



February 22, 2022

**Submitted via regulations.gov**

Dr. Alaa Kamel, DFO  
Office of Chemical Safety and Pollution Prevention (7201M)  
Environmental Protection Agency  
1200 Pennsylvania Ave., NW  
Washington, DC 20460-0001

Re: 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 Version 1.0, 87 Fed. Reg. 3294 (January 21, 2022), Docket ID. No. EPA-HQ- OPPT-2021-0415

Dear Dr. Kamel:

The American Chemistry Council (ACC)<sup>1</sup> appreciates the opportunity to submit comments to the Science Advisory Committee on Chemicals (SACC) and the Environmental Protection Agency's (EPA) regarding the agency's Draft Toxic Substances Control Act (TSCA) Screening Level Approach for Assessing Ambient Air and Water Exposures to Fenceline Communities, Version 1.0 (Screening Level Approach).

**Introduction**

EPA has prepared a screening level methodology for assessing potential air and water pathway chemical exposures to fenceline communities and conducted case studies for three of the first 10 chemicals for which EPA published risk evaluations between 2020 and 2021. Following the SACC review, EPA will review public comments and SACC recommendations, and modify and potentially apply the proposed screening level methodology for seven of the first 10 chemicals for which these evaluations were not previously conducted.

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<sup>1</sup> The American Chemistry Council (ACC) represents the leading companies engaged in the multibillion-dollar business of chemistry. ACC members apply the science of chemistry to make innovative products, technologies and services that make people's lives better, healthier and safer. ACC is committed to improved environmental, health, safety and security performance through Responsible Care®; common sense advocacy addressing major public policy issues; and health and environmental research and product testing. ACC members and chemistry companies are among the largest investors in research and development, and are advancing products, processes and technologies to address climate change, enhance air and water quality, and progress toward a more sustainable, circular economy.



ACC has reviewed the Screening Level Approach and has the following general comments for consideration by the SACC and EPA. In addition, we anticipate providing supplementary detailed comments before the final March 22<sup>nd</sup> deadline established by EPA.

**A. The Screening Level Approach is a component of the typical exposure assessment under TSCA for general populations to chemicals in air and water from industrial emissions.**

Historically within the TSCA Section 5 new chemicals review program and presently in its TSCA Section 6 existing chemical risk evaluations, EPA has organized its exposure assessments among three primary populations: general population, consumer residential population and occupational worker population.<sup>2</sup> Within the exposure assessment for general populations is a consideration for human exposures resulting from facility releases to air, water, and land; the EPA Exposure and Fate Assessment Screening Tool (E-FAST) estimates general population exposures from inhalation, consumption of drinking water, and fish ingestion exposures resulting from facility chemical emissions.<sup>3</sup>

For the benefit of all stakeholders, the agency should provide some background on how it has historically approached general population exposures at the fence line. In addition, the Screening Level Approach should follow the agency's past practices, or the agency should describe why they have deviated from those practices.

**B. The Screening Level Approach is an example of necessary guidance as identified in 15 U.S. Code §2625(l).**

TSCA requires that EPA develop policies, procedures, and guidance that are necessary to carry out the law. The Screening Level Approach is an example of such guidance that will make it easier for stakeholders to participate in the risk evaluation process and support the agency's efforts. We appreciate EPA making the Approach available for peer review and public comment to allow further opportunities for improvement. Moreover, we note that the Approach is subject to the scientific standards described in TSCA and must be *employed in a manner consistent with the best available science*.<sup>4,5</sup>

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<sup>2</sup> <https://www.epa.gov/expobox/exposure-assessment-tools-lifestages-and-populations>

<sup>3</sup> USEPA. 2007. *Exposure and Fate Assessment Screening Tool (E-FAST), Version 2.0, Documentation Manual*. United States Environmental Protection Agency, Washington, D.C.

<sup>4</sup> *Best available science* means science that is reliable and unbiased. Use of best available science involves the use of supporting studies conducted in accordance with sound and objective science practices, including, when available, peer reviewed science and supporting studies and data collected by accepted methods or best available methods (if the reliability of the method and the nature of the decision justifies use of the data). Additionally, EPA will consider as applicable: (1) The extent to which the scientific information, technical procedures, measures, methods, protocols, methodologies, or models employed to generate the information are reasonable for and consistent with the intended use of the information; (2) The extent to which the information is relevant for the Administrator's use in making a decision about a chemical substance or mixture; (3) The degree of clarity and completeness with which the data, assumptions, methods, quality assurance, and analyses employed to generate the information are documented; (4) The extent to which the variability and uncertainty in the information, or in the procedures, measures, methods, protocols, methodologies, or models, are evaluated and characterized; and (5) The extent of independent verification or peer review of the information or of the procedures, measures, methods, protocols, methodologies or models (40 CFR § 702.33).

<sup>5</sup> 15 U.S.C. §2625(h)



EPA should continue to develop and release similar guidance to facilitate greater stakeholder participation in the risk evaluation process.

**C. As a “screening methodology” additional tiers of refinement and assessment should be available in those cases where exposures exceed a threshold.**

*EPA’s Exposure Assessment Guidelines recommend completing exposure assessments iteratively using a tiered approach to “strike a balance between the costs of adding detail and refinement to an assessment and the benefits associated with that additional refinement.”*<sup>6,7</sup> Hazard, exposure, and risk assessments can use a tiered approach, often starting with a screening-level assessment and increasing the level of complexity as required. Lower tier assessments can require few resources and can evaluate large numbers of agents, facilities, scenarios, etc. Complex risk assessments, in contrast, can address the most demanding problems in risk assessment. The goal is to design the assessment to fit the needs of the risk managers/decision makers, balancing the complexity of the assessment against time and resource constraints.<sup>8</sup>

The Screening Level Approach should incorporate additional tiers of assessment that establish refined approaches for estimating fence-line community exposures. EPA should describe its entire process for evaluating fence-line exposures through multiple tiers of assessment and the entire process should include external peer review and consultation with the SACC.

**D. The data and information used in the Screening Level Approach should be evaluated using the appropriate data quality criteria from the Systematic Review process.**

The TRI emissions data are such a critical and influential component of the Screening Level Approach that the variability and uncertainties associated with them should be well documented and accounted for. The same data quality assessment (i.e., Systematic Review) should be applied to those data. The Screening Level Approach provides a lengthy discussion of the uncertainties associated with the release (emissions) estimates (pp. 54–57). The TRI data, while valuable for some purposes, are not sufficiently reliable to serve as the basis for a determination of unreasonable risk under TSCA. Several limitations in relying on TRI information for understanding exposures have been highlighted<sup>9,10</sup> and should be fully considered by the Agency in developing the screening estimates and communicating the results to the public.

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<sup>6</sup> <https://www.epa.gov/expobox/exposure-assessment-tools-tiers-and-types-screening-level-and-refined>

<sup>7</sup> USEPA. 1992. *Guidelines for Exposure Assessment*. United States Environmental Protection Agency, Washington, D.C. EPA/600/Z-92/001. Published on May 29, 1992, Federal Register 57(104):22888-22938.

<sup>8</sup> USEPA. 2019. *Guidelines for Human Exposure Assessment*. United States Environmental Protection Agency, Washington, D.C. EPA/100/B-19/001.

<sup>9</sup> <https://peri.umass.edu/how-accurate-are-the-rsei-data-on-toxic-air-pollution>

<sup>10</sup> <https://citeseerx.ist.psu.edu/viewdoc/download?doi=10.1.1.316.5944&rep=rep1&type=pdf>



In addition, it would be valuable for EPA to conduct a sensitivity analysis of its Screening Level Approach to better understand which data elements may contribute the greatest to uncertainty in the results and should be the focus of the agency’s attention when gathering data.

**E. Environmental releases to air (fugitive and stack emissions) and water occur at the “Releases and Waste Disposal” phase of the chemical life cycle.**

As part of each risk evaluation, EPA considers the life cycle stages of each chemical including manufacturing, processing, distribution, use (industrial, commercial, consumer) and disposal. Generally, individual facilities will be associated with each life cycle stage (e.g., a manufacturer, a distributor, a user, etc.) though some facilities may cover multiple life cycle stages of a chemical. The life cycle diagrams that EPA generates as part of the risk evaluations illustrate that releases may occur at any stage of the chemical life cycle and that they may be considered disposal.

EPA should treat facility emissions to water and air as disposal in the chemical life cycle. TRI emissions to air and surface water are characterized as “Disposal or Other Releases.” Certainly, stack emissions and surface water discharges represent the intentional collection and release of waste chemicals to the environment. EPA should assess emissions at the facility level rather than trying to attribute those emission to individual manufacturing, processing or use conditions of use/occupational exposure scenarios (OES), *at least at the screening level*. The attempt to map emissions to OES is highly speculative, rife with uncertainties, and provides little benefit at the screening level. In the Introduction, EPA speculates on how the screening level analysis may be used to inform risk management action. However, it is premature to discuss risk management before a complete analytical approach is fully developed. EPA should focus its resources on a robust and well-vetted fenceline (general population) exposure assessment methodology.

If the Agency proposes to move ahead with the OES approach, scientific analyses demonstrating that this approach meets the TSCA standard of best available science must be published by the Agency and released for public review and comment and subjected to independent scientific peer review (in accordance with EPA Policy and OMB Bulletins).<sup>11,12</sup>

**F. The Screening Level Approach should include steps where existing data, analyses and risk management action are considered and potentially relied upon.**

It its initial risk evaluations for several of the first 10 chemicals, EPA concluded that exposures to general population via ambient air and disposal pathways (aka fenceline exposures) fall under the jurisdiction of other environmental statutes administered by EPA, e.g., the Clean Air Act. Therefore, EPA did not

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<sup>11</sup> EPA Peer Review Handbook ([https://www.epa.gov/sites/default/files/2020-08/documents/epa\\_peer\\_review\\_handbook\\_4th\\_edition.pdf](https://www.epa.gov/sites/default/files/2020-08/documents/epa_peer_review_handbook_4th_edition.pdf))

<sup>12</sup> Office of Management and Budget's Final Information Quality Bulletin for Peer Review [https://www.epa.gov/sites/default/files/2015-01/documents/omb\\_final\\_info\\_quality\\_bulletin\\_peer\\_review\\_2004\\_1.pdf](https://www.epa.gov/sites/default/files/2015-01/documents/omb_final_info_quality_bulletin_peer_review_2004_1.pdf)



conduct a quantitative evaluation of the risk to the general population from ambient air and disposal pathways.

While the agency may not have initially conducted fenceline exposure assessments in the first 10 risk evaluations, it did acknowledge that there is significant activity in other EPA offices regarding these exposures. In contrast, the present Screening Level Approach does not recognize that there may be valuable expertise and analyses within these programs, or other programs, upon which the agency could rely.

Among the steps in the Screening Level Approach should be an examination of existing available data and exposure analyses before the agency conducts an additional *de novo* fenceline exposure evaluation. For the three case study chemicals (1-BP, NMP and methylene chloride) the number of manufacturers (including importers) who reported under the most recently published Chemical Data Reporting (CDR) rule (2016) is 14–33 facilities. As such, a review of the existing information for those facilities would not be burdensome.

**G. In cases where the number of emitting facilities is large and widely spread across the country (e.g., commercial users), it may be necessary and appropriate for EPA to develop a model scenario or scenarios for a particular life cycle condition of use.**

ACC acknowledges that some life cycle stages, and conditions of use might result in a number of facilities for which individual assessment is not feasible. One example is that of dry cleaners evaluated as part of the 1-BP case study, of which there are likely thousands in the United States. It is reasonable in those circumstances for EPA to develop a *model facility* to serve as the basis for a screening-level fenceline assessment.

However, in the case of 1-BP as a dry cleaning agent (and every other risk evaluation), the approach adopted should consider available data and information. In its 2018 Problem Formulation of the Risk Evaluation for 1-Bromopropane,<sup>13</sup> the agency stated it *believes that few dry cleaners use 1-BP as a dry cleaning solvent*, and it estimated in its 2016 Draft Risk Assessment<sup>14</sup> that about 246 dry cleaning establishments used 1-BP. A more recently published analysis concluded that the number of dedicated dry cleaning machines in operation using 1-BP is expected be reduced to three by 2020.<sup>15</sup> Again, it would not be burdensome for EPA to evaluate this condition of use based on existing information, and the circumstances could be easily confirmed as could potential co-resident exposures (i.e., does co-resident exposure occur among the three current dry cleaners using 1-BP).

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<sup>13</sup> Available at: <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/1-bromopropane-1-bp-problem-formulation>

<sup>14</sup> Available at: [https://www.epa.gov/sites/default/files/2016-03/documents/1-bp\\_report\\_and\\_appendices\\_final.pdf](https://www.epa.gov/sites/default/files/2016-03/documents/1-bp_report_and_appendices_final.pdf)

<sup>15</sup> Smith, C.J., T.A. Perfetti, R.G. Morford. 2020. Use of 1-bromopropane (N-propyl bromide) in dry cleaning is rare and rapidly declining toward obsolescence. *Toxicology Research and Application*, 4: 1–6. DOI: 10.1177/2397847320966961 (ENCLOSED)



**H. In cases where EPA develops a model facility to serve as the basis for the screening-level fenceline assessment, it should work closely with stakeholders of that condition of use to accurately model it.**

The need for a model facility serving as the basis for the screening-level fenceline assessment is most likely to occur when there is diffuse and widely distributed commercial use of a chemical. In those cases, EPA should reach out to the user community to better understand the circumstances related to that use in order to accurately characterize the model facility.

**I. The Screening Level Approach is not suitable for the agency to make risk determination decisions, or to inform risk management actions.**

As noted above, the screening level methodology is not suitable for the agency to make risk determinations because there needs to be higher tiers of assessment incorporated for those cases where the estimated exposure level exceeds the relevant threshold.

In the Introduction, the agency states “the results as presented in this work are not final agency actions and will not be used as presented to support risk management actions or associated rulemaking activities resulting from the published risk evaluations at this time” but in the following paragraph, the agency goes on to state “EPA provides a brief description of how results from the screening level analysis may be used to further inform or support the Agency’s risk management actions and associated rulemaking outcomes under TSCA resulting from published risk evaluations for chemicals undergoing risk evaluation.”<sup>16</sup> EPA needs to reconcile these two contradictory statements by eliminating the latter. The screening level nature of the Screening Level Approach as currently drafted is only suitable for hypothesis generation. The initial screen needs to be followed with additional “ground-truthing” of the data and assumptions, particularly the emissions estimates associated with the TRI data, and by outreach to facilities and companies regarding emissions information, facility modeling and air or water monitoring data.

In addition, while it is useful to understand the agency’s current thinking regarding the future use of the analysis from the Approach,<sup>17</sup> it is not useful for it to be included in this document and should be removed. The SACC will not be involved in the risk management process and speculation regarding potential use of these analyses to inform risk management will more likely serve as a distraction, rather than a benefit, to the work they are being asked to do.

**J. Interpreting and Communicating Results**

EPA must follow the procedures in the Agency’s Risk Characterization Handbook in interpreting and communicating screening level results for ambient air and water exposures to fenceline communities. Given the challenges associated with using TRI information, the Agency must explicitly evaluate and discuss uncertainty and variability, alternative analyses, choices made in selecting parameters and models,

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<sup>16</sup> Page 18

<sup>17</sup> Pages 19-20



and present the conclusions in a manner that transparently communicates the strengths and limitations of the analyses.

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ACC appreciates EPA’s consideration of our comments. As stated earlier, we also intend to provide supplementary detailed comments before the final March 22<sup>nd</sup> deadline established by EPA. Please contact me at 202-249-6415 or [Paul\\_DeLeo@americanchemistry.com](mailto:Paul_DeLeo@americanchemistry.com) if you have any questions.

Sincerely,

Paul C. DeLeo, PhD  
Senior Director, Regulatory and Scientific Affairs

