Comments of the American Chemistry Council

on the

1-Bromopropane (1-BP); Regulation under the Toxic Substances Control Act
89 Fed. Reg. 65066 (August 8, 2024); Docket EPA-HQ-OPPT-2020-0471

September 23, 2024

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Introduction

The American Chemistry Council (ACC) is pleased to submit these comments in response to the U.S. Environmental Protection Agency's (EPA's or the Agency's) proposed risk management rule for 1-Bromopropane (1-BP)[1] under the Toxic Substances Control Act (TSCA). ACC represents the business of chemistry in the United States. Our industry is at the forefront of creating the groundbreaking products that are improving the world all around us by making it healthier, safer, more sustainable, and more productive. ACC's membership manufactures, processes, and uses the 1-BP, a volatile organic compound (VOC) with a variety of industrial, commercial, and consumer uses.

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Executive Summary

ACC appreciates EPA's efforts in its ongoing implementation of the 2016 amendments to the Toxic Substances Control Act (TSCA) to evaluate, determine, and where present, reduce unreasonable risk from uses of chemicals so that the risk is acceptable. Where unreasonable risk is present for a specific condition of use, whether in workplaces or elsewhere, risk management measures should be carefully tailored to address the risk only to the extent necessary for that condition of use.

For occupational exposures, where the agency has information to suggest that exposures that present unreasonable risk can be well-managed as part of a Workplace Chemical Protection Program (WCPP) or performance standards, those requirements are appropriate to manage the risk. Where these measures are available, all public (federal agency) and private (non-government industry and commercial interest) stakeholders should have an equal opportunity to meet the standards set in any risk management rule. Any EPA requirements addressing workplaces should be well-informed by the discipline of industrial hygiene; aligned where possible with existing OSHA requirements; and favoring performance-based rather than prescriptive requirements, which reduce regulatory burden and allow for more flexible approaches to regulatory compliance.

[1] 1-Bromopropane (1-BP); Regulation Under the Toxic Substances Control Act (TSCA), 89 Fed. Reg. 65066 (August 8, 2024).

EPA's final rule here will not be an isolated exercise; under an amended TSCA, EPA will be proceeding with more and more risk management rules. EPA's proposals are seeking to enter the workplace, and each rule may impose another layer of regulation – in some cases, for the same workplace. It will be important for EPA to avoid regulatory redundancy and conflict in its regulations.

We support EPA's development of a consistent approach to setting *de minimis* levels in this and other risk management rules. OSHA GHS limits are generally appropriate as a default or starting approach, although in some cases, as here, a higher *de minimis* limit may be warranted by the specific characteristics of a chemical and exposure (use) patterns.

Discussion

1. EPA's Application of a Single Risk Determination (formerly "Whole Chemical Determination") to 1-BP is Not Consistent with TSCA Requirements.

Section 6(b) of TSCA requires the agency to evaluate risks of chemical substances "under the conditions of use." The term "conditions of use" (COUs) is defined by Section 3(4) as "the circumstances, as determined by the Administrator, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of." A risk evaluation necessarily must consider not just the potential hazard of a substance but exposure. Exposure necessarily differs based on conditions of use. The statute clearly contemplates that each condition of use is evaluated in the risk assessment and also that any subsequent regulation is applied to each condition of use. The best reading of the statute is that risk determinations must also be applied to each condition of use.

EPA, however, implemented a policy decision by press release on June 30, 2021 to make a single risk determination, not based on specific conditions of use, but for the "whole chemical":

> Under the previous administration, EPA made separate unreasonable risk determinations for every condition of use of a chemical. For the first 10 chemicals under TSCA and for any similar chemical that presents significant risks across many uses, EPA will continue to assess and analyze each condition of use, but then the agency plans to make the determination of unreasonable risk just once for the whole chemical when it is clear the majority of the conditions of use warrant one determination. EPA intends to withdraw the previously issued orders for those conditions of use for which no unreasonable risk was found for all the first 10 risk evaluations. The agency then intends to issue revised unreasonable risk determinations for these chemicals as a "whole substance" and seek public comment on this approach.[2]

Under this policy, EPA interprets TSCA to allow it to make a single determination of unreasonable risk, which has the effect of dragging COUs that do not need to be further regulated into a risk management rulemaking. This approach is deeply flawed, flies in the face of

[2] EPA press release, "EPA Announces Path Forward for TSCA Chemical Risk Evaluations" (June 30, 2021), https://www.epa.gov/newsreleases/epa-announces-path-forward-tsca-chemical-risk-evaluations.

common sense, and is the essence of regulatory overreach. We urge EPA to issue "does not present" unreasonable risk determinations for each applicable COU, by order, at the completion of the risk evaluation. For administrative convenience, EPA could issue a single order including all the COUs receiving does-not-present-unreasonable-risk determinations.

2. **When the Agency Elects to Evaluate Worker Exposures, It Should Do So While Evaluating All Conditions of Use, Including Legal Requirements Applicable to Workers and Standard Operating Practices.**

EPA completed its risk evaluation of 1-BP in August 2020. After the risk evaluation was completed, EPA reopened the risk determination section of the evaluation and reissued it, applying another new policy announced by the agency that it would conduct risk evaluations assuming that workers were in fact not wearing personal protective equipment provided by their employers. The agency's policy is to apply this "no PPE" assumption regardless of the specific facts in the administrative record related to the chemical under review. We urge EPA to reconsider this policy, and to ensure that it considers applicable legal requirements, such as OSHA requirements; patterns and practices of behavior; company requirements, including standard operating procedures and accepted industry best practices; industry guidance documents and manuals; training programs; certification programs; enforcement data; voluntary consensus standards; and conclusions of professional society (expert) bodies in industrial hygiene, such as by the American Industrial Hygiene Association (AIHA) and American Conference of Governmental Industrial Hygienists (ACGIH). This review must extend not just to how "the chemical" is already regulated in the workplace, but how the workplace itself is regulated. A particular worker might be handling dozens of different chemicals and processes at a facility under other security and process safety conditions, in which case it could be unreasonable to assume a worker would not wear PPE.

EPA's groundless assumption that PPE is not being worn is not a sufficient evidentiary basis in a particular TSCA risk evaluation on which to base subsequent regulatory action. Nor can EPA point to general data about PPE use to ground this assumption; general data about PPE use is not relevant to the specific conditions of use of the chemical under risk evaluation that the statute requires to be evaluated. We encourage EPA to discontinue applying its "no PPE" policy approach to TSCA risk evaluations.

3. **EPA Should Propose and Justify Appropriately Tailored Risk Management Measures Rather than Proposing Prohibitions.**

EPA's approach to risk management continues to default to proposed prohibitions. EPA proposes to ban multiple uses of 1-BP outright. EPA's rationale for the bans is that it is uncertain whether the sectors associated with these uses can comply with the proposed Worker Chemical Protection Program (WCPP), including the newly proposed direct dermal contact control requirements (DDCC). But EPA must justify its proposed regulatory action with substantial evidence in the administrative record. Assuming – without citing supporting evidence – that those COUs cannot meet the WCPP provisions does not meet that standard.

Congress left intact in the 2016 TSCA Amendments the substantial evidence standard of review. TSCA provides that a reviewing court "shall hold unlawful and set aside" a final rule promulgated under § 6(a) "if the court finds that the rule is not supported by substantial evidence in the rulemaking record ... taken as a whole." TSCA § 19(c)(1)(B)(i), 15 U.S.C. § 2618(c)(1)(B)(i). In a 1eading 1988 case,[3] the D.C. Circuit reviewed the 1976 TSCA legislative history on this provision and concluded that the TSCA standard supports "more searching" scrutiny than under the APA's "substantial evidence" and "arbitrary and capricious" standards:

> This case, therefore, does not turn on an interpretation of the term "substantial evidence" as it appears in the APA, but on an interpretation of the term "substantial evidence in the rulemaking record ... taken as a whole" as it appears in TSCA. Despite the similarity in wording, Congress apparently contemplated that the TSCA standard should be viewed as a distinct standard; otherwise there would have been no need to specifically rule out the APA review standard ….
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> Both the House and the Conference Report thus indicate that it was Congress' intent that review of test rules under section 4 of TSCA [and rules under other sections of TSCA] be more searching than the judicial review undertaken in most agency cases.

EPA's obligation, once making an unreasonable risk determination, is to remove the unreasonable risk, reducing the risk to reasonable or acceptable. EPA is to apply risk management measures only to the extent necessary to do this. "To the extent necessary" is commonly understood to mean that something should only be done to the level or degree that is necessary – and then stop.

EPA has not demonstrated in its proposed rule that bans are necessary. EPA should explain why other risk management options cannot adequately address the unreasonable risk and why a prohibition is necessary.

4. EPA Should Establish an Appropriate *De Minimis* Level for 1-BP.

We support establishment of an appropriate, science-based *de minimis* level for 1-BP. This helps account for impurities that do not contribute to unreasonable risk, and provides significant regulatory burden reduction to the regulated community. We agree that EPA should seek to establish *de minimis* levels as a matter of course in TSCA risk management rules, and here in the 1-BP rule. Generally speaking, there is significant value in at least aligning *de minimis* values with Occupational Safety and Health Administration (OSHA) Globally Harmonized System (GHS) for Classification and Labeling of Chemicals values. In some cases, however, a higher value may be appropriate.

A *de minimis* threshold for reporting purposes is a well-accepted basis for reporting on the presence of a chemical substance. OSHA's Hazard Communication Standard and GHS both use a *de minimis* threshold of 1%/.1% for non-carcinogenic and carcinogenic substances,

[3] *Chemical Manufacturers Ass'n v. US EPA*, 859 F.2d 977, 991-92 (D.C. Cir. 1988) (citations and footnotes omitted). *Accord*, *Vinyl Institute v. EPA*, No. 22-1089 (D.C. Cir., July 5, 2024), 2024 WL 3308356.

respectively. It is well understood that just because a chemical is present in a product at or above a threshold does not mean that it poses an unreasonable risk to health. The presence of a chemical at a *de minimis* level in a product or article can, for that product or article, indicate that the chemical in the product does not present unreasonable risk.

In general, EPA should seek to align *de minimis* thresholds at least with the OSHA Communication Standard. This provides significant reduction in regulatory burden to industry and significantly improves the ability to comply. A *de minimis* level in a TSCA risk management rule can also serve as a proxy whereby the presence of the chemical at or below that level would not be expected to present unreasonable risk based on typical exposure scenarios.
For any established *de minimis* level, we recommend that EPA consider applying this value to products, materials, formulations, and articles with consistency; to reporting and recordkeeping requirements; and to upstream manufacture, import, processing, distribution, recycling and circularity measures, disposal, and/or industrial/commercial/consumer uses.

We encourage EPA to adopt a consistent approach to establishing *de minimis* levels in TSCA risk management rules, and to specifically clarify that impurities or the presence of the chemical at or below the *de minimis* level does not constitute unreasonable risk for the product, article, formulation, or material in which it is present.

5. **For Industrial and Commercial Conditions of Use, EPA Should Apply a Consistent Approach to Workplace Protection.**

EPA is seeking to prohibit many industrial and commercial conditions of use for 1-BP. However, the industrial and commercial conditions of use that are not proposed for an exemption to a ban would be required to meet EPA's newly proposed Existing Chemical Exposure Limit (ECEL) as part of a WCPP to avoid worker exposures above the ECEL.

EPA has provided only a 45-day comment period for industries and businesses to learn of and assess the proposed ECEL, provide existing data or, if data does not currently exist, conduct monitoring, and provide sufficient information that EPA is satisfied that the ECEL and WCPP can be met. EPA seems to be taking the approach that it must have some unspecified, subjective, degree of certainty that a particular business or industry sector can meet the ECEL and the WCPP, but the demonstration that they "can" meet these requirements would be based on their current operations. In other words, companies would need to prove that they are already meeting a proposed ECEL – in which case, there is no justification for the unreasonable risk determination in the first place, and no justification for additional regulatory action.

EPA also does not appear to have a reasoned basis with respect to its differential approaches to the private sector and public sector. Assuming regulation is required to reduce unreasonable risk to reasonable, the same uses by the public and private sector should receive the same risk management measures. This is also important for the federal agencies themselves, since their supply chains will necessarily involve private sector parties who are not contractors directly to the agency. While ACC does not view a 6(g) exemption for worker exposures as necessary if EPA imposes an ECEL and WCPP, EPA's approach to 6(g) exemptions should be consistently applied to both public sector (government) and private sector entities.

6. For Workplace Occupational Safety Risk Management Measures, EPA Should Align its Approach to Chemical Risk Management with the Discipline of Industrial Hygiene.

EPA's approach to chemical risk management is inconsistent with the current practice of workplace occupational safety and industrial hygiene and therefore does not meet the TSCA scientific standard.[4] Instead of focusing only on a single chemical hazard, it is the role of a workplace safety professional to identify all hazards that exist in the workplace, determine the level of acceptable risk, and implement controls to prevent or mitigate risk from workplace hazards to acceptable levels. EPA's approach under TSCA and its subsequent requirements under an Exposure Control Plan (ECP) make the holistic work of evaluating hazards and implementing mitigations more difficult. Occupational health and safety, and industrial hygiene are fields in which professional judgment based on sound scientific data must be exercised. Each workplace is different, even those who are engaged in the same kind of business or owned by the same company.

EPA's risk management approach should align with current standard practice for occupational safety and industrial hygiene, as described further in these comments. This process often begins with evaluating the hazard against a risk matrix. A risk matrix evaluates the severity of the hazard against the likelihood of it occurring. A risk matrix helps the workplace safety professional assess all hazards in the workplace and properly prioritize time, capital, and labor hours to address the risk.

In the case of chemical exposures, the occupational exposure limit (OEL) provides a quantitative example of the difference between reasonable and unreasonable risk. Regardless, preventing, or mitigating, exposures to below the OEL must still fit in with the broader workplace safety program. Hazards associated with prevention or mitigation must be considered in line with hazards associated with chemical exposure. EPA's definition of feasible control must allow for this kind of flexibility.

EPA should consult with industrial hygiene and occupational safety practitioners to better integrate standard practices and best practices for industrial hygiene workplace safety programs into its chemical risk management.

7. The Proposed Existing Chemical Exposure Limit (ECEL) for 1-BP violates TSCA's Scientific Standards Provision [15 U.S.C 2625(h)].

EPA's proposed ECEL for 1-BP would be lower than current occupational exposure limits found throughout the world. The GESTIS[5] database of international limit values for chemical agents (i.e., occupational exposure limits)[6] currently lists 8-hour occupational limit values for 1-BP from 7 national authoritative bodies around the world and the province of Ontario, Canada. The current OELs for 1-BP fall between 0.1 ppm and 25 ppm. In addition, the ACGIH Threshold Limit Value for 1-BP is 0.1 ppm.

[4] *See* 15 U.S.C. 2625(h).
[5] GESTIS is the Information system on hazardous substances of the German Social Accident Insurance.
[6] Available at: https://limitvalue.ifa.dguv.de/

A. EPA should establish a clear and transparent process for development of occupational exposure limits (aka Existing Chemical Exposure Limits) to the extent they are necessary for risk management under TSCA.

One leading benchmark for development of occupational exposure limits is the recent recommendations in the National Academies of Science, Engineering and Medicine (NASEM) *Review of the Department of Defense's Revised Approach to Deriving an Occupational Exposure Level for Trichloroethylene (TCE).*[7] In that NASEM Review, DOD's process for deriving an occupational exposure level for TCE is summarized. The DOD approach is equally applicable to 1-BP as it is a data rich chemical with similar uses to TCE. Two critical features of the DOD approach are the weight of evidence review of available study data and the evidence integration to identify a toxic endpoint of concern.

Similarly, Deveau et al. (2015) present a framework for the identification and systematic evaluation of OELs, which can be used to support risk characterization and risk management decisions in situations where multiple potentially relevant OELs exist.[8]

While the process for developing this information in the context of a human health hazard characterization is similar to that for OEL derivation, it is not identical. For example, the subject population for an OEL, the worker population, is different than the general population that is the subject of the human health hazard characterization especially if the toxic endpoint of concern is not related to reproductive toxicity. The worker population is a differentially exposed population but it is not a susceptible population and worker populations are generally regarded to be healthier than the general population. The derivation of an occupational exposure limits necessitates a problem formulation independent of the human health hazard characterization for the general population.

B. EPA should use a weight of evidence approach to integrate data from various sources in deriving the ECEL for 1-BP.

DOD has developed a holistic framework for evaluating epidemiological, controlled *in vivo*, mechanistic/*in vitro*, and computational evidence that can be used in deriving OELs.[9] Likewise, Maurer et al. (2023) describe their approach for synthesis of the lines of evidence (LOE) from the available data and literature, which often include diverse and not readily comparable types of data similar to those found in the DOD approach.[10] Also, the Occupational Alliance for Risk Science uses systematic review of the available data and literature, formal evidence integration

[7] National Academies of Sciences, Engineering, and Medicine. 2019. Review of DOD's Approach to Deriving an Occupational Exposure Level for Trichloroethylene. Washington, DC: The National Academies Press. https://doi.org/10.17226/25610.

[8] M. Deveau, C-P Chen, G. Johanson, D. Krewski, A. Maier, K. J. Niven, S. Ripple, P. A. Schulte, J. Silk, J. H. Urbanus, D. M. Zalk & R. W. Niemeier (2015) The Global Landscape of Occupational Exposure Limits—Implementation of Harmonization Principles to Guide Limit Selection, Journal of Occupational and Environmental Hygiene, 12:sup1, S127-S144, DOI: 10.1080/15459624.2015.1060327.

[9] Lent EM, Sussan TE, Leach GJ, Johnson MS. Using Evidence Integration Techniques in the Development of Health-Based Occupational Exposure Levels. International Journal of Toxicology. 2021;40(2):178-195. doi:10.1177/1091581820970494.

[10] Maurer LL, Alexander MS, Bachman AN, Grimm FA, Lewis RJ, North CM, Wojcik NC and Goyak KO (2022) An interdisciplinary framework for derivation of occupational exposure limits. Front. Public Health 10:1038305. doi: 10.3389/fpubh.2022.1038305.

and an expert elicitation process to develop its Workplace Environmental Exposure Levels (WEELs®).[11]

There are several examples of current OEL development processes being applied throughout the U.S. that use common elements of systematic review and weight of evidence review of available data and formal evidence integration. While some of these elements were applied in the TSCA risk evaluations, EPA must formalize its approach and establish it for the specific purpose of ECEL development as a part of risk management under TSCA.

C. EPA should adopt existing Federal standards or national consensus standards as occupational exposure limits under TSCA where such that the subject chemical does not present an unreasonable risk under associated conditions of use.

In justifying its development of ECELs as occupational exposure limits for TSCA risk management rules, EPA regularly cites the statements associated with OSHA's Permissible Exposure Limits (PELs) webpage:

> OSHA recognizes that many of its permissible exposure limits (PELs) are outdated and inadequate for ensuring protection of worker health.[12]

EPA does not cite the remainder of OSHA's narrative regarding its PELs:

> Section 6(a) of the OSH Act granted the Agency the authority to adopt existing Federal standards or national consensus standards as enforceable OSHA standards. Most of the PELs contained in the Z-Tables of 29 CFR 1910.1000 were adopted from the Walsh-Healy Public Contracts Act as existing Federal standards for general industry. These in turn had been adopted from the 1968 Threshold Limit Values (TLVs®) of the American Conference of Governmental Industrial Hygienists (ACGIH®). Some consensus standards from the American Standards Association were also adopted at that time, following the 6(a) procedures. Comparable PELs were adopted for shipyards (29 CFR 1915.1000) and construction (29 CFR 1926.55).

As a matter of policy, EPA should adopt existing Federal standards or national consensus standards where meeting such a standard demonstrates that exposure to the subject chemical is controlled such that it does not present an unreasonable risk. Moreover, those regulated entities that can demonstrate they are meeting and can continue to meet such a standard should not be burdened with additional regulatory requirements that do not lead to additional public health benefits. This approach is also consistent with OMB Circular A-119, which among other things seeks to minimize reliance on government-unique standards when an existing standard would meet the Federal Government's objective.

D. No independent verification or peer review of the ECEL or the process to develop the ECEL was conducted.

EPA's quiet approach to ECEL development, lack of verification with outside experts, and general lack of public stakeholder engagement are disappointing. According to the rulemaking

[11] Available at: https://tera.org/OARS/poster.pdf).
[12] https://www.osha.gov/annotated-pels.

record, EPA developed its ECEL for 1-bromopropane in March of 2021.[13] The memo describing the ECEL was posted to the TSCA Section 6(a) Rulemaking Docket for 1-bromopropane (EPA-HQ-OPPT-2020-0471) on May 18, 2022, and the ECEL was publicly released for comment for the first time as part of the proposed risk management rule on August 8, 2024.

Once again, the NASEM Review of DOD's Revised Approach to Deriving an OEL for TCE represents a benchmark for peer review that probably exceeds what is needed for the EPA ECEL for 1-BP. However, the NASEM Review also provides a stark contrast to the EPA approach and highlights critical deficiencies in that approach.

EPA should conduct an independent peer review of its approach to derivation of OELs (aka ECELs). The individual ECELs should also be subject to peer review; however, that could occur with the peer review of the draft risk evaluation if the ECEL is ready at that time. As noted above, the ECEL derivation would be similar but not necessarily identical to the human health hazard characterization.

8. EPA Must Dramatically Improve Transparency Regarding Its Process for Establishing Proposed ECELs.

The Biden Administration has made a commitment to open government and regulatory transparency. Unfortunately, EPA has released the proposed ECELs by generating internal memorandums of limited detail to justify its conclusions and quietly placing them in the associated docket(s) a year or more later without notice or request for public comment. In the year since ECELs were posted to several dockets for the first ten chemicals for risk evaluation, EPA has *not sought* public dialogue with stakeholders, experts, or the regulated community.

EPA did address the Small Business Regulatory Enforcement Fairness Act (SBREFA) by holding a (closed) Small Business Advocacy Review Panel (SBAR Panel) between January and October 2021.[14] However, participation was limited, and the SBAR report was not made available until the proposed rule was released more than 18 months later.

The Fifth U.S. Open Government National Action Plan states:[15]

> Transparency is a cornerstone of open government and can be an important driver of more-equitable outcomes, innovation, and accountability. By making available information about the condition of society, the economy, and the environment, as well as government decisions, activities, data collections, and program outcomes, the public can hold the Federal Government accountable.

Public release of Federal Government research, information, and data can also enable greater evidence building, civic engagement, and public and private sector decision- making; accelerate private-sector breakthroughs for scientific innovations; and identify novel business opportunities.

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[13] U.S. Environmental Protection Agency, Office of Chemical Safety and Pollution Prevention. *Existing Chemical Exposure Limit (ECEL) for Occupational Use of 1-Bromopropane (1-BP)*. March 8, 2021. Available at: https://www.regulations.gov/document/EPA-HQ-OPPT-2020-0471-0031.

[14] https://www.epa.gov/reg-flex/sbar-panel-methylene-chloride-risk-management-rulemaking-under-toxic-substances-control.

[15] https://open.usa.gov/national-action-plan/5/.

More meaningful engagement of the public in the work of government results in better policy design and program administration — as policies more closely reflect and respond to the needs of individual communities — and also builds virtuous cycles of public trust and confidence in the Federal Government and in democratic institutions.

EPA has a detailed, transparent, and credible process for Developing Acute Exposure Guideline Levels (AEGLs). In addition, a recent final rule from OSHA amending its existing standards for occupational exposure to beryllium and beryllium compounds evolved from a Notice of Proposed Rulemaking in August 2015 to issuance of the final rule in January 2017 and included a two-day public hearing in between. Similarly, there is a very detailed and robust process for development of occupational exposure limits that involves the engagement of a variety of experts and stakeholders with a resulting level of confidence in the ultimate outcome.[16]

There are numerous other examples and approaches EPA could and should use to inform the public and regulated industry of its proposed ECELs, and to solicit public feedback regarding the technical aspects of their derivation, and the benefits and cost associated with their implementation.

9. Conditions of Use and Entities That Can Meet the WCPP and ECEL Should Not Be Further Regulated.

EPA requested comments regarding replacing the proposed prohibitions with compliance with the WCPP in instances where regulated entities are able to consistently demonstrate compliance with an ECEL through effective controls. EPA has stated that exposures at or below each ECEL would not result in unreasonable risk for chronic cancer and non-cancer and acute non-cancer inhalation endpoints. As such, any entity that can meet the WCPP and ECEL should not be subject to prohibition.

For industrial processing of a chemical intermediate where the chemical is largely confined to a process reactor, and which requires infrequent tasks (such as loading, unloading, and maintenance of the equipment), management of such infrequent tasks (and exposures) should occur independently of an 8-hour health based occupational exposure limit that may have been developed based entirely different exposure conditions. These should be managed independently of a chronic OEL (or using an OEL based on the same exposure duration assumptions as relevant to the exposure scenario such as an acute daily limit), as appropriate, while maintaining suitable worker protections. A full suite of occupational safety systems and practices should be applied with exposure controls that may deviate from a specified health based OEL if the basis for its establishment is highly disparate from the conditions where it is being applied.

10. EPA Should Provide Additional Clarity and Guidance Regarding Compliance with an ECEL as Part of a WCPP.

With respect to the ECEL, the rule proposes that "the owner or operator must ensure that no person is exposed to an airborne concentration of 1-bromopropane in excess of 0.05 parts of 1-bromopropane per million parts of air (0.05 ppm) as an eight (8)-hour TWA…", and "*ECEL action level* means a concentration of airborne 1- bromopropane of 0.03 parts per million (ppm)

calculated as an eight (8)-hour time-weighted average (TWA)."[16]

A. Compliance with the ECEL should be based on at least six personal breathing zone monitoring samples.

For the purposes of compliance, EPA should clarify when exceedance of the ECEL represents non-compliance. ACC recommends that compliance (or lack thereof) be based on at least six personal breathing zone monitoring samples based on guidance from AIHA.[17] The AIHA guidance notes that there is a point of diminishing return in collecting more than six to ten monitoring measurements based on statistical sampling theory. Given the repetitive nature of tasks associated with exposure scenarios at many manufacturing, processing, and industrial use facilities, a "rolling average" could be calculated based on the prior six measurements. In addition, ACC recommends that the Assigned Protection Factors (APF) for PPE be used where appropriate when determining compliance against the ECEL.

B. EPA should describe how the ECEL may be adjusted for shifts greater than 8 hours.

EPA's New Chemicals Exposure Limits Section 5(e) Order Boilerplate Insert Under the Toxic Substances Control Act (TSCA) New Chemicals Program[18] uses the Brief and Scala approach[19] and stipulates "for non-8-hour work-shifts, the NCEL for that work-shift (NCELn) must be determined by the following equation: NCELn = NCEL x (8/n) x [(24-n)/16], where n = the number of hours in the actual work-shift." Additionally, there are toxicokinetic models for adjusting the OEL such as the maximum adjustment half-life (MAHL) model.[20,21] AIHA offers a free spreadsheet-based tool for Toxicokinetic Extended Shift OEL Adjustment.[22] Another option would be to adjust the IH monitoring result for shifts greater than 8 hours (e.g., 12 hour shifts) to an 8-hour TWA. ACC recommends that EPA use an approach similar to those described above for application of an ECEL to shifts of greater than 8 hours.

C. EPA should acknowledge the current industrial hygiene practice for establishing similar exposure groups (SEGs) in determining representativeness of compliance with the ECEL.

To comply with the ECEL,

> each owner or operator would be required to determine each potentially exposed person's exposure by either taking a personal breathing zone air sample of each potentially exposed person or taking personal breathing zone air samples that are

[16] 88 Fed. Reg. 65115.
[17] Jahn SD, Bullock WH, Ignacio JS, et al. (2015) A Strategy for Assessing and Managing Occupational Exposures. 4th Edition. Washington, DC: AIHA.
[18] Available at: https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/new-chemicals-exposure-limits
[19] Brief, R.S., and R.A. Scala: Occupational exposure limits for novel work schedules. *Am. Ind. Hyg. Assoc. J.* 36:467–469 (1975).
[20] Verma, D.K. 2000. Adjustment of Occupational Exposure Limits for Unusual Work Schedules, Journal of the American Industrial Hygiene Association, 61:3, 367-374, DOI: 10.1080/15298660008984545.
[21] Armstrong, T., D.J. Caldwell, D.K. Verma. 2005. Occupational Exposure Limits: An Approach and Calculation Aid for Extended Work Schedule Adjustments. J. Occupational and Environmental Hygiene, 2: 600–607.
[22] Available at: https://www.aiha.org/public-resources/consumer-resources/apps-and-tools-resource-center/aiha-risk-assessment-tools/toxico-kinetic-extended-shift-oel-adjustment.

> representative of each potentially exposed person's exposure performing the same or substantially similar operations in each work shift, in each job classification, and in each work area (hereinafter identified as an "exposure group").[23]

According to the proposed rule,

> Exposure group means a group consisting of every person performing the same or substantially similar operations in each work shift, in each job classification, in each work area where exposure to chemical substances or mixtures is reasonably likely to occur.[24]

Standard industrial hygiene practice includes the use of a Similar Exposure Group (SEG) in exposure monitoring campaigns. A SEG is *a group of workers having the same general exposure profile for an agent because of the similarity and frequency of the tasks they perform, of the similarity of the materials and processes with which they work, and similarity of the way that they perform the tasks.*[25] EPA should confirm that its definition of an exposure in the proposed rule group aligns with the current standard approach for establishing SEGs.

In addition, EPA should clarify when data from one facility may be representative of other facilities where similar tasks are performed whether the other facilities are or are not under the control of the owner/operator of the facility where the data were collected.

11. EPA Should Further Clarify and Refine Monitoring Requirements for Compliance with the ECEL.

EPA requested comment regarding the feasibility of entities complying with and monitoring for a potential ECEL of 0.05 ppm. EPA aims to obtain more information on potential costs that could be incurred using strategies to meet the requirements of such a standard, such as engineering, administrative, or prescriptive controls and how feasible it would be for entities to implement these strategies in their operations. (VIII.45).[26]

A. Sufficient capacity needs to be available for compliance with the ECEL.

It may not be feasible to comply with requirements to conduct initial monitoring within 6 months after the rule is final due to a lack of laboratory capacity. A large number of entities will be required to comply with a new exposure limit that necessitates a new, lower detection limit. This will stress the industrial hygiene consultants who collect such samples and the laboratories that analyze the samples. EPA should confirm that there is sufficient capacity for companies to comply with the proposed requirements. If there currently is not sufficient capacity among firms that would support those regulated entities who need to satisfy the requirements of the proposed rule, EPA must ensure there is adequate time for such capacity to be established as part of the timeline for compliance with the rule.

B. The Periodic Monitoring Requirements proposed are appropriate except for the

[23] 88 Fed. Reg. 39673.
[24] *Ibid.* at 39716.
[25] Jahn SD, Bullock WH, Ignacio JS, et al. (2015) A Strategy for Assessing and Managing Occupational Exposures. 4th Edition. Washington, DC: AIHA, p. 37.
[26] 89 Fed. Reg. 65110.

recurrent 5-year initial monitoring.

EPA requested comment on the timeframes for periodic monitoring outlined in Table 1 of the proposed regulation.[27] EPA proposes periodic exposure monitoring is required at least once every five years when all initial exposure monitoring is below the ECEL action level (0.03 ppm).[28] This requirement for initial monitoring every five years is unnecessary and overly burdensome for firms that have demonstrated compliance and whose processes have not changed in five years or more. It deviates from the monitoring frequencies in the OSHA Substance Specific Regulated Chemicals Standards. A lack of alignment between regulatory programs can create confusion for regulated entities resulting in possible compliance gaps. Additional monitoring should be based on local risk assessment reviews and *management of change* practices that seek to understand where changes have occurred so monitoring can be conducted to quantify changes in exposure risk. The other Periodic Monitoring Requirements proposed are appropriate as the three month/six month strategy aligns with other OSHA practices with which regulated entities will be familiar.

C. EPA should clarify monitoring requirements for infrequent tasks.

The proposed rule is silent regarding monitoring and compliance for infrequent tasks, (i.e., where workers are potentially exposed to 1-bromopropane for fewer than 30 days per year). The proposed rule appears to be focused primarily on potential exposures that occur on a daily basis and for a significant portion of the working day. EPA should clarify requirements for monitoring and compliance for potential exposures whose frequency and duration vary from an "all day, every day" scenario.

12. ACC Agrees with EPA That the Analysis of Exposure Samples Can Be Assured through Several Credible Programs.

ACC agrees with EPA's proposal regarding the analysis of exposure samples:

> Exposure samples must be analyzed using an appropriate analytical method by a laboratory that complies with the Good Laboratory Practice Standards in 40 CFR part 792 or a laboratory accredited by the American Industrial Hygiene Association (AIHA) or another industry-recognized program.[29]

13. EPA Should Use a 15-day Notification Timeframe for Results of Workplace Monitoring.

ACC agrees with the proposed requirement that the owner or operator must inform persons whose exposures are represented by the monitoring results within 15 working days.[30]

[27] *Ibid.* at 65108, VIII.12.
[28] *Ibid.* at 65117, Table 1.
[29] Proposed 40 CFR 751.807(b)(2)(C).
[30] 89 Fed. Reg. 65117.

14. Attestations That Engineering Controls Do Not Increase Emissions of 1-BP to Ambient Air Outside, and Air Monitoring, Are Unnecessary.

EPA requested comment on whether owners and operators should be required to attest to whether and why the exposure controls they have selected would not result in increased releases of 1–BP to ambient air from the workplace (VIII.42)[31] and how these proposed requirements may impact the availability, feasibility, or cost of engineering controls as a means to reduce workplace exposures to or below the proposed ECEL (VIII.16).[32]

EPA proposes:

> Attestation that exposure controls selected do not increase emissions of 1-bromopropane to ambient air outside of the workplace and whether additional equipment was installed to capture or otherwise prevent increased emissions of 1-bromopropane to ambient air.[33]

This attestation would be a component of the Exposure Control Plan.

The proposed rule states:

> in the instances where efforts to reduce exposures in the workplace to levels below the ECEL could lead to adoption of engineering controls that that may result in more 1–BP being ventilated outside, EPA believes this potential additional exposure would be limited as a result of anticipated revisions to NESHAP requirements following the designation of 1–BP as a HAP under the CAA.
>
> EPA expects that this proposed action, in combination with the emissions standards resulting from anticipated revisions to NESHAP requirements following the designation of 1–BP as a HAP, would reduce risk sufficiently to the general population and fenceline communities. EPA does not intend at this time to revisit the air pathway for 1–BP as part of a supplemental risk evaluation.[34]

ACC agrees with EPA's rationale that any emissions of a HAP under the CAA would be controlled by virtue of associated NESHAPs. Consequently, the proposed attestation should be eliminated.

15. EPA Should Foster Flexibility in Exposure Control Consistent with the Practice of Industrial Hygiene.

EPA requested comment on providing an option of either complying with the ECEL or implementing various administrative and engineering controls, such as those uses employed in a closed-loop system (VIII. 33). ACC recommends that EPA allow flexibility in permissible

[31] *Ibid.* at 65110.
[32] *Ibid.* at 65109.
[33] Proposed 40 CFR 751.807(c)(2)(i)(F); 89 Fed. Reg. 65118.
[34] 89 Fed. Reg. 65103.

exposure controls to eliminate unreasonable risks to chemicals. Given the great variety of workplace scenarios, industrial hygiene practitioners need flexibility in order to characterize potential hazards at each specific site and develop effective exposure control programs. ACC encourages EPA to adopt an approach where regulated entities have the option to comply with an occupational exposure limit, or apply various administrative and engineering controls with known effectiveness in mitigating exposures are options of any regulation.

16. EPA Should Apply Existing Occupational Safety Performance Standards In Its Risk Management Rules Rather Than Prescribing Every Specific Element.

EPA requested comment for a number of specific required elements of a WCPP or Prescriptive Controls:

- EPA is soliciting comment on requiring warning signs to demarcate regulated areas, such as the requirements found in OSHA's General Industry Standard for Beryllium (VIII.17).
- EPA is requesting comment on whether there should be a requirement to replace cartridges or canisters after a certain number of hours, such as the requirements found in OSHA's General Industry Standard for 1,3-Butadiene, or a requirement for a minimum service life of non-powered air-purifying respirators such as the requirements found in OSHA's General Industry Standard for Benzene (VIII.18).
- EPA is soliciting comments on the requirements proposed for appropriate PPE selection. In addition, EPA understands that some workplaces rinse and reuse PPE after minimal use and is therefore soliciting comments on the impact on effectiveness of rinsing and reusing certain types of PPE, either gloves or protective clothing and gear. EPA also requests comment on the degree to which additional guidance related to use of PPE might be appropriate (VIII.22).
- EPA is soliciting comment on prescribing specific engineering or administrative controls that would reduce inhalation exposures enough to address the unreasonable risk across all workplaces engaged in a condition of use (VIII.26).

EPA notes that some of these requirements might be similar to prescriptive requirements in existing OSHA Standards for Toxic and Hazardous Substances (29 CFR 1910 Subpart Z). However, the more general OSHA standards for things like Occupational Health and Environmental Control (29 CFR 1910 Subpart G), Personal Protective Equipment (29 CFR 1910 Subpart I) and General Environmental Controls (29 CFR 1910 Subpart J) are more appropriate references that should be used. In the case of respirator cartridge replacement, the cartridge technology may change over time which would lead to a rigid rule prescribing a replacement schedule that has become obsolete. The Subpart I provisions for Personal Protective Equipment, specifically 29 CFR 1910.134 – Respiratory Protection, specify the requirements for a Respiratory Protection Program that would adapt over time to new technology and situations. EPA should defer to, and incorporate as necessary, existing performance based programs for exposure reduction rather than enumerating specific elements in its regulations.

17. EPA's Economic Analysis is Flawed.

As considered against standards found in OMB Circular A-4 and certain executive orders, EPA's

economic analysis is deficient in the following ways:

- The need for the regulation is mischaracterized.
- Cost is underestimated.
- The methodology for microrisk reductions in cancer incidence should be subject to external, independent peer review.
- The analysis of regulatory alternatives is incomplete.
- The alternatives analysis is notable for its omissions.
- The sensitivity analysis is insufficient.

The need for the regulation is mischaracterized.
EO 12866 says a regulation is necessary if it is "required by statute, necessary to interpret a statute, or made necessary by a compelling public need, such as a failure of private markets . . ." In the case of 1-BP, the proposed rule is required by statute because the agency has made a determination of unreasonable risk under TSCA. However, in Chapter 2, the Agency describes the underlying problem as one of a market failure, describing the negative externality without linking this characterization to data or evidence about the harm imposed from environmentally relevant levels of exposure to people external to market participants. Instead, the Agency offers platitudes drawn from economic textbooks.

We note that the *possibility* of a market failure is not the same as an *actual* market failure—as Circular A-4 makes clear. Absent from the economic analysis is any acknowledgement that the market for 1-BP is a competitive market, with many buyers and many sellers. An abundance of health and safety information on this well-characterized substance is publicly available. In addition, the substance is regulated at the local, state, and federal level to ensure it is managed responsibly.

We recommend that the Agency acknowledge (1) that the market for 1-BP is robust, (2) that the proposed rule is required by statute, and (3) either remove the statement about a negative externality or present evidence suggesting that there exists a negative externality impacting non-market participants. Simply raising the possibility of a market failure does not comport with Circular A-4:

> Ideally, to the extent feasible, you should quantify the extent of any relevant market failure . . . with the resulting estimates integrated into your regulatory analysis.

We should also point out that EPA's determination of unreasonable risk is insufficient to characterize the substance as presenting a negative externality. The Agency's determination of unreasonable risk is based on conservative assumptions (e.g., linear low-dose extrapolation) and therefore does not reflect expected risk, which should be the focus of the benefits component of the economic analysis.

Cost is underestimated.
The economic analysis underestimates the cost of the proposed rule. There are three reasons. The first is that the economic analysis fails to qualify and quantify the loss in consumer and producer

surplus. As Circular A-4 states:

> The opportunity cost of an alternative includes the value of the benefits forgone as a result of choosing that alternative. For instance, the opportunity cost of banning a product . . . is the forgone net benefit (including lost consumer and producer surplus) of that product, taking into account the mitigating effects of potential substitutes . . . You should include these effects in your analysis and provide estimates of their monetary values . .

The Agency must acknowledge the expected loss of producer and consumer surplus—a certainty for any regulation that restricts production/use of a commercial product—and estimate it or explain why it cannot be estimated. The loss in producer and consumer surplus will exceed the cost of compliance—which is focal point of the Agency's economic analysis.

The second reason is that the proposed ECEL is impractical to attain. As noted in the executive summary:

> The ECEL may not be possible to meet with engineering and administrative controls alone and wearing the supplied air respirators that would be necessary to comply may not be practical. For users facing this scenario, the WCPP requirements would have the same effect as a prohibition. If this is the case for just 7% of vapor degreasers, the Option 1 net benefits would be net negative under all scenarios . . . .

According to the executive summary:

> The most notable unquantified and/or uncertain costs are those associated with vapor degreasing requirements . . . if WCPP compliance is not practical the cost of switching to alternative cleaning methods is much higher and has the potential for economically important downstream impacts on other industries that rely on the parts cleaned using vapor degreasing (including aerospace, medical devices, and other manufacturing industries).

The third reason is that the cost of replacing a process employing 1-BP (as a reactant, incorporation into articles, or to make building insulation) with another process was not considered "due to the complexity of the analysis," according to Table 5-2. The Agency notes that switching processes is "not required or expected under the proposed option or primary alternative"—but makes no mention of the second alternative. We are wary of Agency expectations that drop-in substitutes are often available for a chemical used in a manufacturing process; our experience suggests process changes are to be expected.

The methodology for microrisk reductions should be subject to peer review.
According to the economic analysis, "excess cancer risk estimates used in this analysis are the same as used in EPA's 2016 and 2017 proposed TCE rules." No explanation is provided. The Agency should provide the explanation.

The economic analysis uses the concept of a "microrisk" to value avoided cancer incidence. The procedure was developed for application to EPA TSCA risk management rules and was developed by Abt Associates (*Estimated Values of Avoiding Cancer Risks by Cancer Site and Population*, 2023) and funded by EPA. It is not clear to us if the methodology was subject to external peer review. It should be because of its import and in keeping with guidance found in the OMB peer review bulletin. We recommend that EPA subject this methodology to the most rigorous peer review recommended in the OMB bulletin (for "highly influential scientific assessments").

In our view, the timing of avoided cancer risk reduction benefits is uncertain and the Agency should have also monetized health benefits when they are expected to be observed (as recommended in the previous version of OMB Circular A-4), taking into account the latency period and/or the cessation lag.

The analysis of regulatory alternatives is incomplete.
Circular A-4 calls for the analysis of a manageable number of reasonable regulatory alternatives—at least three (one more and less stringent than the preferred alternative). It also offers:

> If a regulation includes a number of distinct provisions, you should analyze the benefits and costs of alternatives to key individual provisions separately, when feasible and appropriate.

For this proposed rule, the economic analysis identifies three regulatory alternatives, the proposal, one that is more stringent, and one that is, presumably, less stringent (primary alternative).

We are struck by the small difference in cost between the proposal and the primary alternative, suggesting a different construction for the primary alternative—one with a less-stringent ECEL for the WCPP. Such an alternative would more closely adhere to Circular A-4.

The alternatives analysis should focus on substitution risk.
In its economic analysis, the Agency solely focused on determining the availability of alternative products at a similar price. Such an exercise is hardly sufficient. For all TSCA risk management rules, the Agency should acknowledge when it chooses not to conduct an analysis of substitution risk and instead chooses to conduct a less rigorous examination (e.g., of the hazards of chemical alternatives, absent exposure considerations). Without an analysis of substitution risk, the agency cannot be sure its regulation does more good than harm. EPA's economic analysis does not estimate the risk of substitutes, even when the available substitutes themselves may be subject to future rulemaking under TSCA as a result of a risk analysis the Agency is obligated to undertake.

The Sensitivity Analysis is insufficient.
The economic analysis includes a sensitivity analysis to reflect the full range of the exposed population. In our view, other factors, mentioned previously, should be included in the sensitivity analysis: (1) higher costs associated with open-top vapor degreasing and (2) lower monetized benefits associated with the reduction in cancer incidence based on the time of design.

18. EPA's Alternatives Assessment is Flawed.

A properly conducted alternatives assessment should include comparative hazard assessment and comparative exposure assessment, but also includes lifecycle analysis and other key factors, such as equivalent or better performance of a product, cost, supply chain availability, and other factors. EPA's assessments continue to focus largely on hazard assessment and are not fully considering the range of alternatives assessment factors set out in the National Academies' A Framework to Guide Selection of Chemical Alternatives. Further, both EPA's economics analysis and alternatives assessment fail to fully evaluate the potential for supply chain shocks and unavailability of both 1-BP and assessed alternatives. Where alternatives are or are likely to be regulated under other TSCA risk management rules, the lack of availability/market shortages should also be factored into these analyses.

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Thank you for the opportunity to comment. Please direct any questions to Karyn Schmidt, Senior Director, Regulatory & Scientific Affairs, Karyn_Schmidt@americanchemistry.com.

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