not to set standards for periods of malfunction is reasonable and entitled to deference.

TCNA argues that EPA arbitrarily and capriciously failed to set standards for periods of malfunction. Industry Br. 52. Because EPA did not use emissions data from periods of malfunction in setting standards, TCNA argues that EPA unlawfully set standards that EPA knew the regulated community had not and could not achieve. *Id.* at 53. TCNA is wrong and ignores clear precedent that is contrary to its position.

This Court recently recognized that because the best-controlled similar source is unlikely to be a malfunctioning source, the CAA, if anything, "prevents [ ] EPA from taking into account the effect of potential malfunctions when setting MACT emission standards" and "[a]t the very least" "permits [ ] EPA to ignore malfunctions in its standard-setting and account for them instead through its regulatory discretion." *U.S. Sugar*, 830 F.3d at 608; *see* 42 U.S.C. § 7412(d)(2), (d)(3). TCNA seeks to distinguish the standards at issue here from the boiler standards at issue in *U.S. Sugar* by arguing that, in this case, the docket contained information from a single facility during some malfunction events. Industry Br. 52. TCNA cites data from times when emission control devices were shut down, resulting in higher than normal emission levels. *See* Dal Italia Responses to EPA 2010 Information Collection Request Startup and Shutdown Events (Sept. 22, 2010), EPA-HQ-OAR-2013-0290-0028, Enclosure 1 ("Dal Italia Responses"), JA238-241. Although some portions of the data were from malfunctions of control devices, EPA reasonably did not use those data to set

standards. EPA's rationale here is essentially the same as the rationale upheld in *U.S. Sugar*. *Compare* 830 F.3d at 606-09 (noting that EPA based its position on "the impracticality of accounting for events that are necessarily unpredictable" and that EPA explained that it would use its enforcement discretion to determine when emission exceedances were excusable) *with* 80 Fed. Reg. at 65,482/3-83/2 (explaining the impracticability of accounting for malfunctions in setting standards and asserting EPA would use its enforcement discretion). As this Court has acknowledged, "[w]hile the existence of malfunctions is entirely predictable, the nature of those malfunctions is not, and it is the malfunction's nature that affects emissions and thus is relevant to the application of emission limits." *U.S. Sugar*, 830 F.3d at 607. And the Court upheld EPA's decision not to set alternative standards to cover malfunctions because the decision to set those standards is purely within EPA's discretion and any such standard applicable to malfunctions "is likely to be hopelessly generic to govern such a wide array of circumstances." *Id.* at 608. Here as well, EPA reasonably declined to consider malfunction data in setting the standards. *See* 80 Fed. Reg. at 65,482/3 (explaining that "accounting for malfunctions in setting emission standards would be difficult, if not impossible"). Further, EPA adequately explained why it did not rely on malfunction data. *Id.* at 65,482/3-83/2; Clay Rule RTC at 73-74, JA406-407.[42]

[42] EPA disagrees with TCNA's assertion that it "knows from data in the docket that the regulated community has not and cannot achieve [the] standards." Industry Br. 53. Because malfunctions are unpredictable, there is no way of knowing when they

TCNA also argues that EPA should have identified legal defenses in the regulations. Industry Br. 54. To the extent TCNA seeks to have EPA write affirmative defenses into the regulations to protect sources that exceed standards due to malfunctions, this Court's past decisions clearly bar EPA from doing so. *NRDC v. EPA*, 749 F.3d at 1057; *U.S. Sugar*, 830 F.3d at 607. And, to the extent TCNA seeks to have EPA simply list defenses without adopting them or otherwise changing their availability, doing so would neither affect a defense's availability nor change a court's role to determine what, if any, defenses are properly considered in determining penalties. *NRDC v. EPA*, 749 F.3d at 1063. In any event, EPA's statement that a source "can raise any and all defenses," 80 Fed. Reg. at 65,483/2, simply states the law, and does not require or empower EPA to specify what defenses could possibly be asserted.

XII. The mercury and dioxin/furan standards for ceramic tile sources do not require the use of activated carbon injection controls.

TCNA's argument that the mercury and dioxin/furan standards for ceramic tile kilns, spray dryers, and tile dryers unlawfully require installation of activated carbon injection controls is based on numerous flawed premises. *See* Industry Br. 55-56. First, TCNA incorrectly suggests that the standards require use of a particular control technology. Similar to the brick standards discussed *supra* in Section VI, EPA set the

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will occur or what their effect on emissions will be. EPA therefore reasonably set the standards based on emissions information demonstrating what sources have achieved. *See U.S. Sugar*, 830 F.3d at 608.

standards for the tile industry in the form of numeric emission limits, at the MACT floor levels. *See* 80 Fed. Reg. at 65,478/2-3, Table 5. Such standards do not require the use of any particular control technology, but instead allow for flexibility in the method sources use to comply. Clay Rule RTC at 104, 105, JA409, 410 (noting that "[i]ndustry may use whatever means and methods they deem necessary to achieve compliance with the emission limits"). And because the standards were set at the MACT floor level, they are based on emissions from the best-performing sources. *See id.* at 103, JA408. The cost of using controls was not (nor could it have been) a consideration in determining the MACT floor. *Id.*; 42 U.S.C. § 7412(d); *NRDC v. EPA*, 489 F.3d 1364, 1376 (D.C. Cir. 2007) ("[C]ost is not a factor that EPA may permissibly consider in setting a MACT floor.").

Second, contrary to TCNA's assertions, EPA was not required to conduct a beyond-the-floor analysis to prove that activated carbon injection controls would be effective for tile industry sources. *See NRDC v. EPA*, 489 F.3d at 1376 ("[The petitioner] relies on an incorrect premise that the MACT level of emissions reduction is invalid if it is based on control technology that a source cannot install."). Although in response to comments, EPA explained that activated carbon injection controls would be appropriate for controlling mercury and dioxin/furan emissions for sources in the tile industry, Clay Rule RTC at 104, JA409, this was not a consideration in setting the standards and therefore would not be a valid basis for vacating the

standards even if EPA had failed to support its reasoning.[43] *See* 42 U.S.C. § 7412(d); *NRDC v. EPA*, 489 F.3d at 1376.

Finally, TCNA's argument that the cost of using activated carbon injection controls would be unconscionable, *see* Industry Br. 56, fails to present a legitimate legal attack on the standards. Because EPA set the standards at the MACT floor level, EPA was prohibited from setting less stringent standards based on costs. *NRDC v. EPA*, 489 F.3d at 1375-76.[44] Instead, the standards must be based on emission levels actually achieved in the source category. TCNA's challenge to the mercury and dioxin/furan emission standards for ceramic tile sources should therefore be rejected.

XIII. EPA set the standards for sanitaryware sources in compliance with the CAA.

To obtain information for determining the MACT floor for sanitaryware sources, EPA sent information collection requests to manufactures of sanitaryware.

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[43] Contrary to TCNA's assertions, EPA *did* conduct a beyond-the-floor analysis and concluded that, for tile industry sources, "the incremental costs of additional control above the MACT floor emission limits are not reasonable relative to the level of emission reduction achieved." 79 Fed. Reg. at 75,659/3. Based on this finding, EPA proposed setting standards at the MACT floor levels. *Id.*

[44] It is only where EPA sets a more stringent "beyond-the-floor" standard that it has to justify the more stringent standards by considering control types, costs, and other factors. 42 U.S.C. § 7412(d)(2); *NRDC v. EPA*, 749 F.3d at 1057. *See also White Stallion*, 748 F.3d at 1238-39 (noting that costs are reflected in MACT floor standards to the extent that MACT floors are determined based on what is already achieved by sources, which presumably reflects what is cost-effective).

See 80 Fed. Reg. at 65,510/1-2. One source from which EPA requested emissions information had installed controls to comply with the new source MACT standards from the 2003 Rule. *See id.* at 65,510/1. That source, "Kiln 10," had stopped running the controls in 2009, after its state operating permit was modified to reflect the vacatur of the 2003 Rule. Industry Br. 57-58; *see* 80 Fed. Reg. at 65,510/1. However, the controls remained functional and attached to the source. *See* Industry Br. 58; 80 Fed. Reg. at 65,510/1-2. When EPA requested information from Kiln 10, it requested that information be gathered while the controls were operating. *See* 80 Fed. Reg. at 65,510/1-2.

Kohler argues that EPA should have based its MACT floor calculations on data from when Kiln 10 was operating *without* its controls. Industry Br. 56-63. Kohler contends that the Kiln 10 data were not representative of any existing source operating at the time when EPA determined the MACT floors, and that the MACT floors for sanitaryware are improperly based on emissions data originating from a vacated standard, rather than on the actual performance of the best-performing sources. *Id.* Additionally, Kohler argues that the standards are inconsistent with EPA's stated objective that emission standards should reflect real-world performance. *Id.* at 62. These arguments are wrong.

A. EPA set the MACT floors as required by the CAA, based on what has been achieved.

Kohler argues that EPA violated the CAA requirement that MACT floors be based on the actual performance of the best-performing sources by artificially creating a better-performing source. Industry Br. 58. EPA did nothing of the sort.

The CAA requires EPA to set the MACT floors based on the "average emission limitation achieved by the best performing 5 sources" for which EPA has emissions information or could reasonably obtain emissions information. 42 U.S.C. § 7412(d)(3)(B). The CAA does not set a time limit for when the emissions information that EPA uses in setting the MACT floor is collected, nor does it specify criteria for what emissions information may be used to show what has been achieved; it simply requires that the emissions limitation has been "achieved." *See id.* Kohler provided data to EPA demonstrating emission levels Kiln 10 actually achieved with controls. 80 Fed. Reg. at 65,510/1-2.[45] Although Kiln 10 does not currently operate the controls, that does not change the fact that it had "achieved" emission reductions with the controls. 42 U.S.C. § 7412(d)(3). And the data provided to EPA were not hypothetical speculation on what Kiln 10 could potentially achieve. Rather, it was real-world emissions information that was produced from the actual operation of Kiln

[45] Kiln 10 not only provided data showing levels it had achieved during testing, it had operated for several years with controls. *See* 80 Fed. Reg. at 65,510/1. In fact, Kiln 10 was operating its controls in the year preceding EPA's request for emissions information. *Id.*

10. *See* 80 Fed. Reg. at 65,510/2. Because information from Kiln 10 demonstrated emission levels actually achieved by the source, EPA permissibly relied on it in determining the MACT floors.[46]

B. EPA was not required to omit emissions data because a source achieved emission reductions to comply with a vacated standard.

Kohler argues that because Kiln 10's controls were installed to comply with a standard that was subsequently vacated, EPA should be prohibited from using Kiln 10's emissions information. Industry Br. 56-60. But vacatur of the 2003 Rule does not affect the appropriateness of EPA's use of the Kiln 10 data. Although the vacatur invalidated the obligation to comply with the 2003 standards, it did not erase the ability of the source to demonstrate emission reductions that were actually achieved in practice. This Court has ruled that EPA acted lawfully in setting MACT floors using data collected from sources complying with a remanded standard. *Med. Waste Inst.*, 645 F.3d at 426. The Court explained that it was "not persuaded that remand without vacatur as opposed to vacatur has the outcome-changing significance that petitioners ascribe to it." *Id.* The same principle applies where, as here, a standard has been vacated. EPA had no reason to doubt that the data from Kiln 10 demonstrated anything other than emission reductions that the source had actually achieved. *See* 80 Fed. Reg. at 65,510/2. Having determined that the data provided "emissions

[46] As explained in the preamble, the only sanitaryware standard affected by the data from Kiln 10 is the existing source dioxin/furan MACT floor. 80 Fed. Reg. at 65,510/2-3.

information," EPA reasonably included the data in the MACT floor calculations. Accordingly, this Court should uphold the sanitaryware standards.

CONCLUSION

The petitions for review should be denied.

Respectfully submitted,

Assistant Attorney General

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CERTIFICATE OF COMPLIANCE WITH WORD LIMITATION

Pursuant to Federal Rule of Appellate Procedure 32(a)(7)(C), I hereby certify that this brief contains **27,902 words** as counted by the Microsoft Office Word 2013 word processing system, and thus complies with the applicable word limitation.

s/ Kate R. Bowers
KATE R. BOWERS

CERTIFICATE OF SERVICE

I hereby certify that on April 28, 2017, I electronically filed the foregoing brief with the Clerk of the Court for the United States Court of Appeals for the District of Columbia Circuit by using the appellate CM/ECF system.

The participants in the case are registered CM/ECF users and service will be accomplished by the appellate CM/ECF system.

s/ Kate R. Bowers
KATE R. BOWERS

February 13, 2024

Comments from Scientists, Academics, and Clinicians on the Tris(2-chloroethyl) Phosphate (TCEP) Draft Risk Evaluation Under TSCA

Submitted online via Regulations.gov to docket EPA-HQ-OPPT-2023-0265-0005

These comments are submitted on behalf of the undersigned scientists, academics, and clinicians. We declare that we have no direct or indirect financial or fiduciary interests in the subjects of these comments. The co-signers' institutional affiliations are included for identification purposes only and do imply institutional endorsement or support. We appreciate the opportunity to provide written comments on EPA's *Draft Risk Evaluation for Tris(2-chloroethyl) Phosphate (TCEP)* (hereafter referred to as the *TCEP Draft Risk Evaluation*) conducted under the Toxic Substances Control Act (TSCA),[1] which requires EPA to evaluate chemical risks based on the "best available science."[2] TCEP is a flame retardant chemical that is also used as a plasticizer and in paints and coatings.

EPA appropriately determined that TCEP as a whole chemical presents unreasonable risk to human health and the environment based on high risks of cancer (including some exposures exceeding 1-in-1,000 cancer risk) and non-cancer effects to workers, consumers and the general population from multiple TCEP conditions of use. However, the TCEP Draft Risk Evaluation also failed to evaluate risks for several conditions of use and relied on scientific methods and assessments that are not consistent with the "best available science,"[3] which can lead to underestimating risk to human and environmental health.

EPA continued to rely on a systematic review methodology that is not consistent with best practices, violating TSCA's "best available science" requirement. The National Academies of Sciences, Engineering, and Medicine ("NASEM") recommended the use of existing systematic review methods and improved approaches for TSCA risk evaluations in 2021, and EPA has still not implemented most of these recommendations.[4] EPA's Science Advisory Committee on Chemicals ("SACC") has also recommended best practices in systematic review to the Agency in multiple reports.[5] EPA should prepare a new TSCA systematic review methodology that is aligned with the best available scientific methods and issue updated draft systematic review protocols for all risk evaluations currently in development, including TCEP.

The TCEP Draft Risk Evaluation also relied on a hazard assessment that violates TSCA's "best available science" requirement. While EPA found that neurotoxicity, reproductive toxicity, developmental toxicity, kidney toxicity and cancer are all likely hazards of TCEP, it failed to

[1] U.S. EPA (2023). Draft Risk Evaluation for Tris(2-chloroethyl) Phosphate (TCEP).
[2] 15 USC §2625 (h).
[3] *Id.*
[4] National Academies of Sciences, Engineering, and Medicine (2021). The Use of Systematic Review in EPA's Toxic Substances Control Act Risk Evaluations.
[5] U.S. EPA (2022). Science Advisory Committee on Chemicals Meeting Minutes and Final Report No. 2022-2, p. 71. https://www.regulations.gov/document/EPA-HQ-OPPT-2021-0414-0044.

provide quantitative estimates of non-cancer risk. We applied methods developed by the World Health Organization ("WHO") to quantify the non-cancer risk of male reproductive harm from chronic oral TCEP exposure, and found that EPA's current approach results in acceptance of exposures producing an upper bound risk of 1-in-40, a risk level 25,000 times higher than the target range that EPA typically applies for protection of carcinogenic risks (1-in-1,000,000). EPA also inappropriately stated that a threshold exists for cancer risk, and did not appropriately use science-based adjustment factors.

EPA also failed to adequately identify and calculate risks posed to potentially exposed or susceptible subpopulations ("PESS"), as required under TSCA.[6] Among the populations exposed to high risks from TCEP are breast-fed infants and people who consume fish (fishers in the general population, subsistence fishers and tribal populations), but EPA failed to consider individuals with pre-existing disease, genetic factors, lifestyle factors, or exposures to other chemical and non-chemical stressors that may increase susceptibility to harm from TCEP exposure. A failure to evaluate risk to these groups violates TSCA and results in risk characterization that is not representative of the human population.

EPA also failed to estimate risks for some TCEP conditions of use (for example, cushions in commercial furniture, consumer paints), claiming that it lacked sufficient data and that most of these uses have been discontinued EPA is obligated under TSCA to estimate risks for all conditions of use that are "reasonably foreseen."[7] Since any use that is voluntarily discontinued could resume, they should be considered "reasonably foreseen" and EPA should include risk estimates for these uses in the final TCEP risk evaluation. TSCA also requires EPA to consider "reasonably available information" when conducting risk evaluations,[8] which includes data and information that EPA "can reasonably generate, obtain, and synthesize for use in risk evaluations."[9] EPA failed to use its authority under TSCA to fill critical data gaps that could result in a more complete assessment of conditions of use. EPA also failed to use its authority to list TCEP to the Toxics Release Inventory ("TRI") in time to generate chemical release data to inform exposure assessments in the TCEP Draft Risk Evaluation, which precluded its ability to adequately assess fenceline community exposures and risks.

Finally, the TCEP Draft Risk Evaluation is the first EPA has released since it completed the initial 10 risk evaluations conducted under the amended TSCA in January 2021, and the first to not undergo panel peer review by EPA's SACC. EPA relied on the SACC to conduct panel peer reviews of the first 10 risk evaluations as well as EPA's proposed methods for fenceline assessment and systematic review to be used in the forthcoming risk evaluations, and provided EPA with numerous critical recommendations for improvement. For the TCEP Draft Risk Evaluation, EPA has chosen to conduct a letter peer review, which precludes collaboration and consensus among reviewers and transparency and public participation in the review process, all of which are critical to maintaining scientific integrity and addressing potential financial conflicts of interest among reviewers. SACC panel peer review would also enable the examination of cross-cutting issues that arise in multiple evaluations and the extent to which EPA has addressed previous SACC recommendations, including those made to improve the fenceline

[6] 15 U.S.C. §§ 2602(12).
[7] 15 USC §2602 (4).
[8] 15 U.S.C. § 2625(k).
[9] 40 C.F.R. § 702.33 (defining "reasonably available information").

screening methodology. We therefore urge EPA to conduct a SACC panel peer review for the TCEP Draft Risk Evaluation and all TSCA risk evaluations that are currently in development

Our detailed comments on the TCEP Draft Risk Evaluation address the following issues:

1. **EPA has made some improvements in its approach to systematic review in the TCEP Draft Risk Evaluation, but additional critical improvements are required.**
   a. **EPA has taken an important step by not using quantitative scoring for study quality evaluation. This should be made explicit in future systematic reviews and in an updated TSCA systematic review handbook.**
   b. **EPA has retained other problematic aspects of its approach to study quality evaluation that are inconsistent with best practices in systematic review.**
   c. **Publication of a chemical-specific systematic review protocol is a critical improvement, but further steps are required for consistency with best practices.**
      i. **A chemical-specific protocol has been prepared, but it was not released in advance of the risk evaluation.**
      ii. **The TCEP systematic review protocol is incomplete.**
      iii. **EPA references inconsistent PECO statements to identify relevant health effects studies that may inappropriately exclude non-apical effects such as cellular-level outcomes.**
      iv. **The TCEP protocol continues to use unclear terminology regarding evidence synthesis and integration.**
      v. **EPA should prepare a new TSCA systematic review methodology that is aligned with the best available scientific methods and issue updated draft systematic review protocols for all risk evaluations currently in development, including TCEP.**

2. **EPA should apply best available scientific methods to improve the TCEP hazard and risk assessment.**
   a. **EPA should apply existing methods to generate quantitative estimates of non-cancer risks from TCEP exposures.**
   b. **EPA's statements regarding a threshold for cancer are not scientifically supported and must be removed.**
   c. **EPA failed to apply an adjustment factor for the subchronic duration of the animal study used for estimating risk of male reproductive effects. This along with other appropriate factors needs to be added into the assessment.**

3. **EPA has not appropriately identified potentially exposed or susceptible subpopulations (PESS), as required by TSCA.**

We appreciate the opportunity to provide public input. Please do not hesitate to contact us with any questions regarding these comments.

Sincerely,

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Detailed comments:

1. **EPA has made some improvements in its approach to systematic review in the TCEP Draft Risk Evaluation, but additional critical improvements are required.**

    a. **EPA has taken an important step by not using quantitative scoring for study quality evaluation. This should be made explicit in future systematic reviews and in an updated TSCA systematic review handbook.**

We support EPA's decision to discard the quantitative scoring method, which was previously used in TSCA systematic reviews and methodology documents to assess study quality and exclude some studies from consideration based on their quantitative scores, despite repeated criticism from peer reviewers and public commenters. EPA originally put forward its approach to systematic review under TSCA in 2018.[10] In its review of the 2018 TSCA systematic review method, the National Academies of Sciences, Engineering, and Medicine ("NASEM") said:

> The reliance on numeric quality scores is problematic because scores do not distinguish between high- and low-quality studies, and the relationship between quality scores and an association or effect is inconsistent and unpredictable…More generally, the use of numerical scoring in critical appraisal does not follow standards for the conduct of systematic reviews.[11]
>
> Do not use numeric scores to evaluate studies.[12]

In 2021, EPA released its *Draft Toxic Substances Control Act (TSCA) Systematic Review Protocol* (hereafter referred to as the *2021 Draft TSCA Method*), asserting that this document addressed the NASEM recommendations. However, the 2021 draft retained a quantitative study scoring method. The review of the 2021 Draft TSCA Method by EPA's Science Advisory Committee on Chemicals ("SACC") reiterated the earlier NASEM recommendation:

> EPA should follow NASEM recommendations and best practices of systematic review by removing its approach to determine an overall quality score based on the combination of quantitative ratings of each individual data quality evaluation metric, which is essentially a quantitative scoring approach.[13]

Since completion of the SACC review of the 2021 method, EPA has not issued an updated systematic review methodology. The TCEP Draft Risk Evaluation and its systematic review protocol provide the first indication of how EPA will proceed in conducting TSCA systematic review. According to the risk evaluation and the protocol, EPA has now taken an important step by discarding the previous quantitative study scoring approach:

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[10] U.S. EPA (2018). Application of systematic review in TSCA risk evaluations.
[11] National Academies of Sciences, Engineering, and Medicine (2021). The Use of Systematic Review in EPA's Toxic Substances Control Act Risk Evaluations, p. 39.
[12] National Academies of Sciences, Engineering, and Medicine (2021). The Use of Systematic Review in EPA's Toxic Substances Control Act Risk Evaluations, p. 40.
[13] U.S. EPA (2022). Science Advisory Committee on Chemicals Meeting Minutes and Final Report No. 2022-2, p. 71. https://www.regulations.gov/document/EPA-HQ-OPPT-2021-0414-0044.

> EPA has updated the data quality evaluation process and will not implement quantitative methodologies to determine both metric and overall data or information source data quality determinations.[14]
>
> To respond to both SACC and public comments regarding the inappropriate use of quantitative methodologies to calculate both "Metric Rankings" and "Overall Study Rankings," *EPA decided to not implement quantitative methodologies to attain either metric and overall data/information source quality determinations.*[15] (emphasis in original)

EPA has instead rated each study quality evaluation metric using only the qualitative terms "high," "medium," "low," and "critically deficient." This is an important improvement to EPA's TSCA systematic review methodology and should be incorporated into an updated TSCA systematic review methodology handbook and applied in all future TSCA risk evaluations.

b. EPA has retained other problematic aspects of its approach to study quality evaluation that are inconsistent with best practices in systematic review.

The TCEP Draft Risk Evaluation retains certain study quality evaluation metrics that are not consistent with best practices, violating TSCA's requirement for EPA to rely on the "best available science"[16] when conducting risk evaluations and make decisions based on the "weight of the scientific evidence."[17] EPA's approach to study quality evaluation typically applies a set of metrics that assessors must evaluate for each relevant study during systematic review. The TCEP systematic review protocol states that the study quality metrics in the *2021 Draft TSCA Method* were retained for the TCEP risk evaluation without revision (with the exception of minor edits to one toxicology metric).[18] In applying the 2021 metrics, EPA inappropriately applied metrics to evaluate study quality based on statistical power and statistical significance, disregarding recommendations by the NASEM. In *The Use of Systematic Review in EPA's Toxic Substances Control Act Risk Evaluations,* the NASEM stated that:

> Many markers of a high-quality study (e.g., whether a study's investigator has performed a sample size calculation and whether the study is reported adequately or has received appropriate ethical approvals) are unlikely to have any direct implication for the potential for a study to be affected by bias.[19]
>
> **Statistical power and statistical significance are not markers of risk of bias or quality**. **Statistical significance is not a measure of association or strength of association and should not be used to evaluate studies**. In fact, combining multiple

[14] U.S. EPA (2023). Draft Risk Evaluation for Tris(2-chloroethyl) Phosphate (TCEP), p. 34.
[15] U.S. EPA (2023). Draft Risk Evaluation for Tris(2-chloroethyl) Phosphate (TCEP) Supplemental File: Systematic Review Protocol for the Draft Risk Evaluation for Tris(2-chloroethyl) Phosphate (TCEP), p. 6.
[16] 15 U.S.C §2625 (h).
[17] 15 U.S.C §2625(i),
[18] U.S. EPA (2023). Draft Risk Evaluation for Tris(2-chloroethyl) Phosphate (TCEP) Supplemental File: Systematic Review Protocol for the Draft Risk Evaluation for Tris(2-chloroethyl) Phosphate (TCEP), p. 51. There are 22 metrics for evaluating epidemiology studies and 24 metrics for evaluation toxicology studies.
[19] National Academies of Sciences, Engineering, and Medicine (2021). The Use of Systematic Review in EPA's Toxic Substances Control Act Risk Evaluations, p. 35.

small, low-powered but similar studies in a synthesis is one of the potential benefits of systematic review.[20] (emphasis added)

Despite these very explicit NASEM statements about the inappropriateness of these metrics being included in the study quality evaluations; EPA continues to use "Statistical power (sensitivity)" as a study quality metric.[21] EPA must discontinue the use of these metrics in the TCEP Draft Risk Evaluation systematic review and for all risk evaluations that are currently in development.

c. Publication of a chemical-specific systematic review protocol is a critical improvement, but further steps are required for consistency with best practices.

i. A chemical-specific protocol has been prepared, but it was not released in advance of the TCEP Draft Risk Evaluation.

Along with TCEP Draft Risk Evaluation, EPA released a *Systematic Review Protocol for the Draft Risk Evaluation for Tris(2-chloroethyl) Phosphate (TCEP)* as a supplemental file. This is the first time EPA has released a chemical-specific systematic review protocol for a TSCA systematic review, which is consistent with best available scientific methods in systematic review and responds to recommendation of the NASEM and the SACC.

However, for future TSCA risk evaluations, EPA must publish a chemical-specific systematic review protocol for public comment first in the process of conducting each risk evaluation (well in advance of completing the draft risk evaluation), which is also consistent with best practices for systematic review.[22,23] EPA's TSCA program should follow the established procedures of EPA's IRIS program, which makes a draft protocol for each assessment publicly available in advance of its release for public comment. Following the public comment process, the IRIS program then publishes an updated protocol, as needed. For example, for the IRIS assessments of five per- and polyfluoroalkyl substances ("PFAS"), a draft protocol was made available for public comment for 45 days. The IRIS program then followed up with a revised protocol to address public comments, with documentation of the changes, that was published before the release of the PFAS draft assessments.[24] EPA should be following this same approach for all TSCA risk evaluations.

ii. The TCEP systematic review protocol is incomplete.

The application of systematic review in the TCEP Draft Risk Evaluation includes elements that are not included in the TCEP systematic review protocol. For example, EPA's TCEP systematic review protocol continues to require an overall study quality rating. EPA says that it is no longer

[20] National Academies of Sciences, Engineering, and Medicine (2021). The Use of Systematic Review in EPA's Toxic Substances Control Act Risk Evaluations, p. 39.
[21] U.S. EPA (2021). Draft Systematic Review Protocol Supporting TSCA Risk Evaluations for Chemical Substances Version 1.0, Table_Apx R-7. Evaluation Criteria for Epidemiological Studies, Metric 13.
[22] Institute of Medicine (2011). Finding what works in health care: Standards for systematic reviews.
[23] National Research Council (2014). Review of EPA's Integrated Risk Information System (IRIS) process.
[24] U.S. EPA (2021). Systematic Review Protocol for the PFAS IRIS Assessments. https://cfpub.epa.gov/ncea/iris_drafts/recordisplay.cfm?deid=345065 (accessed 1 February 2024).

applying a quantitative scoring method to the overall study quality determination, but it does not discuss a new approach to determining overall study quality in either the TCEP systematic review protocol or in the draft risk evaluation. The draft risk evaluation's description of the approach to human health hazard assessment includes:

> EPA considered studies that received **low, medium, or high overall quality determinations** for hazard identification, evidence integration, and dose-response analysis…Information from studies of **uninformative** quality were only discussed on a case-by-case basis for hazard identification and evidence integration and were not considered for dose-response analysis. For example, if an uninformative study identified a significantly different outcome compared with high- or medium-quality studies and the uninformative rating was not expected to influence the specific results being discussed, EPA considered the uninformative study for the hazard outcome being considered.[25] (emphasis added)

The systematic review protocol, however, does not state that the overall quality ratings that may be selected for a study are high, medium, low, or uninformative, nor does it state how ratings of the many individual study metrics are combined to determine an overall rating. The study quality term "uninformative" does not appear anywhere in the protocol. This indicates that the TSCA Draft Risk Evaluation is inappropriately applying methods that are not stated in the systematic review protocol.

To adhere to best practices in systematic review, EPA should not derive an overall study rating, and instead implement the domain-based approach of the Navigation Guide.[26] However, if EPA continues to develop overall study ratings, the method for doing so must be stated in systematic review protocols prior to their application.

In addition, the TCEP Draft Risk Evaluation acknowledges that studies rated as uninformative may provide useful information (for example, in the quotation above); therefore, EPA should not use the term "uninformative" to describe relevant studies.

The TCEP systematic review protocol also fails to present a PECO statement for identifying relevant health hazard studies. A PECO (Population, Exposure, Comparator, Outcome) statement provides criteria used to decide which studies are relevant to include in a systematic review and is a critical element of any systematic review protocol.[27,28] EPA instead references the previous draft PECO statement for TCEP included in the 2021 Draft TSCA Method. Other elements of the hazard evidence identification process similarly reference the 2021 document, which is cited repeatedly in Section 5.5 "Environmental and Human Health Hazard" of the TCEP protocol. Similarly, as discussed above, the 2021 Draft TSCA Method is referenced for the approach to study quality evaluation. Each chemical-specific protocol should be a stand-alone document that

[25] U.S. EPA (2023). Draft Risk Evaluation for Tris(2-chloroethyl) Phosphate (TCEP), p. 247.
[26] Lam J, Koustas E, Sutton P, Padula AM, Cabana MD, Vesterinen H, Griffiths C, Dickie M, Daniels N, Whitaker E, Woodruff TJ. Exposure to formaldehyde and asthma outcomes: A systematic review, meta-analysis, and economic assessment. PLoS One. 2021 Mar 31;16(3):e0248258. doi: 10.1371/journal.pone.0248258.
[27] Institute of Medicine (2011). Finding what works in health care: Standards for systematic reviews.
[28] National Toxicology Program (2019). Handbook for Conducting a Literature-Based Health Assessment Using OHAT Approach for Systematic Review and Evidence Integration.

incorporates all systematic review methods to be applied in conducting the assessment, and should not simply reference previous protocols. Dividing the methods across multiple documents increases the risk of mistakes and confusion in conducting the risk evaluation, and makes review of the risk evaluation challenging for peer reviewers and the public. As recommended by the SACC,[29] EPA should develop a TSCA systematic review handbook that can be cited in future protocols for specific elements that do not vary across risk evaluations, but only a final handbook should be cited in protocols and not the *2021 Draft TSCA Method*.

iii. EPA references inconsistent PECO statements to identify relevant health effects studies that may inappropriately exclude non-apical effects such as cellular-level outcomes.

As noted above, the TCEP-specific systematic review protocol issued in 2023 references the *2021 Draft TSCA Method* concerning the PECO statement used for identification of evidence relevant to assessing TCEP's human health hazards. The protocol states:

> During data screening, EPA followed the process described in Appendix H.5.7 of the 2021 Draft Systematic Review Protocol (U.S. EPA, 2021), to conduct TIAB and full-text screening for TCEP literature search results, as guided by the PECO statement. **The same PECO statement was used during TIAB and full-text screening** for references considered for the evaluation of environmental and human health hazard resulting from exposure to TCEP.[30] (emphasis added)

This statement is unclear because Appendix H.5.7 of the *2021 Draft TSCA Method* presents two different PECO statements: one to be used for title-abstract screening (Table_Apx H-31) and a different PECO to be used for full text screening Table_Apx H-33). The 2023 TCEP systematic review protocol does not indicate which PECO statement has been used in conducting the TCEP risk evaluation. One important difference between the two versions of the PECO statement is in specifying the outcomes considered relevant. In Table_Apx H-31, outcomes are:

> **Human**: All health outcomes (both cancer and non-cancer)
> **Animal and Plants**: All biological effects (including bioaccumulation from laboratory studies with concurrently measured water and tissue concentrations).
>
> **<u>Screener note:</u>**
> - **Measurable biological effects relevant for humans, animals and plants may include but are not limited to:** mortality, behavioral, population, cellular, physiological, growth, reproduction, systemic, point of contact effects.[31]

In Table_Apx H-33, important changes are made to the outcomes (additions are <u>underlined</u>, deletion shown in ~~strikethough~~):

[29] U.S. EPA (2022). Science Advisory Committee on Chemicals Meeting Minutes and Final Report No. 2022-2, p. 33.
[30] U.S. EPA (2023). Draft Risk Evaluation for Tris(2-chloroethyl) Phosphate (TCEP) Supplemental File: Systematic Review Protocol for the Draft Risk Evaluation for Tris(2-chloroethyl) Phosphate (TCEP), pp. 19-20.
[31] U.S. EPA (2021). Draft Systematic Review Protocol Supporting TSCA Risk Evaluations for Chemical Substances Version 1.0, Table_Apx H-31.

Human: All health outcomes (cancer and non-cancer) at the organ level or higher.
Animal and Plants: All apical biological effects (effects measured at the organ level or higher) and bioaccumulation from laboratory studies with concurrently measured media and/or tissue concentrations. Apical endpoints include but are not limited to reproduction, survival, and growth.

Screener note:

- Measurable biological effects relevant for humans, animals and plants may include but are not limited to: mortality, behavioral, population, ~~cellular,~~ physiological, growth, reproduction, systemic, point of contact (irritation and sensitization) effects.
- Effects measured at the cellular level of biological organization and below are to be tagged as supplemental, mechanistic.[32]

The PECO statement in Table_Apx H-33 incorporates several limitations on health effects studies that are considered by EPA to be relevant for hazard identification. For human studies, this second PECO statement specifies that only studies "at the organ level or higher" are to be included. For animal studies, the second PECO statement specifies that only "apical" effects "measured at the organ level or higher" are to be included. The "screener note" for this PECO deletes "cellular" from the list of relevant measurable biological effects and indicates that "Effects measured at the cellular level of biological organization and below are to be tagged as supplemental, mechanistic."[33]

EPA says in the TCEP Draft Risk Evaluation that the same PECO was used for title-abstract and full-text screening, but it never states which version of the PECO was used. If EPA used the second version of the PECO (Table_Apx H-33) in conducting the risk evaluation, this would be contrary to the clear advice of the SACC, which said:

> EPA should not limit PECO/RESO statements to apical endpoints but consider expanding outcomes to include known upstream markers of effect such as biochemical markers of effect or other outcomes at the cellular level.[34]

Public comments on the 2021 Draft TSCA Method also detail the many problems with restricting the included studies to only those with apical outcomes or effects at the organ level or higher.[35] Inclusion of the PECO in the TCEP systematic review protocol would have avoided any confusion regarding which version of the PECO was applied. To adhere to best practices in systematic review, EPA should specify which PECO statement was used in the TCEP Draft Risk Evaluation, and include that PECO statement in the chemical-specific systematic review protocol.

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[32] U.S. EPA (2021). Draft Systematic Review Protocol Supporting TSCA Risk Evaluations for Chemical Substances Version 1.0, Table_Apx H-33.

[33] *Id.*

[34] U.S. EPA (2022). Science Advisory Committee on Chemicals Meeting Minutes and Final Report No. 2022-2, p 29. https://www.regulations.gov/document/EPA-HQ-OPPT-2021-0414-0044.

[35] Comment submitted by University of California, San Francisco Program on Reproductive Health and the Environment (UCSF PRHE): Comments on the Draft Toxic Substances Control Act (TSCA) Systematic Review Protocol. February 18, 2022. EPA-HQ-OPPT-2021-0414-0015. https://www.regulations.gov/comment/EPA-HQ-OPPT-2021-0414-0015.

iv. The TCEP protocol continues to use unclear terminology regarding evidence synthesis and integration.

EPA's use of unclear terminology for evidence synthesis and integration is an additional shortcoming of the TCEP systematic review protocol. The NASEM has recommended the use of the term "evidence synthesis" for assembling the evidence and drawing conclusions from a single evidence stream (e.g. toxicology, epidemiology), and "evidence integration" for the subsequent process of drawing conclusions considering all evidence streams. The SACC review of EPA's 2021 Draft TSCA Method document reiterated this recommendation:

> The EPA did not follow the recommendation of NASEM to separate evidence synthesis from evidence integration. To quote NASEM: "Evidence synthesis deals with more homogeneous data within a single stream, and evidence integration deals with more heterogeneous data from multiple streams."[36]
>
> The EPA could improve the clarify, transparency, and efficiency of its process by adopting the NASEM recommendation to use "synthesis" for drawing conclusions separately for each evidence stream (i.e., human, animal, and mechanistic evidence) and use 'integration' for drawing conclusions considering all evidence streams in combination – in context of the risk evaluation process/needs.[37]

In the TCEP systematic review protocol, however, EPA disregards the advice of both the NASEM and the SACC by continuing to use the term "evidence integration" for both steps.[38] This is one more area in which EPA's approach differs from best practices in systematic review, violating TSCA. In addition, failing to adopt consistent and vetted terminology decreases the clarity of the risk evaluation and creates confusion for peer reviewers and the public regarding the procedures applied to drawing conclusions from a single stream of evidence.

v. EPA should prepare a new TSCA systematic review methodology that is aligned with the best available scientific methods and issue updated draft systematic review protocols for all risk evaluations currently in development, including TCEP.

EPA has made some improvements in its approach to systematic review under TSCA, particularly regarding the discontinuation of its quantitative approach to study quality evaluation. However, EPA has not indicated if these improvements, including changes to study quality evaluation, will be applied in all future TSCA risk evaluations. EPA has instead stated that systematic review methods may vary across TSCA assessments. In doing so, EPA has failed to

[36] U.S. EPA (2022). Science Advisory Committee on Chemicals Meeting Minutes and Final Report No. 2022-2, p 83. https://www.regulations.gov/document/EPA-HQ-OPPT-2021-0414-0044.
[37] U.S. EPA (2022). Science Advisory Committee on Chemicals Meeting Minutes and Final Report No. 2022-2, p 88. https://www.regulations.gov/document/EPA-HQ-OPPT-2021-0414-0044.
[38] U.S. EPA (2023). Draft Risk Evaluation for Tris(2-chloroethyl) Phosphate (TCEP) Supplemental File: Systematic Review Protocol for the Draft Risk Evaluation for Tris(2-chloroethyl) Phosphate (TCEP), pp. 73-75.

implement the more than 200 recommendations issued by the SACC in its review of the *2021 Draft TSCA Method*.

To adhere to best practices in systematic review, including those recommended by the NASEM and SACC, EPA should issue a new TSCA systematic review methodology document that states methods to be applied consistently to all TSCA rulemakings, which must include applying only qualitative methods for study quality evaluation. EPA should also prepare a chemical-specific systematic review protocol for each TSCA risk evaluation it conducts, and these protocols should be complete, stand-alone documents that do not refer to the *2021 Draft TSCA Method* for critical elements, such as PECO statements and methods for study quality evaluation. The chemical-specific protocols for ongoing and future risk evaluations should also be released for public comment well before the draft risk evaluations are completed to allow for public input, scrutiny, and opportunities for improvement. We urge EPA to consistently adopt the practices of the IRIS program for systematic review protocol development and publication across all EPA programs and offices.

2. EPA should apply best available scientific methods to improve the TCEP hazard assessment.

a. EPA should apply existing methods to generate quantitative estimates of non-cancer risks from TCEP exposures.

The TCEP Draft Risk Evaluation continues to rely on the scientifically-deficient methods for non-cancer dose-response analysis and risk characterization employed in previous TSCA risk evaluations. EPA's methods for non-cancer risk evaluation do not provide a quantitative estimate of risk. Instead, they rely on calculation of a margin of exposure ("MOE"), defined as:

> Margin of Exposure = Non-cancer point of departure / Human exposure.[39]

The MOE approach is a scientifically inappropriate approach for characterizing risk and is inconsistent with amended TSCA's requirements to use the "best available science" and to ensure protection of "potentially exposed and susceptible subpopulations" ("PESS").[40] Use of the MOE, which relies on a point of departure ("POD") with no extrapolation to lower doses, is a simplistic approach that only examines the ratio of the POD to the exposure level and determines whether this ratio "is interpreted as a human health risk of concern" or if "the risk is not considered to be of concern."[41] The MOE does not estimate the proportion of the exposed population projected to experience a specified health endpoint or the number of individuals affected, and it perpetuates the scientifically flawed notion that a "safe" or "no risk" level of

[39] U.S. EPA (2023). Draft Risk Evaluation for Tris(2-chloroethyl) Phosphate (TCEP), p. 296.
[40] 15 USC §2625 (h) and 15 USC §2602 (12).
[41] U.S. EPA (2023). Draft Risk Evaluation for Tris(2-chloroethyl) Phosphate (TCEP), p. 296.

chemical exposure can be identified for a diverse exposed population.[42,43] The National Academies[44] and the World Health Organization ("WHO")[45] have outlined more robust methods for risk estimation that more accurately account for variability and vulnerability across the human population and have been demonstrated in published case studies.[46,47,48,49]

We applied the WHO methodology to estimate risks of adverse effects from chronic inhalation and oral exposure to TCEP using EPA's identification of hazards and estimation of points of departure (PODs). Specifically, we estimated risks of male reproductive effects (decreased numbers of seminiferous tubules), using EPA's POD of 2.73 mg/kg-d for oral exposure and 14.9 mg/m^3 for inhalation exposure.[50] The PODs are drawn from a 35-day study in mice. EPA's approach to risk characterization (i.e. selection of a "benchmark MOE") included an interspecies adjustment factor and a human variability adjustment factor, but inappropriately omitted an adjustment factor accounting for the subchronic duration of the mouse study. Our application of the WHO methodology includes an adjustment for study duration along with the interspecies and human variability adjustments.

In applying the WHO methodology (see Technical Appendix for details) to risks of adverse male reproductive effects from oral exposure to TCEP, we found that:

- 0.06 mg/kg-d is the lower bound (95% confidence) chronic human oral dose at which male reproductive effects are expected in 1% of the population,
- 0.02 mg/kg-d is the lower bound (95% confidence) chronic human oral dose at which male reproductive effects are expected in 0.1% of the population,
- 0.008 mg/kg-d is the lower bound (95% confidence) chronic human oral dose at which male reproductive effects are expected in 0.01% (1-in-10,000) of the population.
- EPA's non-cancer risk characterization for oral exposure to TCEP uses 2.73 mg/kg-d as the point of departure, and a benchmark MOE of 30.[51] This means that EPA concludes "the risk is not considered to be of concern"[52] for any chronic exposure less than 2.73 mg/kg-d / 30 = 0.09 mg/kg-d. By applying the WHO methodology, we found that the upper bound risk at an exposure of 0.09 mg/kg-d is 2.5%, or 1-in-40. This risk level is

[42] Woodruff, T. J., Rayasam, S. D. G., Axelrad, D. A., Koman, P. D., Chartres, N., Bennett, D. H., Birnbaum, L. S., Brown, P., Carignan, C. C., Cooper, C., Cranor, C. F., Diamond, M. L., Franjevic, S., Gartner, E. C., Hattis, D., Hauser, R., Heiger-Bernays, W., Joglekar, R., Lam, J., . . . Zeise, L. (2023). A science-based agenda for health-protective chemical assessments and decisions: overview and consensus statement. Environ Health, 21(Suppl 1), 132. https://doi.org/10.1186/s12940-022-00930-3.

[43] McGartland, A., Revesz, R., Axelrad, D. A., Dockins, C., Sutton, P., Woodruff, T. J. (2017). Estimating the health benefits of environmental regulations. Science, 357(6350), 457-458. https://doi.org/10.1126/science.aam8204.

[44] National Research Council (2009). Science and Decisions: Advancing Risk Assessment, Chapter 5.

[45] WHO. (2017). Guidance document on evaluating and expressing uncertainty in hazard characterization. Harmonization project document 11, 2nd edition. https://www.who.int/publications/i/item/9789241513548.

[46] Chiu WA, Axelrad DA, Dalaijamts C, Dockins C, Shao K, Shapiro AJ, Paoli G. Beyond the RfD: broad application of a probabilistic approach to improve chemical dose-response assessment for non-cancer effects. Environmental Health Perspectives, 2018 June;126(6):067009. doi:10.1289/EHP3368.

[47] Nielsen, G. H., Heiger-Bernays, W. J., Levy, J. I., White, R. F., Axelrad, D. A., Lam, J., Chartres, N., Abrahamsson, D. P., Rayasam, S. D. G., Shaffer, R. M., Zeise, L., Woodruff, T. J., Ginsberg, G. L. (2023). Application of probabilistic methods to address variability and uncertainty in estimating risks for non-cancer health effects. Environ Health, 21(Suppl 1), 129. https://doi.org/10.1186/s12940-022-00918-z.

[48] Blessinger, T., Davis, A., Chiu, W. A., Stanek, J., Woodall, G. M., Gift, J., Thayer, K. A., Bussard, D. (2020). Application of a unified probabilistic framework to the dose-response assessment of acrolein. Environ Int, 143, 105953. https://doi.org/10.1016/j.envint.2020.105953.

[49] Ginsberg, G. L. (2012). Cadmium risk assessment in relation to background risk of chronic kidney disease. J Toxicol Environ Health A, 75(7), 374-390. https://doi.org/10.1080/15287394.2012.670895.

[50] U.S. EPA (2023). Draft Risk Evaluation for Tris(2-chloroethyl) Phosphate (TCEP), Table 5-56.

[51] U.S. EPA (2023). Draft Risk Evaluation for Tris(2-chloroethyl) Phosphate (TCEP), Table 5-56.

[52] U.S. EPA (2023). Draft Risk Evaluation for Tris(2-chloroethyl) Phosphate (TCEP), p. 296.

25,000 times higher than the target range that EPA typically applies for protection of carcinogenic risks (see below).

Following EPA's approach for extrapolating from oral exposures to inhalation exposures, the above values can be expressed as inhalation exposures in mg/m^3 by multiplying by 5.44.[53] For example, the lower bound (95% confidence) chronic human inhalation dose at which male reproductive effects are expected in 0.01% (1-in-10,000) of the population is 0.008 x 5.44 = 0.04 mg/m^3.

EPA must incorporate this approach to non-cancer dose-response and risk characterization in the final TCEP risk evaluation. Our analysis demonstrated that EPA's current approach results in acceptance of any exposures less than those producing an upper bound risk of 1-in-40, a risk level that is unacceptably high, even by EPA's own standards; EPA typically applies a target range of protection for carcinogenic risks of 1-in-10,000 (10^{-4}) to 1-in-1,000,000 (10^{-6}).[54] To offer the strongest public health protections, EPA should target any upper bound risks of non-cancer effects from TCEP exposure to be no more than 1-in-1,000,000 risk level.

b. EPA's statements regarding a threshold for cancer are not scientifically supported and must be removed.

EPA has appropriately modeled cancer dose-response as a linear relationship with no threshold, consistent with EPA's *Guidelines for Carcinogen Risk Assessment* for a carcinogen without an identified mode of action (MOA). However, EPA incorrectly states that because TCEP does not act through a known mutagenic MOA, there is a threshold below which there is no cancer risk:

> Because direct mutagenicity is not likely to be the predominant MOA, using linear low dose extrapolation is a health conservative analysis that would overpredict risks **assuming that TCEP acts via a threshold MOA**.[55] (emphasis added)

> Assuming all TCEP exposure is associated with some risk is likely to be health conservative because EPA does not believe that a mutagenic MOA is likely for TCEP and **a threshold below which cancer does not occur is expected to exist**. However, information is lacking with which to determine an appropriate threshold.[56] (emphasis added)

EPA provides no evidence to support its speculation that there is a threshold for TCEP's cancer risk. The absence of a known mutagenic MOA is not sufficient evidence to support these statements, as carcinogens acting by other MOAs can operate with no threshold. Further, the NASEM states that human variability, exposure to other chemicals, and background disease processes alone can result in linear dose-response relationships at low doses, regardless of whether mutagenic MOAs are known:

[53] U.S. EPA (2023). Draft Risk Evaluation for Tris(2-chloroethyl) Phosphate (TCEP), p. 530, Equation_Apx J-3.
[54] U.S. EPA (2023). Draft Risk Evaluation for Tris(2-chloroethyl) Phosphate (TCEP), p. 296.
[55] U.S. EPA (2023). Draft Risk Evaluation for Tris(2-chloroethyl) Phosphate (TCEP), p. 291.
[56] U.S. EPA (2023). Draft Risk Evaluation for Tris(2-chloroethyl) Phosphate (TCEP), p. 334 (repeated on page 418).

> Background exposures and underlying disease processes contribute to population background risk and can lead to linearity at the population doses of concern.[57]
>
> The current EPA practice of determining "nonlinear" MOAs does not account for mechanistic factors that can create linearity at low dose. The dose-response relationship can be linear at a low dose when an exposure contributes to an existing disease process…Effects of exposures that add to background processes and background endogenous and exogenous exposures can lack a threshold if a baseline level of dysfunction occurs without the toxicant and the toxicant adds to or augments the background process. Thus, even small doses may have a relevant biologic effect. That may be difficult to measure because of background noise in the system but may be addressed through dose-response modeling procedures. Human variability with respect to the individual thresholds for a nongenotoxic cancer mechanism can result in linear dose-response relationships in the population…In the laboratory, nonlinear dose-response processes—for example, cytotoxicity, impaired immune function and tumor surveillance, DNA methylation, endocrine disruption, and modulation of cell cycles—may be found to cause cancer in test animals. However, given the high prevalence of those background processes, given cancer as an end point, and given the multitude of chemical exposures and high variability in human susceptibility, the results may still be manifested as low-dose linear dose-response relationships in the human population.[58]

To adhere to best practices in risk characterization, EPA must remove the statements quoted above regarding a cancer threshold for TCEP from the TCEP Draft Risk Evaluation before it is finalized.

c. EPA incorrectly failed to apply an adjustment factor for the subchronic duration of the animal study used for estimating risk of male reproductive effects.

EPA omitted critical uncertainty factors (UFs) when characterizing non-cancer risk in the TCEP Draft Risk Evaluation, violating TSCA's "best available science" requirement. To estimate the non-cancer risks of TCEP, EPA used data from a 35-day mouse study (Chen et al. 2015)[59] to derive a POD for male reproductive effects (decreased number of and degeneration of seminiferous tubules), and employed the "benchmark MOE" bright-line approach to determine whether a chronic exposure is sufficiently below the POD. To calculate the benchmark MOE for risk characterization using the Chen et al. POD, EPA applied an interspecies uncertainty factor (UF) of 3 to account for uncertainties related to any animal-to-human differences remaining after calculation of a human equivalent concentration, and an intraspecies UF of 10 to account for uncertainties around human variability, for an overall UF of 30 (10 x 3). Thus, according to EPA, any exposure less than 30-fold lower than the POD "is interpreted as a human health risk of concern" and for exposures more than 30-fold lower "the risk is not considered to be of concern."[60]

[57] National Research Council (2009). Science and Decisions: Advancing Risk Assessment, p. 8.
[58] National Research Council (2009). Science and Decisions: Advancing Risk Assessment, pp. 129-130.
[59] Chen, G; Jin, Y; Wu, Y; Liu, L; Fu, Z. (2015). Exposure of male mice to two kinds of organophosphate flame retardants (OPFRs) induced oxidative stress and endocrine disruption. Environ Toxicol Pharmacol 40: 310-318.
[60] U.S. EPA (2023). Draft Risk Evaluation for Tris(2-chloroethyl) Phosphate (TCEP), p. 296.

The section of the TCEP Draft Risk Evaluation on determination of the benchmark MOE makes no mention of the subchronic-to-chronic study duration UF that is usually applied to account for the lower dose that may produce the same effect if a chronic study were conducted. Inclusion of a subchronic UF would increase the benchmark MOE and in turn lower EPA's bright line for identifying risks of concern by a factor of 3 to 10. Failure to increase the benchmark MOE applied to the POD for male reproductive effects from Chen et al. with a subchronic UF therefore results in significant underestimation of risk, potentially by up to an order of magnitude. The risk evaluation acknowledges the uncertainty in using a POD from a subchronic study:

> it is uncertain whether the POD would be lower if Chen et al. (2015a) extended the exposure duration.[61]

> Using Chen et al. (2015a) to represent chronic exposure durations adds uncertainty to the risk evaluation. If the specific effect identified by Chen et al. (2015a) were measured in a chronic study in the same species starting in adolescence, the POD could be more sensitive. Therefore, it is possible that risks might be under-predicted.[62]

However, the risk evaluation lacks any discussion of the possible use of a subchronic UF to address that uncertainty. As discussed above, EPA must use probabilistic methods, including adjustment for the subchronic study duration, for dose-response assessment and risk characterization of non-cancer effects.

3. EPA has not appropriately identified potentially exposed or susceptible subpopulations (PESS), as required by TSCA.

In the TCEP Draft Risk Evaluation, EPA identifies the following groups as PESS:

> infants exposed through human milk from exposed individuals, children and male adolescents who use consumer articles or are among the exposed general population, subsistence fishers, tribal populations, pregnant women, workers and consumers who experience aggregated or sentinel exposures, fenceline communities who live near facilities that emit TCEP, and firefighters.[63]

Identification of PESS for each chemical assessed is a critical aspect of conducting risk evaluation under TSCA, and TSCA requires EPA to

> determine whether a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation.[64]

[61] U.S. EPA (2023). Draft Risk Evaluation for Tris(2-chloroethyl) Phosphate (TCEP), p. 283.
[62] U.S. EPA (2023). Draft Risk Evaluation for Tris(2-chloroethyl) Phosphate (TCEP), p. 290.
[63] U.S. EPA (2023). Draft Risk Evaluation for Tris(2-chloroethyl) Phosphate (TCEP), p. 329.
[64] 15 USC §2605(b)(4)(A).

In the final 2017 TSCA Risk Evaluation Framework Rule, EPA defined PESS (using the statutory definition) as:

> a group of individuals within the general population identified by the Administrator who, due to either greater susceptibility or greater exposure, may be at greater risk than the general population of adverse health effects from exposure to a chemical substance or mixture, such as infants, children, pregnant women, workers, or the elderly.[65]

To date, EPA has not employed a consistent or structured approach to identifying PESS in its TSCA risk evaluations, including scope documents for ongoing risk evaluations. EPA's approach and terminology for identifying PESS varied considerably in the first 10 risk evaluations. Among the inconsistencies were differences in whether health conditions related to a chemical's hazards were considered and whether fenceline communities were included.[66,67] For example, fenceline communities were identified as PESS for hexabromocyclododecane (HBCD), but not for 1,4-dioxane, 1-bromopropane (1-BP), or C.I. Pigment Violet 29 (PV-29); children were identified as PESS for 1-BP and HBCD, but not for 1,4-dioxane or PV-29.[68] To remedy the problem of inconsistent and incomplete identification of PESS, Rayasam et al. recommended that:

> EPA should prepare a comprehensive methodology to identify PESS and quantify their risks consistently within and across the TSCA risk evaluations.[69]

EPA has not yet proposed such a methodology. The consideration of PESS in Table 5-69 and Appendix D of the TCEP Draft Risk Evaluation is a useful initial step towards developing a consistent, structured approach to identifying PESS in TSCA risk evaluations. The table gives explicit consideration to each of the following factors that may lead to increased chemical exposures or susceptibility to harm from chemical exposures: lifestage, pre-existing disease, lifestyle activities, occupational and consumer exposures, socio-demographic factors, nutrition, genetics/epigenetics, unique activities, aggregate exposures, and other chemical and non-chemical stressors.

EPA, however, has violated TSCA's mandate to consider each of the relevant factors in identifying populations groups that "due to either greater susceptibility or greater exposure, may be at greater risk than the general population of adverse health effects."[70] The TCEP Draft Risk Evaluation says:

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[65] U.S. EPA (2017). Procedures for Chemical Risk Evaluation under the Amended Toxic Substances Control Act (Final) 40 CFR 702.

[66] Rayasam, S. D. G., Koman, P. D., Axelrad, D. A., Woodruff, T. J., Chartres, N. (2022). Toxic Substances Control Act (TSCA) Implementation: How the Amended Law Has Failed to Protect Vulnerable Populations from Toxic Chemicals in the United States. Environmental science & technology, 56(17), 11969–11982. https://doi.org/10.1021/acs.est.2c02079.

[67] McPartland, J., Shaffer, R. M., Fox, M. A., Nachman, K. E., Burke, T. A., Denison, R. A. (2022). Charting a Path Forward: Assessing the Science of Chemical Risk Evaluations under the Toxic Substances Control Act in the Context of Recent National Academies Recommendations. Environmental health perspectives, 130(2), 25003. https://doi.org/10.1289/EHP9649.

[68] Rayasam, S. D. G., Koman, P. D., Axelrad, D. A., Woodruff, T. J., Chartres, N. (2022). Toxic Substances Control Act (TSCA) Implementation: How the Amended Law Has Failed to Protect Vulnerable Populations from Toxic Chemicals in the United States. Table-S3 Environmental science & technology, 56(17), 11969–11982. https://doi.org/10.1021/acs.est.2c02079.

[69] Rayasam, S. D. G., Koman, P. D., Axelrad, D. A., Woodruff, T. J., Chartres, N. (2022). Toxic Substances Control Act (TSCA) Implementation: How the Amended Law Has Failed to Protect Vulnerable Populations from Toxic Chemicals in the United States. Environmental science & technology, 56(17), 11969–11982. https://doi.org/10.1021/acs.est.2c02079.

[70] 15 U.S.C. § 2605(b)(4)(A); *id*. § 2602(12).

> susceptibility factors that are generally considered to increase susceptibility of individuals to chemical hazards…include pre-existing diseases, alcohol use, diet, stress, among others. The effect of these factors on susceptibility to health effects of TCEP is not known; therefore, EPA is uncertain about the magnitude of any possible increased risk from effects associated with TCEP exposure.[71]

EPA's default approach seems to be that a susceptible subgroup will not be identified as PESS when there are not chemical-specific quantitative data on the magnitude of increased susceptibility for a given susceptibility factor. TSCA does not require chemical-specific quantitative data to identify or evaluate risk to PESS; TSCA simply requires EPA to rely on the "best available science" when evaluating risk to PESS. The best available science demonstrates that both *intrinsic* factors, which include biological traits like age, genetic makeup, and pre-existing health conditions, and *extrinsic* factors, which include psychosocial stress from experiencing income inequality, violence, racism, healthcare inequity, or food insecurity, can individually or collectively increase susceptibility to harm from chemical exposures.[72] EPA should therefore focus first on identifying susceptible subpopulations based on either chemical-specific evidence or the broader literature on intrinsic and extrinsic susceptibility factors, and then, as a separate step, consider how to account for the elevated risks for each group. The initial identification of PESS, however, should not be contingent on chemical-specific data to quantify risk for a susceptible subgroup. Once the appropriate groups are identified as PESS, EPA should then consider the availability of chemical -specific data. When such data are absent, the application of generic adjustment factors (beyond the customary 10x factor for human variability) should be applied to ensure that risks to PESS are not underestimated.[73]

Lifestage. EPA has appropriately identified infants (exposed from human breast milk), children, male adolescents and pregnant women as PESS. However, infants as PESS should not be restricted to human breast milk exposure, as infants are also likely to be exposed to TCEP via ingestion of household dust (e.g. hand to mouth behaviors). In addition, EPA's risk evaluation understates the magnitude of human breast milk exposures for some infants by assuming a maximum breastfeeding duration of one year. Data from the Centers for Disease Control and Prevention ("CDC") indicate that 37.6 percent of infants born in 2020 were breastfeeding at age 12 months, and 17.3 percent were breastfeeding at age 18 months.[74]

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[71] U.S. EPA (2023). Draft Risk Evaluation for Tris(2-chloroethyl) Phosphate (TCEP), p. 418.

[72] Woodruff, T. J., Rayasam, S. D. G., Axelrad, D. A., Koman, P. D., Chartres, N., Bennett, D. H., Birnbaum, L. S., Brown, P., Carignan, C. C., Cooper, C., Cranor, C. F., Diamond, M. L., Franjevic, S., Gartner, E. C., Hattis, D., Hauser, R., Heiger-Bernays, W., Joglekar, R., Lam, J., … Zeise, L. (2023). A science-based agenda for health- protective chemical assessments and decisions: Overview and consensus statement. Environmental Health,21(1), 132. https://doi.org/10.1186/s12940-022-00930-3; Rachel Morello-Frosch et al., *Understanding the Cumulative Impacts of Inequalities in Environmental Health: Implications for Policy*, 30 Health Affs. 879 (2011), https://www.healthaffairs.org/doi/pdf/10.1377/hlthaff.2011.0153; Cliona M. McHale et al., *Assessing Health Risks from Multiple Environmental Stressors: Moving from G×E to I×E*, 775 Mutational Rsch. 11 (2018), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5863617/; Devon C. Payne-Sturges et al*., Methods for Evaluating the Combined Effects of Chemical and Nonchemical Exposures for Cumulative Environmental Health Risk Assessment*, 15 Int'l. J. Env't Rsch. & Pub. Health 2797 (2018), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6313653/; Gilbert C. Gee et al., *Environmental Health Disparities: A Framework Integrating Psychosocial and Environmental Concepts*, 112 Env't Health Persps. 1645 (2004), https://doi.org/10.1289/ehp.7074; Gina M. Solomon et al., *Cumulative Environmental Impacts: Science and Policy to Protect Communities* 37 Ann. Rev. Pub. Health 83, 87–88 (2016), https://www.annualreviews.org/doi/pdf/10.1146/annurev-publhealth-032315-021807; Patricia D. Koman et al., *Population Susceptibility: A Vital Consideration in Chemical Risk Evaluation Under the Lautenberg Toxic Substances Control Act*, 17 PLoS Biology 1, 4 (2019), https://journals.plos.org/plosbiology/article?id=10.1371/journal.pbio.3000372.

[73] Julia R. Varshavsky et al., Current Practice and Recommendations for Advancing How Human Variability and Susceptibility Are Considered in Chemical Risk Assessment, 21(Suppl 1) Env't Health Article No. 133, at 3 (2023), https://doi.org/10.1186/s12940-022-00940-1.

[74] Centers for Disease Control and Prevention (2024). Results: Breastfeeding Rates. National Immunization Survey - Child (NIS-Child). https://www.cdc.gov/breastfeeding/data/nis_data/results.html (accessed 30 January 2024).

EPA's approach to identifying susceptible lifestages is too narrow. Enhanced susceptibility of infants, children, women of reproductive age and people of age 65 years or older is well-established, and these groups should be identified as PESS for each TSCA risk evaluation, regardless of whether there are chemical-specific data to quantify those differences. Further, EPA makes no adjustments to quantify the enhanced risks to the susceptible lifestages. Instead, EPA applies the customary 10x human variability factor, which is routinely applied in EPA risk assessments and is not sufficient to address human variability in response to chemical exposures.[75] EPA acknowledges that "The magnitude of differences in toxicokinetics and toxicodynamics for some individuals may be greater than accounted for by the UF_H of 10,"[76] but it then continues to apply this insufficient value. The WHO's International Programme on Chemical Safety ("IPCS") found that an adjustment factor of approximately 42X is needed to account for the range in human variability in response to chemical exposure when estimating a risk-specific dose intended for a risk of 1% (1-in-100), with larger factors necessary for protection of the population at lower risk levels.[77]

Pre-existing disease. EPA did not identify any groups as PESS based on pre-existing disease or health conditions. EPA identified neurotoxicity, reproductive toxicity, developmental toxicity, and kidney toxicity as likely hazards of TCEP, but it disregarded the prevalence in the U.S. population of vulnerabilities to these hazards. For example, the CDC estimates that 14% of U.S. adults have chronic kidney disease; this affects not just older adults, but also 6% of adults ages 18-44 years.[78] Given that kidney toxicity is a hazard of TCEP, people with chronic kidney disease should be considered a susceptible subpopulation in the TCEP Draft Risk Evaluation. Risk estimation for this group should also incorporate an adjustment factor (in addition to the customary human variability factor) representing the enhanced risk of kidney effects from TCEP exposure. Similarly, population groups with biological susceptibility to the neurotoxic, reproductive and/or developmental effects of TCEP should also be considered PESS, and appropriate adjustments to the estimation of risks of each outcome for these groups should be made.

Individual activities. Subsistence fishers (including tribal populations) are identified as PESS in the TCEP Draft Risk Evaluation based on elevated TCEP exposures. However, no "lifestyle" or "individual" activities are identified for enhanced susceptibility. EPA mentions smoking as a lifestyle factor that could influence susceptibility to chemical exposures, but it failed to identify smokers as PESS because it found no chemical-specific information. Smoking tobacco has numerous biological effects that could enhance susceptibility to the hazards of TCEP, such as adverse effects on the kidney. Smokers should be considered PESS even if there is not direct TCEP-specific evidence. In addition, we recommend using the term "individual activities" instead of "lifestyle activities."

[75] Julia R. Varshavsky et al., Current Practice and Recommendations for Advancing How Human Variability and Susceptibility Are Considered in Chemical Risk Assessment, 21(Suppl 1) Env't Health Article No. 133, at 3 (2023), https://doi.org/10.1186/s12940-022-00940-1.
[76] U.S. EPA (2023). Draft Risk Evaluation for Tris(2-chloroethyl) Phosphate (TCEP), Table 5-69.
[77] WHO (2017). Guidance document on evaluating and expressing uncertainty in hazard characterization. Harmonization project document 11, 2nd edition, Table 4.5. https://www.who.int/publications/i/item/9789241513548.
[78] Centers for Disease Control and Prevention (2023). Chronic Kidney Disease in the United States, 2023. https://www.cdc.gov/kidneydisease/publications-resources/CKD-national-facts.html.

Occupational exposures. EPA appropriately identified firefighters as an occupational group with elevated TCEP exposures. However, in discussing the relevant evidence, EPA omitted the important 2022 study by Trowbridge *et al*.[79] EPA also failed to consider firefighter exposures in its unreasonable risk determination for TCEP. According to Appendix D of the TCEP Draft Risk Evaluation, firefighter exposures are classified as "background" and "EPA did not identify sources of increased COU or pathway specific exposure for firefighters."[80] However, it is highly likely that elevated firefighter exposures arise from the presence of consumer and commercial products containing TCEP in burning structures, and firefighter exposures should be a consideration in EPA's unreasonable risk determinations for those products. In addition, EPA failed to consider that workers may be occupationally exposed to other chemicals sharing common adverse outcomes with TCEP (e.g. neurological, reproductive and kidney effects). People who experience occupational exposures to other toxic chemicals that are linked to similar adverse health outcomes as TCEP can have enhanced susceptibility to the adverse effects of TCEP and should be identified and evaluated as PESS in the TCEP Draft Risk Evaluation.

Geographic factors. Geographic factors were not included in Table 5-69 of the TCEP Draft Risk Evaluation. However, EPA has considered geographic factors as contributors to PESS in previous assessments and appropriately identified fenceline communities near facilities that emit TCEP as PESS in the TCEP Draft Risk Evaluation, so it is unclear why an entry for this factor is omitted from Table 5-69. Although EPA has estimated exposures to fenceline communities, it has not considered the many characteristics that can enhance susceptibility to the effects of TCEP and are common in fenceline communities. In general, people living in fenceline communities are more likely to be people of color and are more likely to experience increased exposures to multiple chemical and non-chemical stressors that make them more susceptible to harm, including a broad range of non-chemical stressors like pre-existing disease, racism, and poverty.[81] EPA is therefore required under TSCA to account for these enhanced susceptibilities when evaluating risks to fenceline communities.

Socio-demographic factors. The TCEP Draft Risk Evaluation says "EPA did not evaluate exposure differences between racial groups."[82] At a minimum, EPA should assess the demographic profile of populations living in locations likely to experience elevated exposures (e.g. sites with TCEP in groundwater, sites near facilities producing, using, or disposing of TCEP). EPA conducted such an analysis for the proposed TSCA risk management rule for trichloroethylene,[83] and this approach should be incorporated in all TSCA risk evaluations. If EPA does not have the data necessary to conduct a robust, accurate, and scientifically-sound environmental justice analysis of chemicals subject to TSCA risk evaluation, it should develop and execute a strategy for obtaining the data and analyzing it. For example, EPA could use its TSCA authorities to gather information from industry on TCEP manufacturing/processing sites and products containing TCEP. EPA failed to use its authority to list TCEP to the Toxics Release

[79] Trowbridge J, Gerona R, McMaster M, Ona K, Clarity C, Bessonneau V, Rudel R, Buren H, Morello-Frosch R (2022). Organophosphate and Organohalogen Flame-Retardant Exposure and Thyroid Hormone Disruption in a Cross-Sectional Study of Female Firefighters and Office Workers from San Francisco. Environ Sci Technol. 56(1):440-450. Doi: 10.1021/acs.est.1c05140.

[80] U.S. EPA (2023). Draft Risk Evaluation for Tris(2-chloroethyl) Phosphate (TCEP), Table_Apx D-1.

[81] Ronald White et al., Env't Just. Health All. For Chem. Pol'y Reform et al., Life at the Fence line: Understanding Cumulative Health Hazards in Environmental Justice Communities (2018), https://ej4all.org/assets/media/documents/Life%20at%20the%20Fenceline%20-%20English%20-%20Public.pdf.

[82] U.S. EPA (2023). Draft Risk Evaluation for Tris(2-chloroethyl) Phosphate (TCEP), Table 5.69.

[83] U.S. EPA (2023). Economic Analysis of the Proposed Regulation of Trichloroethylene Under TSCA Section 6(a), Section 10.6.

Inventory ("TRI") in time to generate chemical release data to inform exposure assessments in the TCEP Draft Risk Evaluation, which precluded its ability to adequately assess fenceline community exposures and risks.

The TCEP Draft Risk Evaluation says:

> EPA did not identify specific evidence that sociodemographic factors influence susceptibility to TCEP although it is known that they can affect susceptibility to disease.[84]

TSCA requires EPA to account for enhanced susceptibility to chemical exposures in chemical risk evaluations. EPA must account for socio-demographic factors associated with enhanced susceptibility in its identification of PESS and in analyzing risks to those groups. For example, people experiencing poverty or racial discrimination may experience psychosocial stress[85,86,87,88,89] that can enhance susceptibility to the adverse effects of toxic chemicals including TCEP, and should be identified as PESS even if there is not direct chemical-specific evidence.

Nutrition. EPA correctly states that "Nutrition can affect susceptibility to disease generally," but it did not identify any PESS because it "did not identify specific evidence that nutritional factors influence susceptibility to TCEP."[90] People with food insecurity or lack of access to nutritious food can experience enhanced susceptibility to the adverse effects of toxic chemicals, including TCEP, and should be identified as PESS even if there is not direct chemical-specific evidence.

Genetics. EPA states that "genetic disorders may increase susceptibility to male reproductive effects; this was addressed through a 10× UF for human variability."[91] EPA assumes that a 10-fold factor is sufficient to account for human variability in response to chemical exposures, including the impacts of genetics and all the other susceptibility factors in the table, even though the National Academies[92] and the WHO[93] have both compiled evidence that a larger factor is necessary to ensure public health protection. EPA must accordingly increase the uncertainty factor it uses to account for enhanced susceptibility to TCEP based on genetic disorders.

Aggregate exposures. EPA has only partially accounted for aggregate exposure in the TCEP Draft Risk Evaluation. EPA aggregated across exposure pathways for consumers and separately for workers, but it did not aggregate exposures for workers who also experience consumer and general population exposures, and did not aggregate exposures for consumers who have

[84] U.S. EPA (2023). Draft Risk Evaluation for Tris(2-chloroethyl) Phosphate (TCEP), Table 5-69.
[85] Clougherty J. and C. Rider (2020). Integration of psychosocial and chemical stressors in risk assessment. *Current Opinion in Toxicology* 22: 25-29.
[86] Couch, S. R., and C.J. Coles (2011). Community Stress, Psychosocial Hazards, and EPA Decision-Making in Communities Impacted by Chronic Technological Disasters. *American Journal of Public Health,* 101(S1), S140-S148.
[87] Gee, G.C., and D.C. Payne-Sturges (2004). Environmental Health Disparities: A Framework Integrating Psychosocial and Environmental Concepts. *Environmental Health Perspectives,* 112(17), 1645-1653.
[88] McEwen, B.S., and P. Tucker (2011). Critical Biological Pathways for Chronic Psychosocial Stress and Research Opportunities to Advance the Consideration of Stress in Chemical Risk Assessment. *American Journal of Public Health,* 101(S1), S131-S139.
[89] Padula, A.M., Z. Rivera-Núñez, and E.S. Barrett (2020). Combined Impacts of Prenatal Environmental Exposures and Psychosocial Stress on Offspring Health: Air Pollution and Metals. *Current Environmental Health Report* 7: 89–100.
[90] U.S. EPA (2023). Draft Risk Evaluation for Tris(2-chloroethyl) Phosphate (TCEP), Table 5-69.
[91] U.S. EPA (2023). Draft Risk Evaluation for Tris(2-chloroethyl) Phosphate (TCEP), Table 5-69.
[92] National Research Council (2009). Science and Decisions: Advancing Risk Assessment, Table 4-1.
[93] WHO (2017). Guidance document on evaluating and expressing uncertainty in hazard characterization. Harmonization project document 11, 2nd edition, Table 4.5. https://www.who.int/publications/i/item/9789241513548.

exposure to multiple consumer products or who experience general population exposures. EPA says that these exposures were not aggregated because it did not have data indicating such co-exposures. EPA should not require chemical-specific evidence to conduct aggregate exposure evidence. It can reasonably model scenarios in which exposures are combined across products and across worker, consumer and general population exposures. For example, some individuals with occupational exposure to TCEP are likely to live close to where they work and would therefore also be exposed as members of the general population.

Other chemical and non-chemical stressors. EPA's approach to consideration of other stressors in identifying PESS and accounting for risks to PESS is too narrow. EPA mentions experimental findings of benzo-a-pyrene interactions with TCEP, but does not specifically identify persons with exposure to benzo-a-pyrene as PESS and makes no effort to account for the elevated risks arising from those exposures. Further, EPA does not give any consideration to other chemical stressors that share common adverse outcomes with TCEP. For example, the draft risk evaluation identifies "differences in numbers and degeneration of seminiferous tubules" as the "Most Critical Endpoint" among TCEP non-cancer effects.[94] EPA's 2023 draft document on application of cumulative risk assessment to phthalates under TSCA discusses the extensive experimental evidence of seminiferous tubule atrophy/degeneration from phthalate exposure and finds that it is "a sensitive, adverse effect frequently reported by board certified pathologists."[95]

EPA should consider males who experienced prenatal exposure to phthalates as a PESS for the TCEP Draft Risk Evaluation to recognize that pre-existing damage to the seminiferous tubules that may have occurred from phthalate exposure would make males more vulnerable to further harm from TCEP exposure. The consequence of early-life phthalate exposure would be that the risks of male reproductive harm would occur at lower TCEP doses than EPA has estimated in the TCEP Draft Risk Evaluation, and an adjustment factor should be incorporated to account for that increased vulnerability to damage of the seminiferous tubules. In addition, TCEP and phthalates can be used together in polyvinyl chloride,[96] further supporting the joint consideration of TCEP and phthalates under TSCA. Direct experimental evidence of joint action of phthalates and TCEP is not necessary; the joint action can be inferred from the evidence of a common adverse outcome. Populations exposed to other chemicals sharing common adverse effects with TCEP should similarly be identified as PESS.

EPA should expand its identification of PESS based on the factors described above and should expand on the approach of Table 5-69 and Appendix D to develop a comprehensive, consistent, and structured methodology for identifying PESS in all TSCA risk evaluations.

[94] U.S. EPA (2023). Draft Risk Evaluation for Tris(2-chloroethyl) Phosphate (TCEP), p. 289.
[95] U.S. EPA (2023). Draft Proposed Approach for Cumulative Risk Assessment of High-Priority Phthalates and a Manufacturer-Requested Phthalate under the Toxic Substances Control Act, p. 69.
[96] European Union Risk Assessment Report: Tris(2-chloroethyl) Phosphate, TCEP. July 2009. https://echa.europa.eu/documents/10162/2663989d-1795-44a1-8f50-153a81133258

Technical Appendix: Analysis of TCEP non-cancer risk using WHO/IPCS methodology

In the *TCEP Draft Risk Evaluation*, EPA selected male reproductive effects (decreased numbers of seminiferous tubules) for estimation of risks from chronic oral and inhalation exposures. For risk characterization of non-cancer health effects, the TSCA risk evaluation calculates a "margin of exposure" (MOE) for each exposure scenario, which is the ratio of the point of departure (POD) to the exposure level. For the TCEP male reproductive effects, the *TCEP Draft Risk Evaluation* concludes that an MOE of 30 or more indicates that "the risk is not considered to be of concern."[97] EPA's approach to risk characterization does not actually estimate risks of adverse effects in the population with chronic exposure to TCEP, but instead simply applies a "bright line" judgment of whether or not the MOE is adequate. A more informative approach for both risk characterization and risk management would be to apply the probabilistic dose-response assessment methods of the International Programme on Chemical Safety (IPCS),[98] part of the World Health Organization (WHO), to estimate the risk of adverse effects at various levels of exposure. The IPCS methodology has previously been described and applied in several peer-reviewed journal articles.[99,100,101,102,103]

We applied the IPCS approach for "quantal-deterministic" endpoints and the "approximate probabilistic" calculation (see IPCS report Fig 3.5, panel C)[104] to estimate risks of reduced numbers of seminiferous tubules from chronic oral and inhalation exposure to TCEP. The analysis involved the following steps:

1. Derivation of IPCS POD and corresponding uncertainty adjustments
2. Application of study duration adjustments
3. Application of interspecies adjustments
4. Application of intraspecies adjustments
5. Calculation of HD_M^I - the human dose (HD) of TCEP associated with a particular magnitude of effect M at a particular population incidence I.

For each aspect of the analysis, including the values used to derive the IPCS POD and the adjustment factors applied to derive the HD_M^I, the IPCS methodology uses a 50th percentile value (P50) as a central estimate and the ratio of 95th percentile to 50th percentile (P95/P50) as a measure of uncertainty. All POD and HD_M^I values presented in this analysis are for continuous exposures.

We demonstrate each of these steps starting with the EPA oral exposure POD to derive a set of oral HD_M^I values for different levels of population incidence, then discuss derivation of a corresponding set of inhalation exposure HD_M^I values.

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[97] U.S. EPA (2023). Draft Risk Evaluation for Tris(2-chloroethyl) Phosphate (TCEP), p. 296.

[98] World Health Organization, International Programme on Chemical Safety (2017). Guidance document on evaluating and expressing uncertainty in hazard characterization, 2nd edition.

[99] Chiu WA, Slob W. A Unified Probabilistic Framework for Dose–Response Assessment of Human Health Effects. Environmental Health Perspectives, 2015 December;123(12): 1241–1254. doi:10.1289/ehp.1409385.

[100] Nielsen, G. H., Heiger-Bernays, W. J., Levy, J. I., White, R. F., Axelrad, D. A., Lam, J., Chartres, N., Abrahamsson, D. P., Rayasam, S. D. G., Shaffer, R. M., Zeise, L., Woodruff, T. J., Ginsberg, G. L. (2023). Application of probabilistic methods to address variability and uncertainty in estimating risks for non-cancer health effects. Environ Health, 21(Suppl 1), 129. https://doi.org/10.1186/s12940-022-00918-z.

[101] Chiu WA, Axelrad DA, Dalaijamts C, Dockins C, Shao K, Shapiro AJ, Paoli G. Beyond the RfD: broad application of a probabilistic approach to improve chemical dose-response assessment for non-cancer effects. Environmental Health Perspectives, 2018 June;126(6):067009. doi:10.1289/EHP3368.

[102] Blessinger T, Davis A, Chiu WA, Stanek J, Woodall GM, Gift J, Thayer KA, Bussard D. Application of a unified probabilistic framework to the dose-response assessment of acrolein. Environment International, 2020 October;143:105953. doi: 10.1016/j.envint.2020.105953

[103] Chiu WA, Paoli GM. Recent Advances in Probabilistic Dose–Response Assessment to Inform Risk-Based Decision Making. Risk Analysis, 2021 April;41(4):596-609. doi: 10.1111/risa.13595.

[104] World Health Organization, International Programme on Chemical Safety (2017). Guidance document on evaluating and expressing uncertainty in hazard characterization, 2nd edition.

STEP 1: Derivation of IPCS POD and corresponding uncertainty adjustments

The IPCS methodology requires the use of an ED_{50} (median effective dose) value as the POD for quantal-deterministic endpoints. Since an ED_{50} is not available from the EPA risk evaluation, we began with EPA's benchmark dose, lower confidence limit (BMDL) and applied adjustments provided by the IPCS methodology. At the same time, we incorporated quantitative uncertainties for each of these adjustments.

EPA used a benchmark response (BMR) of 5% to derive the BMDL for decreased numbers of seminiferous tubules from TCEP exposure. The chronic oral non-cancer $BMDL_{05}$ value expressed as a human equivalent dose (HED) is 2.73 mg/kg-d.[105]

The first POD adjustment in the IPCS methodology is to convert the $BMDL_{05}$ to a BMD_{05} as follows:

$$BMD_{05}(HED) = BMDL_{05}(HED) \times (BMD_{05} / BMDL_{05})$$

This adjustment is used because the *Draft TCEP Risk Evaluation* does not report the BMD_{05} as an HED. However, both the BMD_{05} and $BMDL_{05}$ are available in terms of the animal dosage, before derivation of the HED, and can be used for computation of the BMD_{05} / $BMDL_{05}$ ratio. The necessary values for this ratio were obtained from EPA's supplemental file of BMD modeling results,[106] and the ratio calculated as follows:

$$BMD_{05} / BMDL_{05} = 28.8 / 20.8 = 1.38$$

The $BMD_{05}(HED)$ is then:

$$BMD_{05}(HED) = 2.73 \text{ mg/kg-d} \times 1.38 = 3.77 \text{ mg/kg-d}$$

In the IPCS methodology, uncertainty in the BMD is represented by the P95/P50 ratio, which is equal to the same ratio of BMD / BMDL, or 1.38.

The second POD adjustment is to convert from the BMD to an ED_{50}. The ED_{50} and its uncertainty are determined by applying the following conversion from Chiu et al. 2018: "if ED50 not reported: BMD at the reported BMR is multiplied by an additional factor of 3.0; additional uncertainty through adding 1.5^2 to $(P95/P50)^2$."[107]

The median (P50) estimate of the ED_{50} is then derived by multiplying the $BMDL_{05}(HED)$ by the two adjustment factors (P50). The uncertainty adjustments (P95/P50) for each POD aspect are combined into a composite P95/P50 value. In the IPCS approximate probabilistic calculation template, those values are entered as follows:

[105] U.S. EPA (2023). Draft Risk Evaluation for Tris(2-chloroethyl) Phosphate (TCEP), Table 5-49.
[106] U.S. EPA (2023). Draft Risk Evaluation for Tris(2-chloroethyl) Phosphate (TCEP) Supplemental File: Benchmark Dose Modeling Results for TCEP, Table 1-2.
[107] Chiu WA, Axelrad DA, Dalaijamts C, Dockins C, Shao K, Shapiro AJ, Paoli G. Beyond the RfD: broad application of a probabilistic approach to improve chemical dose-response assessment for non-cancer effects. Environmental Health Perspectives, 2018 June;126(6):067009. Figure 4. doi:10.1289/EHP3368.

Determination of point of departure (POD) and its uncertainty[a] for probabilistic dose-response analysis of oral chronic TCEP exposure		
Aspect	**P50**	**P95/P50**
$BMDL_{05}$(HED)[b]	2.73 mg/kg-d	1
BMD/BMDL ratio[c]	1.38	1.38
BMD-to-ED_{50} adjustment[d]	3.0	1.5
IPCS POD = ED_{50}(HED)	**11.3 mg/kg-d**[e]	**1.68**[f]

[a] Uncertainty is expressed as the ratio of the 95th percentile (P95) to the 50th percentile (P50)
[b] U.S. EPA (2023). Draft Risk Evaluation for Tris(2-chloroethyl) Phosphate (TCEP), Table 5-49.
[c] U.S. EPA (2023). Draft Risk Evaluation for Tris(2-chloroethyl) Phosphate (TCEP) Supplemental File: Benchmark Dose Modeling Results for TCEP, Table 1-2.
[d] Chiu WA, Axelrad DA, Dalaijamts C, Dockins C, Shao K, Shapiro AJ, Paoli G. Beyond the RfD: broad application of a probabilistic approach to improve chemical dose-response assessment for non-cancer effects. Environmental Health Perspectives, 2018 June;126(6):067009, Figure 4.
[e] ED_{50}(HED) = $BMDL_{05}$(HED) x BMD/BMDL ratio x BMD-to-ED_{50} adjustment
[f] (Composite P95/P50) = $10^{[(\log 1)^2 + (\log 1.38)^2 + (\log 1.5)^2]^{0.5}} = 1.68$

Step 2: Application of study duration (subchronic-to-chronic) adjustments

In the study by Chen et al. that provides the finding of male reproductive effects and the $BMDL_{05}$ used by EPA for estimating risks, mice were exposed for a subchronic duration of 35 days rather than a chronic duration.[108] The section of the *TCEP Draft Risk Evaluation* on determination of the benchmark MOE[109] makes no mention of the subchronic-to-chronic study duration uncertainty factor that is usually applied to account for the lower dose that may produce the same effect if a chronic study were conducted, even though this is a standard element of EPA's methodology for non-cancer dose-response assessment.[110] We applied the IPCS adjustments for subchronic-to-chronic study duration: a central estimate (P50) of 2, and representing uncertainty with a P95/P50 factor of 4.[111]

In the IPCS approximate probabilistic calculation template, those values are entered as follows:

Duration adjustments ($AF_{Subchronic}$) for probabilistic dose-response analysis of chronic TCEP exposure		
Aspect	**P50**	**P95/P50**

[108] Chen, G; Jin, Y; Wu, Y; Liu, L; Fu, Z. (2015). Exposure of male mice to two kinds of organophosphate flame retardants (OPFRs) induced oxidative stress and endocrine disruption. Environ Toxicol Pharmacol 40: 310-318.
[109] U.S. EPA (2023). Draft Risk Evaluation for Tris(2-chloroethyl) Phosphate (TCEP), p. 286, "Uncertainty Factors Used for Non-cancer Endpoints."
[110] U.S. EPA (2002). A Review of the Reference Dose and Reference Concentration Processes, p. 4-45. EPA/630/P-02/002F.
[111] World Health Organization, International Programme on Chemical Safety (2017). Guidance document on evaluating and expressing uncertainty in hazard characterization, 2nd edition, Table 4.2.

$AF_{Subchronic}$	2	4

Step 3: Application of interspecies (animal-to-human) adjustments

For interspecies (animal-to-human) adjustments, the IPCS methodology first considers a factor for body-size scaling, and then a factor for remaining toxicokinetic (TK) and toxicodynamic (TD) differences. Since the determination of the EPA $BMDL_{05}$ values incorporate dosimetric adjustments, no further adjustment for body size is necessary (P50 = 1). The uncertainty in the bodyweight scaling is not quantified in this analysis (P95/P50 = 1).

For the TK/TD differences remaining after bodyweight scaling, the IPCS report recommends a central estimate (P50) of 1 (i.e., no additional interspecies differences) and representing uncertainty with a P95/P50 factor of 3.[112] We incorporated these IPCS recommendations, which are entered In the IPCS approximate probabilistic calculation template as follows:

Interspecies adjustments ($AF_{Interspecies}$) for probabilistic dose-response analysis of chronic TCEP exposure		
Aspect	**P50**	**P95/P50**
$AF_{Interspecies-BS}$	1	1
$AF_{Interspecies-TK/TD}$	1	3

Step 4: Application of intraspecies (human variability) adjustments

In the IPCS methodology, the value of the human variability adjustment factor ($AF_{intraspecies}$) varies depending on the incidence of the adverse effect in the exposed population – with a larger adjustment factor necessary to extrapolate from the POD to lower levels of incidence. The IPCS report provides $AF_{intraspecies}$ for several incidence (I) values. The P50 and P95/P50 values for $AF_{intraspecies}$ provided by IPCS for several values of I, along with additional values of I of interest for this analysis, are provided in the following table:

[112] World Health Organization, International Programme on Chemical Safety (2017). Guidance document on evaluating and expressing uncertainty in hazard characterization, 2nd edition, Table 4.3.

Lognormal approximation of uncertainty distributions for intraspecies variability ($AF_{Intraspecies}$) for varying levels of population incidence (I)		
Incidence (I)	**$AF_{Intraspecies}$**	
	P50	**P95/P50**
5%[a]	4.98	2.82
2.5%[b]	6.77	3.43
1%[a]	9.69	4.32
0.1% (1-in-1,000)[a]	20.42	6.99
0.01% (1-in-10,000)[a]	37.71	10.39
0.001% (1-in-100,000)[b]	64.25	14.65

[a] IPCS Table 4.5
[b] Calculated for this analysis using the same methods that were used to derive IPCS Table 4.5

Step 5: Calculation of HD_M^I

The output of the IPCS methodology is generically described as an HD_M^I value – the human dose (HD) associated with a particular magnitude of effect M at a particular population incidence I. For this analysis, the "M" represents the male reproductive effect of reduced numbers of seminiferous tubules. The following tables present the HD_M^I results for I = 5%, 2.5%, 1%, 0.1%, 0.01%, and 0.001% using the POD, $AF_{Subchronic}$, $AF_{Interspecies}$, and $AF_{Intraspecies}$ values shown above.

The IPCS approach is a probabilistic method, so the HD_M^I is a distribution; selected values from that distribution are presented in the tables as follows:

- P05: 5th percentile estimate (lower confidence limit) of HD_M^I (this value is shown in **bold**)
- P50: 50th percentile estimate (median) of HD_M^I
- P95: 95th percentile estimate (upper confidence limit) of HD_M^I.

Calculation of HD_M^I for chronic oral exposure to TCEP: reduced numbers of seminiferous tubules (Incidence = 5%)		
Aspect	**P50**	**P95/P50**
$BMDL_{05}$(HED)	2.73 mg/kg-d	1
BMD/BMDL ratio	1.38	1.38
BMD-to-ED_{50} adjustment	3.0	1.5
IPCS POD = ED_{50}(HED)	**11.3 mg/kg-d**	**1.68**
$AF_{Subchronic}$	2	4
$AF_{Interspecies\text{-}BS}$	1	1
$AF_{Interspecies\text{-}TK/TD}$	1	3
$AF_{Intraspecies\ (I=5\%)}$	4.98	2.82
HD_M^I	1.14 mg/kg-d[a]	8.29[b]
	P05	**P95**
$HD_M^{I\ (c)}$	**0.14 mg/kg-d**	9.4 mg/kg-d

[a] HD_M^I (P50) = IPCS POD / ($AF_{Subchronic}$ x $AF_{Interspecies\text{-}BS}$ x $AF_{Interspecies\text{-}TK/TD}$ x $AF_{Intraspecies}$)
[b] (Composite P95/P50) = $10^{[(\log 1.68)^2 + (\log 4)^2 + (\log 1)^2 + (\log 3)^2 + (\log 2.82)^2]^{0.5}} = 8.29$
[c] HD_M^I (P05) = HD_M^I (P50) / (Composite P95/P50)
HD_M^I (P95) = HD_M^I (P50) x (Composite P95/P50)

Calculation of HD_M^I for chronic oral exposure to TCEP: reduced numbers of seminiferous tubules (Incidence = 2.5%)		
Aspect	**P50**	**P95/P50**
$BMDL_{05}$(HED)	2.73 mg/kg-d	1
BMD/BMDL ratio	1.38	1.38
BMD-to-ED_{50} adjustment	3.0	1.5
IPCS POD = ED_{50}(HED)	**11.3 mg/kg-d**	**1.68**
$AF_{Subchronic}$	2	4
$AF_{Interspecies-BS}$	1	1
$AF_{Interspecies-TK/TD}$	1	3
$AF_{Intraspecies\ (I=2.5\%)}$	6.77	3.43
HD_M^I	0.84 mg/kg-d[a]	9.19[b]
	P05	**P95**
$HD_M^{I\ (c)}$	**0.09 mg/kg-d**	7.7 mg/kg-d

[a] HD_M^I (P50) = IPCS POD / ($AF_{Subchronic}$ x $AF_{Interspecies-BS}$ x $AF_{Interspecies-TK/TD}$ x $AF_{Intraspecies}$)
[b] (Composite P95/P50) = $10^{[(\log 1.68)^2 + (\log 4)^2 + (\log 1)^2 + (\log 3)^2 + (\log 3.43)^2]^{0.5}} = 9.19$
[c] HD_M^I (P05) = HD_M^I (P50) / (Composite P95/P50)
HD_M^I (P95) = HD_M^I (P50) x (Composite P95/P50)

Calculation of HD_M^I for chronic oral exposure to TCEP: reduced numbers of seminiferous tubules (Incidence = 1%)		
Aspect	**P50**	**P95/P50**
$BMDL_{05}$(HED)	2.73 mg/kg-d	1
BMD/BMDL ratio	1.38	1.38
BMD-to-ED_{50} adjustment	3.0	1.5
IPCS POD = ED_{50}(HED)	**11.3 mg/kg-d**	**1.68**
$AF_{Subchronic}$	2	4
$AF_{Interspecies\text{-}BS}$	1	1
$AF_{Interspecies\text{-}TK/TD}$	1	3
$AF_{Intraspecies\ (I=1\%)}$	9.69	4.32
HD_M^I	0.59 mg/kg-d[a]	10.53[b]
	P05	**P95**
$HD_M^{I\ (c)}$	**0.06 mg/kg-d**	6.2 mg/kg-d

[a] HD_M^I (P50) = IPCS POD / ($AF_{Subchronic}$ x $AF_{Interspecies\text{-}BS}$ x $AF_{Interspecies\text{-}TK/TD}$ x $AF_{Intraspecies}$)
[b] (Composite P95/P50) = $10^{[(\log 1.68)^2 + (\log 4)^2 + (\log 1)^2 + (\log 3)^2 + (\log 4.32)^2]^{0.5}} = 10.53$
[c] HD_M^I (P05) = HD_M^I (P50) / (Composite P95/P50)
HD_M^I (P95) = HD_M^I (P50) x (Composite P95/P50)

Calculation of HD_M^I for chronic oral exposure to TCEP: reduced numbers of seminiferous tubules (Incidence = 0.1%)		
Aspect	**P50**	**P95/P50**
$BMDL_{05}$(HED)	2.73 mg/kg-d	1
BMD/BMDL ratio	1.38	1.38
BMD-to-ED_{50} adjustment	3.0	1.5
IPCS POD = ED_{50}(HED)	**11.3 mg/kg-d**	**1.68**
$AF_{Subchronic}$	2	4
$AF_{Interspecies\text{-}BS}$	1	1
$AF_{Interspecies\text{-}TK/TD}$	1	3
$AF_{Intraspecies\ (I=0.1\%)}$	20.42	6.99
HD_M^I	0.28 mg/kg-d[a]	14.58[b]
	P05	**P95**
$HD_M^{I\ (c)}$	**0.02 mg/kg-d**	4.0 mg/kg-d

[a] HD_M^I (P50) = IPCS POD / ($AF_{Subchronic}$ x $AF_{Interspecies\text{-}BS}$ x $AF_{Interspecies\text{-}TK/TD}$ x $AF_{Intraspecies}$)
[b] (Composite P95/P50) = $10^{[(\log 1.68)^2 + (\log 4)^2 + (\log 1)^2 + (\log 3)^2 + (\log 6.99)^2]^{0.5}} = 14.58$
[c] HD_M^I (P05) = HD_M^I (P50) / (Composite P95/P50)
HD_M^I (P95) = HD_M^I (P50) x (Composite P95/P50)

Calculation of HD_M^I for chronic oral exposure to TCEP: reduced numbers of seminiferous tubules (Incidence = 0.01%)		
Aspect	**P50**	**P95/P50**
$BMDL_{05}$(HED)	2.73 mg/kg-d	1
BMD/BMDL ratio	1.38	1.38
BMD-to-ED_{50} adjustment	3.0	1.5
IPCS POD = ED_{50}(HED)	**11.3 mg/kg-d**	**1.68**
$AF_{Subchronic}$	2	4
$AF_{Interspecies\text{-}BS}$	1	1
$AF_{Interspecies\text{-}TK/TD}$	1	3
$AF_{Intraspecies\ (I=0.01\%)}$	37.71	10.39
HD_M^I	0.15 mg/kg-d[a]	19.68[b]
	P05	**P95**
$HD_M^{I\ (c)}$	**0.008 mg/kg-d**	3.0 mg/kg-d

[a] HD_M^I (P50) = IPCS POD / ($AF_{Subchronic}$ x $AF_{Interspecies\text{-}BS}$ x $AF_{Interspecies\text{-}TK/TD}$ x $AF_{Intraspecies}$)
[b] (Composite P95/P50) = $10^{[(\log 1.68)^2 + (\log 4)^2 + (\log 1)^2 + (\log 3)^2 + (\log 10.39)^2]^{0.5}} = 19.68$
[c] HD_M^I (P05) = HD_M^I (P50) / (Composite P95/P50)
HD_M^I (P95) = HD_M^I (P50) x (Composite P95/P50)

Calculation of HD_M^I for chronic oral exposure to TCEP: reduced numbers of seminiferous tubules (Incidence = 0.001%)		
Aspect	**P50**	**P95/P50**
$BMDL_{05}$(HED)	2.73 mg/kg-d	1
BMD/BMDL ratio	1.38	1.38
BMD-to-ED_{50} adjustment	3.0	1.5
IPCS POD = ED_{50}(HED)	**11.3 mg/kg-d**	**1.68**
$AF_{Subchronic}$	2	4
$AF_{Interspecies\text{-}BS}$	1	1
$AF_{Interspecies\text{-}TK/TD}$	1	3
$AF_{Intraspecies\ (I=0.001\%)}$	64.25	14.65
HD_M^I	0.09 mg/kg-d[a]	25.96[b]
	P05	**P95**
$HD_M^{I\ (c)}$	**0.003 mg/kg-d**	2.3 mg/kg-d

[a] HD_M^I (P50) = IPCS POD / ($AF_{Subchronic}$ x $AF_{Interspecies\text{-}BS}$ x $AF_{Interspecies\text{-}TK/TD}$ x $AF_{Intraspecies}$)
[b] (Composite P95/P50) = $10^{[(\log 1.68)^2 + (\log 4)^2 + (\log 1)^2 + (\log 3)^2 + (\log 14.65)^2]^{0.5}} = 25.96$
[c] HD_M^I (P05) = HD_M^I (P50) / (Composite P95/P50)
HD_M^I (P95) = HD_M^I (P50) x (Composite P95/P50)

The above tables present HD_M^I values for oral exposure to TCEP. The corresponding values for inhalation exposure can be derived in two ways, which each provide the same results:

1. Multiply oral HD_M^I values by a factor of 5.44 mg/m^3 per mg/kg-d. This factor is obtained from information provided in the *TCEP Draft Risk Evaluation*.[113]
2. Replace EPA's oral $BMDL_{05}$ (2.73 mg/kg-d) in the above tables with EPA's inhalation $BMDL_{05}$ (14.9 mg/m^3) and recalculate the ED_{50} and the HD_M^I values using the same adjustments.

The National Academies and the WHO/IPCS have both recommended using the lower confidence limit (LCL) on a probabilistic dose-response distribution for use in decision-making, in place of a traditional reference dose (RfD) or reference concentration (RfC). The National Academies said in *Science and Decisions* that:

> multiple risk-specific doses could be provided…in the various risk characterizations that EPA produces to aid environmental decision-making.[114]

[113] U.S. EPA (2023). Draft Risk Evaluation for Tris(2-chloroethyl) Phosphate (TCEP), p. 530, Equation_Apx J-3.
[114] National Research Council (2009). Science and Decisions: Advancing Risk Assessment, p. 140.

> A Risk-Specific Reference Dose: For quantal effects, the RfD can be defined to be the dose that corresponds to a particular risk specified to be de minimis (for example, 1 in 100,000) at a defined confidence level (for example, 95%) for the toxicity end point of concern.[115]

The WHO/IPCS said:

> the LCL of the HD_M^I can be used as a probabilistic RfD to replace the deterministic RfD. In this case, the probabilistic RfD is the dose that protects the population from a specified magnitude and incidence of effect with a pre-specified per cent coverage (confidence).[116]

Consistent with the guidance from the National Academies and the IPCS, we summarize the above results in the following table of the lower confidence limit (5th percentile or P05) risk-specific doses (HD_M^I) for multiple levels of risk (incidence or I), for both oral and inhalation exposures.

Risk-specific dose estimates for chronic exposure to TCEP: reduced numbers of seminiferous tubules		
Incidence (I)	HD_M^I lower -confidence limit (P05)	
	Oral	Inhalation
5%	0.14 mg/kg-d	0.75 mg/m^3
2.5%	0.09 mg/kg-d	0.50 mg/m^3
1%	0.06 mg/kg-d	0.30 mg/m^3
0.1% (1-in-1,000)	0.02 mg/kg-d	0.10 mg/m^3
0.01% (1-in-10,000)	0.008 mg/kg-d	0.04 mg/m^3
0.001% (1-in-100,000)	0.003 mg/kg-d	0.02 mg/m^3

Interpretation of results

Based on application of the WHO/IPCS methodology to TCEP chronic exposures, we find that:

- 0.06 mg/kg-d is the lower bound (95% confidence) chronic human oral dose and 0.30 mg/m^3 is the lower bound (95% confidence) chronic human inhalation dose at which male reproductive effects are expected in 1% of the population.

[115] National Research Council (2009). Science and Decisions: Advancing Risk Assessment, p. 140.
[116] World Health Organization, International Programme on Chemical Safety (2017). Guidance document on evaluating and expressing uncertainty in hazard characterization, 2nd edition, p. 12.

- 0.02 mg/kg-d is the lower bound (95% confidence) chronic human oral dose and 0.10 mg/m^3 is the lower bound (95% confidence) chronic human inhalation dose at which male reproductive effects are expected in 0.1% of the population.
- 0.008 mg/kg-d is the lower bound (95% confidence) chronic human oral dose and 0.04 mg/m^3 is the lower bound (95% confidence) chronic human inhalation dose at which male reproductive effects are expected in 0.01% (1-in-10,000) of the population.
- EPA's non-cancer risk characterization for oral exposure to TCEP uses 2.73 mg/kg-d as the point of departure, and a benchmark MOE of 30.[117] This means that EPA concludes "the risk is not considered to be of concern"[118] for any chronic oral exposure less than 2.73 mg/kg-d / 30 = 0.09 mg/kg-d. Our analysis finds that the upper bound risk at an oral exposure of 0.09 mg/kg-d is 2.5%, or 1-in-40.
- EPA's non-cancer risk characterization for inhalation exposure to TCEP uses 14.9 mg/m^3 as the point of departure, and a benchmark MOE of 30.[119] This means that EPA concludes "the risk is not considered to be of concern"[120] for any chronic inhalation exposure less than 14.9 mg/m^3 / 30 = 0.50 mg/m^3. Our analysis finds that the upper bound risk at an inhalation exposure of 0.50 mg/m^3 is 2.5%, or 1-in-40.

The estimates of HD_M^I presented here were based entirely on input values and equations available from the WHO/IPCS methodology document and from EPA's *TCEP Draft Risk Evaluation*. An important caveat to these calculations is that the values used to represent human variability may be understated. The IPCS default human variability distribution is based on 37 data sets for human toxicokinetic variability and 34 data sets for human toxicodynamic variability. Most of these data sets were obtained from controlled human exposure studies of pharmaceuticals conducted in small samples of healthy adults, representing considerably less variability than found in the general population.[121,122,123] If human variability is underestimated, then the actual dose associated with each incidence level (e.g. I =1%, I = 0.1%) will be lower than the values obtained from this analysis – or in other words, risk at each dose will be underestimated.

[117] U.S. EPA (2023). Draft Risk Evaluation for Tris(2-chloroethyl) Phosphate (TCEP), Table 5-56.
[118] U.S. EPA (2023). Draft Risk Evaluation for Tris(2-chloroethyl) Phosphate (TCEP), p. 296.
[119] U.S. EPA (2023). Draft Risk Evaluation for Tris(2-chloroethyl) Phosphate (TCEP), Table 5-56.
[120] U.S. EPA (2023). Draft Risk Evaluation for Tris(2-chloroethyl) Phosphate (TCEP), p. 296.
[121] WHO. (2017). *Guidance document on evaluating and expressing uncertainty in hazard characterization. Harmonization project document 11, 2nd edition.* https://www.who.int/publications/i/item/9789241513548.
[122] Hattis, D., Lynch, M.K. (2007). Empirically observed distributions of pharmacokinetic and pharmacodynamic variability in humans—Implications for the derivation of single-point component uncertainty factors providing equivalent protection as existing reference doses. In Lipscomb, J.C. & Ohanian, E.V. (Eds.), *Toxicokinetics in risk assessment* (pp. 69-93). Taylor & Francis Group. https://doi.org/10.1201/b14275.
[123] Axelrad, D. A., Setzer, R. W., Bateson, T. F., DeVito, M., Dzubow, R. C., Fitzpatrick, J. W., Frame, A. M., Hogan, K. A., Houck, K., Stewart, M. (2019). Methods for evaluating variability in human health dose-response characterization. Hum Ecol Risk Assess, 25, 1-24. https://doi.org/10.1080/10807039.2019.1615828.

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.

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[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

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[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

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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.

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[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]

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[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

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[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

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[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

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[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

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[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

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[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]

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[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

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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,

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[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

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[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

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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

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[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

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[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

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[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

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[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

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[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

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[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

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[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

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[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

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[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 . . .

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[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

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[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

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[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

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[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"

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[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

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[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

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[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,

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[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,

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[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

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[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

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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.

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[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

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[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

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[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

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[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

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[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

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[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

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[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

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[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

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[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-

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[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.

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[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

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[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.

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[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.

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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,

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Natural Resources Defense Council
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