Submitted via *Regulations.gov*

June 9, 2022*

Michael Regan, Administrator
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

* *These comments supersede the parties' comments filed in above-listed dockets on December 8, 2021.*

Interests of Commenters

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.

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[1] EPA's most recent Phthalates Action Plan states that by 2006, more than 470 million pounds of phthalates were produced annually. U.S. ENV'T PROT. AGENCY, PHTHALATES ACTION PLAN 1 (2012), https://www.epa.gov/sites/default/files/2015-09/documents/phthalates_actionplan_revised_2012-03-14.pdf [hereinafter EPA PHTHALATES ACTION PLAN].

[2] CTRS. FOR DISEASE CONTROL & PREVENTION, FOURTH NATIONAL REPORT ON HUMAN EXPOSURE TO ENVIRONMENTAL CHEMICALS: UPDATED TABLES, MARCH 2021: VOLUME ONE: NHANES 1990-2010 (2021), https://www.cdc.gov/exposurereport/index.html.

[3] Leonardo Trasande et al., *Phthalates and Attributable Mortality: A Population-Based Longitudinal Cohort Study and Cost Analysis*, ENV'T POLLUTION, Jan. 2022, at 1, 1–2, 6, https://www.sciencedirect.com/science/article/pii/S0269749121016031 (associating phthalate exposure with all-cause and cardiovascular mortality that imposes 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 AM. J. PUB. HEALTH 687, 687 (2021), https://ajph.aphapublications.org/doi/full/10.2105/AJPH.2020.306014 (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 amongst 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 subpopulation[s]" 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 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.

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[4] Jennifer A. Dlouhy & Stephen Lee, *New EPA Chief Michael Regan Vows Assault on Environmental Injustice*, BLOOMBERG GREEN (Mar. 16, 2021, 12:33 PM), https://www.bloomberg.com/news/articles/2021-03-16/new-epa-chief-regan-vows-assault-on-environmental-injustice.

[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. Pub. L. No. 114-182, § 6, 130 Stat. 448, 460 (2016). 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); 40 C.F.R. §§ 702.31, 702.41 (2020).

[7] 15 U.S.C. § 2605(b)(4)(A).

[8] *Id.* § 2602(12).

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.[13] Exposure to DEHP is of particular concern because of its potency as a reproductive toxicant:[14] when researchers examined the comparative contributions to androgen

[9] Tamarra M. James-Todd et al., *Racial/Ethnic Disparities in Environmental Endocrine Disrupting Chemicals andWomen's Reproductive Health Outcomes: Epidemiological Examples Across the Life Course*, 3 CURRENT EPIDEMIOLOGY REPS. 161, 162 (2016), https://link.springer.com/article/10.1007%2Fs40471-016-0073-9.
[10] Kelly K. Ferguson et al., *Urinary Phthalate Metabolites and Biomarkers of Oxidative Stress in Pregnant Women:A Repeated Measures Analysis*, 123 ENV'T HEALTH PERSPS. 210, 212 (2015), https://ehp.niehs.nih.gov/doi/pdf/10.1289/ehp.1307996.
[11] *Id.* at 213.
[12] Michael S. 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, 476–77 (2019), https://www.sciencedirect.com/science/article/pii/S0160412018329908.
[13] *Id.*; Ferguson et al., *supra* note 10, at 212.
[14] *See, e.g.*, Julia R. 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*, 50 ENV'T SCI. & TECH. 10,616, 10,616 (2016), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5748889/ [hereinafter *Varshavsky et al., Calculating Phthalates*] (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*

disruption of six phthalates in commerce, DEHP was estimated to contribute the most, accounting for 48% to 64% of observed disruption.[15]

Urinary metabolites of **DIBP** are also present at significantly greater levels in African American mothers than in white mothers.[16] These metabolites are again associated with higher concentrations of oxidative stress biomarkers.[17] Beyond the reproductive and developmental effects of DIBP, the European Union has expressed concern that DIBP may be implicated in immunological disorders such as allergy, asthma, and eczema, possibly at lower levels than those triggering reproductive toxicity.[18] DIBP exposure 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 and Prevention demonstrate that, compared to the overall population, people of

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and Girls, 110 ENV'T INT'L 61, 62, 67 (2018), https://www.sciencedirect.com/science/article/pii/S016041201731036X (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 "significance of the DEHP metabolite in potentially disruptive antiandrogenic effects"); EFSA Panel on Food Contact Materials, Enzymes and Processing Aids, et al., *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*, EFSA J., Sept. 2019, at 1, 14, https://efsa.onlinelibrary.wiley.com/doi/pdf/10.2903/j.efsa.2019.5838 ("[DEHP] adversely affect[s] the male reproductive organs and sexual differentiation during fetal development due to [] anti-androgenic effects."); NAT'L RSCH. COUNCIL, PHTHALATES AND CUMULATIVE RISK ASSESSMENT: THE TASKS AHEAD 42, 106 (Washington, DC: The National Academies Press 2008), https://doi.org/10.17226/12528 [hereinafter COMM. ON THE HEALTH RISKS OF PHTHALATES]. (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., Calculating Phthalates*, *supra* note 14, at 10,620.

[16] Bloom et al., *supra* note 12, at 476; *see also,* Ferguson et al., *supra* note 10, at 213.

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

[18] EFSA Panel on Food Contact Materials, Enzymes and Processing Aids, et al., *supra* note 14, at 14.

[19] *Varshavsky et al., Calculating Phthalates*, *supra* note 14, at 10,620 ("Daily intake of . . . DiBP and DiNP increased by 150–380% [from 2001to 2012].").

[20] For example, DCHP acts not only as a reproductive toxicant, but also as a liver toxicant. VERSAR, INC. & SRC, INC., FINAL TOXICITY REVIEW FOR DICYCLOHEXYL PHTHALATE (DCHP, CASRN 84-61-7), at 14–18, 21–22 (2011), https://www.cpsc.gov/s3fs-public/ToxicityReviewOfDCHP.pdf. 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 Nutrition Examination Survey, 2001-2010*, 122 ENV'T HEALTH PERSPS. 235, 240 (2014), https://ehp.niehs.nih.gov/doi/10.1289/ehp.1306681. DIDP and DINP metabolites are also associated with reduced fertilization rates in IVF treatments. James-Todd et al., *supra* note 9, at 170.

color are disproportionately exposed to nearly all phthalates, including the seven under review.

The tables below reproduce the most recent NHANES data for the 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. 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
	MCPP***	0.896	1.11	0.966	1.08	1.05

General Population (GP) | *Exposure > GP* | *Exposure > White, < GP* | *Least Exposed by Race*

[21] Some data are from CDC's 2019 report, CTRS. FOR DISEASE CONTROL & PREVENTION, 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, and some are from CDC's report update in March 2021. The 2021 data for phthalates mirror the 2019 data, except that the later data exclude DCHP. *See* CTRS. FOR DISEASE CONTROL & PREVENTION, FOURTH NATIONAL REPORT ON HUMAN EXPOSURE TO ENVIRONMENTAL CHEMICALS: UPDATED TABLES, MARCH 2021: VOLUME TWO: NHANES 2011–2016 (2021), https://www.cdc.gov/exposurereport/pdf/FourthReport_UpdatedTables_Volume2_Mar2021-508.pdf [hereinafter CDC VOLUME TWO: NHANES 2011-2016]. 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."

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

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
	MCPP***	7.63	9.18	6.44	7.44	7.48

General Population (GP) | *Exposure > GP* | *Exposure > White, < GP* | *Least Exposed by Race*

** 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 ofdetection (LOD).*
**** MCPP 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 diesters [such as DEHP], may contribute to persistent racial/ethnic disparities in women's reproductive health outcomes," especially among "Black pregnant women."[24]

[23] CDC VOLUME TWO: NHANES 2011-2016, *supra* note 21.
[24] Mary E. Sterrett et al., *Maternal Food and Beverage Consumption Behaviors and Discrepant Phthalate Exposure by Race*, INT'L J. ENV'T RSCH. & PUB. HEALTH, Feb. 2021, at 1.

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 health harms from chemical exposures.[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 (for example, 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 stressors such as poverty, food insecurity, poor housing quality, exposure to violence, and racismbeyond the health care system.[29]

Likewise, "tribes have unique lifeways that place them at different risk due to multiple

[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* Nat'l Tribal Toxics Council, Comment Letter on Perchloroethylene, Draft TSCA Risk Evaluation 7 (July 6, 2020), 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; 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/; Tracey J. Woodruff et al., *Meeting Report: Moving Upstream—Evaluating Adverse Upstream End Points for Improved Risk Assessment and Decision-Making*, 116 ENV'T HEALTH PERSPS. 1568 (2008), https://ehp.niehs.nih.gov/doi/10.1289/ehp.11516.
[28] U.S. ENV'T PROT. AGENCY, GUIDELINES FOR HUMAN EXPOSURE ASSESSMENT, EPA/100/B-19/001, at 41 (2019), www.epa.gov/sites/default/files/2020-01/documents/guidelines_for_human_exposure_assessment_final2019.pdf [hereinafter EPA GUIDELINES FOR HUMAN EXPOSURE ASSESSMENT]
[29] *See, e.g.*, Hilal Al Shamsi et al., *Implications of Language Barriers for Healthcare: A Systematic Review*, OMAN MED. J., Mar. 2020, at 1; 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 AFFS. 879, 879, 882 (2011).

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 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,[34] this finding shows how DIDP exposure may make racial and ethnic subgroups particularly susceptible to DIDP's adverse respiratory effects.

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

[30] Nat'l 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 5 (June 8, 2020), http://www.zendergroup.org/docs/nttc/Commentsnext7.pdf.
[31] *Id.*
[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 ENV'T HEALTH PERSPS. 097006-1, 097006-1 to -2, 097006-9 (2017).
[34] Angela Haczku & Reynold A. Panettieri, Jr., *Social Stress and Asthma: The Role of Corticosteroid Insensitivity*,125 J. ALLERGY & CLINICAL IMMUNOLOGY 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 & CLINICAL IMMUNOLOGY 547, 547 (2014).
[35] Kai-Wei Liao et al., *Increased Risk of Phthalates Exposure for Recurrent Spontaneous Abortion in Reproductive-Aged Women: Taiwan Female Infertility Study (TIFF)*, ENV'T HEALTH PERSPS., 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. *Id.* DEP was one of the three primary components of the phthalate exposure in the study population. *Id.* The abstract of this study was presented at a past annual meeting of ISEE. ISES-ISEE 2018 JOINT ANNUAL MEETING PROGRAM 155 (2018), https://intlexposurescience.org/wp-content/uploads/2019/02/Programma-ISESISEE-27-augustus.pdf.

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, attention, and behavior.[37] This in turn directly diminishes an individual's emotional, social, educational, and professional capacity. Financial costs associated with neurobehavioral impairment reflect lower educational attainment, workplace productivity, and earnings.[38]

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,

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[36] *See, e.g.*, *Endocrine Disruptors*, NAT'L INST. OF ENV'T HEALTH SCIS., https://www.niehs.nih.gov/health/topics/agents/endocrine/index.cfm ("[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 . . . [b]ecause 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, 418 (2018) [hereinafter *Varshavsky et al., Dietary Sources of Cumulative Phthalates*] ("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).

[37] Engel et al., *supra* note 3, at 687–88.

[38] *See* Jalpa A. Doshi et al., *Economic Impact of Childhood and Adult Attention-Deficit/Hyperactivity Disorder in the United States*, 51 J. AM. ACAD. CHILD & ADOLESCENT PSYCHIATRY 990, 997, 999 (2012); Joseph Biederman & Stephen V. Faraone, *The Effects of Attention-Deficit/Hyperactivity Disorder on Employment and Household Income*, MEDSCAPE GEN. MED., July 2006, at 1.

[39] *See* Pub. L. No. 114-182, § 6, 130 Stat. 448, 460–70 (2016); *see also* 162 CONG. REC. 7979 (2016) (statement of Sen. Barbara 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.

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 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

[41] *See id.* § 2625(h) (defining the best available science standard); *id.* § 2605(b)(4)(A) (prohibiting cost or nonrisk considerations in risk evaluations).
[42] 5 U.S.C. § 2602(12) (all emphasis added).

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.

B. 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 Process 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 in 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

[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. *See* 40 C.F.R. § 702.33 (2020). This too can be read to facilitate designation of PESS.

[44] Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act, 82 Fed. Reg. 33,726, 33,732 (July 20, 2017) (codified at 40 C.F.R. pt. 702).

[45] *See* High-Priority Substance Designations Under the Toxic Substances Control Act (TSCA) and Initiation of Risk Evaluation on High-Priority Substances, 84 Fed. Reg. 71,924, 71,927 (Dec. 30, 2019).

[46] *Id.* ("'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.").

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 lifestage, 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]

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.

C. 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]

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[47] EPA GUIDELINES FOR HUMAN EXPOSURE ASSESSMENT, *supra* note 28, at xiv.
[48] *Id.* at xv (emphasis added).
[49] U.S. ENV'T PROT. AGENCY, FRAMEWORK FOR CUMULATIVE RISK ASSESSMENT, EPA/630/P-02/001F, at 63 (2003), https://www.epa.gov/sites/default/files/2014-11/documents/frmwrk_cum_risk_assmnt.pdf [hereinafter EPA FRAMEWORK FOR CUMULATIVE RISK ASSESSMENT] (emphasis added).
[50] *Exposure Assessment Tools by Lifestages and Populations – Highly Exposed or Other Susceptible Population Groups*, U.S. ENV'T PROT. AGENCY, 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).

Consistent with this policy, EPA's environmental justice program defines "[o]verburdened [c]ommunit[ies]"—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] 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 fenceline 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

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[53] *EJ 2020 Glossary*, U.S. ENV'T PROT. AGENCY, https://www.epa.gov/environmentaljustice/ej-2020-glossary (last visited Nov. 23, 2021).
[54] Protecting Public Health and the Environment and Restoring Science to Tackle the Climate Crisis, Exec. Order No. 13,990, 86 Fed. Reg. 7037, 7037 (Jan. 25, 2021).
[55] *Id.*
[56] WHITE HOUSE ENV'T JUSTICE ADVISORY COUNCIL, FINAL RECOMMENDATIONS: JUSTICE40, CLIMATE AND ECONOMIC JUSTICE SCREENING TOOL & EXECUTIVE ORDER 12898 REVISIONS 32 (2021), https://www.epa.gov/environmentaljustice/white-house-environmental-justice-advisory-council-final-recommendations ("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.").
[57] *See id.*
[58] *Id.*

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 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] *Id.*
[60] Earthjustice on behalf of Rubbertown Emergency ACTion et al., Comment Letter on TSCA Risk Evaluations for High-Priority Substances and Substances Undergoing Manufacturer-Requested Risk Evaluations 4 (July 15, 2021).
[61] Earthjustice on behalf of Alaska Cmty. Action on Toxics et al., Comment Letter on Draft Scopes of the Risk Evaluations to be Conducted Under the Toxic Substances Control Act for Di-isononyl Phthalate and Di-isodecylPhthalate ("DINP" and "DIDP") 10–11 (Jan. 11, 2021).
[62] *See* U.S. ENV'T PROT. AGENCY, FINAL SCOPE OF THE RISK EVALUATION FOR DI-ETHYLHEXYL PHTHALATE, EPA-740-R-20-017, at 43 (2020); U.S. ENV'T PROT. AGENCY, FINAL SCOPE OF THE RISK EVALUATION FOR DICYCLOHEXYL PHTHALATE, EPA-740-R-20-019, at 36 (2020); U.S. ENV'T PROT. AGENCY, FINAL SCOPE OF THE RISK EVALUATION FOR DI-ISOBUTYL PHTHALATE, EPA-740-R-20-018, at 39 (2020); U.S. ENV'T PROT. AGENCY, FINAL SCOPE OF THE RISK EVALUATION FOR BUTYL BENZYL PHTHALATE, EPA-740-R-20-015, at 37 (2020); U.S. ENV'T PROT. AGENCY, FINAL SCOPE OF THE RISK EVALUATION FOR DIBUTYL PHTHALATE, EPA-740-R-20-016, at 41 (2020).

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 regulations[65] and guidelines[66]; 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.

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[63] *See Chemical Plant Safety Critical to Environmental Justice*, GREENPEACE (July 15, 2015), www.greenpeace.org/usa/chemical-plant-safety-critical-environmental-justice/ (demonstrating that advocacygroups use the term "fence line community" to refer to people living near polluting facilities).

[64] *See, e.g.*, U.S. ENV'T PROT. AGENCY, FINAL SCOPE OF THE RISK EVALUATION FOR DI-ETHYLHEXYL PHTHALATE, *supra* note 62, at 12, 43; U.S. ENV'T PROT. AGENCY, FINAL SCOPE OF THE RISK EVALUATION FOR DICYCLOHEXYL PHTHALATE, *supra* note 62, at 11, 36; U.S. ENV'T PROT. AGENCY, FINAL SCOPE OF THE RISK EVALUATION FOR DI-ISOBUTYL PHTHALATE, *supra* note 62, at 12, 39; U.S. ENV'T PROT. AGENCY, FINAL SCOPE OFTHE RISK EVALUATION FOR BUTYL BENZYL PHTHALATE, *supra* note 62, at 12, 37; U.S. ENV'T PROT. AGENCY, FINAL SCOPE OF THE RISK EVALUATION FOR DIBUTYL PHTHALATE, *supra* note 62, at 12, 41.

[65] *See* Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act, 82 Fed. Reg. 33,726, 33,732 (July 20, 2017) (codified at 40 C.F.R. pt. 702).

[66] *See* EPA GUIDELINES FOR HUMAN EXPOSURE ASSESSMENT, *supra* note 28.

[67] *See* Tackling the Climate Crisis at Home and Abroad, Exec. Order No. 14,008, 86 Fed. Reg. 7619 (Feb. 1, 2021), https://www.govinfo.gov/content/pkg/FR-2021-02-01/pdf/2021-02177.pdf.

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 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" definition and a chemical's actual presence in commerce: If a chemical substance exists in relevant

[68] 15 U.S.C. § 2602(4).
[69] *See Safer Chemicals, Healthy Families v. U.S. Env't Prot. Agency*, 943 F.3d 397, 421, 423–25 (9th Cir. 2019).

conditions of use in commerce, then EPA *must* include those uses in its risk evaluation.[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 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

[70] *See id.* at 423–24.
[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 Phthalates*, *supra* note 36, at 417 ("Diet is the primary exposure source for most phthalates, which contaminate the food supply through food contact materials and industrialized production.").
[72] *See* 15 U.S.C. § 2605(b)(4)(A).

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 creation EPA 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 insist (or a court compel) that EPA analyze under TSCA those chemical uses that are "non-TSCA"*?

Behind this semantic obfuscation, however, lies the plain text of TSCA. Section 3(4) of this text 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.

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

[73] *See, e.g.*, *Whitman v. Am. Trucking Ass'ns, Inc*., 531 U.S. 457, 466–72 (2001) (holding that EPA cannot consider factors that Congress either explicitly or implicitly prohibited the agency 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. Env't Prot. Agency*, 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" (quoting *Motor Vehicle Mfrs. Ass'n of the U.S. v. State Farm Mut. Auto. Ins. Co*., 463 U.S. 29, 43 (1983)).
[75] 15 U.S.C. § 2602(4) (emphasis added).
[76] *Safer Chemicals, Healthy Families v. U.S. Env't Prot. Agency*, 943 F.3d 397, 421, 425 (9th Cir. 2019).
[77] 15 U.S.C. § 2602(2).

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, as per Section 3(4), 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 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 manufacturers are only now beginning to address.[80] Mac 'n Cheese is a textbook example of a processed food heavily consumed by low-

[78] We use 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. *United States 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. Serrano et al., *Phthalates and Diet: A Review of the Food Monitoring and Epidemiology Data*, ENV'T HEALTH, June 2014, at 1 (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 Phthalates*, *supra* note 36, at 417 (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 Phthalates in Food and Evidence of Their Biological Impact*, INT'L J. ENV'T RSCH. & PUB. HEALTH, Aug. 2020, at 3 (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'T EPIDEMIOLOGY, Oct. 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*, N.Y. TIMES (Feb. 19, 2021),

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 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 immune from regulation. 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 believes or asserts that analysis of phthalate risks from items such as food-contact materials, cosmetics, or that personal care products would be futile because the agency lacks initial Section 6 jurisdiction to act on any

https://www.nytimes.com/2021/02/19/business/annies-mac-cheese-plastic-phthalates.html?searchResultPosition=1.

[81] *See* BREAST CANCER PREVENTION PARTNERS, RIGHT TO KNOW: EXPOSING TOXIC FRAGRANCE CHEMICALS IN BEAUTY, PERSONAL CARE AND CLEANING PRODUCTS 36, 47 (2018), https://www.bcpp.org/resource/right-to-know-exposing-toxic-fragrance-chemicals-report/ (noting that of numerous products tested, "Just for Me—a shampoo marked to kids of color— had the most hazardous chemicals . . .[,]" including **DEP)**; *see also Phthalates*, CAMPAIGN FOR SAFE COSMETICS, 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, https://www.bwwla.org/v2019/wp-content/uploads/2021/04/Black-Women-for-Wellness-x-Lather-Chem-Card.pdf (last visited Dec. 8, 2021) (alerting women to potential phthalate exposure in perfumes, hair sprays, nail polishes, and the "fragrance" component of other cosmetics).

risk-reductionimplications of its examination, EPA has misapprehended or misstated 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).)

(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

[82] *Regulation of Chemicals Under Section 6(a) of the Toxic Substances Control Act*, U.S. ENV'T PROT. AGENCY, https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/regulation-chemicals-under-section-6a-toxic-substances (last visited Nov. 7, 2021); *see also* 15 U.S.C. § 2605(a).

> 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 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 regulate 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

[83] 15 U.S.C. § 2608(a)(1) (emphasis added).
[84] *Id.*
[85] *Id.* § 2608(a)(2).
[86] *Id.* § 2608(a)(5).
[87] *See id.* § 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 id.* § 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] 4,4'-Methylenedianiline; Decision to Report to the Occupational Safety and Health Administration, 50 Fed. Reg. 27,674, 27,674–75, 27,679 (July 5, 1985).

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 [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 examining regulatory options, OSHA ultimately adopted a final rule establishing numerical workplace exposure standards, and mandating additional worker protections—protections it estimated would reduce worker 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]

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[89] *Id.* at 27,675, 27,680.
[90] *Id.* at 27,680.
[91] Health and Safety Standards; Occupational Exposure to 4,4'-Methylenedianiline (MDA), 51 Fed. Reg. 6748, 6748 (Feb. 26, 1986).
[92] Occupational Exposure to 4,4'-Methylenedianiline (MDA), 57 Fed. Reg. 35,630, 35,630, 35,640 (Aug. 10, 1992) (codified at 29 C.F.R. pt. 1910, 1926).
[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," *i.e.,* not to render any statutory language surplus. *Mountain States Tel. & Tel. Co. v. Pueblo of Santa Ana*, 472 U.S. 237, 249 (1985) (quoting *Colautti v. Franklin*, 439 U.S. 379, 392 (1979)).

D. In any future litigation over its risk evaluations, EPA may 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, may 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 "the doctrine of preclusion of inconsistent positions, [which] precludes a party from gaining an advantage by taking one position, and then seeking a second advantage by taking an incompatible position."[94] Judicial estoppel, which concerns the relationship between the court system and litigants,[95] protects the "integrity of the judicial process"[96] by preventing litigants fromusing inconsistent arguments as "a means of obtaining unfair advantage."[97]

In *Safer Chemicals,* EPA told the Ninth Circuit that it would not "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

[94] *Rissetto v. Plumbers & Steamfitters Loc. 343*, 94 F.3d 597, 600 (9th Cir. 1996).
[95] Brief for Appellees People of the State of California, et al. at 43, 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.
[96] *Russell v. Rolfs*, 893 F.2d 1033, 1037 (9th Cir. 1990).
[97] *Arizona v. Shamrock Foods Co.*, 729 F.2d 1208, 1215 (9th Cir. 1984) (quoting *Scarano v. Central R. Co. of N.J.*, 203 F.2d 510, 513 (3d Cir. 1953)).
[98] Brief of Respondents U.S. Env't Prot. Agency, et al. at 36, Safer Chemicals, Healthy Families v. U.S. Env't Prot. Agency, 943 F.3d 397 (9th Cir. 2019).
[99] *See, e.g.*, *N. Alaska Env't Ctr. v. Lujan*, 961 F.2d 886, 891 (9th Cir. 1992).

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 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, 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, outsize exposure to each of multiple phthalate chemicals. The National Academy of Sciences first

[100] Brief of Respondents U.S. Env't Prot. Agency, et al., *supra* note 98, at 49.
[101] *See generally* Engel et al., *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*, SCI. REPS., Mar. 2017, https://www.nature.com/articles/srep45009; Krista L.Y. Christensen et al., *Generation of Hazard Indices for Cumulative Exposure to Phthalates for Use in Cumulative Risk Assessment*, 69 REGUL. TOXICOLOGY & PHARMACOLOGY 380 (2014), https://www.sciencedirect.com/science/article/pii/S0273230014000828; *see also* Gilbert C. Gee & Devon C. Payne-Sturges, *Environmental Health Disparities: A Framework Integrating Psychosocial and Environmental Concepts*, 112 ENV'T 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).

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 possible quantification of the combined risks to health or 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 or 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 individually, such as by increasing the likelihood of an adverse health effect, or by increasing future susceptibility to harm from that chemical or others.[108] Therefore, two important factors in

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[102] *See* COMM. ON THE HEALTH RISKS OF PHTHALATES, *supra* note 14.
[103] *See, e.g.*, *Varshavsky et al., Calculating Phthalates*, *supra* note 14; *see also* Devon C. Payne-Sturges et al., *Methods for Evaluating the Combined Effects of Chemical and Nonchemical Exposures for Cumulative Environmental Health Risk Assessment*, INT'L J. ENV'T RSCH. & PUB. HEALTH, Dec. 2018, at 1 (citing NAS report).
[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 %28CRA%29_EN.pdf.
[105] EPA FRAMEWORK FOR CUMULATIVE RISK ASSESSMENT, *supra* note 49, at 6.
[106] *See* Gina Solomon et al., *Integrating Environmental Justice into Public Health: Approaches for Understanding Cumulative Impacts*, 5 FRONTIERS PUB. HEALTH SERVS. & SYS. RSCH. 10, 11 (2016), 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* Morello-Frosch et al., *supra* note 29, at 879 ("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.*, R. Todd Niemeier et al., *A Mini-Symposium on Cumulative Risk Assessment in the Occupational Setting*, CTRS. FOR DISEASE CONTROL & PREVENTION: NIOSH SCI. 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 psychosocial impacts) for varying health effects").
[108] *See, e.g.*, Ken Sexton & Stephen H. Linder, *Cumulative Risk Assessment for Combined Health Effects from Chemical and Nonchemical Stressors*, 101 AM. J. PUB. HEALTH 581, 581 (2011), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3222498/pdf/S81.pdf ("Exposure to multiple environmental agents, including biologic, 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

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 disruption,[112] 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 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

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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 where exogenous agents cause direct cellular damage, such as neurodegenerative diseases and cancer; and (3) those that contribute to illness through a combination of both physiologic 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.").

[109] HEALTH CANADA, *supra* note 104, at 42.

[110] *See*, *e.g.*, THE NAT'L ACAD. OF SCIS., PHTHALATES AND CUMULATIVE RISK ASSESSMENT: THE TASKS AHEAD - REPORT IN BRIEF 3 (2008) https://www.nap.edu/resource/12528/phthalates_final.pdf (recommending that a cumulative risk assessment of phthalates focus on "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 PUB. HEALTH, Aug. 2020, at 1-2, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7483495/pdf/fpubh-08-00366.pdf ("Fetal and neonatal periods are particularly susceptible to endocrine disorders, which prenatal exposure to phthalates causes. [. . .] [Phthalate-induced] [m]aternal thyroid dysfunction [has been] associated with abnormal fetal development such as growth retardation, inadequate central nervous system development, preterm birth, and so on.").

[113] *See*, *e.g.*, Amy Westervelt, *Phthalates Are Everywhere, and the Health Risks Are Worrying. How Bad Are They Really?*, GUARDIAN (Feb. 10, 2015, 9:00 AM), 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?searchResultPosition=1 (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 VOLUME TWO: NHANES 2011-2016, *supra* note 21 (nationally representative biomonitoring study detecting phthalate metabolites in 90-95% of the study population); *see also* COMM. ON THE HEALTH RISKS OF PHTHALATES, *supra* note 14, at 5 (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 concurrent exposure, but concurrent exposure at all life stages, have been demonstrated").

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]

- In 2014, a Consumer Product Safety Commission body—the Chronic Hazard Advisory Panel on Phthalates—conducted a cumulative risk assessment of five phthalates as a class, and concluded that heightened restrictions were warranted for certain among them, including DINP.[118] The Commission ultimately used the Panel's 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]

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[115] COMM. ON THE HEALTH RISKS OF PHTHALATES, *supra* note 14.
[116] THE NAT'L ACAD. OF SCIS., *supra* note 110, 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 ENV'T PROT. 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 in COMM. ON THE HEALTH RISKS OF PHTHALATES, *supra* note 14, at 11, 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" 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).
[118] U.S. CONSUMER PROD. SAFETY COMM'N, REPORT TO THE U.S. CONSUMER PRODUCT SAFETY COMMISSION BY THE CHRONIC HAZARD ADVISORY PANEL ON PHTHALATES AND PHTHALATE ALTERNATIVES 7–8, 63–67 (2014), https://www.cpsc.gov/s3fs-public/CHAP-REPORT-With-Appendices.pdf.
[119] *See* 16 C.F.R. § 1307.3(b) (2021) (rule "prohibit[ing] children's toys and child care articles" containing traceable amounts of five phthalates).
[120] 15 U.S.C. § 2057c(a)–(b).
[121] HEALTH CANADA, *supra* note 104, at 6.
[122] EUROPEAN CHEMS. AGENCY, OPINION ON AN ANNEX XV DOSSIER PROPOSING RESTRICTIONS ON FOUR PHTHALATES (DEHP, BBP, DBP, DIBP) 3 (2017), https://echa.europa.eu/documents/10162/e39983ad-1bf6-f402-7992-8a032b5b82aa.

- 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 (and, in isolated conditions of use) will yield policies that allow unsafe chemical exposures, because this method "does not reflect the reality of chemical exposures in today's world."[124]

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 into the environment, or the members of which are in some other way suitable for classification as such for purposes of this chapter . . . . [126]

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

[123] EFSA Panel on Food Contact Materials, Enzymes and Processing Aids, et al., *supra* note 14, at 1 ("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 [Tolerable Daily Intake] for these phthalates . . . .").
[124] THE NAT'L ACAD. OF SCIS., *supra* note 110, 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 Implications for Public Health*, 109 AM. J. PUB. HEALTH 982, 982 (2019), 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] *Id.* § 2625(c)(2)(A).

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 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.

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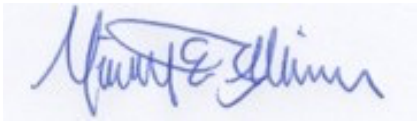
[127] *See* EPA PHTHALATES ACTION PLAN, *supra* note 1, at 2–7.
[128] *Id.* at 1 n.1 (noting that EPA published its first Phthalates Action Plan in 2009).
[129] *See* 15 U.S.C. § 2625(h); 40 C.F.R. §§ 702.31, 702.41 (2020).
[130] *See* 15 U.S.C. § 2601(b) ("[A]dequate authority should exist to regulate chemical substances and mixtures which present an unreasonable risk of injury to health or the environment, and to take action with respect to chemical substances and mixtures which are imminent hazard . . . .").
[131] Morello-Frosch et al., *supra* note 29, at 879.
[132] Press Release, Off. of Chem. Safety & Pollution Prevention, U.S. Env't Prot. Agency, EPA Commits to Strengthening Science Used in Chemical Risk Evaluations (Feb. 16, 2021), https://www.epa.gov/newsreleases/epa-commits-strengthening-science-used-chemical-risk-evaluations.

CONCLUSION

The seven phthalate risk evaluations in process, whose scope was framed during the Trump Administration, manifest an unlawfully cramped 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 conditions of use for phthalates, including those which might in the first instance fall under the risk management jurisdiction of another agency; and (c) perform 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,



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