Environmental Defense Fund Comments on
A Working Approach for Identifying Potential Candidate Chemicals for Prioritization
Docket ID: EPA-HQ-OPPT-2018-0659[1]

Submitted November 15, 2018

Environmental Defense Fund (EDF) appreciates the opportunity to provide comments to the Environmental Protection Agency (EPA) regarding its *A Working Approach for Identifying Potential Candidate Chemicals for Prioritization*.[2]

Environmental Defense Fund (EDF) previously provided comments on EPA's Approaches for Identifying Potential Candidates for Prioritization, submitted on January 25, 2018. EDF Comments on Approaches for Identifying Potential Candidates for Prioritization for Risk Evaluation Under Amended TSCA, https://www.regulations.gov/document?D=EPA-HQ-OPPT-2017-0586-0084. For the most part, those comments are still germane to EPA's Working Approach and EDF incorporates them by reference and reiterates those comments here.

These comments are organized into two main sections: 1) Comments primarily focused on EPA's proposed near-term approaches; and 2) Comments primarily focused on EPA's proposed long-term approach.

[1] https://www.regulations.gov/docket?D=EPA-HQ-OPPT-2018-0659.
[2] U.S. EPA, *A Working Approach for Identifying Potential Candidate Chemicals for Prioritization* (Sept. 27, 2018), https://www.epa.gov/sites/production/files/2018-09/documents/preprioritization_white_paper_9272018.pdf (hereinafter "Working Approach").

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COMMENTS ON EPA'S PROPOSED NEAR-TERM APPROACHES

1. EPA's priorities for identifying potential candidates for prioritization should include considerations of *risk*.

EPA's Working Approach identified three factors that EPA intends to consider for selecting candidates for prioritization in the near term: (1) priorities set by EPA and other agencies, (2) quantity and quality of information, and (3) EPA workload. *Id.* at 8-9. While these are relevant factors, the Working Approach remarkably fails to identify consideration of risk as one of the factors for selecting candidates for prioritization.

Congress expressly required EPA to only consider risk-based factors in the prioritization process:

> (A) ESTABLISHMENT OF PROCESS.—Not later than 1 year after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the Administrator shall establish, by rule, ***a risk-based screening process***, including criteria for designating chemical substances as high-priority substances for risk evaluations or low-priority substances for which risk evaluations are not warranted at the time.

15 U.S.C. § 2605(b)(1)(A). EPA correctly recognized in its Response to Comments that identification of candidates for prioritization should primarily be a risk-based approach.[3] In fact, in the Response to Comments, EPA referred to a risk-based approach as one of EPA's "guiding principles" for this activity.[4] Specifically, EPA stated:

> EPA agrees with the comments that the selection of candidates should be based on both hazard and exposure, as a risk-based approach is required under TSCA. One of EPA's guiding principles is that the approach to identifying potential candidates for prioritization should be risk-based, and therefore consider hazard and exposure in the prioritization process.

EPA must incorporate risk as the primary factor it will consider in its Working Approach.

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[3] U.S. EPA, *A Working Approach for Identifying Potential Candidate Chemicals for Prioritization Summary of Public Comments by Topic* at 6 (Sept. 27, 2018), https://www.epa.gov/sites/production/files/2018-09/documents/publiccommentssummary_dec11_preprioritization_927.pdf (hereinafter "Response to Comments").

[4] *Id.*

EPA's Working Approach acknowledges that using the 2014 Update to the TSCA Work Plan as a starting point for identifying high-priority candidates was the approach that garnered the most consistent support across stakeholders. While it appears that EPA *does* intend to use the 2014 Work Plan as a starting point for the near-term process, what is not clear is whether EPA intends to apply *any* risk-based criteria in its identification of candidates from this list. Does EPA plan to select chemicals from this list based solely on agency priorities, information sufficiency, and work load –ignoring the hazard and exposure data it previously referred to as the basis for a "guiding principle"?

Moreover, Congress created an express preference for chemicals meeting certain criteria in the 2014 Work Plan. 15 U.S.C. § 2605(b)(2)(D). EPA's Working Approach does not reference this preference or state that it intends to follow Congress's guidance in selection of high-priority chemicals. EPA should include those criteria as factors in selecting chemicals from the Work Plan.

In EPA's earlier Discussion Document, published in November 2017 in advance of a December 2017 public meeting, the agency presented five different options for utilizing the Work Plan:[5]

A. Use the 2014 Work Plan Chemicals
B. Integrate the 2014 Work Plan Methodology with high-throughput screening & *in silico* data streams to gather information and identify data needs and assess the chemical landscape (information gathering) for prioritization
C. Update data streams and criteria/factors used in the Work Plan methodology
D. Integrate activities using a sector analysis approach and functional use
E. Other Updates

EDF previously commented on these options, recommending that EPA use an augmented TSCA Work Plan approach to identify potential high-priority candidates (similar to Approach C above). We recommended that the TSCA Work Plan methodology be updated to incorporate statutory requirements it had not included – or not sufficiently addressed (e.g., exposure to children) – and to integrate new information. We incorporate and reiterate our earlier comments here by reference.[6]

[5] U.S. EPA, *Discussion Document Possible Approaches and Tools for Identifying Potential Candidate Chemicals for Prioritization* at 22-24, https://www.regulations.gov/document?D=EPA-HQ-OPPT-2017-0586-0003.
[6] EDF Comment on Discussion Document, https://www.regulations.gov/document?D=EPA-HQ-OPPT-2017-0586-0084.

EPA has provided no acknowledgement of or rationale for what appears to be its decision to abandon its earlier proposed approaches, in particular options B and C, despite the fact that many stakeholders supported an enhanced or augmented Work Plan approach.[7]

In the near term, we recommend that EPA consider the hazard and exposure information available for the 2014 Work Plan chemicals (e.g., the data that informed the exposure, hazard, and PBT scores) in its selection process of candidates for high-priority. This information is readily accessible and would allow EPA to utilize a risk-based decision framework in its process for selecting chemicals, which is necessary to ensure EPA first addresses chemicals that may present significant public health threats.

In the long term, we recommend that EPA utilize an augmented Work Plan approach, as we described in our earlier comments.

Finally, we must note there is considerable irony in EPA's proposal to consider the priorities set by other EPA offices and other agencies in identifying candidates for prioritization. This is because EPA's final Risk Evaluation Rule erroneously asserts authority for the agency to exclude from risk evaluations conditions of use that fall under the jurisdiction of another agency,[8] and EPA's problem formulations for the first 10 chemicals undergoing risk evaluation under TSCA erroneously exclude from those risk evaluations conditions of use or exposure pathways that fall under the jurisdiction of another EPA-administered statute.[9] Hence, for any chemical that receives a high-priority designation based in whole or in part on that chemical being a priority for another office or agency, the risk evaluation of that chemical could well exclude any evaluation of the very exposures and risks of the chemical that were of direct interest to that office or agency.

2. EPA should not limit its Working Approach to chemicals on the Public Inventory.

EPA's TSCA Inventory indicates that there are currently 18,120 chemicals on the confidential portion of the Inventory,[10] with the specific chemical identities having been claimed as confidential business information (CBI). The Working Approach improperly seems to presume that EPA will not consider any confidential chemicals for prioritization, since EPA does not even plan to address these chemicals in its "binning" proposal (which we object to for the reasons

[7] Response to Comments at 6.
[8] 82 Fed. Reg. 33726, 33730 (Jul. 20, 2017), https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0654-0108.
[9] FIRST TEN CHEMICALS FOR RISK EVALUATION, https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/risk-evaluations-existing-chemicals-under-tsca#ten (last visited Nov. 15, 2018).
[10] TSCA CHEMICAL SUBSTANCE INVENTORY, https://www.epa.gov/tsca-inventory/how-access-tsca-inventory#download (last visited Nov. 15, 2018).

given in section 9 below). Working Approach at 18. EPA should not categorically exclude confidential chemicals from consideration for prioritization. In particular, if evidence indicates that particular confidential chemicals are potential high-risk, then EPA should consider designating those chemicals as "high-priority."

Crucially, EPA has not provided any evidence or other indication that confidential chemicals pose any less of a potential risk to human health and the environment. And the standards for establishing that a particular chemical identity should be treated as confidential do not include any low-risk element that ensures that confidential chemicals are of low risk. *See* 15 U.S.C. § 2613(c)(1)(B)-(C). Therefore, EPA cannot presume that confidential chemicals are low-risk. Notably, much of the evidence that would establish that a particular chemical poses a risk must be disclosed as health and safety studies or underlying data that cannot be confidential under TSCA. 15 U.S.C. § 2613(b)(2).

Nonetheless, we recognize the value of focusing on information-heavy chemicals in the near-term, and given that confidential chemicals generally have less information available about them, it makes sense for most initial choices to be of non-confidential chemicals. For example, the identity of Work Plan chemicals are all public, and the Work Plan remains the most prominent source for high-priority chemicals, particularly given the preferences for Work Plan chemicals codified in the law. 15 U.S.C. § 2605(b)(2)(B), (b)(2)(D).

3. Inactive chemicals should be considered as potential candidates for prioritization.

TSCA clearly permits EPA to prioritize, evaluate, and manage inactive chemical substances under section 6. *See* 15 U.S.C. § 2605 (only referring to "chemical substances"). Therefore, when identifying candidates for prioritization, EPA should consider inactive chemicals. Yet EPA has indicated in its Working Approach that it will not consider inactive substances as candidates for prioritization in its near-term approach:

> [I]f chemicals are identified as potential candidates that are not on the 2014 Work Plan, EPA's intends to select chemicals on the TSCA Active Inventory.

Working Approach at 7. It also appears that EPA will not consider inactive chemicals for the long-term binning approach either:

> EPA is considering a longer-term approach to bin the remaining chemicals (those not included on the 2014 TSCA Work Plan) on the *TSCA active inventory*.

Id. at 6 (emphasis added). EPA similarly stated in the Response to Comments that:

> At this time, EPA plans to focus on the active TSCA inventory. EPA believes this is a more effective use of resources, and a more effective strategy to identify those chemicals that may currently pose risk under their conditions of use.

Response to Comments at 10. To the extent EPA moves forward with its long-term binning approach, *see* section 9 below, EDF disagrees with such an exclusive focus on active chemicals. EDF has previously commented on this issue, and incorporates by reference and reiterates the comments submitted on EPA's Approaches for Identifying Potential Candidates for Prioritization at 17-18, https://www.regulations.gov/document?D=EPA-HQ-OPPT-2017-0586-0084. EDF and other groups have also further developed these arguments in a Brief. Safer Chems., Healthy Families v. U.S. EPA, Case No. 17-72260, ECF No. 44-1 at 45-46, https://www.edf.org/sites/default/files/Petitioners_Opening_Brief.pdf. EDF incorporates by reference and reiterates those points here as well.

In sum, EPA's Working Approach entirely ignores that "inactive" chemicals can and should undergo prioritization and risk evaluation. TSCA section 6 authorizes inactive chemicals to be prioritized and evaluated because they constitute "chemical substances," and the relevant provisions make no reference to the date when the chemicals were manufactured or processed. 15 U.S.C. § 2605. In contrast, section 8 of TSCA distinguishes between "active" chemicals, which have been manufactured or processed during the ten years prior to June 22, 2016, and "inactive" chemicals, which have not. 15 U.S.C. § 2607(b)(4)(A)(i)-(iii). EPA must give significance to the intentional distinctions between sections 6 and 8. *See Russello v. United States*, 464 U.S. 16, 23 (1983).

Notably, elsewhere EPA itself does not dispute that inactive chemicals can be prioritized and evaluated under section 6. In the Final Prioritization Rule, EPA correctly stated that inactive chemicals could be subject to prioritization:

> Chemicals that are designated as "inactive" pursuant to the Active/Inactive Inventory rule (RIN 2070-AK24) are still chemicals *[sic]* substances on the TSCA Inventory, and therefore subject to prioritization. Nothing in TSCA prohibits EPA from initiating the prioritization process on an "inactive" chemical substance and ultimately from designating the priority of that chemical substance.[11]

Unable to explain away the statutory text, EPA suggests in its Working Approach that it can ignore inactive chemicals because active chemicals are more likely to "currently pose risk under their conditions of use." Response to Comments at 10. EPA's exclusive focus on active chemicals appears to mirror EPA's unlawful reason for ignoring "legacy activities" in the Final

[11] 82 Fed. Reg. 33753, 33756 (Jul. 20, 2017).

Risk Evaluation Rule. 82 Fed. Reg. 33,726, 33,729-30 (Jul. 20. 2017) (ignoring "legacy activities" to focus on chemicals with only "ongoing" manufacturing, production, and distribution). As EDF has previously explained, however, there is no legal or logical basis for ignoring legacy activities. EDF Comments on Ten Scopes under the Toxic Substances Control Act pp. 4-11, https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0743-0069; EDF Comments on Ten Problem Formulations pp. 21-22, https://www.regulations.gov/document?D=EPA-HQ-OPPT-2018-0210-0066 ("Past conditions of use are known to have occurred in the past and are certainly reasonably foreseen conditions of use, absent compelling evidence that they will not resume.").

Moreover, in amending TSCA, Congress was clearly aware that:

> [T]here may be exposures of concern from substances that are not currently or no longer in commerce, and the section provides EPA authority to prioritize inactive substances that meet certain criteria.

S. Rep. No. 114-67, at 11. Thus, EPA's reason for ignoring inactive chemicals based on the assumption that they do not "currently pose" risk is also contrary to Congress' understanding of the potential or actual risks posed by inactive chemicals.

As EDF previously explained in its comments, there are examples of inactive chemicals that "currently pose" risk. For instance, PBDE flame retardants were largely phased out of use in the mid-2000s due to evidence of health impacts, such as adverse neurological development, and persistence in the environment. However, ongoing use and exposure continue to be widespread. PBDEs can still be found in upholstered furniture, electronic devices such as televisions, and other consumer products still in use and in new imported products.[12].

One study estimated that flame retardants have been added to hundreds of millions of everyday foam products in the U.S., such as couches and foam baby products.[13] National biomonitoring by the Centers of Disease Control (CDC) demonstrates that most people have PBDEs in their

[12] Notably, EPA has never finalized the SNUR that it originally proposed for deca BDE and other PBDEs in 2012, 77 Fed. Reg. 19,861 (April 2, 2012). The SNUR would have required people to notify EPA before manufacturing or processing deca BDE or importing articles containing it or six other PBDEs. Thus, at present, a person could recommence manufacture or processing of deca BDE for its old uses at any time. And articles containing it or six other PBDEs can be imported without triggering prior notification to EPA.

[13] Betts, K. S. "Hand-Me-Down Hazard: Flame Retardants in Discarded Foam Products." *Environ Health Perspect* (2015) Vol 123(31): A56-A63. Available: https://ehp.niehs.nih.gov/123-a56/.

blood and body fat,[14] and a study conducted by UCSF in 2011 demonstrated that 99% of pregnant women have PBDEs in their bodies.[15] Nowhere in its Working Approach or its Response to Comments did EPA address the fact that there are inactive chemicals that clearly pose current or potential risks to human health and the environment, and therefore should be considered for prioritization.

4. Chemicals listed on the Work Plan should carry a presumption of high-priority.

In its Working Approach, EPA states that it "is not bound by the findings of the 2014 Work Plan," and EPA implies that Work Plan chemicals do not carry a presumption of high-priority status. Working Approach at 6-7. While EDF recognizes that, other than the first 10 substances already identified pursuant to TSCA section 6(b)(2)(A), all chemicals will need to go through the same prioritization process, EDF believes that it should be an extremely rare case that a chemical identified on the 2014 EPA Work Plan would not qualify as a high priority substance. Both legally and as a factual matter, identification on the 2014 Work Plan creates a presumption that the chemical is a high-priority substance.

Legally, TSCA requires that, within 3.5 years of enactment, at least 50% of the 20 or more ongoing risk evaluations are to be for chemicals drawn from the 2014 update of the TSCA Work Plan. 15 U.S.C. § 2605(b)(2)(A). EPA has recognized that "[b]y operation of this statutory directive, all TSCA Work Plan chemical substances will eventually be prioritized." 82 Fed. Reg. 33,753, 33,758 (Jul. 20, 2017); 40 C.F.R. § 702.5(c)(2). And this statutory directive presumes that most Work Plan chemicals will be designated high-priority and therefore be subject to risk evaluations; the directive specifies that 50% of risk evaluations, not prioritization decisions, must be conducted on Work Plan chemicals. Therefore, Congress clearly intended that Work Plan chemicals would generally be designated high-priority substances requiring risk evaluations.

Factually, Work Plan chemicals were selected based on "a combination of hazard, exposure (including via uses), and persistence and bioaccumulation characteristics."[16] EPA described the process as focusing on the following factors:

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[14] CDC, National Biomonitoring Program, *Biomonitoring Summary: Polybrominated Diphenyl Ethers and 2,2',4,4',5,5'-Hexabromobiphenyl (BB-153)*, https://www.cdc.gov/biomonitoring/PBDEs_BiomonitoringSummary.html.

[15] Tracey J. Woodruff, et. al., *Environmental Chemicals in Pregnant Women in the United States: NHANES 2003-2004*, 119:6 ENVTL. HEALTH PERSPECT. 878-885 (2011), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3114826/.

[16] U.S. EPA, *TSCA Work Plan for Chemical Assessments: 2014 Update* at 2 (Dec. 2014), https://www.epa.gov/sites/production/files/2015-01/documents/tsca_work_plan_chemicals_2014_update-final.pdf (hereinafter "Work Plan").

- Potential concern for children's health (for example, because of reproductive or developmental effects)
- Neurotoxic effects
- Persistent, bioaccumulative and toxic
- Probable or known carcinogens
- Used in children's products or in products to which children may be highly exposed
- Detected in biomonitoring programs.

Work Plan at 2. Thus, these chemicals were identified based on evidence of significant hazard and exposure potential. Chemicals meeting these criteria generally would merit designation as high-priority because such chemicals almost always "may present an unreasonable risk of injury to health or the environment because of a *potential* hazard and a *potential* route of exposure under the conditions of use, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by the Administrator." 15 U.S.C. § 2605(b)(1)(B)(i) (emphases added).

EPA suggests that "science approaches have evolved and additional information has been developed for chemicals on the 2014 Work Plan." Working Approach at 7. While EPA should always consider all reasonably available information, including new information, the information available at the time of the 2014 Work Plan remains relevant and counsels in favor of designation of these chemicals as high-priority. Moreover, Congress repeatedly relied on the Work Plan as a basis for action in the statute, indicating that Congress viewed the science underlying the Work Plan as reliable and relevant. *See, e.g.*, 15 U.S.C. § 2605(b)(2)(D). For example, Congress required that EPA take immediate action without requiring risk evaluations to regulate certain persistent, bioaccumulative, and toxic chemicals based on their Work Plan scores. 15 U.S.C. § 2605(h). Congress would not have mandated expedited action on Work Plan chemicals if Congress had lacked confidence in the science underlying the Work Plan.

Moreover, in selecting high-priority candidates, TSCA provides that EPA must give preference to chemicals with certain criteria on the Work Plan. Specifically,

> In designating high-priority substances, the Administrator shall give preference to--
> (i) chemical substances that are listed in the 2014 update of the TSCA Work Plan for Chemical Assessments as having a Persistence and Bioaccumulation Score of 3; and
> (ii) chemical substances that are listed in the 2014 update of the TSCA Work Plan for Chemical Assessments that are known human carcinogens and have high acute and chronic toxicity.

15 U.S.C. § 2605(b)(2)(D). EPA must follow this directive in selecting its next high-priority candidates.

For these reasons, EPA should generally presume that chemicals on the 2014 Work Plan are high-priority substances.

5. EPA's Working Approach must include plans for utilizing its mandatory information authorities under TSCA.

EPA has failed to lay out any plan to utilize its mandatory information authorities in its Working Approach for Identifying Potential Candidate Chemicals for Prioritization. Although EPA acknowledges that it has such authorities under TSCA, EPA mentions them only once in the entire document:

> When information gaps are identified, ideally those gaps would be filled early in the process to allow EPA to complete its screening review by the statutory deadline. Identifying information gaps and needs before a chemical enters prioritization is an important component of pre-prioritization and prioritization. The Agency has authorities under TSCA sections 4, 8, and 11 to gather information and request data to fill data gaps.

Working Approach at 4-5. Rather than identify any plan or even intent to actually use its authorities under TSCA sections 4, 8, or 11, EPA refers only to a "public notification" process it plans to use for obtaining information under the Working Approach. *Id.* at 8, 14. Nowhere in the document does EPA explain what this process consists of, or why it would be sufficient to obtain all reasonably available information, in compliance with section 26 of TSCA. EPA's Response to Comments briefly suggests that this public notification process includes "issu[ing] a voluntary call to the public for relevant information or engag[ing] directly with stakeholders," but provides no further explanation. Response to Comments at 21.

EPA's proposal to adopt this approach fails to address EDF's prior comments to EPA that explained how EPA's repeated attempts to use voluntary means of obtaining information have been largely ineffective. EDF Initial Comments on § 6(h) PBTs under the Toxic Substances Control Act, Comment at pp. 12-13, https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0730-0014. EDF incorporates by reference and reiterates those earlier comments here.

EPA has never explained how the failures in the following programs do not argue that EPA needs to develop a plan to require mandatory development and submission of information:

- An EPA advisory committee called for the development of nanomaterial reporting rules in 2005, but EPA instead spent several years developing and carrying out a voluntary

reporting program, the Nanoscale Materials Stewardship Program (NMSP). This voluntary reporting program produced minimal information as revealed by EPA's 2009 interim report on the NMSP.[17] "[I]n the report EPA estimated that companies provided information on only about 10 percent of the chemical substances manufactured at the nanoscale that may be commercially available in 2009." 80 Fed. Reg. 18,330, 18,334 (April 6, 2015). In 2017, over a decade after the information need was identified, EPA finally finalized a § 8(a) reporting rule to acquire the information. 82 Fed. Reg. 3641 (Jan. 12, 2017).

- EPA's Voluntary Children's Chemical Evaluation Program (VCCEP) asked companies to voluntarily "sponsor" specific chemicals and disclose data in order for EPA to characterize health risks to children from certain chemical exposures. According to a 2011 Office of Inspector General (OIG) Report, of the 23 chemicals identified in the program, EPA received sufficient data to assess chemical risks for only 6 of the chemicals over a 10-year period.[18] The OIG Report specifically noted that "[p]rogrammatic effectiveness was hampered by industry partners who chose not to voluntarily collect and submit information, and EPA's decision not to exercise its regulatory authorities under [TSCA] to compel data collection." *Id*. at 3. OIG explicitly recommended that EPA "appl[y] [TSCA] regulatory authorities as appropriate for data collection." *Id*.

- EPA's High Production Volume (HPV) Chemical Challenge program, which started in 1998, was based on companies' sponsorship of chemicals they produced, which entailed a commitment to develop and make public a "base set" of screening-level hazard information on chemicals produced in or imported into the United States in amounts of one million pounds or more annually. However, an EDF report written nine years later and over a year after the submission deadline noted that less than half of the data sets had been submitted and much of the data submitted was incomplete. Richard Denison, High Hopes, Low Marks (July 2007), https://www.edf.org/sites/default/files/6653_HighHopesLowMarks.pdf.

During the public comment process on EPA's Working Approach, EPA must clearly address: (1) the flaws with its prior attempts at voluntary information submissions and how EPA intends to remedy them, (2) how it will use its mandatory information authorities under TSCA, and (3) to the extent that EPA accepts voluntarily submitted information, how EPA plans to ensure completeness, accuracy, and access to all information.

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[17] U.S. EPA, OPPT, *Nanoscale Materials Stewardship Program, Interim Report* (Jan. 2009), https://www.regulations.gov/document?D=EPA-HQ-OPPT-2010-0572-0003.

[18] U.S. EPA OIG, *EPA's Voluntary Chemical Evaluation Program Did Not Achieve Children's Health Protection Goals* 13 (2011), https://www.epa.gov/office-inspector-general/report-epas-voluntary-chemical-evaluation-program-did-not-achieve-childrens.

6. EPA should not rely on its obsolete CHAMP program to identify candidates for low-priority designations.

EPA states that it may identify candidates for low-priority designations using its long-abandoned Chemical Assessment Management Program (ChAMP). Working Approach at 15. This questionable risk characterization program was abandoned by EPA in 2009. This step came after EPA was criticized over, among other things, its over-reliance on exceedingly limited chemical use and exposure information to exonerate even high-hazard chemicals, and a failure to transparently identify and use its information authorities to fill the major gaps in, and address the poor quality of, the hazard data on the chemicals being characterized, despite previous commitments to do so.[19]

EDF carefully reviewed many of ChAMP's "risk characterizations" and identified major flaws in each of them, detailed analyses that we published in a series of blog posts and other documents.[20] One illustration of our concerns was that EPA would assign a low-priority ranking to a chemical it deemed low-hazard regardless of the extent of data gaps and even where its exposure ranking was high. As of April 2009, of the 212 chemicals for which EPA had made prioritization decisions based on its risk characterizations, EPA had ranked 150 of them low-risk, 56 of them medium-risk, and only 6 of them high-risk.

It appears that most or all of EPA's ChAMP-related documents, including its risk characterizations, have been removed from its website.[21]

EDF does not support the resurrection of this obsolete, flawed program to serve as a basis for identifying candidates for low-priority designations.

7. EPA's TSCA Systematic Review document is seriously and significantly flawed and should not be used in selecting candidates for prioritization.

In the Working Approach document, EPA states that:

> TSCA requires that EPA use information in a manner consistent with the best available science and that EPA base decisions on the weight of the scientific

[19] *See* Richard Denison, *ChAMP: Not exactly a heavyweight*, EDF HEALTH BLOG (Apr. 20, 2009), http://blogs.edf.org/health/2009/04/20/champ-not-exactly-a-heavyweight/.
[20] *See* EDF OVERSIGHT OF PAST EPA CHEMICAL PROGRAMS, https://www.edf.org/health/policy/chemical-testing-and-assessment (last updated May 2017).
[21] EPA's hazard characterizations of high-production volume (HPV) chemicals, which were the TSCA office's focus prior to launching ChAMP and continued for some time after ChAMP was superseded in 2009 by the Obama Administration's Enhanced Chemicals Management Program, are available through its ChemView database, are available at https://chemview.epa.gov/chemview.

> evidence. Through the prioritization and risk evaluation process, EPA plans to use a step-wise approach that is consistent with the TSCA science standards. When gathering information to support the priority designation, EPA plans to integrate elements of quality in the data eligibility criteria during the screening process.
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> The initial emphasis will be the exclusion of unacceptable data sources based on data quality criteria outlined in the Application for Systematic Review in TSCA Risk Evaluations EPA document.[36] Specifically, these criteria identify serious flaws that would make the information unreliable to use for risk evaluation purposes.[37]

Working Approach at 13. EDF submitted extensive comments to EPA on its Application of *Systematic Review in TSCA Risk Evaluations* (*TSCA Systematic Review Document). See* EDF Comments on Application of System Review in TSCA Risk Evaluations (August 16, 2018), https://www.regulations.gov/document?D=EPA-HQ-OPPT-2018-0210-0077. EDF fully incorporates and reiterates those earlier comments here by reference.

EPA OPPT's TSCA systematic review document deviates significantly from best practices in systematic review—practices that are empirically-based and have been scientifically reviewed, vetted, and instituted by other agencies and authoritative scientific bodies. As discussed extensively in EDF's previous comments, EPA OPPT's TSCA Systematic Review document is inconsistent with use of the best available science and application of a weight-of-the-scientific-evidence approach as required under TSCA for carrying out sections 4, 5, and 6 of TSCA.

EPA OPPT's current approach to systematic review will lead to violations of EPA's science obligations under TSCA § 26(h), (i), and (k). These directives require that EPA must consider all reasonably available information, and that EPA then must make decisions reflecting the "best available science" and "weight of the scientific evidence" based on the body of evidence as a whole. These statutory commands in TSCA repeatedly emphasize that EPA must make decisions based on the information that is "available," and the courts have recognized that such a duty requires action on the basis of available information even if that information is imperfect. Nevertheless, EPA has crafted its systematic review process to incrementally exclude available information study-by-study, with the possibility of prohibiting use of the best available science simply because one or more of the underlying studies is imperfect in some manner.

With regard to EPA's Working Approach, EDF strongly opposes EPA's decision to rely on data quality criteria outlined in OPPT's TSCA Systematic Review document when gathering and reviewing information to support priority designations. As designed, these criteria will result in the erroneous exclusion of information important to understanding potential chemicals risks.

Specifically, a number of data quality criteria incorrectly and inappropriately conflate study reporting with study quality in a manner that will result in the exclusion of entirely relevant information based on reporting deficiencies rather than actual study quality.

Best practices in systematic review strongly advise against conflating issues of reporting and other aspects of study quality when assessing individual studies. In fact, at points in its TSCA Systematic Review document, OPPT acknowledges the need to delineate between reporting and study quality: "Reporting quality is an important aspect of a study that needs to be considered in the evaluation process. The challenge, in many cases, is to distinguish a deficit in reporting from a problem in the underlying methodological quality of the data/information source." Working Approach at 31.

However, OPPT ultimately chose an approach that deviates from this established best practice: "The TSCA evaluation strategies incorporate reporting criteria within the existing domains rather than adding a separate reporting domain as recommended in some evaluation tools/frameworks." *Id.* at 31.

EPA's decision to conflate reporting issues with study quality and comingle their consideration is significant. For each type study or information source, OPPT's systematic review methodology proscribes a set of data quality evaluation domains that each contain a series of data quality metrics against which the information source is evaluated. The profusion of reporting quality considerations in metrics used to evaluate epidemiological studies provides perhaps the best showcase of the seriousness conflation of reporting and study quality. For several of the metrics used to evaluate epidemiological studies, the absence of a STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) reporting checklist item results in a metric score of unacceptable. A score of unacceptable in a single metric across any data quality domain results in the exclusion of an entire information source or study. Similarly, EPA includes the STROBE checklist items in the list of "serious flaws" for epidemiological studies. This is wholly inconsistent with best practices in systematic review, departs from best available science, and would likely result in EPA not using reasonably available information.

EPA should not rely on the OPPT TSCA Systematic Review document as currently written to carry out any activities under TSCA including all those associated with chemical prioritization. Instead, OPPT must subject the TSCA systematic review document to peer review by established experts in the field, given:

1) the substantial digression from best practices in systematic review;
2) EPA's decision not to adopt leading systematic review approaches for chemical assessment that have been peer reviewed and developed in consultation with systematic review experts; and

3) the significant uncertainty associated with the outcome of applying its approach, including the serious implications for chemical prioritization, risk evaluation, and risk determination.

More broadly, EPA should not exclude relevant chemical information at this very early stage in the chemical evaluation process. Instead, EPA should consider and provide for public consideration all relevant chemical information, even if imperfect, during the chemical prioritization process. Such information is valuable for indicating what types of exposures or hazards may be relevant for a substance under review, and for informing where EPA should employ its information authorities. EPA should wait until the risk evaluation phase to conduct a more robust review of the quality of the evidence using a legitimate systematic review process.

8. EPA should not provide industry an "enhanced stakeholder role" given the clear conflicts of interest and the failures in the past of industry-sponsored programs to yield, credible, complete information.

On page 16 of the Working Approach, EPA states (emphases added):

> *Stakeholders suggested* that, after information from designating the required 20 low-priority chemicals is publicly available, *they may wish to volunteer to sponsor* the development of information that could be used by EPA to identify candidates that may be designated as low-priority chemicals, beyond the required 20. The experience that EPA and stakeholders gain in designating the first 20 low-priority chemicals could set the stage for an *enhanced stakeholder role* in designation of additional substances. Similarly, the experiences EPA and stakeholders gain in designating the first 20 high-priority chemicals could also set the stage for an *enhanced stakeholder role*.

EPA's reference to "stakeholders" is misleading, as the only stakeholders making such comments were from the chemical industry. Unfortunately, a disturbing pattern has emerged under this Administration in which EPA refers to comments supporting an EPA position on an issue that were advanced only by the industry as coming from "stakeholders," omitting or failing to mention the source or alternative viewpoints offered by other "stakeholders."

While it should be obvious, the chemical industry has a clear conflict of interest in decisions about which chemicals are identified as candidates for low- or high-priority substances. EPA's suggestion that it will provide industry an "enhanced role" in the designation of such substances is nothing less than appalling.

It also flies in the face of the evidence from initiatives in the past under which industry interests were asked or allowed to "sponsor" chemicals. Section 5 of these comments details the pattern

of those programs failing to deliver on their promises, including their failure to yield credible or complete information on the chemicals companies agreed to sponsor.

Instead of abdicating its responsibilities and authorities by resorting to enhanced stakeholder roles for industry in selecting the priority to be assigned to a chemical, and to voluntary industry sponsorship programs to fill information gaps, EPA should do the job Congress intended it to do and actually utilize the enhanced mandatory information authorities provided in the 2016 amendments to TSCA – authorities it has yet to even hint at using, two and a half years after the passage of those reforms.

COMMENTS ON EPA'S PROPOSED LONG-TERM APPROACH

9. EPA should not pursue its proposal to "bin" the TSCA Inventory.

For the reasons given below, EDF strongly opposes EPA's proposal to bin the TSCA Inventory.

a. Nothing in TSCA mandates or authorizes binning of the TSCA Inventory.

The 2016 amendments to section 6 of TSCA set forth in considerable detail the processes Congress expects EPA to use to identify chemicals that warrant or do not warrant further evaluation to determine whether they present unreasonable risk to health or the environment, as well as the processes EPA is to use in conducting those risk evaluations. None of those provisions calls for or requires anything remotely approaching EPA's wholly new proposal. EPA also promulgated rules governing the processes of prioritization and risk evaluation. While those rules have numerous serious flaws that are the subject of ongoing litigation, they too contain no provisions dependent on, requiring, or otherwise calling for EPA's new proposal. EPA has hatched this proposal, therefore, out of whole cloth. It is not authorized by TSCA.

In EPA's earlier discussion document on "pre-prioritization,"[22] the agency proposed a limited "binning" (Approach 6, NAMs), but that approach involved only binning two limited lists of chemicals: 1) the TSCA Work Plan list, and 2) the Safer Chemical Ingredients List (SCIL). EPA has given no compelling rationale in its Working Approach document as to why it has decided to expand radically the binning exercise from several hundred chemicals to tens of thousands.

EPA asserts as justification for its proposal that "[o]ther countries, (e.g., Canada) are undertaking similar exercises." Working Approach at 16. This is not the case. In marked contrast to EPA's

[22] U.S. EPA, *Discussion Document Possible Approaches and Tools for Identifying Potential Candidate Chemicals for Prioritization*, https://www.regulations.gov/document?D=EPA-HQ-OPPT-2017-0586-0003.

proposal, Canada's "categorization" of its existing substances inventory was mandated by law, specifically the 1999 amendments to the Canadian Environmental Protection Act (CEPA). CEPA specified and directed the government to apply particular criteria to identify chemicals of concern warranting further scrutiny. The categorization process required two government agencies (Environment Canada and Health Canada) seven years and enormous resources to complete. The European Union engaged in an extended legislative process to adopt its REACH Regulation in 2006, which called for the registration of all substances in commerce produced in volumes of one metric ton or more. That registration process, which has entailed extensive expenditures of resources by the European Chemicals Agency (ECHA) and EU Member State governments, has played out over 12 years, with the final deadline falling at the end of May of this year. The process of evaluating those chemicals, driven by detailed criteria established by law to identify chemicals of concern, will play out over many more years.

These statutorily mandated actions using statutorily mandated criteria, both aimed at identifying chemicals of concern, differ fundamentally from EPA's proposal for binning the TSCA Inventory.

b. Nothing in TSCA requires binning of the TSCA Inventory.

TSCA mandated a quite modest pace for EPA both to identify chemicals warranting or not warranting evaluation and to conduct evaluations of those warranting one, and anticipates an approximate balance in the pace at which high- and low-priority substance designations are made. Section 6(b)(2)(B) states:

> Not later than three and one half years after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the Administrator shall ensure that risk evaluations are being conducted on at least 20 high-priority substances and that at least 20 chemical substances have been designated as low-priority substances.

15 U.S.C. § 2605(b)(2)(B). The limited magnitude and pace Congress set for EPA's prioritization and risk evaluation of chemicals in commerce neither requires nor provides any justification for EPA's proposal to bin the entire TSCA Inventory. Even well into the future, therefore, EPA will need to have identified at most a few hundred chemicals under TSCA's prioritization and risk evaluation processes. This obviates any need for EPA to undertake a review of the tens of thousands of chemicals on the Inventory. Binning would entail a scale of chemical "reviews" far in excess of what is needed and called for under TSCA to ensure its mandates for low-and high-priority designations and risk evaluations can be met.

c. EPA should not divert its already stretched-thin and limited TSCA resources to undertake an exercise not mandated under TSCA.

Stakeholders across the spectrum have raised concerns about EPA's failures to carry out its mandatory duties under TSCA. To cite just a few of many examples:

- The chemical industry has repeatedly complained about EPA's backlog in conducting new chemicals reviews under section 5,[23] and EPA has repeatedly sought to divert more of its resources to that work, including recently shifting staff working on existing chemical risk evaluations to conduct new chemical reviews.
- EDF has repeatedly raised concerns about EPA's lack of progress in meeting its mandates under section 14 to require substantiations of confidential business information (CBI) claims, review those claims, make public its determinations on those claims, and assign unique identifiers to confidential chemical identities. We have also raised concerns about EPA's slow provision for access to CBI by state and local governments, health and environmental professionals and others authorized to have such access under section 14.[24] In response, EPA has routinely cited its limited resources and other competing priorities in implementing TSCA as the major reason for the delays and deferrals of its actions.
- EPA's problem formulations for the first 10 chemicals to undergo risk evaluations under TSCA indicate that EPA will exclude from those risk evaluations even known conditions of use and exposure pathways, which EPA justifies in part by invoking its limited resources. As EDF explained in its comments on those problem formulations, as a matter of law, EPA must analyze those known conditions of use and exposure pathways under TSCA, and EPA should devote resources to that effort.[25]
- The full release of chemical manufacture, processing and use information EPA collected under its Chemical Data Reporting (CDR) Rule in 2016 has yet to be made public, more than two years after it was collected.

Yet EPA is now proposing to divert scarce resources away from these and other needed actions and instead spend them on an activity that is neither mandated nor needed to fulfill its duties under TSCA.

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[23] See, for example, industry participants comments in this transcript of an EPA public meeting: https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0658-0009.

[24] *See* Richard Denison, *EPA practices are hindering transparency and public confidence in TSCA's new chemicals program*, EDF BLOG (Apr. 23, 2018), http://blogs.edf.org/health/tag/confidential-business-information-cbi-2/.

[25] EDF Comments on the First Ten Problem Formulations, https://www.regulations.gov/document?D=EPA-HQ-OPPT-2018-0210-0066.

d. EPA has seriously underestimated the resources needed to fulfill its mandatory duties under TSCA, including those it is not adequately fulfilling.

In the context of proposing and finalizing its user fee rule, EPA provided estimates of activities it is mandated to undertake under TSCA. In EDF's extensive comments on the proposed rule,[26] we identified EPA's many serious omissions and underestimates of needed resources, which in turn led EPA to set fees at lower levels than warranted and authorized by Congress, further exacerbating budget limitations and making it even more difficult for the agency to meet its mandates under the law. Under these circumstances, EPA has no business pursuing activities that are not mandated under TSCA and have a tenuous connection at best to meeting its many TSCA obligations.

e. There is no indication EPA has budgeted the resources needed to carry out the proposed binning.

EPA's fee rule claims it has included estimates of agency costs for "identifying potential candidates for prioritization" under TSCA section 6.[27] However, there is no mention beyond that one sentence, and no actual estimate for that activity was provided either in the proposed or final rule or in any of the associated documents included in the rulemaking docket.[28] EDF has found no other indication that EPA has included in its budget, or even estimated, the resources it has and plans to dedicate to this pre-prioritization activity, let alone for the binning exercise it now proposes. EPA certainly has not made available any such budget numbers or estimates to indicate how much EPA expects or intends to spend on the binning activity, precluding the public from having any ability to understand the magnitude of the proposed undertaking and weigh its costs against any possible benefits. EPA has also not set forth any convincing account of any benefits that it believes will result from this binning activity.

f. EPA's proposal to use binning as a means to "set aside" chemicals as "not containing candidates for high-priority designation" is contrary to TSCA's process and criteria for doing so and subverts Congress' intent to ensure EPA uses a rigorous process to set aside chemicals.

On page 17 of its Working Approach, EPA states (emphases added):

> While the approach of binning the TSCA inventory will help to reduce the size of the pool from which the EPA will draw chemicals for potential prioritization, *its purpose is*

[26] EDF Comments on the Fee Rule, https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0401-0059.
[27] 83 Fed. Reg. 52,701 (Oct. 17, 2018), https://www.federalregister.gov/documents/2018/10/17/2018-22252/fees-for-the-administration-of-the-toxic-substances-control-act.
[28] *See* https://www.regulations.gov/docket?D=EPA-HQ-OPPT-2016-0401.

> *not to identify a list of high-priority candidates. Nor is its purpose to signal that the EPA has concerns with particular chemicals or categories of chemical substances*. The starting point of the TSCA Active Inventory is still a large set of tens of thousands of chemicals. Through the approach, EPA will attempt to identify a portion of the Active Inventory that *can be set aside as not containing candidates for high-priority designation*, so that EPA can focus on chemicals that are most likely to meet the statutory standard of high priority chemicals.

This paragraph makes clear that EPA's purpose in binning is to "set aside" chemicals and not subject them to further scrutiny. There is no statutory basis, however, nor is there any reason or need, for EPA to create a new means to "set aside" chemicals as "not containing candidates for high-priority designation." The 2016 TSCA amendments already include such a mechanism: the authority and mandate for EPA to designate certain chemicals as low-priority substances.

Crucially, Congress has already spoken directly to this issue by creating a process for designating chemicals low-priority. EPA cannot ignore that direction by creating a new process for setting aside chemicals when EPA's alternative process lacks all of the statutory criteria and protections designed to govern that process. EPA's actions in doing so are contrary to law.

Section 6(b)(1)(A) of TSCA already establishes a risk-based process by which EPA is to set aside "low-priority substances *for which risk evaluations are not warranted at the time*." 15 U.S.C. § 2605(b)(1)(A) (emphasis added) And section 6(b)(1)(B)(ii) specifies that a low-priority substance is one that "does not meet the standard ... for designating a chemical substance a high-priority substance."

This aspect of TSCA reform was highly controversial, with many stakeholders concerned that EPA could use the low-priority designation process to prematurely exonerate many chemicals based on limited information and thereby indefinitely or even permanently put them off-limits to the process called for under TSCA to actually evaluate their potential risks.[29] To guard against these possibilities, Congress included several critical limits on EPA's process to designate low-priority substances. Among them:

- MANDATORY SUBSTANTIVE CRITERIA: Such designations must be based on a "risk-based screening process" that considers a number of explicit factors, including a

[29] *See, e.g.*, S. Comm. Hearing (March 18, 2015), https://www.epw.senate.gov/public/index.cfm/hearings?Id=60D1E265-CDAC-7629-3385-2D72DD8FE3EB&Statement_id=EC75BCAE-D5D2-4BC6-AA93-91DE73162246; Testimony of Michael Belliveau before the S. Comm. (Mar. 12, 2014), http://www.ourhealthyfuture.org/sites/default/files/pdfs/belliveau_testimony_-_chemicals_in_commerce_act_discussion_draft.pdf.

consideration of "hazard and exposure potential," "consideration of persistence and bioaccumulation, potentially exposed or susceptible subpopulations and storage near significant sources of drinking water," "the conditions of use or significant changes in the conditions of use of the chemical substance," and "the volume or significant changes in the volume of the chemical substance manufactured or processed." 15 U.S.C. § 2605(b)(1)(A).

- SUFFICIENT INFORMATION: Such designations have to be "based on *information sufficient* to establish, without consideration of costs or other nonrisk factors, that such substance does not meet the standard ... for designating a chemical substance a high-priority substance." 15 U.S.C. § 2605(b)(1)(B)(ii) (emphasis added).
- JUDICIAL REVIEW: Such designations can be judicially challenged by any person. 15 U.S.C. § 2618(a)(1)(C).
- MODEST PACE OF DESIGNATION: TSCA anticipates an approximate balance in the pace at which high- and low-priority substance designations are made by indicating that EPA should make 20 of each type of finding within three and a half years of enactment 15 U.S.C. § 2605(b)(2)(B).
- PUBLIC NOTICE AND COMMENT: TSCA requires that EPA "publish each proposed designation of a chemical substance as a high- or low priority substance, *along with an identification of the information, analysis, and basis used to make the proposed designations, and provide 90 days for public comment on each such proposed designation*." 15 U.S.C. § 2605(b)(1)(C)(ii) (emphasis added).

EPA's binning proposal, as conceived, includes none of these safeguards (though the courts may ultimately conclude that binning decisions are subject to judicial review). Indeed, it appears to be an effort to install a new parallel process, outside of TSCA's statutory boundaries, that EPA will use to set aside thousands of chemicals from any further review indefinitely and with no recourse for the public.

Despite EPA's assertion that "[o]ther countries, (e.g., Canada) are undertaking similar exercises," Working Approach at 16, EPA's stated purpose of identifying chemicals that can be set aside is wholly different from that of both Canada's and the EU's processes, which were aimed at identifying chemicals of concern in order to subject them to further scrutiny.

10. EPA's calculation of a binning score to identify candidate chemicals for prioritization over the long-term introduces several problems.

EPA's long-term approach to identifying candidate chemicals for prioritization involves binning the entire non-confidential portion of the TSCA inventory, by assigning a "binning score" to each chemical. EPA would calculate the binning score by evaluating chemicals across five components: Human Hazard-to-Exposure Ratio, Genotoxicity, Ecological Hazard, Susceptible Population, and Persistence/Bioaccumulation. EPA indicates that "[t]he five components would

be numerically scored and then combined to provide an overall binning score." Working Approach at 18. EPA has not described how it will derive scores within any individual component, nor how it will combine scores across the five components. These eventual arithmetic exercises are incredibly significant; EPA must provide far greater detail and allow ample time for public comment on this aspect of its binning approach if it pursues any binning of the TSCA inventory.

Even apart from EPA's misguided decision to bin the non-confidential portion of the TSCA inventory (see section 9 above), EPA's outlined approach to binning raises several concerns described and discussed in this section.

a. EPA's proposed binning approach detrimentally limits and biases the information sources used to calculate the binning score in a manner that does not reflect use of the best available science or all reasonably available information.

EPA's proposed binning approach clearly favors automation over public health protection. Consequently, the proposed binning approach would limit the information EPA will consider when identifying candidates for prioritization in a manner that would systematically exclude relevant health and safety information and systematically favor regulatory and industry studies. In particular, EPA's proposed approach would exclude the great majority of information published in the scientific literature, including key epidemiological and ecological studies that assess the effects of chemical exposures on humans and ecological organisms.

Instead, EPA proposes to bin the entire TSCA inventory using a limited set of information exclusively developed by industry or EPA itself. Such a limited and biased approach does not represent use of the best available science as required under TSCA section 26(h). This limited approach will also fail to consider reasonably available information in violation of TSCA section 26(k). When carrying out section 6, EPA must use the best available science and reasonably available information, but EPA will clearly not fulfill these duties if it entirely excludes the great majority of the information published in the scientific literature, as it proposes to do.

These flaws are especially evident in the proposed human hazard-to-exposure ratio and genotoxicity scores.

In calculating the human hazard-to-exposure ratio score, EPA proposes for hazard information to rely first on oral *in vivo* repeat dose toxicity studies (a standard regulatory guideline study) where available, then on ToxCast data (EPA generated high-throughput *in vitro* testing data), and then, where neither are available, on the Threshold of Toxicological Concern methodology (an industry-formulated regulatory approach) . For exposure information, EPA will exclusively rely on ExpoCast (EPA generated high-throughput exposure forecasting information). All of these data sources originate from either the regulated community or EPA; set aside would be the vast

amounts of risk-relevant information in the published literature. Under EPA's framework, if an oral *in vivo* repeat dose toxicity study is not available, EPA would immediately move to ToxCast data to derive the human hazard-to-exposure ratio score even if there are other *in vivo* or even human studies available.

In calculating the genotoxicity score, EPA proposes to apply "two, tiered evaluation processes that are based on the type of DNA damage (i.e., mutagenicity, clastogenicity) and the typical standardized genotoxicity tests used in regulatory assessment." If genotoxicity information is not available from these typical tests or using its Toxicity Estimation Software Tool (TEST), EPA will flag the chemical for future information gathering for genotoxicity. Similarly, if clastogenicity information is not available from typical tests or using the Organisation for Economic Cooperation and Development (OECD) QSAR Toolbox, EPA will flag the chemical for future information gathering for clastogenicity.

Taken together, EPA's proposal represents a limited assessment of potential human health impacts biased entirely toward regulatory studies generated by traditional guideline studies and EPA's predictive toxicology programs. EPA should of course consider these sources of information in identifying candidate chemicals for prioritization; however, the agency should also incorporate the valuable information from the broader scientific literature. Instead, EPA proposes to inappropriately and detrimentally ignore such information entirely.

The apparent reason for doing so is a desire to automate the binning process. However, EPA's mission is to protect human health and the environment, not to automate analyses and thereby ignore relevant information. Extracting information from the scientific literature is, of course, much more resource-intensive and complex than extracting information from existing databases of standardized test results. However, this reality argues against binning the entire TSCA inventory, and for an approach that is scaled appropriately so as not to exclude key information.

b. EPA should use caution in utilizing New Approach Methods (NAMs) in identifying candidates for prioritization.

EPA's proposed approach to calculating the human hazard-to-exposure ratio would rely heavily on information derived using New Approach Methods (NAMs). Specifically, EPA plans to use data from NAMs when traditional data (e.g., from oral *in vivo* repeat dose studies) are not available.

EDF submitted extensive comments to EPA on its draft Strategic Plan to Promote the Development and Implementation of Alternative Test Methods (*Strategic Plan)*. *See* EDF Comments on TSCA Alternative Testing Methods Strategy (May 11, 2018), https://www.regulations.gov/document?D=EPA-HQ-OPPT-2017-0559-0832. EDF fully incorporates and reiterates those earlier comments here by reference.

NAMs have a number of important limitations that carry significant implications for their proposed application in EPA's binning approach. For example, NAMs are currently available only for a subset of potential modes of toxicity, and they are not sufficient to characterize and represent the diversity of human and ecological populations. A November 2017 report by the European Chemicals Agency (ECHA), *Non-animal approaches: Current status of regulatory applicability under the REACH, CLP and Biocidal Products regulations*, highlighted similar current limitations of NAMs as they relate to coverage of biological targets and pathways, noting:

> For higher-tier endpoints, specific non-animal approaches that could directly replace vertebrate animal tests are not yet available and not foreseen in the near or even medium-term future, and adaptations are currently the main approaches to reduce the need for new animal testing. In spite of very active ongoing research in the area of non-animal approaches, approaches capable of replacing animal testing for complex endpoints are not yet available. Also the nature of such future approaches cannot be established yet. Furthermore, they may not provide the same level of information on the toxicity of substances as the current animal studies, for instance in terms of dose/concentration-response relationship and adverse effects.[30]

EPA itself correctly and appropriately identified a number of limitations of NAMs in the *Strategic Plan*, captured and paraphrased below:

NAM Type	**Exemplary EPA-identified limitations in the Strategic Plan**
Chemical Characterization	Lack of methods to predict physicochemical properties for unique substances and for chemical classes outside the domain of applicability of existing models
Hazard Identification and Classification	Inadequate coverage of biological targets and pathways; reduced or distinct xenobiotic metabolism compared to *in vivo* responses; relatively simplified assays for inferring integrated physiological responses; and chemical compatibility constraints

[30] European Chemicals Agency, *Non-animal approaches: Current status of regulatory applicability under the REACH, CLP and Biocidal Products regulations* 10 (Nov. 2017), https://echa.europa.eu/documents/10162/22931011/non_animal_approcches_en.pdf/87ebb68f-2038-f597-fc33-f4003e9e7d7d.

Dosimetry and *In Vitro – In Vivo* Extrapolation	Uncertainties in the *in vitro* disposition of chemicals such as plastic and protein binding and partitioning into *in vitro* constituents
Exposure Assessment	Inability to predict exposures in occupational settings and inadequate accounting of exposures from ambient releases

These limitations inevitably give rise to both *false positives* (i.e., erroneously flagging chemicals as having higher concern when they are actually of lower concern) and *false negatives* (i.e., erroneously flagging chemicals as having lower concern when they are actually of higher concern). While EDF believes assay specificity and sensitivity can improve over time through focused scientific research by the agency and larger scientific community, the reality is that EPA's proposed binning approach would erroneously score some chemicals as having lower concern—when they in fact present higher concern—and would set them aside indefinitely on that basis. In contrast, situations where EPA errs in characterizing some chemicals as presenting higher concern—when they in fact present lower concern—will be identified promptly as the agency moves them to the next stage of evaluation and considers such substances for prioritization and risk evaluation.

EPA's Working Approach document also states that:

> Over the long-term (beyond FY2021), the strategy is expected to evolve to incorporate information from NAMs that meet the criteria for reliability and relevance outlined in the draft "Strategic Plan to Promote the Development and Implementation of Alternative Test Methods."

Working Approach at 27. EPA's wording here insinuates that the Strategic Plan contains criteria for what qualifies a NAM as reliable and relevant. The Strategic Plan does not provide such benchmarks; instead, it identifies informational requirements by which the agency asserts it can assess the reliability and relevance of a NAM. Given that neither the Strategic Plan nor EPA's List of Alternative Test Methods and Strategies (or New Approach Methodologies [NAMs])[31] describes benchmarks for what qualifies a NAM as reliable or relevant—or for that matter as "capable of providing information of equivalent or better scientific reliability and quality to that which would be obtained from vertebrate animal testing"—it is entirely unclear how the agency intends to "evolve" the Working Approach's strategy.

[31] U.S. EPA, *List of Alternative Test Methods and Strategies (or New Approach Methodologies [NAMs])* (June 2018), https://www.epa.gov/sites/production/files/2018-06/documents/alternative_testing_nams_list_june22_2018.pdf.

It is also worth stating that the final Strategic Plan fails to provide criteria—either informational or in terms of benchmarks—for evaluating NAMs for their ability to adequately address risks to potentially exposed and susceptible subpopulations.[32] NAMs often do not sufficiently address the distinct exposure and biological considerations that define potentially exposed and susceptible subpopulations—groups EPA is explicitly mandate to protect under TSCA. These additional limitations of NAMs further underscore how misguided EPA proposal is to bin the entire TSCA inventory, rather than focus its attention and resources on selecting candidates from the many chemicals it already knows or has reason to suspect are of concern, and exploring ways that NAMs can help to support and refine such selections, rather than pretend they can serve as a stand-alone approach.

NAMs can play an important role in EPA's broader efforts to prioritize chemicals for risk evaluation. Our concerns about EPA's proposal to use NAMs in its Working Approach should not be interpreted as a disapproval of NAMs or their use in TSCA, but rather of how EPA has chosen to apply them to identify candidate chemicals for prioritization. Moreover, the nature of EPA's reliance on NAMs here is particularly troubling because, as explained above, EPA will simultaneously be ignoring the great majority of information published in the scientific literature. Given the limitations of NAMs, EPA cannot reasonably choose to rely on NAMs while excluding the great majority of published and peer-reviewed scientific literature.

c. EPA's proposal to rely on the "Threshold of Toxicological Concern" (TTC) approach is misplaced.

EPA's proposed approach to calculating the human hazard-to-exposure ratio would institute the Threshold of Toxicological Concern (TTC) approach. Specifically, "….when both *in vivo* and *in vitro* studies are not available, a Threshold of Toxicological Concern would be calculated…." Working Approach at 19.

The TTC approach, as the name implies, is based on an assumption that there is a threshold of exposure below which there is no adverse effect. It assumes that carcinogenicity is the most sensitive health endpoint relative to others (e.g., developmental or reproductive toxicity) and is rooted in decades-old toxicity data generated from testing protocols that do not reflect modern scientific principles and understandings of toxicity, nor real-world chemical exposures across a diverse human population.

[32] Additionally, the *Strategic Plans* continues to provide confidential business information (CBI) allowances for NAMs despite the fact that such information qualifies as health and safety information, which TSCA explicitly bars from CBI protection.

The TTC approach has increasingly been questioned by scientific experts,[33] especially in the context of assessing effects on a diverse human population. Among other shortcomings, the approach does not adequately take into account non-monotonic dose-response curves and additivity to background considerations (e.g., exposure to endocrine-disrupting compounds adding to existing biological processes driven by endogenous hormones).[34]

As with EPA's proposed use of NAMs to identify candidate chemicals for prioritization (see subsection b. above), the limitations of TTC exacerbate further our broader concerns over EPA's proposal to bin the entire TSCA inventory. Instead, EPA should focus its efforts on identifying a reasonable set of chemicals for prioritization from the many it is already aware present or may present concerns.

d. EPA's treatment of genotoxicity hazard is unexplained and, like its approach for deriving the human health hazard-to-exposure ratio, suggests EPA is broadly adopting a threshold assumption in evaluating chemical risks.

EPA distinguishes genotoxicity from other hazard endpoints in its proposed binning score approach by treating this endpoint as its own binning score component. In contrast, EPA collapses all other potential hazard endpoints into the human hazard-to-exposure ratio score component. EPA fails to explain why it treats genotoxicity separately. However, it is fair to presume that EPA has chosen to do so based on outdated concepts of toxicology that have repeatedly been called into question—namely that, with the exception of genotoxic carcinogens, all other hazard endpoints are presumed to have a threshold of exposure below which no effects are expected to be observed in the population.

In *Science and Decisions: Advancing Risk Assessment*,[35] the National Academies discussed at length the strong evidence supporting the opposite presumption. Non-linear dose-response relationships that assume the existence of thresholds of chemical exposure below which no effects are expected to be observed—are the exception rather than the rule, when taking into consideration background exposures, co-exposures, variability across the diverse population and other factors. The *Science and Decisions* report notes:

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[33] *See generally* NAT'L RESEARCH COUNCIL, SCIENCE AND DECISIONS: ADVANCING RISK ASSESSMENT Chp. 5 (2009), https://www.nap.edu/read/12209/chapter/7.
[34] Anna Beronius & Laura N. Vandenberg, *Using systematic reviews for hazard and risk assessment of endocrine disrupting chemicals*, 16:4 Reviews in Endocrine & Metabolic Disorders 273 (Dec. 2015), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4803521/.
[35] NAT'L RESEARCH COUNCIL, SCIENCE AND DECISIONS: ADVANCING RISK ASSESSMENT 135 (2009), https://www.nap.edu/catalog/12209/science-and-decisions-advancing-risk-assessment.

> . . . [A]n individual's risk from exposure to an environmental chemical is determined by the chemical itself, by concurrent background exposures to other environmental and endogenous chemicals that affect toxicity pathways and disease processes, and by the individual's biologic susceptibility due to genetic, lifestyle, health, and other factors. How the population responds to chemical insults depends on individual responses, which vary among individuals.[36]

Instead, EPA has clung to its old habit of taking different approaches in its risk assessments of: 1) carcinogens and 2) noncarcinogens and carcinogens "acting through an MOA [mode of action] considered nonlinear at low doses."[37] EPA applies a linear dose-response framework for the former and a non-linear dose-response framework for the latter. The National Academies strongly argued against this arbitrary distinction and recommended a uniform *linear* approach to the assessment of all hazard endpoints for chemicals. Indeed, even for carcinogens purported to have a non-linear MOA, the National Academies indicated:

> . . . omissions in this overall approach for low-dose nonlinear carcinogens could yield inaccurate and misleading assessments. . . . [T]he current EPA practice of determining "nonlinear" MOAs does not account for mechanistic factors that create linearity at low dose. The dose-response relationship can be linear at a low dose when an exposure contributes to an existing disease process. Effects of exposures that add to background processes and background endogenous and exogenous exposures can lack a threshold if a baseline level of dysfunction occurs without the toxicant and the toxicant adds to or augments the background process. Thus, even small doses may have a relevant biologic effect. That may be difficult to measure because of background noise in the system but may be addressed through dose-response modeling procedures. Human variability with respect to individual thresholds for a nongenotoxic cancer mechanism can result in linear dose-response in the population.[38]

Similarly, for noncarcinogens, the National Academies indicated that "noncarcinogens can exhibit low-dose linearity, for example, when there is considerable interindividual variability in susceptibility and each individual has his or her own threshold, especially when an underlying disease (such as cardiopulmonary disease) can interact with the toxicant (such as particulate matter [PM] or ozone)."[39]

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[36] *Id*. at 135.
[37] *Id*. at 129.
[38] *Id*. at 129-30.
[39] *Id*. at 131.

The National Academies definitively recommended that "cancer and noncancer responses be assumed to be linear as a default. . . [and that] [a]n alternative analytic option. . . is available for cases in which it can be shown that background is unlikely to be an important contributor to risk, according to the recommended evaluation of MOAs and background."[40]

The proposed human hazard-to-exposure ratio score provides further evidence of EPA's threshold approach in the identification of candidate chemicals for prioritization. As already mentioned, EPA has decided to collapse all hazard endpoints other than genotoxicity into the human hazard-to-exposure ratio binning score. Also unlike for the genotoxicity score, EPA has proposed to divide hazard values used in calculating the human hazard-to-exposure ratio score by a level of exposure predicted by ExpoCast. The dichotomy between the approach EPA proposes to take for the genotoxicity score and human hazard-to-exposure ratio score with regard to whether and how exposure or lack thereof is accounted for provides further evidence that EPA intends to continue to apply a threshold approach to characterizing potential chemical risks, a decision that is contrary to best available science.

11. EPA must add additional factors related to vulnerable subpopulations in its scoring process.

TSCA section 6(b)(1) expressly requires that EPA's prioritization process include consideration of potential risks to "potentially exposed or susceptible subpopulations," and EPA must designate a chemical as a high-priority substance if it "may present an unreasonable risk of injury to health or the environment … including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by [EPA]."[41] In turn, section 3(12) of TSCA defines "potentially exposed or susceptible subpopulation" as:

> a group of individuals within the general population identified by [EPA] who, due to either greater susceptibility or greater exposure, may be at greater risk than the general population of adverse health effects from exposure to a chemical substance or mixture, such as infants, children, pregnant women, workers, or the elderly.[42]

Under EPA's proposed binning approach, the only consideration of "potentially exposed or susceptible subpopulations" is in its "Susceptible Population Score." EPA describes this score as follows:

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[40] *Id*. at 180.
[41] 15 U.S.C. § 2605(b)(1)(A), (b)(1)(B).
[42] 15 U.S.C. § 2602(12).

> Calculation of the susceptible population component score would be based on the potential for exposure to children. The presence in children's products would be identified based on both the EPA Consumer Product Database (CPDat) and the EPA Chemical Data Reporting (CDR) results. Substances with no CPDat or CDR data available will be flagged for future information gathering.

Working Approach at 23. This is a wholly inadequate approach that ignores the vast majority of factors impacting whether a chemical is likely to adversely impact vulnerable subpopulations.

Once again, the apparent reason for such a cursory approach to accounting for risks to vulnerable subpopulations is likely EPA's desire to automate the binning process. However, EPA must consider vulnerable subpopulations, even if it requires a more resource-intensive analysis. The need to actually account for vulnerable subpopulations counsels against binning the entire TSCA inventory, and for an approach that is scaled appropriately to allow for analysis of potential risks to these subpopulations.

To reiterate our earlier point: EPA's mission is to protect human health and the environment, not to automate analyses and thereby ignore relevant information.

a. EPA's proposed approach ignores most exposures to children.

EPA's proposed approach is likely to miss the majority of chemical exposures to children. First, CDR data on use in children's products are based on exceedingly limited sources of information. For example, CDR reporting is limited to manufacturers, who typically have limited knowledge about whether or how their chemicals are used in products intended for use by children; such information need only be reported to the extent it is known or reasonably ascertainable by the manufacturer. CDR reporting is subject to volume thresholds and has many exemptions that mean it does not capture information from all manufacturers of all active chemicals. CPDat is an innovative, useful, and important investment by EPA's Office of Research and Development.[43] However, it is not yet sufficiently comprehensive to ensure all potential exposures to children from products are identified.

Second, even if a product is not intended for use by children, it may very well be used by them. Children are also often subject to exposures as bystanders even if they are not themselves using a product. Further, unintentional or accidental exposures are important to consider. For example, many children are accidentally consuming laundry detergent pods. According to the American

[43] Kathie L. Dionisio, et. al, *Exploring consumer exposure pathways and patterns of use for chemicals in the environment*, 2 TOXICOLOGY REPORTS 228 (2015), https://www.sciencedirect.com/science/article/pii/S2214750014001632.

Association of Poison Control Centers, there were nearly 12,000 cases of laundry detergent pod exposure in children five years old and younger reported to poison centers in 2014.[44]

Third, much of children's chemical exposure is likely to come from environmental sources such as contaminated water, air, soil, and dust. For example, chemicals likely to contaminate house dust, where young children could be more highly exposed due to their increased intake of air per unit body weight as well as crawling and mouthing behaviors,[45] warrant scrutiny.

Finally, an approach that relies exclusively on use of chemicals in children's products completely ignores prenatal exposures, which can be as or even more detrimental than exposure during childhood.[46] EPA's own framework for assessing health risks to children applies a lifestage approach, including preconception and prenatal exposures: "Assessing potential health risks to children as a result of their environmental exposure to toxicants includes considering risk from exposure before conception, during the prenatal period, and through childhood and adolescence."[47]

b. EPA's proposed approach ignores children's potential for great susceptibility to chemical exposures.

The proposed approach only considers the extent to which children may be *exposed* to chemicals, not their potential to be more susceptible to adverse health effects from chemical exposures. It is widely understood that children often have greater susceptibility to the adverse effects of hazardous chemicals due to a variety of factors, including their still-developing organ systems and metabolic functioning.

Just a few of the many examples described on EPA's own webpage, "Children Are Not Little Adults!", of children's potential for greater susceptibility to a given level of exposure to a chemical are that they have a more permeable blood-brain barrier; less effective filtration in

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[44] AAPCC, *AAPCC Position Statement on Single-Load Liquid Laundry Packets*, https://aapcc.s3.amazonaws.com/files/library/AAPCC_Laundry_Packet_Position_Statement.pdf.

[45] ATSDR, Environmental Health and Medicine Education, *Principles of Pediatric Environmental Health: Why are Children Often Especially Susceptible to the Adverse Effects of Environmental Toxicants?*." https://www.atsdr.cdc.gov/csem/csem.asp?csem=27&po=3 (last visited Nov. 15, 2018).

[46] David C. Bellinger, *Prenatal Exposure to Environmental Chemicals and Children's Neurodevelopment: An Update*, 4:1 SAFETY & HEALTH AT WORK 1 (2013), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3601292/.

[47] U.S., EPA, ORD, *A Framework for Assessing Health Risks of Environmental Exposures to Children* at 2-3 (Sept. 2006), https://cfpub.epa.gov/ncea/risk/recordisplay.cfm?deid=158363.

nasal passages; and highly permeable skin.[48] Further, chemical exposure during critical windows of development can lead to adverse impacts in fetuses, infants, and children that would not be seen in adults.[49]

Any scientifically sound process for identifying chemicals for prioritization needs to consider, and generate where it is lacking, data on reproductive toxicity and developmental toxicity.

Under EPA's 2012 TSCA Work Plan approach, EPA included a "Children's Health" category in addition to the "Children's Product Use" category. The Children's Health category included reproductive and/or developmental toxicity data from EPA's Integrated Risk Information System (IRIS), National Toxicology Program's (NTP) Center for Evaluation of Risk to Human Reproduction (CERHR), and California Proposition 65.

Under the proposed binning approach, developmental and reproductive toxicity data actually would be down-weighted, as they would only be considered alongside numerous other hazard endpoints through the Human Hazard-to-Exposure Ratio Score (discussed in section 10.d. above). If EPA moves forward with a binning approach, it needs to include a distinct "bin" for susceptibility (i.e., "Children's Health), modeled after that in the 2012 TSCA Work Plan methodology. There is no reason that such effects should not carry at least the same weight as, for example, the Genotoxicity score.

c. EPA's proposed approach ignores all other "potentially exposed or susceptible subpopulations."

This approach completely ignores all other potentially exposed or susceptible subpopulations. Some other populations that EPA should include are:[50]

- Pregnant women*
- Workers*
- Fence line communities
- Elderly*
- People with preexisting conditions

[48] U.S. EPA, *Children Are Not Little Adults!*, https://www.epa.gov/children/children-are-not-little-adults (last updated Oct. 31, 2018).
[49] *Id.*; Landrigan, P. & Goldman, L., *Children's vulnerability to toxic chemicals: A challenge and opportunity to strengthen health and environmental policy*, 30 HEALTH AFF. 842-850 (2011), https://www.ncbi.nlm.nih.gov/pubmed/21543423.
[50] Those marked with asterisks are, along with infants and children, explicitly identified in TSCA as examples of vulnerable subpopulations. 15 U.S.C. § 2602(12).

Under Caveats and Potential Limitations, Working Approach at 28, EPA acknowledges that this "strategy does not fully account for … all populations (e.g., elderly)" and that "[o]ther potentially susceptible populations may be added over time." EPA makes no mention of other subpopulations beyond the elderly, nor does it provide any indication of when or how it intends to address other vulnerable subpopulations.

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In sum, EPA has made a minimal effort to address vulnerable subpopulations through its proposed binning process – a central, required element in EPA's consideration of chemicals risks under TSCA as amended in 2016. While the process for identifying candidates is not covered by the prioritization rule, it is illogical to ignore factors during this initial stage that EPA will have to more fully address during prioritization. Ignoring potential risks to vulnerable subpopulations at this stage will handicap EPA in the long run, as the agency will not identify and take steps to meet data needs related to vulnerable subpopulations ultimately needed to inform prioritization decisions. Worse, EPA will be more likely to erroneously set aside and less likely to prioritize for further evaluation chemicals that may impact the health of vulnerable subpopulations – the very chemicals that are most important to evaluate to protect public health.

12. EPA's binning proposal would perpetuate its reliance on limited and flawed metrics for environmental fate and hazard.

a. EPA's proposed approach exclusively focuses on aquatic toxicity to represent all environmental hazards.

EPA's approach to characterizing environmental hazards has long been myopically focused on one category of environmental organisms: aquatic organisms that live in the water column and are assumed to be exposed only through direct uptake of chemicals from water. This has been driven by the widespread use of standardized test methods using fish, the water flea *Daphnia*, and algae, to represent toxicity to aquatic vertebrates, invertebrates and plants, respectively. These data have in turn been used to underpin predictive models for such toxicity, embodied in EPA's EcoSAR estimation models. Only exceedingly rarely does EPA consider, let alone seek out data on, the toxicity of chemicals to other organisms, e.g., those living in sediment or soil, aquatic mammals, or the myriad other terrestrial or avian species.

This situation has become the proverbial lost keys in the parking lot at night: One looks only under the lampposts because that is where there is light, while ignoring the far larger area where it is at least as likely that the keys lay hidden in the dark.

Rather than expand its focus, EPA increasingly makes unwarranted assumptions and leaps of logic. Two examples from EPA's recent problem formulations for the first 10 chemicals undergoing risk evaluations under TSCA illustrate the problem:

- In the problem formulation for 1,4-dioxane, EPA states: "While no ecotoxicity studies were available for sediment organisms, the toxicity of 1,4-dioxane to sediment invertebrates is expected to be similar to the toxicity to aquatic invertebrates."[51] EPA provides no basis for this assertion of expected similar toxicity.
- In the problem formulation for 1-bromopropane, EPA states: "[T]here were no available sediment, soil, nor avian toxicity studies found in the scientific literature for 1-BP. The toxicity of 1-BP is *expected to be low* based on the lack of on-topic environmental hazard data for 1-BP to sediment and terrestrial organisms in the published literature and the physical/chemical/fate properties (relatively high volatility (Henry's Law constant of 7.3X10-3 atm-m3/mole), high water solubility (2.4 g/L), and low log Koc (1.6) suggesting that 1-BP will only be present at low concentrations in these environmental compartments."[52] Astoundingly, EPA here relies on the *lack* of available data as the primary basis to conclude toxicity must be low.

These are clear data gaps that EPA should seek to fill, rather than resort to hand-waving to dismiss potential hazards and risk it has not examined.

In its Working Approach, EPA appears intent on pursuing the same flawed path. Its "Ecological Hazard Component," Working Approach at 22-23, would rely exclusively on aquatic toxicity, whether measured or modeled using EcoSAR. Even in these cases, EPA also appears to intend to rely on overly simplistic assumptions about water solubility of chemicals to rule out any evidence of toxicity it does find.

b. EPA's proposed approach exclusively focuses on BAF/BCF values to represent all bioaccumulation potential.

Traditionally, EPA has used relatively narrow criteria and information to define and assess persistence or bioaccumulation potential in the environment or organisms. The approach has largely assumed that chemicals are released to aquatic media, remain in the water column, and are taken up by aquatic organisms such as fish, free-swimming invertebrates or algae. For bioaccumulation, accumulation of hydrophobic substances in fat tissue is typically assumed.

Yet a large and growing body of scientific research demonstrates the need to broaden these assumptions and tests for these chemical characteristics. For example, some chemicals can be

[51] U.S. EPA, *Problem Formulation of the Risk Evaluation for 1,4-Dioxane* at 42 (May 2018), https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0723-0064.
[52] U.S. EPA, *Problem Formulation of the Risk Evaluation for 1-Bromopropane* at 41 (May 2018), https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0741-0067.

taken up directly from air and bioaccumulate through food webs in air-breathing terrestrial animals (including humans).[53] Some chemicals, such as PFOA and related perfluorinated compounds, do not meet typical criteria for bioaccumulation that only assess uptake from water into fish and accumulation in fatty tissues. Yet PFOA does have bioaccumulative properties, as it binds to blood proteins and builds up in blood rather than fatty tissue or organs.[54] This is acknowledged in EPA's Drinking Water Health Advisory for PFOA,[55] which makes clear that traditional BCF values are derived using methods that do not capture bioaccumulation and bioconcentration of chemicals like PFOA, despite other clear evidence that they are in fact bioaccumulative:

> It is recognized[,however] that BCFs determined by existing standard methods derived from lipid-partitioning are not an appropriate metric for assessing bioconcentration of PFOA (EFSA 2008; UNEP 2015). Although evidence of PFOA accumulation in many organisms has been documented, reported BAFs and BCFs for the chemical also fall below traditional criteria used to assess bioaccumulation potential (Loi et al. 2011; Martin et al. 2003a, 2003b; Morikawa et al. 2005; Quinete et al. 2009).
>
> Field evidence of PFOA biomagnification, considered to be the preferable metric for assessing bioaccumulation potential (Gobas et al. 2009), has been documented in many organisms from many locations worldwide (UNEP 2015). Trophic magnification has also been evaluated (Environment Canada and Health Canada, 2012; Houde et al. 2006; Kelly et al. 2009; Loi et al. 2011; Martin et al. 2004). Some field trophic studies revealed TMFs greater than 1, which indicates that PFOA accumulated and increased in concentration with increasing trophic level; other studies reported TMFs less than 1 for some food webs. The weight of evidence for trophic magnification was deemed sufficient to consider PFOA to be bioaccumulative by the Stockholm Convention Persistent Organic Pollutants Review Committee (UNEP 2015).

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[53] *See, e.g.*, Kelly, B., et. al., *Food Web–Specific Biomagnification of Persistent Organic Pollutants*, 317:5835 SCIENCE 236-39 (Jul. 13, 2007), http://science.sciencemag.org/content/317/5835/236.

[54] *See, e.g.*, Seals, B., Bartell, S.M., & Steenland K., *Accumulation and Clearance of Perfluorooctanoic Acid (PFOA) in Current and Former Residents of an Exposed Community*, 119:11 ENVTL. HEALTH PERSPECTIVES (2011), http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3018490/; U.S. EPA, *Research on Per- and Polyflouroalykyl Substances (PFAS)* (Aug. 2016), https://www.epa.gov/chemical-research/research-and-polyfluoroalkyl-substances-pfas.

[55] U.S. EPA, *Drinking Water Health Advisory for Perfluorooctanoic Acid (PFOA)* 25 (May 2016), https://www.epa.gov/sites/production/files/2016-05/documents/pfoa_health_advisory_final-plain.pdf.

With respect to persistence, some chemicals that do not meet current test criteria or technical specifications for persistence nevertheless can result in chronic exposures because of the nature of their use and release; such chemicals have been termed "pervasive due to continuous release."[56]

Hence, in evaluating chemicals that may present an unreasonable risk, EPA needs to consider the best available science and think beyond the incomplete and more limited criteria and testing methods typically relied on to assess persistence and bioaccumulation.

Unfortunately, EPA's discussion of its "Persistence and Bioaccumulation Component," Working Approach at 24, suggest it will continue to rely on very limited criteria for these critical chemical parameters. For example, EPA states: "Bioaccumulation is represented based on bioaccumulation factors (BAF) or bioconcentration factors (BCF)."

* * *

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

[56] United Nations Environment Programme/Global Environment Facility (UNEP/GEF) project cited in "Phase Out Persistent, Bioaccumulative, or Highly Toxic Chemicals," Background Paper #2, Louisville Charter (Aug. 2005), http://www.comingcleaninc.org/louisville-charter/2-phase-out-toxic-chemicals.