



Environmental Defense Fund
Oral Comments on
1-Bromopropane for the SACC: Part I
Docket ID: EPA-HQ-OPPT-2019-0235

Submitted September 10, 2019

My name is Stephanie Schwarz and I am a Legal Fellow at EDF. I will make brief comments today, with more detail in the written comments we have already provided to the SACC (attached here).

Recently EPA has publicly stated that a number of the topics discussed are in the realm of policy and are therefore not relevant to the SACC's charge. These include:

1. EPA's decision to exclude all exposures from releases to land, air, and water based on the assumption that other statutes adequately address the exposures;
2. EPA's decision to assume that appropriate personal protective equipment (PPE) is always used, based on the authority of the Occupational Safety and Health Administration (OSHA); and
3. EPA's decision to use a benchmark cancer risk level of 1×10^{-4} to define unreasonable risk to workers.

EDF strongly disagrees that these issues are beyond the scope of the SACC. In fact, they fall squarely within the SACC's charge. All three decisions have major direct *scientific* consequences, as they clearly lead to underestimations of chemicals' risk – to the environment, the general population, workers, and vulnerable subpopulations.

Charge question 7 (in the final agenda), among others, expressly directs the SACC to address the uncertainties and assumptions that EPA uses in the draft risk evaluation. All three of EPA's decisions I just described represent *assumptions* that EPA has not verified or adequately explained, and that introduce major uncertainty into its risk evaluation that EPA has not analyzed. It is vital that the SACC consider and address in its report the scientific consequences of these assumptions and decisions on EPA's characterization of exposure, hazard, and risk. Let me address each of these issues a bit further.

First, the statutory-based exclusions. EPA has asserted that exposures to the general population are "adequately managed" without any analysis whatsoever of the standards under the other

statutes, including standards that are not strictly health based, unlike TSCA's standard. EPA devoted less than 3 pages to justify its decision to eliminate entire pathways, and provided no data or analysis of the exposures and risks that remain and their contribution to total exposure and risk.¹

EPA has failed to provide any scientific rationale for this assumption, and the SACC has been charged with commenting precisely on the adequacy of the support EPA has provided for just such assumptions.

Second, EPA has also assumed that OSHA ensures that suitable PPE is always used in order to find no unreasonable risk to workers, even though EPA has stated elsewhere in the draft risk evaluation that:

- “Few literature sources indicate the use of respirators in 1-BP conditions of use ***;” (p.57) and
- “EPA does not know the actual frequency, type, and effectiveness of glove use in specific workplaces with 1-BP conditions of use.” (p.108)

Despite the lack of data regarding the use of PPE, EPA has made broad assertions about OSHA's authority. In order for the SACC to fully evaluate these assumptions, the SACC should request that EPA provide any feedback EPA has received from OSHA and NIOSH on its assumption regarding PPE use, and more generally, any input they have provided EPA regarding the extent and sufficiency of OSHA's authorities.

Third, EPA's unprecedented use of 1 in 10,000 as the cancer risk benchmark for workers also clearly underestimates risk, and flies in the face of EPA's longstanding policy “that it should reduce risks to less than 1×10^{-6} for as many exposed people as reasonably possible.” National Emission Standards for Hazardous Air Pollutants; Radionuclides, 54 Fed. Reg. 51,654, 51,686 (Dec. 15, 1989).

In sum: TSCA specifically states that the purpose of the SACC is to provide advice on “scientific and technical aspects” related to implementation of TSCA, and EPA's sweeping assumptions regarding environmental exposures, PPE use, and adequacy of a less protective cancer risk benchmark have direct impacts on the scientific integrity of EPA's implementation of TSCA.

The SACC needs to address the scientific consequences of each of these decisions. At the very least, it is the SACC's responsibility to state clearly in its report that they result in serious underestimations of risk.

¹ Those three pages were in the problem formulation for 1-BP; the draft risk evaluation merely alluded to that explanation with no additional analysis. *See* Problem Formulation at pp. 53-55.



**Environmental Defense Fund
Oral Comments on
1-Bromopropane for the SACC: Part II
Docket ID: EPA-HQ-OPPT-2019-0235**

Submitted September 10, 2019

Hi, I'm Lindsay McCormick with EDF. In 2016, Congress strengthened EPA's authority and mandate under TSCA to protect workers by expressly identifying them as a "potentially exposed or susceptible subpopulation." Yet EPA's draft risk evaluation grossly understates the risks to workers and overstates OSHA protections. I will discuss four concerns, which are most germane to charge questions 2 and 6 in the final agenda. More detail on each concern is provided in the written comments we have already provided to the SACC (attached here).

1. First, EPA ignores real-world limitations of PPE and distorts OSHA requirements

EPA heavily relies on an assumption that all workers will always use gloves and respirators and that they will be universally effective. In doing so, EPA ignores the major real-world limitations of PPE.

For example, EPA assumes "workers are properly trained and fitted on respirator use, and that they wear respirators for the entire duration of the work activity where there is potential exposure to 1-BP." (p. 24) These assumptions are wholly unwarranted.

First, any OSHA requirement for employers to provide respiratory protection from 1-BP exposure will apply only extremely rarely for many reasons, including the fact that no OSHA PEL exists for 1-BP. EPA distorts the relevant OSHA requirements when it invokes OSHA's Respiratory Protection Standard at 29 CFR 1910.134 (p. 57) – which only applies for chemicals with an OSHA PEL. Dr. Finkel's comments to the SACC discuss this issue further.

Second and more broadly, even where OSHA respiratory protection requirements do apply to a chemical, OSHA's database of inspections demonstrates significant noncompliance with those requirements. In fiscal year 2018 alone, OSHA cited 2,892 violations of the respiratory protection standard identified in 1,281 separate inspections.¹ Violations of the respiratory

¹ U.S. Department of Labor, Occupational Safety and Health Administration. Industry Profile for OSHA Standard 19100134. Accessed September 9, 2019. Available at:

standard were the 4th most common type of violation in OSHA inspections that year, exceeded only by those for two categories of physical hazard and the Hazard Communication Standard.²

EPA overstates or distorts other OSHA requirements as well. For example, EPA implies that safety data sheet recommendations for PPE are mandatory (p. 289), when in fact, OSHA's standard mandating SDSs specifically states there is, quote, "*no requirement for employers to implement the recommended controls.*"³

2. Second, EPA conflates the risk evaluation and risk management processes by assuming use of PPE

TSCA intentionally divides risk evaluation and risk management into two distinct processes, whereby regulatory measures are considered *after* EPA finds an unreasonable risk. However, by choosing to make risk determinations based on an assumption of universal, effective use of PPE, EPA conflates risk evaluation and risk management and leads EPA either not to find unreasonable risk or to underestimate the magnitude of that risk in a number of scenarios – thereby denying itself the authority to impose mandatory requirements sufficient to control workplace exposures.

Let's look at one example.

In this table from EPA's draft (p. 237), you can see that for cancer risk from dermal exposure, EPA has actually found excessive risk in *every* scenario – even using its 1 in 10,000 benchmark that my colleague Stephanie already noted is unprecedented and unwarranted.

https://www.osha.gov/pls/imis/industryprofile.stand?p_esize=&p_stand=19100134&p_state=FE Federal&p_type=5.

² U.S. Department of Labor, Occupational Safety and Health Administration. Top 1- Most Frequently Cited Standards. Accessed September 9, 2019. Available at: <https://www.osha.gov/top10citedstandards>.

³ Hazard Communication Standard, 77 Fed. Reg. 17574 (March 26, 2012), Available at: <https://www.govinfo.gov/content/pkg/FR-2012-03-26/html/2012-4826.htm>.

Slide 1: Assumption of PPE

Table 4-53. Cancer Risk Estimates for Dermal Exposure Following Occupational Use of 1-BP

Category	Dermal Slope Factor (mg/kg-day) ⁻¹	No Gloves (PF = 1)	Protective Gloves (PF = 5)	Protective Gloves (PF = 10)	Protective Gloves (PF = 20)	Benchmark
Bin 1: Manufacture, Import, Processing, and Disposal	0.006	1.38E-04	2.77E-05	1.38E-05	6.91E-06	1E-04
Bin 2: Vapor Degreaser, Cold Cleaner		1.34E-04	2.68E-05	1.34E-05	6.71E-06	1E-04
Bin 3: Spray Adhesives		1.11E-04	2.21E-05	1.11E-05	N/A	1E-04
Bin 4: Dry Cleaning, Spot Cleaning		1.30E-04	2.60E-05	1.30E-05	N/A	1E-04
Bin 5: Aerosol Spray Degreaser/Cleaner, Other Aerosol and Non-aerosol Uses		1.38E-04	2.77E-05	1.38E-05	N/A	1E-04

(Page 237)

Manufacturing (import) risk determination:

- “**Does not present an unreasonable risk** of injury to health (workers and occupational non-users”
- Risk estimate: Workers: Dermal: 1.38E-04 for workers using no PPE (Table 4-53). Note: **There is no unreasonable risk when PPE (gloves PF=5) are used.**

(Page 261)

Yet, when it comes to the risk determinations, EPA finds no unreasonable risk in several scenarios, including manufacturing (import) which is displayed on the slide, by stating, “there is no unreasonable risk when PPE (gloves PF=5) are used.” (p. 261)

EPA’s failure to make an unreasonable risk determination will mean it will lack any authority to require that such gloves are actually used.

3. Third, EPA understates risk by using the 1×10^{-4} benchmark

Let’s look at this same EPA table through another lens. The shading shows where EPA found excessive risk using a 1 in 10,000 benchmark.

Slide 2: 1×10^{-4} Benchmark

Table 4-53. Cancer Risk Estimates for Dermal Exposure Following Occupational Use of 1-BP

Category	Dermal Slope Factor (mg/kg-day) ⁻¹	No Gloves (PF = 1)	Protective Gloves (PF = 5)	Protective Gloves (PF = 10)	Protective Gloves (PF = 20)	Benchmark
Bin 1: Manufacture, Import, Processing, and Disposal	0.006	1.38E-04	2.77E-05	1.38E-05	6.91E-06	1E-04
Bin 2: Vapor Degreaser, Cold Cleaner		1.34E-04	2.68E-05	1.34E-05	6.71E-06	1E-04
Bin 3: Spray Adhesives		1.11E-04	2.21E-05	1.11E-05	N/A	1E-04
Bin 4: Dry Cleaning, Spot Cleaning		1.30E-04	2.60E-05	1.30E-05	N/A	1E-04
Bin 5: Aerosol Spray Degreaser/Cleaner, Other Aerosol and Non-aerosol Uses		1.38E-04	2.77E-05	1.38E-05	N/A	1E-04

Recall my colleague Stephanie's earlier comment that EPA should be using a much more protective cancer risk benchmark. If EPA used, say, even 1 in 100,000, the table shows it would have found excessive risk in every scenario even assuming gloves with a PF up to 10.

Slide 3: 1×10^{-5} Benchmark

Table 4-53. Cancer Risk Estimates for Dermal Exposure Following Occupational Use of 1-BP

Category	Dermal Slope Factor (mg/kg-day) ⁻¹	No Gloves (PF = 1)	Protective Gloves (PF = 5)	Protective Gloves (PF = 10)	Protective Gloves (PF = 20)	Benchmark
Bin 1: Manufacture, Import, Processing, and Disposal	0.006	1.38E-04	2.77E-05	1.38E-05	6.91E-06	1E-04
Bin 2: Vapor Degreaser, Cold Cleaner		1.34E-04	2.68E-05	1.34E-05	6.71E-06	1E-04
Bin 3: Spray Adhesives		1.11E-04	2.21E-05	1.11E-05	N/A	1E-04
Bin 4: Dry Cleaning, Spot Cleaning		1.30E-04	2.60E-05	1.30E-05	N/A	1E-04
Bin 5: Aerosol Spray Degreaser/Cleaner, Other Aerosol and Non-aerosol Uses		1.38E-04	2.77E-05	1.38E-05	N/A	1E-04

Using EPA’s longstanding policy of aiming to reduce risks for as many exposed people as possible to less than 1 in a million, EPA would have found excessive risk in *every single* scenario – even if gloves with a PF=20 were used.

Slide 4: 1×10^{-6} Benchmark

Table 4-53. Cancer Risk Estimates for Dermal Exposure Following Occupational Use of 1-BP

Category	Dermal Slope Factor (mg/kg-day) ¹	No Gloves (PF = 1)	Protective Gloves (PF = 5)	Protective Gloves (PF = 10)	Protective Gloves (PF = 20)	Benchmark
Bin 1: Manufacture, Import, Processing, and Disposal	0.006	1.38E-04	2.77E-05	1.38E-05	6.91E-06	1E-04
Bin 2: Vapor Degreaser, Cold Cleaner		1.34E-04	2.68E-05	1.34E-05	6.71E-06	1E-04
Bin 3: Spray Adhesives		1.11E-04	2.21E-05	1.11E-05	N/A	1E-04
Bin 4: Dry Cleaning, Spot Cleaning		1.30E-04	2.60E-05	1.30E-05	N/A	1E-04
Bin 5: Aerosol Spray Degreaser/Cleaner, Other Aerosol and Non-aerosol Uses		1.38E-04	2.77E-05	1.38E-05	N/A	1E-04

You can see through these examples how hard EPA has had to work to avoid finding excessive cancer risk from dermal exposure in the occupational setting. In the draft assessment, EPA does not make a single unreasonable risk determination based on cancer risk from dermal exposure.

4. My fourth, and last point is that EPA underestimates exposure by failing to consider combined exposures to workers from different routes and sources.

Not only is the oral pathway not considered at all, the agency has not even bothered to combine exposures from inhalation and dermal exposures.



**Environmental Defense Fund
Oral Comments on
1-Bromopropane for the SACC: Part III
Docket ID: EPA-HQ-OPPT-2019-0235**

Submitted September 10, 2019

I am Dr. Richard Denison with EDF. I'd like to flag our serious concerns with two additional aspects of the draft risk evaluation's consideration of human health hazards, which relate to Charge Questions 5 and 4.1 in the final agenda, respectively. More detail on each concern is provided in the written comments we have already provided to the SACC (attached here).

1. EPA fails to assess cancer risk from short-term exposures.

EPA acknowledges that 1-BP is a mutagenic carcinogen and that linear extrapolation is warranted. Yet, the agency has chosen not to estimate cancer risks from short-term exposures.

For a chemical with a mutagenic MOA, even "a single direct reaction, specifically, a single hit in a single target" can be sufficient to cause cancer, and hence acute exposures pose a cancer risk.

EPA's sole rationale for ignoring these risks is that published methodologies for extrapolating cancer risks from chronic to short-term exposures have uncertainties (p. 180).

EPA cites a 2001 NRC report for support. However, the same NRC report goes on to say that cancer is a potential adverse health effect of short-term exposures to mutagenic carcinogens, and it cites other NRC guidance that specifically says acute exposure guideline levels should be set using linear low-dose extrapolation from chronic doses.

EDF is concerned that EPA ignored sound biologic and statistical principles related to mode-of-action cited by the NRC. EPA erroneously assumes acute exposures to 1-BP, including to consumers, pose *zero* cancer risk. It departs from sound science by effectively adopting a threshold for 1-BP's dose-response, one based on duration of exposure rather than dose *per se*.

The only scientifically supportable and health-protective approach is for EPA to assess cancer risk from acute exposure using linear low dose extrapolation from chronic exposures.

2. EPA lacks access to full studies and relies only on industry-prepared summaries of limited aquatic toxicity testing to conclude 1-BP presents no unreasonable risks to the environment.

All but one of EPA's aquatic toxicity studies it cites as sourced from dossiers available from the European Chemicals Agency (ECHA). EPA claims ECHA dossiers are existing chemical assessments equivalent to EPA and ATSDR governmental assessments. EPA also lists ECHA as the author of these studies. All of these statements are false and highly misleading.

In fact, ECHA dossiers are not assessments and are not government documents. They are compilations of *industry* information submitted to ECHA that have *not* been evaluated for quality or reliability by ECHA or any other governmental entity.

Second, what ECHA provides are not full studies, but only study summaries prepared by industry registrants. **EPA acknowledges that it lacks access to the full studies and hence did not subject them to systematic review** or other quality review and that they bypassed the data screening step of EPA's literature search process.

It is vital that EPA has access to underlying data to ascertain the accuracy of the information and associated statements or conclusions, as well as to determine how much confidence or uncertainty applies to a particular study.

EPA then proceeds to use the results reported in the unverified summaries to draw sweeping conclusions about environmental risk.

EPA has access to only a single study on acute fish toxicity (p. 141) and has no chronic aquatic data at all (pp. 139-140). Instead it extrapolates from the acute fish study and the industry's acute study summaries to estimate chronic toxicity, by applying an "acute-to-chronic ratio", or ACR, that it sets at 10. EPA provides no justification or citation to support this value. Even a cursory search of the literature indicates that an ACR of at least 100 may be needed to be sufficiently protective.

EPA also has no toxicity data for sediment or terrestrial organisms and no monitoring data (pp. 140, 188, 146). Instead, EPA resorts to vague arguments invoking the 1-BP's physical-chemical properties to argue there will be little or no *exposure*.

Based solely on what I just described, EPA nevertheless draws the sweeping conclusion that 1-BP does not present unreasonable risk to the environment as a whole.

The SACC should make clear that EPA's analysis is utterly insufficient to establish that 1-BP does not present an unreasonable risk to the environment.



Environmental Defense Fund
Comments for Toxic Substances Control Act (TSCA)
Science Advisory Committee on Chemicals Review of
Risk Evaluation for
1-Bromopropane (n-Propyl Bromide)
Docket ID: EPA-HQ-OPPT-2019-0235

Submitted August 30, 2019

These comments are being submitted by EDF to assist the TSCA Scientific Advisory Committee on Chemicals (SACC) in its peer review of the draft risk evaluation for 1,4-dioxane. They have been prepared in the very limited time period provided by EPA to submit comments for consideration by the SACC. EDF will be providing comments at the SACC meeting scheduled for September 10-12, 2019. EDF reserves the right to supplement these comments at the SACC meeting and to provide additional comments on the risk evaluations on or before the comment period deadline of October 11, 2019. We request that all of our comments be provided to the SACC for its review and consideration.

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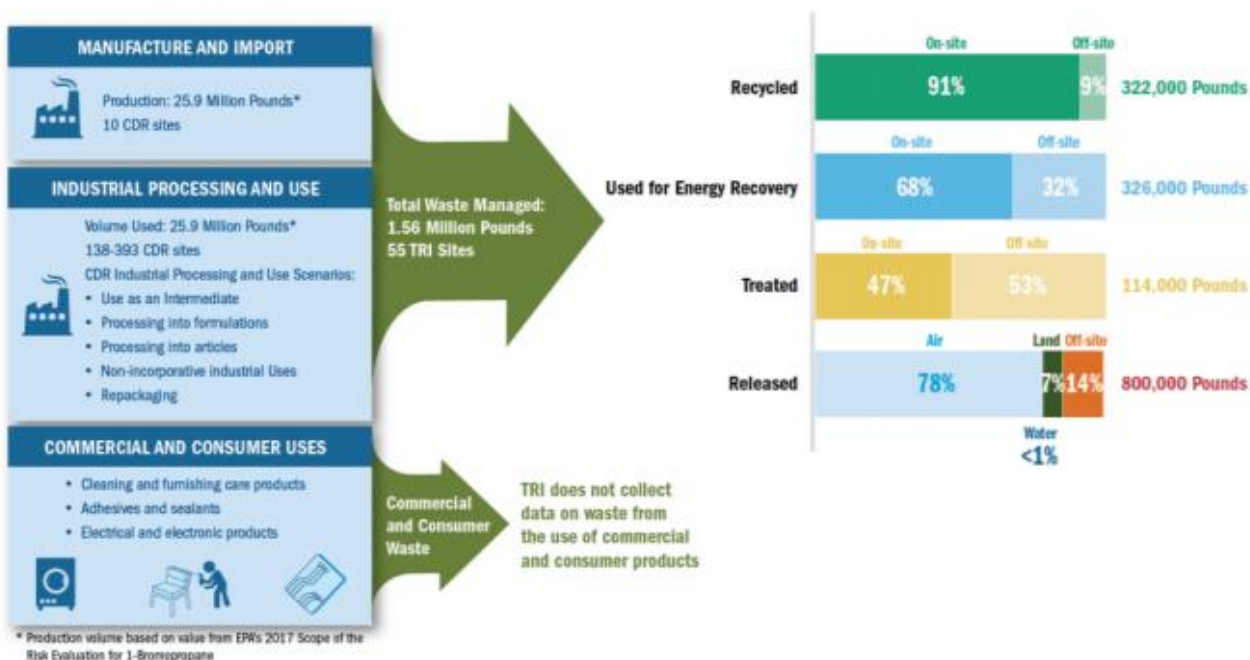
1. EPA’s statutory exclusions are relevant to the SACC’s charge questions.

A. General population

As with the risk evaluations for other chemicals, EPA has excluded exposure pathways based on its assertion that other statutes EPA administers “adequately assess and effectively manage risks” to the general population (and, in some cases, the environment). On this basis EPA has excluded any consideration of the risks presented to the general population and terrestrial organisms by air releases and by landfill disposal of 1-BP.

Based on 2016 TRI data (which for several reasons likely underestimated releases of 1-BP), about 627,000 pounds were reported to have been released to the air, and 148,000 pounds to landfills in 2015 by sources required to report under TRI. In the diagram below,¹ 627,000 pounds is reflected as 78% of 800,000 pounds under “released,” and 148,000 pounds is reflected as 7% of 800,000 pounds. EPA’s exclusion assumes those releases pose zero risk, both in themselves and in combination with other sources of exposure to 1-BP.

CDR and TRI Information for 1-Bromopropane



¹ U.S. EPA, *Introduction to the 2016 TRI National Analysis* (2016), https://www.epa.gov/sites/production/files/2018-01/documents/tri_national_analysis_2016_complete_0.pdf.

1-BP is not listed as a Hazardous Air Pollutant (HAP) under the Clean Air Act; EPA was petitioned to list it and EPA staff under the last Administration preliminarily recommended that the petition be granted. In the draft risk evaluation EPA says that a final decision is expected from the air office by the end of this year; however, that decision date is not mandated and whether the decision will be to grant or deny the petition is not known at this point.

EPA assumes that RCRA adequately manages all wastes disposed of in hazardous and non-hazardous waste landfills. In our previous comments on the 1-BP Problem Formulation, which have been provided to the SACC, EDF raised numerous reasons why this assumption is to be questioned.

Moreover, the releases of 1-BP reported under TRI are occurring *despite* whatever regulatory requirements have been developed and applied.

While EPA might claim that the decision to exclude exposure pathways based on other statutes falls in the realm of policy, its implications for human and environmental health are not. Addressing those implications falls squarely in the purview of and charge to the SACC. EDF urges the SACC to address these implications, which clearly lead to an underestimation of 1-BP's risk to the general population and to the environment in EPA's draft risk evaluation. The decision to exclude these pathways results in EPA ignoring available information about 1-BP exposure and risks, and the decision renders the draft risk evaluation less accurate from a factual and scientific perspective; the SACC should address the implications of this decision for the draft risk evaluation's scientific accuracy.

B. Vulnerable Subpopulations

TSCA requires EPA to consider and evaluate risks to "potentially exposed or susceptible subpopulations" as well as the general population. By excluding all consideration of risks to the general population, EPA has also shirked its duty to consider and evaluate risks to vulnerable subpopulations within the general population (although it has attempted to include them in the context of occupational and consumer exposures).

Examples of potentially exposed subpopulations within the general population that EPA has ignored include people living in proximity to manufacturing, processing, use and disposal sites or other sources of release of or contamination by 1-BP.

Examples of potentially susceptible subpopulations within the general population that EPA has ignored include infants, children, pregnant women, lactating women, women of child bearing age, and men of childbearing age, based on the hazard data EPA has identified in the draft risk evaluation. As described in the draft risk evaluation, there is considerable evidence that 1-BP exhibits reproductive and developmental toxicity (pp. 160-161). While EPA did consider some of these potentially susceptible subpopulations within the worker and consumer populations (pp.

22-23), notably it appears that EPA did not consider men of reproductive age for consumers. (p. 21)

EDF urges the SACC to address the ways in which EPA's statutory exclusions impede or obscure the identification and evaluation of risks to vulnerable subpopulations, which clearly have been underestimated in EPA's draft risk evaluation.

2. EPA has not evaluated the potential for carcinogenic risk from acute exposures.

Despite EPA's acknowledgment that the weight of the evidence indicates 1-BP is a mutagenic carcinogen and that linear extrapolation is warranted (pp. 159, 163), the agency has chosen not to estimate cancer risks based on acute exposures for 1-BP. It provides the following rationale on p. 180:

EPA did not use the IUR or dermal slope factor to calculate the theoretical cancer risk associated with a single (acute) inhalation/or dermal exposure to 1-BP. Published methodology for extrapolating cancer risks from chronic to short-term exposures to mutagenic carcinogens caveat that extrapolation of lifetime theoretical extra cancer risks to single exposures has great uncertainties (NRC, 2001). ... Thus, EPA risk evaluation for 1-BP does not estimate extra cancer risks for acute exposures because the relationship between a single short-term exposure to 1-BP and the induction of cancer in humans has not been established in the current scientific literature.

However, the same NRC document cited by the Agency above goes on to provide additional relevant information on this subject:

Guidance on the development of short-term exposure levels, published by the NRC, identified cancer as one of the potential adverse health effects that might be associated with short-term inhalation exposures to certain chemical substances (NRC 1993a). That guidance document discusses and recommends specific risk-assessment methods for known genotoxic carcinogens and for carcinogens whose mechanisms are not well understood. As a first approximation, *the default approach involves linear low-dose extrapolation from an upper confidence limit on theoretical excess risk*. Further, the NRC guidance states that *the determination of short-term exposure levels will require the translation of risks estimated from continuous long-term exposures to risks associated with short-term exposures*. Conceptually, the approach recommended for genotoxic carcinogens adopted the method developed by Crump and Howe (1984) for

applying the linearized multistage model to assessing carcinogenic risks based on exposures of short duration.²

Later in the same report, the NRC summarizes that: “Guidance published by the NRC (1993a) states that the setting of AEGLs (CEELs) [acute exposure guideline levels (for termed “community emergency exposure levels”)] should involve linear low-dose extrapolation from an upper confidence limit on excess risk for genotoxic carcinogens.”³

As stated in this NRC report, the decision to conduct such extrapolation and modeling should be based on “sound biologic and statistical principles.”⁴ EDF is concerned that EPA did not sufficiently consider such principles related to mode-of-action in arriving at its decision not to model acute cancer risk based on chronic exposure data. In particular, given that 1) the Agency recognizes that “[f]ollowing EPA’s *Guidelines for Carcinogen Risk Assessment* (U.S. EPA, 2005a), the overall weight of the scientific evidence supports a mutagenic MOA for 1-BP induced carcinogenicity” (p. 159), and 2) a mutagenic MOA suggests a role for “a single direct reaction, specifically, a single hit in a single target (Kirsch-Volders et al., 2000),⁵” a linear low dose extrapolation from chronic to acute exposures would be the health-protective approach to take for 1-BP.

EPA’s current approach assumes acute exposures to 1-BP, including to consumers, pose *zero* cancer risk – an assumption that is clearly not warranted based on the weight of the evidence. EPA needs to apply an extrapolation that provides a scientifically sound estimate for cancer risk from acute and short-term exposures to 1-BP.

3. EPA errs in deeming a 1 in 10,000 cancer risk level reasonable for workers

EPA erroneously states that “EPA typically uses a benchmark cancer risk level of 1×10^{-4} for determining the acceptability of the cancer risk in a population.” (p. 226). EPA then uses this benchmark to assess risks to workers. EPA errs in this approach because, as explained below, the typical benchmark is 1×10^{-6} . Moreover, TSCA expressly requires that EPA protect workers, both generally and as a “potentially exposed or susceptible subpopulation,” under TSCA. The 2016 amendments to TSCA strengthened EPA’s already-existing mandate to protect workers. TSCA’s new definition of “potentially exposed or susceptible subpopulation” has no asterisk

² National Research Council, *Standing operating procedures for developing acute exposure guideline levels for hazardous chemicals* pp. 111-112 (2001), https://www.epa.gov/sites/production/files/2015-09/documents/sop_final_standing_operating_procedures_2001.pdf (emphasis added).

³ *Id.* 118.

⁴ *Id.* 116

⁵ Zoë Gillespi, et al., *Risk assessment approaches for carcinogenic food contaminants*, 1:1 INT’L FOOD RISK ANALYSIS J. 1-18 (2011), <https://hrcak.srce.hr/file/107066>.

next to workers, and there is no basis in TSCA for EPA to provide less protection to workers than any other such subpopulation, let alone than the general population.

In implementing TSCA (even before the amendments) and its other environmental statutes, EPA has generally sought to reduce population risks from chemicals in commerce that are carcinogens to below about one case per one million people. See, for example, this EPA statement from a rule finalized under the Clean Air Act in 1989: “EPA believes *** that it should reduce risks to less than 1×10^{-6} for as many exposed people as reasonably possible.”⁶ Nor does EPA only apply this standard under the Clean Air Act. When setting Clean Water Act criteria, “EPA intends to use the 10^{-6} risk level, which the Agency believes reflects an appropriate risk for the general population. EPA’s program office guidance and regulatory actions have evolved in recent years to target a 10^{-6} risk level as an appropriate risk for the general population. EPA has recently reviewed the policies and regulatory language of other Agency mandates (e.g., the Clean Air Act Amendments of 1990, the Food Quality Protection Act) and believes the target of a 10^{-6} risk level is consistent with Agency-wide practice.”⁷ When Congress amended TSCA to include the unreasonable risk standard, it did so knowing that agency practice was to regulate cancer risks at the 1×10^{-6} risk level. It should be presumed that Congress meant to adopt this risk standard when codifying the unreasonable risk standard.

While EPA has applied the 1×10^{-4} risk level in the past, it has done so when analyzing the level set to reflect the maximum risk faced by any individual vs. the level set to protect a broader population. Specifically, EPA has used the “two-step approach” under the Clean Air Act, where EPA includes a “limit on *maximum individual* lifetime [cancer] risk (MIR) of approximately 1 in 10 thousand.”⁸ But that is entirely different than the level set to protect the vast majority of the population in question.

More specifically, the two-step, risk-based decision framework for the National Emission Standard for Hazardous Air Pollutants (NESHAP) program is described as follows by EPA:

First, the rule sets an upper limit of acceptable risk at about a 1-in-10,000 (or 100-in-1 million) lifetime cancer risk for the *most exposed person*. As the rule explains, “The EPA will generally presume that if the risk to that individual [the Maximum Individual Risk] is no higher than approximately 1 in 10 thousand, that risk level is considered acceptable and EPA then considers the other health and risk factors to complete an overall judgment on acceptability.”

⁶ National Emission Standards for Hazardous Air Pollutants; Radionuclides, 54 Fed. Reg. 51,654, 51,686 (Dec. 15, 1989).

⁷ U.S. EPA, Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health (2000), p.2-8, <https://www.epa.gov/sites/production/files/2018-10/documents/methodology-wqc-protection-hh-2000.pdf>.

⁸ 54 Fed. Reg. 38,045 (Sept. 14, 1989) (emphasis added).

Second, the benzene rule set a target of protecting the *most people possible* to an individual lifetime risk level no higher than about *1-in-1 million*.⁹

But in this risk evaluation, EPA has set a benchmark risk level of 1×10^{-4} for the entire worker population, which is the same as the level EPA elsewhere set for the most exposed individual in a population. This approach would subject many tens of thousands of workers to cancer risks that are as much as *two orders of magnitude higher* than warranted. This approach must be rejected on scientific as well as legal grounds.

4. EPA lacks access to full studies and relies only on summaries, prepared by industry, of limited aquatic toxicity testing to conclude 1-BP presents no unreasonable risks to the entire environment.

A. EPA has mischaracterized data cited as sourced from the European Chemicals Agency (ECHA).

On p. 43, EPA claims ECHA dossiers are existing chemical assessments equivalent to EPA and ATSDR governmental assessments: “Examples of existing assessments are EPA’s chemical assessments (e.g. previous work plan risk assessments, problem formulation documents), ATSDR’s Toxicological Profiles, EPA’s IRIS assessments and ECHA’s dossiers.”

But in fact ECHA dossiers are not assessments and are not government documents. They are compilations of *industry* information submitted to ECHA that have *not* been evaluated for quality or reliability by ECHA or any other governmental entity. For EPA to equate them with EPA and ATSDR assessments is simply wrong.

The HERO entries hyperlinked to the ECHA references (reading “ECHA, [date]”) in the text of the draft risk evaluation all list ECHA as the author. This is false and highly misleading; these documents were prepared by the industry registrant, not ECHA.

B. EPA lacks access to the full ECHA studies and did not subject them to systematic review.

EPA’s Charge Question 5.1 to the SACC states that:

Only a few environmental test data endpoints (including ECHA) are available in the public domain for 1-BP. Most are from the ECHA website. EPA attempted to obtain the full ECHA studies with no success. Since the studies were in French

⁹ WHAT DOES EPA BELIEVE CONSTITUTES AN ACCEPTABLE LEVEL OF RISK?, <https://www.epa.gov/national-air-toxics-assessment/nata-frequent-questions#risk2> (emphasis added) (last visited Jul. 19, 2019).

and Japanese (and no U.S.A. sponsor), EPA decided not to make further attempts to find the studies. Given that the ECHA environmental test data results are in the public domain, EPA decided to use the experimental data.¹⁰

As we have described in previous comments, EPA needs access to underlying data to ascertain the accuracy of the information and associated statements or conclusions, as well as to determine how much confidence or uncertainty applies to a particular submission. Even the best study summaries are incomplete descriptions that do not allow for an independent examination of study quality and conclusions reached by authors. Common examples of such conclusions include, “findings were not statistically significant,” “findings are within the range of historical controls,” and “effects observed were non-linear [and therefore biologically questionable or irrelevant].” Divorced from the details of the actual design and results of a study, it is impossible to evaluate the appropriateness of such conclusions. We incorporate our previous comments by reference.¹¹

Despite this, EPA indicates it used the ECHA summaries to characterize environmental hazards (p. 138). Not only is EPA relying only on summaries and lacks access to the full studies, it is relying on industry-prepared summaries that it cannot independently verify and that no government entity has evaluated for quality or accuracy. Also EPA indicates on p. 138 that the ECHA summaries were not subjected to systematic review, but that this did not stop EPA from using them in its analysis. On the following pages, EPA describes the results of these studies, even while indicating that, because it could not obtain the full study summaries, they were not reviewed for study quality. These studies comprise nearly all of the acute aquatic toxicity data EPA has.

Furthermore, it appears that the ECHA study summaries completely bypassed the data screening step of the literature search process (p. 44):

These are key and supporting studies from existing assessments (e.g., EPA IRIS assessments, ATSDR assessments, ECHA dossiers) that were considered highly relevant for the TSCA risk evaluation. These studies bypassed the data screening step and moved directly to the data evaluation step.

¹⁰ EPA Scientific Advisory Committee On Chemicals Charge To The Panel – 1-Bromopropane (1-Bp) CASRN: 106-94-5 p. 6.

¹¹ See, e.g., EDF Problem Formulation Comments at p. 61, <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0741-0085>, and EDF Comments on Procedures for Chemical Risk Evaluation under the Amended Toxic Substances Control Act at p.37, <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0654-0074>.

To the extent that the screening step is more than a screen for relevance and implies any sort of quality or reliability evaluation, bypassing the screening step for ECHA dossiers is totally inappropriate.

C. EPA has limited data and over-relies on ECHA study summaries.

EPA proceeds to use the results of the ECHA-sourced studies it has never obtained to draw conclusions about environmental risk.

With regards to acute aquatic toxicity, EPA states on p. 141:

As a result, only a single acute fish toxicity study identified during the literature search process ((Geiger et al., 1988)) has been evaluated according to the systematic review criteria in *The Application of Systematic Review in TSCA Risk Evaluations* (U.S. EPA, 2018a). Although full studies summarized in ECHA have not been evaluated for data quality, according to the systematic review criteria in *The Application of Systematic Review in TSCA Risk Evaluations*, a qualitative consideration of the results of these summaries indicates that the hazard conclusions of these summaries are consistent with the results of the fish study that was reviewed for data quality. All studies indicate that 1-BP presents a low or moderate hazard to aquatic environmental receptors. As a result, the environmental hazards are primarily described using the acute fish study, which was rated as high confidence (Geiger et al., 1988) (EPA, 2019l). This study constitutes the best available data to assess the environmental hazards of 1-BP. In an effort to utilize all available data characterizing the environmental hazards of 1-BP, the data presented in the ECHA study summaries were considered to contextualize and characterize the potential hazards and risks of 1-BP to aquatic receptors.

With respect to chronic aquatic hazard, EPA states on pp. 139-140:

As no data were available to characterize the hazards of chronic exposure to aquatic species, EPA estimated hazards from chronic exposure using an acute-to-chronic ratio (ACR). The most sensitive species following acute exposure, which in this case were freshwater fish, with a 96-hr LC50 of 67.3 mg/L (the value (Geiger et al., 1988) and 24.3 mg/L (ECHA, 2017) (EPA, 2019d) were divided by an ACR of 10 to estimate chronic values (ChV) for fish. This results in a fish chronic value (ChV) of $67.3 \text{ mg/L} / 10 = 6.73$ and $24.3 \text{ mg/L} / 10 = 2.43 \text{ mg/L}$, respectively. This approach was also used for aquatic invertebrates, where the 48-hr LC50 of 99.3 mg/L is divided by an acute-to-chronic ratio (ACR) of 10 to obtain a chronic value (ChV) for aquatic invertebrates. This results in a ChV of $99.3 \text{ mg/L} / 10 = 9.93 \text{ mg/L}$. (emphasis added).

Both the fish 24.3 mg/L and invertebrate 99.3 mg/L values are those reported by industry in the ECHA dossier. EPA relies on both values. EDF previously criticized EPA's resorting to use of an ACR in our comments on the Problem Formulation for 1-BP (see end of section 23 on p. 97). That critique remains relevant, and EPA has never responded to this point. Specifically, EPA provides no justification for its application of an 'acute-to-chronic ratio' or its specific value of 10, nor does it provide even a citation to the use of such values in other contexts. Even a cursory search of the literature indicates that an ACR of at least 100 may be needed to be sufficiently protective.¹²

Note that:

- EPA uses the ECHA value of 24.3 mg/L for acute fish toxicity as part of the basis for its fish chronic calculation even though that value has not been subject to any quality review because EPA lacks the full study.
- EPA characterizes the only other value it has, from Geiger et al., as the value for the "most sensitive species following acute exposure, which in this case were freshwater fish" (p. 140). That value is higher than the value from the ECHA-sourced study, however.

¹² See Martin May, et al., Evaluation of acute-to-chronic ratios of fish and Daphnia to predict acceptable no-effect levels, 28:1 *Envtl. Sciences Europe* 16 (2016), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5044967/>; Jan Ahlers, et al., Acute to chronic ratios in aquatic toxicity - Variation across trophic levels and relationship with chemical structure, 25:11 *Envtl. Toxicology & Chemistry* (Dec. 2009), [10.1897/05-701R.1](https://doi.org/10.1897/05-701R.1). ('For fish, daphnids, and algae, acute to chronic ratios (ACRs) have been determined from experimental data regarding new and existing chemicals. Only test results in accord with the European Union Technical Guidance Document (TGD) and validated by authorities were considered. Whereas the median ACRs of 10.5 (fish), 7.0 (daphnids), and 5.4 (algae) are well below the ACR safety factor of 100 as implied by the TGD, individual ACRs vary considerably and go up to 4400. The results suggest that a safety factor of 100 is not protective for all chemicals and trophic levels. Neither a correlation between ACR and baseline toxicity as modeled through the logarithmic octanol-water partition coefficient nor an ACR correlation across trophic levels exists. Narcosis is associated with a preference for a low ACR; nevertheless, low ACRs are frequently obtained for nonnarcotics. Analysis of chemical structures led to the derivation of structural alerts to identify compounds with a significantly increased potential for a high ACR, which may prove to be useful in setting test priorities. At present, however, life-cycle tests are the only way to conservatively predict long-term toxicity.' Emphases added).

- EPA also uses the ECHA value of 99.3 mg/L for acute invertebrates (first cited on p. 139) as the sole basis for its invertebrate chronic calculation even though that value has not been subject to any quality review because EPA lacks the full study.

EPA also has no toxicity data for sediment or terrestrial organisms and no monitoring data (pp. 140, 188, 146). On p. 47, EPA states: “During problem formulation, EPA made refinements to the conceptual models resulting in the elimination of the terrestrial exposure pathway from further analysis. Thus, environmental hazard data sources on terrestrial organisms were considered out of scope and excluded from data quality evaluation.” Instead, EPA resorts to vague arguments invoking the 1-BP’s physical-chemical properties to argue there will be little or no *exposure* (pp. 23, 140-141, 186).

Based only on the above very limited data and questionable analysis, EPA nevertheless draws a sweeping conclusion about the entire environment: “As a result, EPA determined that 1-BP does not present unreasonable risk to the environment under the identified conditions of use.” (p. 23) EPA’s analysis is wholly insufficient to establish that 1-BP does not present an unreasonable risk to the environment.

5. Overreliance on personal protective equipment and overstatements of OSHA requirements.

EPA’s risk determinations heavily rely on an assumption that all workers at all points in the value chain and lifecycle of 1-BP will always use personal protective equipment (PPE) (gloves and respirators) and that it will be universally effective:

EPA expects there is compliance with federal and state laws, such as worker protection standards, unless case-specific facts indicate otherwise, and therefore existing OSHA regulations for worker protection and hazard communication will result in use of appropriate PPE consistent with the applicable SDSs in a manner adequate to protect them (p. 289).

In addition to grossly distorting OSHA authorities and requirements (see below), EPA has provided no data or analysis whatsoever to support these sweeping assumptions. OSHA itself has highlighted the major limitations of reliance on PPE with regard to both extent of use and effectiveness, as has EPA in the recent past. These issues are discussed in detail in previous EDF comments, which are incorporated here by reference.¹³

¹³ See, e.g., EDF Comments on TSCA Review and Scoping for First 10 Chemicals under the Lautenberg Act at 6 (Mar. 15, 2017), <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0736-0046>; EDF Comments on Significant New Uses of Chemical Substances; Updates to the Hazard Communication Program and Regulatory Framework; Minor

In a few places in the draft, EPA acknowledges some of the limitations of PPE (p. 57, 206), and the preferability of other options higher up in the industrial hygiene hierarchy of controls (p. 57). But when it comes to determining risk, those limitations and preferences fall away and EPA exclusively relies on “expected” use of PPE to mitigate the risks it has identified. To do so, EPA unrealistically assumes that “workers are properly trained and fitted on respirator use, and that they wear respirators for the entire duration of the work activity where there is potential exposure to 1-BP.” (p. 24) As just one example, EPA finds no unreasonable risk for non-cancer acute inhalation occupational use of 1-BP in manufacturing where the acute MOE for high-end exposure is substantially *lower* than the benchmark MOE (63 and 100, respectively) by assuming universal and effective use of an APF 10 respirator (see Table 4-6, p. 195).

EPA repeatedly overstates or distorts OSHA’s authorities and requirements, claiming that OSHA requires employers to provide PPE (p. 289), implying that OSHA requires the use of respirators for 1-BP (p. 57), and implying that OSHA’s requirement for safety data sheets (SDSs) is sufficient to ensure use of protective measures such as PPE by all downstream users of 1-BP (p. 289). In fact, OSHA authorities and requirements are quite limited and leave most of their applicability to be decided by employers, not OSHA. Among other things, OSHA regulations do not require that persons comply with SDSs. EDF has described these limitations in detail in a recent series of posts to our EDF Health blog.¹⁴ EDF incorporates those by reference. EDF also incorporates by reference the comments submitted by Jonathan Kalmuss-Katz and Randy Rabinowitz.¹⁵

Even if compliance with SDSs *were* mandatory, reliance on them would still be insufficient to ensure use of protective measures by all downstream users. Significant evidence demonstrates that SDSs are often of insufficient quality to be useful and are frequently not understood. Nicol et al. (2008) conducted a systematic search of the literature and identified serious problems with the use of SDSs as hazard communication tools: they are often inaccurate, incomplete, and too technical for workers to understand.¹⁶ The 2012 OSHA Hazard Communication Standard corroborates these findings.¹⁷ For example, the Standard reports that “several studies show that employees do not understand approximately one-third of the safety and health information listed

Amendments to Reporting Requirements for Premanufacture Notices (Nov. 21, 2016), <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2014-0650-0052>.

¹⁴ See Appendix A.

¹⁵ Comments submitted by Jonathan Kalmuss-Katz, Staff Attorney, Earthjustice and Randy Rabinowitz, Executive Director, Occupational Safety & Health (OSH) Law Project <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2019-0238-0021>.

¹⁶ Anne-Marie Nicol, et al., *Accuracy, comprehensibility, and use of material safety data sheets: A review*, 51:11 AM. J. OF INDUS. MED. 861-76 (Jul. 2008), <https://onlinelibrary.wiley.com/doi/abs/10.1002/ajim.20613>.

¹⁷ 77 Fed. Reg. 17574, 17593-95, 17603 (Mar. 26, 2019).

on SDSs prepared in accordance with the current standard” and that “[s]tudies also report that roughly 40% of persons reviewing SDSs found them difficult to understand.”¹⁸

Furthermore, studies conducted by Eastlake et al. (2012) and Dodson et al. (2019), which examined SDSs for engineered nanomaterials developed after the 2012 update to the OSHA Hazard Communication Standard, demonstrate that SDSs often contain insufficient information to adequately communicate health hazards.^{19,20} For example, Hodson et al. (2019) found that of 67 SDSs evaluated, 35.8% were determined to be unreliable based on the Klimisch criteria and 79% “need significant improvement” based on the Eastlake et al. (2012) ranking scheme. The authors concluded “the quality of information on many [nanomaterial SDSs] still cannot be relied upon to offer adequate information on the inherent health and safety hazards, including handling and storage of engineered nanomaterials.”

EPA’s reliance on PPE is not merely a policy determination that is beyond the charge of the SACC. For instance, Charge Question 8 specifically requests that the SACC address the uncertainties and assumptions underlying EPA’s risk characterization. EPA’s reliance on PPE is the foundation of EPA’s no reasonable risk determinations for workers even though EPA has acknowledged, for example, that “[f]ew literature sources indicate the use of respirators in 1-BP conditions of use” (p. 57) and “EPA *does not know* the actual frequency, type, and effectiveness of glove use in specific workplaces with 1-BP conditions of use” (p. 108, emphasis added). EPA’s failure to provide *any* supporting data that PPE is universally used, as assumed by risk determination, is a key assumption regarding *risk* that the SACC can and should comment on, i.e. is that assumption scientifically valid?

6. Further Considerations for the SACC

A. See 1-BP Problem Formulation for cursory analysis of the following pathways. EPA conducted no further analysis in the draft risk evaluation:

- Sediment-dwelling or terrestrial species (p. 21);
- Environmental release pathways leading to surface water, sediment, or land-applied biosolid exposures to ecological receptors (p. 27);
- Air, water, sediment, land application and biosolids pathways (p. 50); and

¹⁸ *Id.* at 17603; *see also* OSHA, *Inspection Procedures for the Hazard Communication Standard (HCS 2012)* (Jul. 2015), https://www.osha.gov/OshDoc/Directive_pdf/CPL_02-02-079.pdf.

¹⁹ Adrienne Eastlake, et al., *A critical evaluation of material safety data sheets (MSDSs) for engineered nanomaterial*, 19:5 J. OF CHEM. HEALTH & SAFETY 1-8 (Sept.-Oct. 2012), <https://www.ncbi.nlm.nih.gov/pubmed/26766894>.

²⁰ Laura Hodson, et al., *An evaluation of engineered nanomaterial safety data sheets for safety and health information post implementation of the revised hazard communication standard*, 26:2 J. OF CHEM. HEALTH & SAFETY 12-18 (Mar.-Apr. 2019), <https://www.ncbi.nlm.nih.gov/pubmed/30906483>.

- Air (inhalation) for ecological terrestrial species, water (drinking water; wastewater; surface water and resulting exposures to ecological aquatic species); biosolids, sediments, and soils. (p. 38)
- B. Only inhalation and dermal pathways for workers and consumers were considered; EPA did not consider the oral pathway (pp. 20-21).
- C. Inhalation to dermal extrapolation was required (p. 22), due to limited dermal toxicity data (e.g., “no repeated-dose toxicity studies by the dermal route were identified,” p. 184). EPA discusses the limitations and uncertainties with this approach in section 3.2.10.5.
- D. EPA states: “EPA believes peer reviewers will be most effective in this role if they receive the benefit of public comments on draft risk evaluations prior to peer review. For this reason, and consistent with standard Agency practice, the public comment period will precede peer review on this draft risk evaluation.” (p. 28) This statement is inaccurate.

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