Environmental Defense Fund

Comments on Revised Draft Technical Support Document for the Cumulative Risk Analysis of Di(2-ethylhexyl) Phthalate (DEHP), Dibutyl Phthalate (DBP), Butyl Benzyl Phthalate (BBP), Diisobutyl Phthalate (DIBP), Dicyclohexyl Phthalate (DCHP), and Diisononyl Phthalate (DINP) Under the Toxic Substances Control Act (TSCA) within the following dockets:

- Dibutyl phthalate (DBP) Docket ID: EPA-HQ-OPPT-2018-0503 (January 7, 2025)
- Diethylhexyl phthalate (DEHP) Docket ID: EPA-HQ-OPPT-2018-0433(January 7, 2025)
- Science Advisory Committee on Chemicals (SACC) Peer Review of the Draft Risk Evaluations of DBP, DEHP, DCHP, and the Technical Support Documents for BBP and Diisobutyl phthalate DIBP Docket ID: EPA-HQ-OPPT-2024-0551 (June 10, 2025)

Submitted: July 21, 2025

Introduction

We support EPA's effort to improve risk evaluations under the Toxic Substances Control Act (TSCA) by incorporating cumulative risk considerations. Current regulatory approaches often evaluate chemicals in isolation, despite the reality that many individuals, especially workers, fenceline communities, and consumers, are routinely exposed to multiple chemicals that are used or released together and result in the same health effects. This siloed approach fails to capture the actual scope of risk faced by these groups and is inconsistent with TSCA's mandate to assess risks to potentially exposed or susceptible subpopulations. Available scientific evidence demonstrates that cumulative exposures are widespread, can significantly increase health risks, and disproportionately impact overburdened communities. While EPA has acknowledged that cumulative risk assessments may be appropriate in certain cases, such as the current Revised Draft Technical Support Document for the Cumulative Risk Analysis ("Revised Draft TSD"),[1] its implementation remains limited and selective. We have previously commented on many

[1] EPA, "Revised Draft Technical Support Document for the Cumulative Risk Analysis of Di(2-ethylhexyl) Phthalate (DEHP), Dibutyl Phthalate (DBP), Butyl Benzyl Phthalate (BBP), Diisobutyl Phthalate (DIBP), Dicyclohexyl Phthalate (DCHP), and Diisononyl Phthalate (DINP) Under the Toxic Substances Control Act (TSCA)," May 2025, https://www.regulations.gov/document/EPA-HQ-OPPT-2024-0551-0053.

concerns regarding EPA's approach to cumulative risk, such as systematic underestimation of exposures and inattention to highly exposed and susceptible subpopulations.[2]

In these comments, we focus on our concerns with EPA's revision to the Draft TSD to include an "Option 2" approach that results in less sensitive risks than previously found in its "Option 1" approach. We provide recommendations for addressing gaps in methodology for the Option 1 approach, such as conducting sensitivity analyses on endpoints selected for the relative potency factor derivation and applying additional uncertainty factors, which would bring EPA's assessments more in line with its statutory obligations and its stated commitments to scientific integrity and public health protection. We also provide comments on the inability of the Option 2 approach to meet the standard of the best available science under TSCA as there was no rationale for this approach and it is inconsistent with the relative potency factor (RPF) approach taken in other parts of the cumulative risk assessment (CRA).

It is imperative that EPA implements the best available science in its assessment of phthalates' cumulative risk to accurately ensure the most protective risk characterization framework and because this is the first CRA under TSCA. As the methodology in this CRA will likely set a precedent for future CRAs of other chemicals, EPA must ensure that it is scientifically sound and as health protective as possible.

1. EDF supports the approach taken in Option 1 of the cumulative risk assessment, with modifications needed

EPA's use of the RPF approach is scientifically sound, as it maximizes scientific data utilization by providing a framework to allow for incorporation of varying dose-response curves for chemicals that act on the same target organ or via the same mode of action. By providing a consistent index measuring exposure in the same units, it allows for combining risk estimates across chemicals and various exposure routes for risk characterization.

Further, EPA and many guidelines recognize the robustness of the RPF approach. Previous EPA and National Research Council mixtures guidelines support the RPF approach,[3] and EPA has stated in the Draft Dibutyl Phthalate Risk Evaluation that "Application of RPF provides a more robust basis for assessing the dose-response to the common hazard endpoint across all assessed

[2] EDF, "Comments on cross-phthalates draft technical support documents," May 6, 2025, https://www.regulations.gov/comment/EPA-HQ-OPPT-2018-0504-0122.

[3] EPA, "Guidelines for the Health Risk Assessment of Chemical Mixtures," September 1986, https://www.epa.gov/sites/default/files/2014-11/documents/chem_mix_1986.pdf; EPA, "Supplementary Guidance for Conducting Health Risk Assessment of Chemical Mixtures," August 2000, https://ordspub.epa.gov/ords/eims/eimscomm.getfile?p_download_id=4486; National Research Council. (2008). *Phthalates and Cumulative Risk Assessment: The Tasks Ahead*. National Academies Press, Washington, D.C.

phthalates. For a subset of the phthalates with a more limited toxicological data set, scaling by the RPF and application of the index chemical POD provides a more sensitive and robust hazard assessment than the chemical-specific POD."[4] Therefore, EDF supports the full RPF approach taken in Option 1 of the CRA outlined in the Revised Draft TSD.

However, there are important modifications and considerations needed to ensure the CRA is as robust as possible. For example, EPA needs to consider sensitivity analyses and additional uncertainty factors to address the differences in sensitivity of risks for diethylhexyl phthalate (DEHP) in the cumulative risk assessment and individual risk evaluation. As detailed in Morgan and Henrion 1990[5] and supported by the EPA's 2003 Framework for Cumulative Risk Assessment,[6] two of the ten requirements for good policy analysis include "Perform systematic sensitivity and uncertainty analysis" and "Iteratively refine the problem statement and analysis." To ensure the best available science is used in the phthalates risk evaluations, EPA must abide by these two requirements as further detailed below.

A. EPA should conduct further sensitivity analyses to determine the effects of various endpoints on the relative potency factors

As determined in the Draft Risk Evaluation for Diethylhexyl Phthalate (DEHP Risk Evaluation), "risk estimates derived from the CRA…are less sensitive than risk estimates derived via the individual DEHP assessment (*i.e.,* cumulative MOEs are larger than MOEs from the individual DEHP assessment for each individual COU)."[7] This suggests that, at minimum, EPA needs to investigate more sensitive endpoints within the phthalate syndrome mechanism/mode of action (MOA) and conduct a sensitivity analysis with derivation of the RPFs for different endpoints to determine which endpoint/key event in the phthalate syndrome MOA results in the most sensitive and protective cumulative risk estimates.

In EPA's 2023 Draft Proposed Approach for Cumulative Risk Assessment of High-Priority Phthalates and a Manufacturer-Requested Phthalate under the Toxic Substances Control Act (2023 Draft Approach), EPA identified a proposed phthalate syndrome MOA that includes a decrease in testosterone synthesis as one of the cellular responses and malformations as one of

[4] EPA, "Draft Risk Evaluation for Dibutyl Phthalate (DBP)," June 5, 2025, https://www.regulations.gov/document/EPA-HQ-OPPT-2018-0503-0111 at 190.

[5] Granger, M.M. and Henrion, M. (1990). *Uncertainty: A Guide to Dealing with Uncertainty in Quantitative Risk and Policy Analysis*. Cambridge University Press.

[6] EPA, "Framework for Cumulative Risk Assessment," May 2003, https://www.epa.gov/sites/default/files/2014-11/documents/frmwrk_cum_risk_assmnt.pdf at 63.

[7] EPA, "Draft Risk Evaluation for Diethylhexyl Phthalate (DEHP)," June 5, 2025, https://www.regulations.gov/document/EPA-HQ-OPPT-2018-0433-0117 at 212.

the adverse organ outcomes.[8] However, EPA only selected 7 "key outcomes" within the phthalate syndrome MOA to explore for use in the CRA. Notably, DEHP's most sensitive endpoint, increase in reproductive tract malformations, was not selected as a key outcome to explore for use in the CRA. Despite stating that "Through EPA's systematic review of the individual phthalates additional key outcomes may be identified and EPA will assess these additional outcomes for relevance for inclusion in the CRA,"[9] EPA failed to follow through. Although reproductive tract malformations was identified as part of the phthalate syndrome MOA and is the most sensitive endpoint for one of the main phthalates included in the CRA, EPA failed to explore this outcome for use in the CRA.

In addition to being one of the phthalate's most sensitive effects, reproductive tract malformations are identified as an adverse effect in many of the phthalates. For example, reduced reproductive organ weight, testicular pathology, and other reproductive tract malformations are found in all the phthalates assessed in the CRA.[10] Further, these organ-related responses are further along in the MOA chain than reductions in fetal testicular testosterone changes, yet the POD for malformations in DEHP is lower than the POD for reduced testosterone. This suggests that changes in testosterone could occur at lower doses than assessed or that there's another point in the MOA that is more sensitive. Therefore, EPA's robust confidence in the reduced testosterone endpoint being based in the fact that it "plays an early role in the phthalate syndrome MOA"[11] should not contribute to the selection of this endpoint for derivation of the RPFs and these inconsistencies must be further explored.

All this evidence points to the need for EPA to explore endpoints or key outcomes downstream in the MOA by conducting a sensitivity analysis for derivation of the RPFs. EPA should conduct this analysis particularly on reproductive tract malformations, the most sensitive endpoint for DEHP, and any other endpoints that are the most sensitive for individual phthalates that were included in the CRA. Failure to do so can result in cumulative risks that have not been captured in the current CRA and will result in an underestimation of risk.

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[8] EPA, "Draft Proposed Approach for Cumulative Risk Assessment of High-Priority Phthalates and a Manufacturer-Requested Phthalate under the Toxic Substances Control Act," February 27, 2023, https://www.regulations.gov/document/EPA-HQ-OPPT-2022-0918-0009, Figure 3-3 at 30.

[9] *Id.* at 32.

[10] EPA, "Draft Proposed Approach for Cumulative Risk Assessment of High-Priority Phthalates and a Manufacturer-Requested Phthalate under the Toxic Substances Control Act," February 27, 2023, https://www.regulations.gov/document/EPA-HQ-OPPT-2022-0918-0009, Table 3-22 at 89.

[11] EPA, "Revised Draft Technical Support Document for the Cumulative Risk Analysis of Di(2-ethylhexyl) Phthalate (DEHP), Dibutyl Phthalate (DBP), Butyl Benzyl Phthalate (BBP), Diisobutyl Phthalate (DIBP), Dicyclohexyl Phthalate (DCHP), and Diisononyl Phthalate (DINP) Under the Toxic Substances Control Act (TSCA)," May 2025, https://www.regulations.gov/document/EPA-HQ-OPPT-2024-0551-0053 at 14.

B. EPA should apply additional uncertainty factors to address database uncertainty between chemicals

In addition to conducting a sensitivity analysis to address the discrepancy between the risks found from the CRA and the individual DEHP risk evaluation, EPA should explore the use of a database uncertainty factor (UF_{DB}) in the CRA. EPA details in the 2023 Draft Approach, regarding their approach of focusing on the most sensitive effect in the phthalate syndrome MOA instead of phthalate syndrome as a whole, that

> One potential challenge associated with this approach is that no single outcome may be identified as the most sensitive across the six toxicologically similar phthalates. However, failure to identify a single outcome as the most sensitive would likely be more a reflection of the available literature for each phthalate, than biology. For example, across available gestational and perinatal studies there is a great deal of variation related to dose selection, exposure timing and duration, species/strain tested, and measured phthalate syndrome-related outcomes.[12]

It is clear that there are evidence gaps in the phthalate syndrome MOA for every phthalate. For example, DEHP's organ-related changes being more sensitive than the reduced testosterone key outcome could suggest, on a biological level, that changes in testosterone could occur at lower doses than assessed or that there is another point in the MOA that is more sensitive. As EPA said in their 2023 Draft Approach, the reasoning for this discrepancy is likely not a reflection of biology but rather of available literature. Therefore, it would be not only appropriate but suggested to apply a UF_{DB} to account for this lack of data availability in the CRA.

Use of the UF_{DB} is especially important in characterizing uncertainties that exist in cumulative risk assessments that are not present in individual chemical risk evaluations. In its 2003 Framework for Cumulative Risk Assessment, EPA identifies that "Without question…there will be uncertainties inherent in a cumulative risk analysis that have not been as important in traditional assessments."[13] Many of these uncertainties arise from development of the RPFs or other dose addition methodology. For example, EPA notes that RPF uncertainties can be partitioned into three groups:

[12] EPA, "Draft Proposed Approach for Cumulative Risk Assessment of High-Priority Phthalates and a Manufacturer-Requested Phthalate under the Toxic Substances Control Act," February 27, 2023, https://www.regulations.gov/document/EPA-HQ-OPPT-2022-0918-0009 at 97.

[13] EPA, "Framework for Cumulative Risk Assessment," May 2003, https://www.epa.gov/sites/default/files/2014-11/documents/frmwrk_cum_risk_assmnt.pdf at 67.

> those that are basic (e.g., uncertainty in the dose-response relationship for the reference chemical), those that deal with chemicals in relation to one another (relative potencies of other chemicals relative to the reference chemical), and those concerning joint mode of action (e.g., members of the common mechanism group may have other modes of action that are not fully captured via the common-mechanism potency calculation).[14]

In the case where DEHP has a more sensitive endpoint than the most sensitive assessed for other phthalates and within the CRA, the uncertainty in the RPF derivation stems from uncertainty concerning joint mode of action.

EPA's Risk Assessment Forum recommends in its Review of the Reference Dose and Reference Concentration Process that "The database UF is intended to account for the potential for deriving an underprotective RfD/RfC as a result of an incomplete characterization of the chemical's toxicity"[15] and suggests "application of a database UF when there are gaps in the data considered essential for setting a reference value."[16] Therefore, EPA should implement a UF_{DB} in the CRA calculations if there are still uncertainties that the phthalate toxicity database is fully capturing the most sensitive cumulative risks after further analysis as suggested in Section 1A of these comments. The size of the database factor to be applied "will depend on other information in the database and on how much impact the missing data may have on determining the toxicity of a chemical and, consequently, the POD."[17] At minimum, it is logical that the CRA should have more sensitive risk estimates than individual phthalate risk estimates.

C. EPA's concerns about overestimation of exposure are unwarranted

EPA repeatedly raises unsubstantiated concerns about overestimation of exposure. For example, in regard to using scenario-based approaches, EPA stated that "[m]odels may utilize conservative assumptions leading to higher exposure estimates."[18] However, the use of some conservative assumptions does not mean that the overall approach will necessarily be conservative (over estimating exposure). Indeed, the Science Advisory Committee on Chemicals (SACC) has

[14] *Id.*

[15] EPA Risk Assessment Forum, "A Review of the Reference Dose and Reference Concentration Processes," December 2002, https://www.epa.gov/sites/default/files/2014-12/documents/rfd-final.pdf at 4-44.

[16] *Id.* at 4-39.

[17] *Id.* at 4-45.

[18] EPA, "Draft Proposed Approach for Cumulative Risk Assessment of High-Priority Phthalates and a Manufacturer-Requested Phthalate under the Toxic Substances Control Act," February 27, 2023, https://www.regulations.gov/document/EPA-HQ-OPPT-2022-0918-0009 at 126.

previously commented on EPA's repeated unsubstantiated concerns about "overestimation of exposure,"[19] and reminded EPA that "assumptions that appear to be conservative are not certain to overestimate exposure."[20] Among examples of conservative assumptions that resulted in underpredictions from previous risk evaluations, the SACC included:

> ...underprediction of biomarker data include Children's Total Exposure to Persistent Pesticides (CTEPP) results for chlorpyrifos, 2,4-D and pentachlorophenol (Morgan et al., 2005; Wilson et al., 2007, Morgan et al., 2008) and, in the occupational realm, underprediction of biomarker data for chlorpyrifos from Pesticide Handler Exposure Database (PHED) (USEPA OPP et al., 2007).[21]

EPA's fixation on potentially overestimating exposure is clearly unwarranted. This is particularly problematic given EPA's systematic underestimation of exposures.[22]

D. EPA should address underestimation of hazard and exposure throughout the Draft Technical Support Document

In addition to our comments in the rest of this section, we re-emphasize points made in our comments submitted on May 6, 2025 on the first Draft Technical Support Document.[23] In those comment, we urged EPA to base risk calculations on the 95th percentile exposure estimates for conditions of use (COUs), rather than the 50th percentile, to better reflect more highly exposed and susceptible populations, including workers, and to align with the high end non-attributable exposure estimates used from National Health and Nutrition Examination Survey (NHANES). Using the 50th percentile excludes exposures faced by 50 percent of the population considered. We also urged EPA to include evaluation of all toxic endpoints associated with phthalates beyond male reproductive endpoints, even if these effects (e.g., liver toxicity and cardiovascular disease) occur at higher doses.

[19] EPA, "Science Advisory Committee on Chemicals Meeting Minutes and Final Report," July 11, 2023, https://www.regulations.gov/document/EPA-HQ-OPPT-2022-0918-0067 at 83.

Field Code Changed

[20] *Id*. at 83

[21] *Id*. at 83

[22] EDF, "Comments on cross-phthalates draft technical support documents," May 6, 2025, https://www.regulations.gov/comment/EPA-HQ-OPPT-2018-0504-0122.

[23] *Id*.

2. EPA should not apply the Option 2 approach to the cumulative risk assessment

In the Revised Draft TSD, EPA proposes a new "Option 2" for estimation of cumulative risk in Section 5.2 that does not utilize RPFs for consumer and occupational COUs but combines these hazard values with non-attributable RPF-adjusted cumulative exposures from NHANES. Option 1, which was the previously proposed method for estimating cumulative risk in the first Draft Technical Support Document, utilizes RPFs in all cumulative risk estimates. Discussed in further detail below, we encourage EPA to use Option 1, with further modifications and analysis recommended in Section 1 of these comments, as this option consistently employs the RPF approach, which is a well-established method that has been used repeatedly and effectively by the Agency and was reviewed by the SACC via the 2023 Draft Approach, and does not suffer from logical inconsistencies found in Option 2.

A. EPA should provide a rationale for why Option 2 is proposed as a second approach for estimating cumulative risk

There is no clear rationale given in the Revised Draft TSD for the appearance of Option 2. In Section 5, EPA states, "option 1 will have a large impact for DCHP, but no impact for DEHP because the individual DEHP POD is so much more sensitive than the index chemical (DBP) POD. Option 2 will have the same impact on cumulative risk estimates for every phthalates [sic], resulting in cumulative risk estimates that are approximately 1.1x more sensitive for both DCHP and DEHP as shown in Section 5.2."[24] This statement describes the impact of Option 2 on cumulative risk estimates, not why this option was suggested. A reader could infer from this description that EPA has proposed Option 2 to address the lack of impact of Option 1 on DEHP cumulative risk estimates, "because the individual DEHP POD is so much more sensitive than the index chemical (DBP) POD."[25] Later, in Section 5.4, EPA notes that a "benefit of option 2 is that it will have the same impact on cumulative risk estimates for every phthalate being evaluated under TSCA", but that Option 2 "involves combining [margins of exposure] (MOEs) calculated using exposures expressed in different units."[26] Descriptions of impacts, benefits and uncertainties of Option 2 still do not provide a solid scientific rationale for applying the RPF approach in only part of a cumulative risk estimate.

[24] EPA, "Revised Draft Technical Support Document for the Cumulative Risk Analysis of Di(2-ethylhexyl) Phthalate (DEHP), Dibutyl Phthalate (DBP), Butyl Benzyl Phthalate (BBP), Diisobutyl Phthalate (DIBP), Dicyclohexyl Phthalate (DCHP), and Diisononyl Phthalate (DINP) Under the Toxic Substances Control Act (TSCA)," May 2025, https://www.regulations.gov/document/EPA-HQ-OPPT-2024-0551-0053 at 62.

[25] *Id*. at 75.

[26] *Id*.

Further, Option 2 is not discussed in the Draft Proposed Principles or the 2023 Draft Approach documents that were subject to review by the SACC.[27] RPF and hazard index approaches are discussed in Section 4.3 of the 2023 Draft Approach, which concluded with selection of the RPF approach because "EPA believes there is sufficient information available to support the development of RPFs for phthalates."[28] All proposed examples of cumulative risk estimates throughout Section 6 in the 2023 Draft Approach were also all based on expressing exposure from each individual phthalate as index chemical equivalents using RPFs.[29] The extensive research conducted by EPA, and work performed by peer reviewers have essentially been discarded in Option 2, with no real well-supported rationale. EPA should describe the reasoning behind Option 2 before making any final decisions on methods for risk characterization.

B. Option 2 is an inconsistent and inappropriate application of the RPF approach and will result in less accurate and less protective risk estimates overall across all phthalates under evaluation

EPA characterizes the use of RPFs for only part the cumulative MOE calculation in Option 2 as "one source of uncertainty," rather than a major weakness.[30] There are several issues that arise when combining unscaled individual exposures for consumer and occupational COUs with scaled, non-attributable exposures from NHANES.

First, assumptions needed for RPFs, the entire basis of this phthalate cumulative risk analysis, are ignored. Option 2 combines "MOEs calculated using exposures expressed in different units, as non-attributable cumulative phthalate exposure is expressed in units of index chemical (DBP) equivalents" with TSCA COU phthalate exposures that "are not scaled by relative potency."[31] EPA selected the RPF approach because various assumptions needed for dose addition are

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[27] EPA, "Draft Proposed Approach for Cumulative Risk Assessment of High-Priority Phthalates and a Manufacturer-Requested Phthalate under the Toxic Substances Control Act," February 27, 2023, https://www.regulations.gov/document/EPA-HQ-OPPT-2022-0918-0009.
EPA, "Draft Proposed Principles of Cumulative Risk Assessment under the Toxic Substances Control Act," February 27, 2023, https://www.regulations.gov/document/EPA-HQ-OPPT-2022-0918-0008.

[28] EPA, "Draft Proposed Approach for Cumulative Risk Assessment of High-Priority Phthalates and a Manufacturer-Requested Phthalate under the Toxic Substances Control Act," February 27, 2023, https://www.regulations.gov/document/EPA-HQ-OPPT-2022-0918-0009 at 102.

[29] *Id*. at 130.

[30] EPA, "Revised Draft Technical Support Document for the Cumulative Risk Analysis of Di(2-ethylhexyl) Phthalate (DEHP), Dibutyl Phthalate (DBP), Butyl Benzyl Phthalate (BBP), Diisobutyl Phthalate (DIBP), Dicyclohexyl Phthalate (DCHP), and Diisononyl Phthalate (DINP) Under the Toxic Substances Control Act (TSCA)," May 2025, https://www.regulations.gov/document/EPA-HQ-OPPT-2024-0551-0053 at 75.

[31] *Id*.

satisfied by the available data.[32] EPA describes data supporting the assumption of toxicological similarity across the phthalates, i.e., a common mode of action for reduced fetal testicular testosterone, and that dose-response data for this endpoint are also available over similar exposure ranges.[33] EPA notes that although RPFs can be applied to chemicals with dissimilar dose-response curves, estimating RPFs carries the assumption that "dose-response curve shapes will be the same" in the low-dose region of the dose-response curve, and the index chemical should not have an "extreme" difference in shape compared to other phthalates under consideration.[34] Therefore, the assumption that dose-response curves are similar is satisfied and phthalates can be assumed to be dilutions of each other (another assumption, no toxicological interactions among phthalates, is implicit but not plainly stated in the 2023 Draft Approach). Uncoupling TSCA COU exposures from RPFs suggests that the phthalates are not dilutions of each other and different PODs are necessary. Summing MOEs across inconsistent scales effectively compares "apples to oranges" and creates an uninterpretable result. If dose-response curves are dissimilar or the phthalates are not toxicologically similar, then EPA should derive reference doses for each phthalate and use the hazard index approach.

Second, use of Option 2 will set a precedent for EPA to continue to inconsistently apply a long-standing, widely adopted scientific standard for cumulative risk estimation, and will open the door to unsound applications of other risk characterization approaches. The addition of unscaled MOEs with a scaled MOEs is not consistent with EPA Guidance on Cumulative Risk Assessment of Pesticide Chemicals That Have a Common Mechanism of Toxicity,[35] which describes the same cumulative MOE approach proposed in Option 1 and is cited throughout the 2023 Draft Approach document in support of the RPF methods. The approach set forth in Option 2 undermines previous EPA guidance and the scientific rigor that underpins the RPF framework.

Third, the invalid comparisons made in Option 2 create misleading risk estimates that will underestimate risk for all chemicals except DEHP and will fail to fully protect public health. Risk estimates that were approximately 1.3 to 3.5 times more sensitive using the cumulative

[32] EPA, "Draft Proposed Approach for Cumulative Risk Assessment of High-Priority Phthalates and a Manufacturer-Requested Phthalate under the Toxic Substances Control Act," February 27, 2023, https://www.regulations.gov/document/EPA-HQ-OPPT-2022-0918-0009 at 98.

[33] *Id*. at 101.

[34] *Id*. at 102.

[35] EPA, "Guidance on Cumulative Risk Assessment of Pesticide Chemicals That Have a Common Mechanism of Toxicity," January 14, 2002, https://www.regulations.gov/document/EPA-HQ-OPPT-2023-0496-0018.

MOEs in Option 1[36] will be reduced to 1.1 times the sensitivity – all to increase the sensitivity of DEHP's risk estimate by only 10%. Adding non-attributable exposure from DBP equivalents estimated using NHANES to DEHP, DINP, BBP, and DCHP is not only nonsensical but will lead to underestimating the actual risk, resulting in insufficiently protective regulation. If Option 2 serves to demonstrate EPA's uncertainty in applying the RPF approach to DEHP, then we suggest EPA use additional adjustment factors and sensitivity analyses, as discussed above, to address this uncertainty rather than applying a risk estimation option that will lead to under regulation of high-risk phthalates.

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EDF appreciates EPA's consideration of these comments.

[36] EPA, "Revised Draft Technical Support Document for the Cumulative Risk Analysis of Di(2-ethylhexyl) Phthalate (DEHP), Dibutyl Phthalate (DBP), Butyl Benzyl Phthalate (BBP), Diisobutyl Phthalate (DIBP), Dicyclohexyl Phthalate (DCHP), and Diisononyl Phthalate (DINP) Under the Toxic Substances Control Act (TSCA)," May 2025, https://www.regulations.gov/document/EPA-HQ-OPPT-2024-0551-0053, Table 5-3 at 80.