May 9, 2016

Wendy C. Hamnett
Director, Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue NW
Washington, DC 20460


Dear Ms. Hamnett:

On behalf of Blue Green Alliance, Earthjustice, Environmental Health Strategy Center, Natural Resources Defense Council, Safer Chemicals Healthy Families and Sierra Club Toxics Committee, we submit the following comments regarding the Toxic Substances Control Act (“TSCA”) Work Plan Chemical Risk Assessment Peer Review Draft for 1-Bromopropane (n-Propyl Bromide) (“Draft Assessment”) prepared by the U.S. Environmental Protection Agency (“EPA” or “the Agency”). We commend EPA for assessing the risks posed by 1-Bromopropane (“1-BP”), a high-production volume chemical with significant toxicity used in a variety of settings, including in consumer products.

It is critically important for EPA to complete its assessment of 1-BP as soon as possible, and to restrict all uses that pose unreasonable risks to workers, consumer-users, and exposed communities. The relative lack of regulation of 1-BP, coupled with EPA’s actions (for example, listing 1-BP as an acceptable substitute for ozone-depleting substances under the Significant New Alternatives Policy (“SNAP”) and regulating the dry cleaning solvent perchloroethylene (“perc”), are significant drivers of the increased use of 1-BP. The fact that EPA’s actions have spurred new uses of 1-BP makes it all the more important for EPA to ensure that it does not harm human health or the environment.

1 The Draft Assessment states: “1-BP’s use may have recently increased in many industrial applications because the chemical is used as an alternative to ozone-depleting substances and chlorinated solvents.” Appendix A at 181; see also Toxics Use Reduction Inst. (“TURI”), Summary of Policy Analysis, Higher Hazard Substance Designation Recommendation: 1-Bromopropane (n-Propyl Bromide) CAS 106-94-5 (May 15, 2014), http://www.mass.gov/eea/docs/eea/ota/tur-prog/policy-analysis-npb-may2014.pdf. TURI concludes that because 1-BP is “subject to relatively few regulatory restrictions at the federal level,” it has “gained popularity as a substitute for other, more strictly regulated HHS solvents.” Id. at 1.
As we explain below, we are concerned that the Draft Assessment does not take into account the full range of exposures to 1-BP. In particular, it fails to consider exposures for communities in the vicinity of facilities where 1-BP is used, processed, or manufactured – nor for the fact that the people affected are likely to be disproportionately low-income and from communities of color. In addition, the Draft Assessment does not address the fact that a urinary metabolite indicative of 1-BP exposure is widely found in the general population, indicating widespread exposure to the general population. The assessment also does not account for dermal exposures despite acknowledging that such exposures occur, nor for cumulative exposures to multiple carcinogenic solvents. Failure to include the full scope of exposures to 1-BP in the risk assessment will result in an underestimation of risk. This underestimation is of great concern, as it could mean that 1-BP will continue to be used in settings that lead to harmful exposures and serious health impacts. As we discuss in more detail below, we urge EPA to include the risks from human exposures to 1-BP via *all pathways* in the final risk assessment, as TSCA requires. In addition, in accounting for the risk to pregnant women and from in utero exposures, EPA’s risk calculation must reflect the uncertainties and data gaps relevant to early life exposure.

Finally, we are troubled that some information about where 1-BP is manufactured is concealed due to a claim of Confidential Business Information (“CBI”). We are also concerned that EPA itself is not certain that all domestic manufacturers of 1-BP are reporting their production. In order to ensure appropriate transparency in the Agency’s work, we urge EPA to re-substantiate all claimed CBI that is cited in its Work Plan Chemical assessments and to pursue enforcement actions against chemical manufacturers that have failed to comply with reporting requirements.

**DETAILED COMMENTS**

1. **The Draft Assessment must consider general and vulnerable population exposures to 1-BP**

The Draft Assessment is incomplete because it does not address the risks posed to communities living near sources that use or manufacture 1-BP. EPA states that it is excluding general population exposures “because no reliable exposure data for calculating general population risks are available.” There are three problems with this approach: First, ignoring known general population exposures is inconsistent with TSCA. Second, the Draft Assessment ignores evidence that communities are exposed to 1-BP as a result of emissions from facilities using this chemical. Third, general population exposures will likely have a disproportionate adverse impact on low-income communities and communities of color.

   a. **TSCA requires EPA to consider risks from all exposures**

Under TSCA, in assessing a chemical substance, EPA must consider whether “the manufacture, processing, distribution in commerce, use, or disposal,” or “any combination of such activities,”

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2 Concerns about the scope of the Draft Assessment highlights why it is better practice for EPA to publish its problem formulations for public comment before moving on to the draft risk assessment. In the future, we urge EPA to allow the public to weigh in on the problem formulation and scope of the assessment.
“presents or will present an unreasonable risk.” EPA must consider and publish a statement with respect to the effects of such substance on health and the magnitude of the exposure of human beings to such substance. EPA cannot fulfill the requirements of TSCA to consider the “combination” of exposures and to document the “magnitude” of human exposures, unless its final 1-BP risk assessment takes into account the risks from all known exposures including the possibility, discussed immediately below, that communities in the vicinity of facilities using or manufacturing 1-BP will inhale the chemical as a result of its presence in ambient air.

b. There is evidence of community exposure to 1-BP from ambient air

There is evidence that communities are exposed to 1-BP on an on-going basis. This is documented within the Draft Assessment’s “Schematic of Human and Environmental Exposure Pathways for 1-BP,” which shows that manufacturing and occupational uses of 1-BP result in emissions to outdoor air that can lead to oral, dermal and inhalation exposures by the general population. Moreover, the Agency for Toxic Substances and Disease Registry’s (“ATSDR”) Draft Profile notes that “[e]xposure of 1-bromopropane to the general population may occur via inhalation of ambient air at locations in close proximity to the emissive use of 1-bromopropane, such as degreasing operations or dry cleaners (NTP 2011), where vapor may migrate.” In addition, when the Occupational Safety and Health Administration (“OSHA”) nominated 1-BP for testing by the National Toxicology Program (“NTP”), it stated:

Various estimates have been made of the potential market for 1-BP in the key uses to which it is likely to be put: metal cleaning and degreasing, adhesives (especially for assembling polyurethane and other foam products), and aerosol spraying. Note that all of these uses are in practice highly emissive applications, resulting in substantial releases to the ambient environment and substantial exposure to workers…

The potential for general population exposures via ambient air is confirmed by the following monitoring and modeling studies:

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5 Draft Assessment at 35, Figure 1-2.
6 ATSDR, Draft Toxicological Profile for 1-Bromopropane, Docket ID No. ATSDR-2016-0003-0001 at 138 (Jan. 2016) (“ATSDR Draft Profile”). See also id. at 7 (“The general population may be exposed to 1-bromopropane in air when it is used during aerosol applications.”)
In 2014, EPA’s Air Quality System database reported only positive detections of 1-bromopropane at one monitoring location. 1-Bromopropane was detected in ambient air of Philadelphia, Pennsylvania at levels of 0.14–0.16 ppb (0.047–0.053 ppbv).\(^8\)

In 2009, average concentrations as high as 3.0 ppb (or 1.0 ppbv) were detected at a monitoring site directly east and upwind of the Superior Tube facility approximately 800 feet from the southeast corner of the company building.\(^9\) 77% of the samples taken from this location in 2009 found 1-BP at levels above the detection limit.\(^10\)

EPA itself has also used air dispersion modeling to estimate ambient 1-BP concentrations 100 meters from facilities that use 1-BP as an adhesive. The estimated concentrations were 0.138 mg/m\(^3\) [27.4 ppb] for facilities with average adhesive use and 1.38 mg/m\(^3\) [274 ppb] for facilities with high adhesive use.\(^11\) Inexplicably, this study is not included in the Draft Assessment.

In comments submitted to the HAP docket, Professor Adam Finkel, former director of Health Standards Programs and Regional Administrator at OSHA, stated:

> In addition to documented concerns about indoor (in or adjacent to facilities using nPB) exposures, the air pollution modeling study done by Exponent in the docket reveals serious concern for outdoor exposure. Table 14 in that document estimates the maximum fenceline risk (lifetime excess cancer risk) from “Fabrication Company B” to be 2.1x10\(^{-5}\).\(^12\)

Recent data from Massachusetts, where certain facilities must report 1-BP emissions,\(^13\) confirm that unregulated 1-BP is released from industrial sources at high levels. In 2010-2011, electronics facilities in Massachusetts reported that more than half of the amount of 1-BP that

\(^8\) ATSDR Draft Profile at 137 (internal citation omitted).


\(^10\) Id. at 5.


\(^12\) Adam Finkel, Comment on Petition to Add n-Propyl Bromide to the List of Hazardous Air Pollutants, Docket ID No. EPA-HQ-OAR-2014-0471-0047 at 3 (March 8, 2015) (noting increased cancer risk at fenceline for facility with indoor level of 1-BP at 30 ppm) (submitted herewith as Attachment 2).

was used was released into the environment in each reporting year.\textsuperscript{14} Although only three companies reported releases, 1-BP was the chemical with the 17\textsuperscript{th}-largest releases reported in Massachusetts.\textsuperscript{15} An electronic capacitor facility, Aerovox Corp., released 11,772 pounds of 1-BP into the environment of the city of New Bedford, Massachusetts in 2012.\textsuperscript{16}

No information is yet available in the Toxic Release Inventory (“TRI”) database regarding releases from facilities that manufacture or process 1-BP because this chemical was just added to the TRI list of reportable chemicals effective January 2016.\textsuperscript{17} However, in adding 1-BP to the TRI list, EPA estimated that 131 facilities using or manufacturing 1-BP, not including dry cleaning facilities, will be required to report release and waste management data.\textsuperscript{18} Moreover, in 2003, when EPA proposed listing 1-BP as an acceptable substitute for ozone-depleting substances under the SNAP program, it estimated that up to 7,330 small industrial end users used 1-BP.\textsuperscript{19} According to Appendix A to the Draft Assessment, the U.S. production volume of 1-BP has increased significantly since 2003, so presumable there are either more small users, or some small users have increased their use.

In addition to accounting for general population exposures from manufacturing and processing, the final risk assessment also must consider community exposures to 1-BP as a result of its use as a dry cleaning solvent replacing perc. Data about community exposures from the use of perc as a dry cleaning solvent can shed light on likely community exposures to 1-BP when it is used as a replacement for perc. Information gathered for the rule setting emission standards for perc shows that toxic air emissions from dry cleaners, over 34,000 nationwide, are often released into the environment.\textsuperscript{20} The approximately 1,300 dry cleaners that are co-located in residential buildings are mostly found in urban areas.\textsuperscript{21} In creating the perc rule, EPA found that individuals

\textsuperscript{14} \textit{Id.} at 4-6 (noting a lower reporting threshold would likely lead to more industries like dry cleaning to report 1-BP releases).

\textsuperscript{15} \textit{Id.} at 4.

\textsuperscript{16} \textit{Mass. Toxics Use Reduction Inst., TURA Data} (last visited May 9, 2016), http://turadata.turi.org/ [enter Company ID “331916”, click “Find ID”, then click “Chemical Quantity Detail for All Years”].

\textsuperscript{17} The Draft Assessment erroneously states that the TRI rulemaking has not been finalized. \textit{Draft Assessment} at 29. The TRI rule was finalized in late 2015. \textit{See} Addition of 1-Bromopropene; Community Right-to-Know Toxic Chemical Release Reporting, 80 Fed. Reg. 72,906 (Nov. 23, 2015).


\textsuperscript{19} Protection of Stratospheric Ozone: Listing of Substitutes for Ozone-Depleting Substances --n-Propyl Bromide, 68 Fed. Reg. 33,284, 33,309 (June 3, 2003).


\textsuperscript{21} \textit{Id.} at 42,725, 42,738.
living in the same building as a dry cleaner are likely to receive significantly higher exposure to emissions of air pollutants from these types of sources. 22 In a study of emissions from New York City dry cleaners, those living in urban areas faced higher indoor levels of perc, and the mean perc levels inside households of people of color were four times higher than in white households. 23 It is unclear whether (and how many) dry cleaners co-located in residential buildings are using 1-BP. If they are, it is reasonable to assume that, as with perc, there will be chronic community exposures.

In sum, there is evidence of potential community exposures to 1-BP from the Draft Assessment, the ATSDR Draft Profile, OSHA’s statement nominating 1-BP for testing by NTP, modeling and monitoring studies, reporting data from Massachusetts, EPA’s economic analysis for the listing of 1-BP on the TRI, and by analogy to community exposures to perc. EPA must consider these potential exposures in the final risk assessment.

c. EPA must consider disparate impact on communities of color and low-income communities

Exposure to 1-BP due to its presence in ambient air from dry cleaning, foam and furniture manufacturing 24 and chemical manufacturing likely disproportionately impacts low-income communities and communities of color. For example, EPA found that air emissions from foam fabricators covered by a separate air toxics rule created disproportionate exposure and other impacts for African Americans, since African Americans are over-represented in communities within a 3 mile radius of foam fabricators. 25 The African American population in areas surrounding foam manufacturing facilities exceeds the national average by 53% (19% versus 13%). 26 In New Bedford, Massachusetts, where an electronic capacitor factory released 11,772

22 Memorandum from Neal Fann, Risk and Exposure Assessment Group, EPA, OAQPS, to Dave Guinnup, Group Leader, Risk and Exposure Assessment Group, EPA, OAQPS, Docket ID No. EPA-HQ-OAR-2005-0155-0494, at 5 (July 2006).

23 Michael J. McDermott et al., Tetrachloroethylene (PCE, Perc) Levels in Residential Dry Cleaner Buildings in Diverse Communities in New York City 5 (June 21, 2005), Docket ID No. EPA-HQ-OAR-2005-0155-0290.


26 79 Fed. Reg. at 48,086. In another furniture manufacturing rule, EPA also found disproportionate exposure and impacts for minorities, in particular Hispanic or Latino groups. See EC/R Inc., Risk and Technology Review - Analysis of Socio-Economic Factors for
pounds of 1-BP into the environment in one year, 16.7% of the population reporting to the Census as Hispanic and 23.5% of people live below the poverty line.  

When it finalizes the 1-BP risk assessment, EPA should consider vulnerable and sensitive populations living in exposed communities and account for the potential health impacts of chronic exposures.

2. **EPA should acknowledge and assess the risk reflected by the widespread presence of urinary metabolites of 1-BP in biomonitoring and epidemiological studies**

We are disappointed and concerned that the Draft Assessment does not mention, let alone attempt to explain, the fact that biomonitoring studies have found a urinary metabolite of 1-Bromopropane -- N-Acetyl-S-(n-propyl)-L-cysteine -- in a large proportion of the population. In finalizing the addition of 1-BP to the TRI list, EPA referred to N-Acetyl-S-(n-propyl)-L-cysteine as the “major metabolite” of 1-BP, and noted that it has been detected in the urine of exposed workers at levels that increased with increasing levels of 1-BP in ambient air. Multiple studies confirm that this metabolite is associated with 1-BP.

A table from the most recent National Health and Nutrition Examination Survey (“NHANES”) is reproduced below. At the 50th percentile of concentration, all groups had measurable quantities of urinary N-Acetyl-S-(n-propyl)-L-cysteine, which CDC refers to as a metabolite of 1-BP.

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In addition, a very recent epidemiological study of 488 women in the third trimester of pregnancy in 7 locations around the country (who participated in the National Children’s Study) found that 99% of the participants had the 1-BP metabolite (N-Acetyl-S-(n-propyl)-L-cysteine) in their urine.\(^{30}\)

The high detection rate of N-Acetyl-S-(n-propyl)-L-cysteine in bio-monitoring studies raises serious questions about the possibility that the general population is experiencing continuous or frequent exposure to 1-BP. This is because the urinary metabolite is not expected to persist over long periods after a single exposure. While exposures to chemicals other than 1-BP could account for the presence of this metabolite, it is incumbent upon EPA to acknowledge the NHANES and National Children’s Study data and address whether these findings raise concerns about widespread exposures to 1-BP.\(^{31}\)


\(^{31}\) Our concern is heightened by the fact that “1-BP can be used . . . as a chemical intermediate in . . . flavors, and fragrances.” Abt Assocs., *Economic Analysis of the Proposed Rule to add 1-Bromopropane to the EPCRA Section 313 List of Toxic Chemicals*, Docket ID No. EPA-HQ-TRI-2015-0011-0011 at 1-5 (Feb. 17, 2015). These uses are not well-regulated and the identity of ingredients is often secret.
If EPA cannot account for the NHANES and National Children’s Study findings, it should promptly move forward to obtain the information it needs to make sense of these data.  

Furthermore, EPA should investigate how these data might be useful in its risk estimate calculations, since these represent actual biomarker estimates of human exposures to 1-BP and would be indicative of the levels that the general population is being exposed to this chemical on a daily basis.  

Although the widespread presence of N-Acetyl-S-(n-propyl)-L-cysteine in bio-monitoring studies suggests that the general population may be experiencing chronic exposures to 1-BP, the Draft Assessment considers only acute inhalation exposures for the general population based on consumer uses of a limited set of products. The potential that the general population is experiencing chronic 1-BP exposures, which could be via dermal as well as inhalation routes, needs to be accounted for in the final risk assessment. 

3. EPA’s Draft Assessment fails to take into account the full range of exposures or the effects of exposure to multiple similar solvents

We are concerned that the Draft Assessment does not include potential harm to workers exposed through dermal contact, despite evidence that workers are harmed by exposure to 1-BP via this pathway. We also do not understand why the Draft Assessment does not include dermal pathways of exposure for consumer-users of 1-BP who are likely not using gloves or other personal protective equipment.

The Draft Assessment itself notes that “dermal and inhalation pathways are expected to be more relevant,” and exposure is possible in both occupational and consumer use scenarios through spilled solutions or by handling treated items without gloves. The ATSDR Draft Profile reaches the same conclusion, noting: “Although the principal route of exposure was likely inhalation, dermal exposure could have been significant since often no gloves were used when handling 1-bromopropane, or the use of gloves, as noted in some reports, may have enhanced dermal uptake of 1-bromopropane by occlusion effect.” The data show the potential for the same worker to be exposed simultaneously or additively to this chemical as a result of both

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32 This study makes clear that the exposure is not associated with direct or secondhand exposure to smoke, which is a major source for other VOCs. R. B. Jain, *Levels of selected urinary metabolites of volatile organic compounds among children aged 6-11 years*, 142 Envtl. Res. 461 (Oct. 2015).

33 Draft Assessment at 83.

34 ATSDR Draft Profile at 8. *See also id.* at 16 (“In occupational studies and case reports described below, exposure to 1-bromopropane occurred primarily via the inhalation route, but dermal exposure may have also occurred. Since in most cases, it is not known whether or not the workers were using protective clothing and/or respirators, the specific contribution of each route of exposure is not possible to determine. *Therefore, the reader should keep in mind that both inhalation and dermal routes combined may have contributed to the effects described.*”) (emphasis added).
inhalation and dermal pathways. EPA has no rational scientific basis for ignoring the dermal route in its own right, or in combination with inhalation exposure.

EPA excludes dermal exposure from the risk assessment because “dermal uptake is likely to be...lower than uptake by inhalation because 1-BP will evaporate quickly.” This is problematic because internal doses are likely to be underestimated when dermal exposure is excluded. Only considering the dominant exposure pathway is not appropriate; if multiple exposure pathways would potentially occur, EPA must consider the cumulative exposures and resulting health effects from these exposures. EPA notes this deficiency but claims it is only an issue in the case of “no-risk” findings where reported margins of exposure (“MOEs”) are close to, but still higher than the benchmark MOE. The benchmark MOE is calculated by dividing the point of departure (POD) by the estimated human exposure. The POD is often the exposure level at which no adverse effects are observed in observational studies. If later versions of this assessment revise the POD and incorporate a higher value, then excluding dermal exposure from the estimated exposure value may result in a reported MOE that is higher than the benchmark MOE. This inflated value would skew the final risk assessment toward allowing continued exposures at higher levels than what the benchmark MOE allows— an unacceptable result. EPA should consider all potential routes of exposure and incorporate all relevant routes into its final risk estimate to provide an accurate estimate of the potential risk, and not simply assume— wrongly— that incorporating one exposure route would be sufficiently protective of all others.

Moreover, difficulty in quantifying dermal exposures is not a basis for ignoring this exposure pathway in the risk assessment. If dermal exposure was not quantifiable, then how can EPA say that it is likely to be “orders of magnitude lower than uptake by inhalation”? Without providing data to justify this claim and the subsequent exclusion of the dermal route of exposure, some attempt must be made to estimate the extent of dermal exposure compared to inhalation exposure among people using products containing 1-BP. Although dermal uptake may be lower relative to inhalation uptake, it can still be significant and should not be ignored as a pathway of exposure. Additionally, the National Institute for Occupational Safety and Health (“NIOSH”) recently calculated that 1-BP has a skin dose to inhalation dose (SI) ratio higher than 0.1, which is the threshold that indicates that skin absorption may significantly contribute to the overall body burden of a substance. Among the reasons stated for discounting the dermal route of exposure, one is that there is “no available toxicokinetic information to develop physiologically-

35 Draft Assessment at 36.
36 Id. at 36, 154.
based pharmacokinetic models or route-to-route extrapolations.” Lack of data is not equivalent to the lack of potential hazard or risk.38

Finally, when EPA finalizes its risk assessment, we urge it to consider not only the health effects of exposure to 1-BP, but also the combined effects of exposures to 1-BP and other similar compounds. This is especially critical in the occupational setting where workers may be exposed to multiple VOC solvents, many of which are carcinogens. There is scientific consensus that carcinogenic risk is at least additive, and exposure to multiple carcinogens increases this risk.39 That is, the more carcinogens a person is exposed to, the greater their risk of cancer over their lifetime, and cancer risks should be summed together.40

EPA should acknowledge that there is particularly high risk for workers and community members exposed to 1-BP as well as other carcinogens through any combination of occupational, consumer, and community ambient air exposure.

4. EPA’s risk calculation fails to fully account for risks to pregnant women and from in utero exposure

EPA states that it is addressing pregnant women’s exposure as a highly vulnerable endpoint. But, EPA’s risk assessment does not make clear how, if at all, EPA’s risk values actually account for the increased vulnerability caused by in utero exposure. Failing to quantitatively account for

38 Indeed, in finalizing a Design for the Environment Alternatives Assessment, EPA correctly responded to a comment stating: “The absence of test data may be assumed by some readers to be an indication of no concern (i.e., they may incorrectly believe that no data is equivalent to the lack of potential hazard or risk).” EPA, Public Comments Submitted on the Draft Final Report, “Flame Retardants Used in Flexible Polyurethane Foam: An Alternatives Assessment Update” at 10 (Aug. 2015), https://www.epa.gov/sites/production/files/2015-08/documents/ffr_response.pdf.

39 See, e.g., Cal. EPA OEHHA, Risk Assessment Guidance Manual (finalized Mar. 6, 2015) at 1-5, 2-4, 8-12, http://oehha.ca.gov/air/hot_spots/hotspots2015.html (“Cancer risks from all carcinogens addressed in the HRA [health risk assessment] are added.”; “Cancer risks from different substances are treated additively in risk assessment generally, and in the Hot Spots Program in part because many carcinogens act through the common mechanism of DNA damage.”).

40 EPA has codified this scientific principle in its own guidelines. See, e.g., Residual Risk Assessment for Petroleum Refineries (Dec. 1, 2015) at 34, EPA-HQ-OAR-2010-0682-0800, https://www.regulations.gov/#!documentDetail;D=EPA-HQ-OAR-2010-0682-0800 (“To combine risks across multiple carcinogens, our assessments use the mixtures guidelines’ [37,38] default assumption of additivity of effects, and combine risks by summing them using the independence formula in the mixtures guidelines.”) (citing EPA, Guidelines for the Health Risk Assessment of Chemical Mixtures, EPA-630-R-98-002 (1986); EPA, Supplementary Guidance for Conducting Health Risk Assessment of Chemical Mixtures at 73, 125 & A-9, EPA-630/R-00-002 (2000)).
such vulnerability within the risk assessment values would mean that EPA’s risk values are underestimates of real-world risk for the most vulnerable population.

EPA appropriately recognizes that pregnant workers are likely to be exposed to 1-BP. Further, exposures during pregnancy are likely to occur among consumers, for whom EPA also calculates risk, and for the community populations in the vicinity of 1-BP sources, as discussed above. However, the equations EPA uses to calculate the cancer and chronic non-cancer risk for workers do not appear to use any age-dependent adjustment factors based on the window of exposure.

EPA states that it is using the following equation to calculate “acute and chronic exposures for non-cancer and cancer risk”:

\[
\text{ADC or LADC} = C \times ED \times EF \times WY / AT.
\]

In this equation, there appears to be no input reflecting uncertainties relevant to early-life exposure and exposure of other vulnerable populations. However, these uncertainties are well-acknowledged. For example:

- “While it is anticipated that there may be differential 1-BP metabolism based on lifestage; currently there are no data available, therefore the impact of this cannot be quantified.”
- “The available data clearly indicate that the nervous system is a target for 1-bromopropane toxicity in humans and animals. Data in humans show that 1-bromopropane can induce morphological alterations in neurons, which may lead to motor and sensory deficits. Studies in animals show that 1-bromopropane can induce...”

41 Draft Assessment at 24.
43 Id.
44 In Appendix H, id., EPA states that the inputs to the equation are as follows:

- ADC = average daily concentration (8-hr TWA) used for chronic non-cancer risk calculations
- LADC = lifetime average daily concentration (8-hr TWA) used for chronic cancer risk calculations
- C = contaminant concentration in air (8-hr TWA)
- ED = exposure duration (8 hr/day)
- EF = exposure frequency (260 days/yr)
- WY = working years per lifetime (40 yr)
- AT = averaging time (LT × 260 days/yr × 8 hrs/day).

45 Draft Assessment at 150.
biochemical, morphological, electrophysiological, and neurobehavioral alterations by mechanisms yet to be elucidated.”

- “Overall, the available human data are inadequate to assess the reproductive toxicity of 1-bromopropane. The available animal data suggest that the reproductive system may be a potential target of concern for 1-bromopropane toxicity in humans.”

In summary, there are many uncertainties and data gaps in relevant health and developmental endpoints, mechanism, and extrapolations from animal data to human risk. While we support EPA’s choice of a POD based on developmental toxicity as a starting point, without additional uncertainty factors, EPA is likely underestimating risk and failing to protect all vulnerable populations, and relevant health endpoints.

We are also concerned that the Draft Assessment understates risks to children resulting from consumer uses. EPA acknowledges likely bystander exposure from consumer use as a result of the fact that the majority of consumers reported using the chemical inside their home, with no open window, door, or exhaust fan, and with the door of the room of use open to the rest of the house. EPA recognizes that children may be exposed in this way. Such early-life exposure is likely to be greater due to children’s lower body weights. However, EPA does not use any increased vulnerability factor to acknowledge higher risks due to such exposure. The use of an age-dependent adjustment factor would be appropriate to avoid underestimation of health risks. The result of not using any such factor means EPA’s risk assessment assumes that adults and children are equally vulnerable to health impacts at the same rate of exposure. This is not correct. Children are not little adults. Children exposed are both likely to take in more of the chemical and to be more vulnerable to adverse health effects. EPA’s assessment of consumer risk is an underestimate because it does not include children’s increased vulnerability.

As a further concern, there appears to be no specific risk assessment value used to account for risk from in utero exposure for pregnant women, or the increased vulnerability resulting from such exposure. This is true even though EPA recognizes that “[t]here is some evidence for mutagenicity and DNA damage associated with exposure to 1-BP in vitro.” The failure to account for this within the risk assessment value calculation also causes an underestimation of health risks.

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46 ATSDR Draft Profile at 67.
47 ATSDR Draft Profile at 72.
48 Draft Assessment at 150.
49 Draft Assessment, App. L at 249-51.
51 Draft Assessment at 94.
Finally, EPA acknowledges in the risk assessment that 1-BP has a mutagenic mode of action.\textsuperscript{52} Consequently, to follow the agency’s own guidelines on cancer risk, EPA must use age-dependent adjustment factors within the calculation of risk to account for the increased vulnerability due to early-life exposure.\textsuperscript{53}

5. **Incomplete information about the manufacturing of 1-BP compromises the Draft Assessment**

Appendix A to the Draft Assessment indicates that only two companies currently manufacture 1-BP in the United States, though a third company is listed as a “possible manufacturer.” All information about one of the two known manufacturers is shown as “CBI,” including the name of the company and its location.\textsuperscript{54} The location of the “possible manufacturer” is not revealed, though its name – Diaz Chemical Corporation -- is provided.

We are concerned in two respects. First, the invocation of “CBI” in the Draft Assessment conceals important information about where in the United States 1-BP is manufactured, and thus which communities may be exposed to ambient 1-BP. We also question why the identity of a 1-BP manufacturer is CBI. Given the very high domestic production volume (over 15 million pounds in 2012), it is important to look at where 1-BP manufacturing plants are located in relation to communities and to assess the potential for exposure. We ask EPA to seek re-substantiation of the CBI claims at issue here, and if the CBI designation is no longer warranted, information about the second manufacturer, including the manufacturing location, should be included in the final risk assessment.

We also note that documents recently received from EPA through a Freedom of Information Act Request by the Environmental Health Strategy Center, reveals that Chemtura Corporation, manufactures 1-BP at a facility called Great Lakes Chemical-Central in Eldorado, Arkansas.\textsuperscript{55} It is unclear whether Chemtura is the claimed-to-be-CBI manufacturer, or if it is yet another manufacturer that was simply not identified in Appendix A. Either way, the fact that Chemtura manufactures 1-BP in Arkansas should be reflected in the final risk assessment.

Second, we are troubled that Diaz Chemical Corporation may be manufacturing 1-BP without reporting its production, or the location of its production, to EPA under the CDR.\textsuperscript{56} The location

\textsuperscript{52} Id. at 24 (“The weight-of-evidence analysis for the cancer endpoint is sufficient to support a probable mutagenic mode of action for 1-BP carcinogenesis.”).

\textsuperscript{53} Even if EPA did not find a mutagenic mode of action, EPA should use age-dependent adjustment factors to assess cancer risk for all carcinogens, as California’s state Office of Environmental Health Hazards has recognized is a scientifically appropriate method to attempt to more fully account for such risks.

\textsuperscript{54} Some of the organizations that submit these comments have filed a Freedom of Information Act request seeking the substantiation that this information is validly CBI, but we have not received a response as of the date these comments were due.

\textsuperscript{55} See Chemtura, Great Lakes, Eldorado Arkansas, 2012 Non-CBI CDR Submissions, submitted herewith as Attachment 3.

\textsuperscript{56} Draft Assessment, App. A-2 at 182.
that Diaz Chemical Corporation might be manufacturing 1-bromopropane is especially important information because in 2002 this company was responsible for a major release of VOCs at a facility in New York State. Many neighboring residents were forced to vacate their houses and the site remains on EPA’s Superfund list.\textsuperscript{57} We strongly urge EPA to investigate. If it turns out that Diaz Chemical Corporation is in violation of TSCA section 8(a), we ask EPA to seek appropriate penalties.

6. We support EPA’s conclusions that 1-BP poses serious risks in a range of applications and urge it to prohibit these uses.

It is scientifically appropriate that EPA recognizes the serious risks that use of 1-BP poses when used in spray adhesives, dry cleaning machines, spot cleaning, vapor degreasing, and aerosol degreasing in both acute and chronic exposure scenarios. There is extensive evidence of harm to workers attributable to worker exposures. For example, in the dry cleaning and laundry industry, which employs approximately 110,000 people, the use of 1-BP is linked to emergency room visits for a number of neurological effects.\textsuperscript{58} Acute and chronic health effects of those working in the cushion or foam fabricator industry were highlighted in a 2013 New York Times article.\textsuperscript{59} There are over 300 foam fabricators in the United States,\textsuperscript{60} and workers in this industry have experienced devastating injuries from exposure, including prolonged numbness, stinging in their feet, spinal pain, and long-term mobility problems.\textsuperscript{61} The science also supports EPA’s recognition of the serious acute inhalation risks to consumers using products containing 1-BP. This chemical is too toxic for consumer use.

We urge EPA to conclude that use of 1-BP—both in occupational and consumer applications—poses “unreasonable risks” within the meaning of TSCA, and to move forward promptly with a Section 6 rulemaking to prohibit its use. We believe that the exposure and risk estimates to 1-BP


presented in this Draft Assessment support this conclusion, and that this would represent a significant step towards adequately protecting the health of the general population as well as those exposed through their occupation.

We strongly urge EPA not to conclude wrongly that engineering controls offer adequate protection for workers. Indeed, in April 29, 2016 comments to the CDC in connection with the Draft Criteria for a Recommended Standard: Occupational Exposure to 1-Bromopropane, an EPA scientist stated that use of engineering controls when using 1-BP in occupational settings “may not be sufficient to achieve the proposed [recommended exposure limit].”\(^{62}\) Moreover, use of engineering controls such as ventilation has significant potential to lead to more 1-BP in the ambient air and is likely to increase exposure for community members living, working, and attending school near these sources.

Furthermore, due to the high risks EPA has quantified, and the risks known to be present but not quantified, particularly for consumers and community members, EPA should make clear in this risk assessment that there is no known use for which 1-BP could be considered safe. Finally, in view of the high risks EPA has found and the additional information showing that EPA’s risk assessment likely underestimates such risks, EPA should remove 1-BP as an acceptable substitute in the SNAP program. EPA also should use all other available authority to prevent and reduce exposure to community members, particularly children, including listing 1-BP as a known hazardous air pollutant.

7. **EPA’s assessment should incorporate evidence from other recent regulatory dockets**

As EPA is undoubtedly aware, other agencies and other EPA Offices are also considering the toxicity of 1-BP and the risks it poses. ATSDR has recently published for public comment a Draft Toxicological Profile of 1-BP.\(^{63}\) The State of New York has petitioned to add 1-BP to the list of hazardous air pollutants (HAPs) under section 112(b) of the Clean Air Act, 42 U.S.C. § 7412(b) and numerous commenters, including the National Association of Clean Air Agencies, and individual state regulators, filed comments in support of that listing. In addition, the Center for Disease Control and Prevention has sought comment on its Draft Criteria for a Recommended Standard for Occupational Exposure to 1-BP. The ATSDR Draft Profile materials are available at docket number ATSDR 2016-0003; HAP petition materials are available at docket number EPA-HQ-OAR-2014-0471; the CDC draft criteria materials are available at docket number CDC-2016-0003-0001. We urge EPA to review the material in these dockets, including comments, and to incorporate any new information about the toxicity of 1-BP into its final 1-BP risk assessment.\(^ {64}\)


\(^{64}\) We recommend that EPA take stronger action under TSCA than the CDC draft criteria reflect, however, as those criteria would allow an unacceptably high cancer risk for workers, and do not take into account consumer exposure or other important factors discussed in these comments.
CONCLUSION

Thank you for the opportunity to present these comments. We would be happy to discuss them with you at your convenience. We can be reached by email at egartner@earthjustice.org or echeuse@earthjustice.org.

Sincerely,

Eve C. Gartner  
Staff Attorney

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EARTHJUSTICE

On behalf of Blue Green Alliance, Earthjustice, Environmental Health Strategy, Natural Resources Defense Council, Safer Chemicals Healthy Families and Sierra Club Toxics Committee