

July 29, 2022

Kelly Summers  
Office of Pollution Prevention and Toxics (7404T)  
Environmental Protection Agency  
1200 Pennsylvania Ave. NW  
Washington, DC 20460-0001

Re: EPA-HQ-OPPT-2016-0732

Dear Ms. Summers:

These comments are submitted on behalf of our client the Halogenated Solvents Industry Alliance, Inc. (“HSIA”). HSIA represents producers and users of halogenated solvents, including perchloroethylene (“PCE”). We appreciate the opportunity to provide these comments in response to the recent Environmental Protection Agency (“EPA”) notice requesting public comment on EPA’s draft revision to the risk determination for PCE issued under Section 6(b) of the Toxic Substances Control Act (“TSCA”). 87 Fed. Reg. 39085 (June 30, 2022).

In the PCE notice, EPA announced that it intends to implement two changes to the approach taken in its original December 2020 risk evaluation for PCE: (i) EPA stated it would make a revised risk determination of unreasonable risk for PCE as a whole chemical, instead of making risk determinations for each of PCE’s conditions of use; and (ii) EPA stated it would no longer assume that all workers wear personal protective equipment (“PPE”) when conducting risk evaluations.

HSIA has significant concerns regarding EPA’s draft revision to the risk determination for PCE. As discussed below, EPA’s proposed whole chemical approach and EPA’s decision no longer to assume the use of PPE are inconsistent with the requirements of TSCA and EPA’s implementing regulations, are not within the scope of EPA’s discretion, and fail to provide the public with an accurate picture of the risks presented by a chemical substance under the substance’s actual conditions of use. HSIA urges EPA to withdraw its proposed revision to the PCE risk determination, to continue to make condition-of-use specific risk determinations for PCE and other chemical substances, and to continue to include reasonable assumptions regarding the use of PPE

for each such condition of use. Such an approach is grounded in the statute and regulations, and is supported by sound science.<sup>1</sup>

I. EPA's Whole Chemical Approach is Inconsistent With TSCA and EPA's Risk Evaluation Regulations

TSCA § 6(b)(4) requires EPA to conduct risk evaluations to determine if a chemical substance presents an unreasonable risk of injury to human health or the environment under that chemical substance's conditions of use. *See* 15 U.S.C. § 2605(b)(4)(A) (“The Administrator shall conduct risk evaluations . . . to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment . . . under the conditions of use.”). Although TSCA itself sets forth basic requirements for the scope and conduct of risk evaluations, the statute directs EPA to promulgate regulations establishing the process for conducting risk evaluations and directs that risk evaluations be conducted and published “in accordance with” those regulations. 15 U.S.C. § 2605(b)(4)(B)-(C).

In 2017, EPA promulgated a final rule establishing the process for conducting risk evaluations. Procedures for Chemical Risk Evaluations Under the Amended Toxic Substances Control Act, 82 Fed. Reg. 33726 (July 20, 2017) (codified at 40 C.F.R. part 702, subpart B) (“Risk Evaluation Rule”). The Risk Evaluation Rule specifies that:

As part of the risk evaluation, EPA will determine whether the chemical substance presents an unreasonable risk of injury to health or the environment *under each condition of uses* [sic] within the scope of the risk evaluation, either in a single decision document or in multiple decision documents.

40 C.F.R. § 702.47 (emphasis added). Accordingly, the plain language of the Risk Evaluation Rule requires EPA to make individual risk determinations for *each condition of use* evaluated for a given chemical substance.<sup>2</sup> And until recently, EPA consistently applied the rule in accordance with that plain meaning.

From June 2020 to January 2021, EPA published risk evaluations for the first ten high-priority chemical substances to undergo risk evaluations under the amended TSCA.<sup>3</sup> Consistent

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<sup>1</sup> We note also that EPA is conducting screening level assessments for fenceline impacts. The notice states that these assessments are ongoing, and that if the results suggest there is additional risk, EPA will determine if the risk management approaches contemplated for PCE will protect against the risks or if the risk evaluation will need to be formally supplemented or revised. To be consistent with the requirements of TSCA and EPA's implementing regulations, EPA will need to reopen the PCE Risk Evaluation if the screening level assessment would have an impact on the risk management rule.

<sup>2</sup> TSCA § 3(4) defines “conditions of use” 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.” 15 U.S.C. § 2602(4).

<sup>3</sup> In 2016, as directed by TSCA § 6(b)(2)(A), EPA chose the first ten “high risk” chemical substances to undergo risk evaluations under the amended TSCA. Those chemical substances are asbestos, 1-bromopropane, carbon tetrachloride,

with the Risk Evaluation Rule, the risk evaluations included individual risk determinations for *each condition of use* evaluated. For conditions of use that EPA determined did not present an unreasonable risk, EPA issued an order reflecting that determination under TSCA § 6(i)(1). For conditions of use that EPA determined do present an unreasonable risk, EPA must adopt restrictions necessary to eliminate the unreasonable risk, pursuant to EPA's risk management rules. *See* 40 C.F.R. § 702.49.

For example, in the PCE Risk Evaluation, published in December 2020, EPA evaluated *each condition of use* identified within the scope of the risk evaluation and determined that PCE presents an unreasonable risk under some, but not all, of those conditions of use.<sup>4</sup> Specifically, EPA determined that PCE does not present an unreasonable risk under two conditions of use: (1) distribution in commerce; and (2) industrial and commercial use in lubricants and greases as solvent for penetrating lubricants and cutting tool coolants.<sup>5</sup> EPA issued an order reflecting its no unreasonable risk determination for those uses under TSCA Section 6(i)(1). 85 Fed. Reg. 82474 (Dec. 18, 2020). This condition-of-use specific approach to determining unreasonable risk is consistent with the Risk Evaluation Rule and provides the public with a clear picture of EPA's decision-making regarding the risks presented and not presented for each chemical substance under the substance's actual conditions of use.

EPA now proposes to jettison its condition-of-use-specific approach in favor of a "whole chemical" approach. In the PCE notice, EPA proposes to withdraw the TSCA § 6(i)(1) order reflecting EPA's no unreasonable risk determination for PCE, not because EPA has determined that the technical or scientific data underlying the risk characterizations have changed, or that PCE presents an unreasonable risk under all conditions of use, but because EPA wrongly asserts that it is authorized to issue a single unreasonable risk finding for PCE under a whole chemical approach. As discussed below, EPA's whole chemical approach is plainly inconsistent with both TSCA and its own Risk Evaluation Rule.

a. EPA's Whole Chemical Approach is Inconsistent with TSCA

The whole chemical approach is inconsistent with the process established under TSCA, as amended, for prioritizing, evaluating, and managing the risks of existing chemical substances. Specifically, TSCA § 6 contemplates the potential for two types of risk determinations at the conclusion of the risk evaluation process. First, when EPA determines a chemical substance does not present an unreasonable risk under its conditions of use, § 6(i)(1) requires EPA to issue a no unreasonable risk order that is considered final agency action. Second, when EPA determines that a chemical substance presents an unreasonable risk under its conditions of use, § 6(b)(4)(A) provides that the EPA's final risk management rule is considered final agency action. A single whole chemical unreasonable risk determination, when there are conditions of use that EPA has

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C.I. Pigment Violet (PV 29), cyclic aliphatic bromide cluster (HBCD), 1,4-dioxane, methylene chloride, n-methylpyrrolidone (NMP), perchloroethylene (PCE), and trichloroethylene (TCE).

<sup>4</sup> *See* EPA Risk Evaluation for Perchloroethylene (Ethene, 1,1,2,2-Tetrachloro-) (Dec. 2020) ("PCE Risk Evaluation") at 42, available at <https://www.regulations.gov/document/EPA-HQ-OPPT-2016-0732-0113>.

<sup>5</sup> *Id.*

determined do not present an unreasonable risk, ignores the possibility of “no unreasonable risk” determinations for a chemical substance under its conditions of use pursuant to § 6(i)(1).

Furthermore, it is unlikely under a whole chemical approach that EPA would ever issue a determination of no unreasonable risk for any chemical substance. That is because substances undergoing a risk evaluation are drawn from pools of substances for which available information already indicates a potential risk, making it highly likely that EPA’s risk evaluation will identify an unreasonable risk under at least one condition of use.<sup>6</sup> Accordingly, the statute’s provisions providing for a potential finding of no unreasonable risk are evidence that Congress did not intend that there would always be a determination of unreasonable risk for every substance being evaluated, and that Congress must have intended for specific conditions of use to be evaluated by EPA and for risk determinations to be made for each of those uses. *See* 15 U.S.C. § 2605(b)(1)(B)(i).

The whole chemical approach is also inconsistent with TSCA because it renders TSCA’s preemption provision for findings of no unreasonable risk superfluous.<sup>7</sup> TSCA Section 18(a) preempts state and local actions to regulate the manufacture, processing, distribution, or use of a chemical substance where EPA has made a no unreasonable risk determination. 15 U.S.C. § 2617(a). The scope of federal preemption extends to “the hazards, exposures, risk, and uses or conditions of use of such chemical substances included in any final action the Administrator takes pursuant to section 6(a) or 6(i)(1),” which final actions include risk management rules (under Section 6(a)) and no unreasonable risk orders (under Section 6(i)(1)). 15 U.S.C. § 2617(a)(1)(A)-(B). Yet, under the whole chemical approach, EPA would withdraw its TSCA § 6(i)(1) order for PCE, and, as discussed above, it is highly unlikely that EPA would ever issue another no unreasonable risk determination in future chemical substance risk evaluations. Thus, the whole chemical approach would effectively write out of TSCA any opportunity for preemption based on specific conditions of use that do not present an unreasonable risk. Therefore, because the whole chemical approach renders a portion of TSCA’s preemption provision superfluous, it is plainly inconsistent with TSCA, and should be rejected.<sup>8</sup>

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<sup>6</sup> Congress limited the pool of chemicals for which the first 10 risk evaluations could be conducted to substances already included in the 2014 update of the TSCA Work Plan for Chemical Assessments, which included chemicals previously selected based on their hazard and potential exposure, as well as other considerations. *See* 15 U.S.C. § 2605(b)(2)(A).

<sup>7</sup> It is a well-established maxim of statutory construction that courts will not adopt interpretations that render a statutory provision superfluous. *Davis Cnty. Solid Waste Mgmt. v. EPA*, 101 F.3d 1395, 1404 (D.C. Cir. 1996); *see also Marx v. General Revenue Corp.*, 568 U.S. 371, 386 (2013) (“[T]he canon against surplusage is strongest when an interpretation would render superfluous another part of the same statutory scheme.”).

<sup>8</sup> TSCA also provides for preemption for EPA’s final risk management rules. Those rules apply only if “manufacture, processing, distribution in commerce, use, or disposal, of a chemical substances or mixture, or [] any combination of such activities, *presents an unreasonable risk* . . . .” 15 U.S.C. § 2605(a) (emphasis added). Conditions of use that do not present an unreasonable risk are not subject to final risk management rules. *See e.g.*, 82 Fed. Reg. at 33744 (“Any [risk management] rule would apply only to the condition(s) of use that present an unreasonable risk, and those that do not present an unreasonable risk will not be subject to risk management.”). Thus, under the whole chemical approach, there would also be no opportunity for preemption based on conditions of use that do not present an unreasonable risk under EPA’s risk management rules.

b. EPA's Whole Chemical Approach is Inconsistent with EPA's Risk Evaluation Rule

Most significantly, the whole chemical approach is inconsistent with EPA's own regulations. As discussed above, 40 C.F.R. § 702.47 provides that "[a]s part of the risk evaluation, EPA will determine whether the chemical substance presents an unreasonable risk of injury to health or the environment *under each condition of uses* [sic] within the scope of the risk evaluation, either in a single decision document or in multiple decision documents." 40 C.F.R. § 702.47 (emphasis added). The language of the regulation unambiguously requires risk determinations for "each condition of use." *Id.* Indeed, if § 702.47 did not envision condition-of-use specific risk determinations then there would be no possibility of issuing "multiple decision documents" for one or more conditions of use. *Id.*

The preamble to EPA's Risk Evaluation Rule confirms that EPA must make risk determinations for each condition of use. There, EPA stated that:

The final step of a risk evaluation is for EPA to determine whether the chemical substance, under the conditions of use, presents an unreasonable risk of injury to health or the environment. EPA will make *individual risk determinations* for all uses identified in the scope. This part of the regulation is slightly amended from the proposed rule, to clarify that the risk determination is part of the risk evaluation, as well as to account for the revised approach to [sic] that ensures *each condition of use covered by the risk evaluation receives a risk determination*.

82 Fed. Reg. at 33744 (emphasis added).<sup>9</sup>

EPA goes on to explain in the preamble that "EPA's determinations will specify whether each condition of use identified for a chemical substance does or does not present an unreasonable risk of injury to health or the environment." *Id.* The preamble also notes that any § 6(a) risk management rule "would apply only to the condition(s) of use that present an unreasonable risk, and those that do not present an unreasonable risk will not be subject to risk management." *Id.* In light of the clear language of EPA's own regulations, 40 C.F.R. § 702.47, and the discussion in the preamble to the Risk Evaluation Rule, EPA's arguments that the regulations do not call for use-by-use risk determinations are not persuasive.

In the PCE notice, EPA repeatedly points to language within the proposed risk evaluation rule, 82 Fed. Reg. 7562 (Jan. 19, 2017) ("Proposed Risk Evaluation Rule"), to argue that a whole chemical approach is appropriate. However, the Proposed Risk Evaluation Rule is not identical to the Risk Evaluation Rule that was codified and that governs EPA's risk evaluation process. And critically, in the preamble to the Risk Evaluation Rule, EPA expressly noted that with respect to unreasonable risk determinations the Agency was taking a different direction from the Proposed

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<sup>9</sup> Under traditional tools of interpretation, the preamble to a regulation may be relied upon as evidence of an agency's contemporaneous understanding of its own regulations. See *Wyo. Outdoor Council v. United States Forest Serv.*, 165 F.3d 43, 53 (D.C. Cir. 1999).

Risk Evaluation Rule and amended proposed § 702.43 (now § 702.47) to reflect a condition of use-by-use approach. *See* 82 Fed. Reg. at 33728-33729, 33740, 33744.

Proposed § 702.43 would have provided:

§ 702.43: Unreasonable risk determination.

The EPA will determine whether the chemical substance presents an unreasonable risk of injury to health or the environment under the conditions of use as identified in the final scope document public pursuant to 40 CFR 702.39(c)(6)(iv).

While this proposed language arguably could be read as allowing for a whole chemical approach, EPA expressly rejected that approach. In the final Risk Evaluation Rule, EPA amended the proposed language to reflect the “revised approach” that “ensures *each condition of use covered by the risk evaluation receives a risk determination.*” 82 Fed. Reg. at 33744 (emphasis added). Accordingly, the codified version reads:

§ 702.47: Unreasonable risk determination.

As part of the risk evaluation, EPA will determine whether the chemical substance presents an unreasonable risk of injury to health or the environment *under each condition of uses* [sic] within the scope of the risk evaluation, either in a single decision document or in multiple decision documents.

40 C.F.R. § 702.47 (emphasis added). EPA’s reliance on the Proposed Risk Evaluation Rule in the PCE notice serves only to highlight the differences between the proposed rule and the final Risk Evaluation Rule, and therefore, reinforces the fact that a whole chemical approach is inconsistent with the risk evaluation process as it was actually codified.

c. Adoption of EPA’s Whole Chemical Approach Would Require Notice and Comment Rulemaking

If EPA would like to adopt a whole chemical approach, it must amend its risk evaluation regulations through notice and comment rulemaking in accordance with the Administrative Procedure Act. *See* U.S.C. § 553. EPA cannot impose a whole chemical approach by reading ambiguity into the Risk Evaluation Rule that does not exist, and then claiming that its strained interpretation is entitled to deference.

The U.S. Supreme Court recently addressed the deference entitled an agency’s interpretation of its own regulations in *Kisor v. Wilkie*, 139 S. Ct. 2400 (2019). There, the Supreme Court revisited the doctrine known as *Auer* deference, which directs courts to defer to an agency’s construction of its own regulation unless such interpretation is “plainly erroneous or inconsistent with the regulation.” *Kisor*, 139 S. Ct. at 2413. In *Kisor*, the Supreme Court placed new limits on *Auer* deference to address concerns that courts were affording agencies too much deference “without significant analysis of the underlying regulation.” *Id.* at 2414. The Court made clear that

deference to an agency's interpretation is only appropriate if the regulation is "genuinely ambiguous." *Id.* at 2415. A court must use all of the "traditional tools" of construction, "carefully consider[ing]" the rule's "text, structure, history, and purpose." *Id.* If there is no uncertainty, then the court must give effect to the plain meaning of the regulation; failure to do so would "permit the agency, under the guise of interpreting a regulation, to create de facto a new regulation." *Id.* Furthermore, if genuine ambiguity cannot be ruled out, then the agency's interpretation must still be "reasonable." *Id.* Again, the court is to apply those same interpretive tools to determine whether the agency's construction fits within the "zone of ambiguity." *Id.*

Not only is EPA's newly adopted interpretation of the Risk Evaluation Rule inconsistent with TSCA, but it does not withstand scrutiny under the standard articulated in *Kisor*. 40 C.F.R. § 702.47 is not "genuinely ambiguous." The regulation plainly requires condition-of-use-specific risk determinations. EPA's interpretation completely reads out of § 702.47 the second part of the regulation which states that the determination will be made "*under each condition of uses* [sic] . . . either in a single decision document or in multiple decision documents." 40 C.F.R. § 702.47. Turning to "traditional tools" of construction, EPA's interpretation is also flatly contradicted by the preamble to the Risk Evaluation Rule, which provides that "EPA will make *individual risk determinations*" to ensure that "*each condition of use covered by the risk evaluation receives a risk determination.*" 82 Fed. Reg. at 33744 (emphasis added).

In the PCE notice, EPA attempts to find support for its whole chemical approach in 40 C.F.R. § 702.31(a) and § 702.41(a)(6). Both provisions generally state that EPA is to determine whether a chemical substance presents an unreasonable risk, thus implying in EPA's view that a risk determination does not turn on separate conditions of use. *See* 87 Fed. Reg. at 39086, 39088. However, neither provision specifically addresses how an "unreasonable risk" determination is to be made. Section 702.31(a) is simply the introductory provision to the entire set of regulations governing risk determinations. Section 702.41(a)(6) merely reminds stakeholders that the level of detail in each evaluation may vary. In fact, the latter provision appears to speak to the use-by-use approach when it states EPA may "refine its evaluations for one or more condition of use in any risk evaluation." *See* 40 C.F.R. § 702.41.

EPA's attempt to read a whole chemical approach into the Risk Evaluation Rule is precisely the type of agency overreach that the Supreme Court warned against in *Kisor*. EPA is attempting "to create de facto a new regulation," "under the guise of interpreting a regulation." *Kisor*, 139 S. Ct. at 2415. EPA should withdraw the PCE notice and continue to make condition-of-use specific risk determinations for PCE and other chemical substances, consistent with the process for risk evaluations set forth in the Risk Evaluation Rule. At the very least, to implement a whole chemical approach for PCE or any other chemical, EPA would have to amend the regulations at 40 C.F.R. part 702, subpart B through notice and comment rulemaking.<sup>10</sup>

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<sup>10</sup> In the PCE notice, EPA also cites to the Ninth Circuit's decision in *Safer Chemicals, Healthy Families v. EPA*, 943 F.3d 397 (9th Cir. 2019) to argue that the Risk Evaluation Rule is ambiguous. However, in that case, the Ninth Circuit did not evaluate whether the Risk Evaluation Rule, and 40 C.F.R. § 702.47 in particular, was genuinely ambiguous under the standard articulated by the Supreme Court in *Kisor*. Nor did the court consider the clear explanatory language within the preamble to the Risk Evaluation Rule.

## II. EPA Has Not Provided a Reasoned Explanation for its Decision to Revise the PCE Determination to Implement the Whole Chemical Approach

In the PCE notice and revised PCE risk determination, EPA seeks to explain why the whole chemical approach is permissible, but does not sufficiently explain why it is needed. EPA states that the whole chemical approach “better align[s] with TSCA’s objective of protecting health and the environment,” but also states that the underlying scientific analysis of the risk evaluation has not changed. 87 Fed. Reg. at 39091. Pursuant to TSCA § 26, EPA must explain how the whole chemical approach to risk determinations is “employed in a manner consistent with the best available science” or a “weight of scientific evidence” approach. *See* 15 U.S.C. § 2625(h), (i). EPA has not sufficiently explained how the whole chemical approach is compelled by the specific factors and scientific and information standards articulated by Congress in TSCA §§ 6 and 26.

EPA’s notice also does not provide clarity on the criteria for making whole chemical determinations of risk, and does not specify the circumstances in which EPA might choose between the two approaches, or how it would make an unreasonable risk determination when EPA finds a mix of conditions of use that are and are not an unreasonable risk. EPA suggests that it may apply the whole chemical approach in its discretion, on a case-by-case basis, 87 Fed. Reg. at 39088. However, this approach would not provide clarity and consistency to stakeholders. For example, stakeholders would have no ability to predict when judicial review would be available for EPA’s determinations of unreasonable risk. In contrast, the condition-of-use approach provides greater transparency in EPA’s implementation of TSCA § 6(b) and better informs EPA’s decision-making process leading to TSCA § 6(a) risk management than a whole-chemical determination by presenting completely, and with objectivity, the findings of EPA’s risk evaluation of the substance under all conditions of use.

## III. EPA Must Consider Compliance With Applicable PPE Requirements in its Risk Determinations

In the PCE notice, EPA proposes “that the risk determination should be explicit that it does not rely on assumptions regarding the use of [PPE] in making the unreasonable risk determination under TSCA Section 6, even though some facilities might be using PPE as one means to reduce workers’ exposures; rather the use of PPE would be considered during risk management.” 87 Fed. Reg. 39087. EPA’s decision to relegate consideration of PPE use to the risk management stage is not consistent with the statute and implementing regulations, which require EPA to determine whether a chemical substance “presents” an unreasonable risk “under the conditions of use.” 15 U.S.C. § 2605(b)(4)(A); *see also* 40 C.F.R. § 702.41.

TSCA § 3(4) defines the term “conditions of use” 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.” 15 U.S.C. § 2602(4). The structure of the definition makes clear that “circumstances” includes aspects of the context in which a chemical substance is manufactured, imported, processed, distributed in commerce, used, or disposed of, including whether workers wear PPE. EPA’s proposal no longer



to assume the use of PPE is contrary to TSCA because it effectively eliminates “circumstances” from the definition of conditions of use. The use of PPE is a circumstance that “is intended, known, or reasonably foreseen.” PPE use therefore belongs as a component of the conditions of use that EPA must consider in its risk evaluations.

To the extent EPA’s whole chemical approach is based on its assumption that some workers may disregard PPE requirements, including requirements imposed by the Occupational Safety and Health Administration (“OSHA”), that is not a valid consideration. In amending TSCA, Congress specifically noted that the term “conditions of use” is “*not intended to include ‘intentional misuse’ of chemicals.*”<sup>11</sup> Moreover, if OSHA PPE requirements are violated, then OSHA may issue enforcement and corrective actions to address those violations. It is unreasonable for EPA, without supporting data, to assume that a significant number of workers across all conditions of use do not comply with PPE requirements.<sup>12</sup>

In addition, TSCA § 26(k) specifically requires EPA to take into consideration *all information* that is reasonably available to EPA concerning both hazard *and exposure* information. In the draft revised risk determination, EPA states that there may be potentially exposed or susceptible subpopulations of workers not covered by OSHA PPE requirements and other OSHA standards, such as self-employed individuals and public sector workers not covered by a State Plan or workers whose employer is out of compliance with the OSHA standards. However, rather than locating and further assessing in a transparent manner the information and data which might support those assumptions, the revised risk determination does not supply any basis in the record for reaching such a conclusion.

Furthermore, in the PCE notice, EPA asserts that it does not need to make any technical or scientific changes to the hazard or exposure assessments in the PCE risk evaluation. 87 Fed. Reg. at 39088 (“EPA . . . does not intend to amend . . . the underlying scientific analysis of the risk evaluation in the risk characterization section of the risk evaluation.”). EPA is required, however, to identify and evaluate the risks to this subgroup of workers in the PCE risk evaluation, which EPA has not done. *See* 40 C.F.R. §§ 702.31, 702.41, 702.43. EPA is also required to ensure that all supporting analysis in its risk evaluations “inform the development of a technically sound determination” of risk using the best available science and weight of the scientific evidence and consider all reasonably available information. *See* 40 C.F.R. § 702.41; 15 U.S.C. § 2625(h), (i), and (k). EPA has not met this standard either. Before proceeding to risk management, EPA must properly investigate and evaluate the risks to this subgroup of workers, and the conditions of use, based on reasonably available information. EPA’s *post-hoc* assumption devoid of supporting record evidence is insufficient.

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<sup>11</sup> *See* U.S. Congress (2015), *Frank R. Lautenberg Chemical Safety for the 21st Century Act, Report together with Minority Views*, 114th Congress, 1st Session, Report 114-67, at 7 (emphasis added), available at <https://www.congress.gov/114/crpt/srpt67/CRPT-114srpt67.pdf>.

<sup>12</sup> EPA’s actions also threaten OSHA’s jurisdiction. Although Congress mandated that EPA assess whether chemical exposures present unreasonable risk to workers, nothing in the statute or its legislative history suggests Congress wanted EPA to displace OSHA’s primacy in assuring safe and healthful workplaces. OSHA should retain primary jurisdiction in regulating the workplace and enforcing workplace health and safety standards and EPA should coordinate with OSHA pursuant to TSCA § 9.

In contrast, EPA's approach in the December 2020 risk evaluation was more reasonable and based on available information cited in the record. Under that approach, EPA assumed compliance with OSHA regulatory requirements for PPE. *See* PCE Risk Evaluation at 41. EPA explained that "existing OSHA regulations for worker protection and hazard communication will result in use of appropriate PPE," and that reasonable evidence supported the assumption that workers were complying with OSHA's requirements. *Id.* EPA also acknowledged that it could not presume, "in the absence of supporting information," a lack of compliance with OSHA's existing regulatory programs. *Id.* Nevertheless, EPA based its decisions on unreasonable risk to workers on "high-end exposure estimates, in order to account for the uncertainties related to whether or not workers are using PPE." *Id.* In the PCE notice, EPA has not explained why its prior findings that OSHA requirements will result in appropriate PPE use are no longer supported. Nor has EPA explained why its prior approach to base decisions on unreasonable risk to workers on "high-end exposure estimates" is no longer a valid method for accounting for uncertainties related to PPE use. Without supporting record evidence or analysis, EPA's decision no longer to assume the use of PPE is not reasonable and should be withdrawn.

Respectfully submitted,



W. Caffey Norman