Draft Revision to Toxic Substances Control Act (TSCA) Risk Determination

for

Colour Index Pigment Violet 29 (PV29)

(Docket ID EPA-HQ-OPPT-2016-0725)

Comments of the American Chemistry Council

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I. Executive Summary

The Draft Revised Unreasonable Risk Determination for C.I. Pigment Violet 29 (PV29), published on March 7, 2022, reflects the second time EPA has taken a "whole chemical approach" to a risk determination as opposed to making risk determinations for individual conditions of use (COUs).[1] It also reflects the assumption that personal protective equipment (PPE) is not used in the workplace, and therefore, PPE will not be considered for risk determinations.

EPA has not adequately supported its decisions to implement a *whole chemical approach* in the PV29 risk evaluation, and to not assume use of PPE in TSCA risk determinations. Moreover, fatal flaws in the final risk evaluation of PV29 resulted in unwarranted determinations of unreasonable risk. ACC's comments express several key concerns with the risk evaluation and risk determination process that need to be addressed, including the below points.

<u>PV29 Risk Evaluation</u>

- The occupational exposure assessment does not reflect conditions of use of PV29.
    - The exposure assessment greatly overestimates the duration, intensity, frequency, and number of exposures of PV29 during its manufacturing, processing, and use.
    - Air monitoring data submitted by the manufacturer of PV29 were not used properly.
- EPA mischaracterized the hazard of PV29 through its erroneous use of carbon black as an analogue.
- PV29 does not present an unreasonable risk of injury to health or the environment under its conditions of use

<u>Whole Chemical Approach</u>

- The Agency has not adequately supported its proposal to implement a whole chemical approach.
- The approach is inconsistent with TSCA and EPA's risk evaluation regulations.
    - A single "whole chemical" unreasonable risk determination, when there are conditions of use that the Agency has determined *do not* present an unreasonable risk, ignores the possibility of "no unreasonable risk" determinations for a chemical under its conditions of use.
- The approach is neither science-based nor risk-based and does not meet the science requirements of TSCA Section 26.
- The approach is arbitrary, and lacks clarity, principles, and criteria.
- The approach will have substantial adverse impacts on the regulated community as well as on the credibility of both EPA and OSHA regulations.

[1] Colour Index Pigment Violet 29 (PV29); Draft Revision to Toxic Substances Control Act (TSCA) Risk Determination; Notice of Availability and Request for Comment, March 07, 2022 (87 Fed. Reg. 12690).

Assumption of No PPE

- Assumptions regarding the lack of use of PPE are inconsistent with TSCA's requirements that EPA determine whether a chemical presents an unreasonable risk under the chemical's "conditions of use."
- These assumptions do not comply with TSCA's Section 26 requirements that TSCA risk evaluations be consistent with best available science and based on weight of the scientific evidence.
- These assumptions are inconsistent with the Occupational Safety and Health Act's statutory and regulatory requirements.
- Addressing PPE (and other OSHA requirements) only in the risk management rule, and not as part of the conditions of use in the risk evaluation, will have significant potential impacts, including the potential for duplicative and inconsistent requirements.

Because EPA has not provided a science-based, reasoned explanation for these changes, EPA should withdraw the PV29 risk evaluation, including the draft revised unreasonable risk determination, and correct the scientific and procedural errors in it. In addition, EPA should provide an opportunity for public comment on the *whole chemical* and no PPE policy decisions before applying these changes to any other chemical substances.

II. PV29 does not present an unreasonable risk of injury to health or the environment under its conditions of use.

In its 2021 Final Risk Evaluation for PV29, EPA mischaracterized the hazards and exposures associated with its conditions of use.[2] The occupational exposure assessment grossly overestimates the duration, intensity, frequency, and number of exposures under its conditions of use. The hazard assessment relied on an inaccurate and unwarranted use of carbon black as an analogue to PV29 in order to characterize the human health hazards.

A. The occupational exposure assessment detailed in the final risk evaluation for PV29 does not reflect known or reasonably foreseeable conditions of its use, and it grossly overestimates exposures.

The conditions of use of PV29 are well known and have been consistent over time. PV29 is manufactured at a single facility in the United States (Sun Chemicals, South Carolina) in a batch process. Data from the 2016 Chemical Data Reporting show relatively consistent production of PV29 of 500,000 lbs. to 600,000 lbs. from 2012 – 2015,[3] and Sun Chemicals (the sole U.S. manufacturer of PV29) has indicated that it manufactured approximately 500,000 lbs. of PV29 in 2017 and 2019.[4] The substantial

[2] Risk Evaluation for C.I. Pigment Violet 29 (Anthra[2,1,9-def:6,5,10-d'e'f']diisoquinoline-1,3,8,10(2H,9H)-tetrone) CASRN: 81-33-4. January 2021

[3] *Id.* (Pages 21-22)

[4] Revised Draft Risk Evaluation for C.I. Pigment Violet 29 Supplemental File: Information Received from Manufacturing Stakeholders, October 2020. Available at: Docket ID EPA-HQ-OPPT-2018-0604-0098.

majority of PV29 (about 90%) is used to make other perylene pigments. The remaining 10% (about 60,000 lbs.) is primarily formulated into paints and colored plastics, with some additional minor uses. Additionally, a small volume (less than 25,000 lbs.) is imported.

1. Domestic Manufacture

EPA has extensive information from the single facility that manufactures PV29 regarding frequency of the batch production process, duration of the batching process and ambient air quality conditions there. The conditions of use in the manufacture of PV29 **are known**. Moreover, the manufacturer submitted an industrial hygiene survey that included a description of various tasks, PPE utilized by employees, duration of tasks, the state of the PV29 product (crystals, fine powder), occurrence of visible powder, and respirable dust monitoring data.[5] The EPA risk evaluation assumed worker exposure to be 1.2 milligrams of dust per cubic meter of air (mg/m^3) (of which 100% was assumed to be PV29) over a 10.5 hour duration occurring 190 times per year despite the fact that PV29 batch manufacturing occurs infrequently and individual tasks were 0.5 to 2.0 hours in duration and total time performing tasks was on the order of 6.5 hours.

2. Processing and Use

About 60,000 lbs. of PV29 are formulated annually into paints and colored plastics. Those paints are then used as automobile basecoats and in refinishing vehicles. According to the manufacturer, the primary particles of PV29 would be observed in an automotive paint as a dispersion with a median size of 0.043 μm (i.e., 43 nm).[6] However, these primary particles do not migrate out of the paint at that size; therefore, workers would not be exposed to these nanoscale particles. Regardless, this erroneous assumption was made by EPA in justifying the use of carbon black as an analogue to PV29. Moreover, EPA used the same assumption of constant exposure by downstream processors and users of PV29 (in this case, 8 hours per day for 250 days per year) when the actual use will be infrequent and episodic.[7]

3. EPA should revise the PV29 exposure assessment to reflect known conditions of use.

As has been noted on several occasions in ACC's comments to EPA regarding the PV29 risk evaluation, the agency did not conduct its exposure assessment of the conditions of use of PV29 that reflect the circumstances under which it is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of. The limited use volume and use pattern make determining the conditions of use fairly certain and the consistent use volume over time demonstrate that it is reasonably foreseeable that the known uses will continue without appreciable increase.

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[5] Ramboll US Consulting, Inc. 2021. *Airborne Particle Size Characterization of C.I. Pigment Violet 29 (PV29)*. Submitted to Docket ID EPA-HQ-OPPT-2021-0277 (This document has not been posted yet in the docket.)

[6] Revised Draft Risk Evaluation for C.I. Pigment Violet 29 Supplemental File: Information Received from Manufacturing Stakeholders, October 2020. Available at: Docket ID EPA-HQ-OPPT-2018-0604-0098.

[7] *Id.* (Table 4-2, page 78).

B. The hazard assessment of PV29 relied on an inaccurate and unwarranted use of carbon black as an analogue in order to characterize the human health hazards.

EPA's scientific rationale for the use of an inhalation study with carbon black as an analogue for a route-specific (inhalation) study for PV29 is flawed due to insufficient reporting and characterization of particle size, use of a carbon-based analogue that is chemically different from PV29, and insufficient physicochemical characterization of nanoscale material in general. These are not scientifically defensible and so are unlikely to meet TSCA's scientific standards.

1. Use of carbon black as an analogue to particulate PV29 is not scientifically defensible because the chemical composition is not similar.

EPA selected carbon black as an analogue to particulate PV29 in the final risk evaluation using the following rationale[8]:

> *Carbon black also is structurally similar to C.I. Pigment Violet 29 with respect that both compounds contain conjugated polyaromatic ring structures.*

However, carbon black (CAS 1333-86-4) can be described as virtually pure elemental carbon in the form of colloidal particles that are produced by partial combustion or thermal decomposition of gaseous or liquid hydrocarbons under controlled conditions. EPA states in the Final Risk Evaluation that "both chemicals are used as pigments or inks and are predominantly comprised of a planar structure of multiple carbon rings".[9] It is possible that the 'conjugated polyaromatic ring structures' stated elsewhere in the Final Risk Evaluation may be PAHs as mentioned in the Elder et al. (2005) study, which states the following for the carbon black test compounds (Printex 90 and Sterling V) that were used in the study:

> *Polycyclic aromatic hydrocarbon (PAH) content was 0.039 mg/kg and 8.8 mg/kg for Printex 90 and Sterling V, respectively (Borm et al., 2005).*[10]

Even though a low fraction of PAHs are present in carbon black, it is important to note that PAHs are tightly bound to the carbon black and are not bioavailable. For example, a study by Borm et al. 2005 shows that PAHs are tightly bound to both of these test compounds and do not cause adduct formation *in vivo.* [11]

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[8] *Id*. (Page 67).

[9] *Id*. (Page 56).

[10] Elder, A., R. Gelein, J.N. Finkelstein, K.E. Driscoll, J. Harkema, G. Oberdörster. 2005. Effects of Subchronically Inhaled Carbon Black in Three Species. I. Retention Kinetics, Lung Inflammation, and Histopathology, *Toxicological Sciences*, Vol. 88(2): 614–629 (Page 615).

[11] Borm, PJ et al. 2005. Formation of PAH-DNA adducts after in vivo and vitro exposure of rats and lung cells to different commercial carbon blacks. *Toxicol Appl Pharmacol*. 2005 Jun 1;205(2):157-67.

In general, using carbon blacks as an analogue to PV29 is not scientifically defensible because unlike PV29, commercial carbon blacks are primarily comprised of elemental carbon.[12] Carbon black can cause inflammatory reactions related to lung overload, especially in rats which are very sensitive to lung overload. As these kinds of repeated-dose inhalation toxicity studies are not available for PV29, it is not appropriate to simply make the assumption that PV29 can also cause similar inflammatory responses.

Additionally, even if the PAHs were bioavailable (which they likely are not), PAHs would behave differently in genotoxicity/mutagenicity assays than PV29. PAHs can be metabolically activated and test positive in genotoxicity assays.[13] By contrast, PV29 was negative in both OECD guideline genotoxicity studies that were conducted in the presence of metabolic activation.[14] As such, the toxicological dissimilarity would nullify the use of PAHs as an analogue (even if it were bioavailable, which it likely is not). The genotoxic properties of PAHs that are absent in PV29 thus confounds its use as an analogue in this assessment as these genotoxic properties would be anticipated to independently influence pulmonary toxicity. (Generally speaking, confounding amongst substances in a situation considered by EPA to be relevant to pulmonary overload should be avoided by assuring that one substance does not have toxicological properties (e.g., is inflammatory, corrosive, mutagenic/genotoxic) that would potentiate an overload response whereas the other does not). As such, EPA's rationale for apparently using the PAHs in carbon black as an analogue to PV29 based on structural similarities in chemical composition to support hazard assessment is not scientifically defensible.

2. The data supporting a 43 nm particle size does not meet EPA's OPPTS 870-Series Guideline criteria for particle size characterization or the quality criteria of its Draft Systematic Review Protocol and is therefore unlikely to meet the scientific requirements of TSCA.

The PV29 particle size data used by EPA were provided in an email that specified that particle size was measured by sedimentation.[15] This information was not submitted as a formal study and no information (that ACC could find) was provided on test reliability or other parameters as required by EPA's draft Systematic Review Protocol.[16] Sedimentation is not the analytical method generally used to characterize particle size for aerosolized particles in EPA's guideline, 870-series inhalation toxicity studies (e.g. 870.4365 and related), nor was particle size measured in the breathing zone during an inhalation study as specified in the Guideline. Together, this indicates that these data are unlikely to meet the scientific requirements of TSCA Section 26, which specifies that EPA must use "scientific information, technical

[12] Long et al. 2013. Carbon black vs. black carbon and other airborne materials containing elemental carbon: physical and chemical distinctions. *Environ Pollution*. 181:271-86. doi: 10.1016/j.envpol.2013.06.009. Epub 2013 Jul 10.

[13] Toxicological Profile for Polycyclic Aromatic Hydrocarbons. ATSDR. August 1995. Available at: https://www.atsdr.cdc.gov/toxprofiles/tp69.pdf

[14] *Id.* (Page 119).

[15] Revised Draft Risk Evaluation for C.I. Pigment Violet 29 (Anthra[2,1,9-def:6,5,10-d'e'r]diisoquinoline-1,3,8,10(2H,9H)-tetrone) Supplemental File:Information Received from Manufacturing Stakeholders CASRN: 81-33-4 *October 2020.* EPA-HQ-OPPT-2018-0604-0098. (Page 28).

[16] Draft Systematic Review Protocol Supporting TSCA Risk Evaluations for Chemical Substances Version 1.0 A Generic TSCA Systematic Review Protocol with Chemical-Specific Methodologies, *December 2021* (Page 444).

procedures, measures, methods, protocols, methodologies, or models, employed in a manner consistent with the best available science."

3. EPA's use of size and chemical similarity alone is insufficient to scientifically justify using carbon black as an analogue to PV29.

In order for EPA to justify the use of carbon black, a nanomaterial, as an analogue to PV29, extensive physicochemical characterizations beyond size and chemical composition are necessary to draw a comparison. It has been established in the scientific literature for over a decade that physicochemical properties in addition to the size and chemical composition of the particle can influence its toxicity. This consensus is reflected in the OECD decision framework to inform decisions for risk assessment of manufactured nanomaterials, which specifies that numerous additional physicochemical properties as "a necessary pre-requisite of toxicological assessment":[17]

> *Few of the existing test guidelines were considered to provide information relevant to the potential toxicological impact of such nanomaterials, and the document identified the following set of physico-chemical characteristics as a necessary pre-requisite of toxicological assessment: agglomeration/aggregation, catalytic properties, composition, concentration, crystalline phase, dustiness, fat solubility/oleophilicity, grain size, hydrodynamic size/particle size measurement/distribution, length, purity, shape, specific surface area, surface charge, surface chemistry, water solubility/hydrophilicity, and zeta potential.*

The scientific consensus that characterization of (many) more than two physicochemical properties of nanoscale materials is necessary to assess toxicological impact is crystallized in the OECD decision framework. As such, EPA's use of only two physicochemical properties (that were not properly characterized) is insufficient.

EPA's determination that PV29 has the potential to cause pulmonary overload based on the Elder et al. (2005) study is indefensible as it is within the limits of EPA's PM 2.5 ambient air quality standards (when averaged over 24 hours) and total dust is within the range of more recent Occupational Exposure Levels (OELs) set by competent authorities.

The detection limit in a study submitted by the manufacturer[18] is 50 $\mu g/m^3$ and the measured mass per unit area for all measurements in this study were below the detection limit. The mass per unit area of particles in the nanoscale range (100 nm or less) would have been captured in all the size ranges measured (PM1, PM2.5, PM4, PM10, and total PM) because the measurements are cumulative. This is inclusive of PM2.5. EPA's current ambient air quality standard for PM 2.5 is 35 $\mu g/m^3$ when averaged over 24 hours.[19] This PM2.5 standard is protective of the general population, which is thought to be more

[17] Physical-Chemical Decision Framework To Inform Decisions For Risk Assessment Of Manufactured Nanomaterials. OECD Series on the Safety of Manufactured Nanomaterials No. 90. ENV/JM/MONO(2019)12.

[18] Airborne Particle Size Characterization of C.I. Pigment Violent 29 (PV29). Color Pigment Manufacturers Association (CPMA). Ramboll. 333 West Wacker Drive, Suite 2700, Chicago, IL 60606. Date: December 2021, Project Number:1690023419. Submitted to Docket ID EPA-HQ-OPPT-2021-0277.

[19] epa.gov/pm-pollution/national-ambient-air-quality-standards-naaqs-pm.

sensitive than occupational populations due to the "healthy worker effect." As such, it is not scientifically credible, nor does it generally make sense, that EPA would have exposure concerns for workers when measured exposures are below a detection limit that is within the range of EPA's own air quality standards for more sensitive sub-populations.

Additionally, the highest measurement of total PV29 dust was 1.2 mg/m^3 (but was otherwise generally much lower in the 0.3-0.6 mg/m^3 range). This is almost 5-fold lower to greater than 15-fold lower than the OSHA standard for respirable dust of 5 mg/m^3. The exposures in the 0.3-0.6 mg/m^3 range are within range of the more recent, lower dust TLV set by the German MAK Commission of 0.3 mg/m^3 at a 4 mg/m^3 concentration of the inhalable fraction.[20]

A route-specific (inhalation) risk assessment is unnecessary due to negligible inhalation exposure and evidence of absence of toxicity up to the limit dose in an oral toxicity study. This would be more consistent with the findings of the 2018 draft risk evaluation.

Risk is a function of both hazard and exposure. The Ramboll study indicates occupational exposure to any nanoscale fraction of PV29 would be within the range of the PM2.5 NAAQs set for the general population.[21] Additional workplace monitoring studies indicate that total dust is less than the current OSHA standard even for high-end exposures and that average exposures are within range of more recent (and more conservative OELs) such as that set by the German MAK Commission. Additionally, the oral study with PV29 had a NOAEL greater than the limit dose of 1000 mg/kg/day.[22] The absence of evidence of adverse effects in an oral study and negligible exposure via workplace exposure monitoring strongly support the assertion that an inhalation risk assessment is not necessary.

Not performing an inhalation risk assessment would be more consistent with the findings of the 2018 draft risk evaluation, which showed no unreasonable risks based on an oral study conducted up to the limit dose even under the precautionary assumption of inhalation of all dust for all COUs. At present, the significant scientific differences between the 2018 draft risk evaluation and 2021 final risk evaluation for PV29 undermine scientific confidence in EPA's risk evaluation process, as they have not been adequately justified.

C. EPA should revise the risk evaluation for PV29 to properly characterize exposures and the human health hazards that would lead to the correct no unreasonable risk characterization under its known conditions of use.

The record for PV29 is clear regarding the known occupational exposures and hazards. ACC has provided comments to the docket on numerous occasions, as have the manufacturers and users of PV29. EPA should use the available information to properly characterize the risks associated with PV29 under its known conditions of use, which include any reasonably foreseeable conditions of use.

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[20] https://onlinelibrary.wiley.com/doi/pdf/10.1002/9783527695539.oth1

[21] Ramboll US Consulting, Inc. 2021. Airborne Particle Size Characterization of C.I. Pigment Violet 29 (PV29). Submitted to Docket ID EPA-HQ-OPPT-2021-0277 (This document has not been posted yet in the docket.)

[22] *Id.* (Page 111).

III. EPA has not adequately supported its decision to implement a whole chemical approach in the PV29 risk evaluation.

The 2016 TSCA amendments were designed to ascertain whether TSCA chemicals present unreasonable risk under the chemical substance's COUs, and where they did, to impose a range of risk management controls on those chemical-specific COUs to ensure they did not continue to present unreasonable risk. TSCA chemicals are important building block chemicals for industrial, commercial, and consumer uses, hence, the importance of consideration of the conditions of use of these substances.

One of the predominant early principles that emerged in the debates on the TSCA amendments was that chemicals should be "safe for their intended uses." This principle recognized that both the inherent toxicity of a chemical *and* the likely exposures under its COUs must be evaluated to determine whether a chemical poses risks to humans and the environment.

The principle of "safe for intended uses" was expanded during the 8-year legislative debate to the concept of "intended, known or reasonably foreseen conditions of use."[23] The term "conditions of use" was defined in the statute to cover the "circumstances" or activities of the manufacture, processing, distribution in commerce, use, or disposal of TSCA chemicals. These circumstances determine what "exposure scenarios" specific to the chemical's COUs the Agency should include in TSCA risk evaluations. In the risk evaluation, the Agency would integrate exposure scenario information with data on the chemical's inherent "hazards" (e.g., potential to cause cancer or non-cancer effects in humans, toxicity to aquatic life). The TSCA amendments made clear that requirements for conducting risk evaluations include consideration of a chemical's "hazards and exposures for the conditions of use" and "the likely duration, intensity, frequency and number of exposures under the conditions of use."[24]

Previously, EPA made multiple "risk determinations" of a single TSCA chemical substance under its multiple COUs. A risk determination's coverage was clear because each risk determination was specifically associated with a chemical substance's COUs that were scoped in the risk evaluation. Under the Agency's proposed whole chemical approach, if a "majority" of the COUs the Agency includes in its risk evaluation are found to present an unreasonable risk, the Agency would, at its discretion, make only one risk determination: a whole chemical determination of unreasonable risk.

A. The whole chemical approach is inconsistent with TSCA and its implementing regulations.

1. TSCA Section 6 is predicated on the Agency making determinations of both "unreasonable risk" and "no unreasonable risk" for the "conditions of use" for each chemical substance.

By essentially removing consideration of individual COUs from the risk determination, the whole chemical approach is inconsistent with the risk evaluation process described in TSCA Section 6. TSCA

[23] TSCA Section 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)

[24] *See* 15 U.S.C. §§ 2605(b)(4)(F)(i) and (iv).

Section 6(b)(4)(A) requires that EPA risk evaluations determine "*whether* a chemical substance presents an unreasonable risk…under the conditions of use."[25] In conducting a risk evaluation, EPA must "integrate and assess available information on hazards and exposures for the conditions of use of the chemical substance" and "take into account, where relevant, the likely duration, intensity, frequency and number of exposures under the conditions of use."[26] Section 6(b)(4) contemplates risk determinations of both "unreasonable risk" and "no unreasonable risk" for a chemical substance based on hazards and exposures under the COUs. The concept of "whole chemical" is not mentioned in the TSCA statute.

TSCA Sections 6(i)(1) and (2), which define final agency action for purposes of judicial review, also contemplate risk determinations of both unreasonable risk and no unreasonable risk.[27] Section 6(i)(1) requires EPA, when it determines a chemical substance *does not present* an unreasonable risk under Section 6(b)(4)(A) (i.e., "under the conditions of use"), to issue an order which will be considered final agency action. Section 6(i)(2), however, provides, when EPA determines a chemical substance *presents* an unreasonable risk under Section 6(b)(4)(A), the final Section 6(a) risk management rule is considered final agency action. TSCA Section 6, therefore, contemplates the potential for two types of risk determinations. A single whole chemical unreasonable risk determination, when there are COUs that the Agency has determined do not present an unreasonable risk, ignores the possibility of "no unreasonable risk" determinations for a chemical substance under its conditions of use.

TSCA gives EPA three years to complete a risk evaluation to allow for a detailed, scientific-based evaluation of the COUs.[28] The whole chemical approach ignores the factors that go into the risk evaluation, pursuant to Section 6(b)(4)(F), and the risk determination, pursuant to Section 6(b)(4)(A). Instead, the whole chemical approach pushes the time intensive COU risk evaluation and determination into the much shorter risk management rule phase.[29]

2. The whole chemical approach impermissibly renders parts of the statute superfluous.

It is "a cardinal principle of statutory construction" that "a statute ought, upon the whole, to be so construed that, if it can be prevented, no clause, sentence, or word shall be superfluous, void, or insignificant."[30] The whole chemical approach, however, renders parts of the statute that relate to no unreasonable risk determinations superfluous.

In addition to Section 6, other sections of TSCA rely on the Agency issuing no unreasonable risk determinations. For example, TSCA Section 18(a)(1)(B)(i) preempts state and local actions to prohibit orrestrict the manufacture, processing, distribution in commerce, or use of chemical substances for which

[25] 15 U.S.C. § 2605(b)(4)(A) (emphasis added).
[26] 15 U.S.C. § 2605(b)(4)(F)(i) and (iv).
[27] 15 U.S.C. § 2605(i)(1), (2).
[28] 15 U.S.C. § 2605(b)(4)(G).
[29] *See* 15 U.S.C. § 2605(c)(1).
[30] *Duncan v. Walker*, 533 U. S. 167, 174 (2001) (internal quotation marks omitted).

EPA has made no unreasonable risk determinations under Section 6(i)(1).[31] The whole chemical approach, in which the Agency would not make no unreasonable risk determinations that would be subject to preemption, makes Section 18(a)(1)(B)(i) superfluous.

Moreover, TSCA Section 19 establishes the procedure and standard for judicial review of, among other things, no unreasonable risk determination orders issued under Section 6(i)(1).[32] Again, the whole chemical approach makes the provisions applicable to judicial review of no unreasonable risk determination orders issued under Section 6(i)(1) superfluous.

Congress could not have intended for TSCA Section 6 to be interpreted such that sections of the statute have no meaning.

B. The whole chemical approach is inconsistent with EPA's Procedures for ChemicalRisk Evaluation under the Amended Toxic Substances Control Act ("Risk Evaluation Rule").

The TSCA Amendments required EPA to establish a process by rule to conduct risk evaluations in accordance with TSCA Section 6(b)(4)(A) (i.e., "under the conditions of use"). The Risk Evaluation Rule promulgated under TSCA contemplates that EPA will make a risk determination for each condition of use:

> *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.[33]

That the rule provides for determinations to be made in single or multiple decision documents allowsEPA to reach different determinations on different conditions of use at different points in time.

Other provisions of the Risk Evaluation Rule envision that EPA will base "unreasonable risk" determinations on an analysis of COUs. For instance, 40 C.F.R. § 702.41(a)(9) states:

> EPA will complete the risk evaluation of the chemical substance addressing all of the conditions of use within the scope of the evaluation. However, EPA may complete its evaluation of the chemical substance under *specific conditions of use*…at any point following the issuance of the final scope document and issue its determination as to whether the chemical substance under those conditions of use does or does not present an unreasonable risk…EPA will follow all of the requirements and procedures in this

[31] 15 U.S.C. § 2617(a)(1)(B)(i). *See* also 15 U.S.C. § 2617(c)(3) (defining scope of preemption to include "the hazards, exposures, risks, and uses or conditions of use of such chemical substances included in any final agency action the Administrator takes pursuant to" Section 6(a) or 6(i)(1).).

[32] 15 U.S.C. § 2618.

[33] 40 C.F.R. § 702.47 (emphasis added).

> Subpart when it conducts its evaluation of the chemical substance under any *individual or specific conditions of use*. (emphasis added)

Similarly, the Risk Evaluation Rule provides that EPA will consider COUs when making final determinations of no unreasonable risk:

> A determination by EPA that the chemical substance, *under one or more conditions of use* within the scope of the risk evaluation, does not present an unreasonable risk…will be issued by order and considered to be a final Agency action, effective on the date of issuance of the order.[34]

The Risk Evaluation Rule does not support EPA's proposed whole chemical approach.

C. EPA has not provided a reasoned explanation of its decision to revise the PV29risk determination to implement the whole chemical approach.

In the Federal Register Notice, EPA makes broad, conclusory statements for taking a whole chemical approach (e.g., to "ensure the public is protected from unreasonable risk from chemicals in a way that is supported by science and the law;"[35] to "ensure that the risk evaluations better align with TSCA's objective of protecting health and the environment;"[36] and because "the 'whole chemical' approach to determining unreasonable risk to health is 'permissible' under EPA's statutory obligations under TSCA 6(b)(4) and the implementing regulations."[37]) None of these statements, however, is a reasoned explanation for the Agency's decision to apply the whole chemical approach to the PV29 risk determination.

EPA also asserts an administrative flexibility rationale for taking a whole chemical approach.[38] EPA provides two examples of how it might exercise its flexibility under this approach: where a single COU, "that does not impact or intersect" with other evaluated uses, drives an unreasonable risk determination, a whole chemical approach might not be warranted; but where a "majority" of a substances' COUs contribute to unreasonable risk, the whole chemical approach might be warranted.[39] These two examples

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[34] 40 C.F.R. § 702.49(d) (emphasis added).

[35] 87 Fed. Reg. at 12691.

[36] *Id*.

[37] *Id.*

[38] *Id.* at 12693 ("The Agency expects that this case-by-case approach will provide EPA greater flexibility in the Agency's ability to evaluate and manage unreasonable risk from individual chemical substances.").

[39] *Id.* ("For instance, circumstances in which an unreasonable risk determination is primarily driven by a single condition of use that does not impact or intersect with other evaluated uses (such as for example, a single consumer use of a substance out of a wide range of other manufacturing, processing and consumer uses evaluated) may warrant different treatment than circumstances in which the majority of the chemical substance's conditions of use contribute to unreasonable risk, and the Agency might adopt different approaches to the risk determinations in those particular instances. EPA anticipates that this flexibility will better serve TSCA's objectives by helping ensure that EPA is best positioned to present, and initiate risk management to address, chemical specific unreasonable risk determinations. EPA believes this is a reasonable approach under TSCA and the Agency's implementing regulations.").

seem to indicate that EPA does not intend to consistently apply the whole chemical approach, even in similar circumstances. EPA also does not address a number of questions raised by its change: What approach is applied when there is more than one COU that drives the risk determination but less than a "majority" of COUs? When does a COU "impact and intersect" with another COU and how does that differ from a COU "contributing" to unreasonable risk? What constitutes a "majority" of COUs, and whatwould prevent addition of low probability, or hypothetical COUs, such that a "majority" finding could be reached in an arbitrary manner? These questions underscore the need for the Agency to address these complicated questions of risk during the three-year risk evaluation period rather than the much shorter period to propose a risk management rule. Again, this rationale is not a reasoned explanation for EPA's change.

D. The whole chemical approach is neither science-based nor risk-based and does not meet the science requirements of TSCA Section 26.

1. EPA broadly characterizes its whole chemical approach as a reasonable, science-based alternative to the "condition-of-use specific" risk determination that the prior administration made in PV29's risk evaluation but has not supported its "science-based" claim.

EPA asserts that since PV29's "chemical specific properties" (identified by EPA as benchmark exceedances for multiple COUs that span across most aspects of the chemical's lifecycle and its irreversible health effects[40]) "cut across the conditions of use," EPA's risk findings andconclusions encompass a majority of those COUs. EPA, however, provides no scientific support for thisclaim, stating simply:

> Since the chemical-specific properties cut across the conditions of use within the scope of the risk evaluation, the Agency's risk findings and conclusions encompass the majority of those conditions of use, and the Agency is better positioned to achieve its TSCA objectives for PV 29 when issuing a whole chemical determination for PV 29, EPA concludes that the Agency's risk determination for PV 29 is better characterized as awhole chemical risk determination rather than condition-of-use-specific risk determinations.[41]

EPA appears to be only evaluating identified hazard, based upon the chemical-specific properties. This approach ignores TSCA's requirements to 1) consider, where relevant, the likely duration, intensity, frequency, and number of exposures under the COUs, pursuant to Section 6(b)(4)(F)(iv); and 2)to describe the weight of scientific evidence supporting the exposure description for the COUs, pursuant to Section 6(b)(4)(F)(v).

This statement does not clarify the role of differential levels of exposure associated with any specific COUs of PV29 as required by TSCA Section 6(b)(4)(F)(iv). Further, EPA's use of "irreversibility of effects" as a unique criterion of effects is a departure from historic EPA practice relative to EPA risk

[40] *Id.*

[41] *Id.*

assessments which would unnecessarily undermine the integrity of EPA risk assessments under TSCA and other statutes.[42] Simply asserting that these "chemical specific properties cut across the conditions of use within the scope" of the PV29 risk evaluation does not make it so. Without a more in-depth explanation, EPA's rationale isnot science-based.

EPA has not addressed several other questions about the scientific integrity of EPA's whole chemical approach. Specifically:

- What is EPA's science basis for concluding that a "majority" of individual COU unreasonable risk determinations warrant a whole chemical unreasonable risk determination?
- How will EPA treat the COUs that it determines do not present an unreasonable risk?
- Does EPA plan to use its whole chemical approach when a "majority" of a chemical's scoped COUs are found NOT to present unreasonable risk?
- In the revised Section 5 Unreasonable Risk Determination, EPA discusses its consideration of COUs considered "singularly or in combinations with other exposures." EPA claims it did not aggregate exposures to estimate risks to PV29, but has EPA done so without fully describing it, as required by TSCA §6(b)(4)(F)(ii)?

EPA does not address these and other questions about its conclusions, either with respect to PV29's risk determination or with respect to its consideration of whole chemical risk determinations for other TSCA chemicals in the future. In sum, EPA has not supported its claim that its whole chemical approach to risk determinations is science-based and has provided no science-based support for why a "majority" of COUs should trigger a whole chemical unreasonable risk determination.

2. Risk determinations under TSCA Section 6 must be consistent with best available science and weight of the scientific evidence under Section 26(h) and 26(i). EPA has not satisfied these requirements in its proposed whole chemical risk determination approach.

Risk determinations are science-based decisions under TSCA Section 6. Therefore, they are subject to Section 26(h)'s requirements for these decisions to be "consistent with best available science" and Section 26(i)'s requirement that these decisions be based on the "weight of the scientific evidence."[43] In the Risk Evaluation Rule, EPA defines best available science as "science that is reliable and unbiased."[44] The Risk Evaluation Rule further states that "[u]se of best available science involves the use of supporting studies conducted in accordance with sound and objective science practices…" and includes a series of

[42] EPA's human health risk assessments are already protective for "irreversible health effects," as they are based on safe levels of exposure to a substance in the most sensitive sub-populations for appropriate routes and durations of exposure. Indeed, the vast majority of risk assessments done across the Agency are based on effects that the Agency does not consider to be reversible (e.g., cancer, systemic effects, target organ effects, etc.). As such, implementing a criterion of "irreversibility of effects" would unnecessarily undermine the integrity of EPA risk assessments under TSCA and other statutes.

[43] 15 U.S.C. §§ 2625(h) and 2625(i).

[44] *See* 40 C.F.R. §702.33.

considerations including, "[t]he 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."[45]

In the Notice, EPA describes its proposed whole chemical approach as a "policy change" or a new "policy direction" which it plans to apply on a chemical-specific, case-by-case basis "in a surgical manner."[46] In therevised Section 5 of the PV29 risk evaluation, EPA concludes that its risk determination for PV29 is "better characterized" as a whole chemical risk determination rather than "condition-of-use specific-risk determinations [sic]."[47] In other words, EPA attempts to characterize its proposal in its revision to the PV29 risk determination as merely a better alternative "presentation" of PV29's unreasonable risk determination in order to provide EPA some flexibility in how it manages the unreasonable risks in its risk management rule – yet without any discussion of the "no unreasonable risk" COUs that are also included in the risk characterization section of PV29's risk evaluation.

EPA does not articulate how its whole chemical risk determination meets the Section 26 requirements of best available science. A determination of unreasonable risk that is based only on a "majority" of COUs and ignores those COUs that EPA has determined present "no unreasonable risk" is not scientifically reliable. Moreover, EPA does not state what "sound and objective science practices" it is using in making its whole chemical unreasonable risk determination. The Agency does not articulate to what extent it has used "technical procedures" to support a single risk determination that only reflects a "majority" of the COUs that were evaluated in the risk evaluation. Consequently, EPA does not explain how this whole chemical approach is consistent with best available science.

EPA mentions TSCA's Section 26(i) requirement that EPA's decisions be based on the weight of the scientific evidence, but merely recites what it considered in the prior administration's risk characterization of PV29.[48] The Risk Evaluation Rule's definition of "weight of scientific evidence"[49] requires more, including that EPA "integrate evidence as necessary and appropriate based upon strengths, limitations, and relevance." EPA's whole chemical approach to the PV29 unreasonable risk determination cannot be described as a "systematic review method" that evaluates streams of evidence and integrates that evidence based on strengths, limitations, and relevance. EPA's whole chemical approach can only be described as an averaging method to assess hazard and does not meet the TSCA Section 26 science standards required for TSCA Section 6 decisions, including risk determinations.

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[45] *Id.*

[46] *See, e.g.,* News Release, EPA Announces Path Forward for TSCA Chemical Risk Evaluations (June 30, 2021); available at https://www.epa.gov/newsreleases/epa-announces-path-forward-tsca-chemical-risk-evaluations; 87 Fed. Reg. at 12691 and 12692.

[47] EPA's Draft Revised Unreasonable Risk Determination for PV29, Section 5.1.1.

[48] *See* 87 Fed. Reg. at 12691 and Draft Revised Unreasonable Risk Determination for PV29, Section 5.1.1.

[49] 40 C.F.R. §702.33 (A "systematic review method, applied in a manner suited to the nature of the evidence or decision, that uses a pre-established protocol to comprehensively, objectively, transparently, and consistently, identify and evaluate each stream of evidence, including strengths, limitations and relevance of each study and to integrate evidence as necessary and appropriate based upon strengths, limitations, and relevance.").

3. EPA's "whole-chemical" approach is not risk-based and will produce misleading, non-science-based decisions about TSCA chemicals.

EPA's whole chemical approach undermines TSCA's statutory requirements for risk-based decision-making. Risk is a function of hazard and exposure. Risk determinations should be driven by the risk characterization's integration of hazard and exposure data and information, which are specific to the chemical substance under its various COUs.

Consistent with TSCA Section 6(b)(4)(F)(iv), risk determinations must address *whether* a chemical substance, under the COUs which EPA scoped into the risk evaluation, presents an unreasonable risk -- or not.

EPA would determine that a TSCA chemical presents unreasonable risk across the board when the risk characterization identifies only some percentage of the chemical's COUs as presenting unreasonable risk. The whole chemical approach ignores EPA findings of "no unreasonable risk" for the chemical in exposure scenarios under other COUs. The whole chemical approach "reads out" of EPA's risk determination those COUs that do *not* present unreasonable risk. This approach results in regulating and communicating on the basis of an incomplete understanding of a chemical's actual risk.

E. EPA's whole chemical risk determination for PV29 lacks clarity, principles, andcriteria demonstrating the arbitrary nature of the whole chemical approach.

1. EPA has provided no principles or criteria by which it will determine when to take a whole chemical approach in TSCA risk determinations.

In its June 30, 2021 announcement of its plan to use a whole chemical approach in revisions to some of the prior administration's risk evaluations, EPA declared that it "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."[50] In the Notice and the proposed revisions to Section 5 of the risk evaluation, the Agency confirmed that it was not re-assessing PV29 under its COUs and not changing EPA's risk characterizations in Section 4 of the 2021 PV29 risk evaluation. It was simply changing PV29's "condition of use based" risk determination to a whole chemical determination. The reasons for this change, however, are not transparent.

EPA has not identified any threshold principles or criteria by which it will decide *whether* to take a whole chemical approach in a risk determination. EPA appears to give itself unbridled flexibility to decide when to apply a whole chemical approach and when not. It merely states it will make "surgical" decisionson a "case by case" basis. This undefined approach to deciding when to count a majority as a whole chemical determination and when not, will produce inconsistent results. EPA's proposal, therefore, isarbitrary.

[50] News Release, *supra* note 2.

Despite EPA's statements implying the whole chemical approach will be the "exception" rather than the rule, there is nothing in the Notice or EPA's revisions to Section 5 that establishes any criteria for EPA's application of a whole chemical approach in future TSCA risk evaluations. Without development of principles and criteria, which must be satisfied on a case-by-case basis before EPA could apply a whole chemical approach, this and future administrations could unduly influence TSCA risk determinations based on considerations other than the best available science. Principles and criteria on the application of this approach, consistent with TSCA's framework, are essential to the credibility of this approach.

2. EPA has not made clear how a whole chemical risk determination will impact risk management rules.

EPA does not discuss in the Notice or the Section 5 revision how the whole chemical approach will impact the risk management rule for PV29. How will EPA address COUs that it finds in the risk characterization to present no unreasonable risk? Will they be included in the rule even though no risk management is needed? Will they be regulated only if they are impacted by COUs that present unreasonable risk? TSCA Section 6(b)(F)(4) provides specific requirements for EPA to evaluate the existing conditions of use during the risk evaluation. Failing to finalize that analysis in the risk evaluation phase by COU, in accordance with Section 6(b)(4)(A), creates additional ambiguity and uncertainty during the risk management rule process.

EPA must be more transparent about its plans with respect to TSCA risk management rules that result from whole chemical risk determinations. At a minimum, EPA should: a) not apply risk management rules to COUs for which rules are not necessary and are not contemplated by TSCA Section 6(i)(1); and b) issue "no unreasonable risk" determinations by order for a chemical's COUs in accordance with TSCA Section 6(i)(1).

F. EPA's whole chemical approach will have substantial impacts.

1. The whole chemical approach to risk determinations undermines TSCA's risk-based decision-making framework.

A whole chemical risk determination of "unreasonable risk" is effectively a return to TSCA before the 2016 amendments, when a chemical's hazard assessment and hazard characterization drove EPA's decisions about the chemical without any consideration of exposure under their "conditions of use." Chemicals were simplistically described as either "toxic" or not, based on lab studies, not in real world condition-of-use circumstances. The whole chemical approach would produce the same result as the pre-2016 approach by ignoring a chemical's COUs and the exposures and populations associated with those uses. This hazard-based approach would artificially increase the number of unreasonable risk determinations made under TSCA, since a "majority" of COUs presenting unreasonable risk would be all that is required to produce one whole chemical unreasonable risk determination.

2. Whole chemical risk determinations could lead to non-science-based market impacts and arbitrary regulations.

A single "unreasonable risk" determination for a chemical overall could be interpreted by the public and the marketplace as a declaration that the substance is toxic in all circumstances, regardless of exposure and PPE. Expectations could be raised that the substance will be banned from commerce. If EPA makesa whole chemical risk determination, but EPA's risk management rules provide "nuanced" risk management controls for such "whole chemicals," the public could be confused.

The marketplace could react similarly to these whole chemical determinations. The marketplace would not wait for EPA's risk management rule. The marketplace would begin the process of "product de-selection" of a chemical as soon as EPA makes a whole chemical determination of unreasonable risk for a chemical. When the European Union's REACH program's hazard-based framework labeled chemicals as "substances of very high concern" (SVHCs), European manufacturers noted that the European marketplace began de-selection of products containing these substances well before the EU regulated them. This could occur with whole chemical determinations of unreasonable risk, even if there are uses – including many beneficial uses – that EPA has determined present no unreasonable risk.

If EPA applies its whole chemical approach broadly, industrial manufacturers' and users' ability to innovate could be seriously harmed. This result would be counter to TSCA's policy prescription in Section 3 for the US to exercise its authority over chemical substances "in such a manner as not to impede unduly or create unnecessary economic barriers to technological innovation while fulfilling the primary purpose of this chapter to assure that such innovation and commerce in such chemical substances and mixtures do not present an unreasonable risk of injury to health or the environment."[51]

State legislatures and regulatory agencies, similarly, would not wait for EPA's risk management rules to act. States could move to propose arbitrary regulations, such as outright bans of these chemicals as soon as EPA's "whole chemical" unreasonable risk determination is finalized.

The impact of EPA's whole chemical approach could ripple through the public's perception, the marketplace, and state regulation.

G. Conclusion on the Whole Chemical Approach

ACC does not support EPA's whole chemical approach to risk determinations as described in the Notice for the reasons discussed above. EPA should withdraw its whole chemical approach because EPA's risk determinations should be risk-based, incorporate COUs, and consider TSCA's "risk-based" decision-making framework generally. Risk determinations also must comply with TSCA Section 26's best available science and weight of the scientific evidence requirements. EPA's decisions must be consistent with other requirements under TSCA, such as the processes for making and implementing "no unreasonable risk" determinations and the requirements for developing risk management rules. The proposed whole chemical approach does not meet these standards and EPA has not provided a reasoned explanation for this change.

[51] 15 U.S.C. § 2601(b)(3).

If, however, EPA decides to retain this new whole chemical approach that is not contemplated in the TSCA statute or in the Risk Evaluation Rule, the Agency should:

- Review this approach in the context of TSCA's risk-based decision-making framework for risk evaluation of COUs and requirements for risk management rules that build upon the COU determinations.
- Develop principles and criteria that would determine when a whole chemical approach could be used, and when it should not be used.
- After reviewing the whole chemical approach in light of ACC's concerns and recommendations, provide the public another opportunity to comment on EPA's review of itsproposed whole chemical approach to risk determinations.
- Clarify in public communications about whole chemical risk determinations that a whole chemical determination of unreasonable risk does not mean that certain uses of the chemical cannot continue; they simply must meet EPA's risk management requirements. EPA might consider a different name for this approach to avoid the public and the media's misunderstanding of these decisions.

IV. EPA has not adequately supported its decision to not assume use of PPE inTSCA risk determinations.

A. Introduction

In the Notice, EPA proposes to apply a "no assumption of PPE" in the PV29 risk determination. Although the Notice is specific to the risk determination of PV29, EPA implies that its proposed "no assumption of use of PPE" approach may be used in future TSCA risk determinations involving occupational exposure.[52]

EPA declares it "does not believe it is appropriate to assume as a general matter that an applicable OSHA requirement or industry practice is sufficient to address the risk, applicable to all potentially exposed workers, or consistently and always properly applied."[53] The Agency then explains that "going forward, EPA intends to make its determination of unreasonable risk from a baseline scenario that does not assume compliance with OSHA standards, including any applicable exposure limits or requirements for use of respiratory protection or other PPE."[54] In other words, EPA proposes to assume for risk determinations there is little or no compliance with OSHA — despite the fact that employers must comply with all applicable OSHA standards.

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[52] *See* 86 Fed. Reg. at 74086; *see also* News Release, *supra* note 2 ("EPA is therefore revisiting the assumption that PPE is always used in occupational settings when making risk determinations for a chemical. Instead, the agency plans to consider information on use of PPE, or other ways industry protects its workers, as a potential way to address unreasonable risk during the risk management process.").

[53] 86 Fed. Reg. at 12694.

[54] *Id.*

In both the Notice and the draft revised Section 5 of the PV29 risk evaluation, EPA distinguishes *the appropriateness of evaluating* levels of risk present in occupational exposure scenarios (both with and without PPE mitigation measures) *from the inappropriateness of making the risk determination based on the assumption of PPE.* In the draft revised Section 5, EPA states it is "appropriate to *evaluate* the levels of risk present in scenarios considering applicable OSHA requirements (e.g., chemical-specific permissible exposure limits (PELs) and/or chemical-specific PELs with additional substance-specific standards) as well as scenarios considering industry or sector best practices for industrial hygiene that are clearly articulated to the Agency,"[55] but EPA makes clear that this information merely "can help inform" EPA's potential risk management actions.[56]

Under its "no PPE assumption," EPA would treat the Occupational Safety and Health Act's (OSHA Act) requirements for PPE and other OSHA mandatory standards in industrial workplaces as irrelevant in TSCA risk determinations. It would have EPA treat PPE only as a "tool" for risk management rather than as part of a chemical's COU which should factor into the chemical's risk determination. This approach is inconsistent with TSCA's requirements to consider conditions of use and Section 26's scientific standards.

B. EPA's proposal not to rely on "intended, known or reasonably foreseen" use of PPEin the PV29 risk determination is inconsistent with TSCA's requirements that EPA determine whether a chemical presents an unreasonable risk under the chemical's "conditions of use."

EPA's proposal not to assume use of PPE in the PV29 TSCA risk determination is inconsistent with TSCA's Section 6(b)(4) risk evaluation requirements relating to "conditions of use." Section 6(b)(4)(A) requires that EPA conduct risk evaluations "to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant in the risk evaluation by the Administrator, *under the conditions of use."*[57] TSCA Section 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."[58] The proposal also fails to "take into account, where relevant, the likely duration, intensity, frequency and number of exposures under the conditions of use" pursuant to TSCA Section 6(b)(4)(F)(iv). Further, ignoring the use of PPE ignores the requirement to "describe the weight of scientific evidence for the identified hazard and exposure" pursuant to Section 6(b)(4)(F)(v). Instead of describing the weight of scientific evidence, EPA ignores the use of industrial hygiene data, as required by OSHA, to evaluate engineering and administrative controls and then the use of PPE as an additional layer of protection.

In the revised risk determination for PV29, EPA proposes to discount certain "known or reasonably foreseen" circumstances of manufacturing under OSHA's mandatory requirements and instead to rely

[55] Draft Revised Unreasonable Risk Determination for PV29, Section 5.2.4 (emphasis added).

[56] *Id.*

[57] 15 U.S.C. § 2605(b)(4)(A) (emphasis added).

[58] 15 U.S.C. §2602(4) (emphasis added).

upon only one condition of use – one in which PPE is *not* required, used, or complied with. EPA justifies its decision by declaring, "it reflects EPA's recognition that unreasonable risk may exist for subpopulations of workers that may be highly exposed because they are not covered by OSHA standards, such as self-employed individuals and public sector workers who are not covered by a State Plan, or because their employer is out of compliance with OSHA standards, or because EPA finds unreasonable risk for purposes of TSCA notwithstanding OSHA requirements."[59]

By assuming PPE is not used in any COU, EPA is ignoring OSHA comprehensive, industry-specific, standards which OSHA-regulated employers and employees must meet. These require employers to assess whether hazards present in their workplace necessitate the use of PPE and, if so, to provide the types of PPE that would protect them from these hazards; to communicate the decision to the employees; to select PPE that properly fits affected employees; to verify the performance of the hazard assessment; and to certify compliance with these requirements.

Among other things, these OSHA-required assessments of hazards in the workplace through industrial hygiene evaluations have resulted in employers implementing engineering controls to reduce exposures such that PPE would not be needed or required. Where engineering controls are not feasible, or provide inadequate protection, PPE is required. In addition to these OSHA requirements, employers have implemented industry or sector best work practices for industrial hygiene. EPA's proposal also ignores that OSHA standards require employer and employee compliance with these standards and that OSHA has authority to enforce them.

Instead, EPA characterizes these "known or reasonably foreseen" COUs in OSHA-regulated facilities as dismissible "assumptions" for purposes of TSCA risk determinations. In its proposal, EPA would treat existing PPE not as part of the workplace "condition of use" that is factored into the risk determination (even though it is characterized in the risk evaluation itself), but simply as a "tool" that EPA would apply in risk management. Therefore, EPA's risk determination does not evaluate the COUs at industrial facilities which must meet OSHA's mandatory standards, requirements, and hierarchy of controls.

EPA asserts that it "does not believe it is appropriate to assume as a general matter that an applicable OSHA requirement or industry practice is sufficient to address the risk, applicable to all potentially exposed workers, or consistently and always properly applied."[60] This statement, however, ignores the OSH Act's purpose, its "general duty clause" for employers and employees, and its hazard communication standards, which are intended to apply to all workers.[61] In the case of OSHA's PPE requirements, while it may be "reasonably foreseen" that in some circumstances workers may not use PPE, on the other hand, the existence of those OSHA standards has and does lead to widespread usage.

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[59] 87 Fed. Reg. at 12694.

[60] *Id.*

[61] The General Duty Clause, Section 5(a)(1) of the OSHA Act, 29 U.S.C. 654(a)(1), applies where there is no standard that applies to the hazard and the employer's own employees are exposed to the alleged hazard. Any hazard for which a Section 5(a)(1) citation/violation is issued to an employer must be reasonably foreseeable.

EPA's proposal to assume no PPE use unless there is 100% compliance by all workers, at all times, under OSHA is unreasonable.

In addition, neither TSCA's definition of "potentially exposed or susceptible subpopulation,"[62] nor the Section 6(b)(4) risk evaluation requirements specify protection of "all" individuals in a potentially exposed or susceptible subpopulation.

When PPE is specifically required under OSHA, it is an integral part of the COUs of manufacturing and processing.[63] PPE is required and utilized as an additional layer of protection. Therefore, under TSCA's requirements that risk determinations be made based upon reasonably available information about a chemical's "conditions of use," EPA should consider PPE and other applicable OSHA standards and practices as part of the COUs in TSCA risk evaluations, including in the risk determinations of those COUs. EPA's proposal would disregard the integral role of PPE under these specific COUs.

C. EPA's proposed change regarding assumptions about compliance with OSHA standards, including PPE, does not comply with TSCA's Section 26 requirements that TSCA risk evaluations be consistent with best available science and based on weight of the scientific evidence.

TSCA Sections 26(h) and 26(i) require EPA to make decisions in Section 6 risk evaluations consistent with "best available science" about whether a chemical's inherent hazards, together with its exposures under the chemical's COUs, present unreasonable risk. EPA's decisions in its risk evaluation must also bebased upon the "weight of the scientific evidence." These Section 26 requirements are applicable to risk evaluations involving workplace COUs when workers are relevant to the risk evaluation. As EPA notes, TSCA risk determinations are part of the risk evaluation,[64] so EPA's risk determinations must also be consistent with the best available science and based on the weight of the scientific evidence. EPA's proposal would allow evaluation and characterization of risks to include consideration of use of PPE but would disallow "assumptions" of PPE and other OSHA requirements from consideration in the risk determinations. This is contrary to requirements in TSCA Section 26 and Section 6(b)(4)(F)(v).

1. EPA should rely upon experts in industrial hygiene, including OSHA and NIOSH.

Industrial hygiene (IH) is a long-standing profession with established workplace hazard recognition, evaluation, and control measures.[65] In order for risk evaluations to meet TSCA Section 26's scientific standards, risk assessors and others involved in evaluating and approving the assessments of workplace risks must meet well-established IH training and certification requirements.[66] The education, training,

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[62] "The term 'potentially exposed or susceptible subpopulation' means a group of individuals within the general population identified by the Administrator who, due to either greater susceptibility or greater exposure, may be at greater risk than the general population of adverse health effects from exposure to a chemical substance or mixture, such as infants, children, pregnant women, workers, or the elderly." 15 U.S.C. § 2602(12).

[63] *See, e.g.,* 29 C.F.R. §§ 1919.132-1910.140.

[64] 87 Fed. Reg. at 12692. Also codified at 40 C.F.R. §702.47.

[65] *See* https://www.osha.gov/sites/default/files/training-library_industrial_hygiene.pdf

[66] *See* http://www.abih.org/become-certified

and certification requirements for a practicing IH are rigorous. IH practices are multidisciplinary and require expertise to integrate the required inputs in order to accurately assess the complexities of workplacehazards and develop risk mitigation measures.

To understand whether current worker protection from exposure to chemicals is consistent with best available science, EPA must consult the expertise of industrial hygienists, including OSHA and NIOSH, to determine whether it can rely upon OSHA controls on exposure as consistent with "best available science" and based upon weight of the scientific evidence.

In its proposed revision "not to assume" PPE in the risk determination and to address PPE only in the risk management rule, however, EPA says it "will" consult with, and "*intends* to strive for consistency with applicable OSHA requirements..."[67] Consistent with TSCA Section 26, EPA should commit to incorporating the expertise of OSHA and other industrial hygienists about current, science-based protection of workers in the workplace. Failure to recognize IH standards that implement OSHA requirements does not comply with the Section 26(h) mandate for EPA to utilize "measures, methods, protocols, methodologies or models, employed in a manner consistent with the best available science."

2. EPA should coordinate with OSHA to ensure risk management decisions are based on best available science.

EPA has not indicated how it will coordinate and consult with OSHA on Section 6 risk management rules under Section 9. TSCA Section 9(a)(6) requires consultation between EPA and OSHA to avoid duplicative requirements,[68] but EPA's assertions that it "will" consult with OSHA and that it will "strive" to be consistent with applicable OSHA requirements and industry practices suggest that such consultation has not occurred. EPA should ensure it is consistent with OSHA's hierarchy of controls approach, which includes long-standing risk management strategies employed by industry, such as engineering controls and industrial hygiene practices, in addition to PPE use. If it does not, EPA's proposed risk management rules involving PPE controls to protect workers from chemical exposures will not be supported by "best available science" and "weight of the scientific evidence."

D. EPA's rationale for its "no assumption of PPE" in risk evaluations is inconsistent with the OSH Act's statutory and regulatory requirements.

1. EPA's rationale is not consistent with the OSH Act or OSHA's implementation of the law.

OSHA regulates worker exposure to chemicals through a variety of broad statutory and more specific regulatory provisions, as well as industry practices that have been built upon the OSH Act's framework. All workers are protected by the OSH Act's General Duty clause[69] and all workers who handle chemicals are protected by OSHA's Hazard Communications standard. In proposing "no assumption" of PPE in

[67] 87 Fed. Reg. at 12694.

[68] 15 U.S.C. 2608(a)(6).

[69] 29 U.S.C. § 654.

riskdeterminations, EPA discounts OSHA's statutory and regulatory framework. The comprehensive requirements under the OSH Act and OSHA's regulations include:

- **The OSH Act's Purpose**. The purpose of the OSH Act is "to assure *so far as possible* every working man and woman in the Nation safe and healthful working conditions andto preserve our human resources."[70] The Act list a series of actions to achieve that purpose, including: encouraging employers and employees in their efforts to reduce the number of occupational safety and health hazards at their places of employment, and to stimulate employers and employees to institute new and to perfect existing programs forproviding safe and healthful working conditions; and authorizing the Secretary of Laborto set mandatory occupational safety and health standards applicable to businesses affecting interstate commerce.[71]

  The OSH Act contemplated implementation through regulatory actions by OSHA, but also through workplace-specific actions by employers and employees, to reduce occupational hazards and to "institute and perfect" existing programs for providing safe and healthful working conditions. These provisions anticipated employer and employee development of workplace-specific engineering controls, industrial hygiene practices, and compliance with same; as well as compliance with OSHA's regulatory standards to protect workers from exposures to specific chemicals and application of a hierarchy of controls to reduce exposures to chemical hazards.

- **Compliance and Enforcement.** Compliance with the OSH Act is achieved through a combination of activities which OSHA performs and activities which the employer performs. Section 8 of the OSH Act authorizes OSHA to conduct inspections and investigations of any workplace where work is performed by employees for an employer.

  This section also requires employers to keep records of their activities to meet the requirements of the OSH Act.[72] Section 10 of the OSH Act includes the procedures for OSHA's enforcement of OSH Act statutory and regulatory requirements.[73]

- **OSHA's Standards.** OSHA's standards generally prescribe a variety of mandatory requirements for assuring "safe and healthful" workplaces in businesses affecting interstate commerce. The mandatory requirements of OSHA's standards, which are relevant to EPA's proposal, include, but are not limited to:

  OSHA's Hazard Communication Standard (29 C.F.R. § 1910.1200)
  OSHA's Hazard Communication Standard addresses worker education and training. "This occupational safety and health standard is intended to address comprehensively the

[70] 29 U.S.C. § 651(b) (emphasis added).
[71] *Id.*
[72] 29 U.S.C. § 657.
[73] 29 U.S.C. § 659.

issue of classifying the potential hazards of chemicals and communicating information concerning hazards *and appropriate protective measures* to employees, and to preempt any legislative or regulatory enactments of a state, or political subdivision of a state, pertaining to this subject." The standard also states: "The measures employees can take to protect themselves from these hazards, including specific procedures the employer has implemented to protect employees from exposure to hazardous chemicals, such as appropriate work practices, emergency procedures, and personal protective equipment to be used."

Personal Protective Equipment (29 C.F.R. §§ 1910.132-1910.140)
This standard requires the employer to "assess the workplace to determine if hazards are present, or are likely to be present, which necessitate the use of personal protective equipment (PPE)." If such hazards are present, or likely to be present, the employer must:

- Select, and have each affected employee use, the types of PPE that will protect the affected employee from the hazards identified in the hazard assessment;
- Communicate selection decisions to each affected employee;
- Select PPE that properly fits each affected employee; and
- Verify that the required workplace hazard assessment has been performed through a written certification that identifies the workplace evaluated; the person certifying that the evaluation has been performed; the date(s) of the hazard assessment; and, which identifies the document as a certification of hazard assessment.

Training (29 C.F.R. § 1910.132(f)(1))
This standard requires the employer to "provide training to each employee who is required by this section to use PPE," including:

- When PPE is necessary;
- What PPE is necessary;
- How to properly don, doff, adjust, and wear PPE;
- The limitations of the PPE; and
- The proper care, maintenance, useful life, and disposal of the PPE.

The standard also requires that each affected employee demonstrate an understanding of the training and the ability to use PPE properly before being allowed to perform work requiring the use of PPE. When the employer has reason to believe that any affected employee who has already been trained does not have the required understanding and skill, the employer must retrain the employee. Retraining is also required when circumstances render training obsolete, *e.g.*, changes in the workplace, and changes in types of PPE to be used.

Personal Protective Equipment Standards for Specific Types of Protection.
These standards provide both general and specific requirements for PPE designed to protect different exposure routes. Relevant to the protection of workers who handle

PV29 include Eye and Face Protection (29 C.F.R. § 1910.133), Respiratory Protection(29 C.F.R. § 1910.134), and Hand Protection (29 C.F.R. § 1910.138).

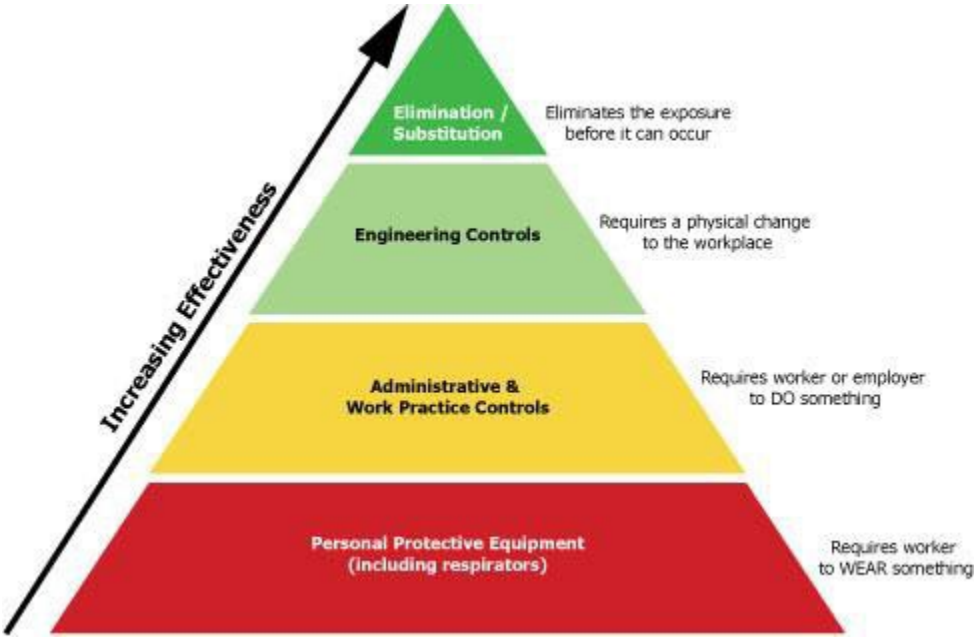
OSHA's Exposure Limitations and other Guidelines
OSHA exposure limitations and other guidelines also help determine what sufficiency of PPE is required to protect workers. These include:

- **OSHA's Permissible Exposure Limits (PELs)**. PELs are OSHA-enforceable legal limits, applicable in general industry (29 C.F.R. § 1910.1000), shipyard employment (29 C.F.R. § 1915.1000), and construction (29 C.F.R. § 1926.1101). OSHA has developed PELs for about 400 substances. Employers must comply with these where employees are potentially exposed to certain chemical hazards.
- **NIOSH's Recommended Exposure Limits (RELs):** The National Institute for Occupational Safety and Health (NIOSH) recommends guideline, not enforceable, occupational exposure limits. The RELs are included in the NIOSH Pocket Guide to Chemical Hazards,[74] which presents key information and data in abbreviated tabular form for 677 chemicals or substance groupings.
- **Other organization's guidelines** that assist in control of occupational health hazards, *e.g.,* ACGIH Threshold Limit Values (TLVs) and Biological Exposure Indices (BEIs);[75] California OSHA PELs;[76] and American Industrial Hygiene Association's (AIHA) Workplace Environmental Exposure Levels (WEELs)[77] subsequently managed by the Toxicology Excellence for Risk Assessment (TERA) Occupational Alliance for Risk Science (OARS) (https://tera.org/OARS/). Some industries also develop occupational exposure limits for chemicals ensureworker safety at their facilities.

Hierarchy of Controls on Exposures:

It is OSHA's long-standing policy that elimination/substitution of exposure to a hazard, before it can occur, is the most effective type of control to protect workers. Where that cannot be done, engineering and work practice controls are the primary means to reduce employee exposure to toxic chemicals, where feasible. Respiratory protection is required to be used if engineering or work practice controls are infeasible or while engineering controls are being implemented.[78] OSHA uses a hierarchy of controls (see illustration below) as a means of determining how to implement feasible and effective controls.[79]

[74] https://www.cdc.gov/niosh/npg/default.html
[75] https://www.acgih.org/science/tlv-bei-guidelines/
[76] https://www.dir.ca.gov/title8/5155table_ac1.html
[77] https://www.aiha.org/get-involved/aiha-guideline-foundation/weels
[78] https://www.osha.gov/chemical-hazards.
[79] https://www.osha.gov/chemical-hazards/controlling-exposure



> At OSHA regulated facilities, when effective engineering controls are not feasible, or while they are being implemented, employers must provide appropriate PPE at no cost to workers, provide appropriate training and education regarding its use, and ensure that workers use it properly.[80]

EPA ignores that OSHA requires employers to review the chemical hazards in the workplace and to require employees to use appropriate PPE where needed to protect them from chemical exposures via inhalation, ingestion, direct injection, dermal and/or eye exposures. EPA ignores that most employers subject to OSHA comply with OSHA's requirements to provide PPE and train their employees how to use it. EPA ignores that OSHA inspects and investigates facilities to enforce PPE and other OSHA requirements.

2. EPA has not provided a reasoned explanation to support its proposal on PPE.

EPA's rationale for its proposed "no assumption of PPE" in risk determinations is not a reasoned explanation. EPA states that the Agency does not "believe" that PPE is "sufficient to address the risk, applicable to *all* potentially exposed workers, or consistently and *always* properly applied," and that it "cannot assume that *all* facilities have adopted these practices for the purposes of making the TSCA risk determination."[81]

EPA has not provided reasonably available data or information to support its "belief" concerning the insufficiency of PPE at OSHA regulated facilities. EPA cites no records of widespread non-compliance

[80] *Id.*
[81] 87 Fed. Reg. at 12694 (emphasis added).

with OSHA by employers who manufacture, process, distribute, use, or dispose of TSCA chemicals generally or PV29 specifically. EPA cites no data or information showing chemical industry workers largely refuse the PPE they are provided by their employers. EPA cites no data that workers are universally being harmed because they do not use PPE. In addition to the regulatory requirements listed above, the OSH Act's General Duty Clause applies to all employers who can be cited for exposing their employees to reasonably foreseeable hazards.

EPA's proposal could inadvertently create regulatory confusion and overlap requirements when attempting to protect workers through a whole chemical determination for PV29 and a risk management rule that would apply to all workplaces involving PV29 within the scope of the risk evaluation, including workplaces that are already subject to OSHA. In other words, if this proposed approach to PPE is applied broadly in all future TSCA risk evaluations, EPA would treat already regulated OSHA employers and employees and non-OSHA regulated employers and employees as operating under identical conditions of use, requiring identical risk management controls and subject to identical enforcement.

The Risk Evaluation Rule requires EPA to base its risk evaluations on reasonably available information.[82] EPA has not met that requirement with respect to sufficiency of PPE in the PV29 risk determination.

E. Addressing PPE (and other OSHA requirements) only in the risk management rule, not as part of the conditions of use in the risk evaluation, has significant potential impacts.

If EPA adopts and applies the "no PPE" assumption to all TSCA risk determinations going forward, itwill have serious impacts on the regulated community as well as on the credibility of both EPA and OSHA regulations:

- **A Modification in TSCA's Focus from Risk-Based Determinations to Assumption-based Risk Management:** In the context of addressing worker exposure to chemicals in TSCA risk evaluations and risk determinations, EPA's proposal would modify TSCA's focus from the science-based decision making in the risk evaluations and the risk determinations, as required by TSCA Sections 6 and 26, to default assumption-based decision-making in risk management rules.
- **Duplicative, Inconsistent and Costly Requirements:** TSCA risk management rules might impose costly requirements that are either duplicative of or inconsistent with those that OSHA has already imposed on employers and employees in OSHA-regulated businesses affecting interstate commerce.
- **Lack of Transparency about Risk Management Rules:** EPA's proposal is not transparent about its plans for implementation of this proposed change in the risk management rule itself. How will EPA require PPE in the risk management rules? Is EPA coordinating with OSHA and/or the regulated community to determine how PPE is used in a COUs? Will EPA incorporate into the Risk Management Rule a requirement that COUs comply with OSHA regulatory requirements? Will EPA establish a single PPEcontrol on all workplaces, whether OSHA regulated or not? Or will EPA require a range of controls depending on what worker protection is already in place, where there is

[82] *See* 40 C.F.R. §702.41(b).

need and where not?

- **Bad Public Policy:** It is bad policy for one federal agency to assume – without supporting data or information -- that another federal agency has not been complying with and enforcing laws under its jurisdiction. EPA's proposal ignores OSHA's standardsand OSHA's expertise in protecting workers.
- **OSHA's Jurisdiction Would Be Threatened:** Although Congress provided EPA additional authority to protect workers (as a potentially exposed or susceptible subpopulation) from exposures to TSCA chemicals through TSCA regulations, nothing in the statute or its legislative history suggests Congress wanted EPA to displace OSHA's primacy in assuring safe and healthful workplaces. Yet EPA's proposal suggests EPA believes it has broad authority to make TSCA regulatory decisions about PPE in the workplace whether or not these decisions are consistent with OSHA's standards and regulations and industrial practice over the years. 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 Section 9.
- **EPA's Resources Will Be Challenged:** EPA lacks the expertise and the resources to regulate *all* workplaces involving potential TSCA chemical exposures and to enforce those requirements. TSCA's risk evaluation and risk management rule process was not intended, or structured, to replace OSHA's workplace regulations. EPA's small risk evaluation teams and risk management teams for each chemical, and all COUs of that chemical, do not have the resources, expertise, or time to replace OSHA's regulatory infrastructure that has been developed over decades of notice and comment rulemaking. Workplaces subject to OSHA, as described above, have developed engineering and administrative controls to comply with such standards. Employees have been trained on standard operating procedures detailing how specific tasks must be taken to safely operate the engineering controls. Hazard assessments, built upon industrial hygiene monitoring, have been developed for each task to implement PPE as an additional layer of protection. Industrial hygiene standards are also followed to confirm the ongoing effectiveness of the engineering controls. Again, EPA should coordinate with OSHA pursuant to TSCA Section 9.
- **Unintended Consequences:** If EPA's proposal is adopted, the Agency will need to develop clear, accurate communications materials to explain EPA's new approach to PPE to the already OSHA-regulated community. A rushed approach to regulating the workplace could implement PPE requirements in a manner not consistent with existing best practices developed under OSHA and other industrial standards, leading to unintended consequences that undermine EPA's objectives for protecting workers. For example, there are specific fit-testing requirements in place that must be built into any new regulations. Also, unwarranted PPE requirements could lead to, for example, heat exhaustion; in some cases, the inability to effectively preform basic tasks because of utilizing chemical gloves when not needed or creating an increased trip hazard if respirators are required at all times.

F. Alternative Recommendation for EPA's Consideration

ACC recommends that EPA take a different approach to addressing the protection of workers as a potentially exposed or susceptible subpopulation under TSCA.

- EPA should consider more targeted ways to address its concerns about the subpopulation of workers who are *not* covered by OSHA standards because they are self-employed individuals orpublic sector workers not covered by their State plan. A more targeted approach would allow EPA to consider different workplace conditions of use in the risk evaluation and risk determination, leading to risk management rules that are targeted to address the chemical substance under COU-specific determinations of unreasonable risk.
- EPA should develop risk evaluations and make risk determinations on the basis of reasonably available information that meets TSCA's Sections 6 and 26 standards, not on the basis of assumptions that PPE is "always" or "never" used in the workplace. This information would formthe basis for risk determinations of either no unreasonable risk or unreasonable risk of the chemical under its workplace COUs and inform risk management rules.
- Rather than assume either "PPE" or "no PPE" in TSCA risk determinations, EPA should seek tosupport its risk determinations with available information from industry/businesses about their current worker exposure controls and the efficacy of those controls. During the scoping process of a TSCA risk evaluation. EPA should request information from the affected industry and businesses – both OSHA-regulated and non-OSHA regulated -- about the worker protection practices that are in place at their facilities to reduce chemical exposures to workers.
- EPA should work with OSHA during the scoping phase about information OSHA might provideEPA about compliance by employers and employees at facilities with mandatory OSHA requirements. If warranted, EPA and OSHA could also discuss improved enforcement of OSHArequirements. EPA should consult with NIOSH and OSHA regarding PPE specifically and other hierarchy of controls generally. EPA should also consult with NIOSH and OSHA about ways EPA could improve its own industrial hygiene expertise.
- In light of TSCA's best available science and weight of the scientific evidence requirements, riskmanagement requirements should also be targeted, depending on whether they apply to OSHA- regulated businesses or non-OSHA regulated businesses.
- EPA could consider the European approach to COUs for the workplace, *e.g.*, where industrial activities have ongoing engineering controls and strong industrial hygiene systems, including PPEand monitoring; professional users of chemicals have some PPE but not necessarily engineering controls with IH programs; and essentially "consumer" uses of chemicals have no PPE.
- When unreasonable risk is found under a chemical's workplace COUs, risk management requirements (whether new for non-OSHA regulated businesses, or additional for OSHA

regulated businesses) should materially contribute to reducing the risk to workers so that it is not unreasonable.

- EPA should consider as a potential risk management action, where warranted by specific COUs'risk evaluations, the establishment of federally enforceable training/certification for self- employed individuals, or public sector workers not covered by a state plan.
- EPA should base its risk management requirements on OSHA standards.

* * *

Because EPA has not provided a science-based, reasoned explanation for these changes, EPA should withdraw the draft revised PV29 risk determination and provide a reasoned explanation for its proposed changes. At a minimum, EPA should provide an opportunity for public comment before applying these changes to any chemical substance.