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 x 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.

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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=FEFederal&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 $1x10^{-4}$ 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 x 10^{-4} Benchmark

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

Category	Dermal Slope Factor $(mg/kg\text{-}day)^{-1}$	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

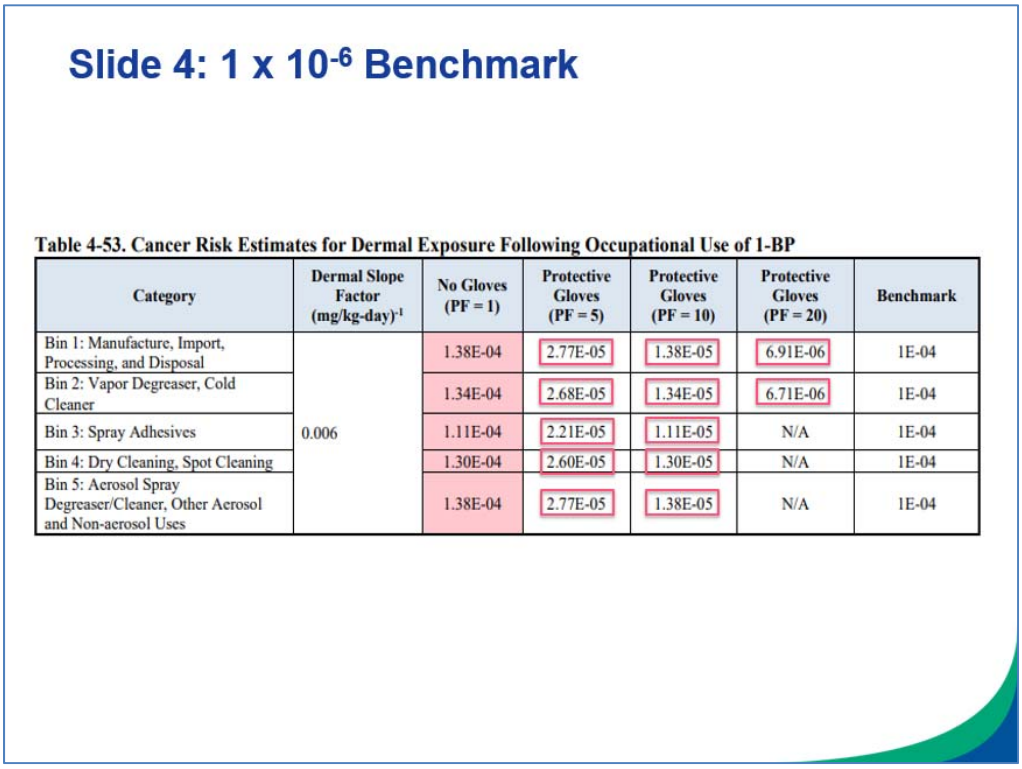
Recall my colleague Stephanie's earlier comment that EPA should be using a much more protective cancer risk benchmark. If EPA used, say, even 1 in 100,000, the table shows it would have found excessive risk in every scenario even assuming gloves with a PF up to 10.

Slide 3: 1 x 10^{-5} Benchmark

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

Category	Dermal Slope Factor $(mg/kg\text{-}day)^{-1}$	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.



You can see through these examples how hard EPA has had to work to avoided 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.