Comments of Environmental Defense Fund, Earthjustice,
Natural Resources Defense Council, and Safer Chemicals Healthy Families
on
Draft Scopes of the Risk Evaluations to Be Conducted for Thirteen Chemical Substances Under the Toxic Substances Control Act and
Draft Scopes of the Risk Evaluations to be Conducted for Seven Chemical Substances Under the Toxic Substances Control Act

Docket ID: EPA–HQ–OPPT–2019–0131

Submitted May 13, 2020

NOTE: These comments are being submitted to the general docket EPA has established for comments on its draft scopes. The comments pertain to each of the 20 draft scopes for which EPA provided notice of availability in this docket. The submitters request that the comments be considered and included in the relevant administrative record for each of the individual chemicals. The chemical-specific dockets to which the comments pertain are as follows:

1. EPA–HQ–OPPT–2018–0451 (1,3-Butadiene);
2. EPA–HQ–OPPT–2018–0426 (1,1-Dichloroethane);
3. EPA–HQ–OPPT–2018–0427 (1,2-Dichloroethane);
4. EPA–HQ–OPPT–2018–0428 (1,2-Dichloropropane);
5. EPA–HQ–OPPT–2018–0488 (Ethylene dibromide (Ethane, 1,2-dibromo-));
6. EPA–HQ–OPPT–2018–0430 (1,3,4,6,7,8-Hexahydro-4,6,6,7,8,8-hexamethylcyclopenta [g]-2-benzopyran (HHCB));
7. EPA–HQ–OPPT–2018–0462 (4,4′-(1-Methylethylidene)bis[2, 6-dibromophenol] (TBBPA));
8. EPA–HQ–OPPT–2018–0444 (o-Dichlorobenzene (Benzene, 1,2-dichloro-));
9. EPA–HQ–OPPT–2018–0446 (p-Dichlorobenzene (Benzene, 1,4-dichloro-));
10. EPA–HQ–OPPT–2018–0458 (Phosphoric acid, triphenyl ester (TPP));
11. EPA–HQ–OPPT–2018–0465 (trans-1,2- Dichloroethylene (Ethene, 1,2-dichloro-, (1E)-));
12. EPA–HQ–OPPT–2018–0421 (1,1,2-Trichloroethane);
13. EPA–HQ–OPPT–2018–0476 (Tris(2-chloroethyl) phosphate (TCEP) (Ethanol, 2-chloro-, 1,1′,1″-phosphate));
14. EPA–HQ–OPPT–2018–0501 (Butyl benzyl phthalate (BBP) (1,2- Benzenedicarboxylic acid, 1-butyl 2-(phenylmethyl) ester));
15. EPA–HQ–OPPT–2018–0503 (Dibutyl phthalate (DBP) (1,2-Benzenedicarboxylic acid, 1,2-dibutyl ester));
16. EPA–HQ–OPPT–2018–0504 (Dicyclohexyl phthalate (1,2-Benzenedicarboxylic acid, 1,2-dicyclohexyl ester));
17. EPA–HQ–OPPT–2018–0433 (Di-ethylhexyl phthalate (DEHP) (1,2-Benzenedicarboxylic acid, 1,2-bis(2-ethylhexyl) ester));
18. EPA–HQ–OPPT–2018–0434 (Di-isobutyl phthalate (DIBP) (1,2-Benzenedicarboxylic acid, 1,2-bis(2-methylpropyl) ester));
19. EPA–HQ–OPPT–2018–0438 (Formaldehyde); and
20. EPA–HQ–OPPT–2018–0459 (Phthalic anhydride (1,3-Isobenzofurandione)).

The 20 draft scope documents that EPA released on April 9 and April 23, 2020, for public comment fail to meet TSCA and EPA regulatory requirements for EPA to identify the specific hazards, exposures and potentially exposed or susceptible subpopulations – and the reasonably available information EPA relies on to identify them -- that EPA expects to consider in the risk evaluations of the 20 subject chemicals. Instead, EPA indicates that these required scope elements will be developed and provided later – thereby denying the public an opportunity to provide comment on the hazards, exposures and potentially exposed or susceptible subpopulations EPA expects to consider, as required at this stage in the process.

Environmental Defense Fund (EDF), Earthjustice, Natural Resources Defense Council, and Safer Chemicals Healthy Families therefore request that EPA publish, and provide an opportunity for public comment of no less than 30 days on, *revised draft scopes* that fully identify the specific hazards, exposures and potentially exposed or susceptible subpopulations – and the reasonably available information EPA relies on to identify them. EPA should simultaneously publish and take comment on its systematic review documentation for each scope.

Legal and regulatory requirements for scopes

Section 6(b)(4)(D) of the Toxic Substances Control Act (TSCA) requires, as the first step in the risk evaluation process for a high-priority chemical, that EPA, "not later than 6 months after the initiation of a risk evaluation, publish the scope of the risk evaluation to be conducted, *including the hazards, exposures, conditions of use, and the potentially exposed or susceptible subpopulations the Administrator expects to consider*." 15 U.S.C 2605(b)(4)(D), emphasis added.

Section 702.41(c) of EPA's final rule, "Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act,"[1] states in relevant part (emphases added):

> The scope of the risk evaluation will include all the following:
>
> (1) The condition(s) of use, as determined by the Administrator, that the EPA plans to consider in the risk evaluation.
>
> (2) The *potentially exposed populations, including any potentially exposed or susceptible subpopulations as identified as relevant to the risk evaluation by the Agency under the conditions of use, that EPA plans to evaluate; the ecological receptors that EPA plans to evaluate; and the hazards to health and the environment that EPA plans to evaluate*.

[1] See 82 Fed. Reg. 33751 (July 20, 2017), available at https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0654-0108, and codified at 40 CFR 702.41(c).

(3) A description of the *reasonably available information* and science approaches EPA plans to use in the risk evaluation.

Section 702.41(c) goes on to state:

(7) Developing the scope.

(i) *Draft scope*. For each risk evaluation to be conducted EPA will publish a document in the Federal Register that specifies the draft scope of the risk evaluation the Agency plans to conduct. *The document will address the elements in paragraphs (c)(1) through (6) of this section*.

Despite these requirements, in its draft scope documents EPA has failed to "address the elements in paragraphs (c)(1) through (6)" of section 702.41(c) section. Instead, EPA has only generally described some broad categories of hazards, exposures, and potentially exposed or susceptible subpopulations, and has suggested it will identify the specific hazards, exposures, and subpopulations – and the reasonably available information it relies on to identify them – only later, well after the current comment periods have closed and possibly even after the scopes are finalized. This approach is not allowed under TSCA and EPA's own Risk Evaluation Rule.

We will illustrate these deficiencies using the example of the draft scope for formaldehyde,[2] but note that virtually identical language and approaches are used in all 20 of the draft scopes.

Failure to co-release the systematic review document to be used to identify required scope elements

In the draft scope for formaldehyde, EPA makes clear that it has not yet identified, and hence has not included in the draft scope, information that TSCA and its own Risk Evaluation Rule require be included in the draft scope. For example, with respect to hazard information, EPA makes clear it has not identified formaldehyde's hazards in the draft scope. EPA states (p. 60, emphases added):

> **Conduct hazard identification (the qualitative process of identifying non-cancer and cancer endpoints) and dose-response assessment (the quantitative relationship between hazard and exposure) for identified human health hazard endpoints.**

[2] "Draft Scope of the Risk Evaluation for Formaldehyde," April 2020, available at https://www.epa.gov/sites/production/files/2020-04/documents/casrn-50-00-0_formaldehyde_draft_scope_4_15_2020_1.pdf.

> *EPA plans to identify human health hazards from acute and chronic exposures* by evaluating the human and animal data that *meet the systematic review data quality criteria described in the systematic review documentation that EPA plans to publish prior to finalizing the scope document*. Hazards identified by studies meeting data quality criteria will be grouped by routes of exposure relevant to humans (oral, dermal, inhalation) and by cancer and noncancer endpoints.

The same or similar language appears in all 20 draft scopes. Notably, in this excerpt EPA alludes to another document – "systematic review documentation" – that it has not yet made public and that EPA states it will use to identify the hazards to be included in the risk evaluations. EPA invokes this yet-to-be-published document more than a dozen times in the draft formaldehyde scope as one that still needs to be developed and then applied in order to identify the specific hazards, exposures and subpopulations it will include in the draft risk evaluation.

EPA seems to recognize that the systematic review documentation is directly relevant to and necessary for development of the scope. Each time it mentions the systematic review documentation, EPA notes that it "plans to publish [it] prior to finalizing the scope document." EPA also states it "plans to seek public comments on the systematic review methods supporting the risk evaluation for formaldehyde" (p. 12).

EPA also makes clear that it will use systematic review to identify the reasonably available information required to be included in the draft scope. On page 10 of the formaldehyde scope, EPA states (emphases added):

> EPA is using the *systematic review process* described in the *Application of Systematic Review in TSCA Risk Evaluations* document (U.S. EPA, 2018a)[3] to guide the process of searching for and screening *reasonably available information*, including information already in EPA's possession, for use and inclusion in the risk evaluation. *EPA is applying these systematic review methods to collect reasonably available information regarding hazards, exposures, PESS, and conditions of use* that will help inform the risk evaluation for formaldehyde.

[3] The signatories to these comments have previously filed comments, including to this docket, opposing EPA's continued reliance on this flawed systematic review approach and urging the agency to adopt a method that reflects best practices in systematic review and has been reviewed and recommended by the National Academies of Sciences, Engineering, and Medicine. See, for example: https://www.regulations.gov/document?D=EPA-HQ-OPPT-2019-0131-0023; https://www.regulations.gov/document?D=EPA-HQ-OPPT-2019-0500-0108; https://www.regulations.gov/document?D=EPA-HQ-OPPT-2018-0210-0095; and https://www.regulations.gov/document?D=EPA-HQ-OPPT-2018-0210-0077.

Yet by indicating EPA will publish separately and at some later point the systematic review document it invokes repeatedly throughout the scope, EPA has wholly divorced any public comment opportunity it will provide on that systematic review document from the current public comment opportunity. Given that the systematic review document is not yet available, the public is unable to consider its content in preparing comments on the draft scope document.

Moreover, it does not appear that even through the release for public comment of the draft systematic review document – which it appears will focus on systematic review *methods* – will EPA actually identify the hazards, exposures and subpopulations it plans to include in the risk evaluation; that identification, EPA appears to indicate, will only occur later, possibly even after the scope is finalized.

Failure to provide all reasonably available information used to identify required scope elements

EPA's own draft scope makes clear it has yet to provide the reasonably available information used to identify hazards, exposures and subpopulations, which is required by its own Risk Evaluation Rule to be included in the draft scope of a risk evaluation:

Hazard information: In the draft scope for formaldehyde, EPA devotes a scant two paragraphs to "Human Health Hazards" (section 2.4.2, p. 35), and references only broad categories of hazard such as developmental toxicity and carcinogenicity,[4] without providing any indication of what specific hazards within these broad categories it expects to consider in the risk evaluation, or the reasonably available information on which EPA relies to identify them. The incomplete and tentative nature of EPA's identification of human health hazards in the draft scope is made clear by the following statement in that section (emphases added):

> EPA is *in the process of identifying* additional reasonably available information through systematic review methods and public input, which *may update the list of potential human health hazards under the scope of the risk evaluation*. If necessary, *EPA plans to update the list of potential hazards in the final scope document* of the formaldehyde risk evaluation.

[4] In contrast, EPA's problem formulation for trichloroethylene (TCE), the document that was equivalent to the scope of the risk evaluation for that chemical, was considerably more specific about the human health hazards of TCE; see pp. 44-46 at https://www.epa.gov/sites/production/files/2018-06/documents/tce_problem_formulation_05-31-31.pdf. That problem formulation was far less specific, however, about potentially exposed or susceptible subpopulations (p. 46), a deficiency EDF noted in its comments on the problem formulation; see pp. 64-68 and 186-187 at https://www.regulations.gov/document?D=EPA-HQ-OPPT-2018-0210-0066.

This statement indicates EPA is still reviewing "reasonably available information," using its yet-to-be-released "systematic review methods," to identify specific hazards that the public cannot comment on because the information and hazards are not identified in the draft scope. Yet EPA intends to include such elements not made available for public comment in the final scope. It would be one thing to make changes to the draft scope based on "public input" received; it is quite another to do so on the basis of a currently undisclosed systematic review process to review information and identify hazards that should have been fully reflected in the draft scope.

Subpopulation information: Similarly, EPA provides three paragraphs on "potentially exposed or susceptible subpopulations" (section 2.5, pp. 35-36), merely quoting TSCA's definition of the term and repeating EPA's earlier identification at the prioritization stage of the broad categories of "children, women of reproductive age (e.g., pregnant women), consumers and workers" as comprising such subpopulations.[5] Here again, EPA makes clear it has yet to develop and present the required reasonably available information necessary to identify specific subpopulations that may be more highly or differentially exposed, or more susceptible to exposures, to formaldehyde (p. 36, emphases added):

> In developing exposure scenarios, *EPA plans to analyze reasonably available information to ascertain whether some human receptor groups may be exposed via exposure pathways that may be distinct to a particular subpopulation or life stage* (e.g., children's crawling, mouthing or hand-to-mouth behaviors) and *whether some human receptor groups may have higher exposure* via identified pathways of exposure due to unique characteristics (e.g., activities, duration or location of exposure) when compared with the general population (U.S. EPA, 2006a). Likewise, *EPA plans to evaluate reasonably available human health hazard information to ascertain whether some human receptor groups may have greater susceptibility* than the general population to the chemical's hazard(s).

Summary and request

The problems described above are by no means limited to the formaldehyde draft scope. Our examination of the draft scope documents for the other chemicals now undergoing public comment reveals that EPA is taking the same or a very similar approach in all of them.

The sequenced approach EPA is taking fails to satisfy TSCA's requirement that the scope of a risk evaluation specify the hazards, exposures, and potentially exposed or susceptible

[5] TSCA's definition of this term is expansive and is by no means limited to these subpopulations; rather, it encompasses other subpopulations such as fenceline communities who may also be disproportionately exposed or susceptible to chemicals.

subpopulations EPA plans to include in its risk evaluation and the reasonably available information on which EPA relies to identify them. Nor has EPA met the Risk Evaluation Rule's requirement that the public be afforded the opportunity to comment on a full draft of that scope that includes these specific elements. By proceeding in this manner, EPA jeopardizes the integrity and legality of the entire risk evaluation process.

EDF, Earthjustice, Natural Resources Defense Council, and Safer Chemicals Healthy Families therefore request that EPA publish – and provide an opportunity for public comment of no less than 30 days on – *revised draft scopes* that include the reasonably available information EPA has indicated it will identify through the systematic review process, and that identify the specific hazards, exposures and potentially exposed or susceptible subpopulations that EPA expects to consider in the risk evaluations of the 20 chemicals for which EPA released draft scope documents on April 9 and April 23, 2020. EPA should simultaneously publish and take comment on its systematic review documentation for each scope. Only in this manner will all of this information directly relevant to the scopes of these 20 risk evaluations be able to be reviewed and commented on at the same time and in an integrated manner, rather than piecemeal. EPA should not finalize the scopes until this additional comment period concludes and EPA has sufficient time to address the comments received.

We would appreciate your prompt attention and response to this request. If you have any questions please contact Dr. Richard Denison, EDF, at rdenison@edf.org.

Sincerely,

Richard A. Denison, Ph.D., Lead Senior Scientist
Environmental Defense Fund

Eve C. Gartner, Managing Attorney, Toxic Exposure & Health Program
Earthjustice

Daniel Rosenberg, Director, Federal Toxics Policy
Natural Resources Defense Council

Liz Hitchcock, Director
Safer Chemicals Healthy Families