



**BLACK WOMEN
FOR WELLNESS**



Submitted via *Regulations.gov*

December 8, 2021

Administrator Michael Regan
U.S. Environmental Protection Agency
1200 Pennsylvania Ave. SW
Washington, D.C. 20460-0001

RE: EPA-Initiated TSCA Risk Evaluations for 5 High-Priority Phthalates, Docket #s:

- Dibutyl Phthalate (DBP): EPA-HQ-OPPT-2018-0503
- Butyl Benzyl Phthalate (BBP): EPA-HQ-OPPT-2018-0501
- Di-ethylhexyl Phthalate (DEHP): EPA-HQ-OPPT-2018-0433
- Di-isobutyl Phthalate (DiBP): EPA-HQ-OPPT-2018-0434
- Dicyclohexyl Phthalate (DCHP): EPA-HQ-OPPT-2018-0504

And Manufacturer-Requested TSCA Risk Evaluations for 2 Phthalates, Docket #s:

- Di-isodecyl Phthalate (DIDP): EPA-HQ-OPPT-0218-0435
- Di-isononyl Phthalate (DINP): EPA-HQ-OPPT-0218-0436

INTRODUCTION

Defend Our Health, Black Women for Wellness, Alaska Community Action on Toxics, and Breast Cancer Prevention Partners submit these comments to inform EPA's ongoing risk evaluations of five health-hazardous phthalates. These chemicals, which the agency has designated "high-priority" chemical substances for risk evaluation under Section 6(b) of the Toxic Substances Control Act (TSCA), are: Dibutyl Phthalate (DBP), Butyl Benzyl Phthalate (BBP), Di-ethylhexyl

Phthalate (DEHP), Di-isobutyl Phthalate (DIBP), and Dicyclohexyl Phthalate (DCHP). Our comments follow the Table of Contents below.

These comments should also inform EPA's ongoing assessment of two phthalates for which risk evaluations were requested under Section 6(b) by a chemical manufacturer: Di-isodecyl Phthalate (DIDP) and Di-isononyl Phthalate (DINP). The best available science requires EPA to evaluate and manage the cumulative risk of exposure to *all* phthalates under review, treating them as a single "category of chemical substances" pursuant to Section 26(c) of TSCA.

The signatory organizations advocate for health-protective environmental policies, with a focus on society's most vulnerable members. These comments were drafted through the Environmental Law Clinic at the UC Berkeley School of Law (Clinic). The Clinic trains students to enhance environmental health and justice by deploying the law to protect those least politically empowered. The Clinic also works to ensure that the life experiences of its clients' members inform the highly technical regulatory space in which health-consequential decisions are made.

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INTRODUCTION

Phthalates are versatile man-made chemicals that impart flexibility to brittle plastics, make the scent of perfume linger, and perform myriad other industrial functions. Produced and used in volumes of nearly a half-*billion* pounds per year in U.S. commerce,¹ biomonitoring data reveal that phthalates have now insinuated themselves into the bodies of nearly all Americans.² Phthalates are associated with, among other serious health effects: reproductive toxicity, harm to the developing brain, cancer, cardiovascular disease, diabetes, and obesity.³ Pursuant to TSCA’s mandate to protect the public health against “unreasonable risk” from chemical exposures, EPA is currently conducting a post-market review of five phthalates it deems “high priority” for risk evaluation, and two additional phthalates for which manufacturers have requested risk evaluations.

This comment centers three issues critical to protecting the health of the Americans most vulnerable to adverse health effects from phthalates: Black, Indigenous, and People of Color (BIPOC). Specifically, we describe why EPA’s phthalate risk evaluations must:

- (1) Designate BIPOC as a **“potentially exposed or susceptible subpopulation”**;
- (2) Analyze the **“conditions of use”** associated with greatest phthalate exposure, which include food ingestion and use of cosmetics and personal care products; and
- (3) Conduct a **cumulative risk assessment** that encompasses all seven phthalates.

¹ EPA’s most recent Phthalates Action Plan states that by 2006, more than 470 million pounds of phthalates were produced annually. U.S. EPA, Phthalates Action Plan (Mar. 14, 2012), https://www.epa.gov/sites/default/files/2015-09/documents/phthalates_actionplan_revised_2012-03-14.pdf.

² CDC, FOURTH NATIONAL REPORT ON HUMAN EXPOSURE TO ENVIRONMENTAL CHEMICALS: UPDATED TABLES, MARCH 2021: VOLUME ONE, <https://www.cdc.gov/exposurereport/index.html>.

³ Leonardo Trasande, Buyun Liu, & Wei Bao, *Phthalates and Attributable Morbidity: A Population-based Longitudinal Cohort Study and Cost Analysis*, ENV’TAL POLLUTION (2021), <https://www.sciencedirect.com/science/article/pii/S0269749121016031> (last visited Dec. 8, 2021) (associating phthalate exposure with all-cause and cardiovascular mortality that imposes direct societal costs surpassing \$39 billion/year); Stephanie M. Engel et al., *Neurotoxicity of Ortho-Phthalates: Recommendations for Critical Policy Reforms to Protect Brain Development in Children*, 111 AMERICAN J. OF PUB. HEALTH 687, 687 (2021), <https://ajph.aphapublications.org/doi/full/10.2105/AJPH.2020.306014> (last visited Nov. 8, 2021) (cumulating “robust data . . . indicat[ing] that exposure to ortho-phthalates can impair brain development”).

Each of these issues was mishandled in the risk evaluation scoping phase. EPA now has an opportunity to course-correct, and to respect the letter and purpose of TSCA. In so doing, the agency will effectuate your vision as EPA Administrator: “If we protect the least among us, we can create a rising tide that elevates the level of environmental protection and equity for every American in this great country.”⁴

ANALYSIS

I. EPA Must Designate Black, Indigenous, and People of Color as a “Potentially Exposed or Susceptible Subpopulation” with Respect to Phthalates.

The best available science indicates that Black, Indigenous, and People of Color (BIPOC) are disproportionately exposed to phthalates, and are disproportionately health-impacted, such that EPA must identify BIPOC as a “potentially exposed or susceptible subpopulation” (PESS) in its risk evaluations. This action would effectuate Congress’ intent—manifest in the strengthening amendments to TSCA Section 6 in 2016—to protect the most vulnerable from toxic harm.⁵

TSCA requires EPA to evaluate chemicals using the “best available science,”⁶ and to “consider[] . . . potentially exposed or susceptible subpopulations” in its risk evaluations.⁷ TSCA defines a PESS as any group that “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

⁴ Jennifer A. Dlouhy and Stephen Lee, *New EPA Chief Michael Regan Vows Assault on Environmental Injustice*, Bloomberg Green (Mar. 16, 2021), <https://www.bloomberg.com/news/articles/2021-03-16/new-epa-chief-regan-vows-assault-on-environmental-injustice> (last visited Dec. 8, 2021).

⁵ The Frank R. Lautenberg Chemical Safety for the 21st Century Act (Lautenberg Act) fortified the original TSCA of 1976 by establishing mandatory parameters for EPA chemical substance risk evaluations. As amended, TSCA states: “[T]he Administrator shall conduct risk evaluations . . . 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* identified as relevant to the risk evaluation by the Administrator, under the conditions of use.” 15 U.S.C. § 2605(b)(4)(A) (all emphasis added).

⁶ 15 U.S.C. § 2625(h) (emphasis added); *Procedures for Risk Evaluation Under the Amended Toxic Substances Control Act*, 40 C.F.R. § 702 (2017).

⁷ 15 U.S.C. § 2605(b)(4)(A).

substance or mixture.”⁸ The best available science clearly demonstrates that people of color face both greater susceptibility *and* greater exposure to phthalates than do white people.

A. BIPOC are more exposed to, susceptible to, and harmed by phthalates than the general population.

1. BIPOC phthalate exposure

Numerous peer-reviewed studies demonstrate that at a population level, people of color are more heavily exposed to phthalates than are white people. For example, among U.S. women of reproductive age, non-Hispanic Black and Mexican American women have higher concentrations of **DBP** metabolites than non-Hispanic white women.⁹ Mothers of color also have higher concentrations of DBP metabolites than white mothers, and such metabolites are associated with higher concentrations of oxidative stress biomarkers.¹⁰

BBP follows this same pattern. Indeed, in a study of multiple phthalates, BBP metabolites were most strongly associated with oxidative stress biomarkers.¹¹ Another study found that African American mothers had significantly greater levels of urinary BBP metabolites than white mothers, compounded by greater levels of more than seven other phthalate metabolites.¹²

African American mothers likewise have significantly greater levels of urinary **DEHP** metabolites than white mothers, compounded by greater levels of more than seven other

⁸ 15 U.S.C. § 2602(12) (emphasis added).

⁹ Tamarra M. James-Todd, et al., *Racial/Ethnic Disparities in Environmental Endocrine Disrupting Chemicals and Women’s Reproductive Health Outcomes: Epidemiological Examples Across the Life Course*, 3 *Current Epidemiology Reports* 161, 162 (2016), <https://link.springer.com/article/10.1007%2Fs40471-016-0073-9> (last visited Dec. 8, 2021).

¹⁰ Kelly K. Ferguson et al., *Urinary Phthalate Metabolites and Biomarkers of Oxidative Stress in Pregnant Women: A Repeated Measures Analysis*, 123 *ENV’TAL HEALTH PERSPS.* 210 (2015), <https://ehp.niehs.nih.gov/doi/pdf/10.1289/ehp.1307996> (last visited Dec. 8, 2021).

¹¹ *Id.* at 213.

¹² Bloom et al., *Racial Disparity in Maternal Phthalates Exposure; Association with Racial Disparity in Fetal Growth and Birth Outcomes*, 127 *ENV’T INT’L* 473, 476 (2019), <https://www.sciencedirect.com/science/article/pii/S0160412018329908> (last visited Nov. 11, 2021).

phthalate metabolites.¹³ Exposure to DEHP is of particular concern because of its potency as a reproductive toxicant¹⁴: when researchers examined the comparative contributions to androgen disruption of six phthalates in commerce, DEHP was estimated to contribute the most, accounting for 48 to 64% of observed androgen-disruption.¹⁵

Urinary metabolites of **DIBP** are also present at significantly greater levels in African American mothers than in white mothers, and are compounded by greater levels of more than seven other phthalate metabolites.¹⁶ These higher levels of phthalate metabolites are also associated with higher concentrations of oxidative stress biomarkers.¹⁷ Beyond the reproductive and developmental effects of DIBP, the European Union has expressed concern that this phthalate may be implicated in immunological disorders such as allergy, asthma, and eczema,

¹³ *Ibid.*; see also Kelly K. Ferguson et al., *supra* note 10, at 213 (same).

¹⁴ See, e.g., Varshavsky et al., *A Novel Method for Calculating Potency-Weighted Cumulative Phthalates Exposures with Implications for Identifying Racial/Ethnic Disparities among U.S. Reproductive-Aged Women in NHANES 2001-2012*, 50 ENV'TAL SCI. & TECH. 10616, 10617 (2016), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5748889/> (last visited Nov. 11, 2021 (listing DEHP as one of several phthalates that “exert[s] toxicity primarily through androgen disruption”); Abby G. Wenzel et al., *Influence of Race on Prenatal Phthalate Exposure and Anogenital Measurements Among Boys and Girls*, 110 ENV'T INT'L 61, 62, 67 (2018), <https://www.sciencedirect.com/science/article/pii/S016041201731036X> (last visited Nov. 11, 2021) (finding that DEHP acts as an antiandrogen “by disrupting Sertoli and Leydig cell development, and by interfering with androgen steroidogenesis,” noting these findings are “concordant with previous reports suggesting anti-androgenic effects of prenatal exposure to DEHP,” and highlighting the “significant of the DEHP metabolite in potentially disruptive antiandrogenic effects”); Vittorio Silano et al., EFSA Panel on Food Contact Materials, Enzymes, and Processing Aids (CEP), *Update of the Risk Assessment of di-butylphthalate (DBP), butyl-benzyl-phthalate (BBP), bis(2-ethylhexyl)phthalate (DEHP), di-isononylphthalate (DINP), and di-isodecylphthalate (DIDP) for Use in Food Contact Materials*, 17 EFSA J. 5838, 5852 (2019), <https://efsa.onlinelibrary.wiley.com/doi/pdf/10.2903/j.efsa.2019.5838> (last visited Dec. 8, 2021) (“[DEHP] adversely affect[s] the male reproductive organs and sexual differentiation during fetal development due to [anti-androgenic effects]”); NAT'L RSCH. COUNCIL, COMM. HEALTH RISKS OF PHTHALATES, PHTHALATES AND CUMULATIVE RISK ASSESSMENT: THE TASK AHEAD 42, 106 (2008), <http://www.nap.edu/catalog/12528/phthalates-and-cumulative-risk-assessment-the-task-ahead> (last visited Dec. 8, 2021) (noting “clear evidence of adverse development effects [from DEHP] in animals”; “[DEHP is] able to disrupt male sexual differentiation by interfering with androgen biosynthesis; this culminates in what has been described as the phthalate syndrome or more generally as the androgen-insufficiency syndrome”).

¹⁵ Varshavsky et al., *supra* note 14, at 10622.

¹⁶ Bloom et al., *supra* note 12, at 476; see also Ferguson et al., *supra* note 10, at 213 (same).

¹⁷ Bloom et al., *supra* note 12, at 482.

possibly at even lower levels than those that trigger reproductive toxicity.¹⁸ Exposure to DIBP has increased over time.¹⁹

Although the literature contains less express discussion of racial patterning with respect to **DCHP**, **DIDP**, and **DINP** exposures, the health harms of these chemicals are likewise well established,²⁰ as is their over-concentration in BIPOC. Specifically, biomonitoring data from the National Health and Nutrition Examination Survey (NHANES) administered by the Centers for Disease Control demonstrate that, compared to the overall population, people of color are disproportionately exposed to nearly all phthalates, including the seven phthalates under review.

The tables below reproduce the most recent NHANES data for all seven phthalates currently undergoing EPA risk evaluation.²¹ These show a strong pattern of racial disparity in exposure even at the 50th percentile (*i.e.*, the average exposure scenario). Still more worrisome, they show an extreme pattern at the 95th percentile, *i.e.*, for the most highly exposed individuals.

¹⁸ Silano et al., *supra* note 14, at 5852.

¹⁹ Varshavsky et al., *supra* note 14, at 10623 (“Daily intake of DiBP and DiNP increased by 150–380% [from 2001 to 2012].”).

²⁰ For example, DCHP acts not only as a reproductive and toxicant, but also as a liver toxicant. Memorandum from Kent R. Carlson and Leslie E. Patton, Toxicologists, Directorate for Health Sciences, to Michael Babich, Project Manager, Phthalates, Section 108 of CPSIA, *Toxicity Review of Dicyclohexyl phthalate (DCHP)* (Oct. 24, 2010), at 18-25. Metabolites of DIDP and DINP are associated with (among other health harms) childhood asthma. Ami R. Zota et al., *Temporal Trends in Phthalate Exposures: Findings from the National Health and Nutritional Examination Survey, 2001-2010*, 122 ENV'TAL HEALTH PERSPS. 235, 240 (2014), <https://ehp.niehs.nih.gov/doi/10.1289/ehp.1306681> (last visited Nov. 28, 2021). DIDP and DINP metabolites are also associated with reduced fertilization rates in IVF treatments. James-Todd et al., *supra* note 9, at 170 (2016) (citations omitted).

²¹ Some data are from CDC's 2019 report, CDC, FOURTH NATIONAL REPORT ON HUMAN EXPOSURE TO ENVIRONMENTAL CHEMICALS: UPDATED TABLES, JANUARY 2019: VOLUME ONE (2019), https://www.cdc.gov/exposurereport/pdf/FourthReport_UpdatedTables_Volume1_Jan2019-508.pdf (last visited Dec. 8, 2021), and some are from CDC's report update in March 2021. The 2021 data for phthalates mirror the 2019 data, except that the March 2021 data exclude DCHP. *See* CDC, FOURTH NATIONAL REPORT ON HUMAN EXPOSURE TO ENVIRONMENTAL CHEMICALS: UPDATED TABLES, MARCH 2021: VOLUME TWO (2021), https://www.cdc.gov/exposurereport/pdf/FourthReport_UpdatedTables_Volume2_Mar2021-508.pdf (last visited Dec. 8, 2021). Neither the 2019 nor 2021 report is paginated, but a computer word search can locate any metabolite listed in Tables 1 and 2 of this comment, looking at those labeled “creatinine corrected.”

These chemical-specific data are independently concerning. They are yet more so given that exposures to individual phthalates compound with exposures to other phthalates to produce harm,²² thereby magnifying disparities in health impact by race.

Table 1. 50th Percentile Concentration of Phthalate Metabolites in Urine (in ug/g of creatinine) of Seven Phthalates, NHANES 2015-16

| Phthalate | Metabolite | Black | Hispanic | Asian | White | Overall |
|--------------------------------|------------|-------------------------|----------|-------------------------------------|-------|------------------------------|
| DEHP | MEHP | 1.19 | 1.4 | 1.95 | 1.14 | 1.24 |
| | MEHHP | 5.43 | 6.32 | 6.03 | 5.34 | 5.53 |
| | MEOHP | 3.33 | 4 | 4.04 | 3.36 | 3.47 |
| | MECPP | 7.81 | 10.1 | 9.6 | 8.04 | 8.5 |
| DiBP | MiBP | 8.99 | 9.2 | 9.28 | 7.75 | 8.33 |
| | MHiBP | 2.74 | 2.97 | 2.88 | 2.65 | 2.73 |
| DBP | MHBP | 0.728 | 0.933 | 1.03 | 0.916 | 0.897 |
| | MnBP* | 10.1 | 10.4 | 11.2 | 9.58 | 9.91 |
| BBP | MBzP | 5 | 4.25 | 3.17 | 4 | 4.17 |
| DCHP** | MCHP | < LOD | < LOD | -- | < LOD | < LOD |
| DINP | MINP | <LOD | <LOD | <LOD | <LOD | <LOD |
| | MONP | 1.76 | 2.00 | 1.82 | 1.72 | 1.77 |
| | MCOP | 6.33 | 8.24 | 5.60 | 6.78 | 6.89 |
| DIDP | MCNP | 1.64 | 1.71 | 1.25 | 1.79 | 1.73 |
| | MCP*** | 0.896 | 1.11 | 0.966 | 1.08 | 1.05 |
| <i>General Population (GP)</i> | | <i>Exposure > GP</i> | | <i>Exposure > White, < GP</i> | | <i>Least Exposed by Race</i> |

²² Environmental Defense Fund, Comment on Draft Scopes of the Risk Evaluations to Be Conducted for Seven Chemical Substances Under the Toxic Substances Control Act (June 8, 2020), at 79.

Table 2. 95th Percentile Concentration of Phthalate Metabolites in Urine (in ug/g of creatinine) of Seven Phthalates, NHANES 2015-16

| Phthalate | Metabolite | Black | Hispanic | Asian | White | Overall |
|--------------------------------|------------|-------------------------|----------|-------------------------------------|-------|------------------------------|
| DEHP | MEHP | 7.08 | 5.88 | 11.5 | 5.58 | 5.93 |
| | MEHHP | 30 | 30 | 43.2 | 21.8 | 27.2 |
| | MEOHP | 19.8 | 18.6 | 27.7 | 14.6 | 16.9 |
| | MECPP | 45.2 | 48.3 | 67.8 | 33.6 | 39.1 |
| DiBP | MiBP | 39.6 | 42.5 | 45.4 | 27.6 | 32.4 |
| | MHiBP | 11.8 | 14.2 | 14.9 | 9.93 | 11.1 |
| DBP | MHBP | 4.67 | 4.24 | 4.81 | 3.58 | 3.87 |
| | MnBP* | 46.8 | 40 | 51.8 | 32.9 | 36.1 |
| BBP | MBzP | 50.7 | 41.3 | 20 | 35.5 | 36.8 |
| DCHP** | MCHP | 0.88 | 1.2 | -- | < LOD | < LOD |
| DINP | MINP | 5.33 | 7.11 | 5.85 | 4.92 | 5.33 |
| | MONP | 16.8 | 21.1 | 27.2 | 18.8 | 19.2 |
| | MCOP | 77.0 | 80.1 | 92.5 | 75.2 | 75.2 |
| DIDP | MCNP | 9.68 | 6.69 | 7.70 | 8.99 | 8.33 |
| | MCP*** | 7.63 | 9.18 | 6.44 | 7.44 | 7.48 |
| <i>General Population (GP)</i> | | <i>Exposure > GP</i> | | <i>Exposure > White, < GP</i> | | <i>Least Exposed by Race</i> |

* MnBP is a metabolite of both DBP and BBP.

** DCHP data are from 2009-10, the last years of measurement due to consistent results below the level of detection (LOD).

*** MCP is also a metabolite of DnOP and several higher molecular weight phthalates.

EPA must identify BIPOC as a PESS to adequately identify, evaluate, and address racial disparities in exposure to phthalates. EPA must also examine how racial disparities intersect with other vulnerability factors such as age and sex, because NHANES data demonstrate that women and children are severely over-exposed to phthalates.²³ It is important for EPA to evaluate whether and how these trends overlap, compounding exposure and health risks for all women; for pregnant women in particular; and for pregnant women of color more specifically. For example, one recent study found that “[d]ifferential exposure to endocrine-disrupting chemicals, including phthalate

²³ CDC, FOURTH NATIONAL REPORT ON HUMAN EXPOSURE TO ENVIRONMENTAL CHEMICALS: UPDATED TABLES, MARCH 2021 (2021), *supra* note 21 (unpaginated).

diesters [such as DEHP], may contribute to persistent racial/ethnic disparities in women’s reproductive health outcomes,” especially among “Black pregnant women.”²⁴

NHANES data provide strong evidence that people of color, and potentially Indigenous people, experience greater exposure to the five phthalates under review. (NHANES does not track phthalate exposure rates for tribal communities.²⁵) This evidence alone supports and likely compels EPA to identify BIPOC as PESS because of the statute’s precautionary approach to risk evaluation.²⁶

2. *BIPOC susceptibility*

Peer-reviewed studies likewise demonstrate that at a population level, people of color are particularly susceptible to phthalate-related health harms.²⁷ EPA identifies “race/ethnicity” as a vulnerability factor that overlaps with social vulnerabilities, increasing susceptibility to harm from environmental exposures.²⁸ Social vulnerabilities include factors such as limited access to healthcare; language barriers (a non-English-speaking patient may struggle to communicate their symptoms to a doctor, resulting in suboptimal treatment); racism within the healthcare system that may lead to belated interventions and associated poor medical outcomes; and broader social

²⁴ Mary E. Sterrett et al., *Maternal Food and Beverage Consumption Behaviors and Discrepant Phthalate Exposure by Race*, INT’L J. ENVTL. RES. & PUB. HEALTH, Feb. 2021, at 1.

²⁵ In comments to EPA in a non-phthalate TSCA risk evaluation docket, the National Tribal Toxics Council has voiced its concern about “the paucity of data on tribal risks.” See National Tribal Toxics Council, Comment Letter on Perchloroethylene: Draft TSCA Risk Evaluation at 7, http://www.zendergroup.org/docs/nttc/comment_pce_risk.pdf.

²⁶ See *infra* Section I.B (discussing PESS provision in TSCA).

²⁷ See, e.g., Gina M. Solomon et al., *Cumulative Environmental Impacts: Science and Policy to Protect Communities*, 37 ANN. REV. PUB. HEALTH 83 (2016), <https://www.annualreviews.org/doi/full/10.1146/annurev-publhealth-032315-021807> (last visited Nov. 7, 2021); Michael Gochfeld & Joanna Burger, *Disproportionate Exposures in Environmental Justice and Other Populations: The Importance of Outliers*, 101 AM. J. PUB. HEALTH S53 (2011), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3222496/> (last visited Nov. 7, 2021); Tracey J. Woodruff, et al., *Meeting Report: Moving Upstream—Evaluating Adverse Upstream End Points for Improved Risk Assessment and Decision-Making*, 116 ENV’TAL HEALTH PERSPS. 1568 (2008), <https://ehp.niehs.nih.gov/doi/10.1289/ehp.11516> (last visited Nov. 7, 2021).

²⁸ U.S. EPA, GUIDELINES FOR HUMAN EXPOSURE ASSESSMENT at xv (Oct. 2019), www.epa.gov/sites/default/files/2020-01/documents/guidelines_for_human_exposure_assessment_final2019.pdf (last accessed Dec. 8, 2021).

stressors such as poverty, food insecurity, poor housing quality, exposure to violence, and racism beyond the health care system.²⁹

Likewise, “tribes have unique lifeways that place them at different risk due to multiple exposure pathways not experienced by the general population.”³⁰ These factors include tribal diets, housing, working conditions, water sources, and water use.³¹ According to the National Tribal Toxic Council, “lifeways of tribal members clearly make them a PESS under TSCA, because their exposures cannot be represented adequately under the general population.”³²

The peer-reviewed scientific literature on phthalates demonstrates how racial and social vulnerabilities intersect to increase susceptibility to phthalate-related adverse health outcomes. The phthalate **DIDP**, for example, is associated with wheezing in five-year-old boys whose mothers had higher urinary DIDP concentrations during pregnancy.³³ Given racial and ethnic disparities in asthma prevalence, this finding shows how DIDP exposure may make racial and ethnic subgroups particularly susceptible to DIDP’s adverse respiratory effects.³⁴

Similarly, women of color disproportionately use cosmetics and personal care products containing the phthalate **DEP**. In 2018, a study identified an association between recurrent

²⁹ See e.g., Hilal Al Shamsi et al., *Implications of Language Barriers for Healthcare: A Systematic Review*, 35 OMAN MED. J. 122, 122 (2020); Khiara M. Bridges, *Implicit Bias and Racial Disparities in Health Care*, AM. BAR ASS’N, https://www.americanbar.org/groups/crsj/publications/human_rights_magazine_home/the-state-of-healthcare-in-the-united-states/racial-disparities-in-health-care/; Rachel Morello-Frosch et al., *Understanding the Cumulative Impacts of Inequalities in Environmental Health: Implications for Policy*, 30 HEALTH AFF. 879, 879, 882 (2011).

³⁰ National Tribal Toxics Council, Comment Letter on Draft Scopes of the Risk Evaluations to be Conducted for 7 Chemical Substances Under the Toxic Substances Control Act (June 8, 2020) at 4-5, <http://www.zendergroup.org/docs/nttc/Commentsnext7.pdf> (last visited Dec. 8, 2021).

³¹ *Ibid.*

³² *Id.* at 2.

³³ See Céline Vernet et al., *In Utero Exposure to Select Phenols and Phthalates and Respiratory Health in Five-Year-Old Boys: A Prospective Study*, 125 ENVTL. HEALTH PERSP. 097006-1, 097006-1 (2017).

³⁴ Angela Haczku A & Reynold A. Panettieri, Jr., *Social stress and Asthma: The Role of Corticosteroid Insensitivity*, 125 J. ALLERGY CLIN. IMMUNOL. 550, 550 (2010); Lara J. Akinbami et al., *Trends in Racial Disparities for Asthma Outcomes Among Children 0 to 17 years, 2001-2010*, 134 J. ALLERGY CLIN. IMMUNOL. 547, 547 (2014).

spontaneous abortion and phthalate exposure (including DEP exposure) in Taiwanese women, after controlling for numerous race- and ethnicity-neutral variables.³⁵

Given the structural similarity of the phthalates under EPA review, these exposure findings apply with varying force to each of the phthalates undergoing risk evaluation.

3. BIPOC health risk

BIPOC's greater exposure and susceptibility to phthalates combine to produce health risks greater than for the general population. These health risks have serious medical and social implications. As endocrine-disrupting chemicals (EDCs), phthalates are linked to hormone disruption. Because of the centrality of hormone regulation to bodily function, this can in turn cause cancer; metabolic disorders, such as diabetes; asthma; reproductive disorders; diminished immune response to vaccines; and neurobehavioral impairments such as attention-deficit/hyperactivity disorder (ADHD), among other effects.³⁶

Endocrine disruptors also exacerbate social inequity. When EDCs interfere with brain development, for example, they increase the risk of childhood disorders associated with learning,

³⁵ Kai-Wei Liao, *Increased Risk of Phthalates Exposure for Recurrent Spontaneous Abortion in Reproductive-Aged Women: Taiwan Female Infertility Study (TIFP)*, ENVTL. HEALTH PERSP., <https://ehp.niehs.nih.gov/doi/10.1289/isesisee.2018.P03.2530> (last visited Nov. 27, 2021). The study included controls for age, education, plastic food container use, and other potential confounders. DEP was one of the three primary components of the phthalate exposure in the study population. The abstract of this study was presented at a past annual meeting of ISEE.

³⁶ See, e.g., National Institute of Environmental Health Sciences, *Endocrine Disruptors*, <https://www.niehs.nih.gov/health/topics/agents/endocrine/index.cfm> (last visited Nov. 28, 2021) (“[E]ndocrine disruptors . . . are linked with developmental, reproductive, brain, immune, and other problems. Endocrine disruptors are found in many everyday products, including some plastic bottles and containers, liners of metal food cans, detergents, flame retardants, food, toys, cosmetics, and pesticides . . . Because people are typically exposed to multiple endocrine disruptors at the same time, assessing public health effects is difficult.”); Julia R. Varshavsky, et al., *Dietary Sources of Cumulative Phthalates Exposure Among the U.S. General Population in NHANES 2005-2014*, 115 ENV'T INT'L 417, 417-18 (2018) (“Although pregnancy and childhood are vulnerable to their developmental toxicity, phthalates are associated with health impacts across the life course, including obesity, diabetes, reduced sperm quality, and cancer.”); Vernet et al., *supra* note 33, at 097006-1 (discussing the relationship between childhood asthma and phthalates).

attention, and behavior.³⁷ This in turn directly diminishes an individual’s emotional, social, educational, and professional capacity. Financial costs associated with neurobehavioral impairments predict lower educational attainment, remedial schooling and discipline, and diminished earnings and workplace productivity.³⁸

B. Identifying BIPOC as a PESS is consistent with the language of TSCA.

The Lautenberg Act amended TSCA to address disproportionate chemical risks to PESS.³⁹ TSCA now requires EPA to consider risks to PESS at every stage of the risk evaluation process, including when the agency (1) identifies high-priority chemicals for evaluation; (2) determines the scope of risk assessments; (3) conducts risk assessments; and (4) regulates chemicals to eliminate unreasonable risk.⁴⁰ Thus, identifying PESS, and adopting regulations where needed to protect PESS from unreasonable risk, are central requirements of amended TSCA. EPA must also assess risks to PESS in a manner consistent with best available science, and without regard to cost or other “nonrisk” factors.⁴¹

The statutory definition of PESS is sufficiently flexible and precautionary to encompass BIPOC with respect to phthalate exposure. TSCA defines a "potentially exposed or susceptible subpopulation” 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

³⁷ Engel et al., *supra* note 3, at 687-88 (2021).

³⁸ See, Jalpa A. Doshi et al., *Economic Impact of Childhood and Adult Attention-Deficit/Hyperactivity Disorder in the United States*, 51 J. AMERICAN ACAD. CHILD ADOLESCENT PSYCHIATRY 990, 990 (2012); Joseph Biederman & Stephen V. Faraone, *The Effects of Attention- Deficit/Hyperactivity Disorder on Employment and Household Income*, 8 MEDSCAPE GEN. MED. 12, 12 (2006).

³⁹ See *supra* note 5; see also 162 CONG. REC. S3512 (June 7, 2016) (statement by Sen. Boxer) (“[T]he standard for evaluating whether a chemical is dangerous is far better than in the old TSCA. The [Lautenberg] bill requires EPA to evaluate chemicals based on risks, not costs, and considers the impact on vulnerable populations [PESS]. This is really critical. The old law was useless. . . . [T]hese fixes make this bill better than current Federal law.”).

⁴⁰ See 15 U.S.C. § 2605 (2018).

⁴¹ See 15 U.S.C. § 2625(h) (2018) (defining the best available science standard); 15 U.S.C. § 2605(b)(4)(A) (2018) (prohibiting cost or nonrisk considerations in risk evaluations).

general population of adverse health effects from exposure to a chemical substance or mixture, such as infants, children, pregnant women, workers, or the elderly.⁴²

Although the statute lists specific groups that may be identified as PESS, this list is non-exclusive: the phrase “such as” precedes listed groups, making plain that they are but examples.

Further, Congress’s word choices indicate an intent for EPA to adopt a precautionary approach to identifying, evaluating, and mitigating risks to PESS. Congress used the word “*potentially*” to modify the words “exposed” and “susceptible,” indicating that EPA need not demonstrate with certainty that a subpopulation experiences greater exposure or susceptibility before identifying it as a PESS. The phrase “*may be at greater risk*” similarly supports an inference that Congress intended EPA to err on the side of caution to protect vulnerable subpopulations. Additionally, the disjunctive phrase “*either greater susceptibility or greater exposure*” facilitates identification of vulnerable subgroups, increasing the statute’s protective force.

TSCA’s structure also supports this precaution-oriented interpretation of its PESS language. TSCA requires EPA to identify PESS in advance of conducting a risk assessment, *i.e.*, at a point in the risk evaluation process when information is necessarily incomplete. This is consistent with Congress’s health-protective intent in passing the Lautenberg Act. Thus, the text, structure, and purpose of TSCA all support identifying subpopulations as PESS where, as here, those groups face potentially greater exposure *or* susceptibility to the chemical under review.

C. Identifying BIPOC as a PESS is consistent with EPA regulations, and with agency-wide exposure assessment guidelines.

EPA regulations and agency-wide exposure assessment guidelines support identification of BIPOC as a PESS. EPA’s definition of PESS in regulations governing the risk evaluation

⁴² 5 U.S.C. § 2602(12) (2018) (emphasis added).

process both mirrors TSCA’s language and confirms the agency’s broad latitude to supplement the statutory list of exemplar PESS.⁴³ As EPA explained in the rulemaking record:

EPA interprets the statutory [PESS] definition broadly and believes it does not prevent EPA from including any subpopulation that may be at greater risk due to greater susceptibility or exposure, or from identifying additional subpopulations other than those listed in the statute, where warranted. . . . [I]t would be difficult for the Agency to list all the potential subpopulations that the Agency might have reason to include in a risk evaluation.⁴⁴

Although EPA considered and rejected the notion of adding Indigenous and/or other subpopulations to the statutory list via regulation,⁴⁵ in response to comments on a related rulemaking, EPA agreed that it *could* identify Indigenous communities as a PESS if appropriate for the chemical substances under evaluation.⁴⁶ Thus, EPA has expressly acknowledged that it has regulatory authority to identify BIPOC as a PESS when doing so is factually warranted, as here.

Identifying BIPOC as a PESS with respect to phthalates is also consistent with EPA’s Guidelines for Exposure Assessment. Last updated in 2019, these Guidelines “present the current policies and practices of exposure assessors across the Agency.”⁴⁷ The Guidelines specifically recognize race and ethnicity as factors relevant to accurate exposure assessment:

Consistent with the Agency’s guidance in Framework for Cumulative Risk Assessment (U.S. EPA 2003d), exposure assessors need to be aware of environmental justice issues, including unique population characteristics and sociodemographic factors that might increase exposure or predispose a life stage, vulnerable group or population to greater risk. These factors can include age, sex, genetic susceptibility, cultural characteristics, behaviors, occupation, socioeconomic status, access to a healthy diet, *race/ethnicity* and geographic location.⁴⁸

⁴³ The regulatory definition of PESS mimics the statutory definition, except insofar it contemplates sub-delegation of PESS determinations within EPA, by giving the “Agency” rather than the “Administrator” discretion to identify PESS. 40 CFR § 702.33. This too can be read to facilitate designation of PESS.

⁴⁴ 82 Fed. Reg. 33732 (July 20, 2017).

⁴⁵ See 84 Fed. Reg. 71927 (Dec. 30, 2019).

⁴⁶ *Ibid.* (“Potentially exposed or susceptible subpopulations’ could include subpopulations with unique lifeways, such as tribes, and will be considered as part of the risk evaluation process.”)

⁴⁷ U.S. EPA, GUIDELINES FOR HUMAN EXPOSURE ASSESSMENT, *supra* note 28, at xiv U.S. EPA.

⁴⁸ *Id.* at xv (emphasis added).

The above-referenced EPA Framework for Cumulative Risk Assessment (2003) similarly states that vulnerable subpopulations “can be defined using age, *race*, gender, and other factors.”⁴⁹

EPA’s website further elaborates on the agency’s Guidelines for Exposure Assessment with regard to “Highly Exposed or Other Susceptible Population Groups,” stating that “there are intrinsic and extrinsic (or acquired) factors that affect an individual’s or population’s susceptibility to pollutants.”⁵⁰ EPA lists race as one such factor affecting susceptibility.⁵¹ Evaluating racial disparities in the context of a risk assessment is thus consistent with agency-wide exposure assessment guidelines, and the agency’s own regulatory interpretation.

D. Identifying BIPOC as a PESS is consistent with EPA’s environmental justice commitments, and with the Biden Administration’s Executive Order on Protecting Public Health and the Environment.

EPA’s environmental justice policy supports race-conscious chemical risk evaluations.

According to EPA’s website:

Incorporating measures of population vulnerability (differential exposures), including *racial*, social, and cultural aspects, in developing and implementing environmental laws, regulations, and policies is an important goal of EPA’s Environmental Justice program.⁵²

Consistent with this policy, EPA’s environmental justice program defines “overburdened communities”—a phrase conceptually similar to PESS—as “[m]inority, low-income, tribal, or indigenous populations or geographic locations in the United States that potentially experience disproportionate environmental harms and risks.”⁵³

⁴⁹ U.S. EPA, FRAMEWORK FOR CUMULATIVE RISK ASSESSMENT 63 (2003) (emphasis added), https://www.epa.gov/sites/default/files/2014-11/documents/frmwrk_cum_risk_assmnt.pdf (last visited Dec. 8, 2021).

⁵⁰ U.S. EPA, *Exposure Assessment Tools by Lifestages and Populations - Highly Exposed or Other Susceptible Population Groups*, <https://www.epa.gov/expobox/exposure-assessment-tools-lifestages-and-populations-highly-exposed-or-other-susceptible> (last visited Nov. 23, 2021)

⁵¹ *Id.*

⁵² *Id.* (emphasis added).

⁵³ U.S. EPA, *EPA EJ Glossary 2020*, (last visited Nov. 23, 2021), <https://www.epa.gov/environmentaljustice/ej-2020-glossary>.

The Biden Administration’s Executive Order (Order) on Protecting Public Health and the Environment likewise supports race-conscious risk evaluation. According to the Order:

It is . . . the policy of my Administration to listen to the science; to improve public health and protect our environment . . . to limit exposure to dangerous chemicals and pesticides; to hold polluters accountable, including those who disproportionately harm communities of color and low-income communities . . . and to prioritize both environmental justice and the creation of the well-paying union jobs.⁵⁴

The Order directed all federal agencies “to address the promulgation of Federal regulations and other actions during the last 4 years that conflict with these important national objectives.”⁵⁵ The predecessor (Trump) EPA is primarily responsible for the scoping documents on phthalates wherein BIPOC were not identified as a PESS.⁵⁶ The Order supports EPA action to correct this.

In furtherance of the Order, the White House Environmental Justice Advisory Council evaluated the existing phthalates scoping documents, and determined that they underestimated risks to PESS.⁵⁷ This Council recommended revising the scoping documents “so fence line communities are identified as subpopulations that face greater risk than the general population.”⁵⁸ The Council noted that EPA “must revise the TSCA scope documents for . . . high-priority chemicals undergoing review so fenceline communities are identified as subpopulations that face greater risk than the general population. If it does this, EPA would have to calculate these communities’ risks separately from the risks the general population faces, and then ultimately it

⁵⁴ Exec. Order No. 13990, Protecting Public Health and the Environment and Restoring Science to Tackle the Climate Crisis, 80 Fed. Reg. 7037 (Jan 20, 2021).

⁵⁵ *Id.*

⁵⁶ WHITE HOUSE EVNTL. JUSTICE ADVISORY COUNCIL, FINAL RECOMMENDATIONS: JUSTICE40 CLIMATE AND ECONOMIC JUSTICE SCREENING TOOL & EXECUTIVE ORDER 12898 REVISIONS (2021), at 32 (“The revised TSCA requires EPA to specially consider groups who are at greater risk of harm from chemical exposures when it evaluates, and then manages, chemical risks. The Trump Administration failed to protect fenceline communities from unreasonable risk.”), <https://www.epa.gov/environmentaljustice/white-house-environmental-justice-advisory-council-final-recommendations> (last visited Dec. 8, 2021).

⁵⁷ *See ibid.*

⁵⁸ *Ibid.*

would have to manage the specific risk they experience from TSCA chemicals so it is no longer unreasonable.”⁵⁹

In similar fashion, public comments to date in phthalate risk evaluation dockets have urged EPA to identify as PESS those populations at greater risk of chemical exposure because of “their proximity to a polluting facility or contaminated site.”⁶⁰ They have further noted that because “racial and ethnic minorities in the United States face higher levels of psychosocial stressors than non-minorities,” they are particularly (and appropriately) concerned about those geographically defined communities that are “burdened with both intrinsic and extrinsic susceptibility factors, like those living in close proximity to petrochemical facilities in the Gulf Coast regions of Louisiana and Texas, [which] are particularly vulnerable to harm from chemical exposures and must be considered potentially exposed or susceptible subpopulations in [phthalate] risk evaluations.”⁶¹ Accordingly, EPA’s phthalate scoping documents state explicitly that the agency may identify “fence line communities” as PESS in phthalate risk evaluations.⁶²

Although the Council and commenters are correct that phthalate scoping documents underestimate risks to PESS living in proximity to exposure sources, the articulation and conception of “fence line community” is far too narrow to capture BIPOC vulnerability to

⁵⁹ *Ibid.*

⁶⁰ Comments of Earthjustice on behalf of Rubbertown Emergency ACTION, et al., TSCA Risk Evaluations for High-Priority Substances and Substances Undergoing Manufacturer-Requested Risk Evaluations (July 15, 2021), EPA-HQ-OPPT-2018-0503 (Dibutyl phthalate, CASRN 84-74-2), at 4.

⁶¹ Comments of Earthjustice on behalf of Alaska Community Action on Toxics, et al., Draft Scopes of the Risk Evaluations to be Conducted Under the Toxic Substances Control Act for Di-isononyl Phthalate and Di-isodecyl Phthalate (“DINP” and “DIDP”), EPA-HQ-OPPT-2018-0435, EPA-HQ-OPPT-2018-0436, at 10-11.

⁶² See U.S. EPA, EPA-740-R-20-017, FINAL SCOPE OF THE RISK EVALUATION FOR DI-ETHYLHEXYL PHTHALATE [DEHP] (2020), at 43; U.S. EPA, EPA-740-R-20-019, FINAL SCOPE OF THE RISK EVALUATION FOR DICYCLOHEXYL PHTHALATE [DCHP] (2020), at 36; U.S. EPA, EPA-740-R-20-018, FINAL SCOPE OF THE RISK EVALUATION FOR DI-ISOBUTYL PHTHALATE [DiBP] (2020), at 39; U.S. EPA, EPA-740-R-20-015, FINAL SCOPE OF THE RISK EVALUATION FOR BUTYL BENZYL PHTHALATE [BBP or BBzP] (2020), at 37; U.S. EPA, EPA-740-R-20-016, FINAL SCOPE OF THE RISK EVALUATION FOR DIBUTYL PHTHALATE [DBP] (2020), at 41.

phthalate health effects, insofar as it suggests an exclusive focus on place-based exposures.⁶³ Identifying only place-based subpopulations as PESS would unduly limit the focus of the phthalate risk evaluations, because phthalates additionally and indeed primarily harm BIPOC through ingestion (food) and other routes of exposure unrelated to geography. Thus, EPA should identify *BIPOC as a whole* as a PESS for phthalates, to avoid dangerously under-estimating racial disparities in phthalate exposures, susceptibility, and health risks.

For all of these reasons, EPA must supplement the list of groups identified as PESS in its phthalate scoping documents (children, women of reproductive age, consumers, and workers),⁶⁴ by also identifying BIPOC as a PESS. EPA's failure to do so would violate TSCA's command to use the best available science; would contradict EPA's own prior statements related to its understanding of PESS, as articulated in EPA regulations⁶⁵ and guidelines⁶⁶; and would run counter to current federal policies and pronouncements on environmental justice.⁶⁷ Indeed, failure to identify BIPOC as a PESS for phthalates would systematically underestimate this subpopulation's risk, exacerbating health harms to BIPOC and thus magnifying social inequality.

⁶³ See e.g., GREENPEACE, *Chemical Plant Safety Critical to Environmental Justice*, (last visited Nov. 26, 2021), <https://www.greenpeace.org/usa/chemical-plant-safety-critical-environmental-justice/> (demonstrating that advocacy groups use the term "fence line community" to refer to people living near polluting facilities).

⁶⁴ See, e.g., U.S. EPA, EPA-740-R-20-017, FINAL SCOPE OF THE RISK EVALUATION FOR DI-ETHYLHEXYL PHTHALATE [DEHP] (2020), at 32-33; U.S. EPA, EPA-740-R-20-019, FINAL SCOPE OF THE RISK EVALUATION FOR DICYCLOHEXYL PHTHALATE [DCHP] (2020), at 28; U.S. EPA, EPA-740-R-20-018, FINAL SCOPE OF THE RISK EVALUATION FOR DI-ISOBUTYL PHTHALATE [DiBP] (2020) at 30-31; U.S. EPA, EPA-740-R-20-015, FINAL SCOPE OF THE RISK EVALUATION FOR BUTYL BENZYL PHTHALATE [BBP or BBzP] (2020), at 29-30; U.S. EPA, EPA-740-R-20-016, FINAL SCOPE OF THE RISK EVALUATION FOR DIBUTYL PHTHALATE [DBP] (2020), at 30-31.

⁶⁵ See *Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act*, 82 Fed. Reg. 33726, 33732 (July 20, 2017) (codified at 40 C.F.R. § 702).

⁶⁶ See U.S. EPA, GUIDELINES FOR HUMAN EXPOSURE ASSESSMENT, *supra* note 28.

⁶⁷ See Exec. Order No. 14,008, 86 Fed. Reg. 19 (Feb. 1, 2021), *available at* <https://www.govinfo.gov/content/pkg/FR-2021-02-01/pdf/2021-02177.pdf> (last visited Nov. 7, 2021).

II. EPA Must *Analyze the* “Conditions of Use” Associated with High Phthalate Exposure, Regardless of Which Agency Has Initial Jurisdiction to *Regulate* Risk.

A. TSCA requires EPA risk evaluations to encompass *all* “conditions of use” relevant to assessing health risk from the chemical under review.

TSCA, as amended and strengthened in 2016, compels EPA to include in chemical risk evaluations all “conditions of use” relevant to the health risks posed by the specific chemicals under review. “Conditions of use” are statutorily defined as “the circumstances, as determined by the [EPA] Administrator, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of.”⁶⁸ This language is sufficiently broad to require EPA to evaluate all factually relevant conditions of use, and to do so in a single chemical risk evaluation. Conditions of use for phthalates would include, among others, use of phthalates in food-contact materials, cosmetics, personal care products, medical products, and flexible plastics in consumer goods, because phthalates are “known . . . to be manufactured, processed, distributed in commerce, used, [and] disposed of” in all of these functions.

The U.S. Court of Appeals for the Ninth Circuit recently confirmed EPA’s the breadth of EPA’s analytic authority in conducting risk evaluations. In *Safer Chemicals, Healthy Families v. U.S. EPA*, 943 F.3d 397 (9th Cir. 2019) (*Safer Chemicals*), the court used a plain meaning approach and found that Congressional intent was clear: Under TSCA’s definition for conditions of use, during the risk evaluation stage EPA has legal authority to consider *all* reasonably foreseeable conditions of use, including those that typically fall outside of the Agency’s initial authority to regulate.⁶⁹ The court further emphasized the connection between TSCA’s “conditions of use”

⁶⁸ 15 U.S.C. § 2602(4).

⁶⁹ See *Safer Chemical, Health Families v. U.S. EPA*, 943 F.3d 397, 421, 425-26 (9th Cir. 2019).

definition and a chemical’s actual presence in commerce: If a chemical substance exists in relevant conditions of use in commerce, then EPA *must* include those uses in the risk evaluation process.⁷⁰

For phthalates, conditions of use related to food, cosmetics, personal care products, and medical devices are all known and intended uses in commerce. EPA must accordingly assess risks from those conditions of use in its TSCA risk evaluation irrespective of how risk management responsibility might be allocated among federal agencies in the event that EPA makes a finding of unreasonable risk.

B. TSCA prohibits EPA from excluding the most relevant conditions of phthalate use for *non-risk* reasons.

EPA’s scoping documents for phthalates unlawfully exclude as conditions of use those phthalate uses that sister agencies, such as the Food and Drug Administration, would in the first instance have jurisdiction to regulate. This means that EPA proposes to exclude from its phthalate risk evaluations *precisely those chemical uses associated with significant human exposures*, namely: the use of phthalates in food-contact materials, cosmetics, and personal care products.⁷¹ EPA’s exclusion of such uses is unlawful, because the agency’s consideration of agencies’ respective regulatory jurisdiction constitutes a “nonrisk” consideration that TSCA flatly prohibits.

The Lautenberg Act strengthened TSCA significantly by expressly prohibiting “[the] consideration of . . . nonrisk factors” in TSCA risk evaluations.⁷² EPA’s decision to exclude what it terms “non-TSCA uses” from its phthalate risk *evaluations* simply because another agency would have initial regulatory jurisdiction over eventual risk *management* constitutes obvious and

⁷⁰ *Id.* at 423.

⁷¹ EPA’s proposal to exclude food-contact materials is particularly troubling, given the outsize contribution of processed foods to phthalate exposure. See Varshavsky, *et al.*, *Dietary Sources of Cumulative Phthalate Exposure Among the U.S. General Population in NHANES 2005-2014*, *supra* note 36, at 417 (2018) (“Diet is the primary exposure source for most phthalates, which contaminate the food supply through food contact materials and industrialized production”).

⁷² 15 U.S.C. § 2605(b)(4)(A).

impermissible consideration of a “nonrisk factor[.]” at the risk evaluation stage, in contravention of statutory instruction. Courts have consistently invalidated EPA rules where the agency relied on factors that Congress forbade it from considering,⁷³ and can likewise be predicted to do so here.⁷⁴

Related, and important, the phrase “non-TSCA uses” is inapt and misleading. This locution stems neither from statute nor regulation, but rather, is an ad hoc EPA creation used repeatedly in its phthalate scoping documents. Although mere repetition of a made-up phrase does not imbue it with legal force, it does create a convenient tautological fortress: *How could stakeholders or a court compel EPA to analyze under TSCA those chemical uses that are “non-TSCA”?*

Behind this semantic obfuscation, however, lies the plain text of TSCA—text that in Section 3(4) of the statute defines “conditions of use” expansively, 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.*”⁷⁵ Although Section 3(4) gives the EPA discretion to determine the relevant conditions of use for each chemical substance—for example, EPA could reasonably conclude that a screwdriver, but not a coffee mug, might be used to pry open a paint can lid—a U.S. Court of Appeals has explained that “that discretion may only be exercised within the bounds of the statutory definition itself.”⁷⁶ The statutory definition of conditions of use is clearly concerned with the existence of any use condition *relevant* to chemical exposure, not with which agency may regulate such use at the later risk-management stage.

⁷³ See e.g., *Whitman v. Am. Trucking Ass’ns*, 531 U.S. 457, 467-68 (2001) (holding that EPA cannot consider factors that Congress either explicitly or implicitly prohibited from consideration); *Les v. Reilly*, 968 F.2d 985, 990 (9th Cir. 1992) (striking down EPA regulations where agency directly contradicted statutory language, thus undermining Congressional intent).

⁷⁴ See, e.g., *Mingo Logan Coal Co. v. EPA*, 829 F.3d 710, 718 (D.C. Cir. 2016) (stating that an agency action “[is] arbitrary and capricious if the agency has relied on factors which Congress has not intended it to consider.” (citing *State Farm*)).

⁷⁵ 15 U.S.C. § 2602(4) (emphasis added).

⁷⁶ *Safer Chemicals*, 943 F.3d at 425.

Further, nothing in Section 3(2)—which defines the term “chemical substance,”⁷⁷ and thus serves as on-ramp to an EPA risk evaluation for a chemical—counsels otherwise. This Section’s sole purpose is to define chemicals over which EPA has at least *some* jurisdiction, such that the chemicals (here, various phthalates) may properly enter the risk evaluation process. Nothing in Section 3(2) limits the scope of EPA’s evaluation of a properly selected chemical, either based on which agency has initial jurisdiction over certain conditions of use or otherwise. Because phthalates are indisputably “chemical substances” under TSCA, and are properly undergoing risk evaluation, Section 3(2) is here irrelevant.

EPA’s coinage and deployment of the phrase “non-TSCA uses” is not merely unfortunate, but tendentious, insofar as it suggests that there exist conditions of use that EPA simply lacks legal authority to *evaluate*. This is wrong. To the contrary, EPA must evaluate the risk from all conditions of use that are “intended, known, or reasonably foreseen.” A more accurate description of so-called “non-TSCA uses” is, instead, “*uses outside EPA’s initial jurisdiction*”—the phrase we use in these comments.⁷⁸

The best available science indicates that phthalate conditions of use beyond EPA’s initial jurisdiction are the main contributors to human exposure to phthalates,⁷⁹ and particularly, the use

⁷⁷ 15 U.S.C. § 2602(2).

⁷⁸ We choose the phrase “initial jurisdiction” to distinguish TSCA’s jurisdictional arrangement from the concept of “primary jurisdiction.” The legal doctrine of primary jurisdiction, which is here irrelevant, provides courts the discretion to stay or dismiss a party’s claims to allow an expert agency to make a decision in the first instance. *U.S. v. W. Pac. R.R. Co.*, 352 U.S. 59, 62–63 (1956). The focus here is not on the circumstances under which courts may defer to agencies, but rather, on how Congress has through TSCA allocated regulatory authority *among* agencies.

⁷⁹ See, e.g., Xu-Liang Cao, *Phthalate Esters in Foods: Sources, Occurrence, and Analytical Methods*, 9 COMPREHENSIVE REVS. FOOD SCI. & FOOD SAFETY 21 (2010) (finding that major sources of phthalates in food stem from migration of phthalates from materials that come into contact with food during processing, storage and transfer); Samantha E. Serran, et al., *Phthalates and Diet: A Review of the Food Monitoring and Epidemiology Data*, 13 ENV’TAL HEALTH 43 (2014) (observing that “diet is considered a significant exposure pathway [for phthalates]” and estimating daily intakes of DEHP across typical consumption patterns); Varshavsky, et al., *Dietary Sources of Cumulative Phthalate Exposure Among the U.S. General Population in NHANES 2005-2014*, *supra* note 36 at 417 (2018) (concluding that “dining out may be an important source of biologically relevant cumulative phthalates exposure among the U.S. population”); Angela Giuliani, et al., *Critical Review on the Presence of*

of phthalates in food contact materials, which is regulated by the FDA. As recently reported in the New York Times, a 2017 investigation by Defend our Health revealed high levels of phthalates in mass-market Mac ‘n Cheese products that select manufacturers are only now beginning to address.⁸⁰ Mac ‘n Cheese is a textbook example of a processed food heavily consumed by low-income consumers and those in food deserts, who are disproportionately BIPOC.

Cosmetics and personal care products are likewise widely understood sources of considerable phthalate exposure, and preferential exposure to BIPOC women in particular.⁸¹ These uses are thus of critical relevance to EPA’s risk *evaluation*, even if in the first instance a sister agency (the FDA) has responsibility for risk *regulation*. TSCA’s command is clear and unambiguous: EPA’s risk evaluations must reflect the cumulative contributions to risk from phthalates both within and beyond the agency’s own initial jurisdiction.

C. If EPA finds an unreasonable risk from phthalates, TSCA is structured to ensure that *some* federal agency reduces that risk.

If EPA risk evaluations for phthalates find that these chemicals pose “unreasonable” risk— a certain outcome if such analyses include all relevant conditions of use, are conscientiously

Phthalates in Food and Evidence of Their Biological Impact, 17 INT’L J. ENV’TAL RSCH. & PUB. HEALTH 5655 (2020) (identifying food intake and drinking water as “the major route of human exposure, accounting for more than 67%”); Lariah Edwards, et al., *Phthalate and Novel Plasticizer Concentrations in Food Items from U.S. Fast Food Chains: A Preliminary Analysis*, J. EXPOSURE SCI. & ENV’TAL EPIDEMIOLOGY (2021) (detecting numerous phthalates in a selection of popular food items and food handling gloves).

⁸⁰ Michael Corkery, *Annie’s Pledges to Purge a Class of Chemicals from its Mac and Cheese*, New York Times (Feb. 19, 2021), <https://www.nytimes.com/2021/02/19/business/annies-mac-cheese-plastic-phthalates>.

⁸¹ See Breast Cancer Prevention Partners, *Right to Know: Exposing toxic fragrance chemicals in beauty, personal care and cleaning products* at 47 (noting that of numerous products tested, “Just For Me—a shampoo marked to kids of color— had the most hazardous chemicals,” including **DEP**, <https://www.bcpp.org/resource/right-to-know-exposing-toxic-fragrance-chemicals-report/> (last visited Dec. 8, 2021); see also Campaign for Safe Cosmetics, *Phthalates* (2021), <https://www.safecosmetics.org/get-the-facts/chemicals-of-concern/phthalates/> (last visited Dec. 8, 2021) (explaining that phthalates, including **DEHP** and **DBP**, are found in “[c]olor cosmetics, fragranced lotions, body washes and hair care products, nail polish and treatment,” and noting that these two phthalates are already banned in cosmetics sold in the European Union); Black Women for Wellness, *Toxic-Free Beauty Pocket Guide* (alerting women to potential phthalate exposure in perfumes, hair sprays, nail polishes, and the “fragrance” component of other cosmetics, <https://www.bwwla.org/v2019/wp-content/uploads/2021/04/Black-Women-for-Wellness-x-Lather-Chem-Card.pdf> (last visited Dec. 8, 2021).

performed, and are consistent with the best available science—TSCA is structured to ensure that *some* federal agency reduces this risk to a level of reasonableness. Specifically, Sections 6 and 9 interlock to create a situation in which no TSCA-identified risk is ultimately unregulable. Section 6 confers on EPA substantial initial jurisdiction to control chemical exposures, and Section 9 confers further, contingent jurisdiction that enables EPA to act as back-stop if an agency with initial jurisdiction fails to do so. Thus, to the extent EPA asserts or believes that analysis of phthalate risks from items such as food-contact materials, cosmetics, or personal care products would be futile because the agency lacks initial Section 6 jurisdiction to act on any risk-reduction implications of its examination, EPA has ignored or misapprehended its contingent authority under Section 9.

TSCA Section 6 grants EPA comprehensive authority to “prohibit or limit the manufacture, processing, distribution in commerce, use, or disposal of a chemical if EPA evaluates the risk and concludes that the chemical presents an unreasonable risk to human health or the environment.”⁸²

As per Sections 6 and 9, this risk mitigation may occur in one of four ways:

- (1) Where a chemical condition of use is regulatable under a non-TSCA statute that EPA administers, Congress has instructed EPA to use the non-TSCA law in the first instance. (TSCA Section 9(b); 15 U.S.C. § 2608(b).)
- (2) Where no such statute exists and no other agency has relevant legal authority, TSCA acts as gap-filler, instructing EPA to regulate risk directly. (TSCA section 5(e) & 6(a); 15 U.S.C. §§ 2604(e), 2605(a).)
- (3) Where chemical conditions of use implicate the jurisdiction of another federal agency, EPA must issue a report to such agency that contains EPA’s finding of unreasonable risk and its recommendations for risk management. (TSCA Section 9; 15 U.S.C. § 2608(a)(1).)

⁸² EPA, *Regulation of Chemicals under Section 6(a) of the Toxic Substances Control Act*, available at <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/regulation-chemicals-under-section-6a-toxic-substances#background> (last visited Nov. 7, 2021); 15 U.S.C. § 2605(1).

- (4) If a sister agency neglects to regulate the risk to a level of insignificance after receiving a section 9 report, EPA may exercise jurisdiction under TSCA to do so. (TSCA Section 9; 15 U.S.C. § 2608(a)(4).)

This statutory scheme is as comprehensive as it is complex, ensuring that TSCA can fill gaps in pre-existing EPA authorities, and that EPA can back-stop other agencies in the event of their regulatory dereliction. Section 9 in particular represents an elegant means of simultaneously recognizing agencies' areas of primary expertise; avoiding regulatory duplication; and ensuring that *some* federal agency will mitigate chemical risks that EPA has determined to be unreasonable.

This Section provides:

If the Administrator determines that the . . . chemical substance [that has undergone EPA risk evaluation] . . . presents an unreasonable risk of injury to health or the environment . . . including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by the Administrator . . . and determines . . . that such risk may be prevented or reduced to a sufficient extent by action taken under a Federal law not administered by the Administrator, the Administrator *shall* submit to the agency which administers such law a report which describes such risk and includes in such description a specification of the activity or combination of activities which the Administrator has reason to believe so presents such risk.⁸³

A federal agency that receives a Section 9 report must generally respond within 90 days.⁸⁴

If the recipient agency acts on the report (either by initiating action to address the risk, or by formally disagreeing with EPA's risk determination), then EPA may not regulate the conditions of use of the chemical and resulting risk identified in that report.⁸⁵ (In such a case, however, EPA does remain obligated to take appropriate action on risks from conditions of use not identified in that report.⁸⁶) If, however, the recipient agency fails to act within the specified timeframe, EPA acquires not only legal authority but the affirmative *obligation* to take action under TSCA Sections

⁸³ 15 U.S.C. § 2608(a)(1) (emphasis added).

⁸⁴ 15 U.S.C. § 2608(a)(2).

⁸⁵ *Id.*

⁸⁶ 15 U.S.C. § 2608(a)(5).

5 or 6, as applicable, to eliminate the chemical's unreasonable risk.⁸⁷ A section 9 report thus functions as a right of first refusal to the recipient agency: Regulate this risk, or EPA will in your stead.

Although EPA appears to have used Section 9 but a single time to date, the lone historic deployment of this section demonstrates its latent power. In 1985, EPA examined the chemical 4,4'-methylenedianiline (4,4' MDA), then used directly in applications such as epoxy resins and dyes, and also as a feedstock in the manufacture of polyurethane foams and other products.⁸⁸ Based on animal bioassay data, EPA concluded that 4,4' MDA presented “a significant risk of serious harm to humans from cancer” that, under TSCA's framework, posed “an unreasonable risk of injury to the health of exposed workers.”⁸⁹ Noting that “[a]ll known exposure to 4,4'-MDA occurs in the workplace,” EPA thereupon issued a formal report to the Occupational Safety and Health Administration (OSHA), on the basis that the unreasonable risk “may be eliminated or reduced to a sufficient extent by actions taken under the OSHAct [Occupational Safety and Health Act].”⁹⁰

What occurred next was exactly the risk mitigation that Section 9 contemplates. OSHA quickly agreed with EPA's determination of significant risk to the health of exposed workers; it agreed with EPA that OSHA had the power to mitigate such risk; and it preliminarily determined that adoption of an occupational standard for worker exposure to MDA was feasible.⁹¹ After extensive examination of regulatory options, OSHA ultimately adopted a final rule establishing numerical workplace exposure standards, and mandating additional worker protections—

⁸⁷ See 15 U.S.C. § 2608(a)(3)-(4) (if the recipient agency fails to respond to EPA's report in a timely manner, “the [EPA] Administrator *shall* (A) initiate or complete appropriate action under section 2605(a) of this title; or (B) take any action authorized or required under section 2606 of this title, as applicable.”) (emphasis added); see also 15 U.S.C. § 2605(a) (stating that if the Administrator finds an unreasonable risk, the Administrator shall regulate “to the extent necessary so that the chemical substance or mixture no longer presents such risk”).

⁸⁸ 50 Fed. Reg. 27674, 27674 (July 5, 1985).

⁸⁹ *Id.* at 27675.

⁹⁰ *Id.* at 27680.

⁹¹ 51 Fed. Reg. 6748 (Feb. 26, 1986).

protections it estimated would reduce risk by 87 to 98 percent.⁹² With respect to phthalates, too, EPA's sister agencies have extensive regulatory tools with which to mitigate existing high levels of exposure risk. Section 9 compels EPA to trigger their use.

The existence and logical structure of TSCA Section 9 reflect Congress' intent that EPA consider health and environmental risks of chemicals expansively and holistically at the risk evaluation stage, even for chemical uses that might in the first instance be subject to another agency's regulatory jurisdiction. As such, the notion of "non-TSCA uses" excludable from an EPA risk evaluation is nonsensical: excluding risk-relevant conditions of use outside of EPA's usual jurisdiction would read Section 9 out of the statute entirely, contrary to the interpretive canon of nonsurplusage.⁹³

D. In any future litigation over its risk evaluations, EPA will be judicially estopped from advancing its current interpretation of "conditions of use."

EPA's arguments to the Ninth Circuit in the *Safer Chemicals* case, there unsuccessful in defeating liability, will here bar EPA from prevailing in any litigation claim stemming from its improper "conditions of use" interpretation in the phthalate scoping documents. The doctrine of judicial estoppel is a "the doctrine of preclusion of inconsistent positions, [which] precludes a party from gaining an advantage in one position, and then seeking a second advantage by taking an incompatible position."⁹⁴ Judicial estoppel, which concerns the relationship between the court

⁹² 57 Fed. Reg. 35630 (Aug. 10, 1992).

⁹³ As the U.S. Supreme Court has explained, it is "[an]elementary canon of construction that a statute should be interpreted so as not to render one part inoperative." *Colautti v. Franklin*, 439 U.S. 379, 392 (1979), *aff'd*, *States Telephone Telegraph Co. v. Pueblo of Santa Ana*, 472 U.S. 237, 249 (1985).

⁹⁴ *Rissetto v. Plumbers and Steamfitters Loc. 343*, 94 F.3d 597, 600 (9th Cir. 1996).

system and litigants,⁹⁵ protects the “integrity of the judicial system”⁹⁶ by preventing litigants from using inconsistent arguments as “a means of obtaining unfair advantage.”⁹⁷

In *Safer Chemicals*, EPA told the Ninth Circuit that it would be improper under TSCA to “definitively exclude a priori specific conditions of use from risk evaluation.”⁹⁸ EPA has therefore represented to a federal appellate court that it will comprehensively examine conditions of use from a chemical substance, and then use its discretion and expert judgment to make a risk determination. In the phthalates scoping documents, however, EPA does the antithesis: it engages in a priori exclusions, based on (ostensible) jurisdictional considerations, which is exactly what the agency represented that it would not do. The Ninth Circuit has previously authorized the use of judicial estoppel in an environmental context,⁹⁹ and its potential application and implications here are clear. As the agency itself has conceded in court: “If EPA were to, for example, exclude a use with no explanation of why the exclusion is consistent with TSCA, it would likely be invalid on its face and would not withstand judicial review.”¹⁰⁰

In sum, EPA’s failure to identify the use of phthalates in food, cosmetics, personal care products, and medical devices as conditions of use in phthalate risk evaluations runs directly contrary to Congressional instruction in two ways. First, by considering a non-risk factor in defining conditions of use for phthalates, EPA has taken an action that Congress expressly forbid. Second, by not considering the best available science regarding conditions of use that constitute

⁹⁵ Brief for Appellees People of the State of California, et al., *California ex rel. Lockyer v. U.S. Dep’t of Agric.*, 575 F.3d 999 (9th Cir. 2009) (Nos. 07-15613, 07-15614, 07-15695), 2007 WL 4454083, at *43.

⁹⁶ *Russell v. Rolfs*, 893 F.2d 1033, 1037 (9th Cir. 1990) (quoting *Rockwell Int’l Corp. v. Hanford Atomic Metal Trades Council*, 851 F.2d 1208, 1210 (9th Cir. 1988)).

⁹⁷ *Arizona v. Shamrock Foods*, 729 F.2d 1208, 1215 (9th Cir. 1984) (quoting *Scarano v. Central R. Co. of N.J.*, 203 F.2d 510, 513 (3rd Cir. 1953)).

⁹⁸ Brief for Respondents Environmental Protection Agency, et al., *Safer Chemicals*, 943 F.3d 397 (9th Cir. 2019) (Nos. 17-72260, 17-72501, 17-72968, 17-73290, 17-73383, 17-73390), 2018 WL 3879023 at *36.

⁹⁹ See, e.g., *N. Alaska Env’t Ctr. v. Lujan*, 961 F.2d 886, 891 (9th Cir. 1992).

¹⁰⁰ Brief for Respondents Environmental Protection Agency, et al., *Safer Chemicals*, *supra* note 98, 2018 WL 3879023 at *49.

significant and thus highly relevant sources of exposure, EPA is failing to do what Congress expressly commanded. EPA must therefore identify all relevant conditions of use for the phthalates under evaluation, based only on chemical-specific risks and science. Further, it may do so confident that TSCA Sections 5, 6, and 9 collectively ensure that any unreasonable risk so identified can ultimately be regulated sufficiently to ensure human health for the general population, and for PESS such as BIPOC.

III. EPA Must Conduct a Cumulative Risk Assessment of Phthalates

The best available science on phthalates requires cumulative risk assessment to accurately characterize the realities of co-exposures to multiple chemicals that produce similar health harms and cumulative toxicity. The best available science, including numerous peer-reviewed studies (one of which received an award from EPA itself), has consistently demonstrated the cumulative impact of phthalates on human health.¹⁰¹ Cumulative risk assessment is particularly critical to protect the health of BIPOC, because of their concurrent, outside exposure to each of multiple phthalate chemicals.

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¹⁰¹ Engel et al., *Neurotoxicity of Ortho-Phthalates: Recommendations for Critical Policy Reforms to Protect Brain Development in Children*, *supra* note 3; Jung-Wei Chang et al., *Estimated Daily Intake and Cumulative Risk Assessment of Phthalates in the General Taiwanese after the 2011 DEHP Food Scandal*, 7 *Sci. Reps.* 45009 (2017), <https://www.nature.com/articles/srep45009> (last visited Nov. 8, 2021); Krista L.Y. Christensen et al., *Generation of Hazard Indices for Cumulative Exposure to Phthalates for Use in Cumulative Risk Assessment*, 69 *Regulatory Toxicology & Pharmacology* 380 (2014), <https://www.sciencedirect.com/science/article/pii/S0273230014000828> (last visited Nov. 8, 2021); Gilbert C. Gee & Devon C. Payne-Sturges, *Environmental Health Disparities: A Framework Integrating Psychosocial and Environmental Concepts*, 112 *Env'tl Health Persps.* 1645 (2004) (recipient of the 2007 U.S. EPA Scientific and Technological Achievement Award, Level II, for advancing the interdisciplinary study of racial/ethnic disparities in environmental health and cumulative risk).

The National Academy of Sciences first called for cumulative risk assessment of phthalates over a decade ago.¹⁰² Public health researchers responded by developing methodologies for calculating cumulative phthalates exposure,¹⁰³ as did agencies in the U.S. and abroad.¹⁰⁴

EPA explains cumulative risk assessment as the “analysis, characterization, and quantification of the combined risks to health and the environment from multiple agents or stressors.”¹⁰⁵ In a cumulative risk assessment, substances with common characteristics or adverse health effects can be grouped together for evaluation of risks caused by so-called “co-exposures,” or from a combination of exposures and susceptibility factors such as pregnancy and inadequate access to healthcare.¹⁰⁶

The purpose of a cumulative risk assessment is to account for the reality that humans are not exposed to chemicals in isolation, but are instead exposed to complex mixtures of chemicals from varied sources.¹⁰⁷ Such co-exposures can amplify the effects of exposure to any one chemical

¹⁰² See Nat’l Acad. Sci., *Phthalates and Cumulative Risk Assessment: The Tasks Ahead* (2008), available at <https://www.nationalacademies.org/our-work/health-risks-of-phthalates> (last visited Nov. 7, 2021).

¹⁰³ See, e.g., Varshavsky et al., *A Novel Method for Calculating Potency-Weighted Cumulative Phthalates Exposure with Implications for Identifying Racial/Ethnic Disparities among U.S. Reproductive-Aged Women in NHANES 2001–2012*, *supra* note 14; 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).

¹⁰⁴ See, e.g., Health Canada, *Proposed Approach for Cumulative Risk Assessment of Certain Phthalates under the Chemicals Management Plan* (2015), https://www.ec.gc.ca/ese-ees/723C9007-1CBE-427D-BC20-755F25013B53/Approach_Phthalates%20%28CRA%29_EN.pdf (last visited Dec. 8, 2021).

¹⁰⁵ U.S. ENVIRONMENTAL PROTECTION AGENCY, *Framework for Cumulative Risk Assessment* 6 (2003), available at https://www.epa.gov/sites/default/files/2014-11/documents/frmwrk_cum_risk_assmnt.pdf (last visited Nov. 11, 2021).

¹⁰⁶ See, e.g., Gina Solomon et al., *Integrating Environmental Justice into Public Health: Approaches for Understanding Cumulative Impacts*, 5 FRONTIERS IN PUB. HEALTH SERVS. AND SYS. RESEARCH 10, 11 (2016), available at <https://uknowledge.uky.edu/cgi/viewcontent.cgi?article=1223&context=frontiersinphssr> (noting that “[c]umulative exposures to environmental stressors against a background of vulnerability can result in heightened health impacts and disparities in life expectancy across a population”); see also Rachel Morello-Frosch et al., *Understanding the Cumulative Impacts of Inequalities in Environmental Health: Implications for Policy*, *supra* note 29 (“We conclude that current environmental policy, which is focused narrowly on pollutants and their sources, should be broadened to take into account the cumulative impact of exposures and vulnerabilities encountered by people who live in neighborhoods consisting largely of racial or ethnic minorities or people of low socioeconomic status.”).

¹⁰⁷ See, e.g., Todd Niemeier, et al., *A Mini-Symposium on Cumulative Risk Assessment in the Occupational Setting*, CTR. FOR DISEASE CONTROL AND PREVENTION (CDC) NAT’L INST. FOR OCCUPATIONAL SAFETY & HEALTH

individually, such as by increasing the likelihood of an adverse health effect, or by increasing one's future susceptibility to harm from that chemical or others.¹⁰⁸ Therefore, two important factors in determining whether to conduct a cumulative risk assessment are (1) whether substances co-occur in one or more environmental media,¹⁰⁹ and (2) whether the substances have similar biological characteristics or adverse health effects.¹¹⁰

Phthalates have similar biological characteristics and adverse health effects,¹¹¹ including but not limited to endocrine disruption¹¹², making cumulative risk assessment appropriate and necessary. Phthalates are also known to cause exposure through many routes, ranging from consumption of foods that have been in contact with food packaging or processing equipment, to

(NIOSH) BLOG (Nov. 26, 2018), <https://blogs.cdc.gov/niosh-science-blog/2018/11/26/cra/> (describing cumulative risk assessment as a “science-policy tool designed to organize and analyze data for the intended purposes of characterizing and potentially quantifying the combined risks, or cumulative risk, from co-exposure to multiple chemical and non-chemical stressors (e.g., biological, physical, or psychological impacts) for varying health effects”) (citations omitted).

¹⁰⁸ See, e.g., Ken Sexton & Stephen H. Linder, *Cumulative Risk Assessment for Combined Health Effects From Chemicals and Nonchemical Stressors*, 101 AM. J. PUB. HEALTH 581, 581 (2011), available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3222498/pdf/S81.pdf> (“Exposure to multiple environmental agents, including biological, chemical, physical, radiologic, and psychosocial stressors, can, under the right circumstances, modify the toxic effects of these same agents acting alone. . . . There is empirical evidence that interactive effects from exposure to a mixture of environmental stressors can contribute to three categories of adverse health effects: (1) those where exogenous agents interfere with normal development and distort physiological function, such as neurobehavioral abnormalities and sex steroid hormonal disruption; (2) those whose exogenous agents cause direct cellular damage, such as neurodegenerative diseases and cancer; and (3) those that contribute to illness through a combination of both physiological disruption and cell damage, for example, in cardiovascular disease. Because traditional risk assessment has not routinely taken account of the potential for combined effects from exposure to diverse environmental factors, like those found in the real world, there is growing urgency about the need to develop effective and practical tools for assessing cumulative health risks.”) (citations omitted).

¹⁰⁹ Health Canada, *Proposed Approach for Cumulative Risk Assessment of Certain Phthalates under the Chemicals Management Plan*, *supra* note 104, at 42.

¹¹⁰ See, e.g., Nat'l Acad. Sci., *Phthalates and Cumulative Risk Assessment: The Tasks Ahead - Report in Brief* at 3 (2008), available at https://www.nap.edu/resource/12528/phthalates_final.pdf (recommending that a cumulative risk assessment of phthalates focus on the chemicals' similar mechanisms of action and “common adverse outcomes.”).

¹¹¹ See *id.* (“The report concludes that a cumulative risk assessment should be conducted for phthalates and identifies other chemicals that also affect development of the male reproductive system, and therefore should be considered for inclusion in this risk assessment. Phthalates reduce concentrations of testosterone, an important androgen (or male sex hormone) that contributes to the development of male sex organs.”).

¹¹² See, e.g., Yiyu Qian et al., *The Endocrine Disruption of Prenatal Phthalate Exposure in Mother and Offspring*, 8 FRONTIERS IN PUB. HEALTH 1, 1 (2020), available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7483495/pdf/fpubh-08-00366.pdf> (“Phthalates are a group of ubiquitous synthetic endocrine-disrupting chemicals. Fetal and neonatal periods are particularly susceptible to endocrine disorders, which prenatal exposure to phthalates causes.”).

cosmetics containing phthalates, to exposures from contact with products like vinyl and PVC piping.¹¹³ According to the most recent data, roughly 90-95% of the general population is likely to be exposed to several different phthalates on any given day.¹¹⁴

The scientific precedent for conducting a cumulative risk assessment of phthalates is well established both in the U.S. and abroad:

- In 2008, the National Academy of Sciences (NAS) published a framework for cumulative risk assessment using phthalates as a case study.¹¹⁵ This framework stemmed from an express EPA request that NAS review the health effects of phthalates and evaluate whether a cumulative risk assessment would be necessary.¹¹⁶
- In 2011, the Danish EPA conducted a cumulative risk assessment of four phthalates (DEHP, BBP, DBP, and DIBP) to account for their similar effects and overlapping exposure pathways. The study ultimately led to heightened restrictions on the use of the phthalates in products intended for indoor use, as well as those likely to contact skin or mucous membranes directly.¹¹⁷

¹¹³ See, e.g., Amy Westervelt, *Phthalates Are Everywhere, and the Health Risks are Worrying. How Bad Are They Really?*, THE GUARDIAN (Feb. 10, 2021), <https://www.theguardian.com/lifeandstyle/2015/feb/10/phthalates-plastics-chemicals-research-analysis> (describing phthalates as “next to impossible to avoid” and noting that the chemicals’ many uses include “household items (vinyl flooring), personal care products (hair care, body wash, some cosmetics), fragrance, household cleaners, and food”); see also Liza Gross, *This Chemical Can Impair Fertility, but It’s Hard to Avoid*, N.Y. TIMES (Aug. 25, 2020) (<https://www.nytimes.com/2020/08/25/parenting/fertility-pregnancy-phthalates-toxic-chemicals.html>) (describing phthalates as “used everywhere.”).

¹¹⁴ Because phthalates have a relatively short half-life, the extremely high prevalence of phthalate metabolites in the general population suggests constant, chronic, and widespread exposure. See CDC, FOURTH NATIONAL REPORT ON HUMAN EXPOSURE TO ENVIRONMENTAL CHEMICALS: UPDATED TABLES, MARCH 2021 (2021), *supra* note 21 (nationally representative biomonitoring study detecting phthalate metabolites in 90-95% of the study population); National Academy of Sciences, *Phthalates and Cumulative Risk Assessment: The Tasks Ahead* (2008), *supra* note 102, at 2 (describing “documented simultaneous exposure to multiple phthalates in the general population, including children and adults,” and concluding after a review of key studies that “not only multiple exposures, but multiple exposures at all stages of life, have been demonstrated.”).

¹¹⁵ National Academy of Sciences, *supra* note 102.

¹¹⁶ *Id.* at 1 (“Given the health concerns about [phthalates], EPA asked the National Research Council to convene a committee to determine whether cumulative risk assessment – an approach that focuses on the health risks posed by multiple chemicals over multiple pathways, routes and times – of this chemical class should be conducted, and, if so, to identify approaches that could be used for the assessment.... The committee’s report concludes that the risks associated with phthalate exposure should be evaluated using a cumulative risk assessment and provides specific guidance on approaches to that cumulative risk assessment.”).

¹¹⁷ See Danish Environmental Protection Agency, ANNEX XV: RESTRICTION REPORT PROPOSAL FOR A RESTRICTION 10 (2011), <https://echa.europa.eu/documents/10162/c6781e1e-1128-45c2-bf48-8890876fa719> (relying on the National Academy of Sciences conclusion that “[c]umulative risk assessment based on common adverse outcomes is a feasible and physiologically relevant approach to the evaluation of the multiplicity of human exposures” (*supra* note 102, at 11) to find that “the use of dose addition as a method to assess the combined exposure to DEHP, BBP, DBP and DIBP can be justified.”) See also *id.* at 7 (detailing risk management measures taken in response to the cumulative risk assessment).

- In 2014, a Consumer Protection Safety Commission body—the Chronic Hazard Advisory Panel on Phthalates—conducted a cumulative risk assessment of five phthalates (including DINP) as a class, and concluded that heightened restrictions were warranted.¹¹⁸ The Commission ultimately used the Panel’ findings as the basis for heightened restrictions on phthalates in baby toys and other children’s products,¹¹⁹ which built on earlier prohibitions Congress had enacted through the Consumer Product Safety Improvement Act.¹²⁰
- In 2015, the Canadian Government proposed a cumulative risk assessment approach to the study of phthalates, because “preliminary information found in the public literature, including assessments by other international jurisdictions, indicates that their mode of action is likely to be similar.”¹²¹
- In 2017, the European Chemical Agency conducted a cumulative risk assessment of DBP, BBP, DEHP, and DIBP that resulted in a mandate that the chemicals “not be placed on the market.”¹²²
- In 2019, the European Food Safety Authority conducted a cumulative risk assessment of phthalates that ultimately informed its establishment of a tolerable daily intake level for DBP, BBP, DEHP, and DINP.¹²³

In contrast to such approaches, EPA’s method to date of assessing the risks of each phthalate individually (as well as, in isolated conditions of use) will yield “inadequate policies that allow unsafe chemical exposures,” because it “does not reflect the reality of chemical exposures in today’s world.”¹²⁴

¹¹⁸ *Chronic Hazard Advisory Panel (CHAP) on Phthalates*, U.S. CONSUMER PRODUCT SAFETY COMMISSION, <https://www.cpsc.gov/s3fs-public/CHAP-REPORT-With-Appendices.pdf> (last visited Nov. 23, 2021).

¹¹⁹ See 16 C.F.R. § 1307 (2017) (issuing a final rule “prohibiting children’s toys and child care articles” containing traceable amounts of five phthalates).

¹²⁰ U.S.C. § 2057c(a)-(b) (2011).

¹²¹ Health Canada, *Proposed Approach for Cumulative Risk Assessment of Certain Phthalates under the Chemicals Management Plan*, *supra* note 104, at 6.

¹²² ECHA COMMITTEE FOR RISK ASSESSMENT (RAC) and ECHA COMMITTEE FOR SOCIO-ECONOMIC ANALYSIS (SEAC), OPINION ON AN ANNEX XV DOSSIER PROPOSING RESTRICTIONS ON FOUR PHTHALATES (DEHP, BBP, DBP, DIBP) 3 (2011), available at <https://echa.europa.eu/documents/10162/e39983ad-1bf6-f402-7992-8a032b5b82aa>.

¹²³ EFSA, UPDATE OF THE RISK ASSESSMENT OF DI-BUTYLPHthalATE (DBP), BUTYL-BENZYL-PHTHALATE (BBP), BIS(2-ETHYLHEXYL)PHTHALATE (DEHP), DI-ISONONYLPHTHALATE (DINP) AND DI-ISODECYLPHTHALATE (DIDP) FOR USE IN FOOD CONTACT MATERIALS 1 (2019), available at <https://efsa.onlinelibrary.wiley.com/doi/pdf/10.2903/j.efsa.2019.5838> (“Based on a plausible common mechanism (i.e. reduction in fetal testosterone) underlying the reproductive effects of DEHP, DBP, and BBP, the Panel considered it appropriate to establish a group-TDI for these phthalates....”).

¹²⁴ NAS, *supra* note 102, at 2; see also Veena I. Singla, et al., *The Environmental Protection Agency Toxic Substances Control Act Systematic Review Method May Curtail Science Used to Inform Policies, With Profound*

EPA has clear authority under Section 26(c) of TSCA to take a class-based approach to risk evaluation and risk management, which further supports the evaluation of the cumulative risk posed by all seven phthalates currently subject to risk evaluation. Under Section 26(c), any action that EPA may take for a single chemical substance, the agency may also take for a category of chemical substances,¹²⁵ *i.e.*, a *class* of multiple chemicals, such as all phthalates.

Section 26(c) offers a clear definition that anticipates the need to regulate chemicals that are similar to one another, such as phthalates, as a single class:

The term “category of chemical substances” means a group of chemical substances the members of which are similar in molecular structure, in physical, chemical, or biological properties, in use, or in mode of entrance into the human body or the environment, or the members of which are in some other way suitable for classification as such for purposes of this chapter¹²⁶

EPA has long established that phthalates have a similar molecular structure and enter the human body and the environment in similar ways, and it has reported on the similarity in the physical, chemical and biological properties of phthalates.¹²⁷ Indeed, EPA first proposed *more than a decade ago* to assess and manage eight phthalates as class under TSCA, covering six of the seven phthalates that are currently subject to ongoing risk evaluation, including **DINP** and **DIDP**.¹²⁸

Failure to conduct a cumulative risk assessment of the phthalates now under review would not only violate TSCA’s explicit requirement that EPA make decisions based on the best available

Implications for Public Health, 109 Am. J. Pub. Health 982, 982 (2019), available at <https://ajph.aphapublications.org/doi/pdf/10.2105/AJPH.2019.305068> (describing the “systematic review” risk assessment methodology used during the Trump administration as “systematic in name only” because it “falls far short of best practices for systematic review” and “exclude[s] relevant research from chemical assessments, leading to underestimation of health risks and resulting in inadequate policies that allow unsafe chemical exposures, thus harming public health.”).

¹²⁵ See 15 U.S.C. § 2625(c)(1).

¹²⁶ 15 U.S.C. § 2625(c)(2)(A).

¹²⁷ See U.S. Environmental Protection Agency, Phthalates Action Plan (Rev. March 14, 2012), https://www.epa.gov/sites/default/files/2015-09/documents/phthalates_actionplan_revised_2012-03-14.pdf (last visited Dec. 6, 2021).

¹²⁸ *Id.* (noting that EPA published its first Phthalates Action Plan in 2009).

science,¹²⁹ but also undermine Congress’s aim of protecting human health and the environment.¹³⁰ Racial and ethnic minorities (and also, people of low socioeconomic status) are “more frequently exposed to multiple environmental hazards and social stressors” and suffer from “poorer health outcomes than others.”¹³¹ Any risk evaluation that EPA conducts should account for the full range of risks that these populations face, including the harms associated with cumulative exposures.

In February of 2021, EPA renewed its commitment to upholding Executive Orders and "other directives provided by the Biden-Harris Administration to ensure that all agency actions meet statutory obligations, be guided by the best available science, ensure the integrity of Federal decision-making, and protect human health and the environment."¹³² This commitment compels use of a cumulative assessment for phthalates, both to protect the health of the general population, and the more precarious health of BIPOC.

CONCLUSION

The seven phthalate risk evaluations in process, whose scope was framed during the Trump Administration, manifest an unlawfully crabbed reading of TSCA that disrespects science and disserves public health. In determining whether the phthalates undergoing risk analysis pose an unreasonable risk, EPA must, in its risk evaluation: (a) identify BIPOC as a whole a PESS; (b) examine all reasonably foreseeable condition of use for phthalates, including those which might in the first instance fall under the risk management jurisdiction of another agency; and (c) perform

¹²⁹ See 15 U.S.C. § 2625(h); 40 C.F.R. § 702 (2017).

¹³⁰ See 15 U.S.C. § 2601(b) (“[A]dequate authority should exist to regulate chemical substances and mixtures which present an unreasonable risk to health or the environment, and to take action with respect to chemical substances and mixtures which are imminent hazards....”).

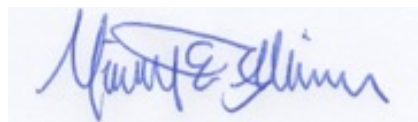
¹³¹ Morello-Frosch, et al., *supra* note 29.

¹³² Press Release, U.S. EPA Office of Chemical Safety and Pollution Prevention (OCSPP), EPA Commits to Strengthening Science Used in Chemical Risk Evaluations (Feb. 16, 2021), *available at* <https://www.epa.gov/newsreleases/epa-commits-strengthening-science-used-chemical-risk-evaluations>.

a cumulative risk assessment that treats the class of seven phthalates as a “category of chemical substances” for purposes of risk assessment and risk management.

All of these actions will fulfill TSCA’s command to use the best available science; will effectuate Congress’s health-protection goals; and will give tangible expression to the Biden Administration’s stated commitment to environmental justice.

Sincerely,



Michael Belliveau
Executive Director
Defend Our Health

Jan Robinson Flint
Executive Director
Black Women for Wellness

Pamela K. Miller
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