

**Comments of the Attorneys General of Massachusetts, California, Delaware, Illinois,
Maryland, Minnesota, New Jersey, New Mexico, New York, Oregon, Rhode Island,
Washington, Wisconsin, the District of Columbia, and the Corporation Counsel of the City
of New York**

August 17, 2026

Via electronic submission to www.regulations.gov

**Re: Docket ID No. EPA-HQ-OPPT-2018-0462; Multistate Comments in Response to the
U.S. Environmental Protection Agency’s Draft 4,4’-(1-Methylethylidene)bis[2,6-
dibromophenol] (TBBPA) Risk Evaluation Under the Toxic Substances Control Act**

The Attorneys General of Massachusetts, California, Delaware, Illinois, Maryland, Minnesota, New Jersey, New Mexico, New York, Oregon, Rhode Island, Washington, Wisconsin, the District of Columbia, and the Corporation Counsel of the City of New York (together, the “States”) submit these comments regarding the U.S. Environmental Protection Agency’s (“EPA”) Draft 4,4’-(1-Methylethylidene)bis[2,6-dibromophenol] (“TBBPA”) Risk Evaluation Under the Toxic Substances Control Act (“TSCA”) (“Draft Risk Evaluation”).¹ TBBPA is a widely used brominated flame retardant. Exposure to TBBPA may result in detrimental health impacts, including diseases associated with its neuro-, immuno-, and reproductive toxicities and cancer, and infants and children are particularly vulnerable to TBBPA exposure. In the Draft Risk Evaluation, although EPA preliminarily determines that TBBPA poses an unreasonable risk to human health and the environment, EPA violates TSCA by considering only an extremely limited universe of the known uses for TBBPA and failing to consider the holistic exposures to populations including workers, consumers, and the general population. Of the twenty-four COUs EPA did consider for the highly toxic substance TBBPA, the agency proposes to conclude that only four of them contribute to TBBPA’s unreasonable risk to health and the environment.

EPA’s Draft Risk Evaluation also violates TSCA by failing to consider a class-based analysis of flame retardants like TBBPA and ignoring aggregate and cumulative risks. If the Draft Risk Evaluation is finalized in its current form, it would also be arbitrary and capricious in violation of the federal Administrative Procedure Act (“APA”) for failing to account for the States’ reliance interests while threatening to undermine existing protections several of the undersigned States have adopted to restrict the use of TBBPA to protect our residents against its harmful health effects.

Accordingly, EPA should withdraw the Draft Risk Evaluation. In issuing any future risk evaluation for TBBPA, EPA should revise the cancer hazard assessment to find that TBBPA is “Likely to Be Carcinogenic to Humans” and conduct dose-response assessment with a linear no-threshold model in accordance with EPA’s Guidelines for Carcinogen Risk Assessment; revise the non-cancer hazard assessment and risk characterization to fully account for neurobehavioral

¹ See Notice of Availability and Request for Comment, 91 Fed. Reg. 36,138 (June 16, 2026).

and thyroid effects of TBBPA; and re-evaluate the risks posed by TBBPA in a manner that complies with the agency’s obligations under TSCA, consistent with the best available science and its own guidelines, to conduct a thorough evaluation of the risks presented by this highly toxic chemical substance so that all unreasonable risks can be fully addressed during risk management.

I. Background of EPA’s Action

a. Brief History of TSCA

Congress enacted TSCA, 15 U.S.C. §§ 2601, et seq., in 1976 for the express purpose of “prevent[ing] unreasonable risks of injury to health or the environment associated with the manufacture, processing, distribution in commerce, use, or disposal of chemical substances.”² To that end, TSCA authorized EPA “to look at the hazards in total,”³ and to assess for regulation the “chemicals themselves”—as opposed to looking only at individual products containing chemicals, or specific chemical discharges and emissions.⁴

In 2016, Congress, recognizing that TSCA was failing in its purpose, passed the Frank R. Lautenberg Chemical Safety for the 21st Century Act (the “Lautenberg Act”)⁵ with bipartisan support, reforming TSCA to more effectively carry out its purpose of preventing unreasonable risks of injury to health and the environment. Notably, under the Lautenberg Act, Section 6 of TSCA now provides that if EPA determines “that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance . . . presents an unreasonable risk of injury to health or the environment,” EPA must take regulatory measures—up to and including a complete prohibition on use and distribution—“to the extent necessary so that the chemical substance . . . no longer presents such risk.”⁶ Under the amended Act, EPA is also no longer required to use the least burdensome means to address a chemical’s risk to health or the environment.⁷

To carry out the goal of minimizing risk to health and the environment, the Lautenberg Act created a comprehensive risk evaluation process, which is triggered upon designation of a chemical substance as high priority.⁸ Through this process, EPA must determine whether a chemical “presents an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors.”⁹ Among other things, that analysis must consider any “unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant to the risk evaluation by [EPA], under the conditions of use.”¹⁰ The Act defines

² S. Rep. No. 94-698, at 1 (1976); *see Safer Chems. v. EPA*, 943 F.3d 397, 406–07 (9th Cir. 2019) (discussing Congress’s purpose in enacting TSCA).

³ S. Rep. No. 94-698, *supra* note 2, at 2 (1976).

⁴ *Safer Chems.*, 943 F.3d at 406.

⁵ Pub. L. No. 114-182, 130 Stat. 448 (2016) (codified at 15 U.S.C. §§ 2601, et seq.).

⁶ 15 U.S.C. § 2605(a).

⁷ *See id.*; H. Rep. No. 114-176, at 23 (2015).

⁸ *See* 15 U.S.C. § 2605(b); H. Rep. No. 114-176 at 23–25.

⁹ 15 U.S.C. § 2605(b)(4)(A).

¹⁰ *Id.*

“conditions of use” as “the circumstances, as determined by [EPA], under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of.”¹¹ And a “‘potentially exposed or susceptible subpopulation’ means a group of individuals within the general population identified by [EPA] 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.”¹²

When conducting a risk evaluation, EPA is required to make a determination based on the “weight of scientific evidence,” using the “best available science” and all “reasonably available information.”¹³ EPA is not permitted to consider “costs or other nonrisk factors,”¹⁴ meaning EPA must assess the risk to human health and the environment without regard to “the costs or benefits of the substance or of possible restrictions on the substance” under other statutory schemes.¹⁵

A risk evaluation itself has three linked components. The first component requires EPA to prepare an initial scope document that identifies the focus of the risk evaluation, including the hazards, exposures, conditions of use, and potentially exposed or susceptible subpopulations that EPA expects to consider.¹⁶

The second component requires EPA to analyze “available information” on the hazards and exposures, “including information that is relevant to specific risks of injury to health or the environment.”¹⁷ Among other things, this compels EPA to consider the types of human and environmental hazards, the relationship between the dose of the chemical substance and the health and environmental effects, and all relevant potentially exposed and susceptible subpopulations.¹⁸ EPA must also identify the likely duration, intensity, frequency, and number of exposures to a chemical under the known and expected conditions of use.¹⁹ EPA must then integrate and assess the reasonably available information on hazard and exposure.²⁰

In the third component of the risk evaluation, EPA must determine whether the chemical presents an unreasonable risk to health or the environment.²¹ A determination that a chemical poses no unreasonable risk ends the TSCA process and is deemed “final agency action” subject

¹¹ *Id.* § 2602(4).

¹² *Id.* § 2602(12).

¹³ *Id.* § 2625(h)–(i), (k); 40 C.F.R. § 702.37.

¹⁴ *See id.* § 2605(b)(4)(F).

¹⁵ *See* S. Rep. 114-67, at 17 (2015).

¹⁶ *See* 15 U.S.C. § 2605(b)(4)(D).

¹⁷ *Id.* § 2605(b)(4)(F).

¹⁸ *See id.*

¹⁹ *See id.*

²⁰ *See id.* § 2605(b)(4)(F)(i).

²¹ *See id.* § 2605(b)(4)(A).

to judicial review.²² If EPA determines that a chemical presents an unreasonable risk to health or the environment, the agency must swiftly move to the final stage—risk management.²³

During the risk management stage, EPA must implement rules to eliminate the unreasonable risk, including use restrictions, limitations on production, warning labels, recordkeeping, or product or disposal bans.²⁴

When proposing or promulgating any rule under Section 6(a) of TSCA, 15 U.S.C. § 2605(a), EPA must consider and publish a statement on: the effects of the substance or mixture on health and the magnitude of human exposure; the effects of the substance or mixture on the environment and the magnitude of the environmental exposure; the benefits of using the substance or mixture; the likely economic consequences of a restriction, taking into account the effect on the economy, small business, technological innovation, the environment, and public health; the costs and benefits of the proposed ban or restriction and the primary alternatives considered by EPA; and the cost-effectiveness of the proposed ban or restriction and the primary alternatives considered by EPA.²⁵

EPA must select the means for banning or restricting the substance based on the factors listed above. If a ban or restriction substantially prevents a condition of use, EPA must consider a phase-in of the restriction and whether a technically and economically feasible alternative to the substance will be available when the ban or restriction is in place.²⁶ EPA may exempt critical or essential uses of the substance from bans and restrictions. To grant an exemption, EPA must find that no technically and economically feasible safer alternative is available; that compliance with the ban or restriction would significantly disrupt the national economy, national security, or critical infrastructure; or that the condition of use provides a substantial benefit to health, the environment, or public safety.²⁷

EPA must propose a rule banning or restricting a substance within one year of publication of the risk evaluation and must promulgate a final rule within two years of publication of the risk evaluation. With certain exceptions, these deadlines can be extended for a total of two years.²⁸ The risk management measures adopted by EPA, along with the unreasonable risk determination, are subject to judicial review under TSCA.²⁹

²² *See id.* §§ 2605(i)(1), 2618(a)(1)(A).

²³ *See id.* § 2605(a).

²⁴ *Id.*

²⁵ *Id.* § 2605(c)(2).

²⁶ *Id.* §§ 2605(c)(2)(B)–(C).

²⁷ *Id.* § 2605(g).

²⁸ *Id.* § 2605(c)(1)(C).

²⁹ A final risk evaluation with a determination of no unreasonable risk is immediately subject to judicial review; a determination that there is an unreasonable risk is subject to judicial review only when a final risk management rule is promulgated. *See id.* §§ 2605(i)(2), 2618(a)(1)(A).

It is through this robust process, grounded in science and guided by a mandate to protect health and the environment from unreasonable risk, that TSCA requires EPA to protect the public from toxic substances like TBBPA.

b. Regulation of TBBPA Under TSCA

Bringing to bear the new requirements under the Lautenberg Act, in December 2019, EPA identified TBBPA as one of twenty high-priority substances for risk evaluation.³⁰ A high-priority substance is defined as “a chemical substance that [EPA] concludes, without consideration of costs or other nonrisk factors, may present an unreasonable risk of injury to health or the environment because of a potential hazard and a potential route of exposure under the conditions of use, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by [EPA].”³¹ EPA thereafter issued draft scope documents for public comment, which identified the hazards, exposures, conditions of use, and the potentially exposed and susceptible subpopulations that would ultimately be included in the risk evaluation.³² Certain States and other commenters on EPA’s draft scope document highlighted the multiple ways in which EPA had failed to comply with TSCA’s requirements in the draft scope document, and expressed concern that EPA’s approach would underestimate or incompletely evaluate the significant risk that the high-priority chemicals posed to health and the environment.³³ On September 4, 2020, EPA issued the final scope documents for the high priority chemicals and initiated the risk evaluation process for TBBPA.³⁴

On June 16, 2026, EPA issued the Draft Risk Evaluation, the subject of these comments.³⁵ EPA states that it “used the best available science to prepare the draft risk evaluation and preliminarily determined, based on the weight of scientific evidence, that TBBPA poses unreasonable risk to human health and the environment driven primarily by certain COUs analyzed in the draft risk evaluation.”³⁶ In the Draft Risk Evaluation, preliminarily determines that only *four* of the twenty-four conditions of use that it evaluates significantly contributes to the unreasonable risk of injury of TBBPA to human health or the environment.³⁷ Specifically, EPA preliminarily finds that three conditions of use significantly contribute to the unreasonable

³⁰ See High-Priority Substance Designations Under the Toxic Substances Control Act (TSCA) and Initiation of Risk Evaluation on High-Priority Substances; Notice of Availability, 84 Fed. Reg. 71,924 (Dec. 30, 2019).

³¹ 15 U.S.C. § 2605(b)(1)(B).

³² See Draft Scopes of the Risk Evaluations to Be Conducted for Thirteen Chemical Substances Under the Toxic Substances Control Act; Notice of Availability, 85 Fed. Reg. 19,941 (Apr. 9, 2020).

³³ See e.g., Att’y’s Gen. of N.Y., et al., Comments on Draft Scopes of the Risk Evaluations To Be Conducted for Seven Chemical Substances Under the Toxic Substances Control Act (June 8, 2020), EPA-HQ-OPPT-2019-0131-0046; Env’t Def. Fund, Comments on Draft Scopes of the Risk Evaluations to Be Conducted for Thirteen Chemical Substances Under the Toxic Substances Control Act (May 26, 2020), EPA-HQ-OPPT-2018-0462-0034.

³⁴ Final Scopes of the Risk Evaluations to Be Conducted for Twenty Chemical Substances Under the Toxic Substances Control Act; Notice of Availability, 85 Fed. Reg. 55,281 (Sep. 4, 2020).

³⁵ ENV’T PROT. AGENCY, DRAFT RISK EVALUATION FOR 4,4’-(1-METHYLETHYLIDENE)BIS[2,6-DIBROMOPHENOL] (TBBPA) at 9 (June 2026), EPA-740-D-26-023 (“Draft Risk Evaluation”).

³⁶ 91 Fed. Reg. at 36,139.

³⁷ Draft Risk Evaluation, *supra* note 35, at 9.

risk of TBBPA based on inhalation exposures to workers, and that one condition of use significantly contributes to the unreasonable risk of TBBPA to the environment due to surface water releases.³⁸ EPA also preliminarily determines that the remaining 20 conditions of use do not significantly contribute to the unreasonable risk of injury of TBBPA to human health or the environment.³⁹ EPA further preliminarily concludes that none of TBBPA's conditions of use "significantly contribute to unreasonable risk to [occupational non-users]; consumers, including bystanders; or the general population, including fenceline populations."⁴⁰

II. TBBPA Presents Numerous Health Threats to Our Residents

a. Health Risks from TBBPA

TBBPA is a crystalline solid and "one of the most widely used brominated flame retardants."⁴¹ Brominated flame retardants, like TBBPA, prevalent since the 1970s, aim to reduce the flammability of certain commercial products, including "furniture, circuit boards, textiles, polystyrene foams, epoxy resins, and padding materials."⁴² "TBBPA has historically been the flame retardant with the largest production volume worldwide."⁴³

In the United States, EPA estimates that 100–500 million pounds of TBBPA were produced every year from 1994 to 2011. EPA further estimates that in 2015, 50–100 million pounds of TBBPA were produced, in 2019, 20–100 million pounds of TBBPA were produced, and in 2023, 10–50 million pounds of TBBPA were produced.⁴⁴ In addition, millions of pounds of TBBPA and products containing TBBPA are imported into the United States every year.⁴⁵

TBBPA is used as a reactive flame retardant in plastics and other polymers,⁴⁶ and as an additive flame retardant in those and other materials, integrated into the materials via physical blending and thus capable of release through dust and indoor air in both residential and industrial settings.⁴⁷ TBBPA has strong lipophilic characteristics, allowing it to dissolve readily in fats and oils, enabling bioaccumulation and biomagnification in individual organisms and up food chains, particularly in aquatic ecosystems, while also having a higher solubility in water compared to other brominated flame retardants.⁴⁸

³⁸ *Id.*

³⁹ *Id.*

⁴⁰ *Id.*

⁴¹ *Id.* at 237; 91 Fed. Reg. at 36,139.

⁴² Baoji Miao et al., *A Review on Tetrabromobisphenol A: Human Biomonitoring, Toxicity, Detection and Treatment in the Environment*, 28 MOLECULES 1 (2023), <https://pmc.ncbi.nlm.nih.gov/articles/PMC10054480/>.

⁴³ Draft Risk Evaluation, *supra* note 35, at 17.

⁴⁴ *Id.*

⁴⁵ See Material Research L3C, *Tetrabromobisphenol A (TBBPA): Technical Report on Conditions of Use* (Nov. 21, 2019), EPA-HQ-OPPT-2018-0462-0016.

⁴⁶ Products made from recycled plastic can also contain TBBPA originating from the recycled plastic. Draft Risk Evaluation, *supra* note 35, at 40.

⁴⁷ *Tetrabromobisphenol A Uses in Modern Industry*, GUIDECHEM.COM (June 21, 2024), <https://www.guidechem.com/guideview/lab/tetrabromobisphenol-a-uses.html>; Miao et al., *supra* note 42, at 11.

⁴⁸ Miao et al., *supra* note 42, at 11.

TBBPA exposures pose significant risks to both health and the environment. The expanding body of research around TBBPA has brought to light numerous alarming health impacts associated with exposure to TBBPA,⁴⁹ leading to its classification by the International Agency for Research on Cancer (“IARC”) as a Group 2A Carcinogen in 2016, indicating that it is “probably carcinogenic to humans.”⁵⁰ Two countries have since submitted a proposal to the European Chemicals Agency to reclassify TBBPA as a Group 1B carcinogen under the Classification, Labelling and Packaging Regulation, which would result in immediate bans to its use in food contact materials.⁵¹

EPA’s cancer hazard assessment for TBBPA does not represent the best available science. EPA’s assumption of a threshold for carcinogenic effects is not scientifically justified. In contravention of recommendations by the National Academies,⁵² EPA neglected to consider the additivity of TBBPA to background biology before considering a “safe” dose, or threshold for carcinogens and background chemical exposures that increase circulating estrogen—a “key event[.]” in EPA’s proposed TBBPA mode of action for uterine tumors,⁵³ which are common tumors in U.S. women. Consistent with its own Guidelines for Carcinogen Risk Assessment, EPA should revise the draft hazard assessment for TBBPA to “likely to be carcinogenic to humans” and to quantify the dose-response relationship with a linear no-threshold approach.

In addition to its likely carcinogenic properties, TBBPA is a known endocrine disruptor—a chemical compound that exhibits capacity to disrupt hormonal function within the body—and

⁴⁹ *Id.* at 1–34.

⁵⁰ Yann Grosse, et al., *Carcinogenicity of Some Industrial Chemicals*, 17 THE LANCET 419–20 (2016), https://www.researchgate.net/profile/Heiko_Kaefferlein/publication/318232367_Carcinogenicity_of_some_industrial_chemicals/links/59f218ea458515bfd081cd59/Carcinogenicity-of-some-industrial-chemicals.pdf; Int’l Agency for Rsch. on Cancer (IARC), *Some Industrial Chemicals*, in 15 IARC MONOGRAPHS ON THE EVALUATION OF CARCINOGENIC RISKS TO HUMANS 30, 280 (2018), <https://publications.iarc.who.int/Book-And-Report-Series/Iarc-Monographs-On-The-Identification-Of-Carcinogenic-Hazards-To-Humans/Some-Industrial-Chemicals-2018>.

⁵¹ Statement, Int’l Bromine Council (BSEF), Harmonised Classification and Labelling (CLH) Proposal for Tetrabromobisphenol-A (TBBPA) by Norway & Co-submitted by Denmark (Nov. 20, 2020), <https://www.bsef.com/news/bsef-statement-harmonised-classification-and-labelling-clh-proposal-for-tetrabromobisphenol-a-tbbpa-by-norway-co-submitted-by-denmark/>; see also BENCHCHEM, *Regulatory Status of Tetrabromobisphenol A (TBBPA): A Transatlantic Divergence* (May 2026), https://pdf.benchchem.com/1683/Regulatory_Status_of_Tetrabromobisphenol_A_TBBPA_A_Transatlantic_Divergence.pdf.

⁵² The National Academies of Sciences, Engineering, and Medicine recommended that dose-response modeling analysis always include evaluation of background exposure and susceptibility in order to select modeling approach. The assessment of “background exposure” and “background disease processes” would involve characterization of other chemicals or nonchemical stressors that influence the same general pathologic processes as the chemical under evaluation. Such consideration should aid the evaluation of the shape of the dose-response relationship, including the potential for low-dose linearity and high-risk subpopulations and hence appropriate methodologic approaches for the dose-response analysis. Background exposures and susceptibility factors can result in linear low-dose response relationships that would otherwise be considered low-dose nonlinear on the basis of MOA alone. See Nat’l Rsch. Council, *Science and Decisions: Advancing Risk Assessment* 139 (2009), <https://www.nationalacademies.org/read/12209>.

⁵³ Draft Risk Evaluation, *supra* note 35, at 128.

has been found to exhibit neuro-, immuno-, and reproductive toxicity.⁵⁴ Exposure to TBBPA can negatively impact thyroid and neuroendocrine function, which may lead to the development of metabolic diseases and other similar health conditions.⁵⁵ TBBPA exposure can also alter thyroid and sex hormone levels and affect sperm quality, which can contribute to infertility.⁵⁶ Likewise, TBBPA has been reported to negatively impact neurodevelopment through maternal exposure and has been linked to premature birth.⁵⁷ Moreover, as an endocrine disruptor, TBBPA's impact on the regulation of hormonal systems can lead to "functional disorders and developmental abnormalities across multiple organ systems," which cannot be accounted for by "focusing on isolated systemic effects."⁵⁸ And, endocrine disruption is likely one of the mechanisms by which TBBPA acts to induce cancer.⁵⁹ Despite these many health impacts, in its risk evaluation, EPA inappropriately eliminates thyroid effects in its identification of endpoint for derivation of its Point of Departure for estimation of "safe" dose.⁶⁰

As EPA itself noted, "TBBPA has been found in drinking water, ground water, ambient air, indoor air, fish, human breast milk, and dust and soil."⁶¹ Human exposure to TBBPA can occur via inhalation, ingestion, and dermal routes, with ingestion (including via the mouthing of toys and other articles by children) being the primary manner in which exposure occurs.⁶² Exposure to consumer products that contain TBBPA, at home or within manufacturing facilities has been documented to result in direct exposure via ingestion, inhalation, and dermal means, while indirect pathways such as ingestion of agricultural and other foods due to leaching of TBBPA into ecosystems via contaminated soil or effluent and wastewater, or food processing—resulting in TBBPA frequently being "found in human tissues, serum, and milk."⁶³

⁵⁴ Miao et al., *supra* note 42, at 7–11; Awuchi Chinaza Godswill & Awuchi Chibueze Godspel, *Physiological Effects of Plastic Wastes on the Endocrine System (Bisphenol A, Phthalates, Bisphenol S, PBDEs, TBBPA)*, 4 INT'L J. OF BIOINFORMATICS AND COMPUTATIONAL BIOLOGY 11–29 (2019), https://www.academia.edu/41383823/Physiological_Effects_of_Plastic_Wastes_on_the_Endocrine_System_Bisphenol_A_Phthalates_Bisphenol_S_PBDEs_TBBPA; Yuxing Liao et al., *Environmental Relevant Concentrations of TBBPA Cause Complex Toxicological Mechanisms*, 414 TOXICOLOGY LETTERS 1 (2025), <https://www.sciencedirect.com/science/article/abs/pii/S0378427425027134>; Yongin Kim et al., *Effects of TBBPA Exposure on Neurodevelopment and Behavior in Mice*, 26 INT'L J. OF MOLECULAR SCIS. 1–23 (2025), <https://pmc.ncbi.nlm.nih.gov/articles/PMC12346716/>; Huihui Wu, et al., *Effects of Tetrabromobisphenol A (TBBPA) on the Reproductive Health of Male Rodents: A Systematic Review and Meta-Analysis*, 781 SCI. OF THE TOTAL ENV'T 1 (2021), <https://www.sciencedirect.com/science/article/abs/pii/S0048969721018131>; Kylie Rock et al., *Sex-Specific Behavioral Effects Following Developmental Exposure to Tetrabromobisphenol A (TBBPA) in Wistar Rats*, 75 NEUROTOXICOLOGY 1 (2019), <https://pmc.ncbi.nlm.nih.gov/articles/PMC6935469/>.

⁵⁵ Miao et al., *supra* note 42, at 9; BENCHCHEM, *supra* note 51.

⁵⁶ Miao et al., *supra* note 42, at 8; Wu et al., *supra* note 54.

⁵⁷ Miao et al., *supra* note 42, at 8; Kim et al., *supra* note 54.

⁵⁸ Yuxing Liao et al., *Molecular Mechanisms of Tetrabromobisphenol A (TBBPA) Toxicity: Insights from Various Biological Systems*, 288 ECOTOXICOLOGY AND ENV'T SAFETY 10 (2024), <https://www.sciencedirect.com/science/article/pii/S0147651324014945#sec0130>.

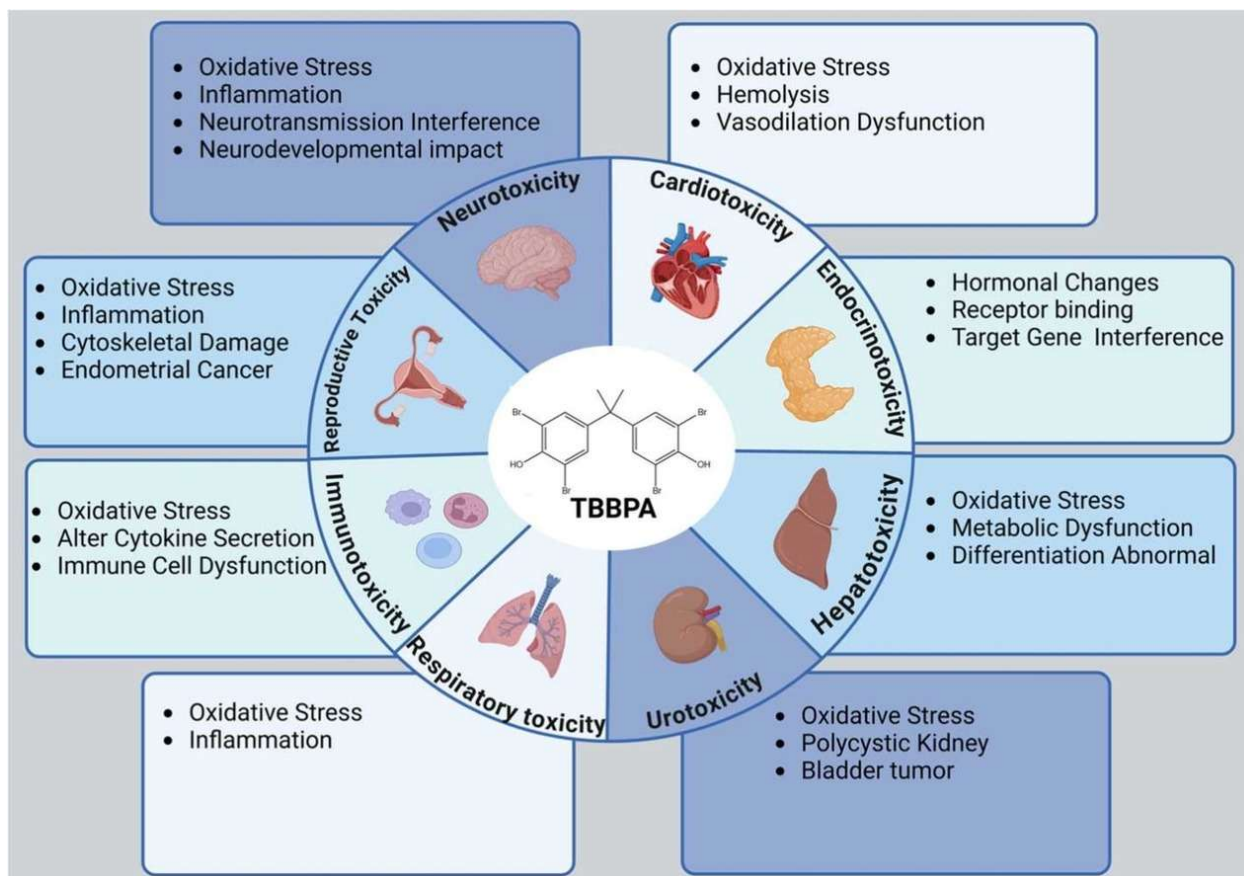
⁵⁹ IARC, *Some Industrial Chemicals*, *supra* note 50, at 280.

⁶⁰ See Draft Risk Evaluation, *supra* note 35 at 125.

⁶¹ 91 Fed. Reg. at 36,139.

⁶² Miao et al., *supra* note 42, at 2–4.

⁶³ Kim et al., *supra* note 54; see also Miao et al., *supra* note 42, at 5.



The figure above provides a visual representation of the numerous bodily systems that can be impacted by TBBPA exposure (Liao et al. (2024), *supra* note 58).

Emerging research has also identified concerning linkages between TBBPA pollution and microplastic pollution, finding that “aging microplastics can bind to TBBPA, inhibiting its degradation in soil and creating composite contaminants that may biomagnify through the food chain, thereby posing greater risks than individual contaminants alone.”⁶⁴ The presence of TBBPA in the environment poses risks to the ecosystems by negatively affecting reproduction, development and survival, and by extension to the health of human populations. In the same way that TBBPA threatens human health and safety, “TBBPA is harmful to a wide range of aquatic organisms and can threaten their reproduction, development, and survival even at relatively lower concentrations.”⁶⁵

In the Draft Risk Evaluation, EPA failed to incorporate the best available science and made several scientifically unsupported assumptions that, if adopted, will result in acceptance of serious risks to human health. EPA has inappropriately concluded that there is a safe level below which there is no risk of cancer from TBBPA. This is contrary to the recommendations of the National Academies of Sciences, Engineering and Medicine.⁶⁶ The evidence instead supports a

⁶⁴ Liao et al. (2024), *supra* note 58, at 10.

⁶⁵ Miao et al., *supra* note 42, at 12.

⁶⁶ *Science and Decisions: Advancing Risk Assessment*, *supra* note 52 at 129–130.

linear no-threshold dose-response model, consistent with EPA's own Guidelines for Carcinogen Risk Assessment.⁶⁷ EPA has also disregarded several relevant animal studies demonstrating neurobehavioral and thyroid effects of TBBPA, without scientific justification.⁶⁸

Moreover, EPA disregarded the best available science for non-cancer risks. For instance, EPA identified neurobehavioral effects as the most sensitive effects of TBBPA exposure but then disregarded these effects when characterizing risks. EPA dismissed effects on the thyroid in its evaluation of TBBPA regardless of the body of evidence demonstrating a consistent pattern of adverse effects on the thyroid. EPA summarized the evidence regarding thyroid effects of TBBPA by stating that “[o]verall, a collection of studies suggests thyroid homeostasis disruption, specifically decreased circulating T4, as a sensitive marker of TBBPA toxicity in rats.”⁶⁹ EPA, however, followed this statement with a conclusion that “the Agency was not confident in the adversity of the identified thyroid health effects and did not consider thyroid toxicity for dose-response analysis given the uncertainties regarding human relevance of the observed TBBPA effects in animal models.”⁷⁰ The impact of omitting the most sensitive and relevant endpoint is a substantial underestimate of the health risks associated with exposure to TBBPA.⁷¹

Despite the wide range of cancer and non-cancer harms indicated by the best available science discussed above, EPA in the Draft Risk Evaluation failed to properly consider many of those impacts, disregarding concerns about endocrine disruption and neuro-, immuno-, and reproductive toxicity, and the full risk of cancer from TBBPA.⁷²

b. Communities Burdened by Environmental Injustice Face Increased Threats from TBBPA

Communities burdened by environmental injustice, including overburdened populations, fenceline communities, and other vulnerable individuals, are potentially exposed or susceptible subpopulations that EPA must consider. Potentially exposed or susceptible subpopulations, “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.”⁷³

Our most vulnerable residents are at heightened risk of harm from TBBPA because the Draft Risk Evaluation fails to properly consider cancer and non-cancer risks, and as discussed further *infra* Section IV, does not undertake a class-based analysis of flame retardants like TBBPA, and ignores aggregate and cumulative risks. EPA's failure to sufficiently consider the

⁶⁷ See EPA, GUIDELINES FOR CARCINOGEN RISK ASSESSMENT 2-54 to 2-58 (March 2005), https://www.epa.gov/sites/default/files/2013-09/documents/cancer_guidelines_final_3-25-05.pdf.

⁶⁸ See e.g., Pamela D. Noye et al., *Evaluating chemicals for thyroid disruption: Opportunities and challenges with in vitro testing and adverse outcome pathway approaches*, 127 ENV'T HEALTH PERSPS. 1 (2019), <https://pubs.acs.org/evhpaz/article/127/9/095001/5245432/Evaluating-Chemicals-for-Thyroid-Disruption>.

⁶⁹ *Id.* at 63.

⁷⁰ *Id.*

⁷¹ *Id.* at 64.

⁷² See Draft Risk Evaluation *supra* note 35, at 124–27.

⁷³ 15 U.S.C. § 2602(12).

heightened vulnerabilities of certain populations to TBBPA, as well as the cumulative impact of TBBPA's interaction with existing environmental and health burdens for communities with environmental justice concerns leaves our most vulnerable communities at risk. Because EPA must consider potentially exposed and susceptible subpopulations, its failure to fully do so here violates TSCA.⁷⁴

Exposures to TBBPA, and its subsequent effects, impact some populations more drastically than others. Babies and young children are particularly susceptible to TBBPA exposure via breastfeeding and increased instances of hand-to-mouth contact and mouthing of electronic toys, which is especially concerning due to their incompletely developed immune systems and greater exposure per body weight through ingestion and inhalation compared to adults, and their still developing organs and tissues.⁷⁵ “[W]orkers in electronic waste recycling sites face higher TBBPA exposure risks” than the general population.⁷⁶ And exposure to TBBPA may pose heightened risks to communities burdened by environmental injustice, who already face disparate exposure to other harmful chemical pollutants and non-chemical stressors.

EPA must consider the cumulative effects that exposure to TBBPA could have on those communities,⁷⁷ to comply with the requirements of TSCA and adequately protect our residents. The myriad health and environmental burdens that potentially exposed and susceptible subpopulations and communities with environmental justice concerns experience leave them vulnerable to the additive health harms of TBBPA. Indeed, our residents in those communities already suffer exposure to multiple sources of pollution and disproportionately experience a range of negative health impacts—including higher rates of hypertension, heart disease, stroke, asthma, obesity, diabetes, and lung cancer.⁷⁸

Those communities are also often burdened by multiple sources of pollution and environmental stressors like the effects of climate change,⁷⁹ which disproportionately harm communities of color, communities with higher concentrations of low-income residents, and

⁷⁴ *Id.* § 2605(b)(4)(F).

⁷⁵ Miao et al., *supra* note 42, at 3; *see also* Kim et al., *supra* note 54.

⁷⁶ Liao et al. (2025), *supra* note 54.

⁷⁷ 15 U.S.C. § 2625(h) (under the “best available science” requirement, EPA must consider aggregate exposures and cumulative risks); *see also infra* Section IV.b & c.

⁷⁸ Rachel Morello-Frosch et al., *Understanding the Cumulative Impacts of Inequalities in Environmental Health: Implications for Policy*, 30 HEALTH AFFS. 879–880 (2011), <https://escholarship.org/content/qt1kq0196d/qt1kq0196d.pdf>; Philip J. Landrigan, *Environmental Justice and the Health of Children*, 77 MOUNT SINAI J. MED. 178, 180 (2010), <https://doi.org/10.1002/msj.20173>; Eun-Hye Yoo & John E. Roberts, *Differential Effects of Air Pollution Exposure on Mental Health: Historical Redlining in New York State*, 948 SCI. OF THE TOTAL ENV'T 1 (2024), <https://doi.org/10.1016/j.scitotenv.2024.174516>.

⁷⁹ *See* EPA, *Interim Framework for Advancing Consideration of Cumulative Impacts*, at 4 (Nov. 2024), <https://www.epa.gov/system/files/documents/2024-11/epa-interim-cumulative-impacts-framework-november-2024.pdf> (“Environmental public health research has shown that the cumulative impacts of longstanding place-based inequalities in exposures to environmental hazards are significant, with health disparities linked to these inequalities” (citations omitted)); *see also* Morello-Frosch et al., *supra* note 78.

Indigenous Peoples and members of Tribal Nations.⁸⁰ EPA’s own research has concluded that “communities nationwide that are located near facilities using extremely hazardous substances are indeed disproportionately populated with Black, Asian, Hispanic, and low-income residents; and that even greater proportions of these historically underserved populations are located near facilities with histories of chemical accidents involving fires, explosions, and/or toxic vapors.”⁸¹ Low-income communities and communities of color also “experience unusually high [toxic] exposures in home and neighborhood . . . [and] are also disproportionately affected by hazardous occupational exposures.”⁸² Indigenous Peoples and members of Tribal Nations also suffer heightened exposure to environmental contaminants on or near Tribal lands, which present a disproportionate risk of adverse health impacts, including on reproductive health.⁸³

As a result of cumulative and varied exposures—including from oil and gas extraction, concentrated animal agriculture, industrial pollution, and releases of hazardous materials from disasters—communities of color and low-income communities are especially vulnerable to toxic substances,⁸⁴ like TBBPA. Finalization of the Draft Risk Evaluation that could preempt state laws and regulations concerning TBBPA absent grandfathering, and the resulting increased exposure to TBBPA, could have an additive effect on these many harms that communities with environmental justice concerns already face.

⁸⁰ Christopher W. Tessum et al., *PM_{2.5} Polluters Disproportionately and Systemically Affect People of Color in the United States*, 7 SCI. ADVANCES 1 (2021); see also United Church of Christ Comm’n for Racial Just., *Toxic Wastes and Race in the United States: A National Report on the Racial and Socio-Economic Characteristics of Communities with Hazardous Waste Sites* (1987), <https://perma.cc/6L8E-E4GW>; United Church of Christ Just. & Witness Ministries, *Toxic Wastes and Race at Twenty, 1987–2007* (2007), <https://perma.cc/SM6W-A7DD>; see also Ihab Mikati et al., *Disparities in Distribution of Particulate Matter Emission Sources by Race and Poverty Status*, 108 AM. J. PUB. HEALTH 480 (2018), <https://perma.cc/Z9CZ-UXLE>; Qian Di et al., *Air Pollution and Mortality in the Medicare Population*, 376 NEW ENGLAND J. MED. 1 (2017), <https://pmc.ncbi.nlm.nih.gov/articles/PMC5766848/>; Alique Berberian et al., *Racial Disparities in Climate Change-Related Health Effects in the United States*, 9 CURRENT ENV’T HEALTH REP. 451–52 (2022), <https://link.springer.com/article/10.1007/s40572-022-00360-w>; Mary H. Hayden et al., *Chapter 15: Human Health*, in A.R. CRIMMINS ET AL., U.S. GLOB. CHANGE RSCH. PROGRAM, FIFTH NATIONAL CLIMATE ASSESSMENT (2023), https://toolkit.climate.gov/sites/default/files/2025-07/NCA5_Ch15_Human-Health.pdf.

⁸¹ DENNIS GUIGNET ET AL., EPA NAT’L CTR. FOR ENV’T ECON., DISPROPORTIONATE ENVIRONMENTAL RISKS: AN ANALYSIS OF CHEMICAL FACILITIES AND ACCIDENTS IN THE U.S. 20 (Oct. 2024), https://www.epa.gov/system/files/documents/2024-10/2024-08_0.pdf.

⁸² Michael Gochfeld & Joanna Burger, *Disproportionate Exposures in Environmental Justice and Other Populations: The Importance of Outliers*, 101 AM. J. OF PUB. HEALTH S53 (2011), <https://pmc.ncbi.nlm.nih.gov/articles/PMC3222496/pdf/S53.pdf>.

⁸³ Elizabeth Hoover et al., *Indigenous Peoples of North America: Environmental Exposures and Reproductive Justice*, 120 ENV’T HEALTH PERSPS. 1645, 1647 (2012). For an example of disproportionate risk of adverse health impacts, see Raoul S. Liévanos, *Air-Toxic Clusters Revisited: Intersectional Environmental Inequalities and Indigenous Deprivation in the U.S. Environmental Protection Agency Regions*, 11 RACE & SOC. PROBS. 161 (2019) (finding that spatial concentrations of multiply marginalized Indigenous peoples in the U.S. were a significant predictor of area exposure to airborne carcinogenic pollution in the Mid-Atlantic EPA region).

⁸⁴ See Jill Johnston & Lara Cushing, *Chemical Exposures, Health and Environmental Justice in Communities Living on the Fenceline of Industry*, 7 CURRENT ENV’T HEALTH REPS. 48–57 (2020), <https://pmc.ncbi.nlm.nih.gov/articles/PMC7035204/#ABS1>.

III. State Interests

Recognizing the many and varied threats that TBBPA poses to health and the environment, several of the undersigned States have taken steps to ban or restrict its use. In regulating TBBPA, the States have identified the disproportionate risk that the chemical substance poses to susceptible populations, including infants and children, and have therefore moved to restrict the use of TBBPA in certain instances, including consumer products.

Massachusetts

In January 2021, Massachusetts banned a range of flame retardants that are known to threaten health and the environment. Specifically, Massachusetts law states that a “manufacturer or retailer shall not sell, offer or manufacture for sale, distribute in commerce or import into the commonwealth” any “bedding, carpeting, children’s product, residential upholstered furniture or window treatment” containing more than 1,000 parts per million of certain toxic flame retardants, including TBBPA.⁸⁵

California

California also regulates TBBPA in consumer and other products. In 2018, the California Legislature enacted Assembly Bill 2998, which as of January 1, 2020, prohibits the sale or distribution in commerce of new juvenile products, mattresses, and upholstered furniture, and reupholstered furniture, containing greater than 1,000 parts per million of TBBPA or other covered flame retardants.⁸⁶ The Legislature was concerned with the growing body of evidence associating flame retardant chemicals with adverse health effects, and specifically referenced information concerning TBBPA.⁸⁷ TBBPA is included on California’s Proposition 65 List because the International Agency for Research on Cancer has determined that TBBPA is probably carcinogenic to humans.⁸⁸ As such, products containing TBBPA sold in California must generally bear warnings.⁸⁹

New York State

New York has taken action to limit the use of TBBPA and other flame retardants in consumer products. In 2021, New York State enacted legislation to prohibit the sale of certain consumer products, such as furniture, mattresses, and electronics, that contain certain flame retardants, including TBBPA, effective December 1, 2024.⁹⁰ New York State also enacted legislation to require manufacturers of electronic display stands and enclosures to submit annual

⁸⁵ Mass. Gen. Laws Ann. ch. 21A § 28.

⁸⁶ Cal. Assemb., B. 2998, 2017-2018 Reg. Sess.; Cal. Bus. & Prof. Code § 19100 et seq..

⁸⁷ Cal. Assemb., Comm. on Env’t Safety and Toxic Materials, Analysis of Assemb. Bill 2998 (2018).

⁸⁸ Cal. Off. of Env’t Health Hazard Assessment, *Notice of Intent to List N,N-Dimethylformamide, 2-Mercaptobenzothiazole, and Tetrabromobisphenol A* (June 30, 2017), <https://oehha.ca.gov/proposition-65/crn/notice-intent-list-nn-dimethylformamide-2-mercaptobenzothiazole-and-tetrabromobisphenol>.

⁸⁹ Cal. Health & Safety Code § 25249.6.

⁹⁰ See N.Y. Env’t Conservation Law, Article 37, Title 10.

reports, beginning in 2022, that disclose the use of organohalogen flame retardants, including TBBPA, in their products.⁹¹ Since these laws went into effect, manufacturers of electronic displays have reported a dramatic decrease in the use of organohalogens in their products, from 287 models containing organohalogens in 2022 to only 30 models containing organohalogens in 2025.

Oregon

In Oregon, TBBPA has been identified as a high priority chemical of concern for children's health when used in children's products, under the Oregon Toxic Free Kids Act.⁹² As a high priority chemical, TBBPA is subject to eventual removal or substitution, absent a waiver, from children's products that are mouthable, a cosmetic, or for children under three years of age.⁹³

Washington

In 2016, just before the enactment of the Lautenberg Act, Washington State enacted a statutory prohibition on TBBPA and four other specific organohalogen flame retardants above 1,000 parts per million in children's products and residential upholstered furniture.⁹⁴ In addition, in 2023, following an evaluation that showed safer flame retardants are feasible and available, the Washington Department of Ecology promulgated a rule under its Safer Products for Washington law,⁹⁵ that prohibits intentionally added organohalogen flame retardants—of which TBBPA is one—in electronic enclosures and in recreational foam products.⁹⁶

IV. Argument

EPA's Draft Risk Evaluation is legally deficient under both TSCA and the APA, resulting in an insufficiently protective Draft Risk Evaluation. First, EPA violates TSCA by making separate risk determinations for workers, consumers, and the general population. Second, EPA violates TSCA by failing to consider TBBPA within a class of other flame retardants. Third, EPA violates TSCA by failing to consider aggregate exposures and risks from TBBPA. Fourth, EPA violates TSCA by similarly failing to consider cumulative risks from TBBPA. Fifth, the Draft Risk Evaluation is arbitrary and capricious under the APA because EPA fails to account for state reliance interests in their existing state regulations which may be impacted by EPA's final risk evaluation for TBBPA. Finally, the Draft Risk Evaluation violates principles of cooperative federalism and contravenes TSCA's purpose. For those reasons, EPA should withdraw the Draft Risk Evaluation.

⁹¹ *Id.* § 37-1009.

⁹² Or. Admin. Rules § 333-016-2020(11); *see* Or. Rev. Stat. § 431A.250 et seq..

⁹³ Or. Admin. Rules § 333-016-3010.

⁹⁴ Wash. Rev. Code § 70A.430.030.

⁹⁵ Wash. Rev. Code § 70A.350.

⁹⁶ Wash. Admin Code § 173-337-112(1)(c)(i), (4)(c).

- a. The Draft Risk Evaluation Violates TSCA
 - i. TSCA Requires EPA to Comprehensively Evaluate Risks

EPA properly determines that TBBPA presents an unreasonable risk to human health and the environment but improperly fails to include all the intended, known, or foreseeable uses of TBBPA in the conditions of use addressed in the Draft Risk Evaluation and makes separate risk determinations for workers, consumers, and the general population.⁹⁷ EPA determined that “[o]f the 24 COUs that EPA evaluated, 20 COUs were preliminarily determined *not* to significantly contribute to the unreasonable risk of injury of TBBPA to human health or the environment” and that “[n]o COUs for TBBPA significantly contribute to unreasonable risk to [Occupational Non-Users]; consumers, including bystanders; or the general population, including fenceline populations.”⁹⁸ The limited scope of the Draft Risk Evaluation and EPA’s separate findings of no unreasonable risk to ONUs, consumers, and the general population runs afoul of TSCA’s clear command to analyze the risk of each chemical substance comprehensively and collectively.

Congress enacted TSCA to address a specific problem: the piecemeal regulation of toxic chemicals and the absence of a single agency with “authority to look comprehensively at the hazards associated with the chemical.”⁹⁹ Pre-TSCA laws authorized different agencies to address the hazards associated with discrete uses of particular chemicals in consumer products or occupational settings, and agencies could “only look at the hazards within their jurisdiction in isolation from other hazards associated with the same chemical.”¹⁰⁰ In enacting TSCA Section 6, 15 U.S.C. § 2605, Congress sought to give EPA “the authority to look at the hazards *in total*.”¹⁰¹ And when Congress strengthened the provisions of Section 6 in 2016, it reinforced this fundamental purpose.¹⁰²

The text of Section 6 reflects Congress’s aim of ensuring that EPA comprehensively evaluate the hazards of each chemical substance as a whole. TSCA Section 6(b) requires EPA to determine “whether a *chemical substance* presents an unreasonable risk of injury to health or the environment.”¹⁰³ Section 6(a) provides that EPA must promulgate risk management rules if it determines 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.”¹⁰⁴

Other provisions of TSCA further confirm that EPA must make a single risk determination for the chemical substance as a whole. TSCA Section 19(a) authorizes judicial

⁹⁷ 91 Fed. Reg. at 36,139; Draft Risk Evaluation, *supra* note 35, at 180–87.

⁹⁸ Draft Risk Evaluation, *supra* note 35, at 9.

⁹⁹ S. Rep. No. 94-698, *supra* note 2, at 2.

¹⁰⁰ *Id.*

¹⁰¹ *Id.* (emphasis added).

¹⁰² See S. Rep. No. 114-67, at 7 (2015).

¹⁰³ 15 U.S.C. § 2605(b)(4)(A) (emphasis added).

¹⁰⁴ *Id.* § 2605(a) (emphasis added).

review of any “order” under Section 6(i).¹⁰⁵ And Section 6(i), in turn, provides that “a determination” by EPA “that *a chemical substance*” does or does not present an unreasonable risk is an order constituting final agency action for judicial review purposes.¹⁰⁶ That provision makes clear that EPA must make a single, binary determination as to “whether *a substance meets or does not meet* the safety standard.”¹⁰⁷

ii. EPA Should Evaluate TBBPA Within a Class or Category of Other Flame Retardants

EPA should evaluate and regulate TBBPA as a class with other flame retardants rather than in isolation.¹⁰⁸ TSCA requires EPA to conduct risk evaluations using the “best available science.”¹⁰⁹ The best available science dictates that a class-based approach helps prevent “regrettable substitutions” where a harmful chemical is simply exchanged for another harmful chemical, as has been the case with flame retardants.¹¹⁰ And TSCA further authorizes EPA to conduct risk evaluations for categories of chemical substances.¹¹¹

For example, the U.S. Consumer Product Safety Commission is evaluating and regulating additive organohalogen flame retardants as a class.¹¹² In 2017, the Consumer Product Safety Commission granted a petition requesting action on these flame retardants.¹¹³ The petitioners, a coalition of consumer and health advocates, argued that these flame retardants, “due to their inherent physical-chemical properties . . . are toxic, migrate widely out of products regardless of how the products are used, bioaccumulate, and present a serious public health concern.”¹¹⁴ The Commission directed further study of the effects of the flame retardants as a class and, in the meantime, found “overwhelming scientific evidence” regarding the potential toxicity and risks of exposure, particularly to vulnerable populations, and called for eliminating the use of these

¹⁰⁵ See *id.* § 2618(a).

¹⁰⁶ See *id.* § 2605(i) (emphases added).

¹⁰⁷ S. Rep. No. 114-67, *supra* note 102, at 17 (emphasis added).

¹⁰⁸ 15 U.S.C. § 2625(c) (authorizing EPA to conduct risk evaluations for categories of chemical substances); see also *id.* § 2625(h).

¹⁰⁹ *Id.* § 2625(h); 40 C.F.R. § 702.37(a)(2).

¹¹⁰ See Joseph Allen, Opinion, *Stop Playing Whack-A-Mole with Hazardous Chemicals*, WASHINGTON POST (Dec. 15, 2016), https://www.washingtonpost.com/opinions/stop-playing-whack-a-mole-with-hazardous-chemicals/2016/12/15/9a357090-bb36-11e6-91ee-1addfe36cbe_story.html.

¹¹¹ 15 U.S.C. § 2625(c).

¹¹² U.S. Consumer Prod. Safety Comm’n, *Organohalogen Flame Retardant Chemical Assessment*, <https://www.cpsc.gov/Business--Manufacturing/Organohalogen-Flame-Retardant-Chemicals-Assessment> (last accessed Aug. 14, 2026).

¹¹³ *Guidance Document on Hazardous Additive, Non-Polymeric Organohalogen Flame Retardants in Certain Consumer Products*, 82 Fed. Reg. 45,268, 45,268 (Sep. 28, 2017).

¹¹⁴ *Id.*

chemicals in certain products.¹¹⁵ In turn, the National Academies of Sciences, Engineering, and Medicine employed a class-based approach to assess the hazards posed by flame retardants.¹¹⁶

As discussed above, several states have also evaluated and regulated TBBPA as a class with other flame retardants.¹¹⁷ And EPA has previously evaluated other chemicals, including phthalates, as classes.¹¹⁸ For these reasons, EPA should revise its Draft Risk Evaluation to incorporate a class-based approach.

iii. TSCA Requires EPA to Evaluate Aggregate Exposures and Risks

Recognizing that multiple exposures to chemical substances can create an unreasonable risk to human health and the environment, even if any individual exposure does not, TSCA requires EPA to consider aggregate exposures and risks, and “when supported by reasonably available information, consistent with the best available science and based on the weight of scientific evidence, include an aggregate exposure assessment in the risk evaluation.”¹¹⁹ Here, considering risks from aggregate exposures is required by the best available science requirement under 15 U.S.C. § 2625(h).¹²⁰ As no other environmental law enables EPA to evaluate exposure across all environmental media, TSCA analyses are particularly important in addressing the

¹¹⁵ *Id.* at 45,269.

¹¹⁶ Nat’l Academies of Sci., Eng’g, and Med., *A Class Approach to Hazard Assessment of Organohalogen Flame Retardants* (2019), <https://nap.nationalacademies.org/catalog/25412/a-class-approach-to-hazard-assessment-of-organohalogen-flame-retardants>.

¹¹⁷ See, e.g., Mass. Gen. Laws Ann. ch. 21A § 28 (restricting the sale of certain consumer goods containing more than 1,000 parts per million of twelve flame retardants, including TBBPA, in certain consumer products including bedding and children’s products); see also Rev. Code Wash. § 70A.350.010 et seq. (designating organohalogen flame retardants as a priority chemical and directing the department to implement regulatory actions for consumer products that are a significant source or use of the chemical); WASH. DEP’T OF ECOLOGY, REGULATORY DETERMINATIONS REPORT TO THE LEGISLATURE (June 2022), <https://apps.ecology.wa.gov/publications/documents/2204018.pdf>; see also Md. Health-General Code Ann. § 24-306.1 (“A person may not import, sell, or offer for sale any juvenile product, mattress, upholstered furniture, or reupholstered furniture that contains more than 0.1% of flame-retardant chemicals by mass.”); R.I. Gen. Laws § 23-26-3.1(a) (stating that “no manufacturer, wholesaler, or retailer may manufacture, knowingly sell, offer for sale, or distribute for use in this state any residential upholstered bedding or furniture that contains one thousand parts per million (1,000 ppm) or greater of any non-polymeric organohalogen flame retardant chemical” and that “[t]his class includes any chemical containing the element bromine or chlorine bonded to carbon that is added to a plastic, foam, fabric, or textile”); Me. Rev. Stat. § 1609-A(2) (stating that “a person may not sell or offer to sell or distribute for promotional purposes upholstered furniture containing in its fabric or other covering or in its cushioning materials more than 0.1% of a flame-retardant chemical or more than 0.1% of a mixture that includes flame-retardant chemicals”).

¹¹⁸ See EPA, *Phthalates; EPA Phthalates Risk Evaluations* (Dec. 31, 2025), <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/phthalates#gold> (stating that EPA conducted a “cumulative exposure analysis, which examined exposure to multiple phthalates simultaneously”).

¹¹⁹ 40 C.F.R. § 702.39(d)(8); see also 15 U.S.C. § 2605(b)(4)(F)(i), (ii), (iv); 40 C.F.R. § 702.33 (definitions).

¹²⁰ See *Science and Decisions: Advancing Risk Assessment*, supra note 52, at 266–67; see also Sci. Advisory Committee on Chemicals, *Meeting Minutes and Final Report, Draft TSCA Screening Level Approach for Assessing Ambient Air and Water Exposures to Fenceline Communities Version 1.0*, at 18 (Mar. 2022), <https://www.regulations.gov/document/EPA-HQ-OPPT-2021-0415-0095> (containing “key recommendation” that EPA “[i]nclude aggregate and cumulative exposures from populations exposed at work who live in the community, or who may also be exposed to multiple facility emissions”).

additive and cross-media risks of toxics. Although EPA concluded that TBBPA presents an unreasonable risk to human health and the environment,¹²¹ in failing to evaluate aggregate exposures, EPA understates TBBPA's risks, especially to potentially exposed and susceptible subpopulations who may face greater exposure to the chemical.¹²² As EPA acknowledges, potentially exposed or susceptible subpopulations may "have greater exposure to TBBPA per body weight (e.g., infants, children, adolescents)[,]" "may experience exposure from multiple sources[,]" or "[have] higher exposures than others."¹²³

Yet, as EPA admits, it did not consider such aggregate exposures and did not adequately explain its failure to do so.¹²⁴ Although the Draft Risk Evaluation acknowledges that "TBBPA has been found in drinking water, ground water, ambient air, indoor air, fish, human breast milk, and dust and soil[,]"¹²⁵ EPA states that it "did not consider aggregate exposure for the general population exposed to environmental releases" because it did not identify "pathways of concern (i.e., ambient air, surface water, drinking water, and fish ingestion) to TBBPA exposure...for the general population, including [potentially exposed and susceptible subpopulations]."¹²⁶ In addition, "EPA did not consider aggregate exposure scenarios across COUs" because it purportedly "did not find any evidence to support such an aggregate analysis[.]"¹²⁷

And although "EPA considered potential aggregate occupational exposures to TBBPA resulting from dermal and inhalation routes, as well as aggregate consumer exposures from dermal, inhalation, and oral routes[,]" EPA recognized that "[e]xposure to TBBPA through consumer products or other sources that are not assessed under TSCA could contribute to total exposure to TBBPA and increase susceptibility to further exposure associated with COUs."¹²⁸ Indeed, there are several studies that indicate potential TBBPA human exposure via consumer products.¹²⁹ Yet EPA inexplicably failed to take those additional exposures into account. EPA

¹²¹ 91 Fed. Reg. at 36,139.

¹²² See 15 U.S.C. § 2602(12) (definitions).

¹²³ Draft Risk Evaluation, *supra* note 35 at 10; see also Procedures for Chemical Risk Evaluation Under the Toxic Substances Control Act (TSCA), 89 Fed. Reg. 37,028, 37,039–40 (May 3, 2024) (stating that "[t]hose experiencing 'greater exposure' could include individuals or communities experiencing higher levels of exposure to a chemical substance due to . . . aggregate exposure via multiple conditions of use (e.g., a worker who lives in close proximity to facilities emitting air pollutants).").

¹²⁴ See 40 C.F.R. § 702.39(d)(8).

¹²⁵ 91 Fed. Reg. at 36,139.

¹²⁶ Draft Risk Evaluation, *supra* note 35 at 124.

¹²⁷ *Id.* at 165.

¹²⁸ *Id.* at 163.

¹²⁹ See, e.g., WASH. DEP'T OF ECOLOGY, FLAME RETARDANTS IN GENERAL CONSUMER AND CHILDREN'S PRODUCTS 25 (June 2021), <https://apps.ecology.wa.gov/publications/documents/1404021.pdf> (detecting TBBPA in several plastic products such as a car charter and a heated mattress foot warming pad); Oluwatoyin T. Fatunsin et al., *Children's Exposure to Hazardous Brominated Flame Retardants in Plastic Toys*, 720 SCI. OF THE TOTAL ENV'T 1 (2020), <https://doi.org/10.1016/j.scitotenv.2020.137623> (detecting TBBPA in some UK plastic toys); Megan Liu, Sicco H. Brandsma & Erika Schreder, *From E-Waste to Living Space: Flame Retardants Contaminating Household Items Add to Concern About Plastic Recycling*, 365 CHEMOSPHERE 1 (2024), <https://doi.org/10.1016/j.chemosphere.2024.143319> (detected TBBPA in 75% of 203 black plastic products).

must properly aggregate TBBPA exposures so that any unreasonable risks can be fully addressed during risk management.¹³⁰

iv. TSCA Requires EPA to Consider Cumulative Risks

TSCA also requires EPA to consider cumulative risks of exposure to TBBPA alongside other health stressors when evaluating TBBPA. Cumulative risk assessment generally refers to the “analysis, characterization, and possible quantification of the combined risks to health or the environment posed by multiple agents or stressors.”¹³¹ In enacting TSCA in 1976, Congress recognized that “[o]ftentimes an unreasonable risk will be presented because of the interrelationship or cumulative impact of a number of different substances or mixtures” and provided EPA with the “authority to protect health and the environment in such situations.”¹³²

Considering cumulative risks is essential to the determination of whether a chemical presents an unreasonable risk to potentially exposed or susceptible subpopulations, a determination required by TSCA.¹³³ As mentioned above, potentially exposed or susceptible subpopulations may be at greater risk of harm from a chemical due to greater susceptibility.¹³⁴ As explained by the National Research Council, “simultaneous exposure to multiple chemical and nonchemical stressors and other factors . . . could influence vulnerability.”¹³⁵ Indeed, EPA recognized that “[s]ome groups or life stages may be more biologically susceptible to TBBPA” and that “[o]ther factors that may increase susceptibility include chronic disease, genetic factors, co-exposures, and behavior/lifestyle.”¹³⁶

Moreover, the best available science requirement under 15 U.S.C. § 2625(h) compels EPA to consider cumulative risks. EPA’s Science Advisory Committee on Chemicals has emphasized that “[t]he best possible science includes cumulative impacts.”¹³⁷ EPA itself has also stated that “the best available science may indicate that the development of a cumulative risk assessment is appropriate to ensure that risk to human health and the environment adequately characterized.”¹³⁸ In addition, the National Research Council has warned that without consideration of cumulative risk in risk evaluations, “risk assessment might become

purchased in Seattle, WA from 2020 to 2022); Gillian Z. Miller et al., *Toys, Decor, and More: Evidence of Hazardous Electronic Waste Recycled into New Consumer Products*, 7 J. OF ENV’T PROT. 1 (2016), <https://www.scirp.org/journal/paperinformation?paperid=63907> (reported high levels of TBBPA in Mardi Gras-like beads sold in the U.S. market).

¹³⁰ 15 U.S.C. § 2605(a).

¹³¹ *Science and Decisions: Advancing Risk Assessment*, *supra* note 52, at 213.

¹³² H. Rep. No. 94-1679, at 61 (1976).

¹³³ 15 U.S.C. § 2605(b)(4)(A).

¹³⁴ *See* 15 U.S.C. § 2602(12) (definitions).

¹³⁵ *Science and Decisions: Advancing Risk Assessment*, *supra* note 52 at 213.

¹³⁶ Draft Risk Evaluation, *supra* note 35 at 160–61.

¹³⁷ Sci. Advisory Committee on Chemicals, *Meeting Minutes and Final Report*, *supra* note 120 at 47.

¹³⁸ 89 Fed. Reg. at 37,039.

irrelevant.”¹³⁹ And according to the National Academies of Sciences, Engineering, and Medicine, “mov[ing] beyond source-by-source and pollutant-by-pollutant research and risk assessment” provides “a fuller characterization of the cumulative and potentially synergistic health risks from multiple environmental and social stressors that disproportionately impact communities of color and the poor.”¹⁴⁰

Here, however, the Draft Risk Evaluation utterly fails to consider or even mention cumulative risks. At a minimum, EPA must consider the cumulative risks from TBBPA and other flame retardants in its final risk evaluation. Indeed, the highest levels of flame retardants in the general population have been found in young children in communities of low socio-economic status and communities of color.¹⁴¹ EPA’s failure to consider cumulative risk is therefore especially concerning. EPA must consider these cumulative risks in order to be prepared to satisfy its statutory obligation to address any such unreasonable risks to these populations during risk management.

b. EPA’s Failure to Consider Reliance Interests Violates the APA

In finalizing its risk evaluation for TBBPA, EPA must also consider the “serious reliance interests” that may exist.¹⁴² The current regulatory framework for TBBPA permits states to regulate the use of TBBPA, but EPA’s action here threatens to potentially restrict state authority to regulate TBBPA. And because the States cannot control the use of TBBPA in other states, we must rely on our own regulations or federal regulation of TBBPA to sufficiently protect the health of our residents and the environment. By failing to properly analyze the States’ “serious reliance interests” in their continued ability regulation TBBPA, a final risk evaluation based on EPA’s Draft Risk Evaluation would be arbitrary and capricious.¹⁴³

In the Draft Risk Evaluation, EPA fails to properly consider the reliance interests of the states that currently regulate TBBPA. Although EPA acknowledges some existing state regulatory measures,¹⁴⁴ it fails to “assess whether there [a]re reliance interests, determine whether they [a]re significant, and weigh any such interests against competing policy concerns.”¹⁴⁵ The States’ expectations that a sound risk evaluation and a resulting strongly

¹³⁹ *Science and Decisions: Advancing Risk Assessment*, *supra* note 52 at 213.

¹⁴⁰ Nat’l Acad. of Sci., Eng’g, and Med., *Transforming EPA Science to Meet Today’s and Tomorrow’s Challenges* 35 (2023), <https://www.nationalacademies.org/read/26602>.

¹⁴¹ See, e.g., Margaret C. Weiss, Luyu Wang & Robert M. Sargis, *Hormonal Injustice: Environmental Toxicants as Drivers of Endocrine Health Disparities*, 51 *ENDOCRINOLOGY AND METABOLISM CLINICS OF AMERICA* 1 (2023), <https://doi.org/10.1016/j.ecl.2023.05.009>; Lesliam Quiros-Alcala et al., *Concentrations and Loadings of Polybrominated Diphenyl Ethers in Dust from Low-Income Households in California*, 37 *ENV’T INT’L* 592 (2011), <https://doi.org/10.1016/j.envint.2010.12.003>.

¹⁴² See *Dep’t of Homeland Sec. v. Regents of Univ. of Cal.*, 591 U.S. 1, 33 (2020).

¹⁴³ See *id.* at 30 (citing *Encino Motorcars v. Navarro*, 579 U.S. 211, 222 (2016)).

¹⁴⁴ Draft Risk Evaluation, *supra* note 35, at 221.

¹⁴⁵ *Dep’t of Homeland Sec. v. Regents of Univ. of Cal.*, 591 U.S. at 33.

protective risk management rule to address the significant health burdens on our residents from TBBPA represent tangible reliance interests that EPA has not addressed.

As set forth above, several States have taken steps to protect our residents and the environment from the harmful consequences of TBBPA exposure, EPA's authority under TSCA is an important complement to those efforts. States have many tools to regulate the use of toxic substances, but TSCA may in some circumstances constrain what states can do to address the public health costs of TBBPA exposure once EPA has acted under TSCA.¹⁴⁶ The Draft Risk Evaluation is obviously flawed because, among other things, EPA failed to consider aggregate exposures and risks and cumulative risks, thereby understating the risk of TBBPA. Finalizing this deficient Draft Risk Evaluation would adversely impact the States' ability to ensure the health of our residents and environment are adequately protected from the harms of TBBPA.

To satisfy its obligations under the APA and advance TSCA's express purpose of protecting against unreasonable risk to public health and the environment, and in recognition of the rights of states to protect their residents against health harms from toxic substances, EPA must consider the reliance interests of States in its risk evaluation for TBBPA.

c. EPA Should Not Regulate in a Manner that Leaves Our Residents in Danger of Exposure to TBBPA

By enacting and later amending TSCA, Congress made clear its intent for EPA to prevent unreasonable risk to health and the environment associated with exposures to toxic chemical substances like TBBPA, setting forth a risk reduction model that ought to sufficiently regulate toxic chemicals so that EPA does not unnecessarily preempt robust state regulation. Given that EPA's Draft Risk Evaluation for TBBPA fails to comply with the mandates of TSCA and could possibly limit the authority of the States to regulate its use, EPA should withdraw it, to avoid inadequate regulation of TBBPA in a limited manner that would leave many exposure pathways unaddressed. As discussed *supra* Section II, the best available science indicates a wide range of harms to public health that EPA fails altogether to consider—these include non-cancer risks like neuro-, immuno-, and reproductive toxicity, as well as cancer risks, such as cancers induced by endocrine disruption—harms that are disproportionately borne by residents in our States that are more susceptible to the negative impacts of TBBPA. By disregarding those harms and moving to regulate TBBPA in the limited manner proposed by the Draft Risk Evaluation, EPA also defies the purpose and spirit of TSCA to the possible detriment of the ability of our States to protect residents from risky exposures to TBBPA.

By employing a legally and scientifically deficient process that could potentially tie the States' hands with respect to their own efforts to protect our residents, the Draft Risk Evaluation is also at odds with principles of cooperative federalism. In the absence of a risk evaluation based on the best available science, EPA should withdraw the Draft Risk Evaluation to avoid

¹⁴⁶ See 15 U.S.C. § 2617(a)(1)(B)(ii).

regulating TBBPA in a manner that is less protective than existing State protections. Should EPA intend to move forward despite the overwhelming evidence that TBBPA presents unreasonable risk to health and the environment, the existence of state regulations and scientific evidence of wide-ranging health harms should at the very least caution EPA against wading in to regulate in a manner that could prevent states from acting to protect their residents from the known risks posed by TBBPA.

V. Conclusion

EPA's Draft Risk Evaluation utterly fails to comply with TSCA's requirements for how the agency must conduct its risk evaluations. Consequently, any risk management actions developed from the current Draft Risk Evaluation, if not substantially reworked to comply with those applicable legal requirements, would fail to comply with law. Left uncorrected, the deficiencies in the Draft Risk Evaluation will fatally compromise the agency's final risk evaluation and any subsequent risk management of TBBPA and fail to protect human health and the environment—leaving our residents in danger from myriad health harms in the process. For the foregoing reasons, the undersigned Attorneys General and Corporation Counsel request that EPA withdraw the Draft Risk Evaluation and re-evaluate the risks posed by TBBPA in a manner that complies with EPA's obligations under TSCA.

Sincerely,

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