Comments of Environmental Defense Fund on

Science Advisory Committee on Chemicals (SACC); Notice of Public Meeting and Request for Comments on Draft Toxic Substances Control Act (TSCA) Screening Level Approach for Assessing Ambient Air and Water Exposures to Fenceline Communities

Docket ID: EPA-HQ-OPPT-2021-0415

Submitted: March 22, 2022

Introduction

Environmental Defense Fund (EDF) commends EPA for developing a draft methodology to assess fenceline exposures and risks from chemicals undergoing risk evaluation under the Toxic Substances Control Act (TSCA) in response to the previous administration's failure to consider significant exposure pathways including air and water. However, we have major concerns about the draft screening level fenceline approach ("fenceline approach"), particularly related to its screening-level and narrow scope, risk underestimation, and problematic implications for risk management. Furthermore, the current version of the fenceline approach does not appear to put communities first. Individuals living in fenceline communities have long been overlooked and their concerns ignored. EPA's failure to reach out to fenceline communities or other relevant stakeholders for feedback, a critical component for successful and meaningful environmental justice research, deprived it of key community-based input, data and other information. This could erode communities' trust regarding EPA's intentions with the approach and impact its effectiveness.

While EPA states that this draft approach "version 1.0" will one day be supplanted by a possible version 2.0 in the future, the agency clearly plans to use this version now to make important risk management decisions, including decisions that specific fenceline exposures do *not* present an unreasonable risk. EPA's discussion of the possible "outcomes" of its fenceline approach indicates that any "unreasonable risk" it identifies that is not already found in the risk evaluation will need to be further substantiated. In contrast, if the fenceline approach estimates that there is "no unreasonable risk" then the agency will not require any further substantiation. EPA's implicit rationale in this asymmetric approach is that it believes its screening approach is conservative. While some factors used in the methodology may indeed be conservative, in reality, it systematically underestimates risks overall. This likely means that EPA will exclude real-world exposure pathways as well as underestimate exposures to fenceline communities, ultimately undermining risk management approaches.

Our comments detail the numerous ways in which EPA's approach systematically underestimates risk. We highlight three major examples. These and others are discussed at greater length in the body of our comments.

- **EPA excluded important environmental pathways of exposure**, including from land disposal/deposit, groundwater, plume deposits/vapor intrusion, consumption of contaminated fish and other aquatic organisms ("fish"), spills, leaks and accidental releases, as well as legacy exposures and background exposures from non-TSCA uses.

- **EPA did not aggregate multiple exposure sources or settings within a given condition of use**, such as combined exposures from multiple facilities, multiple pathways (e.g., air and water), and combined exposures from being a member of more than one relevant population (e.g., both a resident of a fenceline community and a worker who is also exposed to the chemical on the job).

- **EPA did not aggregate exposure and risk across conditions of use.** Real-world scenarios in which fenceline community residents may be subject to combined risks from two or more conditions of use are not considered. For example, EPA's approach fails to account for the aggregate chemical exposure and risk faced by a person who lives both near an industrial facility *and* next door to a dry cleaner emitting a given chemical (e.g., 1-bromopropane).

Further, the fenceline approach does not rely on sufficiently robust data. For example, the use only of annual TRI release data will obfuscate release peaks, such as accidental releases, and facility start up and shut down events. Where possible, EPA should integrate real-world fenceline air, water, and soil monitoring data to reflect the reality of individuals' exposures. Of note, EPA has authority under TSCA Sections 4 and 8 to require or call in such data from chemical companies. We recommend that in future applications of the methodology, EPA acquire such monitoring data, and do so sufficiently early in the process so that it can be fully incorporated.

The many ways in which the fenceline approach excludes or underestimates exposure demonstrate that the best available science, required by TSCA Section 26(h), is not being used to estimate risks to fenceline communities. This is particularly glaring given that individuals in fenceline communities generally have higher than average exposures and are a "potentially exposed or susceptible subpopulation," a group identified in TSCA for specific consideration.

EPA has sufficient time to revise the approach *before* applying it to at least six of the first 10 chemicals assessed under TSCA, given its current proposal to take the time to further substantiate any unreasonable risk determinations with additional analyses. At a minimum, EPA should include in this version 1.0 all appropriate pathways of exposure, aggregate exposures, and incorporate more robust data sources to reflect how individuals living in a fenceline community are actually exposed to these chemicals.

Moving forward, we also encourage EPA to implement a cumulative risk assessment framework within the context of the fenceline approach. EPA's traditional, single-chemical approach – which ignores how other chemical exposures may impact the risk posed by the specific chemical in question – underestimates actual risk to public health. This is particularly the case for fenceline communities, who are often exposed to multiple chemicals simultaneously and disproportionally bear the health burden.

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1. EPA should consult with fenceline communities on the fenceline approach.

Given the current limitations and concerning gaps in the current fenceline approach, it does not appear to include meaningful feedback from fenceline communities or other relevant stakeholders. There is no explicit language in the approach that states that EPA conducted any meaningful outreach to or included any feedback from relevant groups. In order for the fenceline approach to truly reflect the real experiences of fenceline communities, there should be engagement with community groups. This centering on the communities' needs and concerns is a central feature of exposure science conducted using an environmental justice framework.[1] This concern regarding EPA's outreach and engagement with communities while developing the approach was also addressed during the SACC meeting on this fenceline approach. We encourage the agency to consult with fenceline communities and relevant stakeholders on the current and future versions of the fenceline approach. Engagement with affected community groups and relevant stakeholders is crucial to meet the needs and reflect the lived experiences of members of fenceline communities and is fundamental to an assessment of whether a chemical poses unreasonable risks to fenceline communities under its conditions of use.

EPA's Office of Pollution Prevention and Toxics has long had infrastructure in place to conduct outreach to and obtain input from industry. It should develop the infrastructure to do this for fenceline communities and other "potentially exposed and susceptible populations."

Recommendation: EPA should conduct outreach to, consult with, and incorporate feedback from fenceline communities on this and future versions of the fenceline approach.

2. EPA's screening level approach is an inappropriate mechanism to estimate risks to fenceline communities who are potentially exposed or susceptible subpopulations – a group identified in TSCA for specific consideration.

We question why EPA has chosen to use an approach to estimate risks to fenceline communities that is "screening-level" rather than the more robust assessment framework used to estimate risks to other populations. Individuals in fenceline communities are burdened with higher exposures to toxic chemicals than most other individuals. It is important that EPA's assessment of these risks reflect their reality as much as possible.

A screening-level assessment is typically intended to be a broad, conservative assessment that includes all pathways. This would generally be followed by a more focused and refined assessment. The fenceline approach conflicts with this in two ways. First, as discussed in these comments, the approach has an extremely narrow focus that underestimates risks to fenceline communities. Second, the fenceline approach indicates that there will be a further assessment (for which EPA provides no information) only if a new "unreasonable" risk is found for a condition of use, not where EPA has found no "unreasonable" risk.

As currently constructed, this fenceline approach will adversely affect fenceline communities in two ways. The risks they face will have been excluded (e.g., risks from the chemical in

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[1] Van Horne Y.O., Alcala C.S., Peltier R.E., *et al.* (2022). An applied environmental justice framework for exposure science." *J Expo Sci Environ Epidemiol.*, 1-11. https://doi.org/10.1038/s41370-022-00422-z

groundwater), or underestimated (e.g., because the fenceline approach considers exposures from two different facilities separately and does not take into account well-documented peak releases and exposures such as from facility shutdown, startup and malfunction (SSM) events). Even where a risk is identified for a condition of use that is further "substantiated," the exclusion and/or underestimation will not be part of the factual basis used to determine the appropriate risk mitigation option under TSCA Section 6(a). This is particularly problematic for chemicals where exposure from the excluded pathway is already well documented or where the exposure has been significantly underestimated. It is highly unlikely to be included during the more detailed assessment since EPA has already decided these risks are not important.

Also, where EPA has determined, based on the fenceline approach, that a condition of use does not pose an "unreasonable" risk, it has stated it will "expeditiously propose[] no restrictions on the chemical being used" for that condition of use. There is no further refinement or analysis that EPA intends to conduct to substantiate that conclusion. Thus, this condition of use for the chemical will be characterized as essentially safe, even where that is not true or where risks from the use are determined not be "unreasonable" but contribute to significant risks from the whole chemical. Given institutional barriers and the legal process, it will be very difficult for EPA to revise this conclusion. Thus, fenceline communities would continue to bear the risks despite EPA's conclusions of "no unreasonable risk."

Recommendation: Rather than use the asymmetric approach taken in the fenceline methodology, EPA should develop a robust assessment methodology that more accurately assesses the risks faced by fenceline communities. If EPA chooses to first conduct a screening-level assessment, it should be a comprehensive assessment that does not exclude sources, pathways of exposure, or accidental or other peak releases – followed by a refined assessment. However, this second path would result in additional work for EPA – an already strapped agency – and would delay needed action to mitigate risks to overburdened communities.

3. EPA's fenceline approach is not conservative, but rather systematically underestimates health risks to fenceline communities – a potentially exposed or susceptible subpopulation under TSCA.

Individuals who live in communities near facilities that manufacture and use toxic chemicals generally are exposed to these chemicals at higher levels than the general population. It is crucial that EPA use the best available science to estimate the risk posed by a chemical under all its conditions of use. Slicing and dicing the exposures associated with the conditions of use of the chemical will not provide an accurate, or even remotely realistic, estimate of the exposures and risks faced by members of these communities, who are "potentially exposed or susceptible subpopulations."

To accurately consider the risks to a chemical faced by a fenceline community, EPA must consider the aggregate exposures to members of the community. To do so, EPA must use the best available science as required by TSCA Section 26. Unfortunately, EPA fails to do this throughout the fenceline approach in multiple ways, including by 1) excluding pathways of exposure, such as exposure from groundwater 2) excluding background exposures from non-TSCA uses, 3) considering pathways of exposure in isolation of other pathways; 4) considering conditions of use in isolation of other conditions of use; 5) considering exposures from individual facilities in isolation of other facilities; and 6) considering only average exposures and not higher exposures such as those resulting from accidents, malfunctions, and facility start-ups and shutdowns. By outright excluding exposures, considering exposures in isolation, and excluding peak or otherwise elevated exposures, EPA has developed an approach that systematically underestimates exposures and thus risks.

Yet, based on statements throughout the document that highlight conservative assumptions,[2] and the asymmetry of potential outcomes described in the Introduction to the fenceline approach, it appears that EPA inaccurately considers this to be a "conservative" methodology.

EPA's discussion of the possible "outcomes" of its fenceline approach indicates that any "unreasonable risk" it identifies that is not already found in the risk evaluation will need to be further substantiated. In contrast, if the fenceline approach estimates that there is "no unreasonable risk" then the agency will not require any further substantiation. EPA's implicit rationale in this asymmetric approach is that it believes its screening approach is conservative.

However, while some factors used in the methodology may indeed be conservative, that does not balance out the systematic underestimate of risks overall. This will result in EPA excluding real-world exposure pathways as well as underestimating exposures to these "potentially exposed or susceptible subpopulations," ultimately undermining decisions that could lead to effective risk management approaches. Thus, not only is this approach scientifically unsound, it conflicts with the intent of the TSCA requirement to consider exposures and risks to potentially exposed or susceptible subpopulations.

A key part of the 2016 reform of TSCA is the requirement that EPA consider risks to "potentially exposed or susceptible subpopulations," defined as "a group of individuals within the general population identified by [EPA] who, due to either greater susceptibility or greater exposure, may be at greater risk than the general population of adverse health effects from exposure to a chemical substance or mixture, such as infants, children, pregnant women, workers, or the elderly."[3] Under this provision, EPA must consider the fenceline communities living in proximity to facilities that release toxic chemicals which qualify just for their "greater exposure" alone.

EPA must consider these groups in each step in TSCA's process: in prioritizing chemicals for risk evaluation; in evaluating risks to both new and existing chemicals; and in regulating identified risks. Hence, EPA must specifically identify, evaluate, and mitigate risks to groups of people who may have greater exposures to a chemical (for example, because of where they work or live) or susceptibility to the effects of such exposure (for example, because of other health conditions, exposures to other chemicals, and stressors such as poverty). If EPA determines

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[2] Very few statements highlight assumptions that result in underestimation of exposure.

[3] 15 U.S.C. § 2602(12) ("TSCA Section 3(12)")

under TSCA that a "susceptible subpopulation" faces an unreasonable risk, it must issue regulations that eliminate that risk for that community.[4]

Communities who experience greater exposures from various conditions of use of chemicals are often marginalized communities – groups and communities that experience discrimination and exclusion (social, political, and economic) because of unequal power relationships across economic, political, social, and cultural dimensions. Thus, in addition to experiencing greater exposures, these communities often experience non-chemical stressors which further increases their risks for health effects from chemical exposures. EPA's careful consideration of these communities is needed to uphold the Biden Administration's commitment to prioritize environmental justice and "hold polluters accountable, including those who disproportionately harm communities of color and low-income communities."[5]

As with many of the first 10 chemicals, for some of the next 20 chemicals EPA is reviewing, there is already evidence that some communities face greater exposures. For example, EPA already indicated in the earlier dossier for 1,3-butadiene that:

> Elevated concentrations of 1,3-butadiene have been measured in the vicinity of heavily trafficked areas, refineries, chemical manufacturing plants, and plastic and rubber factories (OEHHA 2013). Populations living in areas near oil refineries, chemical manufacturing plants, and plastic and rubber factories—where 1,3-butadiene is manufactured or used—would be expected to have higher exposures (ATSDR 2012).[6]

Assessments of risk to fenceline communities need to routinely be a core component of future risk evaluations. These risk evaluations will need to be conducted using the best available science. Thus, as an integral component of the risk evaluation, the fenceline approach will also need to incorporate the best available science.

Recommendation: Given the importance of an accurate assessment of risks that fenceline communities face and the requirements of TSCA to consider "potentially exposed or susceptible subpopulations" and to use the best available science, EPA should revise its fenceline approach to comprehensively estimate aggregate exposures and risks from all pathways and all TSCA sources. EPA should also account for accidental and other peak exposures and consider background exposures. EPA should include a robust, comprehensive assessment of risks faced by fenceline communities by a chemical under its conditions of use in its TSCA risk evaluations.

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[4] U.S.C. § 2605(a) and (b)(4)(a) ("TSCA Section 6")

[5] The White House. (2021). *Exec. Order No. 13,990, Protecting Public Health and the Environment and Restoring Science to Tackle the Climate Crisis*. 86 Fed. Reg. 7037. https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/20/executive-order-protecting-public-health-and-environment-and-restoring-science-to-tackle-climate-crisis/

[6] EPA. (2019). *Proposed Designation of 1,3-Butadiene (CASRN 106-99-0) as a High-Priority Substance for Risk Evaluation,* at 34. https://www.regulations.gov/document/EPA-HQ-OPPT-2018-0451-0012

A. EPA excluded exposure pathways relevant to fenceline communities.

The fenceline approach considers ambient air and ambient water exposures but excludes other relevant exposure pathways that could substantially contribute to exposure and subsequent risk. We are concerned about EPA's decision to exclude such pathways, as doing so systematically underestimates potential risk to fenceline communities. Such exclusions are also contrary to TSCA.

a. EPA excluded environmental pathways of exposure.

The fenceline approach excludes evaluation of exposure from land, groundwater, vapor intrusion, consumption of contaminated fish, and spills, leaks, and other accidental releases (p. 18). The listed pathways are not merely hypothetical "worst-case scenario" assumptions, but rather reflect the multitude of pathways that contribute to fenceline community exposures.

Many of the chemicals that are currently undergoing risk evaluation under TSCA, or will in the future, expose communities through some or all of the pathways that EPA excluded from consideration. Below, we use the three chemical case studies as examples to highlight the importance of considering all environmental pathways of exposure, even if some pathways may be less relevant to certain chemicals due to physical-chemical properties. Systematic evaluation of all exposure pathways is crucial, especially given EPA's intention to apply the fenceline approach to a diverse set of chemicals with differing physical-chemical properties.

Methylene chloride (MC)

- Land: According to the past three years of TRI data, MC is released to land via landfills, underground injection wells, surface impoundments, or other types of containment, indicating potential for soil contamination. The primary source of land contamination is the disposal of MC products and containers to landfills.[7]
- Groundwater: Due to its physical and chemical properties, MC can move from soil into groundwater, evidenced by measured concentrations in groundwater,[8] leading to potential contamination of drinking water sources.
- Vapor intrusion: After soil and/or groundwater becomes contaminated, methylene chloride has been shown to contaminate indoor air as a result of vapor intrusion.[9]

[7] ATSDR. (2000). *Toxicological Profile for Methylene Chloride*, at 180. https://www.atsdr.cdc.gov/toxprofiles/tp14.pdf

[8] *Id.* at 3

[9] Burke, T. & Zarus, G. (2012). Community Exposures to Chemicals through Vapor Intrusion: A Review of Past ATSDR Public Health Evaluations. *J Environ Health.*, *75*(9), 36-41. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4692377/

- Fish: MC has been detected in freshwater organisms such as oysters, clams, and marine bottom fish, demonstrating the importance of including fish consumption as an exposure pathway.[10]
- Accidental releases: Spills, leaks, and other accidental releases are reasonably foreseen and are therefore required to be assessed as conditions of use under TSCA.

1-Bromopropane (1-BP)

- Land: According to the past three years of TRI data, 1-BP is released to land via landfills, underground injection wells, surface impoundments, or other types of containment. It is also regulated as a hazardous waste under RCRA. In the final risk evaluation, EPA acknowledged many land disposal pathways relevant to 1-BP, but wrongfully excluded them as out of scope.
- Groundwater: 1-BP is highly mobile in water; thus, releases to land via sludge application or disposal may leach into groundwater and contaminate private drinking water wells.[11]
- Vapor intrusion: Once in groundwater, vapor intrusion is expected to be a potential source of 1-BP exposure based on evidence from similar volatile organic compounds.[12]
- Fish: There is limited data on the bioaccumulation potential in fish and other aquatic organisms.[13] More data is needed before ruling out fish consumption as a potential exposure pathway.
- Accidental releases: The Toxics Use Reduction Institute in Massachusetts has determined that spills or accidental releases are major sources of environmental contamination of 1-BP.[14] Furthermore, ATSDR's Toxicological Profile for 1-BP provides real-world examples of known accidental releases of 1-BP, including groundwater contamination caused by leaking underground waste water tanks, and indoor air contamination due to leaking dry clean machinery.

N-Methylpyrrolidone (NMP)

- Land: According to the past three years of TRI data, NMP is released to land via landfills, underground injection wells, surface impoundments, or other types of containment to a greater extent than air. It is unclear why EPA has excluded the most prominent TRI release-type for this chemical.

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[10] IARC. (1999). *IARC Monographs Volume 71 – Dichloromethane Exposure Data.* https://publications.iarc.fr/_publications/media/download/2290/fd058148cf1d573b23571f91e4e4d8eea55dea51.pdf

[11] ATSDR. (2016). *1-Bromopropane – ToxFAQs™.* https://www.atsdr.cdc.gov/toxfaqs/tfacts209.pdf

[12] ATSDR. (2017). *Toxicological Profile for 1-Bromopropane*, at 146. https://www.atsdr.cdc.gov/toxprofiles/tp209.pdf

[13] *Id*. at 143

[14] TURI. (2014). *Summary of Policy Analysis, Higher Hazard Substance Designation Recommendation: 1-Bromopropane (n-Propyl Bromide) CAS 106-94-5*. https://www.mass.gov/doc/turi-policy-analysis-1-bromopropane-n-propyl-bromide-cas-106-94-5/download

- Groundwater: The chemical is mobile in soil and may leach into groundwater from landfills, where private drinking water wells can become contaminated.[15]
- Vapor intrusion: There is limited information on the potential for vapor intrusion, which EPA should address as a data gap in its final risk evaluation for NMP.
- Fish: Despite limited potential for bioaccumulation, fish consumption is still a potential exposure source, especially for communities that may rely on local waterways that are contaminated on a consistent basis.
- Accidental releases: Spills, leaks, and other accidental releases are reassembly foreseen and should be considered in EPA's assessment of fenceline risks from NMP.

Any such approach that fails to consider all pathways of exposure to the fenceline communities is inconsistent with TSCA. The statute directs EPA to "determine whether a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant to the risk evaluation by the Administrator, under the conditions of use."[16] In turn, "conditions of use" is defined broadly to include the "circumstances" under which the chemical is "intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of."[17] In addition, TSCA directs EPA to "take into consideration" all "reasonably available information" – including "hazard and exposure information, under the conditions of use" – when conducting risk evaluations.[18] Not only does TSCA thus require consideration of all exposure pathways, EPA itself has acknowledged that the previous Administration's "approach to exclude certain exposure pathways … resulted in a failure to consistently and comprehensively address potential exposures to potentially exposed or susceptible subpopulations, including fenceline communities …"[19]

EPA must therefore consider all pathways through which the individuals in fenceline communities may be exposed to the chemical in question. It should develop a scientifically-sound, rational basis for assessing the level of exposure via each pathway, supported by scientific evidence. Once the agency has assessed the level of the exposure, it also should aggregate these exposures with other sources of exposure. Only after making these assessments may EPA decline to further analyze an exposure pathway. For EPA to ignore a pathway, or to provide insufficient evidence or unsubstantiated rationales for not assessing an exposure pathway, would constitute

[15] EPA. (2017). *Scope of the Risk Evaluation for N-Methylpyrrolidone (2-Pyrrolidinone, 1-Methyl-) CASRN: 872-50-4.* https://www.epa.gov/sites/default/files/2017-06/documents/nmp_scope_6-22-17_0.pdf

[16] 15 U.S.C. § 2605(b)(4)(A) ("TSCA Section 6(b)(4)(A)")

[17] 15 U.S.C. § 2602(4) ("TSCA Section 3(4)")

[18] 15 U.S.C. § 2625(k) ("TSCA Section 26(k)")

[19] EPA. (2021). *EPA Announces Path Forward for TSCA Chemical Risk Evaluations*. https://www.epa.gov/newsreleases/epa-announces-path-forward-tsca-chemical-risk-evaluations

arbitrary and capricious decision making for failing to consider an important aspect of the problem.[20]

Recommendation: We encourage EPA to use available data from the final TSCA risk evaluations, other EPA offices, the literature, and international authoritative bodies to assess all possible environmental exposure pathways. EPA should systematically examine all exposure pathways, even if it initially expects exposures to be low, as the aggregation of low-level exposures across exposure pathways can lead to risk, and EPA should transparently disclose its findings for all pathways.

b. EPA excluded exposures from historical or legacy contamination from TSCA uses.

We are concerned about EPA's decision to not account for exposure due to historical or "legacy" contamination. It is critical that EPA assess potential exposures from historical contamination, especially for chemicals with persistent, bioaccumlautive, and toxic (PBT) properties. If EPA does not take into account exposures from non-TSCA sources and historical contamination and considers only the exposures and risks resulting from TSCA-subject activities, it will underestimate the overall risk to fenceline community members and thus will underestimate the TSCA risks that are "unreasonable." Failure to consider legacy exposures would be inconsistent with scientific standards and weight of the scientific evidence requirements established in TSCA Sections 26(h), (i), and (k).[21]

Recommendation: EDF strongly urges EPA to account for exposures from historical or legacy contamination from TSCA uses. This is the only way to ensure that the agency captures the full picture of chemical exposures and risks faced by fenceline communities.

c. EPA excluded background exposures from unspecified sources and non-TSCA uses.

The fenceline approach does not account for background exposures that cannot be attributed to a specific condition of use nor background exposures from non-TSCA uses, defined as uses that fall outside of TSCA's definition of "chemical substance."[22] All such background exposures may contribute to an individuals' total chemical exposure and subsequent health risks. Therefore, background exposures should be accounted for, preferably through direct incorporation into probabilistic dose-response and exposure modeling, as recommend by NAS.[23]

In terms of background exposures that cannot be attributed to a specific condition of use, EPA is still obligated to consider such exposures if it intends to not underestimate risk. In the final risk evaluation for MC, EPA acknowledged the existence of background levels of MC in residential

[20] *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.,* 463 U.S. 29, 43 (1983).

[21] 15 U.S.C. § 2625

[22] 15 U.S.C. § 2602(2) ("TSCA Section 3(2)")

[23] National Research Council. (2009). *Science and Decisions: Advancing Risk Assessment*. Washington, DC: The National Academies Press. https://doi.org/10.17226/12209

and consumer environments, but did not include such exposures because they were "not attributable to a specific condition of use."[24] This makes clear EPA's troubling position that it will not take into account known or measured background exposures if the source is unspecified. We strongly disagree with this approach and urge EPA to consider all known background exposures, including those that cannot directly be attributed to a specific condition of use.

Finally, below we discuss the importance of each non-TSCA background exposure pathway, using the three case study chemicals as examples.

Methylene chloride (MC)

- Dietary: Methylene chloride exposure can occur via intake of contaminated food, such as fish, root crops, and leaf crops.[25] Additionally, the chemical is used as an extraction solvent for oils, waxes, fats, spices, and hops in agricultural chemical manufacturing and food processing,[26] leading to further potential food-based exposures.
- Pharmaceuticals: The chemical is used as a solvent in the pharmaceutical industry; therefore, background exposures to MC from pharmaceutical manufacturing and use is possible and should be assessed.
- Cosmetics: Methylene chloride was banned as an ingredient of cosmetic products by FDA in 1989, and there is no recent evidence on concentrations of methylene chloride in cosmetics.[27] Thus, this background exposure pathway may not be applicable to the evaluation of risk from methylene chloride; nonetheless, it is still important to consider.

1-Bromopropane (1-BP)

- Dietary: One biomonitoring study on 1-BP found that control subjects exhibited high background levels of urinary bromide, which were subsequently linked to dietary exposure (Zhang et al., 2001).[28]
- Pharmaceuticals: 1-BP is used as a chemical intermediate in pharmaceutical manufacturing,[29] making potential exposure via pharmaceuticals a concern.
- Cosmetics: There is limited existing data on the presence of 1-BP in cosmetics.

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[24] EPA. (2020). *Risk Evaluation for Methylene Chloride (Dichloromethane, DCM) CASRN: 75-09-2*, at 437. https://www.epa.gov/sites/default/files/2020-06/documents/1_mecl_risk_evaluation_final.pdf

[25] OECD. (2011). *SIDS Initial Assessment Profile (Dichloromethane)*, at 5. https://hpvchemicals.oecd.org/ui/handler.axd?id=b8ea971c-0c2c-4976-8706-a9a68033daa0

[26] EPA. (2020). *Risk Evaluation for Methylene Chloride (Dichloromethane, DCM) CASRN: 75-09-2*, at 44. https://www.epa.gov/sites/default/files/2020-06/documents/1_mecl_risk_evaluation_final.pdf

[27] 21 CFR 700.19. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=700.19

[28] EPA. (2020). *Risk Evaluation for 1-Bromopropane (n-Propyl Bromide) CASRN: 106-94-5*, at 191. https://www.epa.gov/sites/default/files/2020-08/documents/risk_evaluation_for_1-bromopropane_n-propyl_bromide.pdf

[29] NTP. (2013). *Report on Carcinogens Monograph on 1-Bromopropane*. https://ntp.niehs.nih.gov/ntp/roc/thirteenth/monographs_final/1bromopropane_508.pdf

N-Methylpyrrolidone (NMP)

- Dietary: NMP is currently approved for use as a solvent and co-solvent inert ingredient in pesticide formulations for both food and non-food uses and is exempt from the requirements of a tolerance limit.[30]
- Pharmaceuticals: NMP is used as an intermediate in the pharmaceutical industry and as a penetration enhancer for topically applied drugs,[31] potentially contributing to additional background exposures.
- Cosmetics: NMP is used in the manufacture of cosmetics, which may lead to exposure.[32]

In sum, background exposures from unspecified or non-TSCA uses should be taken into account when assessing risk from chemicals reviewed under TSCA. Regardless of findings of inapplicability for certain background exposure pathways for certain chemicals, it is critical that EPA systematically examine all sources of background exposures, regardless of regulatory jurisdiction, to ensure that relevant background exposures are captured in the risk assessment. Failure to consider exposures from those uses would be inconsistent with scientific standards and weight of the scientific evidence requirements established in TSCA Sections 26(h), (i), and (k).[33] In the case that a background exposure pathway does not lead to significant exposure, it should still be considered and discussed.

Recommendation: EDF strongly urges EPA to account for all sources of background exposures, including those that originate from unspecified or non-TSCA uses. This is the only way to ensure that the agency captures the full picture of chemical exposures and risks faced by fenceline communities. EPA should consult existing literature, federal agencies (e.g., FDA), and international bodies (e.g., OECD) to obtain and integrate data on background exposures into its fenceline assessment, and ultimately for all risk assessments conducted under TSCA. The agency has the expertise and experience to account for background exposures, evidenced by the Office of Water's application of a "relative source contribution" (RSC) factor when calculating ambient water quality criteria (AWQCs) or maximum contaminant level goals (MCLGs) for drinking water,[34] which enables the agency to indirectly account for other potential sources that contribute to an individuals' total exposure.

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[30] EPA. (2020). *Risk Evaluation for n-Methylpyrrolidone (2-Pyrrolidinone, 1-Methyl-) (NMP) CASRN: 872-50-4*. https://www.epa.gov/sites/default/files/2020-12/documents/1_risk_evaluation_for_n-methylpyrrolidone_nmp_casrn_872-50-4.pdf

[31] WHO. (2001). *Concise International Chemical Assessment Document 35 N-METHYL-2-PYRROLIDONE*, at 7. https://www.who.int/ipcs/publications/cicad/en/cicad35.pdf

[32] *Id*.

[33] 15 U.S.C. § 2625

[34] EPA. (2000). *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health, [EPA-822-B-00-004]*. https://www.epa.gov/sites/default/files/2018-10/documents/methodology-wqc-protection-hh-2000.pdf

B. EPA's fenceline approach fails to include important ambient water pathways and the vapor-to-dermal route of exposure.

For the limited assessment that EPA did do of ambient air and water pathways, the agency failed to include important ambient water pathways (e.g., showering and bathing) and the vapor-to-dermal route of exposure. This approach contributes to the overall underestimation of risks from TSCA manufacturing, processing, use, and disposal.

a. EPA's ambient water assessment fails to include important ambient water pathways.

While EPA assessed dermal and oral exposure from exposure from recreational swimming in bodies of water, it did not consider bathing or showering in tap water – an activity that individuals partake in regularly. Such activities can result in exposure from direct dermal contact, vapor-to-skin contact, and incidental ingestion.

Recommendation: As recommended by the SACC, EPA should consider exposure through bathing or showering in its assessment of exposure from ambient water.

b. EPA's fenceline approach fails to include the vapor-to-dermal route of exposure.

EPA failed to consider the vapor-to-skin dermal route of exposure in its assessment of ambient air and water exposure. EPA's assessment of the ambient air pathway from polluting facilities focused exclusively on the inhalation route of exposure. To the extent that the compound in question is emitted into the air in the vapor phase, EPA needs to assess the risk from dermal uptake in addition to inhalation. Dermal uptake of vapor would also be relevant to groundwater and vapor intrusion pathways (which, as discussed previously, EPA excluded entirely). Dermal exposure via vapor is a particularly important route of exposure for NMP.

Recommendation: As recommended by the SACC, EPA should consider the vapor-to-skin dermal route of exposure.

C. EPA considered conditions of use and individual routes of exposure in isolation.

In addition to ignoring certain pathways of exposure altogether, the fenceline approach considers exposures and risks from conditions of use individually and separately, rather than in the combined manner in which people experience them. This approach contributes to the overall underestimation of risks from TSCA manufacturing, processing, use, and disposal.

a. EPA did not aggregate multiple exposure sources or settings within a given condition of use.

The fenceline approach does not consider multiple exposures to a person within each condition of use, such as combined exposures from multiple facilities, multiple pathways (e.g., air and water), and combined exposures from being a member of more than one relevant population, particularly from more than one potentially exposed or susceptible subpopulation.

EPA's approach does not estimate exposures to individuals in communities from multiple facilities within each condition of use. There are many communities where individuals are exposed to chemicals under the same condition of use from more than one facility. For example, the people who live in downtown and midtown Detroit[35] are within 10,000 meters of both the FCA US Jefferson North Assembly Plant[36] and the Ford Motor Co. Dearborn Truck Plant[37]. These facilities reported releases for 2020 to TRI of, among other chemicals, 1,2,4-trimethylbenzene (42,897 lbs. and 40,340 lbs., respectively), xylene (mixed isomers) (99,946 lbs. and 69,350 lbs., respectively), and ethylbenzene (19,249 lbs. and 15,076 lbs., respectively). Given these facilities are both transportation equipment plants and will have similar operations, they will likely be within the same condition of use, and use and release many of the same chemicals.[38] Yet the exposures that the communities face from each of these facilities will be considered in isolation. EPA should aggregate the exposures individuals in fenceline communities face.

Although many of the workers at these facilities live nearby, the fenceline approach does not consider that an individual living in the fenceline community may also be a worker in such a facility.[39] This, of course, underestimates the exposures they face. EPA should consider individuals who are exposed to the chemical both when at home and at work and should also consider the different relevant routes of exposure, e.g., there may be dermal exposure in the workplace that is not present in the home.

Finally, in addition to excluding pathways of exposure, the fenceline approach does not combine the exposures for the pathways it does estimate even from the same facility under the same condition of use. EPA considers the risks resulting from air releases separately from the risks resulting from surface water discharges. EPA should aggregate these exposures and risks.

Even within a specific activity EPA did not aggregate exposures. For instance, for incidental swimming ingestion and dermal contact were not aggregated or presented because these risks (in

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[35] Detroit is in Wayne County Michigan, a county in which 116 facilities reported 10,381,806 lbs. of releases to TRI.

[36] 2101 Connor Ave, Detroit, Michigan 48215

[37] 3001 Miller Rd, Dearborn Michigan 48120

[38] This is typical for communities in which a particular industry sector is concentrated. The facilities in an industry sector often produce and use many of the same chemicals. This is also typical for the Detroit area – long known as the Motor City.

[39] It is worth noting that EPA finalized its risk evaluations using $1x10^{-4}$ cancer benchmark for workers – in contrast to $1x10^{-6}$ for other populations. EDF has strongly urged EPA not to take such an approach (e.g., see EDF oral comments on the 1-bromopropane risk evaluation: https://www.regulations.gov/comment/EPA-HQ-OPPT-2019-0235-0034), as it accepts a higher risk for workers despite being identified as "potentially exposed or susceptible subpopulation" under TSCA. In the context of addressing fenceline communities, will EPA continue to use different risk benchmarks for the same person – whether they are living in the community versus working in the facility, or, in some instances, both? The different benchmark appears to be based on non-risk factors in conflict with TSCA.

isolation) were at least an order of magnitude from the benchmark. Of course, individuals in fenceline communities would be unlikely to be exposed to the chemical only via swimming, which is why the exposures from swimming should be aggregated with other exposures. This is another example of the slicing and dicing of exposures and risks that the fenceline approach takes.

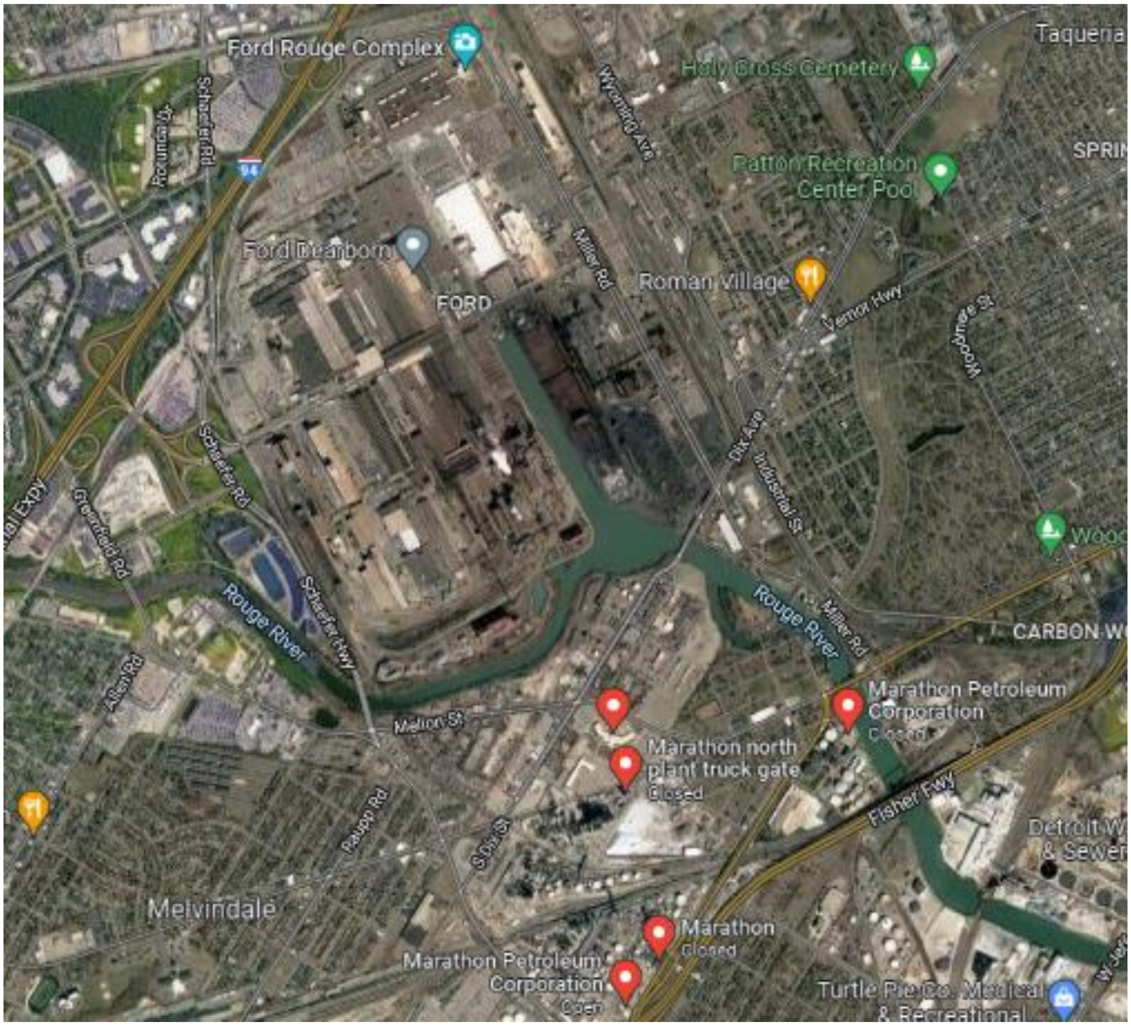
b. EPA did not aggregate exposure and risk across conditions of use.

The fenceline approach considers exposures and risks from different conditions of use individually and separately, rather than in the combined manner in which people experience them. EPA should aggregate exposures from different conditions of use, including those from industrial facilities and small businesses imbedded in a community.

EPA should start by aggregating exposures from multiple facilities classified under different conditions of use. Consider the Ford Motor Co. Dearborn Truck Plant[40] described above. Among the other industrial facilities nearby is the Marathon Petroleum Co about two miles away. The Marathon Petroleum Co. reported releases to TRI for 2020 of, among other chemicals, 1,2,4-trimethylbenzene (2,430 lbs.), xylene (mixed isomers (7,900 lbs.) and ethylbenzene (1,850 lbs.), three of the same chemicals reported by the nearby Ford Motor Co Dearborn Truck Plant. While likely a different condition of use, this is an exposure for those living and working near these facilities -- an area that includes residents, schools, recreational areas, and many small businesses where local residents work -- that will be experienced in addition to their exposure from the Ford Plant.

EPA should also consider that an individual in the community may also work at or live or work next to a commercial business where the same toxic chemical is used. The exposure the individual faces is the sum of the exposures from this condition of use as well as from the Ford Motor Co Dearborn Truck Plant and the Marathon Petroleum Co. facility.

[40] 3001 Miller Rd, Dearborn Michigan 48120



As another example, the nearby town of River Rouge adjacent to Detroit is heavily burdened by chemical-releasing facilities. EES Coke Battery, located on Zug Island in Detroit, released large amounts of hydrochloric acid (35,000 lbs.) in 2020 based on TRI data (in addition to many other toxic chemicals such as benzene, sulfuric acid, and toluene). Less than a mile away, Carmeuse River Rouge Operations[41] in River Rouge also released 32,157 lbs. of hydrochloric acid in 2020. Located between these facilities are several other industrial facilities, including Shell Oil Products and Chemtrade Solutions LLC. Of note, as illustrated in the image below, there is a residential neighborhood directly to the southeast of these industrial facilities – with houses located just 84 meters away from Carmeuse River Operations and 42 meters away from the Shell Oil Product facility's storage tanks.

[41] See aerial footage of the Carmeuse River Rouge Operations Lime Factory and the adjacent neighborhood in River Rouge, Michigan at https://www.youtube.com/watch?v=iS8Jlr5rtf8

Also see Table 2 in the Appendix, where we present an analysis demonstrating that similar to the case of River Rouge, Michigan, nationwide, TRI reporting facilities tend to cluster together. In one case, 121 TRI facilities are located within 10 kilometers of a facility reporting release of at least one of the first 10 chemicals assessed under TSCA.

Finally, this individual may also use one or more consumer products containing the toxic chemical. The risk that individuals face from the toxic chemical would then be the result of this aggregate exposure from these three conditions of use.

Assessing the exposure from each of the three independently and then failing to aggregate the exposures to assess the risk faced by an individual will clearly result in an underestimate of the exposure faced by the individual. Considering only the incremental exposure to a chemical and making a determination of the risk of the chemical and whether that risk is “unreasonable” simply sidelines science in the decision making. Slicing and dicing exposures to fenceline communities is at odds with a methodology intended to estimate exposures to fenceline communities.

Recommendation: To assess the risk of the chemical under its conditions of use, EPA should consider the aggregate of all the exposures posed by a chemical under a condition of use and across all conditions of use.

D. EPA makes unsupported claims that long-term residence in a community is a conservative assumption.

In a section that discusses assumptions and uncertainties in risk characterization (p. 61), EPA states:

> ***Exposure Duration***
> This analysis provides exposure and hazard values based on a 24-hour exposure. This assessment assumes that an individual living nearby a facility will be exposed to a chemical at a similar concentration for all hours of the day—either they are present at home all day or remain close-by. This uncertainty may result in an overestimation of exposure and risk, especially for chronic durations, for exposed individuals who may regularly travel farther away from exposure sources and would not be chronically exposed at the same concentration continuously. Similarly, chronic and lifetime exposure and risk estimates are only relevant to individuals who reside at the same location for years or decades. These longer-term exposures would vary for individuals who did not remain within the same range of a particular facility.

However, EPA does not provide or cite any data or provide any other support for these summary statements. Nor does EPA consider that people may both live and work in the community, either at an industrial facility or at a commercial business, school, hospital, restaurant, a home-based day care facility, or other entity in the community. Also, many people, either by choice or by necessity, remain in a community for decades. This includes members of the community who may wish to move away but do not have the economic resources to move to another community.

Rather than simply stating that this may result in an "overestimation of exposure and risk" EPA should provide the data or other information to support this contention. EPA should also state what percentage of the population it considers it to be an overestimate for. These data should be specific for frontline communities rather than communities that are not near facilities. To support its contention that residents "regularly travel farther away from exposure sources" (which we take to include traveling to work in another community), EPA should include information on how the differences in the economic makeup of frontline communities vs other communities may affect patterns of job location.

Recommendation: EPA should provide data or other information to support contentions about residence time in fenceline communities.

4. EPA should improve the underlying data and models used to assess risk to fenceline communities.

A. EPA should proactively use its information authorities to fill fenceline exposure data gaps.

EPA has extensive authority under TSCA to acquire data, including fenceline monitoring data, from chemical companies. TSCA Sections 8 and 11 authorize EPA to require companies to report existing chemical information, while sections 4 and 10 authorize EPA to require the development of new information. Under these authorities, EPA could require chemical manufacturers and processors to provide available, or generate new, community-level exposure data for chemicals undergoing TSCA risk evaluation (e.g., data on monitoring of fenceline air, soil, and water, workplaces, point-source emissions, releases from disposal sites, and climate vulnerability).

Notably, a May 2021 White House Environmental Justice Advisory Council (WHEJAC) report to President Biden, Vice President Harris, and the Council on Environmental Quality (CEQ) identified use of TSCA as an environmental justice priority. Among the Council's specific recommendations was to use TSCA "aggressively to gather information about fenceline communities' real-world exposures."[42]

Moving forward, EPA should require submission of fenceline monitoring data from companies and do so sufficiently early in the process so that the data can be fully incorporated into the assessment. In our comments on EPA's proposed Tiered Data Reporting approach, we commented extensively on the importance of acquiring such data early in the process of prioritizing chemicals for review. For example, early collection of information using Section 8 authorities is essential to identify data gaps and provide sufficient time for EPA to fill them using its TSCA Section 4 information development authorities. We incorporate those comments here by reference.[43]

Beyond acquiring robust data from the chemical industry, EPA should also proactivity pursue additional data sources from local, state, and federal government as well as local communities. During the SACC Meeting, several committee members recommended integrating existing federal government information (e.g., hazardous waste sites from ATSDR and Superfund; EPA's water contaminant occurrence data from the Six-Year Review and the Unregulated Contaminated Monitoring Rule as well as USGS non-regulatory water monitoring data), state resources (e.g., Washington State fish tissue data) in addition to proactively reaching out to municipal government, tribal councils, and fenceline communities themselves who may have useful monitoring data.

Recommendation: We also note that under TSCA Section 10, EPA has authority to conduct (in coordination with other government agencies) or contract with other entities to conduct research, development, or monitoring, including to inform TSCA prioritization, risk evaluation or risk management. EPA should take advantage of this authority to partner with other agencies such as the Department of Health and Human Services to "conduct such research, development, and monitoring" to fill information gaps. This could be achieved through a government-run fenceline monitoring system combined with research grants to affected communities.

B. There are major shortcomings in EPA's estimates of releases, including its analysis of Toxics Release Inventory (TRI) data.

In the absence of monitoring data, we understand that EPA will rely at least in part on Toxics Release Inventory (TRI) data for its fenceline approach. However, the agency's analysis of TRI data oversimplifies the data in a number of ways that underestimate exposure.

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[42] WHEJAC. (2021). *Interim Final Recommendations*. https://www.epa.gov/sites/default/files/2021-05/documents/whejac_interim_final_recommendations_0.pdf

[43] EDF. (2021). *Comments on Development of Tiered Data Reporting To Inform TSCA Prioritization, Risk Evaluation, and Risk Management.* https://www.regulations.gov/comment/EPA-HQ-OPPT-2021-0436-0057

EPA underestimated chemical releases by relying only on TRI data and assuming that annual TRI releases are spread out evenly across all facility operating days (e.g., see p. 56). Likewise, EPA appears not to consider other sources of data that would provide information on accidental releases, malfunctions or releases from facility start-up or shut-down – which are often required during reasonably foreseen climate events such as storms, including hurricanes.[44] Releases during startup, shutdown and malfunctions can be significantly larger than releases from normal operations. This approach obfuscates spikes in releases that may lead to acute health impacts to the surrounding community. Unfortunately, many such events occur in fenceline communities that are already subject to elevated exposures such as those communities near the Gulf of Mexico home to many large petrochemical and chemical manufacturing communities that produce and use many highly toxic chemicals, including 1,3-butadiene, TCE and perchloroethylene.

EPA also over-relied on a single year of TRI data (2019), which may underestimate exposure. TRI releases and reporting facilities can vary, sometimes dramatically from one year to the next[45]. See, for example, Table 1 in the Appendix, which illustrates the variability in the number of releasing facilities and volume between 2015-2019 for 1-bromopropane, methylene chloride, and N-methylpyrrolidone. Is not clear if the 2016-2019 TRI data were reviewed to see if there were any anomalies in the 2019 data and whether the 2018 data or another year's data may be more representative.

EPA should instead consider TRI data from the last five years and the projections for the subsequent two years[46] (see section 8 of the Form R) and use the highest reported (or adjusted-based on section 8 data) releases in that timeframe given that the magnitude of the releases can fluctuate from year to year depending on economic and other factors. Given that EPA is required to consider reasonably foreseen uses of the chemical, the agency should consider the larger releases.

EPA did not capture all relevant emitting facilities in its case studies. In its application of the fenceline approach for 1-bromopropane, methylene chloride, and N-methylpyrrolidone case studies, EPA appears to have missed relevant TRI reporting facilities. For example, based on the Supplemental File "SF FLA Environmental Releases to Ambient Air for 1-BP," the 1-bromopropane case study appears to have excluded the fourth-largest TRI-reporting 1-bromopropane air emitter based on 2019 TRI data provided in TRI Explorer (the Lincoln, Nebraska facility Molex LLC). EPA needs to resolve these discrepancies.

With only TRI annual release data as a guiding post, these models may not reflect the everyday realities that fenceline communities experience, and should be bolstered by real-world fenceline air, water, and soil monitoring data. During the SACC Meeting, several committee members raised this concern, noting in particular that monitored data are needed to validate the models.

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[44] Environment Texas. (2020). *Refineries, chemical plants release over 4 millions pounds of pollution as a result of Hurricane Laura*. https://environmenttexas.org/blogs/blog/txe/refineries-chemical-plants-release-over-4-millions-pounds-pollution-result-hurricane

[45] For example, Western Pneumatic Tube Co LLC in Kirkland, Washington reported 60,036 lbs. of 1-bromopropane released as fugitive emissions to air in 2020 and 117,548 lbs. in 2019.

The lack of monitoring data is particularly problematic given the many unconservative assumptions incorporated into the models (see Section 4D) and that EPA has evaluated the air and water pathways in isolation and has not accounted for the partitioning of chemicals from the air into water (or vice versa) to replicate the chemicals' behavior in the real world.

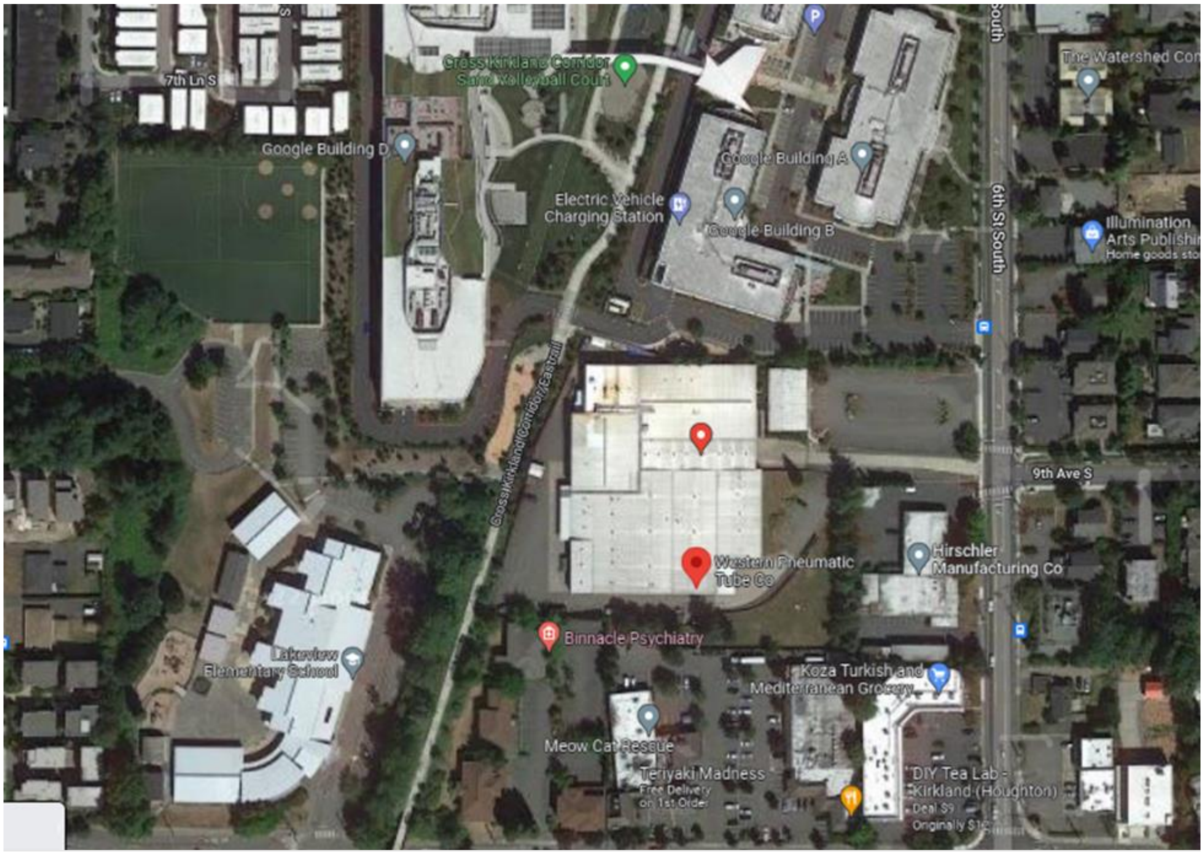
We also note that EPA sometimes uses opaque shorthand to refer to specific TRI data elements, which may not be clear to everyone. When EPA refers to "uses/sub-uses," we assume that they are referring to "activities and uses of the toxic chemical" reported in section 3 of the Form R. It is not limited to "use" but also includes information on manufacture, including subcategories of manufacture, e.g., manufacture as a byproduct, and processing, including subcategories, e.g., processing as a formulation component. At a minimum, it should be explained that these data are for activities broader than the common conception of use.

Recommendation: In finalizing its fenceline approach, EPA should rectify the shortcomings of its release analysis and should incorporate data on accidental releases and data on peaks of exposure**.** EPA should use TRI section 8 data to consider reasonably foreseen increases in releases.

C. EPA's air pathway pre-screen analysis fails to capture exposures and risks within 100 meters of an emitting facility.

EPA should eliminate the air pathway pre-screening analysis used to decide whether or not to employ a full-screening methodology. EPA has proposed to use the Integrated Indoor/Outdoor Air Calculator (IIOAC) model to estimate exposures at three pre-defined distances from a facility releasing a chemical into the ambient air (100, 1,000, and 1,000 meters) and exclude the air pathway from further consideration if no risk is found at this stage (see pp. 28-30). However, the IIOAC model cannot predict emission levels below 100 meters – precisely where the greatest emissions may be. For example, Table 3-6 of the full screen for 1-bromopropane and Table 3-18 of the full screen for methylene chloride demonstrate that mean daily average exposures are higher at distances less than 100 meters than at distances greater than 100 meters for every condition of use assessed. This may very well lead to a decision to prematurely screen out a real risk. EPA acknowledges this limitation (p. 57), yet EPA nonetheless proceeds with the proposed approach.

This limitation is not theoretical. In fact, it is not uncommon for people to reside, work, attend school, or otherwise spend significant time within 100 meters of an industrial or waste facility. As an illustrative example, below is an image of Western Pneumatic Tube Co LLC. in Kirkland, Washington, which manufactures welded tubing for the aerospace industry. In 2019, this facility was one of the biggest emitters of 1-bromopropane according to TRI data, releasing 117,548 lbs. in fugitive air emissions. The image below demonstrates that there are restaurants, a doctor's office, and a school all within 100 meters of the facility address. Specifically, Binnacle Psychiatry is located 35 meters, a Japanese restaurant 98 meters, and Lakeview Elementary School 100 meters away. There are also residential neighborhoods surrounding the facility, with the closest house located 140 meters away. (Note that we have no way to verify that the address the company provided to EPA via TRI is the exact emitting site of Western Pneumatic Tube Co LLC.; as EPA notes, absence of such data from TRI is a limitation in its methodology.)



This issue described above is compounded by the many limitations of the TRI data on which the IIOAC model relies, as described in section 3(B) of these comments, which is likely to result in underestimating emissions. EPA should not employ such a cursory pre-screen to rule out a full screening of risks from ambient air.

Recommendation: We recommend that EPA drop this pre-screening analysis altogether.

D. EPA's air model assumptions are not conservative and do not incorporate life-stage specific exposure factors.

EPA's air modeling employs several non-conservative assumptions. Because TRI does not require reporting of stack parameters such as stack height, EPA relied on default assumptions in the air models. EPA explained during the March 15th SACC Meeting that the default inputs vary and are sometimes mean or median values. Further, in response to a SACC committee member's comment about the lack of transparency around these input parameters, an EPA representative responded that the answers are provided in the model's user manual and that "generally speaking … the stack parameters were taken across a national average."

EPA's use of average stack parameters is likely to underestimate the population at risk. For example, EPA used a default average stack emission release point of 10 meters for both the pre-screen using the IIOAC model (p. 58) as well as for the full screening using AERMOD (Excel file: SF FLA Air Pathway Input Parameters for AERMOD for 1-BP and MC). Because a lower stack height will result in a plume with a smaller dispersion, such an assumption likely will result in a conclusion that fewer people in the surrounding community will be subject to any associated risk. EPA's decision to use an average stack height is related to its decision to only model risks from the air pathway out to 10,000 meters – which several SACC members noted may not be appropriate for some compounds, depending on their fate and transport. EPA should take a conservative approach and consider a range of stack heights and continue modeling until a distance where the risk is negligible.

Furthermore, as discussed during the SACC Meeting, EPA assumed 1.8 meters height for all receptor's breathing height, which is not reflective of the height of the average women or child. While this likely will not greatly alter the risk calculations, it is exemplary of EPA's failure to incorporate age-specific and other relevant factors.

It is problematic that EPA has not taken into consideration lifestage-specific exposure factors for receptors under the air pathway (e.g., increased respiration rates for pregnant women). EPA states (p. 61, emphasis added):

> Inhalation risk estimates are based on air concentrations and *were not adjusted for potential lifestage-specific differences*, consistent with current EPA guidance which assumes that lifestage-specific differences in inhalation dosimetry are covered by the 10× intraspecies uncertainty factor (UF_H) (U.S. EPA, 2012a).

However, in the final TSCA Methylene Chloride Risk Evaluation, EPA used a default intra-species uncertainty/variability factor of 10 for acute non-cancer (and 3 for chronic non-cancer)to account for variation in sensitivity within the human population due to "limited information."[47] For the acute endpoint, EPA specifically notes an extensive list of susceptible populations that the default intra-species uncertainty factor is intended to address, including: fetus due to higher carbon monoxide affinity for hemoglobin and slower carbon monoxide elimination, individuals with higher CYP2E1 enzyme levels and who consume large amounts of alcohol, and those with preexisting heart disease.

It is not at all apparent that this uncertainty factor takes into account age-specific exposure factors, such as inhalation rate. EPA should always strive to incorporate specific data when available, rather than rely on a default uncertainty factor to generically capture intra-species variability. Unlike the factors described in the final risk evaluation, EPA has available information on the variability of exposure factors such as inhalation rates and height by age group. Of note, EPA's 2011 Exposure Factors Handbook includes inhalation rates for school children playing near a contaminated site.[48]

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[47] EPA. (2020). *Risk Evaluation for Methylene Chloride (Dichloromethane, DCM) CASRN: 75-09-2*. https://www.epa.gov/sites/default/files/2020-06/documents/1_mecl_risk_evaluation_final.pdf

[48] EPA. (Accessed 2022, March 20). *Exposure Assessment Tools by Routes - Inhalation.* https://www.epa.gov/expobox/exposure-assessment-tools-routes-inhalation

Recommendation: We recommend that EPA use conservative stack parameter assumptions and incorporate appropriate exposure factors into the air pathway analyses.

E. EPA excluded Occupational Exposures Scenarios (OES) based on faulty land-use considerations.

a. EPA failed to address the reasonably foreseen circumstance that there may be changes in land use over time.

EPA failed to address the reasonably foreseen circumstance that there may be changes in land use over time. Through its Land Use analysis, EPA overlayed the emissions information with land use information using ArcGIS and Google Maps to analyze whether nearby land is used for residential, industrial/commercial business, or other public spaces (pp. 39, 88). EPA proceeded to remove Occupational Exposure Scenarios (OES) based on the conclusion that the surrounding land is "uninhabited" and thus does not present an exposure concern.

For example, Table 3-27 in the methylene chloride case study shows that EPA excluded six of eight OESs from further consideration because fenceline community exposures are not "reasonably anticipated" based on land use analysis. EPA fails to consider the reasonably foreseen circumstance that land use can change over time (e.g., due to increasing cost-of-living in urban centers).[49] EPA's approach is particularly problematic given EPA's intention to make unreasonable risk determinations on specific OESs, resulting in EPA deeming that specific OESs do not pose a risk simply due to the land use patterns at this moment in time.

Recommendation: EPA should reverse its decision not to consider exposure and risk from facilities surrounded by uninhabited land given that land use changes around emitting facilitates are reasonably foreseen, including the fact that residential or public areas may be built around these facilities in the future. EPA should instead include all facilities in the assessment and consider the current land use surrounding each facility as a factor during the risk management stage. If included, the land use analysis should be revisited at regular intervals to assess changes that could impact risk. Beyond EPA's TSCA risk management decisions, such land use information could be helpful for local zoning officials in understanding risk and electing not to build in areas already burdened with chemical pollution.

b. EPA inappropriately dismissed risk based on company addresses as the basis for its land use analysis.

EPA's draft approach states that "[w]here radial distances showing an indication of risk occur within the boundaries of the facility … EPA does not reasonably expect an exposure to fenceline communities to occur and therefore does not expect an associated risk" (p. 40). The agency

[49] *See, for example*, Our World in Data. (Accessed 2022, March 20). *Land use over the longer-term, World, 0 to 2016.* https://ourworldindata.org/grapher/land-use-over-the-long-term?country=~OWID_WRL and Dadashpoor, H., Azizi, P., & Moghadasi, M. (2019). *Land use change, urbanization, and change in landscape pattern in a metropolitan area.* https://doi.org/10.1016/j.scitotenv.2018.11.267

underscored this point during the March 15th SACC Meeting. It therefore appears that EPA is using a single point, defined by the address the company provides through TRI, as the basis for its land use comparison. However, the latitude/longitude of this address is most likely not the precise emissions point. As EPA itself explains (p. 58):

> That lat/long may represent the mailing address location of the office building associated with a very large facility rather than the actual release location (*e.g.*, a specific process stack). This discrepancy between the (0,0) coordinate from which an exposure concentration is modeled for the full-screening level analysis and the actual release point could result in an exposure concentration that does not represent the actual distance where fenceline communities may be exposed.

It is therefore nonsensical to exclude an OES if the model indicates that risks peter out *within* the facilities boundary – because EPA simply does not know the true emitting location within that boundary.

Recommendation: A more appropriate approach would be to assume the emission point could begin at any point along the boundary of the facility and accordingly begin the radial distance buffers at the boundary of the facility (e.g., by using ArcGIS polygon shape file data for the facilities) and compare land use to these buffers. Absent perimeter data information, in the short term EPA could at least identify the location of the emissions for large facilities from Clean Air Act permits. Consistent with this suggestion, in response to Charge Question 2 during the March 16th SACC Meeting, the committee recommended that the exact point should be determined, or otherwise a "worst case scenario" location should be used.

F. EPA did not consider increases in production and use as reasonably foreseen uses.

Production and use of chemicals can vary depending upon a variety of economic and other factors. One input that could be used to assess future activity is the Pollution Prevention Act data reported in Section 8 of the TRI Form R. These TRI data include projections of the quantities of the chemical released or otherwise managed as waste for the two years following the reporting year. TRI data also includes information on the production ratio and activity ratio which can be used to determine trends in the production and use of the chemical. This trend information as well as economic data could inform a determination of whether there will likely be reasonably foreseen increases in releases. Any reasonably foreseen increases in releases should be addressed in an assessment of risks to fenceline communities.

Recommendation: EPA should consider future production and use increases as reasonably foreseen uses of the chemical.

5. EPA should not apply a different benchmark for workers from the rest of the populations.

For the case studies in the fenceline approach, EPA identifies the hazard values used. The values are provided for occupational scenarios, consumers and fenceline communities. Of note is the differing cancer benchmarks used for the same chemical and in some instances for the same person. The cancer benchmark for occupational exposures is $1x10^{-4}$ and for fenceline community and consumer exposure is 1×10^{-6} – a factor of 100 difference. EPA has not provided a risk-based consideration that would account for the difference in choice of cancer benchmarks, nor does there appear to be one. Workers and fenceline community individuals are both "potentially exposed or susceptible subpopulations." Individuals may live in the fenceline community and work at a facility releasing a chemical into that community's environment. In that case, which benchmark would be applied? It does not make sense that two different cancer risk benchmarks would be applied to the same individual. It makes even less sense for it also to be for the same chemical.

Recommendation: EPA should apply the $1x10^{-6}$ cancer benchmark for all individuals.

6. EPA should modify its approach to deriving toxicity values and characterizing risk to ensure fenceline communities are sufficiently protected.

Uncertainty and variability are two key considerations in chemical risk assessments that result from the extrapolation of a relatively limited dataset, mostly compromised of cell-based and animal toxicity data, to assess risk to a wide range of diverse human populations.

In deterministic assessments of non-cancer human health effects, EPA traditionally applies five default "uncertainty factors" (UFs) to account for uncertainties and variabilities when deriving a reference dose or concentration. Specifically, these factors attempt to account for:

- (1) the variation in sensitivity among the members of the human population (i.e., inter-individual variability) [UF_H]
- (2) the uncertainty in extrapolating animal data to humans (i.e., inter-species uncertainty) [UF_A]
- (3) the uncertainty in extrapolating from data obtained in a study with less-than-lifetime exposure to lifetime exposure (i.e., extrapolating from subchronic to chronic exposure) [UF_S]
- (4) the uncertainty in extrapolating from a LOAEL rather than from a NOAEL [UF_L]
- (5) the uncertainty associated with extrapolation when the database is incomplete or when there are deficiencies in the database related to particular organ systems as well as life stages [UF_D][50]

Typically, the default value assigned to each uncertainty factor is assumed to be a factor of 1, 3, or 10, depending on the nature of the original toxicity data, though the accuracy and impact of such default values remains under characterized.

A. EPA should employ a database uncertainty factor where data is found to be limited.

The database uncertainty factor (UF_D) accounts for deficiencies in the study database that may have otherwise resulted in the identification of a more sensitive effect for certain endpoints or life stages. Even though the UF_D is one of the five uncertainty factors traditionally applied in

[50] EPA. (2012). *A Review of the Reference Dose and Reference Concentration Processes*, at 4-38. https://www.epa.gov/sites/default/files/2014-12/documents/rfd-final.pdf

chemical risk assessment – and is commonly employed by other offices and programs at EPA, including ORD/IRIS – the agency did not employ a database uncertainty factor in any of its first 10 completed TSCA risk evaluations, nor the case studies presented in the fenceline approach.

We are concerned about EPA's exclusion of a database uncertainty factor given the implications for risk characterization of fenceline communities. Using methylene chloride (MC) as an example, EPA did not to apply a UF_D for the selected developmental neurotoxicity and hematological effects in the final TSCA risk evaluation, despite the fact that an earlier agency assessment of the chemical conducted by ORD/IRIS used an UF_D of 3 to address identified limitations in data for these end points.[51] Similarly, EPA did not use a UF_D in the risk evaluation for 1-BP, despite a limited evidence base of toxicological data.

Recommendation: To ensure accurate and health-protective risk characterization to fenceline communities, EPA should systematically assess whether a database uncertainty factor is needed for each chemical assessed under the fenceline method, and transparently discuss the rationale for including or excluding such a factor.

B. EPA's use of the traditional default intra-species variability equal to 10 for non-cancer effects may underestimate potential risk to susceptible subpopulations like fenceline communities.

As early as 2002, EPA recognized that "a 10-fold [intra-species] factor may sometimes be too small because of factors that can influence large differences in susceptibility, such as genetic polymorphisms."[52]

Recent evidence demonstrates that a default UF_H of 10 may be insufficient to protect those most at risk, including fenceline communities who are disproportionately exposed to chemical and non-chemical stressors (see Section 1 for more detail). For example, an analysis of dose-response functions of asthmatic subjects indicated sensitivity to nitric acid 20 times greater than healthy individuals.[53] This is just one of many case studies that demonstrate the limitations, including potential underestimation of risk, of relying on a high-end default uncertainty factor of 10 to account for intra-species variability.

Potential underestimation of risk from the use of such as factor is especially likely when attempting to explicitly assess risk to susceptible subpopulations like fenceline communities, whose background and baseline health vulnerabilities may cause their dose-response relationship to significantly differ from that of the general population by greater than a factor of 10. For this reason, it is critical that EPA employ chemical-specific or default distributions to inform its

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[51] EPA (2011). *Toxicological Review of Dichloromethane (Methylene Chloride)*, at 197. https://cfpub.epa.gov/ncea/iris/iris_documents/documents/toxreviews/0070tr.pdf

[52] EPA. (2012). *A Review of the Reference Dose and Reference Concentration Processes*, at 4-44. https://www.epa.gov/sites/default/files/2014-12/documents/rfd-final.pdf

[53] National Research Council. (2009). *Science and Decisions: Advancing Risk Assessment*. Washington, DC: The National Academies Press, at 150. https://doi.org/10.17226/12209

assessment of intra-species variability, as discussed in more detail in section 6(B)(c) of these comments.

Recommendation: EPA should assess whether a default UF_H of 10 is sufficiently protective of potentially exposed or susceptible subpopulations such as fenceline communities, using chemical-specific or surrogate data as a point of comparison.

C. EPA should use chemical-specific or default distributions rather than point estimates to characterize uncertainty and variability.

In the first 10 chemical risk evaluation conducted under TSCA, EPA largely took a deterministic approach to incorporating variability and uncertainty, in which default factors were relied upon. In contrast to the use of point estimate default factors, the preferred method is to incorporate the full distributional information on each component factor by using probabilistic approaches, such as a Monte Carlo approach or a simple analytic approach (for example, when adjustments can be described by lognormal distributions). These distributions can be defined from empirical databases.[54]

We commend EPA for directly integrating inter- and intra-species variability into its dose-response modeling and considering probabilistic pharmacokinetic/pharmacodynamic (PBPK/PD) modeling, where data allowed. We also appreciate EPA's discussion of the data limitations that prevent use of such models. However, it is unclear if the limited data were robust enough to make use of other available methods besides direct PBPK/PD modeling, such as the use of ratios for TK and/or TD parameters, calculated using data on these parameters from both the general population and one or more sensitive human populations, or whether the agency attempted to develop distributions for the other relevant uncertainty factors (e.g., subchronic to chronic, database).[55]

In the case of limited data on a specific chemical, EPA may not be able to make use of the chemical-specific probabilistic methods discussed above. However, generic or default distributions based on surrogate chemicals and endpoints can be employed in the face of limited chemical-specific data.[56] Specifically, in the case of limited chemical-specific data, the NAS recommended that EPA "develop default-adjustment distributions that quantitatively characterize the adjustments and key uncertainties typical in dose-response assessment, including cross-species extrapolation in PK and PD and extrapolations among dose route, dosing intervals (for

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[54] National Research Council. (2009). *Science and Decisions: Advancing Risk Assessment*. Washington, DC: The National Academies Press, at 160. https://doi.org/10.17226/12209

[55] EPA. (2014). *Guidance for Applying Quantitative Data to Develop Data-Derived Extrapolation Factors for Interspecies and Intraspecies Extrapolation [EPA/R-14/002F].* https://www.epa.gov/sites/default/files/2015-01/documents/ddef-final.pdf

[56] National Research Council. (2009). *Science and Decisions: Advancing Risk Assessment*. Washington, DC: The National Academies Press, at 165. https://doi.org/10.17226/12209

example, subchronic to chronic), and data gaps." These default distributions can be based on chemical structures and physio-chemical properties, including taking a class-based approach.[57]

Thus, while lack of information needed for probabilistic modeling of uncertainty factors is a real concern, there are available tools to overcome these limitations, including but not limited to the development of generic or default *distributions* rather than point estimates. Guidance on the development and implementation of "default-adjustment distributions" is provided in the NAS 2009 report *Science and Decisions*.

Recommendation: We urge EPA to use chemical-specific distributions to capture uncertainty and variability when the data are available to do so. If chemical-specific data is not available, we recommend that EPA add more detail to its discussion of why certain variability components, such as toxicodynamic differences, could not be modeled probabilistically. EPA should clearly discuss the data limitations – including what data are missing – and why such limitations prevented the use of chemical-specific distribution extrapolations. Among other things, this discussion should address the data requirements for toxicokinetic and toxicodynamic variability modeling, as laid out in the agency's 2014 guidance for applying data to develop "data-derived" extrapolation factors for inter- and intra-species variability.[58]

In the case of limited chemical-specific data, EPA should employ default distributions for adjustments in extrapolations, rather than rely on default point-estimate uncertainty factors. This approach would enable EPA to represent variability and uncertainty more accurately and transparently, and offers an opportunity for further refinement, including the identification, gathering and development of needed information.

7. EPA's hypothetical outcomes of the fenceline approach are tilted toward making findings of no unreasonable risk.

A. EPA indicates an intention to use the fenceline screening asymmetrically, in favor of finding no unreasonable risk.

EPA's description of how it may use the fenceline approach to inform its risk management "outcomes" reveals a troubling imbalance toward employing the screening-level method in the service of making determinations that chemicals' uses pose no unreasonable risk, versus using the screening to support determinations of unreasonable risk (pp. 18-20).

As an example of this asymmetry, EPA describes hypothetical scenarios in which "no unreasonable risk" was identified in the final risk evaluation for two specific conditions of use of a chemical. In one scenario ("Outcome One"), the fenceline approach does not identify any unreasonable risk to fenceline communities. EPA states it would then use this screening result to "expeditiously propose [] no restrictions on the chemical being used as no unreasonable risk is

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[57] *Id*. at 204

[58] EPA. (2014). *Guidance for Applying Quantitative Data to Develop Data-Derived Extrapolation Factors for Interspecies and Intraspecies Extrapolation [EPA/R-14/002F]*. https://www.epa.gov/sites/default/files/2015-01/documents/ddef-final.pdf

identified or expected." In this scenario, EPA does not consider uncertainties related to that condition of use.

In a different hypothetical scenario ("Outcome Five"), the fenceline approach does identify unreasonable risks. However, in contrast to the first scenario, the agency does *not* rely on the screening results to "expeditiously" move forward to manage the risks, which would represent an action parallel to "Outcome One." Instead, EPA "recognizes the additional screening level analysis has some [condition of use]-specific uncertainties which should be considered prior to proposing a risk management rule" and plans to "further substantiate the unreasonable risk finding."

Thus, via its hypothetical "outcomes," EPA has characterized the fenceline approach as robust enough for the agency to propose no restrictions on a chemical, but not robust enough to propose restrictions on a chemical. EPA inappropriately highlights uncertainties associated only with one potential outcome. This asymmetry is troubling, particularly given the underestimation of risks (summarized in Section 3 of these comments) that EPA has baked into the screening level fenceline approach.

Because this methodology outright excludes exposures, considers exposures in isolation, and excludes elevated exposures, it does not actually consider the risk of the chemical under the conditions of use. In addition to not meeting the requirements of Section 26(h) to use the best available science, the fenceline approach is scientifically insufficient to support a determination that a chemical does not present an unreasonable risk. It is concerning that despite all this, EPA has biased the fenceline approach towards no unreasonable risk determinations.

Recommendation: EPA should modify its fenceline approach so that it accurately estimates risks to fenceline communities rather than systematically underestimate those risks as the current version does. Until it does, EPA should substantiate its estimates when the fenceline approach indicates "no unreasonable risk," as well as "unreasonable risk."

B. EPA's hypothetical scenarios take a use-by-use approach to risk determination that is inconsistent with the law.

In discussing the hypothetical chemical, EPA indicates that if it does not find unreasonable risk to fenceline communities for a particular conditions of use for which it previously found no unreasonable risk, it anticipates "expeditiously" proposing that no restrictions be placed on the chemical for that condition, and publishing a proposed rule to that effect (p. 19). This indicates that EPA may be intending, when applying the fenceline approach, to take a use-by-use determination of a chemical's risk. But such a practice is inconsistent with the requirement under TSCA that EPA consider all hazards and exposures that contribute to the total risk presented by a substance as a whole.[59] This Administration has elsewhere recognized that EPA should follow such a "whole chemical approach," rather than make risk determinations use-by-use, and it should certainly continue this practice in applying its evaluation of risks to fenceline communities.

[59] *See* 15 U.S.C. §§ 2601(b) ("TSCA Section 2(b)"); 2605(a) ("TSCA Section 6(a)"); and 2605(b) ("TSCA Section 6(b)")

The holistic risk determination demanded by TSCA takes into account that multiple exposures to the same chemical from different sources will increase risk.[60] In addition, the whole chemical approach embraces the reality that although risks from one particular use of a chemical may be minimal, the risks from a combination of uses of that chemical may provide a basis for an unreasonable risk determination. This is particularly true for potentially exposed or susceptible subpopulations that are more susceptible to harm from even low-level exposures, or may have more extensive exposures than the general population, such as members of fenceline communities. In addition, the whole chemical approach is consistent with TSCA Section 6(a), which requires EPA to issue a risk management rule if it determines that "any combination of" a chemical's "manufacture, processing, distribution in commerce, use, or disposal" presents an unreasonable risk.[61] EPA cannot rule out that a combination of a chemical's conditions of use, or a subset of its uses, presents an unreasonable risk until after it has considered all of its conditions of use collectively.

In addition to being contrary to the letter and purpose of TSCA, the use-by-use approach suggested in the hypothetical scenarios section is inconsistent with EPA's actions to move past such practices of the previous Administration. In its first two revised TSCA risk determinations, released this year, EPA has proposed to supersede those use-by-use determinations by now employing a "whole chemical substance" approach:

> Specifically, in this draft revision to the risk determination EPA finds that HBCD, as a whole chemical substance, presents an unreasonable risk of injury to health and the environment when evaluated under its conditions of use. This draft revision supersedes the condition of use-specific no unreasonable risk determinations in the September 2020 HBCD risk evaluation (and withdraw the associated order) and makes a revised determination of unreasonable risk for HBCD as a whole chemical substance. [62]

These revised determinations for HBCD and PV29 were the first revisions proposed for the chemicals evaluated by the previous Administration; more determinations applying the whole

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[60] *See* 15 U.S.C. § 2605(b)(4)(F) ("TSCA Section 6(b)(4)(F)")

[61] 15 U.S.C. § 2605(a)

[62] EPA. (2021). *Cyclic Aliphatic Bromide Cluster (HBCD); Draft Revision to Toxic Substances Control Act (TSCA) Risk Determination; Notice of Availability and Request for Comment*. 86 Fed. Reg. 74082. https://www.regulations.gov/document/EPA-HQ-OPPT-2019-0237-0088; *See also* EPA. (2021). *Colour Index Pigment Violet 29 (PV29); Draft Revision to Toxic Substances Control Act (TSCA) Risk Determination; Notice of Availability and Request for Comment*. 87 Fed. Reg. 12691. https://www.regulations.gov/document/EPA-HQ-OPPT-2016-0725-0073 (similar language)

chemical approach, revising the use-by-use approach, will follow.[63,64] By appearing, troublingly, to contemplate maintaining the use-by-use risk determination framework of old, EPA's discussion of the possible outcomes of its fenceline approach therefore stands in contrast to its move to a whole chemical approach. EPA's fenceline approach should not trigger a return to non-holistic evaluations of risk; instead, the fenceline screening should serve to broaden the agency's understanding of each chemical's risk and its approach to managing it.

Recommendation: EPA should not make use-by-use determinations of the risk to fenceline communities and should apply its whole chemical approach to ensure that all conditions of use are considered in determining risk to these communities.

C. EPA's hypothetical scenarios includes an inappropriate application of TSCA Section 9.

As EPA appears to acknowledge, TSCA is the law that must be used to address unreasonable risk from a substance, rather than another law administered by EPA, unless EPA determines that the risk could be "eliminated or reduced to a sufficient extent by actions taken under the authorities contained" in that law[65] (see "Outcome Four," p. 20). Even if EPA were to determine that the other law may eliminate unreasonable risk, EPA may determine in its discretion that it serves the public interest to take actions under TSCA, rather than the other EPA-administered law, to protect against the risk.[66] EPA would use TSCA in that case.[67]

Although the Clean Air Act is invoked only as a hypothetical example (in "Outcome Four") of how EPA may employ Section 9(b), we are concerned about its use as an example. Only if EPA were to determine that the CAA eliminates the unreasonable risk, and that it is not in the public interest to use TSCA to address that risk, may EPA proceed to employ CAA. Examples of issues that would make the CAA inappropriate for use under Section 9 include: if the CAA provision does not mandate protection of workers and if the CAA provision allows for higher risk thresholds than TSCA. EPA must scrutinize such features of any law it proposes to act under to eliminate the risk, and must act under TSCA if the other law falls short. To "coordinate" its actions by employing a law that does not provide populations such as fenceline communities with the protection to which TSCA entitles them would result in risk management actions by which EPA fails to fulfill its duties under TSCA.

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[63] *Id.* at 74083 ("This revision would be consistent with EPA's plans to revise specific aspects of the first ten TSCA chemical risk evaluations in order to ensure that the risk evaluations better align with TSCA's objective of protecting health and the environment.")

[64] EPA. (2021). "EPA Announces Path Forward for TSCA Chemical Risk Evaluations." https://www.epa.gov/newsreleases/epa-announces-path-forward-tsca-chemical-risk-evaluations

[65] 15 U.S.C. § 2608(b)(1) ("TSCA Section 9(b)(1)")

[66] *Id.*

[67] In its discussion of Section 9(b), it appears that EPA made a wording error in indicating that the subsection provides for "referrals." Section 9(a) ("Laws not administered by the Administrator") involves referrals, 15 U.S.C. § 2608(a), not Section (b) ("Laws administered by the Administrator").

We also note EPA's statement that the "CAA has expertise with area source regulations which require specific localized control on certain emission sources" and thus requirements under the CAA "can reduce both worker exposures as well as total fugitive emissions released to ambient air." However, the CAA expertise does not extend to expertise or authority on worker exposure. Even if total fugitive emissions reductions may equate with overall worker reductions at the facility, this will not necessarily equate with uniform reductions for all workers or assurance that workers will not face unreasonable risks. Since the CAA does not focus on worker protection, some or most workers may continue to face unreasonable risks. Also, EPA's referral would be based on the requirements at the time of the referral. Any subsequent equipment or process changes made at the facility would need to be compliant with the CAA requirements and would not need to consider worker protection. Thus, EPA's example does not hold.

8. EPA's fenceline approach highlights the need for a paradigm shift toward cumulative risk assessment.

The characterization of risks to fenceline communities warrants a more robust assessment than a screening level approach, especially considering that fenceline communities clearly constitute a "potentially exposed or susceptible subpopulation" under TSCA section 3.

To make matters worse, EPA did not attempt to do even the most cursory screening analysis of demographic and other factors related to environmental justice (see p. 11). This is contrary to the Biden Administration's commitment to prioritize environmental justice and "hold polluters accountable, including those who disproportionately harm communities of color and low-income communities."[68]

In developing its fenceline approach, EPA maintained its longstanding practice of evaluating exposure and risks resulting from a single chemical, without consideration of how other chemical and non-chemical exposures or stressors may impact the risk posed by the specific chemical in question. While this individual chemical perspective is the traditional and typical practice for chemical risk assessment under TSCA, it is a narrow approach that significantly underestimates actual risks. This is especially true for individuals in fenceline communities, who are often exposed to multiple chemical and non-chemical (e.g., poverty, racial discrimination) stressors simultaneously, which may exacerbate adverse health effects from the chemical in question. Furthermore, ignoring all relevant chemical and non-chemical non-stressors fails to meet the TSCA requirement of using the best available science.[69]

A. Fenceline communities are disproportionately impacted by co-exposures to chemical that have similar impacts.

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[68] The White House. (2021). *Exec. Order No. 13,990, Protecting Public Health and the Environment and Restoring Science to Tackle the Climate Crisis*. 86 Fed. Reg. 7037. https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/20/executive-order-protecting-public-health-and-environment-and-restoring-science-to-tackle-climate-crisis/

[69] 15 U.S.C. § 2625(h) ("TSCA Section 26(h)")

People living in fenceline communities are often exposed to multiple chemicals that can affect the same health endpoints. It is well-recognized that chemical exposures do not occur singly or in isolation. Rather people are exposed to multiple chemicals simultaneously. Thus, failing to account for these chemical co-exposures underestimates the risks. This is because these co-exposures may render an individual more susceptible to risks associated with other chemicals.

Evidence of co-exposures of chemicals to communities is growing. Comments from Earthjustice et al on the draft scopes of the first twenty high-priority substances to undergo TSCA risk evaluation included TRI data to identify communities in Texas and Louisiana that are exposed to more than one of these chemicals.[70] Communities in Cancer Alley represent 0.5% of the total U.S. population, however, this area is subject to at least one-third of the entire nation's releases to several of the high-priority chemicals, including formaldehyde, ethylene dibromide, 1,1-dichloroethane, ethylene dichloride, and 1,1,2-trichloroethane.[71] The comments also discuss how the Greater Houston region experiences greater exposures to several of the next 20 chemicals. Additionally, air monitoring data from the peer-reviewed literature has detected both formaldehyde and ethylene dibromide in the Greater Houston region.[72] This underscores that people in this region experience much greater exposure to these chemicals than the general population.

EPA's failure to consider co-exposures is particularly problematic for chemicals that contribute towards common adverse health outcomes. For example, formaldehyde and ethylene dibromide can cause or exacerbate respiratory effects and are of particular concern to communities that are disproportionately affected by asthma.[73] Communities that are exposed to high concentrations of 1,3-butadiene, such as communities in the Greater Houston area, are also likely to be exposed to higher concentrations of secondary formaldehyde than the general population since 1,3-

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[70] Earthjustice *et al.* (2020). *Comments on Draft Scopes of the Risk Evaluations for the First Twenty High-Priority Substances under the Toxic Substances Control Act.* https://earthjustice.org/sites/default/files/files/20_05_26_tx_la_tsca_first_20_hp_appx_rfs.pdf

[71] The Texas-Louisiana Gulf region is the 500-mile stretch along the Gulf of Mexico from Houston, TX to the TX/LA border.

[72] Sexton, K., Linder, S.H., Marko, D., *et al.* (2007). Comparative assessment of air pollution-related health risks in Houston. *Environ Health Perspect.*, *115*(10), 1388-93. doi: 10.1289/ehp.10043

[73] Hoppin, J.A., Umbach, D.M., London, S.J., *et al.* (2009). Pesticide use and adult-onset asthma among male farmers in the Agricultural Health Study. *Eur Respir J.*, *34*(6), 1296-1303. https://erj.ersjournals.com/content/34/6/1296

butadiene can react atmospherically with other chemicals to form formaldehyde.[74] Both chemicals have been linked to incidences of leukemia.[75,76]

Recommendation: The current fenceline approach fails to consider co-exposures to other chemicals. EDF recommends that the agency include co-exposures to multiple chemicals when evaluating risks to chemicals, as this represents fenceline communities' lived experiences.

B. Fenceline communities are disproportionately impacted by non-chemical stressors.

In addition to being exposed to multiple chemicals, people living in fenceline communities are often exposed to non-chemical stressors that can act on the same health effects as chemical stressors. Non-chemical stressors include experiencing discrimination, having limited financial resources and limited access to education and health care, and being subject to other social inequities and marginalization.[77,78] Exposure to non-chemical stressors can occur at the individual, community, and macro social scales (e.g., state- or country-wide). Biologically, non-chemical stressors can contribute to the same health effects as chemical stressors, which makes them critically important to consider in chemical risk evaluations, especially when TSCA calls for the specific protection of potentially exposed or susceptible subpopulations.

Fenceline communities often fit the definition of marginalized communities, groups and communities that experience discrimination and exclusion (social, political, and economic) because of unequal power relationships across economic, political, social, and cultural dimensions.[79] Research has already documented that communities experiencing pollution to

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[74] Parrish, D.D., Ryerson, T.B., Mellqvist, J., *et al.* (2012). Primary and secondary sources of formaldehyde in urban atmospheres: Houston Texas region. *Atmos. Chem. Phys.*, *12*(7), 3273-88. https://doi.org/10.5194/acp-12-3273-2012

[75]Chen, W.Q. & Zhang, X.Y. (2022). 1,3-Butadiene: a ubiquitous environmental mutagen and its associations with diseases. *Genes and Environ*, *44*(3). https://doi.org/10.1186/s41021-021-00233-y

[76] Kang, D.S., Kim, H.S., Jung, J.H. *et al.* (2021). Formaldehyde exposure and leukemia risk: a comprehensive review and network-based toxicogenomic approach. *Genes and Environ*, *43*(13). https://doi.org/10.1186/s41021-021-00183-5

[77] Barrett E.S. & Padula A.M.. (2019). Joint Impact of Synthetic Chemical and Non-chemical Stressors on Children's Health. *Curr Environ Health Rep.*, *6*(4), 225-235. https://doi.org/10.1007/s40572-019-00252-6

[78] Payne-Sturges, D.C., Scammell, M.K., Levy, J.I., *et al.* (2018). Methods for Evaluating the Combined Effects of Chemical and Nonchemical Exposures for Cumulative Environmental Health Risk Assessment. *Intl. J. Envtl. Research & Pub. Health*, *15*(12). https://dx.doi.org/10.3390%2Fijerph15122797

[79] Van Horne Y.O., Alcala C.S., Peltier R.E., *et al.* (2022). An applied environmental justice framework for exposure science." *J Expo Sci Environ Epidemiol.*, 1-11. https://doi.org/10.1038/s41370-022-00422-z

toxic chemicals are also dealing with the stress and burden of non-chemical stressors.[80] For example, a survey conducted by Mohai et al found that respondents who identified as Black and reported having lower educational and income levels were significantly more likely to live within a mile of a polluting facility based on TRI data.[81] A 2022 study reported that proximity to military facilities intensifies racial and ethnic environmental inequalities in exposure to airborne toxics, measured using NATA data, for Latinx and Black populations.[82]

In some instances, it is not just one industrial facility in a community or within a mile from a community, rather several facilities are clustered in a small area. For example, data from EPA's EasyRSEI database confirm that the Texas/Louisiana Gulf region, which is disproportionately exposed to several of the next 20 chemicals, has clusters of co-located facilities that emit 1,3-butadiene.[83] Data in the fenceline approach documents also point to facility clustering in fenceline communities. Table 2 in the Appendix demonstrates that on average, facilities that release at least one of the first 10 chemicals assessed under TSCA are surrounded by other TRI-reporting facilities (specifically an average of one within 1 km, eight within 5 km, and 19 within 10 km). While not illustrated here, preliminary analyses of these TRI data indicate that communities living in the largest clusters of TRI-reporting facilities emitting chemicals currently or recently undergoing TCSA review are disproportionately communities of color and low-income communities.

Recommendation: In this version 1.0, EDF recommends that EPA consider aggregate exposures. Moving forward, EDF recommends that EPA update the fenceline approach to consider the role of non-chemical stressors that act on the same endpoints as chemical stressors.

C. Available frameworks for cumulative risk assessments and environmental justice.

For EPA to fully account for all the risks to fenceline communities, the agency should employ a cumulative risk assessment approach, which considers risks to individuals and the population resulting from co-exposures to multiple chemical and non-chemical stressors. To do so would also be consistent with the use of "the best available science" as stated in TSCA[84] and, as discussed above, would be consistent with the TSCA's explicit language to consider the risks to

[80] Johnston, J. & Cushing, L. (2020). Chemical Exposures, Health, and Environmental Justice in Communities Living on the Fenceline of Industry." *Curr Environ Health Rep.*, *7*(1), 48-57. https://doi.org/10.1007/s40572-020-00263-8

[81] Mohai, P., Lantz, P.M., Morenoff, J., *et al.* (2009). Racial and socioeconomic disparities in residential proximity to polluting industrial facilities: evidence from the Americans' Changing Lives Study. *Am J Public Health*, *99*(Suppl 3), S649-S656. https://dx.doi.org/10.2105%2FAJPH.2007.131383

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[83] EPA. (Accessed 2022, March 20). *EasyRSEI Dashboard*. https://edap.epa.gov/public/extensions/EasyRSEI/EasyRSEI.html.

[84] 15 U.S.C. § 2625(h) ("TSCA Section 26(h)")

potentially exposed or susceptible subpopulations.[85] Additionally, the National Academy of Sciences has advocated for, and provided recommendations to, advance cumulative risk assessment of chemicals.[86,87]

Several conceptual models are available to support the planning and implementation of this type of cumulative risk assessment process.[88,89,90,91] In a recent study, Pullen-Fedinick et al. (2021), the authors demonstrate a process using publicly available data and simple geospatial techniques to incorporate cumulative approaches into risk assessments under TSCA. The article focuses on formaldehyde and identifies potentially exposed or susceptible subpopulations, specifically subpopulations who face greater exposure to formaldehyde and are more susceptible to the health risks of formaldehyde as a result of being exposed to other chemicals with similar health endpoints.

While robust methodologies are still being developed, particularly in the area of incorporating non-chemical stressors, EPA's Office of Research and Development (ORD) recently published draft guidance on implementing cumulative impact assessment in the near-term.[92] This new ORD guidance aims to "promote the use of cumulative impact assessment across the Agency," which "aligns with recommendations from the National Environmental Justice Advisory Council and the White House Environmental Justice Advisory Council that urge increased attention to the cumulative impacts of multiple chemical and non-chemical stressors on disadvantaged, underserved, and environmentally overburdened communities, including tribes (NEJAC, 2004,

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[85] 15 U.S.C. § 2602(12) ("TSCA Section 3(12)")

[86] National Research Council. (2008). *Phthalates and Cumulative Risk Assessment: The Tasks Ahead*. Washington, DC: The National Academies Press. https://doi.org/10.17226/12528

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[92] EPA. (2022). *Cumulative Impacts: Recommendations for ORD Research*. https://www.epa.gov/healthresearch/cumulative-impacts-research

2014; WHEJAC, 2021)."[93] The document is currently being reviewed by the Scientific Advisory Board (SAB).

Importantly, while assessing cumulative risks from chemical and non-chemical stressors can be more complicated than traditional single chemical risk evaluations, there is sufficient data and methodologies available to the agency to take action now. This message was echoed by numerous members of the SAB at the most recent public meeting on cumulative impacts research.

Recommendation: EDF recommends that OPPT coordinate with ORD and other authoritative bodies to implement a cumulative risk assessment framework in the near-term, specifically in the context of the fenceline approach.

9. EPA should use the correct terminology in referring to N-methylpyrrolidone.

Throughout the fenceline approach EPA consistently uses the term "n-methyl pyrrolidone" rather than the correct "N-methyl pyrrolidone." "N" indicates that the methyl group is on the nitrogen. In chemical nomenclature, "n" (short for "normal") is used to signal that an alkyl group is straight-chained. Of course, this is not needed for the single carbon methyl group.

Recommendation: EPA should correct the name for N-methyl pyrrolidone throughout the document.

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

[93] *Id*.

APPENDIX

In collaboration with Dr. Mary Collins from SUNY University, we analyzed TRI on-site release data from 2015-2019[94] for facilities releasing chemicals recently or currently undergoing TSCA risk evaluation (i.e., the first 10 chemicals, next 20 chemicals, and manufacturer-requested risk evaluations). We focused on on-site releases as most relevant to fenceline communities geographically located next to the emitting facilities.

Table 1 illustrates the variability in both the number of reporting facilities and the sum pounds released by year for EPA's case study chemicals N-methylpyrrolidone, methylene chloride, and 1-bromoporpane, across all reported on-site releases (not limited to air and water).

Table 1. TRI On-Site Releasing Facilities 2015-2019 for NMP, MC, and 1-BP[95]

	N-Methylpyrrolidone		**Methylene chloride**		**1-Bromopropane**	
TRI Reporting Year	No. of TRI Facilities	Sum TRI Releases (lbs.)	No. of Facilities	Sum Releases (lbs.)	No. of Facilities	Sum Releases (lbs.)
2015	400	5,126,110	275	2,366,428	N/A	N/A
2016	405	6,727,590	270	2,623,013	62	814,958
2017	394	7,173,902	260	2,720,170	73	1,047,271
2018	397	5,912,635	261	2,775,320	75	1,023,992
2019	388	5,119,264	247	2,714,487	65	1,023,776

To evaluate clustering of emitting facilities, we analyzed the number of TRI-reporting facilities in close proximity (i.e., within 1, 5 and 10 kilometers) to facilities reporting release to TRI of any of the first 10 TSCA Chemicals in 2019. Table 2 illustrates that such facilities often cluster together, with a maximum of 121 facilities within 10 kilometers (i.e., the maximum distance EPA evaluated in the draft method for the air pathway) of the evaluated facility.

[94] Raw data was pulled from EPA's "TRI Basic Data Files: Calendar Years 1987- Present." https://www.epa.gov/toxics-release-inventory-tri-program/tri-basic-data-files-calendar-years-1987-present.

[95]Note that the sum released provided in this table differ from those provided in our initial comments to the SACC on the fenceline approach. We identified an error in the preliminary analysis presented in those comments.

Table 2. Number of TRI Facilities in Close Proximity to TRI Facilities Releasing the First 10 TSCA Chemicals

Buffer Distance	Minimum	1st Quartile	Mean	3rd Quartile	Maximum
1 km	0	0	1	1	11
5 km	0	2	8	11	58
10 km	0	5	19	24	121

We also integrated the TRI data with demographic information of communities living within 1, 5, and 10 kilometer radii of the releasing facility using the American Census Survey (ACS). We incorporated demographic information on elements such as race, household income, median home value, and age (<5 year, females 15-49 years, and >65 years) to evaluate trends and disproportionate exposures to particular populations. Due to the limited timeframe of the comment period, we have not completed all of these data analyses. However, they are available upon request.

Table 3 below summarizes self-identified race in the ACS for populations living near facilities reporting emissions of 1-bromoproprane, methylene chloride, and N-methylpyrrolidone as compared to the average in the county in which the facility is located. County level comparisons are more relevant than national level comparisons because they provide a more precise depiction of the local demographics than a national average that is not at all similar to a neighborhood. Preliminary analyses demonstrate that "non-white"[96] individuals are overrepresented close to facilities emitting these three chemicals, regardless of the radial buffer.

Table 3. Non-white population within 5km and 10km of NMP, MC, and 1-BP releasing facilities, as compared to county averages.

	N-Methylpyrrolidone (average 2015-2019)		**Methylene chloride** (average 2015-2019)		**1-Bromopropane** (average 2016-2019)	
Radii	5 km	10km	5 km	10km	5 km	10km
Percent population non-white	41%	40%	37%	37%	34%	32%
Proportional increase in non-white population as compared to county	14%	10%	9%	10%	12%	7%

[96] "Non-white" is based on the terminology used in ACS, and it reflects people who self-identify as a race other than non-Hispanic white.