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EPN COMMENTS ON DRAFT SCOPING DOCUMENTS OF THE RISK EVALUATIONS OF 20 CHEMICALS UNDER THE TOXIC SUBSTANCES CONTROL ACT (TSCA)

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EPN has reviewed the draft scoping documents for the next set of 20 High-Priority Substances. While the agency released these documents in two batches, with different but overlapping public comment periods, EPN determined it to be more efficient to evaluate them as a single package. The 20 chemicals are:

Batch 1: 1,3-Butadiene; o-Dichlorobenzene; p-Dichlorobenzene; 1,1-Dichloroethane; 1,2-Dichloroethane; *trans*-1,2-Dichloroethylene; 1,2-Dichloropropane; Ethylene dibromide; 1,3,4,6,7,8-Hexahydro-4,6,6,7,8, 8-hexamethylcyclopenta [g]-2-benzopyran (HHCB); 4,4'-(1-Methylethylidene)bis[2,6-dibromophenol] (TBBPA); Phosphoric acid, triphenyl ester (TPP); 1,1,2-Trichloroethane; and Tris (2-chloroethyl) phosphate (TCEP) and

Batch 2: Butyl benzyl phthalate (BBP), Dibutyl phthalate (DBP), Dicyclohexyl phthalate (DCHP), Diethylhexyl phthalate (DEHP), Di-isobutyl phthalate (DIBP), Formaldehyde, and Phthalic anhydride.

EPN first presents general comments, which pertain to all 20 scoping documents, and then provides comments unique to each of them, as appropriate. The general comments are organized by the key elements of the scoping document and outlined in (40 CFR 702.41(c)).

GENERAL COMMENTS

Conditions of Use and Conceptual Models

EPA has not identified whether legacy uses exist for any of these 20 chemicals, despite the fact that several of the chemicals have the potential for such uses. The Ninth Circuit has ordered EPA to consider legacy uses and disposal of legacy use chemicals in TSCA risk evaluations; thus, EPA must document in the scoping documents whether such uses exist for each chemical and must evaluate the risks of any legacy uses identified. Absent this step, the risk evaluations will be incomplete and non-compliant with the requirements of the Risk Evaluation Rule.

In the conceptual models, EPA has identified a number of exposure pathways that are regulated under other environmental statutes and is not committing to evaluating their risks. EPN has pointed out in comments on EPA's first set of 10 draft chemical risk evaluations that TSCA risk evaluations should not exclude incorporation of exposures via pathways that are or could be regulated under environmental statutes such as the Clean Air Act (CAA), Safe Drinking Water Act (SDWA), Clean Water Act (CWA), and Resource Conservation and Recovery Act (RCRA). TSCA risk evaluations should reflect and incorporate real-world circumstances. Standards and non-regulatory guidance established under these other programs may be years

out of date, may be technology-based rather than risk-based, and may not be complied with at all times or in all locations. These pathways add to the aggregate risk of workers and Occupational Non-users (ONUs), consumers and bystanders, and to the general population, including, for instance, more highly-exposed residents near the fence line of point sources. Furthermore, a comprehensive analysis of all pathways of exposure under TSCA may lead to recommendations that a drinking water standard or air standard should be promulgated or updated rather than that a restriction be placed on a chemical's use through an action under TSCA. Recommendations for action under another statute are an appropriate end result of a TSCA evaluation and are consistent with Section 9 of TSCA. Section 9 directs the Administrator "to coordinate actions taken under TSCA with actions taken under other federal laws administered by EPA, such as CAA and CWA. If risk is already managed effectively under a different statute, regulation under TSCA is not necessary." Section 9 specifies that TSCA evaluations are to include an assessment of these exposure scenarios so that a decision can be made on the need for action under the appropriate statute. No draft risk evaluation, to date, has provided satisfactory documentation that risks have been managed effectively under other statutes.

Potentially Exposed Populations and Ecological Receptors

In most cases related to the assessment of consumer and bystander exposures from consumer uses, EPA is proposing to assess the potential exposure to consumers by the inhalation and dermal routes and occasionally by the oral route, but only by the inhalation route for bystanders. We would argue that there are likely to be many instances in which the bystander is not simply positioned passively several feet away during the use activity, but is interacting much more actively—perhaps touching the treated article and then engaging in hand-to-mouth behavior. Given this likelihood, we would recommend that bystander exposure via dermal and oral routes be incorporated into the risk assessments.

None of the 20 scoping documents confirm whether or not adequate data exist on the impact of these chemicals on wildlife, even when the chemical is known to bioaccumulate in fish or where monitoring data exist, documenting its presence in air, ground and/or surface water, sediment, or soil. No ecological targets are identified, though both aquatic and terrestrial organisms are acknowledged as possible targets. If data are truly lacking, this is the time for the agency's enhanced testing authority to be exercised.

Reasonably Available Information & Scientific Approach

EPN is concerned that EPA continues to use the same flawed TSCA systematic review process for sorting, selecting, and integrating information for these 20 chemicals as it did for the first 10. EPN urges EPA to discontinue use of this TSCA process until it has been formally peer-reviewed and revised to follow accepted scientific principles. EPN is aware that the National Academies of Sciences (NAS) has begun its review of the draft guidance "Application of Systematic Review in TSCA Risk Evaluations." However, this review likely will not be completed before the studies have been selected for these 20 chemical risk evaluations.

Analysis Plan

EPN notes that none of the analysis plans for the 20 chemicals indicate whether EPA will use the unvetted policy of selecting the most "representative" study(ies) instead of the study(ies) with the most sensitive human health endpoint for hazard characterization. EPA employed this "representative study" concept for the first time in the draft trichloroethylene (TCE) risk evaluation. The factors for selecting a "representative" health endpoint do not include sensitivity and appear to be arbitrary and capricious, designed to provide the agency with complete discretion to ignore the most sensitive endpoint. There is no scientific justification for this new policy, which is at odds with longstanding agency-wide risk assessment practices. EPA should not use this representative policy for *any* chemical risk evaluations conducted under TSCA or any other statute.

Peer Review Plan

Assistant Administrator Dunn has expressed interest in eliminating the Science Advisory Committee on Chemicals (SACC) peer review of some or all of the draft chemical evaluations for the next 20 chemicals and others going forward. The agency must engage SACC in public review of the draft evaluations for this next set of chemicals as there are a number of process and substance issues that remain unresolved from the first ten draft chemical risk evaluations. If EPA agrees with EPN's recommendation to develop risk evaluations on groups of similar chemicals, SACC can function more efficiently as it will have fewer individual chemical review events to plan and execute. It is also imperative that SACC meetings be scheduled *after* the public comment periods have ended, rather than in the middle of them, so the expert peer reviewers have the full benefit of all the comments. Not all of the public commenters have the capacity or time to prepare substantive and thoughtful comments during the rushed pre-SACC meeting period. Unfortunately, EPA has previously scheduled SACC meetings on risk evaluations before the public comment period has closed for those evaluations. This is not acceptable and, actually, inconsistent with agency-wide peer review guidance.

COMMENTS ON INDIVIDUAL CHEMICALS

EPA should conduct cumulative assessments of similar chemicals. It is imperative that the agency clearly state whether or not there is known or anticipated exposure to more than one isomer or closely-related substance. The following criteria should be applied when determining when a cumulative assessment would be appropriate: 1) Concomitant exposure attendant to a category or subcategory of conditions of use; 2) Close structural similarities, that is, members of the same chemical class; 3) Shared metabolic pathways and byproducts of metabolism; 4) Similar toxicity profiles; and 5) Similar modes/mechanisms of action of shared toxicity endpoints.

Cumulative Assessment Candidates:

1) The two Dichlorobenzenes (o-DCB and p-DCB),
2) The two Dichloroethanes (1,1-DCE and 1,2-DCE).

In addition to the two isomers being assessed together in a cumulative assessment, they should also be assessed cumulatively, when having common conditions of use (COUs) and other exposures, toxicity endpoints, and metabolites and metabolic pathways, with tetrachloroethylene (PERC); 1,1,2,2-tetrachloroethane; trichloroethylene (TCE); 1,1,1-trichloroethane; and 1,2-dichloroethylene, as noted in Table 3-4 of the draft Trichloroethylene Risk Evaluation.

3) *trans*-1,2-Dichloroethylene and 1,1,2-Trichloroethane should be assessed together along with the two Dichloroethanes and the other chemicals listed in Table 3-4 as noted above.

4) TBBPA should be assessed in a group with the other structurally-related flame retardants used in plastics/printed circuit boards for electronics (TBBPA-bis(dibromopropyl ether), (TBBPA-bis(allyl ether), and TBBPA-bis(methyl ether).

5) TCEP should be assessed in concert with the other structurally-related chlorinated phosphate ester flame retardants used in furniture foams, textiles, and paints and coatings (2-Propanol, 1-chloro-, 2,2',2"-phosphate (TCPP) and 2-Propanol, 1,3-dichloro-, phosphate (3:1) (TDCPP)).

   Both groups of flame retardant assessments should incorporate all the elements recommended in EPA's fact sheet entitled "Assessing Risks from Flame Retardants."(Available at https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/fact-sheet-assessing-risks-flame-retardants)

6) The Phthalates
   Butyl benzyl phthalate (BBP), Dibutyl phthalate (DBP), Dicyclohexyl phthalate (DCHP), Di-ethylhexyl phthalate (DEHP), and Di-isobutyl phthalate (DIBP) should be assessed as a group. And, to this group should be added Di-*n*-octyl phthalate (DnOP), Diisodecyl phthalate (DIDP), and Diisononyl phthalate (DINP). All three were on the 2014 TSCA Work Plan in the phthalate group, and risk evaluations for the latter two are underway as a consequence of manufacturers' requests. In addition, several phthalates have been identified as endocrine disruptors. This mode of action should be addressed for all of the phthalates.

   Combined assessments of this group of chemicals has been recommended and/or implemented previously in the 2008 NAS report *Phthalates and Cumulative Risk Assessment: The Task Ahead* and in the Consumer Product Safety Commission's (CPSC) July 2014 report of the Chronic Hazard Advisory Panel on Phthalates and Phthalate Alternatives. In fact, such an approach would be consistent with EPA's own stated point of view:

   > Risk Management Approach:
   > Phthalates are used in products that are subject to rules under EPA, FDA, and the CPSC. People may be exposed to phthalates from a variety of product uses, as well as from

industrial releases and environmental exposures; these exposure pathways should be assessed together to appropriately characterize exposures and avoid underestimating risk. The assessment of combined exposure is important to determine the potential impacts of these chemicals. Focusing individually on these phthalates would likely underestimate their impact since they appear to produce similar adverse effects. Also, many phthalates are interchangeable in their uses as plasticizers for flexible PVC products, so restrictions on one could simply shift use to another of similar toxicity. Given this cumulative impact, the management of the risk from combined exposure requires a coordinated approach by all three agencies and, as appropriate, additional federal agencies. Therefore, EPA intends to work closely with CPSC and FDA to address the range of exposures (U.S. EPA. 2012. Phthalates Action Plan Revised 03/14/2012 available at https://www.epa.gov/sites/production/files/2015-09/documents/phthalates_actionplan_revised_2012-03-14.pdf).