United States
Environmental Protection Agency

Office of Chemical Safety and
Pollution Prevention
August 2021

EPA Response to Public Comments Received on the Draft Scopes of the Risk Evaluations Under the Toxic Substances Control Act (TSCA) for:

Di-isodecyl Phthalate (DIDP)
(1,2-Benzenedicarboxylic acid, 1,2-diisodecyl ester and 1,2-Benzenedicarboxylic acid, di-C9-11-branched alkyl esters, C10-rich)
CASRN 26761-40-0 and 68515-49-1

and

Di-isononyl Phthalate (DINP)
(1,2-Benzene-dicarboxylic acid, 1,2-diisononyl ester, and 1,2-Benzenedicarboxylic acid, di-C8-10-branched alkyl esters, C9-rich)
CASRNs 28553-12-0 and 68515-48-0

August 2021

Summary of Public Comments Received on the Draft Scopes of the Risk Evaluations for DIDP and DINP Under the Toxic Substances Control Act (TSCA) August 2021

In this document, the U.S. Environmental Protection Agency (EPA) is responding to comments received during the public comment periods following announcement of draft scopes of the risk evaluations under the Toxic Substances Control Act (TSCA) to be conducted for two categories of chemical substances for which EPA received manufacturer requests for risk evaluation (MRREs) on May 24, 2019. The two categories are: di-isodecyl phthalate (DIDP) (1,2-benzenedicarboxylic acid, 1,2-diisodecyl ester and 1,2-benzenedicarboxylic acid, di-C9-11-branched alkyl esters, C10-rich); Chemical Abstracts Service Registry Number (CASRN) 26761-40-0 and 68515-49-1 and di-isononyl phthalate (DINP) (1,2-benzene-dicarboxylic acid, 1,2-diisononyl ester, and 1,2-benzenedicarboxylic acid, di-C8-10-branched alkyl esters, C9-rich); CASRN 28553-12-0 and CASRN 68515-48-0.

Comments were received during a 45-day public comment period following the announcement of the draft scope documents for the risk evaluations for DIDP and DINP under TSCA (85 FR 76072 and 76077, respectively [November 27, 2020]). During the comment period, the public was invited to submit comments on EPA's draft scope documents, including additional data or information relevant to the chemical substances or that otherwise could be useful to the Agency in finalizing the scope of the risk evaluations. To the extent that comments provided information on conditions of use, as well as other elements of the draft scope documents, those comments and other submitted information (*e.g.*, relevant studies and assessments) were used to inform revisions to the draft scope documents and may be considered in subsequent phases of the risk evaluation process.

EPA created individual dockets for DIDP and DINP to receive chemical-specific information. From both dockets combined, EPA received 11 submissions; however, some commenters opted for one submission describing all their comments and submitted it to both dockets and other commenters chose to submit different comments to individual chemical-specific dockets. Therefore, EPA considered seven of those submissions unique. EPA received submissions from six different entities, including potentially affected businesses or trade associations, environmental and public health advocacy groups and academia (including some submissions signed by more than one group), a group of state attorneys general, other organizations, and one anonymous comment.

Comments addressed the overall risk evaluation process (*e.g.*, the overall approach to the scope documents and risk evaluation process; including collection, consideration, and systematic review of relevant information); the specific elements of the scope documents (*e.g.*, hazard, exposure, and potentially exposed or susceptible subpopulations [PESS]), and information specific to the chemical substances (*e.g.*, relevant studies, assessments, conditions of use [COUs]).

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Overall Risk Evaluation Process

Approach to Scope Documents

Comment: One commenter (EPA-HQ-OPPT-2018-0435-0028; EPA-HQ-OPPT-2018-0436-0025) stated that each draft scope, "fails to satisfy the substantive requirements of TSCA and the EPA implementing regulations for these risk evaluations, including identifying the hazards, exposures, conditions of use, the potentially exposed or susceptible subpopulations (PESS), and the information and scientific approaches that EPA plans to use in the risk evaluation. See 15 U.S.C. § 2605(b)(4)(D); 40 C.F.R. § 702.41(c)."

Response: The Agency disagrees with the view that the draft scope documents fail to satisfy the substantive requirements of TSCA and notes that each scope provides specific information on how the Agency fulfilled elements required by TSCA section 6(b)(4)(D) and 40 CFR 702.41. In accordance with 40 CFR 702.41(c), each draft scope document and final scope document includes the following information: the COUs that EPA plans to consider during risk evaluation; the PESS, hazards and exposures that EPA plans to evaluate; a description of the reasonably available information and science approaches EPA plans to use; and a conceptual model, analysis plan, and plan for peer review for each category of chemical substances. Please note that elements of the above comments (e.g., hazard, exposure, and PESS) are addressed in appropriate sections elsewhere in this document.

The identification of hazards, exposures, COUs, and PESS that EPA expects to consider as well as scientific approaches that EPA plans to use in each risk evaluation is consistent with requirements of TSCA sections 26(h) and (i), as well as 40 CFR 702.41 and involved consideration of the reasonably

available information for DIDP and DINP in accordance with TSCA section 26(k) and 40 CFR 702.41 within the time period allotted by the statute. The scope documents describe how EPA considered the reasonably available information for DIDP and DINP, including relevant information, procedures, methodologies, and protocols, as well as applicable statutory and regulatory requirements and criteria, and how information sources used are relevant to the applicable criteria and considerations. The documents also include citations for all references included in the literature review of each of these chemical substances and links to those references that are publicly available.

Comment: One commenter (EPA-HQ-OPPT-2018-0435-0028; EPA-HQ-OPPT-2018-0436-0025) noted that EPA did not publish the draft scopes within 3 months of initiation of the risk evaluations as required by EPA's own regulations (40 CFR 702.41(c)(7)(ii)) and was concerned that the draft scopes are "contrary to law under the Administrative Procedure Act, 5 U.S.C. §§ 551, et seq."

Response: The applicable regulation (40 CFR 702.41(c)(7)(ii)) states that EPA "generally expects to publish the draft scope no later than 3 months from the initiation of the risk evaluation process…" The timing of receipt and initiation of draft scopes on the manufacturer requested risk evaluations for DIDP and DINP coincided with the revision and publication of the first 10 risk evaluations and development of draft and final scope documents for the next 20 high priority substances (HPS) under TSCA, therefore the scopes for DINP and DIDP came out later than the generally expected 3 months. EPA believes that the quality of the DINP and DIDP scopes benefited from the lessons learned in developing the draft and final scopes for the 20 HPS. In particular, 6 of the 20 HPS are phthalates, and EPA was able to refine some of the scoping approaches for the manufacturer-requested phthalates (DINP and DIDP) as a result of the effort on the EPA-sponsored phthalate scopes (e.g., DEHP). The draft scope documents were subject to public notice and comment and otherwise complied with substantive statutory and regulatory requirements in TSCA section 6(b)(4)(D) and 40 CFR 702.41.

Potentially Exposed or Susceptible Subpopulations

Comment: A commenter (EPA-HQ-OPPT-2018-0435-0028, EPA-HQ-OPPT-2018-0436-0025) stated the draft scopes must be revised to require that the DIDP and DINP risk evaluations determine whether those chemicals present an unreasonable risk to PESS. Another commenter (EPA-HQ-OPPT-2018-0435-0032, EPA-HQ-OPPT-2018-0436-0028) indicated that EPA illegally excludes relevant PESS. The commenter stated that "intrinsic factors (such as life stage or underlying disease) and extrinsic factors (such as psychosocial stress from poverty, violence, or racial injustice) contribute to susceptibility to harm from chemical exposures" and these nonchemical factors should be taken into consideration when determining PESS. The commenter expressed concern that communities "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, are particularly vulnerable to harm from chemical exposures" and urged EPA to consider these communities, noted by the commenter as predominantly communities of color, as PESS in the risk evaluations for DIDP and DINP. The commenter further stated that "TRI data indicates these communities face greater exposures than the general population to many of the 20 high priority chemicals." The commenter presented data regarding import of DIDP and DINP by several facilities located in the Texas and Louisiana Gulf Region. The commenter urged EPA to identify these communities as PESS in order to comply with TSCA. The same commenter (EPA-HQ-OPPT-2018-0435-0032, EPA-HQ-OPPT-2018-0436-0028) indicated that fence line communities should be considered PESS due to unique harms and exposure fence line communities face and strongly encouraged EPA to consider them as such.

Response: EPA expects to consider the following PESS based on reasonably available information, including studies reporting developmental and reproductive effects, in the risk evaluation: children, women of reproductive age (e.g., women who may be pregnant), workers, occupational non-users, consumers, and bystanders (U.S. EPA, 2012). Other PESS may be identified based on reasonably available information. Additionally, EPA plans to analyze reasonably available data in order to determine whether some human receptor groups may be exposed via exposure pathways that may be distinct to a particular subpopulation or life stage (e.g., reproductive age females who may be or become pregnant; lactating women; infants, toddlers, children at various developmental stages in life, and elderly) and whether some human receptor groups may have higher exposure via identified pathways of exposure due to unique characteristics (e.g., activities, duration, location of exposure) when compared with the general population (U.S. EPA, 2006). Likewise, EPA plans to evaluate reasonably available human health hazard information in order to determine whether some human receptor groups may have greater susceptibility than the general population to the chemical's hazard(s). Based on these analyses, EPA may expand the PESS considered in the risk evaluation.

Communities living in close proximity to identified sources of emissions from manufacturing, processing, use or disposal may experience greater exposure than the general population. In reviewing the reasonably available exposure information, EPA considers the spatial and temporal relevance of the information in building each exposure scenario for the identified conditions of use, including any information regarding chemical emissions. EPA has not completed its full evaluation, synthesis, and integration of the exposure literature. EPA acknowledges that exposures (and any subsequent risk) vary due to differences among individuals, populations, spatial and temporal scales, and other factors, and strives to present both a central tendency and a high-end estimate. In estimating exposures, EPA utilizes guidance as provided in EPA's Guidelines for Human Exposure Assessment (U.S. EPA, 2019), which defines "High-End" as the 90% to 99.99% exposure. When the impact of ambient air is considered in the scope documents, concentrations are obtained (or modeled) at the fence line and in the surrounding communities at varying distances in close proximity to the emitting source(s).

EPA expects to strengthen consideration and presentation of PESS issues and increase consideration of environmental justice issues. EPA plans to include fenceline analyses where appropriate to screen for potential effects with emphasis on PESS and environmental justice communities, followed by more in-depth analysis where warranted. EPA will continue to develop the science of how to better consider different dimensions of susceptibility when selecting critical endpoints, PODs, determination of uncertainty factors, and margins of exposure.

Comment: A commenter (EPA-HQ-OPPT-2018-0435-0032, EPA-HQ-OPPT-2018-0436-0028) mentioned that given the strong evidence that the developing fetus is exposed to multiple phthalates, and the fact that prenatal phthalate exposure can lead to catastrophic health outcomes, the developing fetus should be explicitly considered a PESS. The commenter expressed concern that a failure to evaluate the developing fetus would lead to a vast underestimation of risk to the most susceptible life stage to phthalate exposure.

Response: EPA identifies critical and supporting studies during the data evaluation phase where quality and relevance are determined. This data evaluation phase is where the studies' key endpoints are carried forward for dose response analysis. Following data evaluation, EPA will organize, extract, and synthesize the evidence for each substance and provide a basis for conclusions including any conclusions regarding risks to PESS. Because there are many individual factors that may influence susceptibility to exposure-related health effects, susceptibilities may differ depending upon the chemical

and its conditions of use. In its synthesis and integration of the evidence, EPA considers the mechanistic understanding of how a health outcome develops, including whether differences in susceptibility may be explained by an analysis of toxicokinetic or toxicodynamic differences across life stages or populations.

EPA recognizes and agrees that the fetus may be exposed to chemical stressors and that the fetus is potentially exposed via maternal exposures. EPA is aware of critical windows of exposure for some adverse effects on the reproductive system associated with gestational exposures in humans and animals. As such, women of reproductive age (e.g., women who may be pregnant or breastfeeding) are considered PESS for the phthalates designated as High-Priority Substances in addition to DIDP and DINP. The consideration of women of reproductive age as PESS is intended to be assessed and be protective of both maternal and fetal health.

Aggregate and Cumulative Exposure

Comment: A commenter (EPA-HQ-OPPT-2018-0435-0029, EPA-HQ-OPPT-2018-0436-0026) stated that for many of the conditions of use being evaluated, co-exposure to DIDP and DINP will occur and in instances where co-exposure is anticipated, a cumulative assessment should be conducted. The commenter further stated that DIDP and DINP should be assessed in combination with the five high priority substances (*i.e.*, BBP, DBP, DEHP, DIBP, DCHP) as a single category under TSCA.

Comment: Another commenter (EPA-HQ-OPPT-2018-0435-0032, EPA-HQ-OPPT-2018-0436-0028) indicated that EPA has failed to take into account the recommendation of the National Research Council (NRC) of the National Academy of Sciences, which is to evaluate phthalates as a class of chemicals in a cumulative risk assessment (CRA). The commenter urged EPA to use the best available science and evaluate DIDP, DINP, and the five high priority phthalates (*i.e.,* DEHP, DCHP, DIBP, BBP, and DBP) as a class and conduct a CRA. Based on the current draft scope documents, the commenter was not clear if EPA plans to conduct a CRA for DINP, DIDP, and the other five high priority phthalates (*i.e.*, DEHP, DCHP, DIBP, BBP, and DBP). This commenter indicated that a CRA should be conducted on phthalates because of widespread human exposure to multiple phthalates given their presence in a variety of consumer products, and because exposure is associated with common adverse health outcomes, such as neurodevelopmental harm and harm to the male reproductive system. The commenter again urged EPA to conduct a CRA of DINP, DIDP, and the five high priority phthalates in order to assess the cumulative effects of phthalates on neurodevelopment and the male reproductive system.

Response: Two separate manufacturer requests for evaluation were made specifically for DIDP (CASRN 26761-40-0 and 68515-49-1) and for DINP (CASRNs 28553-12-0 and 68515-48-0) and not for other chemicals or other phthalates. Since EPA's authority to conduct a manufacturer-requested risk evaluation is tied to the "chemical substance [or category of chemical substances]…that a manufacturer of the chemical substance has requested…be subjected to a risk evaluation," (TSCA section 6(b)(4)(C)) EPA cannot add additional phthalates to the scope of the risk evaluations for DIDP and DINP, as doing so would go beyond the scope of the risk evaluation. Under TSCA section 6(b)(4)(F), EPA is not required to conduct cumulative risk evaluations; rather, EPA must describe whether aggregate or sentinel exposure were considered, and the basis for that consideration. Note that the Agency identified other phthalates for prioritization on March 21, 2019, (including benzyl butyl phthalate [BBP], CASRN 85-68-7; dibutyl phthalate [DBP], CASRN 84-74-2; dicyclohexyl phthalate [DCHP], CASRN 84-61-7; di(2-ethylhexyl)phthalate [DEHP], CASRN 117-81-7; and diisobutyl phthalate [DIBP], CASRN 84-69-5), but these actions are separate from these manufacturer requested risk evaluations.

Comment: One commenter (EPA-HQ-OPPT-2018-0435-0028, EPA-HQ-OPPT-2018-0436-0025) stated that EPA must consider aggregate exposures when conducting risk evaluations for DINP and DIDP, and that the current draft scopes fail to indicate that EPA will do so. The commenter further stated that EPA must revise their draft scopes to clearly state that the risk evaluations of DINP and DIDP will address the additive and cross-media risks of these phthalates. Another commenter (EPA-HQ-OPPT-2018-0435-0032, EPA-HQ-OPPT-2018-0436-0028) stated that in the draft scopes for DINP and DIDP, EPA has failed to indicate that they will aggregate relevant exposures in the final risk evaluations for these phthalates. The commenter further stated that in order to protect PESS, EPA must combine all relevant exposure pathways and conditions of use when assessing potential risks posed by DINP and DIDP.

Response: TSCA section 6(b)(4)(F)(ii) directs EPA to "describe whether aggregate or sentinel exposures to a chemical substance under the conditions of use were considered, and the basis for that consideration" in risk evaluations. This statutory provision does not require EPA to incorporate aggregate exposures into the risk evaluation.

EPA defines aggregate exposures as the combined exposures to an individual from a single chemical substance across multiple routes (i.e., dermal, inhalation, or oral) and across multiple pathways (i.e., exposure from different sources) at 40 CFR 702.33. EPA defines sentinel exposures as the exposure from a single chemical substance that represents the plausible upper bound of exposure relative to all other exposures within a broad category of similar or related exposures," at 40 CFR 702.33. EPA considers reasonably available information and uses the best available science to determine whether to consider aggregate or sentinel exposures for a particular chemical.

EPA recognizes that a worker may be exposed via inhalation, dermal, and oral routes at the workplace. EPA also recognizes that when the worker leaves the facility, there may be additional exposures from being in the general population and from using consumer products. EPA will evaluate reasonably available data and determine whether to consider aggregate exposure assessment for DIDP and DINP.

The magnitude, frequency, and duration of exposures and the associated routes of exposure will depend upon the conditions of use. EPA acknowledges that workers, consumers, and the general population may be exposed via the inhalation, dermal, and oral routes and that these exposures may be additive across routes, pathways, receptors, and chemical stressors. Exposure scenarios will be developed based on the reasonably available information, weight of the scientific evidence, and best available fit-for-purpose approaches. Aggregate assessments may not be appropriate in all cases; for example, if there is not sufficient information that can be reliably modeled to perform additive inhalation and dermal exposures. EPA has not yet completed its data evaluation phase of systematic review of the reasonably available literature and is not yet able to discern the fit-for-purpose approach for DINP and DIDP.

Physical-Chemical Properties and Fate

Comment: A commenter (EPA-HQ-OPPT-2018-0435-0030) asserted that EPA's representative structure for DIDP is inaccurate and stated that, based on the isomer distribution, a more accurate representative structure would show di-methyl octanol side chains.

Response: EPA has revised the representative chemical structure of DIDP based on the dominant isomer to more accurately depict di-methyl octanol side chains.

Comment: A commenter (EPA-HQ-OPPT-2018-0435-0030) stated that the flash point data for DIDP is too low and that one of the flashpoint values in Table 11 of the DIDP Data Extraction and Data

Evaluation Tables for Physical and Chemical Property Studies is reported as 122 °C. The commenter stated that this value is too low for DIDP and that typical flash point value for DIDP is greater than 200 °C.

Response: In Table 2-3 (Physical and Chemical Properties of DIDP) of the DIDP scope document and in Table 11 of the DIDP Data Extraction and Data Evaluation Tables for Physical and Chemical Property Studies, the flashpoint preliminarily selected for use in the risk evaluation is 232 °C (as indicated in bold font in Table 11). This value exceeds 200 °C. This value remains unchanged from that in the DIDP draft scope document. Values in Table 2-3 may be updated as EPA continues to evaluate and integrate additional information through systematic review.

Comment: Another commenter (EPA-HQ-OPPT-2018-0435-0030) stated that the boiling point values reported in Table 4 of the DIDP Data Extraction and Data Evaluation Tables for Physical and Chemical Property Studies are too low. The commenter stated that reported boiling point in the ECHA 2013 risk assessment report for DIDP exceeds 400 °C.

Response: Experimental values for the boiling point of DIDP identified in EPA's systematic review process (as described in a draft systematic review protocol to be released later this year) were observed at reduced pressure (4 mm Hg). The submitted data (ECHA 2013 risk assessment) (ECHA, 2013) will undergo data quality evaluation and extraction and be considered in risk assessment of DIDP. EPA will consider the new submitted data source in the risk assessment and revise the boiling point of DIDP depending upon data quality evaluation of the submitted data source.

Comment: Another commenter (EPA-HQ-OPPT-2018-0435-0030 EPA-HQ-OPPT-2018-0436-0027) stated that the water solubility data for DINP and DIDP are erroneously high (see proposed values in public comments). The commenter expressed concern that listing water solubility values several-fold greater than what the commenter considered accurate water solubility values could lead to significant errors when considering aquatic toxicity data. The commenter stated that DINP and DIDP do not produce acute or chronic toxicity to aquatic organisms at or below its maximum attainable water solubility and that a water solubility value in the mg/L range could generate erroneous concerns as to why existing studies were not conducted at that concentration.

Response: The proposed water solubility values presented in the draft scopes are subject to change as EPA completes the systematic review process as described in a draft systematic review protocol to be released later this year). EPA has incorporated the commenter's proposed value into the systematic review process for the draft risk evaluations of DIDP/DINP. As part of that process, EPA will conduct data quality evaluations and data extraction to identify a water solubility value for the draft risk evaluations. Additionally, characteristics other than water solubility (e.g., adsorption to sediment particles or organic material suspended in the water column) may affect toxicity to aquatic organisms and such information may be considered relevant during systematic review.

Exposure

Comment: A commenter (EPA-HQ-OPPT-2018-0435-0030, EPA-HQ-OPPT-2018-0436-002) indicated that exposure data on low molecular weight (LMW) phthalates (*i.e.*, DBP, BBP, DEHP, DIBP, and DCHP) are not relevant for estimating exposure to DINP. The commenter referenced the exposure section of Table Apx A-3 (Hazards Title and Abstract and Full-text population, exposure, comparator, and outcome [PECO] Criteria for DINP) from the DINP scoping document and expressed concern that the physical and chemical properties and conditions of use for these LMW phthalates are different from

those of DINP, stating "patterns and routes of exposure to these substances is expected to be significantly different to DINP." The commenter was unclear why EPA anticipates that exposure to LMW phthalates are relevant for the exposure section of the PECO statement in the DINP scoping document.

Response: The HPS phthalates, DIDP, and DINP (both of which have structural isomers identified) went through the title-abstract (TIAB) screening portion of the systematic review process (as described in a draft systematic review protocol to be released later this year) simultaneously, which is why all eight phthalates are indicated in the exposure section of Table Apx A-3. During TIAB screening, if a reference was specific to other phthalates, but not DINP, those references were not automatically considered in the systematic review for DINP. If, during screening, multiple phthalates of interest were considered PECO-relevant within one study, all the relevant phthalates were tagged at that time for inclusion in the systematic reviews of the respective phthalates.

Comment: A commenter (EPA-HQ-OPPT-2018-0435-0032, EPA-HQ-OPPT-2018-0436-0028) urged EPA to consider exposures to phthalates from microplastics contained within landfill leachate, including from RCRA landfills, stating that there is currently no mention of whether EPA will evaluate DIDP and DINP contained within nano- and microplastics in landfill leachate. The same commenter referenced a prior comment made by EPA's SACC regarding HBCD-containing polystyrene, which stated that EPA should "consider including a limited discussion on the role of micro- and nano-plastic inputs from HBCD-containing polystyrene as vectors to aquatic systems." The commenter stated that examining the environmental fate and distribution of DINP and DIDP entrained within nano- and microplastics is crucial and needed to adequately assess exposure.

Response: The pathway for examining exposure to environmental and human receptors from landfill leachate is already included in the Conceptual Model for Environmental Releases and Wastes: Environmental and General Population Exposures and Hazards in the DIDP and DINP scope documents. Additionally, disposal (including disposal to landfills) is included as a condition of use in both the DIDP and DINP scope documents. If microplastics contained within landfill leachate is identified as an exposure vector during the systematic review of DIDP and DINP, then those references will be evaluated according to our systematic review processes (as described in a draft systematic review protocol to be released later this year) and integrated into the draft risk evaluations, as appropriate.

Consumer Exposure

Comment: A commenter (EPA-HQ-OPPT-2018-0435-0032, EPA-HQ-OPPT-2018-0436-0028) urged EPA to make appropriate, realistic assumptions regarding exposure, particularly with regard to mouthing of products by children, by using the best available science in its risk evaluations. The commenter urged EPA to conduct exposure assessments for consumer products, including toys, floor coverings, and building materials, as outlined in the DIDP and DINP scope documents using appropriate mouthing rate estimations as found in EPA's *Exposure Factors Handbook* for mouthing time and frequency of mouthing of objects in infants and children at the 95th percentile.

Response: EPA plans to evaluate reasonably available oral and mouthing exposure data and information during systematic review (as described in a draft systematic review protocol to be released later this year), including chemical-specific oral exposure data, experimental studies, and applicable exposure models. In estimating exposures for the risk evaluation, EPA utilizes guidance as provided in EPA's Guidelines for Human Exposure Assessment (U.S. EPA, 2019), which defines "High-End" as the

90th to 99.99th percentile exposure. Additionally, EPA utilizes the Exposure Factors Handbook (U.S. EPA, 2011) recommendations in Chapter 4 for non-dietary mouthing exposure factors.

Occupational Exposure

Comment: One commenter (EPA-HQ-OPPT-2018-0435-0030, EPA-HQ-OPPT-2018-0436-0027) mentioned that DIDP and DINP, as pure substances, do not exist in solid form. The same commenter indicated that DIDP and DINP are only manufactured, stored, and transported in liquid form, but that the substances may be incorporated into compounded PVC pellets that can be imported. The commenter further stated that due to low volatility and low migration from PVC, solid/inhalation exposure through these routes is expected to be minimal. In conclusion, the commenter recommended pathways of solid contact and dust inhalation be removed from the occupational exposure analysis for the following conditions of use: domestic manufacture; import; incorporation into formulation, mixture, or reaction; incorporation into articles; non-incorporative activities; and repackaging.

Response: EPA acknowledges that DIDP and DINP, as pure substances, do not exist in solid form and must be compounded into a pellet or dry powder. As mentioned in Appendix E, 2016 CDR references import of DIDP in dry powder form and import of DINP in pellet form. Also, as mentioned in Appendix F, 2016 CDR references manufacture in unknown forms (CBI withheld). Though solid contact and dust inhalation exposure may be minimal, EPA plans to consider all relevant exposures shown in Appendix F. If it is determined that any exposure is negligible, such results will be explained in the risk evaluations.

Comment: One commenter (EPA-HQ-OPPT-2018-0435-0032, EPA-HQ-OPPT-2018-0436-0028) indicated that EPA must consider oral exposures to workers and ONUs. The commenter added that considering oral exposure resulting from inhaling dust and particulates is an important first step, but TSCA requires EPA to consider all known or reasonably foreseen exposure pathways for all relevant conditions of use.

Response: For certain conditions of use, EPA plans to consider inhalation exposure to dust/particulates for workers and ONUs. As inhalation exposure to dust/particulates may occur, EPA plans to consider potential exposure for particulates that deposit in the upper respiratory tract from inhalation exposure and may be ingested via the oral route.

Comment: One commenter (EPA-HQ-OPPT-2018-0435-0032, EPA-HQ-OPPT-2018-0436-0028) indicated EPA must consider dermal and inhalation exposures to ONUs through their contacts with liquids, solids, and vapors during manufacturing, import, processing, and disposal. Another commenter (EPA-HQ-OPPT-2018-0435-0028, EPA-HQ-OPPT-2018-0436-0025) mentioned that EPA cannot exclude exposures to ONUs via the dermal route from its risk evaluations.

Response: ONUs are defined as workers who do not directly handle the chemical, but perform work in an area where the chemical is present. Where information is reasonably available, EPA may provide a more granular analysis of exposure by specific work activities. While EPA typically assumes ONUs perform work in the far-field when modeling exposure, EPA may model specific work activity patterns on a case-by-case basis. As mentioned in Section 2.3.5 and in Appendix F of the scope documents, EPA plans to analyze inhalation of mist, dust, and vapor for workers and ONUs, as well as dermal exposure for workers and ONUs to mists and dust that deposit on surfaces.

Comment: One commenter (EPA-HQ-OPPT-2018-0435-0028, EPA-HQ-OPPT-2018-0436-0025) stated that EPA discounts the risk to workers by assuming that workers will use personal protective equipment (PPE) and that the PPE will protect against DIDP and DINP exposure. Furthermore, the same commenter stated that EPA must consider whether DIDP and DINP present an unreasonable risk to exposed workers without preemptively discounting that risk by assuming the use and effectiveness of PPE. Another commenter (EPA-HQ-OPPT-2018-0435-0032, EPA-HQ-OPPT-2018-0436-0028) stated that EPA must not assume the use of PPE at the risk evaluation stage and urged EPA to make appropriate, realistic assumptions regarding exposure, particularly with regard to PPE usage by workers. The same commenter continued by stating that EPA would be conflating risk evaluation and risk management in violation of TSCA.

Response: The Agency appreciates this feedback regarding consideration of worker protection practices, such as the use of PPE. EPA agrees with the commenters and plans to no longer make risk determinations based on assumptions about the use of PPE or other control technologies. However, EPA plans to develop exposure scenarios with and without the use of PPE or other control technologies to inform any potential risk management required subsequent to an unreasonable risk determination for workers. In the risk evaluation, EPA plans to examine the effects of engineering controls and PPE on occupational exposures to support any potential risk management in the event of an unreasonable risk determination. OSHA recommends employers utilize the hierarchy of controls to address hazardous exposures in the workplace. The hierarchy of controls strategy outlines, in descending order of priority, the use of elimination, substitution, engineering controls, administrative controls, and lastly PPE. EPA plans to identify the engineering controls and PPE relevant to occupational exposure scenarios based on reasonably available information on control technology and effectiveness. Furthermore, to better inform any potential risk management, EPA plans to assess in the risk evaluation worker exposure pre- and post-implementation of engineering controls (e.g., local exhaust ventilation) and with and without the use of PPE (e.g., respirator).

Comment: One commenter (EPA-HQ-OPPT-2018-0435-0030, EPA-HQ-OPPT-2018-0436-0027) stated that the sections on recycling need to be modified because these chemicals, once processed into PVC compound (as dry blend, pellet, or plastisol) or final article, cannot be recovered as a pure substance from the process/article and recycled. The commenter noted that compounded PVC resin and final articles containing these chemicals can be recovered and reused.

Response: EPA agrees that final articles containing PVC resin, including post- and pre-consumer resin, are recycled. Appendix E.1.2.5 (Recycling) in the DIDP and DINP scope documents has been revised to include recycling of PVC resins containing DIDP and DINP.

Comment: One commenter (EPA-HQ-OPPT-2018-0436-0027) mentioned that 3M™ Weatherban™ Acrylic Sealant 606-NF is an adhesive sealant, pointing out that the Agency lists 3M™ Weatherban™ Acrylic Sealant 606-NF White in the "Other Uses" category. The commenter recommended that the product should instead be grouped in the section titled "E.1.3.3 Adhesives, Sealants, Paints, and Coatings."

Response: The industrial use of this product has been moved from "E.1.3.5 Other Uses" to "E.1.3.3 Adhesives, Sealants, Paints, and Coatings."

Comment: One commenter (EPA-HQ-OPPT-2018-0436-0027) mentioned that exposure to DINP from mist associated with "adhesives and sealants; paints and coatings; cleaning and furniture care products;

solvents for cleaning or degreasing" is unlikely, as the referenced cleaning solvent for lithographic presses (Gans Deep Klene) is a thick viscous cream. The commenter suggested that the only possible exposure to DINP through this product is dermal contact.

Response: Although exposure to DINP from mists generated during application of adhesives and sealants may be minimal, EPA plans to consider all relevant exposures shown in Appendix F. If it is determined that the exposure is negligible, such results will be explained in the risk evaluation.

Human Hazard

Comment: One commenter (EPA-HQ-OPPT-2018-0436-0024) stated that, "it is important that the EPA broaden their study on this chemical and amend their draft use report, specifically regarding consumer products, because DINP in unsafe concentrations can lead to abnormalities in fetal development and potentially the creation of cancerous tumors, according to the Vermont Department of Health. California has also designated DINP as a carcinogen on California's Proposition 65 list, according to the Vermont Department of Health. If DINP is found to be present in consumer products in unsafe concentrations, DINP presents a significant concern in regards to child development and cancerous development, which warrants a more extensive review of the chemical and its uses, with as few as possible listed unknown data slots."

Response: EPA thanks the commenter for this information. Following data evaluation, EPA will organize, extract, and synthesize the evidence for DINP, and provide a basis for conclusions, including any conclusions regarding effects on fetal development and carcinogenicity. The California EPA report titled "Evidence of the Carcinogenicity of diisononyl Phthalate (DINP)" is included in the "OPPT Evidence Map for Di-isononyl phthalate" (Tomar et al., 2013) and will be considered by EPA when the evidence for the carcinogenicity of DINP is synthesized as described in a draft systematic review protocol to be released later this year.

Risk Determination

Comment: One commenter (EPA-HQ-OPPT-2018-0435-0031) stated that Consumer Product Safety Commission (CPSC's) conclusions (2014, p. 104–105) provide an appropriate level of confidence that DIDP poses no unreasonable developmental toxicity risk to humans, including susceptible populations such as children, through the use of toys.

Response: EPA has already identified the CHAP 2014 reference in the OPPT Evidence Map for DIDP (CHAP, 2014). This reference will undergo consideration in the systematic review process for DIDP (as described in a draft systematic review protocol to be released later this year) to inform the risk determination for the condition of use of DIDP in toys.

Information Considered

Comment: One commenter (EPA-HQ-OPPT-2018-0435-0030, EPA-HQ-OPPT-2018-0436-0027) noted that use of modeled, analogue, and read-across data is only appropriate when experimental data is not available for a critical endpoint. The commenter further noted that a tremendous amount of experimental data is available for DINP and DIDP, which is further demonstrated by the Agency's own literature review.

Comment: A commenter (EPA-HQ-OPPT-2018-0435-0032, EPA-HQ-OPPT-2018-0436-0028) stated: "EPA must first consider all information reasonably available to it, including information that can reasonably be generated, before relying on surrogate data or exposure models to fill data gaps. Surrogate

data and models should only be used if EPA lack the ability to reasonably obtain or generate information about DIDP and DINP themselves."

Response: As part of the risk evaluation process, EPA may identify additional data through systematic review and will evaluate all reasonably available information. EPA prefers to use experimentally measured data when it is reasonably available and when it meets the criteria of EPA's systematic review process as described in a draft systematic review protocol to be released later this year. When experimental data are not reasonably available, do not meet the Agency's systematic review criteria, and/or there are data needs that limit EPA's ability to thoroughly evaluate the chemical, EPA plans to look at modeled, analogue, surrogate, or read-across data to try to estimate the potential risk of that chemical.

Data Gathering

Comment: One commenter (EPA-HQ-OPPT-2018-0435-0028; EPA-HQ-OPPT-2018-0436-0025) stated that, "to the extent EPA is missing information relevant to the DINP or DIDP risk evaluations, it must use all statutory tools at its disposal to generate or obtain relevant data to inform those risk evaluations." The commenter stated that EPA failed to do so and relies instead on surrogate data and proxy models and that this action violates its directive under TSCA to consider all reasonably available information. The commenter stated TRI is among the statutes' tools available to EPA to obtain missing information, including release data related to DINP and DIDP, and that DIDP and DINP meet the statutory criteria for listing under TRI. The commenter urged EPA to list phthalate esters as a category on the TRI. The same commenter stated that establishment of a robust profile of the potential for environmental impacts should be pursued through the Agency's use of its enhanced testing authorities under section 4 of the "new" TSCA.

Comment: Another commenter (EPA-HQ-OPPT-2018-0435-0032, EPA-HQ-OPPT-2018-0436-0028) indicated that EPA will not be able to identify the most exposed communities without data showing which communities are exposed and recommended listing DINP and DIDP on the TRI. Additionally, the commenter stated that by listing phthalates on the TRI, the Administrator must consider the cumulative effect of exposure to multiple phthalates and exercise discretion to impose a reduced reporting threshold for phthalate esters as a category or for DINP and DIDP.

Response: Under 40 CFR 702.37(b)(4), the manufacturer requests for risk evaluation must include, "a list of all the existing information that is relevant to whether the chemical substance, under the circumstances identified by the manufacturer(s), presents an unreasonable risk of injury to health or the environment. The list must be accompanied by an explanation as to why such information is adequate to permit EPA to complete a risk evaluation addressing the circumstances identified by the manufacturer(s)." For risk evaluations requested by manufacturer(s), EPA determines if the data in the submission is sufficient to conduct the risk evaluation. In some cases, when information available to EPA is limited, the Agency will rely on models, the use of modeled data is in line with EPA's final Risk Evaluation Rule, and EPA's risk assessment guidelines.

Amending the TRI database is beyond the scope of the risk evaluations for DIDP/DINP. The TRI program was authorized by section 313 of the 1986 Emergency Planning and Community Right-to-know Act (EPCRA). Any additions or removals of chemicals on the TRI would occur pursuant to EPCRA section 313 and its associated regulatory authority. Additionally, while EPA may decide to add DINP, DIDP, and/or other phthalates to the list of chemicals subject to reporting under TRI, the notice-and-comment process necessary to do so would not result in additional relevant information being made

available to EPA within the timeframe of this action. EPA intends to complete these risk evaluations before any such data from TRI reports could reasonably be made available to the Agency.

Comment: A commenter (EPA-HQ-OPPT-2018-0435-0029; EPA-HQ-OPPT-2018-0436-0026) stated that both the DIDP and DINP requests are missing sources the commenter would consider relevant to the two risk evaluations, including: NRC (2008) "Phthalates and Cumulative Risk Assessment: The Task Ahead" (http://www.nap.edu/catalog/12528.html) and UNEP/WHO (2012) "State of the science of Endocrine Disrupting Chemicals," an assessment of the state of the science of endocrine disruptors prepared by a group of experts for the United Nations Environment Programme (UNEP) and WHO" (https://www.who.int/ceh/publications/endocrine/en/).

Response: EPA thanks the commenter for this information. Both NRC (2008) "Phthalates and Cumulative Risk Assessment: The Task Ahead" (NRC, 2008) and UNEP/WHO (2012) "State of the science of Endocrine Disrupting Chemicals (UNEP/WHO, 2013) are now included in the OPPT Evidence Maps for DIDP and DINP. Both references will be incorporated into the systematic review process as described in a draft systematic review protocol to be released later this year.

Systematic Review

Comment: A commenter (EPA-HQ-OPPT-2018-0435-0030, EPA-HQ-OPPT-2018-0436-0027) stated that methodologies to estimate daily intake from biomonitoring data exist. The commenter references the exposure section of the Hazard PECO statement in Table_Apx A-3 (Hazards Title and Abstract and Full-text PECO Criteria for DINP), noting "[w]hereas field studies (*e.g.*, biomonitoring) where there is no prescribed exposure dose(s) will be excluded if there is no evaluated hazardous effect, and tagged as supplemental field, if there is an evaluated hazardous effect." The commenter stated there are methodologies in the peer-reviewed literature to calculate the daily intake dose using biomonitoring data and further asserted that, although studies which describe biomonitoring data without evaluation of a hazard may be of limited use in developing a dose response function, they provide valuable information on total daily exposure. The commenter requested that these studies should be marked as "supplemental" rather than be excluded.

Response: Per the Hazards title and abstract PECO criteria outlined in Table_Apx A-3 (Hazards Title and Abstract and Full-Text PECO Criteria for DINP) for DINP, EPA acknowledges that biomonitoring studies that do not evaluate a hazard endpoint will be excluded for hazard consideration. These studies are, however, included in the systematic review process through the Population element of the PECO statement for Exposure data on the general population, consumers, and environmental receptors (see Table_Apx A-5). It is current practice to include studies with biomonitoring data for exposure assessment.

Regulatory Nexus

Comment: A commenter (EPA-HQ-OPPT-2018-0435-0028, EPA-HQ-OPPT-2018-0436-0025) cited TSCA section 9(b)(1) and 15 U.S.C. § 2608(b)(1) to state that EPA must complete the risk evaluation and make risk findings before coordinating action under other EPA-administered statutes. The same commenter further stated that, although regulations through other EPA programs may reduce exposure potential from a particular pathway, EPA can only eliminate unreasonable risk to human health and the environment by cumulatively assessing all known exposure pathways, including those that may be addressed by other EPA programs. The commenter urged EPA to revise the DIDP and DINP scopes to include exposures and certain release of those chemicals that other EPA-administered statues may address.

Comment: A commenter (EPA-HQ-OPPT-2018-0435-0028; EPA-HQ-OPPT-2018-0436-0025) requested EPA to recognize that there "may be releases of DIDP and DINP from industrial sites to wastewater treatment plants, surface water, air and landfills" as well as "during use or through recycling and disposal." The commenter expressed concern that the draft scopes for DIDP and DINP indicated that certain exposure pathways ("air emissions via inhalation as well as from surface water, drinking water, liquid, and solid waste releases; orally via drinking water, fish and soil ingestion; and dermally from contact with groundwater and soil") for the general population would be excluded in the DIDP and DINP risk evaluations and that excluded pathways can result in serious health risks.

Response: In the case of DIDP and DINP, specifically, all pathways indicated in the Conceptual Model for Environmental Releases and Wastes: Environmental and General Population Exposures and Hazards are included as exposure pathways. EPA does not plan to exclude these pathways due to overlap with other EPA-administered statues or regulatory programs or other EPA-administered laws.

Conditions of Use

Classification of Conditions of Use

Comment: One commenter (EPA-HQ-OPPT-2018-0436-0029) encouraged EPA to use the CPSC terminology for "plasticized toys" to refer to these regulated products.

Response: EPA believes that "plasticized toys" are accounted for by the "Toys, playground, and sporting equipment" subcategory of use, consistent with EPA's "Instructions for Reporting 2016 TSCA Chemical Data Reporting."

Comment: One commenter (EPA-HQ-OPPT-2018-0435-0031; EPA-HQ-OPPT-2018-0436-0029) asked EPA to keep all toys in scope, but narrow the focus of its evaluation to plasticized toys and recognize that the other types of plastics used in toys do not use phthalates. The same commenter said children's toys should be evaluated separately from playground equipment and sporting equipment, as well as from adult (sex and other) toys. This commenter also said EPA should consider classifying certain mouthable products as a "childcare article" rather than as a toy. This commenter further asked that EPA recognize children's toys as a stand-alone category "due to the federal regulations that are already in place for all children's toys in the case of DINP and state and international regulations in place for mouthable children's toys in the case of DIDP."

Response: EPA believes that "plasticized toys" are accounted for by the "Toys, playground, and sporting equipment" subcategory of use, consistent with EPA's "Instructions for Reporting 2016 TSCA Chemical Data Reporting" that defines the toy/playground/sporting equipment subcategory as "Chemical substances contained in toys, playground, and sporting equipment made of wood, metal, plastic or fabric that are intended for consumer or commercial use should be reported under this code. Examples of products include toys (dolls, cars, puzzles, and games), playground equipment (gym sets, playhouses and structures, swing sets) and sporting equipment (bicycles, skates, balls, team sports equipment) intended for indoor or outdoor use, and playground surfaces (rubber, mulch)." EPA recognizes that not all types of toys contain phthalates.

These CDR instructions call out one particular mouthable product (pacifiers) separately in "Plastic and rubber products not covered elsewhere" with the subcategory definition, "Chemical substances contained in rubber and plastic products not covered elsewhere that are intended for consumer or commercial use should be reported under this code. Examples of plastic and rubber products not

covered elsewhere include tires, shower curtains, non-metal cookware (non-electric), non-food specific containers (bags, bottles, and jars), rubber bands, and waders." EPA plans to evaluate adult toys under the "rubber and plastic products not covered elsewhere" subcategory.

Recommended Conditions of Use or Significant Changes in Conditions of Use

Comment: One commenter (EPA-HQ-OPPT-2018-0435-0030; EPA-HQ-OPPT-2018-0436-0027) stated that DINP/DIDP are not sold for uses beyond industrial processing; therefore, it is not expected to be repackaged into smaller containers and this activity should be covered under distribution as a life cycle stage.

Response: In our outreach on conditions of use, EPA received confirmation (EPA-HQ-OPPT-2018-0504-0019) that repackaging takes place for DIDP and DINP and therefore this condition of use will remain in scope.

Comment: One commenter (EPA-HQ-OPPT-2018-0435-0030) stated that the primary use activity of DIDP characterized by EPA as, "processing aid specific to petroleum production for processing (incorporation into formulation, mixture, or reaction product) in oil and gas drilling, extraction and support activities," should instead be characterized as "lubricant."

Response: Manufacturers (including importers) are required by the CDR rule to report to EPA information concerning the manufacturing, processing, and use of certain chemical substances listed on the TSCA Chemical Substance Inventory. DIDP was reported in 2012 and 2016 CDR as a "processing aid specific to petroleum production for processing (incorporation into formulation, mixture, or reaction product) in oil and gas drilling, extraction and support activities." EPA considers uses reported in 2012 and 2016 CDR for DIDP as reasonably foreseen conditions of use for DIDP and therefore this condition of use will remain in scope.

Comment: One commenter (EPA-HQ-OPPT-2018-0435-0030) stated that DINP is not used in personal care products and is not listed in the Personal Care Products Council's Cosmetic Ingredients Database. The commenter states that this use is not appropriate for DINP and should be removed.

Response: EPA made multiple attempts but was unable to reach the entity who reported "personal care products" to CDR for additional information. Many "personal care products" meet the definition of cosmetics under section 201 of the Federal Food, Drug and Cosmetics Act, 21 U.S.C. § 321 and these uses are excluded from the definition of "chemical substance" in TSCA section 3(2)(B)(vi). Since EPA was unable to confirm this is a TSCA condition of use for DINP, "personal care products" has been removed from Table 2-2.

Comment: One commenter (EPA-HQ-OPPT-2018-0435-0030) stated that the manufacturers are not aware of any known use of DINP as a fragrance.

Response: EPA's methods for confirming conditions of use included searches in databases; review of safety data sheets (SDS); and outreach with industry, states, and trade associations. Multiple SDS were located listing DINP as a fragrance ingredient and therefore this condition of use is in scope.

Comment: One commenter (EPA-HQ-OPPT-2018-0435-0030) stated that DINP is not used in petroleum refineries.

Response: Manufacturers (including importers) are required by the CDR rule to report to EPA information concerning the manufacturing, processing, and use of certain chemical substances listed on the TSCA Chemical Substance Inventory. DINP was reported in 2012 and 2016 CDR as being used in petroleum refineries, which is considered a reasonably foreseen condition of use for DINP. Therefore, this condition of use will remain in scope.

Comment: A commenter (EPA-HQ-OPPT-2018-0436-0028) identified 66 uses for DINP that they believed were not included in the draft scope document. Specifically, the commenter requested that EPA include use as: steering wheel cover, truck tarpaulins, undercoatings (automotive), door gaskets (building materials), fire-rated mastic, gypsum board, paint rollers, pool liners, profiles, putty, PVC siding capstock, roller window shades, roofing membranes, tarp, threshholds, epoxy terrazzo flooring membrane, vinyl floor runner, vinyl sheet flooring, vinyl siding capstock, vinyl-backed carpet, mixed metal stabilizer (chemical processing), baby furniture, breast feeding pillows, car seats, children's costumes, inflatable toy, jewelry, children's, pencil case, play yards, sling carriers, strollers and carriages, teether, walkers, air fresheners, artificial turf infill/rubber, blanket storage bags, cooling liquids in refrigerators, exercise balls, fragrance, headsets, needleworking supplies, oil-based electric heaters, shower curtains, table cloths, technical foil, traffic cones, fiber optics, transmission cable insulation, conveyor belts, cow milking equipment (inflations), lid gaskets, nutritional supplements, tequila, vinyl gloves (foodservice), outdoor furniture fabric, polyurethane coated fabric, disposable gloves (medical), cosmetics, personal care products, perfume, soap packaging, ultra high molecular weight polyethylene, recycled vinyl additive, artificial/synthetic leather, handbags/ luggage, and wastewater treatment programs.

Response: EPA thanks the commenters for the information provided. EPA has reviewed the use information provided. EPA believes most of the uses identified are adequately accounted for by the current subcategories of use, as defined in "Instructions for Reporting 2016 TSCA Chemical Data Reporting." Other uses (conveyor belts, cow milking equipment [inflations], lid gaskets, nutritional supplements, tequila, cosmetics, and perfume) meet the definition of food, food contact substances, or cosmetics under section 201 of the Federal Food, Drug and Cosmetics Act, 21 U.S.C. § 321. These uses are excluded from the definition of "chemical substance" in TSCA section 3(2)(B)(vi) and are not included in Table 2-2 of the DINP scope. EPA conducted further research to determine if the additional conditions of use should be added to the scope documents. EPA's methods for confirming conditions of use included searches in databases; review of SDS; and outreach with industry, states, and trade associations. EPA has added use subcategories for "Processing aids not otherwise listed (e.g., mixed metal stabilizer)," "Foam seating and bedding products," and "Air care products" to the final scope for DINP. EPA has not confirmed the use of DINP in "Cooling liquids in refrigerators" or "Oil-based electric heaters." EPA will require additional information on these specific uses for DINP to better assess whether they are adequately incorporated by the existing categories of use or require separate categorization of use.

Comment: One commenter (EPA-HQ-OPPT-2018-0436-0028) provided the names of 33 additional DINP companies and identified approximately 390.9 million pounds of DINP that were imported between 2015–2020 using Datamyne.

Response: The Agency's risk evaluation process relies on volumes of manufacture (including importation) that are reported to the Agency through CDR. CDR data represent actual recent volumes. While the EPA considers Datamyne information, it also is known to contain inaccuracies. For example, Datamyne may incorrectly assume that net container weights are evenly distributed among products.

User errors in searches can also lead to additional volumes being attributed inaccurately. CDR is therefore the data source used consistently across TSCA risk evaluation.

Toys as Condition of Use

1) A commenter (EPA-HQ-OPPT-2018-0435-0031 and EPA-HQ-OPPT-2018-0436-0029) asserts that CPSC's limit of 0.1% DINP in plasticized toys represents negligible exposure to consumers, workers, and the environment; therefore, EPA should either: make an early finding of no unreasonable risk; refrain from consideration of toys entirely in the risk evaluation; or limit its consideration to that allowed by federal and/or state law and current industry practices (0.1%).

Comment: The commenter (EPA-HQ-OPPT-2018-0435-0031 and EPA-HQ-OPPT-2018-0436-0029) noted that CPSC set a regulatory limit of 0.1% of DINP and DIDP in children's toys (Consumer Product Safety Act Improvement of 2008 [CPSIA]). The Commenter stated that "EPA should use the best available data, recommendations, and regulations issued by the CPSC, based on findings of a Chronic Hazards Advisory Panel (CHAP), as guideposts for the evaluation of consumer exposure to these chemicals. The regulation of these chemicals by California and the EU also should inform EPA's evaluation of these chemicals in toys." In addition to consumer exposures, this commenter asserted that EPA's occupational exposure scenarios must be guided by the requirement that the plasticized or flexible plastics their companies purchase can include no more than 0.1% by weight of these chemicals based on federal and state law. Finally, the commenter asserted that these limits result in *de minimis* contaminants to the environment, so that plasticized toys make no material contribution to environmental exposure and risk.

The commenter asked that EPA consider the merits of relying on CPSC's preemptive limit of 0.1% and either: (1) exclude review of consumer exposure to DINP in children's toys from the scope of the risk evaluation entirely because it is duplicative of CPSC's federal limit of 0.1% and state preemption that is already established under the CPSA; (2) make an early determination of no unreasonable risk for consumer exposure to DINP in plasticized toys because the "scarce presence of DINP and DIDP, if any, in plasticized toys does not pose unreasonable risks to the public, susceptible subpopulations, or the environment"; or (3) refrain from evaluating levels in children's toys that are higher than this amount (0.1%), since such levels are unlawful. Regarding this last point, although the 0.1% limit for DIDP was subsequently lifted (CHAP, 2014), the commenter notes that, "if DIDP were used in manufacturing plasticized toys, they would need to be compliant with California law at a minimum, and typically the EU regulations are also a factor. Therefore, we ask EPA to recognize that these products are not reasonably expected to contain DIDP in concentrations over 0.1%, that the potential for consumer exposure to DIDP via mouthable, plasticized toys has been extensively reviewed, and that DIDP in toys is already heavily regulated by other agencies."

Comment: Another Commenter (EPA-HQ-OPPT-2018-0436-0027) similarly pointed out that DINP is not used in toys and childcare products and specifically directed EPA to Table B-1, in which "the Agency identifies use of DINP in baby products based on reported presence in nursing pillows by a 2008 Danish Environmental Protection Agency (EPA) report. The Agency notes that 'it is unknown whether this is an ongoing use in the United States.' In the United States, DINP is not permitted for use in all children's toys and childcare articles at concentrations greater than 0.1% by Federal Law, effective April 25, 2018. Hence, as noted by the Agency, this use is historical and does not reflect existing use for DINP."

Response: As relates to DINP and DIDP, section 108 of CPSIA placed an interim prohibition on the manufacture for sale, offer for sale, distribution in commerce, or importation of numerous phthalates, including DINP and DIDP, in toys and childcare articles at concentrations greater than 0.1 percent. 15 U.S.C. 2057c(b)(1). The CSPC interim prohibition on the manufacture for sale, offer for sale, distribution in commerce, or importation of DINP in children's toys and childcare articles became permanent in 2017. See 82 FR 49982 (October 27, 2017). The prohibition was expanded to prohibit all children's toys (not just those that can be placed in a child's mouth) and childcare articles that contain concentrations of more than 0.1 percent of DINP. 16 CFR Part 1307 (October 27, 2017). However, the interim prohibition on the manufacture for sale, offer for sale, distribution in commerce, or importation of DIDP in children's toys was lifted in the final rule. 16 CFR Part 1307 (October 27, 2017). Use and disposal of the toys presently in the market are conditions of use, as they are known, intended, and reasonably foreseen actions. Manufacture, processing, and distribution are not known, intended, or reasonably foreseen uses of DINP as they are banned by the CPSC. However, evaluation of children's toys was specifically requested as a condition of use by the American Chemistry Council's High Phthalates Panel in their requests for risk evaluations of DIDP and DINP. Therefore, use and disposal of toys will remain in scope for DINP. Manufacture, processing, distribution, use, and disposal of toys will remain in scope for DIDP.

2) The manufacturer request process requires submitters to list the circumstances for which they are requesting that EPA conduct a risk evaluation, and why they represent COUs. American Chemistry Council's High Phthalates Panel submitted their requests on behalf of the manufacturers on May 24, 2019, specifically requesting DINP and DIDP use in toys be evaluated.

Comment: One commenter (EPA-HQ-OPPT-2018-0435-0029, EPA-HQ-OPPT-2018-0436-0026) stated that, "EPA generally narrows the scope of the TSCA risk evaluation to exclude situations it says are better dealt with under other laws and regulatory schemes. But, in this case, it retains review of PVC for children's toys and childcare articles as a COU, even though CPSC has already conducted assessments and made regulatory decisions on this use. Why?" Additionally, another commenter (EPA-HQ-OPPT-2018-0436-0029) stated as one alternative that the commenter supports an "EPA finding that consumer exposure to DINP via plasticized toys is a condition of use that does not need to be included in the scope of the TSCA risk evaluation for DINP, because federal preemption already is established through the CPSA."

Response: When EPA receives a manufacturer request for a risk evaluation, the Agency starts its review process, which is laid out in 40 CFR 702.37. First, EPA makes a determination as to whether the request is facially complete (whether the request appears to meet the requirements laid out in 40 CFR 702.37(b)-(d)) and notifies the public within 15 days of receipt of a facially complete request. The Agency then assesses, and makes a preliminary determination, as to whether the circumstances identified constitute COUs under 40 CFR 702.33, and whether the COUs warrant inclusion in the risk evaluation for the chemical substance or category of chemical substances. At this time, EPA assesses what additional COUs warrant inclusion in the scope of the risk evaluation. Within 60 business days of receiving a facially complete request EPA opens a docket, providing a 45-day public comment period. During this comment period the public may submit comments and information related to the requested risk evaluation. Commenters are encouraged at that time to identify any information that was not included, or comment on the COUs requested by the requesting manufacturer(s) or identified by EPA. Within 60 days of the end of the comment period EPA reviews the request and determines whether it meets the criteria and requirements in 40 CFR 702.37. EPA may not grant a request unless it determines that the circumstances identified in the request constitute conditions of use for the chemical

substance. EPA granted the manufacturer requests for DINP and DIDP on December 2, 2019. Under 40 CFR 702.37(b)(3), the manufacturer requests for risk evaluation must identify, "the circumstances on which they are requesting that EPA conduct a risk evaluation and include a rationale for why these circumstances constitute conditions of use under § 702.33." Children's toys were specifically requested as a COU (EPA-HQ-OPPT-2018-0435-0005, EPA-HQ-OPPT-2018-0436-0004) and are therefore included in the scopes of these risk evaluation.

As relates to DINP and DIDP, the manufacturer requests for risk evaluations asserted that their use in toys constitutes COUs under TSCA. Section 108 of CPSIA placed an interim prohibition on the manufacture for sale, offer for sale, distribution in commerce, or importation of numerous phthalates, including DINP and DIDP, in toys and childcare articles at concentrations greater than 0.1 percent. 15 U.S.C. 2057c(b)(1). The CSPC interim prohibition on the manufacture for sale, offer for sale, distribution in commerce, or importation of DINP in children's toys and childcare articles became permanent in 2017. See 82 FR 49982 (October 27, 2017). The prohibition was expanded to prohibit all children's toys (not just those that can be placed in a child's mouth) and childcare articles that contain concentrations of more than 0.1 percent of DINP under 16 CFR Part 1307 (October 27, 2017). However, the interim prohibition on the manufacture for sale, offer for sale, distribution in commerce, or importation of DIDP in childrens toys was lifted in the final rule, 16 CFR Part 1307 (October 27, 2017). As mentioned above, children's toys were requested by the manufacturer as a COU in the risk evaluations of DIDP and DINP (EPA-HQ-OPPT-2018-0435-0005, EPA-HQ-OPPT-2018-0436-0004) and are included in the scopes of these risk evaluations.

Non-TSCA Uses

Comment: One commenter (EPA-HQ-OPPT-2018-0435-0030) stated that DINP has narrow use in food additives and related products. TSCA section 3(2) defines "chemical substance" to exclude certain uses/products, including any food, food additive, drug, cosmetic, or device (as defined in section 201 of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 321) when manufactured, processed, or distributed in commerce for use as a food, food additive, drug, cosmetic, or device. Activities and releases associated with such uses/products are therefore not "conditions of use" (defined in TSCA section 3(4) to refer to circumstances associated with a "chemical substance") and EPA does not plan to evaluate them during risk evaluation.

Response: EPA did not list food additives and related products as a reasonably foreseen condition of use for DINP.

Comment: One commenter (EPA-HQ-OPPT-2018-0435-0032; EPA-HQ-OPPT-2018-0436-0028) stated that EPA must consider background exposures to phthalates from "non-TSCA uses" in the general population, including exposures from plastic food packaging materials. The commenter stated that EPA's plan to exclude from consideration uses of DINP and DIDP subject to statutes such as the Federal Food Drug and Cosmetics Act ignores the reality of human exposure and violates TSCA. The commenter further stated that failure to account for these non-TSCA background sources of exposure to DINP and DIDP will result in final risk evaluations that vastly underestimate risk for the conditions use being assessed and will therefore fail to protect human health.

Response: As described in the preamble to the Risk Evaluation Rule (See Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act, 33726 Fed. Reg. 33735 (July 20, 2017), EPA may consider potential risk from non-TSCA uses in evaluating whether a chemical substance presents an unreasonable risk. Although EPA would not regulate non-TSCA uses, the potential

exposures of non-TSCA uses may help inform the Agency's risk determination for the exposures from uses that are covered under TSCA (e.g., as background exposures that would be accounted for, should EPA decide to evaluate aggregate exposures).

Federal Preemption

Comment: Commenter EPA-HQ-OPPT-2018-0435-0031 and EPA-HQ-OPPT-2018-0436-0029 requested EPA to recognize "that there is sufficient information with which to conclude that the conditions of use associated with toys presents no unreasonable risks based on the current restrictions and prior evaluations of these chemicals." The commenter further requested that EPA make a determination based on the following language the commenter quoted from 82 FR at 33729 "at any point after EPA has issued its final scope document, in cases where EPA has sufficient information to determine whether or not the chemical substance presents an unreasonable risk under particular conditions of use, the agency may issue an early determination for that subset of conditions of use." The commenter requested that EPA apply preemptive pause on a determination of no unreasonable risk for DINP and DIDP in toys upon public release of the final scoping documents.

Response: Pause preemption is not triggered for manufacturer-requested risk evaluations that are granted. See TSCA section 6(b)(4)(E)(iv)(I). The scope of pause preemption is addressed in TSCA section 18(c). A variety of exemptions and waivers could affect preemption. Additionally, EPA is evaluating the conditions of use related to toys concurrently with other conditions of use outlined in the final scoping documents. EPA does not intend to make an early determination of no unreasonable risk for any of the conditions of use outlined in the final scoping documents.

Submitted Data and Information

Hazard and Exposure Potential

Comment: One commenter (EPA-HQ-OPPT-2018-0436-0027) informed EPA of Health Canada's 2015 supplemental report for DINP titled "Supporting documentation: Carcinogenicity of phthalates – common MOA by tumor types," which is only available upon request and details Health Canada's conclusions regarding mode of action and human relevance for DINP-induced rodent tumors.

Response: EPA thanks the commenter for the information provided. The reference (HERO ID 7303384) has been added to the OPPT Evidence Map for DINP.

Other Information

Comment: One commenter (EPA-HQ-OPPT-2018-0436-0027) stated that the Classification and Labeling (C&L) Inventory referred to in DINP Table_Apx D-3 is obsolete and is superseded by a harmonized classification and labeling consensus opinion, adopted on March 9, 2018, by the European Chemicals Agency Committee for Risk Assessment. The commenter points out that the new harmonized opinion concludes that "no classification for DINP for either effects on sexual function and fertility, or for developmental toxicity is warranted."

Response: EPA has removed the reference to the C&L Inventory from Table_Apx D-3 in the DINP final scoping document. We thank the commenters for the suggested reference "Opinion proposing harmonised classification and labelling at EU level of 1,2-Benzenedicarboxylic acid, di-C8-10-branched alkylesters, C9- rich; di-'isononyl' phthalate; (DINP)." EPA considers all reasonably available information for the risk evaluation of DINP. Through EPA's systematic review process (as described in a draft systematic review protocol to be released later this year), this reference has already been identified as a reference for consideration in the risk evaluation of DINP (ECHA, 2018).

Comment: One commenter (EPA-HQ-OPPT-2018-0436-0027) stated that ExxonMobil Chemical Company was not the sole manufacturer requesting the DINP risk evaluation and that the list of manufacturers requesting the risk evaluation can be found on the Agency's website.

Response: EPA appreciates this correction and has updated the DINP final scope document.

Comment: One commenter (EPA-HQ-OPPT-2018-0436-0027) pointed out that the Australian priority existing chemical (PEC) designation in DINP Table_Apx D-3 is obsolete and that the risk assessment was completed and published in September 2012. The commenter stated that Australia concluded that the risk assessment indicated "low risk of adverse effects on these organs, reproductive system and growth," and that as a result of the risk assessment, there is no restriction on the current use of DINP in toys, childcare articles and cosmetics in Australia.

Response: EPA has updated DINP Table_Apx D-3 to remove the reference to the PEC and include the assessment under Human Health Tier II of the Inventory Multi-Tiered Assessment and Prioritisation (IMAP).

Comment: Multiple commenters (EPA-HQ-OPPT-2018-0436-0024, EPA-HQ-OPPT-2018-0436-0027, EPA-HQ-OPPT-2018-0436-0028) recommended revisions to the draft use reports. One commenter (EPA-HQ-OPPT-2018-0436-0024) stated that, "it is important that the EPA broaden their study on this chemical and amend their draft use report, specifically regarding consumer products, because DINP in unsafe concentrations can lead to abnormalities in fetal development and potentially the creation of cancerous tumors, according to the Vermont Department of Health." The same commenter (EPA-HQ-OPPT-2018-0436-0024) also stated that, "Because the Draft Uses Report displays a significant amount of unknown data, evidenced by the lack of information provided in tables 2-4, B-1 and because DINP does present a significant risk of harm to human beings, it is necessary that the EPA do more research on the chemical in regards to the plastic products it is found in that are used by consumers, especially children, and the concentrations at which this chemical is deemed to be harmful."

Response: The draft use reports provide publicly available information on the manufacturing (including importing), processing, distribution in commerce, use, and disposal of DIDP and DINP. These documents were used to inform decisions regarding conditions of use and were posted in the dockets as supporting documents. These documents do not reflect information received directly from other sources such as manufacturers, processors, etc., which further informed the conditions of use in the draft scope documents. EPA solicited public comment on the draft scope documents for the risk evaluations, and revisions to the draft use reports are not being considered at this time.

Comment: One commenter (EPA-HQ-OPPT-2018-0436-0024) stated that it is necessary to more closely evaluate the risks associated with DINP in products that can be ingested and in plastics as they pertain to the production of children's toys and other consumer products. Since Table B-1 in the Draft Uses Report for DINP also lists the chemical or activity function as "unknown," the commenter indicated a need for EPA to obtain additional information in regard to the manufacturing necessity of this chemical in commercial and consumer products.

Response: The Tier 1 and Tier 2 tables in the chemical use reports are not determinative of conditions of use, but instead were intended to inform EPA's deliberations on whether certain activities are known, intended, or reasonably foreseen for each chemical. The tables are intended to capture, in broad

strokes, the evidence that may indicate whether activities are "circumstances, as determined by the Administrator, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of," per TSCA's definition of "conditions of use." This is consistent with the approach described in the Risk Evaluation Rule. EPA plans to consider toys (processing, commercial uses, consumer uses, and disposal) as a condition of use for DINP.

Comment: References for consideration in the risk evaluation of DIDP and DINP were provided by commenters (EPA-HQ-OPPT-2018-0435-0030; EPA-HQ-OPPT-2018-0436-0027; EPA-HQ-OPPT-2018-0435-0031; EPA-HQ-OPPT-2018-0436-0029; EPA-HQ-OPPT-2018-0435-0032; EPA-HQ-OPPT-2018-0436-0028; EPA-HQ-OPPT-2018-0435-0028; EPA-HQ-OPPT-2018-0436-0025). One commenter (EPA-HQ-OPPT-2018-0435-0032; EPA-HQ-OPPT-2018-0436-0028) stated "TSCA requires EPA to consider reasonably available information in the DINP and DIDP risk evaluations" and that EPA did not consider an array of data sources on DIDP and DINP. The commenter expressed concern that failing to consider these data sources would threaten the integrity of the risk evaluations for DIDP and DINP.

Response: EPA considers reasonably available information and uses the best available science to evaluate existing chemicals under TSCA, as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act. EPA thanks the commenter for providing these references, as all studies submitted via public comment will be considered for the draft risk evaluations of DIDP and DINP.

CHAP. (2014). Chronic Hazard Advisory Panel on phthalates and phthalate alternatives (with appendices). Bethesda, MD: U.S. Consumer Product Safety Commission, Directorate for Health Sciences. https://www.cpsc.gov/s3fs-public/CHAP-REPORT-With-Appendices.pdf.

ECHA. (2013). Evaluation of new scientific evidence concerning DINP and DIDP in relation to entry 52 of Annex XVII to REACH Regulation (EC) No 1907/2006. Helsinki, Finland. http://echa.europa.eu/documents/10162/31b4067e-de40-4044-93e8-9c9ff1960715.

ECHA. (2018). Committee for Risk Assessment (RAC). Opinion proposing harmonised classification and labelling at EU level of 1,2-Benzenedicarboxylic acid, di-C8-10-branched alkylesters, C9-rich; di-"isononyl" phthalate; (DINP). CLH-O-0000001412-86-201/F. https://echa.europa.eu/documents/10162/56980740-fcb6-6755-d7bb-bfe797c36ee7.

NRC. (2008). Phthalates and cumulative risk assessment: The task ahead. Washington, DC: National Academies Press. http://dx.doi.org/10.17226/12528.

Tomar, RS; Budroe, JD; Cendak, R. (2013). Evidence of the carcinogenicity of diisononyl phthalate (DINP). Sacramento, CA: California Environmental Protection Agency. https://oehha.ca.gov/media/downloads/proposition-65/chemicals/dinphid100413.pdf.

U.S. EPA. (2006). A framework for assessing health risk of environmental exposures to children (pp. 1-145). (EPA/600/R-05/093F). Washington, DC: U.S. Environmental Protection Agency, Office of Research and Development, National Center for Environmental Assessment. http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=158363.

U.S. EPA. (2012). Phthalates action plan. Washington, DC. https://www.epa.gov/sites/production/files/2015-09/documents/phthalates_actionplan_revised_2012-03-14.pdf.

UNEP/WHO. (2013). State of the science of endocrine disrupting chemicals - 2012. An assessment of the state of the science of endocrine disruptors prepared by a group of experts for the United Nations Environment Programme (UNEP) and WHO [Website]. Geneva, Switzerland: World Health Organization. http://www.who.int/ceh/publications/endocrine/en/.