U.S. Environmental Protection Agency

Colour Index Pigment Violet 29 (PV29); Revision to Toxic Substances Control Act (TSCA) Risk Determination

EPA–HQ–OPPT–2016–0725

Response to Public Comments

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Acronyms and Abbreviations

COU	Condition of use
EPA	U.S. Environmental Protection Agency
NIOSH	U.S. National Institute for Occupational Safety and Health
ONU	Occupational non-user
OSHA	U.S. Occupational Safety and Health Administration
OSH Act	Occupational Safety and Health Act of 1970
PEL	Permissible exposure limit
PESS	Potentially exposed or susceptible subpopulation
PPE	Personal protective equipment
PV29	Colour Index Pigment Violet 29
SACC	Scientific Advisory Committee on Chemicals
TSCA	Toxic Substances Control Act
UFP	Ultrafine particulates
U.S.	United States
U.S.C.	United States Code

Introduction

On March 7, 2022, the U.S. Environmental Protection Agency (EPA) published a notice of availability and request for comment on a draft revision to the Toxic Substances Control Act (TSCA) Risk Determination for Colour Index Pigment Violet 29 (PV29). In the notice, EPA announced that public comments would be accepted until April 21, 2022.

EPA received a total of 14 public comments and determined that all comments are unique and responsive to the request for comments. Following this introduction, Table 1, Index of Comment Submissions Sorted by Submission Number, identifies the commenter name and the comment number for the 14 unique submissions included in this summary.

The comment summaries and responses that follow are organized into issue topic areas, as indicated in the table of contents.

Table 1: Index of Comment Submissions Sorted by Submission Number

Submission Number	Organization
EPA-HQ-OPPT-2016-0725-0075	Environmental Protection Network
EPA-HQ-OPPT-2016-0725-0076	PRINTING United Alliance
EPA-HQ-OPPT-2016-0725-0077	Chemical Users Coalition
EPA-HQ-OPPT-2016-0725-0078	Environmental Defense Fund
EPA-HQ-OPPT-2016-0725-0079	Eastman Chemical Company
EPA-HQ-OPPT-2016-0725-0080	Alliance for Automotive Innovation
EPA-HQ-OPPT-2016-0725-0081	American Chemistry Council
EPA-HQ-OPPT-2016-0725-0082	Color Pigments Manufacturers Association
EPA-HQ-OPPT-2016-0725-0083	Safer Chemicals Healthy Families et al.
EPA-HQ-OPPT-2016-0725-0084	Institute of Scrap Recycling Industries, Inc.
EPA-HQ-OPPT-2016-0725-0085	Occupational Safety and Health Law Project
EPA-HQ-OPPT-2016-0725-0086	National Association of Manufacturers
EPA-HQ-OPPT-2016-0725-0087	Air Conditioning, Heating, and Refrigeration Institute
EPA-HQ-OPPT-2016-0725-0088	American Coatings Association

Section 1 – General support for the draft revision to the risk determination

Comments that provided general support also provided more substantive comments that are summarized in other portions of the summary report.

Several commenters provided general support for the PV29 revised unreasonable risk determination including non-governmental environmental and health advocacy organizations (0078, 0075, 0085, and 0083). The organizations explained that they favored the change to a whole chemical approach because, among other things, the whole chemical approach better aligns with the goals of TSCA and the 2016 Lautenberg amendments. The organizations believe that by removing the assumption that workers wear personal protective equipment (PPE), EPA can adopt risk management that better protects not only workers but potentially exposed or susceptible subpopulations.

EPA RESPONSE:
EPA appreciates the support for the revised unreasonable risk determination.

Section 2 – General opposition to the draft revision to the unreasonable risk determination

An industry trade organization (0077) stated that the draft revisions to the risk determination will change public interpretations of risk, have unwarranted impacts on future risk management decision-making and cause unintended regulatory impacts on articles containing certain substances.

EPA RESPONSE:
EPA would like to reiterate that this action pertains specifically to the unreasonable risk determination for PV29. While EPA intends to consider and may take additional similar actions on other of the first ten chemical substances with completed TSCA section 6 risk evaluations, EPA is taking a chemical-specific approach to revising the risk determination of this risk evaluation and is incorporating new policy direction in a surgical manner, while being mindful of Congressional direction on the need to complete risk evaluations and move toward any associated risk management activities.

With respect to impacts from this revised unreasonable risk determination on risk management of PV29, EPA will propose a regulatory action with requirements under TSCA section 6(a) to the extent necessary so that PV29 no longer presents unreasonable risk. The public will have an opportunity to comment on the proposed regulatory action, and EPA will consider such public comments and any additional information before finalizing the rulemaking. As a result, EPA expects that impacts to PV29 containing articles will be considered during rulemaking. EPA encourages the commenter to submit specific comments about regulatory impacts on PV29-containing articles during the future public comment period for the PV29 risk management rule.

Section 3 – Legal issues

Other comments discussing legal issues with the whole chemical approach, including its consistency with TSCA, are discussed below in Section 4.1.

EPA received comments related to the process of revising the risk determination. A couple of industry trade organizations (0081, 0082) requested that EPA withdraw the draft revision to the risk determination and provide an explanation for the proposed changes and additional public comment opportunity before applying the changes. Furthermore, the commenter believes the whole chemical approach lacks clarity and will have substantial impacts on future chemical analysis.

One industry trade organization (0082) stated that although the draft revised risk determination reads as if it were a drop-in replacement for existing Section 5 of the final risk evaluation, in other instances, the draft risk determination references revisions that would be made to Section 5. The industry trade organization urged that it is even more problematic that the draft risk determination says that "the discussion of the issues in this draft revision to the risk determination would supersede any conflicting statements in the prior PV29 Risk Evaluation (January 2021) and the response to comments document." The commenter asserted that this is not an acceptable approach to drafting documents with legal effect that the public would rely on and suggested that EPA integrate Section 5 into what would become a revised final risk evaluation so that it is complete and internally consistent, which may require revising other sections of the document as well.

An advocacy group (0078) commented at length that the *Kisor* case cannot be applied to question the viability of the whole chemical approach as the Supreme Court in this case reaffirmed the long-standing principle that courts must generally defer to agencies' reasonable interpretations of their own ambiguous regulations, and that the list of considerations provided by the Court in *Kisor* favors a reviewing court granting deference to EPA on its whole chemical approach.

EPA RESPONSE:

The draft revised unreasonable risk determination for PV29 was published in March 2022 along with the Federal Register Notice explaining the whole chemical approach to the PV29 risk determination, and why EPA believes that a whole chemical approach to PV29 better aligns with TSCA's objective of protecting health and the environment. EPA provided notice and an opportunity for public comment on the draft revised risk determination for PV29 and the approach described in the Federal Register Notice.

With respect to EPA's approach to changing the PV29 risk determination, or the comment that EPA should not issue a replacement risk evaluation Section 5, but rather a completely new risk evaluation, the revised Section 5 of the PV29 Risk Evaluation is sufficient to describe the determination of unreasonable risk of PV29 as a "whole chemical substance" and to explain the change in approach regarding assuming use of PPE by workers. As mentioned, the whole chemical risk determination approach does not impact the underlying data and analysis presented

in the risk characterization of the PV29 Risk Evaluation. The risk evaluation already includes exposure analysis with and without PPE. Table 4-4 in the risk evaluation presents risk estimates for each condition of use with and without PPE. EPA has made no changes to this scientific analysis. The Agency believes that the revised risk determination is sufficiently clear that it supersedes any conflicting statements in the January 2021 risk evaluation that it is neither necessary nor an appropriate use of resources to reissue the entire risk evaluation.

EPA appreciates comments concerning the application of *Kisor v. Wilkie,* 139 S. Ct. 2400 (2019), to EPA's draft revised unreasonable risk determination for PV29. Similar to the commenter's view, EPA maintains that its interpretation of 40 CFR 702.47 as permitting the issuance of either condition of use-specific or whole chemical risk determinations is a reasonable interpretation of that regulation, and would be entitled to *Auer* deference when using the multifactor test set forth in *Kisor*.

Section 4 – Revisions to the risk determination

Section 4.1 – Whole chemical approach vs. individual condition of use (COU)

Section 4.1.1 – Support for the whole chemical approach

Some commenters (0075, 0078, 0083), in expressing support for the whole chemical approach for PV29, urged that the approach is consistent with the language and purpose of TSCA. For example, an advocacy organization (0083) stated that TSCA requires whole chemical determinations of unreasonable risk to satisfy the mandate to integrate and assess available information on hazards and exposures from the COU, especially in cases of potentially exposed or susceptible subpopulations, multiple routes of exposure, and combined risk to exposed populations across the chemical's COUs and life-cycle stages. A couple of advocacy organizations (0078, 0083) reasoned that TSCA unambiguously mandates EPA to conduct a whole chemical risk determination as the language of the statute referencing decision-making for a chemical substance dictates that EPA cannot segment its determination into separate findings of unreasonable risk for some COUs and no unreasonable risk for others. One advocacy group (0078) urged EPA to take a whole chemical approach for all chemicals' future risk determination to fulfill TSCA's mandate that EPA identify the full risk posed by each chemical.

Another advocacy organization (0085) expressed support for the whole chemical approach, urging that PV29 is better characterized as a whole chemical for purposes of the risk determination. The commenter reasoned that all the exposure data for PV29 are from a single manufacturing workplace; the data do not provide specific information about exposure in non-manufacturing COUs and thus do not permit separate risk determinations for each COU. The commenter concluded that EPA therefore lacks data that would permit exempting any COU from its unreasonable risk determination. The commenter asserted that a whole chemical approach better aligns with TSCA's objective of protecting health and the environment.

Some commenters (0078, 0083) stated that EPA is correct to rely on the 2019 Ninth Circuit's interpretation of the governing regulation in *Safer Chemicals v. EPA* to conduct a whole chemical risk determination.

EPA RESPONSE:
EPA appreciates the comments in support of the whole chemical approach. As EPA explained in the Federal Register Notice announcing the availability of the draft revised risk determination for PV29, notwithstanding EPA's choice to issue condition of use-specific risk determinations to date, EPA interprets its risk evaluation regulation to also allow the Agency to issue whole chemical risk determinations. Either approach is permissible under the regulation, and the Ninth Circuit Court of Appeals also recognized the ambiguity of the regulation on this point in *Safer Chemicals v. EPA*. EPA plans to consider the appropriate approach for each chemical substance risk evaluation on a case-by-case basis, taking into account considerations relevant to the specific chemical substance in light of the Agency's obligations under TSCA. EPA expects that this case-by-case approach will provide greater flexibility to evaluate and manage unreasonable risk from individual chemical substances. 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.

For PV29, the whole chemical approach is appropriate because there are benchmark exceedances for substantial number of conditions of use (spanning across most aspects of the chemical lifecycle–from manufacturing (including import), processing, industrial and commercial use, and disposal) for worker and occupational non-user health and the severity of the health effects associated with PV29 exposures. Because these chemical-specific health hazards and exposures cut across the conditions of use within the scope of the risk evaluation, a substantial number of conditions of use (10 of the 14 evaluated) drive the unreasonable risk, and the Agency is better positioned to achieve its TSCA objectives for PV29 when issuing a whole chemical determination for PV29, it is appropriate for the Agency to make a determination that the whole chemical presents an unreasonable risk.

Section 4.1.2 – Opposition to whole chemical approach

Some commenters, including industry trade associations (0077, 0081, 0080, 0082), opposed the whole chemical approach. Their comments against the whole chemical approach, included:

- 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 (0081).
- EPA has provided no principles or criteria by which it will determine when to take a whole chemical approach in risk determinations (0081).
- The whole chemical approach would have substantial unintended consequences, including prolonged uncertainty for the regulated community, non-science-based market

impacts, and the continued use of resources to research uses which pose no risk (0081, 0080).

- The whole chemical approach would result in a negative finding on uses that may not have an unreasonable risk, regrettable substitutions as manufacturers seek to quickly implement functional alternatives, and public confusion, as the public will not know which uses are safe and which pose risk (0081, 0080).
- Another industry trade organization (0079) stated that the whole chemical approach would result in overarching, less targeted risk management measures. In addition, the commenter warned of potential supply chain disruptions resulting from regulating upstream activities to manage downstream risk.

An industry trade organization (0077) urged EPA to continue to make COU-specific risk determinations for PV29 and other chemical substances because such an approach is grounded in the statute and regulations and supported by sound science; this commenter said that using the whole chemical approach would result in skewed understandings of the risk of chemical substances.

An industry trade organization (0077) also said that EPA's policy changes implemented in the revised PV29 and other risk determinations may lead to unwarranted impacts on importers of articles containing a chemical substance for which EPA conducts a risk evaluation. The commenter explained that in the January 2021 PV29 Risk Evaluation, EPA concluded that consumer uses of PV29 in professional quality watercolor and acrylic artist paint and industrial/commercial use in automobile plastics and industrial carpeting do not present an unreasonable risk. However, the commenter noted that by taking a whole chemical approach, EPA may influence a public perception that these COUs present an unreasonable risk. Also, the whole chemical approach may increase the likelihood that EPA will regulate the use of PV29 in articles that were previously deemed to not present an unreasonable risk, specifically because EPA views TSCA section 6(a) as permitting EPA to regulate upstream activities in order to address downstream activities driving unreasonable risk even if those upstream activities do not drive the unreasonable risk.

An industry trade organization (0088) expressed concern for the potential for a whole chemical approach during risk mitigation that would be a "one size fits all" approach, and how this approach may compound with flaws from assumptions made within the risk evaluation. The commenter said that this approach would extend risk mitigation to COUs that do not pose unreasonable risk.

EPA RESPONSE:

As EPA explained in the Federal Register Notice announcing the availability of the draft revised risk determination for PV29, EPA acknowledges a lack of specificity in the statute and inconsistency in the regulations with respect to the presentation of risk determinations in TSCA section 6 risk evaluations. Notwithstanding EPA's choice to issue condition of use-specific risk

determinations to date, EPA interprets its risk evaluation regulation to also allow the Agency to issue whole chemical risk determinations. Either approach is permissible under the regulation.

EPA has articulated the basis for a whole chemical approach to PV29 in detail in the Federal Register Notice announcing the availability of the draft revised risk determination for PV29. As explained therein, the Agency has inherent authority to replace, revise, reconsider, or repeal previously made decisions to the extent permitted by law, with a reasoned explanation. *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009); *see also Motor Vehicle Mfrs. Ass'n v. State Farm Mutual Auto. Ins. Co.*, 463 U.S. 29, 42 (1983). The revised unreasonable risk determination for PV29 reflects EPA's objective of conducting a technically sound, manageable evaluation to determine whether the chemical substance—not just individual uses or activities—presents an unreasonable risk. EPA plans to consider the appropriate approach for each chemical substance risk evaluation on a case-by-case basis, taking into account considerations relevant to the specific chemical substance. In the case of PV29, ten of the fourteen conditions of use drive the unreasonable risk and the chemical-specific properties cut across the conditions of use within the scope of the risk evaluation; therefore, EPA has concluded that the risk determination for PV29 is better characterized by the whole chemical approach. EPA believes this is a reasonable approach under TSCA and the Agency's implementing regulations.

Responding to commenters' ideas concerning conditions of use which were identified in the January 2021 PV29 Risk Evaluation as not presenting unreasonable risk, in this final revised risk determination, EPA identifies which conditions of use drive the unreasonable risk and which conditions of use do not drive the unreasonable risk of PV29. Furthermore, there is no change in the underlying PV29 risk characterization with regard to conditions of use that may relate to replacement parts or articles. As indicated in the final revised unreasonable risk determination, distribution in commerce, industrial and commercial uses in plastic and rubber products in automobile plastics and industrial carpeting, and consumer uses of PV29 in professional quality watercolor and acrylic artist paint do not drive the unreasonable risk of PV29. Consistent with the statutory requirements of TSCA section 6(a), EPA will propose risk management actions to the extent necessary so that PV29 no longer presents an unreasonable risk. EPA expects to focus its risk management action on the conditions of use that drive the unreasonable risk. However, it should be noted that, under TSCA section 6(a), EPA is not limited to regulating the specific activities found to drive unreasonable risk and may select from among a suite of risk management requirements in section 6(a) related to manufacture (including import), processing, distribution in commerce, commercial use, and disposal as part of its regulatory options to address the unreasonable risk. As a general example, EPA may regulate upstream activities (e.g., processing, distribution in commerce) in order to address downstream activities (e.g., consumer uses) driving unreasonable risk even if the upstream activities do not drive the unreasonable risk.

Under TSCA section 6(c)(2)(D) and (E), any relevant consideration of replacement parts and articles will take place during the risk management rulemaking stage, based on the risk evaluation findings. The public will have an opportunity to provide comments and any additional information during the comment period of the proposed risk management rule.

Section 4.1.3 – Inconsistency with TSCA and Risk Evaluation Rule

Several commenters (0077, 0080, 0081, 0082, 0087) asserted that a whole chemical approach is inconsistent with TSCA and its implementing regulations. One commenter (0081) stated that by proposing a whole chemical approach, EPA contradicts TSCA and its implementing regulations, and did not use sound reasoning. In support of this, a few industry trade organizations (0081, 0077, 0082) cited TSCA section 6(b)(4)(F)(i) and (iv) and stated that EPA must integrate and assess available information on hazards and exposures for the COUs of the chemical substance and consider the likely duration, intensity, frequency and number of exposures under the COUs. One of the industry trade organizations (0082) claimed that risk management may therefore only be applied to a COU that drives the unreasonable risk and that EPA's statement that it "is not limited to regulating the specific activities found to drive unreasonable risk and may select from among a suite of risk management options related to manufacture, processing, distribution in commerce, commercial use, and disposal in order to address the unreasonable risk" is incorrect. An industry trade organization (0077) urged that a whole chemical approach would functionally disable TSCA section 6(c)(2)(E), as well as Congress' intent for including it, since the provision makes clear that the extent to which articles should be regulated is dictated by what risks a risk evaluation identifies as stemming from exposure to a chemical substance in an article, and articles should not be regulated to ameliorate risk presented by other conditions of use.

A couple commenters (0077, 0079) stated that the whole chemical approach is inconsistent with the structure created by Congress in the Lautenberg Amendments to TSCA in 2016. Specifically, one of the industry trade organizations (0077) said that future risk evaluations will be conducted for chemical substances that EPA has already determined "may present" an unreasonable risk through the prioritization process. The commenter stated that if the whole chemical approach is used, the distinction between the "may present" an unreasonable risk standard for prioritization and the "presents" standard for triggering risk management regulations would be lost.

Another industry trade organization (0087) stated that because EPA has a statutory obligation under TSCA to evaluate all of a chemical substance's COUs, so too should the Agency continue to apply risk management actions to specific use cases and not to the whole chemical in all its uses. The commenter suggested that EPA should publish risk evaluations that reflect the applicable level of risk based on various uses, documenting both cases of reasonable and unreasonable risk.

As to inconsistency with the Risk Evaluation Rule, a few commenters (0071, 0081, 0082) urged that the Risk Evaluation Rule unambiguously states that EPA will make unreasonable risk determinations for each COU. The commenter claimed that making unreasonable risk determinations on a COU-by-COU basis is essential to the mechanisms outlined in the Risk Evaluation Framework rule. The commenter concluded that, until EPA revises the Risk Evaluation Rule to provide for whole chemical risk determinations, any final risk management rule premised on a whole chemical risk determination would have been issued without observance of procedure required by law and hence would be illegal.

A few commenters (0077, 0081, 0082) stated that the practical effect of the whole chemical approach is that there are unlikely to be any determinations of no unreasonable risk. The commenters urged that the whole chemical approach thus impermissibly renders parts of the statute – the provisions for a finding of no unreasonable risk – superfluous. The industry trade organizations stated that the inclusion in the statute of provisions for a finding of no unreasonable risk, including, for example, TSCA section 18(a)(1)(B)(i), is evidence that Congress must have intended for specific COUs to be evaluated by the Agency and risk determinations made for each of those uses. On the other hand, an advocacy group (0078) discounted this position, asserting that whether industry actors believe that a whole chemical approach may result in fewer findings of "no unreasonable risk" has no bearing on the legitimacy of EPA's approach under TSCA.

A couple of industry trade organizations (0081, 0080), supported by another industry trade organization (0082), stated that if the individual COU approach is no longer employed, then any opportunity for obtaining the federal preemption of state or local requirements provided for under TSCA Section 18(a) for COUs that pose no unreasonable risk would either be delayed by years until EPA promulgated a final risk management rule or potentially eliminated depending on the scope of the risk management rule. One commenter (0080) noted that the consequence of allowing states to issue chemical regulations while EPA assesses a chemical and until EPA issues a final risk management rule could create an unworkable and confusing set of requirements for any sector.

EPA RESPONSE:

EPA followed the requirements under TSCA section 6(b)(4) in issuing this revised unreasonable risk determination for PV29, including all requirements for a risk evaluation under TSCA section 6(b)(4)(F). Specifically, Section 4 of the final risk evaluation describes how EPA integrated and assessed reasonably available information on hazards and exposures for the conditions of use for PV29 considering factors such as environmental releases, environmental monitoring and biomonitoring, toxicity testing with fish, aquatic invertebrates, and aquatic plants, and physical and chemical properties, as well as use of carbon black to estimate toxicity and frequency, duration, intensity and number of exposures to workers and consumers.

As EPA explained in the Federal Register Notice announcing the availability of the draft revised risk determination for PV29, EPA plans to consider the appropriate approach for each chemical substance risk evaluation on a case-by-case basis, taking into account considerations relevant to the specific chemical substance in light of the Agency's obligations under TSCA. For PV29, the whole chemical approach is appropriate because there are benchmark exceedances for substantial number of conditions of use (spanning across most aspects of the chemical lifecycle–from manufacturing (including import), processing, industrial and commercial use, and disposal) for worker and occupational non-user health, and the severity of the health effects associated with PV29 exposures. Since these chemical-specific properties cut across the conditions of use within the scope of the risk evaluation, the Agency's risk findings and conclusions encompass a substantial amount of the conditions of use and the Agency is better positioned to achieve its TSCA objectives for PV29 when using a whole chemical unreasonable risk determination for

PV29, EPA concludes that the Agency's risk determination for PV29 is better characterized as a whole chemical risk determination rather than condition of use-specific risk determination.

As explained in the Federal Register Notice to the draft revised unreasonable risk determination for PV29, EPA has the inherent authority to reconsider previous decisions when permitted by law and supported by reasoned explanation. *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009); *see also Motor Vehicle Mfrs. Ass'n v. State Farm Mutual Auto. Ins. Co.*, 463 U.S. 29, 42 (1983). EPA acknowledges a lack of specificity in the statute and inconsistency in the regulations with respect to the presentation of risk determinations in TSCA section 6 risk evaluations. In the January 2021 PV29 Risk Evaluation, EPA applied 40 CFR 702.47 based on one particular passage in the preamble to the final Risk Evaluation Rule[1], which stated: "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 FR 33726, 33744. However, in contrast to this portion of the preamble of the final Risk Evaluation Rule, the regulatory text itself and other statements in the preamble reference a risk determination for *the chemical substance* under its conditions of use, rather than separate risk determinations for each of the conditions of use of a chemical substance. The text of 40 CFR 702.47 states: "[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" (emphasis added). Other language reiterates this perspective. For example, 40 CFR 702.31(a) states that the purpose of the rule is to establish the EPA process for conducting a risk evaluation to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment as required under TSCA section 6(b)(4)(B). Likewise, there are recurring references to whether the chemical substance presents an unreasonable risk in 40 CFR 702.41(a). Notwithstanding the one preambular statement about condition of use-specific risk determinations, the preamble to the final rule also contains support for a risk determination on the chemical substance as a whole. In discussing the identification of the conditions of use of a chemical substance, the preamble notes that this task inevitably involves the exercise of discretion on EPA's part, and, "[a]s EPA interprets the statute, the Agency is to exercise that discretion consistent with the objective of conducting a technically sound, manageable evaluation to determine whether a chemical substance—not just individual uses or activities—presents an unreasonable risk." (82 FR at 33729).

Therefore, notwithstanding EPA's choice to issue condition of use-specific risk determinations to date, EPA interprets its risk evaluation regulation to also allow the Agency to issue whole chemical risk determinations. Either approach is permissible under the regulation, and the

[1] Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act (82 FR 33726) (July 20, 2017).

Agency's interpretation is entitled to *Auer* deference when using the multifactor test set forth in *Kisor*. As such, notice and comment rulemaking is not necessary before revising the PV29 risk determination.

The unreasonable risk determination does not consider costs or other nonrisk factors. In making the unreasonable risk determination, EPA considers relevant risk-related factors, including, but not limited to: the effects of the chemical substance on health and human exposure to such substance under the conditions of use (including cancer and non-cancer risks); the effects of the chemical substance on the environment and environmental exposure under the conditions of use; the population exposed (including any PESS); the severity of hazard (including the nature of the hazard, the irreversibility of the hazard); and uncertainties. EPA takes into consideration the Agency's confidence in the data used in the risk estimate. This includes an evaluation of the strengths, limitations, and uncertainties associated with the information used to inform the risk estimate and the risk characterization. Therefore, the PV29 chemical unreasonable risk determination takes in consideration the hazard of PV29 and the exposures from all conditions of use of PV29.

Furthermore, there is no change in the underlying PV29 risk evaluation nor in the revised risk determination for PV29 with regard to conditions of use that may relate to articles. In the final revised risk determination, EPA identifies which conditions of use drive the unreasonable risk of PV29. Consistent with the statutory requirements of TSCA section 6(a), EPA will propose risk management action to the extent necessary so that PV29 no longer presents an unreasonable risk. EPA expects to focus its risk management action on the conditions of use that drive the unreasonable risk. However, it should be noted that, under TSCA section 6(a), EPA is not limited to regulating the specific activities found to drive unreasonable risk and may select from among a suite of risk management requirements in section 6(a) related to manufacture (including import), processing, distribution in commerce, commercial use, and disposal as part of its regulatory options to address the unreasonable risk. As a general example, EPA may regulate upstream activities (e.g., processing, distribution in commerce) in order to address downstream activities (e.g., consumer uses) driving unreasonable risk even if the upstream activities do not drive the unreasonable risk.

There is no change in the underlying PV29 risk evaluation nor in the proposed revised risk determination for PV29 with regard to conditions of use that may relate to replacement parts or articles. The revised risk determination identifies conditions of use that drive unreasonable risk from PV29. Under TSCA section 6(c)(2) (D) and (E), any relevant consideration of replacement parts and articles will take place during the risk management rulemaking stage, based on the risk evaluation findings. The public will have an opportunity to provide comments and any additional information during the comment period of the proposed risk management rule.

TSCA section 18(c)(3) defines the scope of federal preemption with respect to any final rule EPA issues under TSCA section 6(a). That provision provides that federal preemption of "statutes, criminal penalties, and administrative actions" applies to "the hazards, exposures, risks, and uses or conditions of use of such chemical substances included in any final action the Administrator takes pursuant to [TSCA section 6(a)]." EPA reads this to mean that states are

preempted from imposing requirements through statutes, criminal penalties, and administrative actions relating to any "hazards, exposures, risks, and uses or conditions of use" evaluated in the final risk evaluation and informing the risk determination that EPA addresses in the TSCA section 6(a) rulemaking. For example, federal preemption applies even if EPA does not regulate in that final rule a particular COU, but that COU was evaluated in the final risk evaluation.

EPA also notes that there are separate statutory standards and processes for designating chemical substances as high-priority for risk evaluation and conducting TSCA risk evaluations. Under TSCA section 6(b), EPA must designate as a high-priority substance "a chemical substance that the Administrator concludes, without consideration of costs or other nonrisk factors, may present an unreasonable risk of injury to health or the environment because of a potential hazard and a potential route of exposure under the conditions of use, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by the Administrator." (TSCA section 6(b)(1)(B)(i)). EPA is required to consider statutorily-prescribed factors when conducting prioritization and to provide several opportunities for public comment, and the prioritization process must last between 9-12 months (TSCA section 6(b)(1)(A), (C)). Once EPA designates a chemical substance as a high-priority substance for risk evaluation, EPA must then initiate a longer 3- to 3.5-year risk evaluation process. Through that risk evaluation process, EPA must "determine whether a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant to the risk evaluation by the Administrator, under the conditions of use." (TSCA section 6(b)(4)(A)). That process is subject to separate statutory requirements and considerations applicable to risk evaluations (e.g., TSCA section 6(b)(4)(D), (F)). If EPA finds unreasonable risk through a risk evaluation, EPA must proceed to address that unreasonable risk through TSCA section 6(a) risk management action. Although EPA must conduct a risk evaluation after designating a chemical substance as a high-priority substance, and the reasonably available information and findings informing prioritization will also inform EPA's risk evaluation on a high-priority substance, the standards and processes for TSCA prioritization and risk evaluation are separate and distinct.

Section 4.1.4 – Other comments on the whole chemical approach

A couple of industry trade organizations (0081, 0077), supported by another industry trade organization (0082), requested that EPA:

- Review the whole chemical approach in the context of TSCA's risk-based decision-making framework and requirements for risk management rules (0081);
- Explain how the change to a whole chemical approach may affect risk management (0081, 0077);
- Develop principles and criteria that would dictate when and how the whole chemical approach would be applied and when it would not (e.g., will it be applied if 50% of the COUs show unreasonable risk? 10%? at least one?) (0081, 0077). How will EPA treat the COUs that it determines do not present an unreasonable risk in its risk management plan when a whole chemical approach has been taken? (0081); and

- Explain how the whole chemical approach is employed in a manner consistent with the best available science or a weight of scientific evidence approach or compelled by the factors and standards dictated by Congress in the amendments to TSCA section 26 (0077).

An advocacy group (0075) provided strong support for the whole chemical approach conceptually, but:

- requested guidance providing greater detail regarding the decisional logic to be used when making a whole chemical risk determination, such as factors/criteria to be considered, the number/percentages of COUs determined to present an unreasonable risk, impacts of exposures on general population, etc.
- proposed an alternative that EPA issue a blanket statement, declaring that any chemical/class/mixture that has been subjected to a prioritization process and received a final designation of High Priority would automatically receive a single risk determination based upon the whole chemical approach.

EPA RESPONSE:
EPA appreciates other comments received in connection with the PV29 draft revised unreasonable risk determination. As stated previously, this action pertains only to the risk determination for PV29. While EPA may consider similar actions on other first ten chemicals, EPA is taking a chemical-specific approach to reviewing these risk evaluations and is incorporating new policy direction in a surgical manner, while being mindful of Congressional direction on the need to complete risk evaluations and move toward any associated risk management activities.

The revised unreasonable risk determination for PV29 is based on the peer reviewed risk characterization of the January 2021 risk evaluation, which is based on reasonably available information pursuant to TSCA section 26(k) and 40 CFR 702.33, and developed in accordance with TSCA section 26(h) to make decisions under TSCA section 6 in a manner consistent with the best available science. Changing the risk determination to a whole chemical approach does not impact the underlying data and analysis presented in the risk characterization of the risk evaluation.

Furthermore, EPA plans to consider the appropriate approach for each chemical substance risk evaluation on a case-by-case basis, taking into account considerations relevant to the specific chemical substance in light of the Agency's obligations under TSCA. For PV29, the whole chemical approach is appropriate because there are benchmark exceedances for substantial number of conditions of use (spanning across most aspects of the chemical lifecycle–from manufacturing (including import), processing, industrial and commercial use, and disposal) for worker and occupational non-user health, and the severity of the health effects associated with PV29 exposures. Since these chemical-specific properties cut across the conditions of use within the scope of the risk evaluation, the Agency's risk findings and conclusions encompass a substantial amount of the conditions of use and the Agency is better positioned to achieve its TSCA objectives for PV29 when using a whole chemical unreasonable risk determination for

PV29, EPA concludes that the Agency's risk determination for PV29 is better characterized as a whole chemical risk determination rather than condition of use-specific risk determination. Finally, as required by TSCA, the designation of a chemical substance as a high-priority substance triggers a requirement for EPA to conduct a risk evaluation of that chemical substance, and EPA will determine through the risk evaluation whether that chemical substance presents an unreasonable risk under the conditions of use; therefore, EPA will only be issuing statements regarding the unreasonable risk determination during risk evaluation and not during prioritization.

With respect to the risk management, consistent with the statutory requirements of TSCA section 6(a), EPA will propose risk management action to the extent necessary so that PV29 does not present unreasonable risk. In the revised risk determination for PV29, EPA has identified the conditions of use that drive the unreasonable risk from PV29 and will focus its risk management efforts on addressing that unreasonable risk, as required by TSCA. The public will have another opportunity to provide comments during the comment period of the proposed risk management rule.

Section 4.2 - Determination of unreasonable risk from baseline scenario

Section 4.2.1 - Support for EPA's intention not to assume PPE or other mitigation measures are in place

Some non-governmental environmental and health advocacy groups (0075, 0078, 0083, 0085) supported EPA's decision to no longer rely on the assumption that workers always and properly use PPE when evaluating exposures in a risk evaluation, agreeing that EPA's baseline for estimating risk to workers should not assume the use of PPE. One advocacy organization (0083) stated that the assumption lacked legal basis, departed from established federal workplace protection policy and practice, and is contrary to the realities of worker exposure to chemicals. The advocacy organization stated that EPA's revised policy approach follows the recommendation of its Science Advisory Committee on Chemicals (SACC) to base unreasonable risk determinations for workers on measured or estimated exposure levels in the absence of PPE.

A couple of advocacy organizations (0078, 0083) discussed the many limitations of PPE, including EPA's own statements that respirators are often not feasible and may be used only intermittently by workers even where legally required. The commenters urged that the U.S. Occupational Safety and Health Administration (OSHA) and the National Institute for Occupational Safety and Health (NIOSH), too, have acknowledged the limitations of PPE, having prioritized hazard elimination, substitution, engineering and administrative controls over the use of PPE in the hierarchy of controls. An advocacy organization (0078) said that PPE does not address exposures to workers who are bystanders, as they are not wearing the PPE, and further urged that the use of a respirator cannot be used to determine if exposure is lessened sufficiently so that unreasonable risk is mitigated, because EPA does not know the baseline for a particular facility. The same commenter warned that OSHA regulations concerning PPE only apply when the employer determines that workers are subject to sufficient hazards from chemical exposure and whenever else the employer decides it is necessary. Therefore, the employer

decides both whether and what hazards exist and whether use of PPE is necessary. One of the advocacy organizations (0083) also noted the SACC's assessment that EPA's characterization of unreasonable risk relying on use of PPE is not sufficiently supported by the practical realities of many workplaces.

An advocacy organization (0078) cited TSCA section 6(b)(4)(A), stating that this provision precludes EPA from considering risk mitigation in its workplace risk determinations. The advocacy organization claimed that consideration of the use of PPE – or any other mechanism to mitigate exposure and risk – is a non-risk factor and should thus not be considered in any form as part of the risk evaluation.

EPA RESPONSE:
EPA appreciates the feedback concerning assumptions on the use of PPE, the interaction of EPA and OSHA regulation, and worker protection.

As stated in the revised unreasonable risk determination for PV29, EPA believes it is appropriate to evaluate the levels of risk present in scenarios considering applicable OSHA requirements, as well as scenarios considering industry or sector best practices for industrial hygiene because such evaluation can help inform potential risk management actions (i.e., by informing EPA's assessment of the feasibility and efficacy of different risk management options). However, as commenters note, EPA cannot reasonably assume that all facilities will have adopted these practices. Therefore, EPA is making 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. This 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, or because their employer is out of compliance with OSHA standards, or because many of OSHA's chemical-specific permissible exposure limits largely adopted in the 1970's are described by OSHA as being "outdated and inadequate for ensuring protection of worker health,"[2] or because OSHA has not issued a permissible exposure limit (PEL) (as is the case for PV29), or because EPA finds unreasonable risk for purposes of TSCA notwithstanding existing OSHA requirements.

In accordance with TSCA section 26(k), EPA considers reasonably available information when conducting TSCA section 6 risk evaluations and risk management rules. When undertaking unreasonable risk determinations as part of TSCA risk evaluations, EPA cannot assume as a general matter that workers always or properly use PPE, although it does not question the public comments received regarding the occupational safety practices often followed by industry respondents. Under TSCA section 6(a), EPA must apply one or more risk management requirements to the extent necessary so that a chemical substance no longer presents unreasonable risk. Those requirements may include restrictions on the manufacture, processing, distribution in commerce, commercial use, or disposal of a chemical substance.

[2] As noted on Occupational Safety and Health Administration. Permissible Exposure Limits – Annotated Tables. Accessed June 13, 2022. https://www.osha.gov/annotated-pels.

Section 4.2.2 - Opposition to EPA's intention not to assume PPE or other mitigation measures are in place

Several commenters (0077, 0081, 0082, 0087) expressed opposition to EPA's proposal to not assume the use of PPE when making its unreasonable risk determination for PV29. For example, some industry trade organizations (0077, 0081, 0082) commented that EPA's decision not to assume the use of PPE is inconsistent with the definition of COUs under TSCA and contravenes explicit requirement under TSCA section 26(k) to take into consideration information relating to a chemical substance or mixture, including hazard and exposure information, under the COUs, that is reasonably available to the Administrator. One industry trade organization (0077) added that when EPA rendered unreasonable risk determinations for workers in the PV29 risk evaluation and the other nine initial risk evaluations, EPA's assumption that workplaces comply with the OSHA regulations was reasonable, appropriate, and driven by data. The industry trade organization urged that such an approach is grounded in the statute and regulations and is supported by sound science. Relatedly, an industry trade organization (0082) said that EPA acted reasonably in the past by assuming that workers at automobile coating and refinishing workplaces would wear APF25 respirators.

An industry trade organization (0081) urged that EPA's proposal to determine risk without considering the effects of current occupational safety standards and PPE practices is not supported by the record nor reasonably justified by any of the reasons offered by the Agency. Specifically, the commenter asserted that EPA cited no data or records to support its belief concerning the insufficiency of PPE at OSHA regulated facilities. The commenter further stated that EPA also has not presented any evidence of widespread refusal to comply with OSHA requirements and urged that OSHA does require the use of appropriate PPE where needed to protect workers from chemical exposures at jobsites. Similarly, another industry trade organization (0080) stated that EPA's proposed approach would likely leave the public with the perception that facilities are out of compliance with federal and state safety standards, would artificially increase the calculated human health risk for particular uses of a chemical, and would create a false and misleading perception of worker risk.

An industry trade organization (0080) stated that if EPA believes that certain workplace risks are not being adequately controlled, then EPA has an obligation under TSCA section 9(a) to consult with OSHA before superseding OSHA's authority. Any such result from coordination and consultation with OSHA should also be made publicly available to further transparency, process, and due diligence. An industry trade organization (0087), in expressing opposition to EPA's proposed baseline scenario, urged EPA to consider the authority of other federal agencies and avoid creating overlap with existing laws and regulations, as doing so creates confusion and unnecessary burden on the regulated community.

An industry trade organization (0081) stated that EPA's proposal is not transparent about its plans for implementation of the proposed change in the risk management rule itself and would request the Agency to develop clear, accurate communication materials to explain EPA's new approach to PPE to the already OSHA-regulated community. The commenter stated that EPA's

proposal could inadvertently create regulatory confusion and potentially subject companies to overlapping workplace protection requirements for workplaces that are already subject to OSHA. The industry trade organization added that such requirements would be costly and either duplicative of or inconsistent with those that OSHA has already imposed on employers and employees in OSHA-regulated businesses. Further, the commenter urged that EPA's rationale for no assumption of PPE in risk evaluations is inconsistent with the statutory and regulatory requirements in the Occupational Safety and Health Act of 1970 (OSH Act) and that EPA must consult with OSHA and NIOSH to understand whether current worker protection from exposure to chemicals is consistent with best available science before making any determinations about the adequacy of OSHA controls.

An industry trade organization (0080) suggested that EPA continue the approach of presenting both scenarios – PV29 use with and without PPE – in its risk determinations, claiming that doing so would provide the appropriate bounding scenarios for PV29 risk exposures in the workplace. The same commenter stated that waiting until EPA proceeds to the risk management phase to include the use of OSHA-required PPE and related workplace standards creates a false impression of risk that lacks transparency, will be misleading to the public, and overestimates the risk of exposure in workplaces that require workers to follow PPE practices. In addition, it would create an extra layer of work for EPA and industries to work through the risk management phase, when adequate protections may already be in place.

An industry trade organization (0087), relying on the plain language of TSCA to support its assertion that EPA should take PPE into account when evaluating exposure potential, cited 15 U.S.C. section 2605 (b)(1)(A), "The process to designate the priority of chemical substances shall include a consideration of the hazard and exposure potential of a chemical substance," as well as 15 U.S.C. section 2605 (b)(4)(D), which states a requirement to "integrate and assess available information on hazards and exposures for the conditions of use of the chemical substance." The commenter noted that this requirement is also stated repeatedly throughout the Lautenberg Chemical Safety Act. The industry trade organization concluded that the law is clear that for EPA to make a determination of risk when evaluating a chemical, it must analyze both hazard and exposure, and it is not possible to accurately evaluate exposure potential without taking exposure mitigation procedures – including OSHA PPE requirements – into account. Similarly, an industry trade organization (0082) stated that TSCA likely does not authorize EPA's proposal to make its determination of unreasonable risk from a baseline scenario that does not assume compliance with OSHA standards. The commenter asserted that the statute requires EPA to make decisions based on the particular circumstances of each COU of the relevant chemical and does not allow EPA to simply adopt a "protective" assumption that ignores the reality of how a particular chemical is used at categories of workplaces.

EPA RESPONSE:

In the final risk evaluations for the first ten chemical substances, the previous administration generally assumed that for certain conditions of use workers were always provided, and used, PPE in a manner that achieved the stated assigned protection factor (APF) for respiratory protection, or protection factor (PF) for dermal protection. EPA, however, has revisited the assumption that PPE is always used, and always used properly and effectively, in occupational

settings when making risk determinations for a chemical substance and this revised approach is reflected in the revised unreasonable risk determination for PV29. EPA made this change in approach due to data on violations of PPE use that indicated assumptions that PPE is always provided to workers, and worn properly, are not justified.[3] Further, some occupational exposures are not covered by OSHA standards, such as those of self-employed individuals and public sector workers who are not covered by a State Plan. EPA understands that there could be occupational safety protections in place at workplace locations; however, not assuming use of PPE 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, or their employers are out of compliance with OSHA standards, or because many of OSHA's chemical-specific permissible exposure limits largely adopted in the 1970's are described by OSHA as being "outdated and inadequate for ensuring protection of worker health"[4], or because OSHA has not issued a chemical-specific permissible exposure limit (PEL) (as is the case for PV29), or because EPA finds unreasonable risk for purposes of TSCA notwithstanding OSHA requirements. Continued use of this assumption could result in a risk evaluation that underestimates the risk, and in turn, a risk management rule that may not provide the needed protections. EPA plans to consider reasonably available 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. In EPA's view, the risk determination should not rely on assumptions regarding the use of PPE; rather, the use of PPE should be considered during risk management.

When conducting the PV29 risk evaluation, EPA considered reasonably available information on PV29 hazards and exposures under the conditions of use, including information on current industry practices, occupational controls and PPE use at commercial and industrial facilities handling PV29 as explained in Section 2.3 of the final risk evaluation. EPA used this information when developing exposure assessments for PV29. This information is also helpful to inform potential risk management actions. However, as noted before, EPA cannot reasonably assume that all facilities will have adopted these practices. Therefore, EPA is making 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.

The revised unreasonable risk determination for PV29 is based on the peer reviewed risk characterization of the January 2021 PV29 Risk Evaluation, which is based on reasonably available information pursuant to TSCA section 26(k) and 40 CFR 702.33, and developed in accordance with TSCA section 26(h) to make decisions under TSCA section 6 in a manner consistent with the best available science.

[3] OSHA Standards and Violation Data https://www.osha.gov/top10citedstandards
[4] As noted on Occupational Safety and Health Administration. Permissible Exposure Limits – Annotated Tables. Accessed June 13, 2022. https://www.osha.gov/annotated-pels.

The final risk evaluation already includes exposure analysis with and without PPE. Table 4-4 in the final risk evaluation presents risk estimates for each condition of use with and without PPE. EPA has made no changes to this analysis. Therefore, removing the assumption that workers always and appropriately wear PPE when making the unreasonable risk determination does not create a need for new analysis. Removing the assumptions of PPE use in making the whole chemical risk determination for PV29 did not alter the conditions of use that drive EPA's unreasonable risk determination for PV29 as a whole chemical. The revision to the risk determination clarifies that EPA does not rely on the assumed use of PPE when making the risk determination for the whole substance. Overall, ten conditions of use would drive the PV29 whole chemical unreasonable risk determination due to risks identified for human health.

EPA disagrees with those commenters who thought that eliminating the assumed use of PPE for risk determination purposes would be misleading to the public. EPA explicitly stated in the draft revised PV29 risk determination and accompanying Federal Register Notice that basing the unreasonable risk determination on the baseline scenario without PPE should not be viewed as an indication that EPA believes there are no occupational safety protections in place at any location or that there is widespread non-compliance with applicable OSHA standards. Rather, it reflects EPA's recognition that unreasonable risk may exist for workers (which are included in the risk evaluation as a potentially exposed or susceptible subpopulation) 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 many of OSHA's chemical-specific permissible exposure limits largely adopted in the 1970's are described by OSHA as being "outdated and inadequate for ensuring protection of worker health"[5], or because OSHA has not issued a chemical-specific permissible exposure limit (PEL) (as is the case for PV29), or EPA finds unreasonable risk for purposes of TSCA notwithstanding OSHA requirements. In some cases, baseline conditions may reflect certain mitigation measures, such as engineering controls, in instances where exposure estimates are based on monitoring data at facilities that have engineering controls in place.

Because the requirements and application of TSCA and OSHA regulatory analyses differ, it is appropriate that EPA conduct risk evaluations and, where it finds unreasonable risk to workers, develop risk management requirements for chemical substances that OSHA also regulates, and it is understood that EPA's findings and requirements may sometimes diverge from OSHA's. However, it is also appropriate that EPA consider the standards that OSHA has already developed, so as to limit the compliance burden to employers by aligning management approaches required by the agencies, where alignment will adequately address unreasonable risk to workers.

[5] As noted on Occupational Safety and Health Administration. Permissible Exposure Limits – Annotated Tables. Accessed June 13, 2022. https://www.osha.gov/annotated-pels.

As a general matter, when undertaking risk management actions, EPA will consider occupational risk mitigation measures that could address unreasonable risk identified by EPA, and for any such measures included in a proposed or final TSCA risk management rule, EPA intends to seek consistency with applicable OSHA requirements that address the unreasonable risk. When undertaking risk management actions, EPA intends to develop occupational risk mitigation measures to address any unreasonable risks identified by EPA, especially in cases where current OSHA standards may not apply or be sufficient to address the unreasonable risk.

EPA identified the conditions of use that drive the unreasonable risk in the risk determination, and options will be developed during the process of the Agency working on the risk management rulemaking to address the unreasonable risk presented by the chemical substance. The risk management rulemaking stage is not when EPA determines which conditions of use drive the unreasonable risk.

Under TSCA section 9(a), if EPA determines, in the Administrator's discretion, that an unreasonable risk may be prevented or reduced to a sufficient extent by action taken under a federal law that is not administered by EPA, EPA must submit a report to the agency administering that other authority and undertake a statutorily prescribed referral process. EPA retains the discretion to make this finding in the first instance.

Consistent with TSCA section 9(d), EPA is regularly consulting and coordinating TSCA activities with OSHA and other relevant federal agencies for the purpose of achieving the maximum applicability of TSCA while avoiding the imposition of duplicative requirements. Informed by the mitigation scenarios and information gathered during the risk evaluation and risk management process, the Agency might propose rules that require risk management practices that may be already common practice in many or most facilities. Adopting clear, comprehensive regulatory standards will foster compliance across all facilities (ensuring a level playing field) and assure protections for all affected workers, especially in cases where current OSHA standards may not apply or be sufficient to address the unreasonable risk. EPA appreciates the suggestion to formalize a consultation process with OSHA, as well request for transparency regarding such consultations. EPA will continue to coordinate with OSHA and other relevant federal agencies during TSCA risk evaluation and risk management activities and expects to refine its consultation process as the Agency conducts additional risk evaluations and risk management rulemakings. The results of any consultation with OSHA, as well as EPA's rationale for proposed risk management requirements, including consideration of the OSHA hierarchy of controls, would be reflected in the proposed rule to address the unreasonable risk presented by PV29.

Section 4.2.3 - OSHA requirements and industry best practices

An industry trade organization (0081) provided several suggestions for how EPA could address the protection of workers as a potentially exposed or susceptible subpopulation including: considering other ways to address concerns about the population of workers not covered by OSHA standards, developing risk evaluations that don't assume that PPE is either always or never used in the workplace, working with OSHA during the scoping phase and discussing

improved enforcement of OSHA requirements, considering the European approach to COUs for the workplace, and more.

EPA RESPONSE:

EPA agrees that for purposes of making the TSCA unreasonable risk determination, it is inappropriate to assume as a general matter that industry best practices are consistently and always properly applied or that all facilities have adopted these practices. Once EPA has determined that a chemical substance presents an unreasonable risk, EPA is required to address the identified unreasonable risk through rulemaking. EPA intends to consider current best workplace practices as it develops TSCA section 6(a) risk management action to address the unreasonable risk determined in the PV29 risk evaluation, for instance to help inform EPA's assessment of the feasibility and efficacy of different risk management options. The best workplace practices could also include information from other countries, such as the European approach mentioned by the commenters.

OSHA's mission is to ensure that employees work in safe and healthful conditions. The OSH Act establishes requirements that each employer comply with the General Duty Clause of the Act (29 U.S.C. 654(a)), as well as with occupational safety and health standards issued under the Act. The General Duty Clause of the OSH Act requires employers to keep their workplace free from recognized hazards that are causing or are likely to cause death or serious physical harm to employees. The General Duty Clause is cast in general terms, and does not establish specific requirements like exposure limits, PPE, or other specific protective measures that EPA could potentially consider when developing its risk evaluations or risk management requirements. Because the requirements and application of TSCA and OSHA regulatory analyses differ, it is appropriate that EPA conduct risk evaluations and, where it finds unreasonable risk to workers, develop risk management requirements for chemical substances that OSHA also regulates, and it is understood that EPA's findings and requirements may sometimes diverge from OSHA's. It is appropriate, however, that EPA consider the chemical standards that OSHA has already developed, so as to limit the compliance burden to employers by aligning management approaches required by the agencies, where alignment will adequately address unreasonable risk to workers.

As a general matter, when undertaking risk management actions, EPA intends to strive for consistency with applicable OSHA requirements and industry best practices, including appropriate application for the hierarchy of controls, to the extent that the requirements, controls, and practices eliminate the identified unreasonable risks. Informed by the mitigation scenarios and information gathered during the risk evaluation and risk management process, the Agency might propose rules requiring risk management practices that may be already common practice in many or most facilities. Adopting clear, comprehensive regulatory standards will foster compliance across all facilities (ensuring a level playing field) and assure protections for all affected workers. EPA will undertake a separate public notice and comment period as part of the TSCA section 6(a) risk management rulemaking for PV29 and will consider public comments and any additional information before finalizing the rulemaking. Consistent with TSCA section 9(d), EPA is consulting and coordinating TSCA activities with OSHA and other relevant federal

agencies for the purpose of achieving the maximum applicability of TSCA while avoiding the imposition of duplicative requirements. Consultation with other relevant federal agencies is also required during the risk evaluation process under EPA's implementing regulations at 40 CFR 702.39.

As required by TSCA, when conducting risk evaluations, EPA identifies relevant potentially exposed or susceptible subpopulations (PESS), and Section 4.3.1 of the PV29 Risk Evaluation describes workers and female workers of reproductive age as PESS. Notwithstanding the analysis done for PV29, EPA acknowledges the suggestions by several commenters to identify workers as a potentially exposed or susceptible subpopulation for future risk evaluations and encourages the commenters to submit chemical-specific comments on PESS to assist during future risk evaluations' comment periods.

Section 4.2.4 - Other comments regarding determination of unreasonable not assuming PPE or other mitigations measures are in place

An advocacy organization (0078) expressed support for EPA's proposal to discard the assumptions of existing worker protection, including use of PPE during risk determinations. However, the commenter took issue with EPA's statement in the revised risk determination that in some risk evaluations, levels of risks to workers may be evaluated with and without OSHA requirements and industry best practices scenarios that are clearly articulated to the Agency. The advocacy organization urged that EPA should not use worker mitigation characterizations and scenarios during risk evaluation, EPA should also recognize that there are limitations to such information during risk management.

EPA RESPONSE:
EPA agrees that for purposes of making the TSCA unreasonable risk determination, it is inappropriate to assume as a general matter that industry best practices are consistently and always properly applied or that all facilities have adopted these practices. Once EPA has determined that a chemical substance presents an unreasonable risk, EPA is required to address the identified unreasonable risk through rulemaking. EPA intends to consider current best workplace practices as it develops TSCA section 6(a) risk management action to address the unreasonable risk determined in the PV29 risk evaluation, for instance to help inform EPA's assessment of the feasibility and efficacy of different risk management options.

As a general matter, when undertaking risk management actions, EPA intends to strive for consistency with applicable OSHA requirements and industry best practices, including appropriate application for the hierarchy of controls, to the extent that the requirements, controls, and practices eliminate the identified unreasonable risks. Informed by the mitigation scenarios and information gathered during the risk evaluation and risk management process, the Agency might propose rules requiring risk management practices that may be already common practice in many or most facilities. Adopting clear, comprehensive regulatory standards will foster compliance across all facilities (ensuring a level playing field) and assure protections for all affected workers. Consistent with the statutory requirements of TSCA section 6(a), EPA will propose risk management action to the extent necessary so that PV29 no longer presents an unreasonable risk. EPA will undertake a separate public notice and comment period as part of the

TSCA section 6(a) risk management rulemaking for PV29, and will consider public comments and any additional information before finalizing the rulemaking.

Section 4.2.5 - Permissible exposure limits (PELs)

In response to EPA's statement in the draft revision to the PV29 risk determination that the Agency intends to make its unreasonable risk determination from a baseline scenario that does not assume compliance with OSHA standards, a couple of commenters (0078, 0088) discussed OSHA's PELs. For instance, in expressing support for EPA's proposed assumption, an advocacy organization (0078) remarked that OSHA itself has noted that many of its PELs are "outdated and inadequate for ensuring protection of worker health." The commenter concluded that therefore, even when a company may be in compliance with an OSHA requirement, its worker protection program may nevertheless result in unreasonable risks to workers.

On the other hand, an industry trade organization (0088) urged that EPA's proposed baseline scenario unnecessarily focuses on the inadequacy of OSHA PELs. The industry trade organization professed that the reason for the disclaimer on OSHA's website for PELs – which states "OSHA recognizes that many of its PELs are outdated and inadequate for ensuring protection of worker health" – is to alert industry that mere compliance with OSHA PELs does not meet legal obligations established under section 5 of the OSH Act, known as the "general duty clause." The commenter said that the OSHA website explains that employers may need to refer to "alternate occupational exposure limits that may serve to better protect workers," such as limits of the California Division of Occupational Safety and Health, NIOSH, and values established by foreign governments. Further, the commenter mentioned OSHA's enforceable industry action level, which is usually set at half the PEL and requires industry to take action, as determined by industrial hygienists, if an individual could be exposed at the industry action level. The commenter concluded that, in effect, EPA is poised to derive exposure limits that are wildly divergent from those of recognized established bodies and warned that doing so would undermine the Agency's credibility, as well as the credibility of industry management when implementing safety programs.

EPA RESPONSE:
EPA notes that for PV29 there is no established chemical-specific OSHA PEL and therefore the consideration of a PV29 PEL was not a factor in the revised unreasonable risk determination. EPA recognizes that some level of respiratory protection could be used at some workplaces due to the OSHA PEL for respirable dust particulates (OSHA PNOR PEL); however, EPA has revisited the assumption that PPE is always used properly and effectively in occupational settings when making risk determinations for a chemical substance and this revised approach is reflected in the revised unreasonable risk determination for PV29.

As a general matter, when undertaking risk management actions, EPA intends to strive for consistency with applicable OSHA requirements and industry best practices, including appropriate application for the hierarchy of controls, to the extent that the requirements, controls, and practices address the identified unreasonable risks according to TSCA section 6(a).

Section 4.2.6 - Other comments on OSHA requirements or best practices

Some commenters discussed other OSHA requirements and best practices besides PELs and PPE. For example, an industry trade organization (0082) discussed engineering controls and administrative controls. To illustrate the effectiveness of engineering controls, the same commenter (0082) discussed the engineering controls that are in place at the only PV29 plant in the U.S., including fans and bay doors open to the outdoors. The commenter said that EPA staff have visited the plant and witnessed first-hand the effectiveness of these and other controls used to minimize worker exposure to PV29. The commenter also stated that restricting employees that are not wearing specified PPE from areas where PV29 is handled is an example of an effective administrative control.

An advocacy group (0083) discussed how OSHA and NIOSH manage chemical risks using the "hierarchy of controls." The commenter stated that EPA has set a positive precedent endorsing the hierarchy of controls proposing its use in the asbestos risk management rule.

Another commenter (0085) simply noted that no OSHA standards cover PV29 and that such a chemical can thus pose an unreasonable risk under TSCA.

An industry trade organization (0086) suggested that EPA pursue increased collaboration and understanding with regulated industries given the presumption of limited PPE. The commenter said there is a need to ensure consistent chemical review and close consideration of nuanced evaluations and specific risk determinations based on varying applications, versus a single risk determination for a chemical.

An advocacy organization (0085) supported using, as a model in the risk management of PV29, the OSHA requirements and best practices that provide effective worker protection through management commitment, employee participation, information and training, hierarchy of controls and ancillary requirements, and, where appropriate, medical removal.

An industry trade organization (0088) suggested that EPA adopt and reference existing OSHA requirements to address any requirement related to respirator use, including record keeping requirements so as not to impose additional and unnecessary costs, particularly for small businesses.

EPA RESPONSE:
EPA encourages the commenters to submit specific comments about worker protection measures, including engineering controls and administrative controls, during the future public comment period for the PV29 risk management rule. As part of that rulemaking, EPA will consider reasonably available information on worker protection measures, including information provided by regulated industries.

Consistent with TSCA section 9(d), EPA is consulting and coordinating TSCA activities with OSHA and other relevant federal agencies for the purpose of achieving the maximum applicability of TSCA while avoiding the imposition of duplicative requirements. Consultation

with other relevant federal agencies is also required during the risk evaluation process under EPA's implementing regulations at 40 CFR 702.39.

Section 4.2.7 - Other comments regarding impacts to the risk management of PV29

A few commenters discussed how EPA's proposed baseline scenario would affect subsequent risk management for PV29. An industry trade organization (0082) stated that if EPA assumes non-use of PPE (or other worker protections) when making unreasonable risk determinations, then EPA should estimate risk assuming use of those protections as a tool for informing a subsequent risk management rulemaking. The commenter explained that these risk estimates would enable EPA to determine with precision which risk management actions are the minimum necessary so that the chemical substance no longer presents such risk.

An advocacy organization (0075) expressed support for EPA's proposal to shift its consideration of application of PPE from the unreasonable risk determination process to the development of risk management options. However, the advocacy organization also suggested that EPA should make the same assumptions both when making unreasonable risk determinations and considering risk management options -- that EPA cannot assume that an applicable OSHA requirement or industry practice is consistently and properly applied.

A chemical manufacturer (0079) commented that proposing rules that require risk management practices that may already be common practice in many facilities is duplication of work by EPA. The commenter said that to manage the identification of risk more efficiently, the risk management rules should be tailored to those applications where at-risk workers are identified. The commenter went on to suggest that for completeness, EPA should include an Appendix that models those uses where risk management measures are/should already be implemented and note exposure levels where risk would be identified if these measures are eliminated. There would then be no further need to identify risk management measures for these activities.

EPA RESPONSE:
As stated earlier, EPA believes it is appropriate to evaluate the levels of risk present in scenarios considering applicable OSHA requirements as well as scenarios considering industry or sector best practices for industrial hygiene because such evaluation can help inform potential risk management actions (i.e., by informing EPA's assessment of the feasibility and efficacy of different risk management options). However, as commenters note, EPA cannot reasonably assume that all facilities will have adopted these practices. Therefore, EPA is making 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. This 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, or because their employer is out of compliance with OSHA standards, or because many of OSHA's chemical-specific permissible exposure limits largely adopted in the 1970's are described by OSHA as being "outdated and inadequate for ensuring protection of

worker health"[6], or because OSHA has not issued a chemical-specific permissible exposure limit (PEL) (as is the case for PV29), or because EPA finds unreasonable risk for purposes of TSCA notwithstanding existing OSHA requirements.

Under TSCA section 6(a), if EPA determines through risk evaluation that a chemical substance presents unreasonable risk under its conditions of use, then EPA must promulgate risk management requirements to the extent necessary so that the unreasonable risk is no longer presented. Informed by the mitigation scenarios and information gathered during the risk evaluation and risk management process, the Agency might propose rules that require risk management practices that may already be common practice in many or most facilities; although, EPA should not assume that such practices are always implemented by all facilities. Adopting clear, comprehensive regulatory standards will foster compliance across all facilities (ensuring a level playing field) and assure protections for all affected workers, especially in cases where current OSHA standards may not apply or be sufficient to address the unreasonable risk.

Section 5 - Conditions of Use (COUs) that drive the unreasonable risk determination

Section 5.1 – Manufacturing

An industry trade organization (0082), discussing the PV29 Risk Management, stated that based on the scientific evidence now available to EPA regarding the exposures to PV29, EPA should conclude that there is no longer an unreasonable risk present at the Bushy Park facility, which is the only U.S. facility that manufactures PV29, and that no additional risk management requirements are required for the manufacturing COU. The commenter added that they had a study performed on the airborne particulates at the facility which concluded that "'airborne [ultrafine particulates (UFP)] were not generated as part of the PV29 grind and blend pack-out process'" which is the process that is the most likely to generate the highest concentrations, and smallest particle sizes, of PV29. Another industry trade organization (0081), supported by the other industry trade organization (0082), discussed the manufacture of PV29 and said that EPA incorrectly assumed that the duration of worker exposure would be over 10.5 hours, occurring 190 times per year, despite the fact that, in actuality, PV29 batch manufacturing occurs infrequently and individual tasks take about 0.5 to 2 hours, with the total time performing tasks being about 6.5 hours.

The same commenter asserted for the same reasons that no additional risk management requirements are required for the processing COUs involving PV29, such as incorporation into plastic pellets, paints, and inks. The commenter also stated that it would be appropriate for EPA to conclude that no unreasonable risk exists for any downstream use of PV29 unless it involves the "agitation and dispersion of PV29 particles in a way absent at the Bushy Park facility", or at

[6] As noted on Occupational Safety and Health Administration. Permissible Exposure Limits – Annotated Tables. Accessed June 13, 2022. https://www.osha.gov/annotated-pels.

a minimum, the risk management rule should encourage downstream facilities to conduct their own studies of ultrafine particles.

EPA RESPONSE:

The revised unreasonable risk determination for PV29 is based on the peer reviewed risk characterization in the January 2021 PV29 Risk Evaluation, based on reasonably available information pursuant to TSCA section 26(k) and 40 CFR 702.33, and developed in accordance with TSCA section 26(h) to make decisions under TSCA section 6 in a manner consistent with the best available science. The policy changes described in the Federal Register Notice announcing the availability of the draft revised risk determination for PV29 do not amend or impact the underlying data and analysis presented in the risk characterization of the January 2021 PV29 Risk Evaluation. The policy changes do not impact the characterization of risk estimates by condition of use (summarized in Section 4 of the final risk evaluation), or the occupational exposures to workers and ONUs (summarized in Section 2.3 of the final risk evaluation).

In the final revised risk determination, EPA identifies which conditions of use drive the unreasonable risk of PV29. Consistent with the statutory requirements of TSCA section 6(a), EPA will propose risk management action to the extent necessary so that PV29 no longer presents an unreasonable risk. Therefore, EPA expects to focus its risk management action on the conditions of use that drive the unreasonable risk.

EPA appreciates the information provided by the commenter on December 15, 2021, regarding exposures at the manufacturing facility of PV29. As suggested by the commenter, EPA will be considering that information in the development of the risk management rule. EPA's consideration of the information received will be explained in the proposed rulemaking under TSCA section 6(a) and EPA will consider public comments and any additional information before finalizing the rulemaking.

Section 5.2 – Processing

An industry trade organization (0084) stated that the Finding of Unreasonable Risk for Recycling via Inhalation should be withdrawn as it was not based on actual data for recycling of PV29. The commenter remarked that EPA even stated that it did not find PV29-specific information for recycling. The commenter also expressed concern that the Agency selected carbon black as an analogue in an inhalation study and questioned why the Draft Revision called the peer reviewed hazard and exposure assessments and associated risk characterization "robust" as the commenter would describe the risk characterization as having high uncertainty and low confidence. The commenter also discussed the risk evaluation for workers and occupational users and non-users at recycling facilities and stated that the potential exposures determined from four types of processing for the inhalation risk evaluation are much higher than what would typically be found in recycling processes. The commenter stated that EPA did not properly distinguish recycling from the other three types of processing and that EPA should withdraw the finding of unreasonable risk for recycling and conduct a new risk evaluation.

EPA RESPONSE:
As noted in section 3.2.3.1 of the final Risk Evaluation, sub-chronic or chronic inhalation toxicity data is not available for PV29, thus analogue data was considered to inform potential human health hazards. Carbon black is a suitable analogue for PV29 because both compounds are pigments and are respirable, poorly soluble particulate matter that are expected to cause increased lung burden via inhalation exposures and potentially kinetic lung overload at higher exposure concentrations or longer exposure durations. Both compounds are expected to cause adverse effects to the respiratory tract such as irritation, inflammation, and proliferation. Carbon black also is structurally similar to PV29 since both compounds contain conjugated polyaromatic ring structures.

For each condition of use, risks were estimated based on central tendency and high-end exposure estimates of PV29 particles in air based on workplace monitoring studies. The particle size distribution data used for risk characterization was based on the reported range of values for the workplace submitted by the manufacturer and importer of PV29, which was the only reasonably available information to the Agency to conduct the risk evaluation, and therefore applied to other conditions of use. EPA acknowledges uncertainty exists in the risk characterization, and discusses this in section 4.2.4 of the final Risk Evaluation. In addition, EPA developed the risk evaluation in accordance with TSCA, incorporating determinations based on high-end exposure estimates to account for individuals or sub-populations with greater exposure (PESS) as well as to capture individuals with sentinel exposure.

The Agency is not changing the underlying data and analysis presented in the risk characterization of the January 2021 PV29 Risk Evaluation; however, the Agency intends to take the information provided by the commenter into consideration during risk management. The Agency does plan to address the unreasonable risk of PV29 during recycling operations in the risk management process and welcomes any new information, data, or studies that would aid in developing the risk management requirements to protect workers and ONUs in recycling facilities, so that PV29 no longer presents an unreasonable risk.

Section 5.3 – Industrial/commercial use: automotive paints and coatings

An industry trade organization (0080) stated that exposure to PV29 dust in automotive painting and coating operations at their facilities is highly unlikely, because PV29 is fully incorporated into the paint or coating by the paint manufacturer prior to use in the facility, so there is no concern of inhalation of the powder form of PV29 like in manufacturing facilities. The commenter said that EPA incorrectly assessed inhalation exposures for automotive workers using the maximum concentration of powders at a PV29 manufacturing site. The commenter said the lack of exposure, particularly in their facilities due to robotic sprayers, should be incorporated by EPA prior to assigning any risk management strategy and that the data support a finding of "no unreasonable risk" for these uses. At a minimum, the commenter requested that EPA reflect actual exposure patterns when developing risk mitigation measures moving forward.

EPA RESPONSE:
EPA understands that for some automotive painting operations there are robotic sprayers in negative air pressure spray booths; in these scenarios workers and ONUs would only come into contact with paints and coatings containing PV29 during cleaning, repair, and maintenance of the robotic equipment within the negative air pressure spray booths. The Agency believes that other automotive spray painting, sanding, grinding, and repair services expose workers and ONUs to PV29 aerosolized particles due to disturbance of previously painted surfaces through airborne distribution. These exposures are drivers of the unreasonable risk presented by PV29. The Agency intends to take this information into consideration during the risk management effort; however, the Agency is not changing the underlying data and analysis presented in the risk characterization of the January 2021 PV29 Risk Evaluation. Informed by the mitigation scenarios and information gathered during the risk evaluation and risk management process, the Agency might propose rules that require risk management practices that may be already common practice in many or most facilities. Adopting clear, comprehensive regulatory standards will foster compliance across all facilities (ensuring a level playing field) and assure protections for all affected workers

Section 5.4 – Industrial/commercial use: Merchant Ink for commercial printing

An industry trade organization (0076) stated that EPA should incorporate the best available information, specifically information provided by the Printing United Alliance, regarding end users of products that incorporate PV29 in the category of "Merchant Ink Users." The commenter said that because PV29 is not used within the printing community, that industry should not be subject to any risk management requirements.

EPA RESPONSE:
EPA appreciates the information the commenter provided. EPA understands that this organization's members have confirmed they do not use PV29 in their merchant ink activities; however, the Agency notes that PV29 was historically used in merchant printing ink activities and is therefore a reasonably foreseen use for companies outside of the commenter's association membership. EPA believes it is possible to apply risk management requirements under TSCA section 6 in a manner that would not impact companies which do not use merchant inks containing PV29.

Section 6 - Comments regarding COUs that do not drive the revised unreasonable risk determination

An advocacy organization (0075) stated that in Chapter 5 of the Risk Evaluation for PV29, there is no mention of the four COUs that did not meet the unreasonable risk standard, which deprives the reader of the full picture. The commenter explained that, in order to help the reader understand why EPA is implementing the whole chemical approach for PV29, it would be helpful to discuss the other four COUs that don't drive the unreasonable risk determination. The commenter suggested that text from section 5.4.1 *No Unreasonable Risk Determination* should

be pasted into this revised risk determination as a new paragraph 4 on Page 1. The commenter also provided additional suggestions for updating figures.

EPA RESPONSE:
The revised unreasonable risk determination is for PV29 as a whole chemical substance. In the final revised risk determination, EPA lists which conditions of use drive the unreasonable risk and which do not drive the unreasonable risk determination for PV29.

Consistent with the statutory requirements of TSCA section 6(a), EPA will propose risk management regulatory action to the extent necessary so that carbon tetrachloride no longer presents an unreasonable risk. EPA expects to focus its risk management action on the conditions of use that drive the unreasonable risk. However, it should be noted that, under TSCA section 6(a), EPA is not limited to regulating the specific activities found to drive unreasonable risk and may select from among a suite of risk management requirements in section 6(a) related to manufacture (including import), processing, distribution in commerce, commercial use, and disposal as part of its regulatory options to address the unreasonable risk. As a general example, EPA may regulate upstream activities (e.g., processing, distribution in commerce) to address downstream activities (e.g., consumer uses) driving unreasonable risk, even if the upstream activities do not drive the unreasonable risk.

Section 7 - Comments regarding EPA's withdrawal of the associated orders

A couple of commenters (0080, 0085) provided feedback regarding EPA's withdrawal of the associated orders. An industry trade organization (0080) requested that EPA not withdraw the order for PV29 COUs that were found not to present an unreasonable risk. This commenter requested that EPA not withdraw the existing associated orders to avoid regulatory issues in states which promulgate risk management rules before EPA finalizes their federal rule and create preemption concerns over state and federal requirements. The industry trade organization requested that EPA keep the associated orders in place until a second round of risk evaluations for the 10 Work Plan chemicals have been completed to provide additional certainty throughout the process and until new risk management rules are in place. Conversely, an advocacy organization (0085) expressed general support for the withdrawal of the associated orders for PV29.

EPA RESPONSE:
EPA is issuing a final revised unreasonable risk determination for the PV29 risk evaluation after consideration of the public comments received on the draft. For purposes of TSCA section 6(i), EPA is making a risk determination on PV29 as a whole chemical. Under the revised approach, the "whole chemical" risk determination for PV29 supersedes the no unreasonable risk determinations for PV29 that were premised on a condition of use-specific approach to determining unreasonable risk and also contains an order withdrawing the TSCA section 6(i)(1) order in Section 5.4.1 of the January 2021 PV29 Risk Evaluation.

Consistent with the statutory requirements of TSCA section 6(a), the Agency will propose risk management actions to the extent necessary to address the unreasonable risk presented by PV29. EPA does not plan to conduct a second risk evaluation on PV29.

TSCA section 18(c)(3) defines the scope of federal preemption with respect to any final rule EPA issues under TSCA section 6(a). That provision provides that federal preemption of statutes, criminal penalties, and administrative actions applies to the hazards, exposures, risks, and uses or conditions of use of the chemical substance included in any final action the Administrator takes pursuant to TSCA section 6(a). EPA reads this to mean that states are preempted from imposing requirements through statutes, criminal penalties, and administrative actions relating to any hazards, exposures, risks, and uses or conditions of use evaluated in the final risk evaluation and informing the risk determination that EPA addresses in the TSCA section 6(a) rulemaking. For example, federal preemption applies even if EPA does not regulate in that final rule a particular COU, but that COU was evaluated in the final risk evaluation.

Section 8 - Other comments related to the draft revision of the risk determination

Section 8.1 - Comments discussing the scientific analysis

An industry trade organization (0082) stated that though the draft revised risk determination stated that it does not intend to amend or reevaluate the scientific analysis, the draft "opines that alveolar hyperplasia is an 'irreversible' effect" without elaborating further or mentioning the word "irreversible" in the risk evaluation. The commenter stated that studies show that it can be reversed, and the final risk evaluation stated that EPA determined that alveolar hyperplasia is a non-cancer health effect and determined that PV29 is not likely to be carcinogenic. The commenter said that if EPA wishes to supplement the final risk evaluation to address this issue, it should reopen the risk evaluation for public comment.

Another industry trade organization (0084) stated that if EPA allows revision of section 5 of the PV29 Risk Evaluation and takes comment on the revision, the EPA must also allow the public to review the bases of the Unreasonable Risk Determination, particularly because there are significant issues with the scientific analysis.

EPA RESPONSE:
EPA disagrees that it is necessary to reopen the January 2021 PV29 Risk Evaluation for public comment as changing the risk determination to a whole chemical approach does not impact the underlying data and analysis presented in the risk characterization of the PV29 risk evaluation which was subject to public notice and comment as well as scientific peer review. EPA also views the peer reviewed hazard and exposure assessments and associated risk characterization as upholding the standards of best available science and weight of the scientific evidence per TSCA sections 26(h) and (i). As indicated in the January 2021 PV29 Risk Evaluation, chronic exposure to PV29 is expected to increase lung burden which may result in kinetic lung overload, a pharmacokinetic phenomenon, which is not due to the overt toxicity of the chemical, but rather the possibility that PV29 dust overwhelms the lung clearance mechanisms over time. The

inhalation toxicity data on the analogue carbon black demonstrated increased lung burden, alveolar hyperplasia, inflammatory and morphological changes in the lower respiratory tract. However, inhaled particles may have systemic effects. In the January 2021 Risk Evaluation, EPA characterized those health effects as severe; however, the draft revised unreasonable risk determination described them as irreversible. Since the Agency is not changing the underlying data and analysis presented in the risk characterization of the January 2021 PV29 Risk Evaluation, it is correcting the statement about the irreversibility of the health effects in the final revised unreasonable risk determination and describing them as severe, consistent with the risk characterization of the January 2021 PV29 Risk Evaluation.

Section 8.1.1 – Strength of the information and type of assessment supporting the risk evaluation

Two commenters provided feedback on the strength of the information and type of assessment used to support the risk evaluation under TSCA.

An industry trade organization (0081) stated that EPA used data provided in an email that specified that the particle size was measured by sedimentation. The commenter notes that the Agency should have used another characterization for aerosolized particles, based on EPA's guideline, 870-series toxicity studies (e.g., 870.4365 and related); and the particle size was not measured in the breathing zone which as specified in the guideline. For all of these reasons the commenter believes the particle size data used by the Agency are unlikely to meet the scientific requirements of TSCA section 26.

An advocacy group (0075) provided strong support for the whole chemical approach conceptually, but:

- suggested a multi-route exposure and risk assessment be conducted for both the general population and any relevant subpopulation.
- proposed the Office of Pesticides Program be consulted as this office has conducted multi-route occupational exposure and risk assessments for decades.
- suggested recommendations related to COU-specific assessments.

EPA RESPONSE:
The revised unreasonable risk determination for PV29 is based on the peer reviewed risk characterization of the January 2021 PV29 Risk Evaluation, which was developed according to TSCA section 26(h) requirements to make science-driven decisions consistent with best available science. Changing the risk determination to a whole chemical approach does not impact the underlying data and analysis presented in the risk characterization of the risk evaluation.

With respect to data and information used in the risk evaluation regarding particle size, Table 2-6 in the final risk evaluation presents particle size distribution (PSD) data with particle size diameters ranging from nanometers to micrometers. The wide variability in particle sizes makes it unclear how these data correspond to the particle size workplace dust. Therefore, EPA assumed the range of PSD to be 0.043 µm to 10.4 µm in the workplace breathing zone based on

PSD data from Sun Chemical Corporation. Note that 46.9 µm from BASF is not included in this range for the final risk evaluation. The median particle size of 46.9 µm was initially used in the risk evaluation process leading up to the draft risk evaluation. Once EPA received two PSD datasets from Sun Chemical Corporation after the SACC meeting and before publication of the final risk evaluation, EPA re-evaluated the analogue used for the risk evaluation and decided to base the analogue for PV29 on the particle size of 0.043 µm. Based on the particle size of 0.043 µm, EPA changed the analogue from barium sulfate (particle size of 4.3 µm) to carbon black (particle size of 0.014 µm for high-surface area carbon black and a particle size or 0.070 µm for low-surface area carbon black). In addition to having a similar particle size, carbon black was selected as an analogue for PV29 due to similar physical-chemical properties, similar chemical composition, and both are pigments. There were sub-chronic and chronic inhalation toxicity studies for carbon black that were used to inform potential human health hazards for PV29 in the final risk evaluation: 1) 13-week sub-chronic inhalation toxicity study (Elder *et.al*, 2005); and 2) Chronic inhalation study (Nikula *et.al*, 1995). Table 5-1 in the revised unreasonable risk determination shows the type of effect and the exposure route to workers and ONUs for each condition of use that drives the unreasonable risk determination for PV29.

EPA requested data submissions on particle size studies through a voluntary information request and through a TSCA Section 4 Test Order. The document mentioned by the commenter is a compilation of information received by EPA from the domestic manufacturing and industry stakeholders for PV29, and includes email correspondences, SDS sheets and questionnaires about workplace practices. The data available through the submissions was considered in the systematic review and documented in "*C.I. Pigment Violet 29 (81-33-4) Systematic Review: Supplemental File for the TSCA Risk Evaluation*," a supplemental document containing the data evaluation scoring sheets for the study reports that the Agency used to inform the risk evaluation (Docket Number: EPA-HQ-OPPT-2018-0604-0040). EPA reiterates that the whole chemical approach does not impact the underlying data and analysis presented in the risk characterization of the PV29 risk evaluation.

EPA appreciates the recommendations on how to improve the risk assessment methodology with respect to general population, multi-route occupation exposures and specific condition of use assessments. For PV29, EPA decided not to aggregate exposure pathways because the only route of concern is chronic inhalation to PV29, and the lungs are the site of the adverse effects. Additional exposure pathways such as dermal and oral routes are expected to be low since absorption from dermal or oral exposure is expected to be negligible based on the insolubility of PV29. Therefore, oral and dermal routes are not expected to influence the toxicity in the respiratory tract. As mentioned, the whole chemical approach does not impact the underlying data and analysis presented in the risk characterization of the PV29 risk evaluation. EPA encourages the commenter to submit chemical-specific comments during future risk evaluations' comment periods.

Section 8.2 – Other comments

A chemical manufacturer (0079) stated that revising the risk determination for PV29 would not aid the EPA in implementing risk management measures needed to protect human health and the environment.

An industry trade organization (0084) stated that the updated risk determination should mention the high uncertainty and low confidence of the risk characterization. The commenter explained that the draft revised risk determination mentions "uncertainty" many times throughout its 12 pages in different contexts; for example, the human health risk estimation section mentions uncertainty due to a "lack of quantitative monitoring data and lack of product specific information of [PV29] within consumer products". The commenter stated that this discussion of uncertainty and lack of data should lead the EPA to conclude that there is high uncertainty and low confidence in the risk characterization and warned that not characterizing the risk characterization in this manner shows a lack of transparency.

An industry trade organization (0088) stated that EPA's risk evaluation for PV29 does not adequately inform risk mitigation because it does not provide a concentration of airborne particulates that would lead to lung overload. The commenter also stated that lung overload is not adequately supported by available data, for example, EPA "assumes" that the body would not natural clear trace particles but does not provide data regarding the rates of clearance compared to rates of accumulation. The commenter also expressed concern for the potential ECEL as a toxicologically relevant threshold that EPA is attempting to develop and stated that toxicologically relevant exposure levels should have been determined prior to the risk evaluation. The commenter suggested that, prior to developing an ECEL, the Small Business Advocacy Review panel should "carefully consider risk mitigation strategies typically implemented by industrial hygienists." The commenter also suggested that a PEL of 5 mg/m3 should be the reference value for risk mitigation activities.

An industry trade organization (0084) stated that, ideally, the Draft Revision should be a "drop-in replacement" for section 5 and the revised Risk Evaluation would not reference this revision process. An advocacy organization (0075) stated that it is not clear where the final revised Chapter 5 would be made available to the public and suggested that it be inserted into a new document titled "Revised Final 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," which would also contain all of the unchanged chapters. The commenter also stated that Page 7, section 5.2.1, Paragraph 1, lines 3-4 refer to Table 4.4 as "providing 'health risk estimates for all conditions of use,'" which is correct but makes the title of the table misleading. The commenter suggested that the title be revised to "Risk Estimations for Inhalation Exposure Scenarios."

EPA RESPONSE:
The Agency acknowledges the assumptions that were made and uncertainties present in the January 2021 PV29 Risk Evaluation. Those assumptions and uncertainties were taken into consideration in determining which conditions of use drive the unreasonable risk, as discussed in Section 5.2.4 of the revised unreasonable risk determination document, which is based on the

assumptions and key sources of uncertainty presented in Section 4.2.4. of the January 2021 PV29 Risk Evaluation. The final revised Section 5 of the PV29 Risk Evaluation will be made available to the public.

With respect to the comment that toxicologically relevant exposure levels should have been determined prior to the risk evaluation, EPA would like to note that it is during the risk evaluation that EPA identifies points of departure for the health effects of the chemical substance under evaluation, after doing a systematic review of all reasonably available information and taking in consideration the scientific standards and the weight of the scientific evidence, as required by TSCA section 26 (h) and (i).

The Agency also appreciates the commenter's suggestion that the Small Business Advocacy Review panel consider risk mitigation strategies that are typically implemented by industrial hygienists prior to developing an EPA existing chemical exposure limit (ECEL). EPA is considering risk management options under TSCA Section 6 to address the unreasonable risk posed by PV29. While an ECEL is one possible risk management option, EPA is still determining if there are monitoring methods for PV29 suitable to implement an ECEL. EPA would note that there is no OSHA PEL for PV29 and an ECEL value would be based on the risk evaluation of PV29. EPA appreciates the recommendation of consider a PEL of 5 mg/m3 during risk management and invites the commenter to provide any additional information to be considered during the development of the TSCA section 6(a) proposed rule to address the unreasonable risk of PV29. EPA consideration of the information received will be explained in the proposed rulemaking under TSCA section 6(a), and will consider public comments and any additional information before finalizing the rulemaking.

EPA has edited Section 5.2.1. of the final revised unreasonable risk determination for PV29 to clarify the title of Table 4-4 as "Risk Estimates for Occupational Inhalation Exposure Scenarios."

Section 9 - Comments on potential revisions to other risk determinations for the first ten chemicals

An advocacy organization (0083) stated that the Agency must make holistic risk determinations for all of the initial 10 risk evaluations and apply the whole chemical approach to all risk evaluations moving forward. In other words, EPA should only consider a whole chemical approach because it accurately profiles the unreasonable risk a chemical may pose to human health and the environment.

EPA RESPONSE:
EPA appreciates the comment. As EPA explained in the Federal Register Notice announcing the availability of the draft revised risk determination for PV29, EPA plans to consider the appropriate approach for each chemical substance risk evaluation on a case-by-case basis, taking into account considerations relevant to the specific chemical substance in light of the Agency's obligations under TSCA.