Environmental Defense Fund Comments on

Agency Information Collection Activities; Proposed Revisions to an Existing Collection (EPA ICR No. 1139.12; OMB Control No. 2070–0033)

Docket ID: EPA-HQ-OPPT-2015-0436

Submitted July 30, 2020

Environmental Defense Fund (EDF) submits the following comments in response to the notice published by the Office of Pollution Prevention and Toxics (OPPT) at the Environmental Protection Agency (EPA) regarding the above-mentioned Information Collection Request (ICR) proposal under the Toxic Substances Control Act (TSCA), which EPA published at 85 Fed. Reg, 33151 (June 1, 2020).[1]

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[1] 85 Fed. Reg. 33,151 (June 1, 2020), available at https://www.regulations.gov/document?D=EPA-HQ-OPPT-2015-0436-0015.

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1. EPA's proposed ICR signals the agency's intent to continue not adequately using its TSCA information authorities to fill data gaps.

A constant criticism of EPA's draft risk evaluations for the first 10 chemicals has been the dearth of information on which EPA has relied to draw firm risk conclusions. Stakeholders like EDF[2] and EPA's own Science Advisory Committee on Chemicals (SACC)[3] have repeatedly pointed to the lack of sufficient, reliable information on the chemicals' presence in and releases into various environmental media; their presence in and releases from industrial, commercial, and consumer products and materials; the extent and magnitude of workplace exposure levels; key human hazard endpoints; and ecological hazards to sediment- and soil-dwelling and terrestrial as well as aquatic organisms. Concerns have also been repeatedly raised about EPA's over-reliance on models and on modeled vs. measured physical-chemical and environment fate data, especially in the absence of rigorous uncertainty analyses and incorporation of uncertainty into EPA's risk conclusions.

Unfortunately, it appears from the proposed ICR that EPA's intent with the next 20 risk evaluations is more of the same flawed approach it used in the draft risk evaluations issued to date. In EPA's supporting statement for the revised ICR,[4] EPA is proposing to drastically reduce

[2] See, for example: Environmental Defense Fund Comments on the Draft Risk Evaluation of 1-Bromopropane, (Oct. 11, 2019), https://www.regulations.gov/document?D=EPA-HQ-OPPT-2019-0235-0047; EDF Comments on Draft Risk Evaluation of Trichloroethylene (Apr. 27, 2020), https://www.regulations.gov/document?D=EPA-HQ-OPPT-2019-0500-0108; EDF Comment on the 1,4-Dioxane Draft Risk Evaluation (Aug. 30, 2019), https://www.regulations.gov/document?D=EPA-HQ-OPPT-2019-0238-0058; EDF Comments on Draft Risk Evaluation of Methylene Chloride (December 30, 2019), https://www.regulations.gov/document?D=EPA-HQ-OPPT-2019-0437-0073.

[3] See, for example: SACC peer review report on the methylene chloride draft risk evaluation, https://www.regulations.gov/document?D=EPA-HQ-OPPT-2019-0437-0080; SACC peer review report on 1-bromopropane draft risk evaluation, https://www.regulations.gov/document?D=EPA-HQ-OPPT-2019-0235-0061; SACC peer review report on the 1,4-dioxane and HBCD draft risk evaluations, https://www.regulations.gov/document?D=EPA-HQ-OPPT-2019-0238-0063.

[4] Available at https://www.regulations.gov/document?D=EPA-HQ-OPPT-2015-0436-0018.

and alter the battery of tests it would consider requiring companies to conduct under any section 4 action it undertakes for three years.

The supporting statement indicates that for the ICR *currently* in effect, the following 10-test battery would be used (see Table A-1, p. 52 of ICR supporting statement):

- Algal Acute Toxicity
- Daphnid Acute Toxicity
- Fish Acute Toxicity
- Gene Mutations in Somatic Cells
- Subchronic Oral Toxicity
- Prenatal Developmental Toxicity (2 species)
- Reproduction/Fertility Effects
- Salmonella Reverse Mutation Assay
- In vivo Bone Marrow Cytogenetics
- Developmental Neurotoxicity

Three of these tests are deemed "long-duration" tests: Prenatal Developmental Toxicity (2 species); Reproduction/Fertility Effects; and Developmental Neurotoxicity.

This battery is quite similar to the test battery developed by the Chemicals Program of the Organization for Economic Cooperation and Development (OECD) known as the Screening Information Data Set (SIDS), which was expressly developed as the ***minimum*** information necessary to conduct a ***screening-level*** hazard assessment.[5] The SIDS and EPA's test battery in its current ICR fall well short of what would be needed to inform just the hazard component of a full risk evaluation under TSCA. While SIDS was not developed to address exposure, EPA's test battery absolutely should (see discussion later in this section).

Yet EPA is now proposing to radically reduce even this level of testing, instead specifying a different 7-test battery to be used under its revised ICR (Table A-2, p. 53 of ICR supporting statement):

- Melting Point
- Boiling Point

[5] OECD, *Chapter 2. Data Gathering and Testing: SIDS, the SIDS Plan and the SIDS Dossier* in MANUAL FOR THE ASSESSMENT OF CHEMICALS (2012), http://www.oecd.org/env/ehs/risk-assessment/chapter2datagatheringandtestingsidsthesidsplanandthesidsdossier.htm. This page describes the SIDS as "the minimum amount of data that is required for making an initial hazard assessment of chemicals."

- Vapor Pressure
- log Kow
- Water Solubility
- Ready Biodegradation
- Acute Toxicity to Daphnia

The proposed battery includes no mammalian toxicity tests, and no tests for chronic or even subchronic toxicity to any type of organism. It consists of only a single toxicity test of any sort – for acute toxicity to an aquatic invertebrate (Daphnia) – with the remaining six tests limited to physical-chemical and environment fate parameters measured in a laboratory setting (see section 5 below for the many scientific concerns raised by EPA's over-reliance on such data in evaluating chemical risks). Further, it lacks any elements intended to assess human or environmental exposure.

Ironically, the ICR's proposed list does not even cover the minimal endpoints for which EPA recently issued a test order to the manufacturers of Pigment Violet 29 (PV29), one of the first 10 chemicals to undergo risk evaluation that has been plagued with data deficiencies. Despite glaring and extensive data gaps, in March 2020, EPA issued two TSCA section 4 test orders requiring two companies to test PV29 for only two parameters: solubility and respirable particles.[6] Only one of these parameters is in the proposed ICR test battery.

Equally ironically, the ICR acknowledges EPA's very broad authority under TSCA to mandate data development beyond physical-chemical properties and environment fate – including health and environmental toxicity and monitoring and other exposure data – even as it proposes this highly limited test battery. On page 8 of the ICR supporting statement, EPA states:

> TSCA section 4 allows for the prescription of protocols and methodologies for the development of information on health and environmental effects including carcinogenesis, mutagenesis, teratogenesis, behavioral disorders, cumulative or synergistic effects, and any other effect which may present an unreasonable risk of injury to health or the environment. TSCA also allows for the prescription of protocols and methodologies for the assessment of exposure potential to humans and the environment. TSCA allows for protocols and methodologies to be prescribed for chemical characteristics including persistence, acute toxicity, subacute toxicity, chronic toxicity, and any other characteristic which may present such a risk. The methodologies that may be prescribed include serial or tiered testing, in vitro tests, whole animal tests, and epidemiologic studies, with the

[6] Available at https://www.regulations.gov/docket?D=EPA-HQ-OPPT-2020-0070/.

stipulation that EPA consult with the National Institute for Occupational Safety and Health prior to prescribing epidemiologic studies of employees.

Yet EPA proposes to include virtually none of these parameters in its ICR, despite their direct relevance to risk evaluation and the already identified need for such data for the next 20 chemicals to undergo risk evaluations – see section 2.A. below.

2. EPA's proposed test battery will fail to address even the already identified data gaps for the next 20 chemicals undergoing risk evaluation.

A. Testing needs for the next 20 chemicals now undergoing risk evaluation.

Even though EPA indicates the information obtained pursuant to this ICR will be used for the purpose of informing its TSCA risk evaluations (p. 12 of ICR supporting statement), the ICR revision proposal does not indicate which, if any, of the 20 chemicals with draft scopes would even be subject to this limited testing. Nor do EPA's draft scopes[7] indicate any intent on EPA's part to require *any* testing for physical-chemical properties, environment fate, health or environmental toxicity, or to require any monitoring or other exposure data to be developed.

Yet even EPA acknowledges serious data gaps for those 20 chemicals that extend far beyond the short list of tests to which it is proposing to limit the ICR. These gaps also extend well beyond the list of endpoints included in the ICR *currently* in effect – and as noted in section 1 above, even the current list only roughly constitutes what hazard data are needed to conduct a *screening-level* risk assessment, not a full risk evaluation.

For example, according to EPA's Proposed High-Priority Designation documents for the 20 chemicals currently undergoing risk evaluation, the majority of them lack data on immunotoxicity and respiratory sensitization. Specifically, EPA identified such data for only eight of the 20 chemicals. Likewise, a number of the 20 chemicals have either no or very limited aquatic toxicity data. For example, for both TCEP and 1,1-dichloroethane EPA identified only a single acute aquatic fish study in each case, no acute data on aquatic plants or invertebrates, and no chronic aquatic toxicity data.[8]

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[7] EPA's draft scopes for the next 20 chemicals undergoing risk evaluations are available at https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/chemicals-undergoing-risk-evaluation-under-tsca.

[8] See: https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/chemicals-undergoing-risk-evaluation-under-tsca. In each Proposed High Priority Designation document, see the tables titled "Potential Human Health Hazards Identified" and "Potential Environmental Hazards Identified" for each subject chemical.

B. Testing needs for other Work Plan chemicals to undergo risk evaluation after the next 20 chemicals.

Beyond the next 20 chemicals, in other contexts EPA staff are signaling the need for EPA to conduct more robust testing under TSCA, and the need to start the data development process soon, for chemicals EPA will need to prioritize and conduct risk evaluations for going forward. For example, in a presentation EPA staff made last week (on July 24, 2020) to EPA's Children's Health Protection Advisory Committee (CHPAC),[9] one of the presentation slides outlining EPA's amended charge to the CHPAC's TSCA Workgroup stated:

> Under this charge, the CHPAC would identify recommendations for CEH [children's health protection] implications for the remaining chemicals on the Work Plan, including which chemicals have children's health relevant data gaps where OPPT could seek reporting or testing under Sections 8 and 4, respectively. (slide 22)

Another slide read:

> Referring to the text on EPA's authority to request new data and report on existing data from a manufacturer in Sections 4 and 8, among the remaining Work Plan chemicals, which ones with potential CEH concern have significant data gaps which could be addressed by obtaining data, including through either the Section 4 or Section 8 mechanisms?
>
> a. For example, are there chemicals currently on the workplan list to which children have high exposure but for which additional health effects data may be needed (or vice versa)?
>
> b. For the specific chemicals on the workplan, what assays or types of studies may be needed to adequately assess CEH exposure or effects in order to prioritize chemicals on the Work Plan list or to conduct the Risk Evaluation? (slide 26)

EPA is clearly anticipating the need to conduct testing using its section 4 authorities in order to address information gaps relevant to children's health protection. Yet the ICR's proposed scaled-back test battery altogether lacks parameters that would address this need. Instead, the proposed ICR would *eliminate* from the current ICR's test battery several tests that are directly relevant to this area of need:

- Prenatal Developmental Toxicity (2 species)
- Reproduction/Fertility Effects
- Developmental Neurotoxicity

[9] The CHPAC meeting agenda showing this agenda item is available at https://www.epa.gov/sites/production/files/2020-07/documents/chpac_agenda_july_2020.pdf.

* * *

The proposed ICR appears to be wholly out of step with EPA's own anticipated testing needs under TSCA in the near and mid-term.

3. EPA has been ignoring requests to use its information authorities to fill data gaps for years.

EDF, among other stakeholders, has been calling on EPA to mandate information submission or development under TSCA sections 4 and 8 for years, including specifically on the next 20 chemicals identified for risk evaluation since June 2019; however, the agency has so far failed to use any of its authorities to generate or otherwise acquire data for the 20 high-priority chemicals despite clear data gaps. (As mentioned in section 2.A. above and discussed further in this section, not one of EPA's 20 draft scopes makes even a single mention of EPA ever using the information authorities Congress enhanced when it reformed TSCA in 2016 to address data gaps and needs.)

For example, EPA has left data gaps identified for TCEP and TBBPA unaddressed for nearly five years – and testing limited to the battery specified in the proposed ICR would not begin to address these gaps. In 2015, EPA released TSCA Work Plan Initial Problem Formulations for three clusters of flame retardant chemicals, including the "Chlorinated Phosphate Ester (CPE) Cluster" – which included the current high-priority chemical TCEP – and the "Tetrabromobisphenol A (TBBPA) and Related Chemicals Cluster" – which included the current high-priority chemical TBBPA. At the time, EDF recommended that EPA should develop and present a plan to fill major data gaps, specifically by promulgating section 4 test rules (although the test order authority added by the 2016 TSCA amendments could now be used instead) or sections 8(a) or 8(d) rules, or issuing other data call-ins for the chemicals in these three flame retardant clusters. We specifically recommended the following regulatory actions be taken to address identified data gaps:[10]

Chlorinated Phosphate Ester (CPE) Cluster (includes TCEP)

- Section 4 test rule and/or section 8(d) data call-in for inhalation and dermal route-specific toxicity data (identified in assessment as a critical data need).

[10] See EDF Comments, "TSCA Work Plan Chemical Problem Formulation and Initial Assessment: Chlorinated Phosphate Ester Cluster Flame Retardants," November 18, 2015, at p. p.17. Available: https://www.regulations.gov/document?D=EPA-HQ-OPPT-2015-0068-0015, and "TSCA Work Plan Chemical Problem Formulation and Initial Assessment: Tetrabromobisphenol A and Related Chemicals Cluster Flame Retardants," November 18, 2015, at p. 17. Available: https://www.regulations.gov/document?D=EPA-HQ-OPPT-2014-0730-0022.

- Section 4 test rule for exposure monitoring studies of U.S.-based industrial workers.
- Section 8(a) reporting rule on the number of individuals exposed in their place of employment and the duration of exposure.

Tetrabromobisphenol A (TBBPA) and Related Chemicals Cluster:

- Air/dust exposure monitoring studies at U.S.-based recycling facilities and reporting on the number of recycling workers exposed. EPA may need to use other authorities to obtain this information.
- U.S. data on recycling and disposal of discarded electronics. EPA may need to use other authorities to obtain this information.
- Section 4 test rule and/or section 8(d) data call-in for dose response data on exposure to TBBPA and incidence of hepatoblastomas.

Based on our review of the draft scopes for these chemicals and EPA's ChemView database, it does not appear that EPA has acted to fill any of these data gaps in the subsequent five years. EPA must move promptly to do so now in order to meet TSCA's requirement that EPA obtain all "reasonably available information."

4. Limiting the scope of this ICR to screening tests will only exacerbate the constraints EPA will face in order to require more advanced testing in a timely manner.

On page 7, EPA states (emphasis added):

> TSCA section 4(a)(4) established that when requiring the development of new information under TSCA section 4(a), EPA must employ a tiered screening and testing process, under which the results of screening tests or assessments of available information inform the decision whether to require more advanced testing. It is therefore assumed, for the purposes of estimating burden for this three-year period, that testing would consist primarily of screening-level tests. *If other types of testing are required in the future, the burden estimates will be modified as needed at that time.*

EPA has frequently expressed concern about the constraints it asserts it faces when considering requiring longer-term testing, given statutory deadlines under TSCA. Yet in this language EPA indicates it would wait to initiate the lengthy process of modifying the ICR or portions of it until it made a decision in a specific case to require more advanced testing. This would exacerbate even further the timing concern, making it even less likely that EPA would decide it could undertake such testing in the time allowed.

EPA needs instead to prepare estimates in this ICR of the frequency and associated burden associated with such more advanced testing. While this entails uncertainty, so do the estimations EPA has included in the ICR of the number and scope of section 4 testing actions.

5. EPA's proposed narrow list of tests will perpetuate its flawed approach of dismissing routes of exposure based on qualitative analysis and modeling based only on physical-chemical and environmental fate properties.

The narrow list of tests EPA includes in the proposed ICR signals EPA's intent to continue to conduct risk evaluations that are ill-informed by actual hazard and exposure data and instead will rely on the kinds of questionable assumptions and extrapolations from limited physical-chemical and environment fate data — an approach that has been heavily criticized.

This intent is reinforced by examining EPA's draft scopes for the next 20 chemicals to undergo risk evaluation under TSCA. EPA indicates it intends to repeat the flawed approaches it used in the draft risk evaluations for the first 10 chemicals of: a) relying solely on physical-chemical properties to dismiss exposure pathways, and b) utilizing modeled values based on physical-chemical properties. Both approaches have been criticized by the SACC as insufficient.[11]

As an example of the former of the two approaches, in the draft scope for 1,1,2-trichloroethane,[12] EPA indicates that despite having no data on the levels of the chemical present in biosolids (or any other media, p. 40), biosolids are "unlikely to be a route to general population since 1,1,2-trichlorethane is not expected to sorb onto biosolids" (p.86). This appears to be part of a general strategy to dismiss exposure pathways, as similar language is found in the draft scopes for 1,2-dichlorethane (p. 91), o-dichlorobenzene (p. 104), and trans-1,2-dichloroethylene (p. 97).[13]

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[11] See, e.g., the SACC peer review report on the methylene chloride draft risk evaluation, https://www.regulations.gov/document?D=EPA-HQ-OPPT-2019-0437-0080' the SACC peer review report on 1-bromopropane draft risk evaluation, p. 13, https://www.regulations.gov/document?D=EPA-HQ-OPPT-2019-0235-0061; and the SACC peer review report on the 1,4-dioxane and HBCD draft risk evaluations, p. 41, https://www.regulations.gov/document?D=EPA-HQ-OPPT-2019-0238-0063.

[12] Available at https://www.epa.gov/sites/production/files/2020-04/documents/casrn-79-00-5_112-trichloroethane_draft_scope.pdf.

[13] Available at, respectively, https://www.epa.gov/sites/production/files/2020-04/documents/casrn-107-06-2_12-dichloroethane_draft_scope.pdf; https://www.epa.gov/sites/production/files/2020-04/documents/casrn-95-50-1_o-dichlorobenzene_draft_scope.pdf; and https://www.epa.gov/sites/production/files/2020-04/documents/casrn-156-60-5_trans-12-dichloroethylene_draft_scope.pdf.

Furthermore, *how* and *how quickly* chemicals partition in the environment is dependent on environmental conditions. For example, as noted by the SACC, "volatilization depends on the environmental phase (water, soil, sediment, etc.) that the chemical is in and the environmental conditions (temperature, wind speed) associated with the adjacent phase" and "[n]o information on kinetics or rates of flux from one phase to another can be implied from equilibrium properties."[14] By assuming equilibrium instead of obtaining actual data on concentrations in various compartments, EPA will continue to ignore chemicals of concern that can occur in high concentrations in different environmental compartments prior to reaching equilibrium, if it is reached at all.

With respect to the second approach, while models based on physical-chemical properties of chemicals can be useful in providing a preliminary understanding of both hazard and exposure, they are inappropriate for dismissing exposure and risk outright, especially without a corresponding and supportive uncertainty analysis to understand the sensitivity of the conclusions to the model.

If EPA bases its future testing requirements on the proposed narrow list of physical-chemical and environment fate data included in the proposed ICR, it is doomed to repeat these failures in its future risk evaluations.

6. EPA routinely lacks adequate occupational exposure monitoring data that testing under the ICR could provide – but will not provide as proposed.

For the first 10 chemicals undergoing risk evaluation, EPA heavily relied on models to estimate worker exposure due to its lack of access to occupational exposure data. Concerns with this approach were repeatedly raised by EPA's SACC. For example, during the March 24-27, 2020, TCE SACC Peer Review meeting, several reviewers raised concern over EPA's lack of sufficient occupational exposure data, including for occupational non-users (ONUs) – and suggested EPA undertake a more concerted effort to acquire data from OSHA, NIOSH, and companies to fill these gaps. Peer reviewers indicated that the same data gap issues have arisen in multiple draft risk evaluations and will continue to arise unless addressed; they suggested that EPA begin looking forward to the next 20 chemicals slated for risk evaluations to proactively fill such data gaps.

However, it is not at all clear from the scoping documents that EPA is making any effort to acquire more robust occupational exposure monitoring data than it did for the first 10 chemicals. For example, while EPA mentions its intention to review OSHA and NIOSH data (e.g., "EPA

[14] See the SACC peer review report on 1-bromopropane draft risk evaluation, p. 13, https://www.regulations.gov/document?D=EPA-HQ-OPPT-2019-0235-0061.

plans to review available TCEP exposure monitoring data for specific conditions of use. Example exposure data include workplace monitoring data collected by government agencies such as OSHA and NIOSH, and monitoring data in published literature," TCEP scope, p. 37), it is apparent from Appendix E.3 that EPA has not actually identified OSHA data for many chemicals (e.g., "Based on a preliminary data gathering, there are no OSHA Chemical Exposure and Health Data (CEHD) specific to TCEP," TCEP draft scope, p. 64). EPA makes no mention of collaborating with agencies or requiring companies to generate the needed data. Instead, it appears that EPA intends to continue to rely upon limited exposure monitoring data, supplemented by surrogate data and exposure models (e.g., see p. 37 of Analysis Plan in TCEP draft scope). This hardly constitutes best available science.

The ICR could be an opportunity to signal and pave the way for EPA to use its authorities to acquire better occupational exposure data both for the next 20 chemicals as well as subsequent risk evaluations. As proposed, the ICR utterly fails to do so.

7. It is not clear whether the ICR's estimates for the number of testing actions to be taken account for testing of new chemicals under TSCA section 5.

The proposed ICR acknowledges that TSCA section 4 provides EPA with authority to require testing to "review a notice submitted under TSCA section 5" and to "implement a requirement imposed in a rule, order, or consent agreement under TSCA section 5(e) or (f)" (p. 6). The ICR also states that "EPA may also need to develop information under TSCA section 4 pursuant to other authorities provided under TSCA section 4(a)(2), including pursuant to TSCA section 5" (p. 9). However, the number of testing actions specified in the proposed ICR appear to fall far short of those needed to address testing needed under section 5 as well as section 6 of TSCA.

EPA projects 0.5 test rules, 10 test orders, and 0.5 enforceable consent agreements per year – each action addressing seven chemicals (i.e., 77 in total). But this total amounts to a small fraction of the hundreds or thousands of new chemical notices and applications received annually by EPA. While under this Administration EPA has sought to avoid imposing testing requirements on any new chemicals, that was clearly not Congress' intent in reforming TSCA in 2016. Those reforms explicitly addressed a major failing of the old law under which EPA was compelled to allow onto the market chemicals without adequate information to assess their safety. Under the reforms, information insufficiency by itself requires EPA to regulate a new chemical, including by requiring testing; see TSCA section 5(e)(1)(i).

EPA's determination documents for new chemicals[15] regularly acknowledge limitations to the available data – but then fail to regulate those chemicals or require testing, based on highly

[15] Available at https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/chemicals-determined-not-likely.

questionable assumptions or reliance on data from surrogate chemicals without providing any estimation of the reliability of such information or requiring subsequent testing to determine whether the assumptions are warranted or the surrogate data are reliable.

While in the past EPA has generally imposed testing requirements by including them in section 5 consent orders it negotiated with new chemical notice submitters, Congress gave EPA explicit authority under section 4 to require testing for purposes of implementing section 5. EPA needs to explicitly address this authority by including in its projections of section 4 testing actions those taken to address the major data gaps presented by most new chemicals reviewed by the agency.

8. The ICR's discussion of TSCA's confidentiality provisions is improved relative to that in the separate voluntary ICRs EPA recently proposed, but it still does not accurately reflect TSCA section 14.

This proposed ICR's description of TSCA's requirements for confidentiality and disclosure of information under TSCA in section 3(f) (p. 11) is generally more accurate and complete than that in the separate, recently proposed voluntary ICRs; see section 4 of EDF's comments on those proposed ICRs.[16]

However, elsewhere in the proposed ICR EPA makes statements that are inaccurate or insufficiently qualified. We describe four such instances below in detail.

- On page 4, EPA states: "*Confidentiality of responses*: Respondents may claim all or part of a document confidential."

  Most of the information submitted to EPA in response to a section 4 action will not be eligible for protection from disclosure at all under TSCA. Section 14(b) of TSCA identifies several types of information that cannot be claimed or withheld as confidential. 15 U.S.C. § 2613(b). These include health and safety studies or information obtained from them – the very types of information EPA is likely to collect under the ICR. If EPA receives such information from submitters, it cannot withhold that information from the public. Submitters should not claim such information as confidential and even if they do so, it cannot be withheld regardless of the claim. EPA needs to clearly indicate this in the ICR and inform potential submitters that such information is ineligible for being claimed as confidential.

  With respect to health and safety information, TSCA and EPA's own regulations make clear that information on the physical-chemical and environmental fate parameters specified in the

[16] Available at https://www.regulations.gov/document?D=EPA-HQ-OPPT-2018-0611-0016 and https://www.regulations.gov/document?D=EPA-HQ-OPPT-2018-0612-0016.

proposed ICR's test battery constitute health and safety information ineligible for CBI protection under TSCA. TSCA defines "health and safety study" to mean "any study of any effect of a chemical substance or mixture on health or the environment or on both, including underlying information and epidemiological studies, studies of occupational exposure to a chemical substance or mixture, toxicological, clinical, and ecological studies of a chemical substance or mixture, and any test performed pursuant to this Act." 15 U.S.C. § 2602(8). EPA regulations at 40 C.F.R. § 716.3 state that "[i]t is intended that the term health and safety study be interpreted broadly" and encompass "[a]ny data that bear on the effects of a chemical substance on health or the environment." The regulations are explicit that tests to determine the chemical and physical properties and fate and transport behavior of a substance fall within the definition, along with studies of a chemical's human health effects and ecotoxicity. 40 C.F.R. § 720.3(k)(2)(iii).

- On page 8, EPA states (emphasis added):

> *[T]o the extent that reported information is not considered to be CBI*, environmental groups, environmental justice advocates, industry, state and local government entities and other members of the public may have access to this information for their own use.

This language implies that most or much of the information reported pursuant to the section 4 action will be considered to be CBI, which is not the case; in fact the opposite should be the presumption: that little if any of the submitted information will be considered CBI, and that it should be so considered only if it meets all of the applicable requirements of TSCA section 14. These include the requirements that:

- submitters "assert to the Administrator a claim for protection from disclosure concurrent with submission of the information" (section 14(c)(1)(A));
- the claim is accompanied by a statement that the criteria specified in section 14(c)(1)(B) are met;
- if a claim pertains to a chemical identity, the additional requirements of section 14(c)(1)(C) are met;
- unless the information falls into one of the categories specified under section 14(c)(2), the claim is substantiated in accordance with section 14(c)(3);
- the claim is accompanied by the certification specified under section 14(c)(5) that the information accompanying the claim is true and correct;
- EPA determines that none of the exceptions to protection from disclosure specified in section 14(d) are applicable; and
- EPA review any claim for information other than that falling into one of the categories specified under section 14(c)(2) in accordance with the requirements of

section 14(g) and determine that the claim meets all applicable requirements and warrants approval for the applicable period of time specified under section 14(e).

- Another part of the language on page 8 cited above is inaccurate (emphasis added):

> [T]o the extent that reported information is not considered to be CBI, environmental groups, environmental justice advocates, industry, *state and local government entities and other members of the public* may have access to this information for their own use.

This language fails to reflect TSCA's provisions for access to CBI by various entities:

- TSCA section 14(d)(4) explicitly provides state and local (as well as Tribal) government entities and certain other members of the public with access to CBI. 15 U.S.C. § 2613(d)(4).
- TSCA section 14(d)(5) explicitly provides certain "other members of the public" – specifically any "health or environmental professional employed by a Federal or State agency or tribal government or a treating physician or nurse in a nonemergency situation" – with the ability to gain access to CBI. 15 U.S.C. § 2613(d)(5).
- TSCA section 14(d)(6) also explicitly provides certain "other members of the public" – specifically any "treating or responding physician, nurse, agent of a poison control center, public health or environmental official of a State, political subdivision of a State, or tribal government, or first responder (including any individual duly authorized by a Federal agency, State, political subdivision of a State, or tribal government who is trained in urgent medical care or other emergency procedures, including a police officer, firefighter, or emergency medical technician)" – with the ability to gain access to CBI in the event of an emergency. 15 U.S.C. § 2613(d)(6).

The ICR must accurately reflect these provisions of TSCA.

- On pages 23, 26 and 28, EPA states:

> CBI substantiation to support confidentiality claims for relevant data elements for the overall submission throughout the testing period (see list of transactions in Table 4) must be provided in conjunction with the study plan transmittal. The CBI substantiations address chemical identity (chemID) and other data elements.

It is not at all clear on what basis EPA could consider the data elements or study plan pursuant to a section 4 action *not* to constitute health and safety information. This extends to chemical identity in the context of a submission of health and safety

information, which is not eligible for protection from disclosure except under very narrow circumstances delineated at the end of TSCA section 14(b)(2). 15 U.S.C. § 2613(b)(2).[17] As noted previously, such information is not eligible for protection from disclosure. EPA's reference to CBI substantiation – which applies only to claims for information eligible for CBI protection – erroneously implies that the data elements or study plan pursuant to a section 4 action are eligible and could be protected from disclosure – which would be contrary to TSCA.

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EDF appreciates the opportunity to provide comments and EPA's consideration of them.

[17] EDF has commented extensively on the general ineligibility for CBI protection of chemical identity in the context of submissions of health and safety information. See, for example, section 3 (pp. 7-13) of EDF's Comments on Needed Improvements to EPA's CBI Claim Reviews and Public Access to Information, submitted to EPA on January 24, 2020, available at https://www.regulations.gov/document?D=EPA-HQ-OPPT-2019-0637-0007.