with Plan B, and Plan A is the surviving plan in the merger.

(B) *Analysis and conclusion.* The merger is a merger of a plan described in paragraph (e)(1)(i) of this section with a plan that is not described in paragraph (e)(1)(i) of this section and is not a merger described in paragraph (e)(3)(ii) or (4) of this section. Under paragraph (e)(3)(i)(A) of this section, Plan A will no longer be a plan described in paragraph (e)(1)(i) of this section and will be subject to paragraph (b) of this section after the merger (unless an exception described in paragraph (d)(4) of this section, relating to new or small businesses, applies to Employer R).

(ii) *Example 2*—(A) *Facts.* The facts are the same as in paragraph (e)(7)(i) of this section (*Example 1*), except that there is an acquisition described in § 1.410(b)–2(f), and the plan merger occurs within the transition period described in section 410(b)(6)(C)(ii).

(B) *Analysis and conclusion.* The merger satisfies the requirements of paragraph (e)(3)(ii) of this section. Accordingly, Plan A will continue to be excepted from paragraph (b) of this section as a plan described in paragraph (e)(1)(i) of this section after the merger.

(iii) *Example 3*—(A) *Facts.* Plan C, a multiple employer plan, was established on January 1, 2021. Plan D, a plan maintained by Employer T that is not a multiple employer plan, was adopted on January 1, 2024. Plan D merges with Plan C on December 31, 2024.

(B) *Analysis and conclusion.* The merger is described in paragraph (e)(4)(i) of this section and because Plan D is not a plan described in paragraph (e)(1)(i) of this section, the merger is not excepted under paragraph (e)(4)(ii) of this section. Similarly, because there was no transaction described in § 1.410(b)–2(f), the merger is not described in paragraph (e)(3)(iii) of this section. Accordingly, with respect to Employer T, Plan C will not be a plan described in paragraph (e)(1)(i) of this section and will be subject to paragraph (b) of this section after the merger (unless an exception described in paragraph (d)(4) of this section, relating to new or small businesses, continues to apply to Employer T). However, under paragraph (e)(4)(iii) of this section, the merger does not affect whether Plan C is treated as a plan described in paragraph (e)(1)(i) of this section with respect to any other employers.

(iv) *Example 4*—(A) *Facts.* Plan E, a plan maintained by Employer U that is not a multiple employer plan, was adopted on January 1, 2021. Plan F, a multiple employer plan, was established on January 1, 2024. Plan E merges with Plan F on December 31, 2024.

(B) *Analysis and conclusion.* Under paragraph (e)(4)(ii) of this section, the portion of Plan F that applies with respect to Employer U will continue to be excepted from paragraph (b) of this section as a plan described in paragraph (e)(1)(i) of this section after the merger. However, under paragraph (e)(4)(iii) of this section, the merger does not affect whether Plan F is treated as a plan described in paragraph (e)(1)(i) of this section with respect to any other employers.

(v) *Example 5*—(A) *Facts.* Plan G, a plan maintained by Employer V that is not a multiple employer plan, was adopted on January 1, 2021. Plan G is amended, effective January 1, 2026, to add an additional participating employer, a subsidiary that is 100 percent owned by Employer V.

(B) *Analysis and conclusion.* Because the expansion of eligibility is not an amendment relating to an action described in paragraph (e)(2), (3), or (4) of this section, Plan G will continue to be excepted from paragraph (b) of this section as a plan described in paragraph (e)(1)(i) of this section after the amendment pursuant to paragraph (e)(6)(i) of this section.

(vi) *Example 6*—(A) *Facts.* Plan J, a multiple employer plan, was established on January 1, 2021. Employer W adopts Plan J on January 1, 2022. Effective January 1, 2026, the assets and account balances attributable to the employees of Employer W are spun off to form a new plan, Plan K, maintained solely by Employer W.

(B) *Analysis and Conclusion.* Under paragraph (e)(5)(ii) of this section, Plan K will be excepted from paragraph (b) of this section as a plan described in paragraph (e)(1)(i) of this section.

(f) *Applicability dates*—(1) *Statutory applicability date.* Section 414A applies to plan years beginning after December 31, 2024.

(2) *Regulatory applicability date.* This section applies to plan years beginning after [DATE SIX MONTHS AFTER DATE OF PUBLICATION OF FINAL RULE]. For earlier plan years, a plan is treated as having complied with section 414A if the plan complies with a reasonable, good faith interpretation of section 414A.

Douglas W. O'Donnell,

Deputy Commissioner.

[FR Doc. 2025–00501 Filed 1–10–25; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 751

[EPA–HQ–OPPT–2021–0277; FRL–8331–02–OCSPP]

RIN 2070–AK87

C.I. Pigment Violet 29 (PV29); Regulation Under the Toxic Substances Control Act (TSCA)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA or Agency) is proposing to address the unreasonable risk of injury to human health presented by C.I. Pigment Violet 29 (CASRN 81–33–4, also known as PV29), under its conditions of use as documented in EPA's January 2021 Risk Evaluation for PV29 and the September 2022 Revised Risk Determination for PV29 prepared under TSCA. TSCA requires that EPA address by rule any unreasonable risk of injury to health or the environment identified in a TSCA risk evaluation and apply requirements to the extent necessary so the chemical no longer presents unreasonable risk. To address the identified unreasonable risk, EPA is proposing requirements to protect workers from the unreasonable risk of PV29 during manufacturing and processing, certain industrial and commercial uses of the chemical, and disposal, while also allowing for a reasonable transition period prior to enforcement of said requirements.

DATES: Comments must be received on or before February 28, 2025. Under the Paperwork Reduction Act (PRA), comments on the information collection provisions are best assured of consideration if the Office of Management and Budget (OMB) receives a copy of your comments on or before February 13, 2025.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA–HQ–OPPT–2021–0277, online at *https://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *https://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT:

For technical information: Carolyn Mottley, Existing Chemicals Risk Management Division (7404M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; telephone number (202) 566–1955; email address: *mottley.carolyn@epa.gov.*

For general information: The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554–1404; email address: *TSCA-Hotline@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Executive Summary

A. Does this action apply to me?

You may be potentially affected by this action if you manufacture (defined under TSCA to include import), process, distribute in commerce, use, or dispose of PV29. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities include:

- Synthetic Dye and Pigment Manufacturing (NAICS code 325130);
- Plastics Material and Resin Manufacturing (NAICS code 325211);
- Other Basic Inorganic Chemical Manufacturing (NAICS code 325180);
- Paint and Coating Manufacturing (NAICS code 325510);
- Custom Compounding of Purchased Resins (NAICS code 325991);
- Automobile and Light Duty Motor Vehicle Manufacturing (NAICS code 336110);
- Motor Vehicle Body Manufacturing (NAICS code 336211);
- Automotive Body, Paint, and Interior Repair and Maintenance (NAICS code 811121);
- Printing Ink Manufacturing (NAICS code 325910);
- Motor Vehicle Parts (Used) Merchant Wholesalers (NAICS code 423140);
- Recyclable Material Merchant Wholesalers (NAICS code 423930);
- Carpet and Rug Mills (NAICS code 314110);
- All Other Miscellaneous Textile Product Mills (NAICS code 314999);
- Artificial and Synthetic Fibers and Filaments Manufacturing (NAICS code 325220);
- Floor Covering Retailers (NAICS code 449121);
- Materials Recovery Facilities (NAICS code 562920);
- Sewage Treatment Facilities (NAICS code 221320);
- Solid Waste Collection (NAICS code 562111);
- Solid Waste Landfill (NAICS code 562212);
- Solid Waste Combustors and Incinerators (NAICS code 562213); and
- Other Nonhazardous Waste Treatment and Disposal (NAICS code 562219).

This action may also affect certain entities subject to import certification and export notification rules under TSCA (*https://www.epa.gov/tsca-import-export-requirements*). Persons who import any chemical substance in bulk form, as part of a mixture, or as part of an article (if required by rule) are subject to the TSCA section 13 (15 U.S.C. 2612) import certification requirements and the corresponding regulations at 19 CFR 12.118 through 12.127; see also 19 CFR 127.28. Those persons must certify that the shipment of the chemical substance complies with all applicable rules and orders under TSCA. The EPA policy in support of import certification appears at 40 CFR part 707, subpart B. In addition, any persons who export or intend to export a chemical substance that is the subject of this proposed rule are subject to the export notification provisions of TSCA section 12(b) (15 U.S.C. 2611(b)) and must comply with the export notification requirements in 40 CFR part 707, subpart D.

If you have any questions regarding the applicability of this proposed action to a particular entity, consult the technical information contact listed under **FOR FURTHER INFORMATION CONTACT**.

B. What is the Agency's authority for taking this action?

Under TSCA section 6(a) (15 U.S.C. 2605(a)), if EPA determines through a TSCA section 6(b) risk evaluation that a chemical substance presents an unreasonable risk of injury to health or the environment, EPA must by rule apply one or more requirements listed in TSCA section 6(a) to the extent necessary so that the chemical substance or mixture no longer presents such risk.

C. What action is the Agency taking?

Pursuant to TSCA section 6(b), EPA determined that PV29 presents an unreasonable risk of injury to health, without consideration of costs or other nonrisk factors, including an unreasonable risk to potentially exposed or susceptible subpopulations (PESS) identified as relevant to the Risk Evaluation for C.I. Pigment Violet 29 (2021 Risk Evaluation for PV29), under the conditions of use (Refs. 1, 2). The term ''conditions of use'' is defined in TSCA section 3(4) (15 U.S.C. 2602(4)) to mean the circumstances under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of. A detailed description of the conditions of use that contribute to EPA's determination that PV29 presents an unreasonable risk is provided in Unit III.B. Accordingly, to address the unreasonable risk, EPA is proposing, under TSCA section 6(a) to:

(i) Require use of assigned protection factor (APF) 50 respirators and equipment and area cleaning to address the risk from inhalation exposure to dry powder PV29 (also referred to as regulated PV29), where dry powder PV29 is expected to be present, for the following conditions of use, as outlined in Unit IV.A.1:

- Domestic manufacture;
- Import;
- Incorporation into formulation, mixture or reaction products in paints and coatings;
- Incorporation into formulation, mixture or reaction products in plastic and rubber products; and
- Intermediate in the creation or adjustment of color of other perylene pigments;
- Recycling;
- Industrial and commercial use in automobile (original equipment manufacturer (OEM) and refinishing) paints and coatings;
- Industrial and commercial use in coatings and basecoats paints and coatings;
- Industrial and commercial use in merchant ink for commercial printing; and
- Disposal.

(ii) Require manufacturers (including importers), processors, and distributors in commerce of regulated PV29 to provide downstream notification of the requirements, as outlined in Unit IV.A.2.

(iii) Require recordkeeping, as outlined in Unit IV.A.2.

EPA notes that not all TSCA conditions of use of PV29 are subject to this proposal. As described in the 2021 Risk Evaluation for C.I. Pigment Violet 29 (Ref. 1) and the September 2022 revised unreasonable risk determination (Ref. 2), four conditions of use of PV29 do not contribute to the unreasonable risk: distribution in commerce; industrial/commercial use in plastic and rubber products—automobile plastics; industrial/commercial use in plastic and rubber products—industrial carpeting; and consumer use in professional quality watercolor and acrylic artist paint. Consumer use in professional quality watercolor and acrylic artist

paint was the only consumer condition of use evaluated as part of the 2021 PV29 Risk Evaluation. EPA is requesting public comment on all aspects of this proposal.

D. Why is the Agency taking this action?

Under TSCA section 6(a), ''[i]f the Administrator determines in accordance with subsection (b)(4)(A) that the manufacture, processing, distribution in commerce, use or disposal of a chemical substance or mixture, or that any combination of such activities, presents an unreasonable risk of injury to health or the environment, the Administrator shall by rule . . . apply one or more of the [section 6(a)] requirements to such substance or mixture to the extent necessary so that the chemical substance or mixture no longer presents such risk.'' PV29 was the subject of a risk evaluation under TSCA section 6(b)(4)(A) that was issued in January 2021 (Ref. 1). In addition, EPA issued a revised unreasonable risk determination for PV29 in September 2022 (Ref. 2), determining that PV29, through a single risk determination for the chemical substance under its conditions of use, presents an unreasonable risk of injury to health under the conditions of use. As a result, EPA is proposing to take action to the extent necessary so that PV29 no longer presents such risk. The unreasonable risk and the conditions of use that contribute to the unreasonable risk are described in Unit III.B.

The 2022 Revised Unreasonable Risk Determination for C.I. Pigment Violet 29 reaffirmed that the same 10 conditions of use found to present unreasonable risk of injury to health in the 2021 Risk Evaluation for C.I. Pigment Violet 29 contribute to the unreasonable risk of injury to health as a single chemical substance. As part of the rulemaking process, EPA is required to assess the potential impact of its regulations on small businesses through the Small Business Regulatory Enforcement Fairness Act (SBREFA), which amended the Regulatory Flexibility Act (RFA). Since regulation of PV29 under TSCA was expected to have a significant economic impact on a substantial number of small entities, also referred to as SISNOSE, EPA convened a Small Business Advocacy Review (SBAR) Panel to ensure future regulation of PV29 would have minimal impact on small businesses' operation while maximizing protection of human health. Small businesses selected for the panel, referred to as Small Entity Representatives (SERs), provided comments to the Agency to describe how a PV29 regulation would impact their operations, including their use of PV29, current protections taken when using PV29 in their facilities, and how possible regulatory options the Agency could take would impact their operations.

Comments from multiple (ink, disposal, paint, and manufacturing) SERs during the SBAR Panel indicated that, in their experience, once a pigment is incorporated into a matrix, it no longer retains its original properties. For example, the statement from SERs would imply that dry powder PV29 would not have the same toxicological profile as PV29 mixed into paint, similar to the Proposition 65 warning position from California's EPA for titanium dioxide, which includes ''airborne, unbound particles of respirable size'' and states that the warning does not cover titanium dioxide when it remains bound within a product matrix (Ref. 3). One commenter cited the Proposition 65 warnings for Carbon Black in California, where the risk to human health for the pigment is limited to ''airborne, unbound particles of respirable size.'' EPA's interpretation of the comment and the Proposition 65 warning is that after the pigment is mixed into solution, there are no further human health inhalation risks of concern (Refs. 3, 4).

Information provided by SERs and their representatives during the SBAR panel process indicates encapsulating PV29 into pigment for a paint requires dispersants and a dispersion medium to be mixed with pigment, and once PV29 is incorporated into paint, it does not retain its dry particle properties. In addition, in a memo written by the Agency to clarify assertions made in the 2021 Risk Evaluation, once PV29 is encapsulated into plastics, paints, and inks, it is not expected to be reactive or leachable, and thus would not be biologically available (Ref. 5). For the purpose of risk management, EPA has interpreted this statement to mean that encapsulated PV29 will not present the same human health hazards as dry powder PV29. This information was factored into the development of the proposed regulatory options for PV29.

The Agency recognizes that strict workplace controls can be implemented to address unreasonable risk of PV29. For these reasons, this rule proposes to allow PV29's continued use, with additional worker protection for the conditions of use where PV29 is used in a dry powder form. This proposed approach will address the unreasonable risk of injury to health presented by PV29 to the extent necessary so that the chemical no longer presents unreasonable risk.

E. What are the estimated incremental impacts of this action?

EPA's Economic Analysis of the estimated incremental impacts associated with this rulemaking can be found in the rulemaking docket (Ref. 6). As described in more detail in the Economic Analysis (Ref. 6), EPA was unable to quantify all incremental costs of this proposed rule. EPA's estimate of the costs of this proposed rule are estimated to range from $1.6 million to $1.7 million per year annualized over 15-years at a 2% discount rate (Ref. 6). Cost estimates are described in this Unit and more fully in Section 4 of the Economic Analysis. The cost estimates for the proposed rule include costs of rule familiarization, labeling and downstream notification, PPE, and equipment cleaning. PPE cost estimates are estimated as incremental to baseline conditions and include the costs of the equipment itself, as well as the costs of a medical evaluation, fit testing, and equipment cleaning that ensure proper use and maintenance of the PPE. There may be some unquantified costs associated with respirator use and estimates of numbers of facilities importing or using regulated PV29. The extent to which respirators might reduce worker productivity or necessitate offering higher wages to workers who must wear respirators is unknown and therefore unquantified in the Economic Analysis.

Unit IV. details which actions apply to which conditions of use. EPA estimates that 22 firms associated with 22 sites may be manufacturing (including importing), processing, or using regulated (*i.e.,* dry powder) PV29. A single domestic firm is manufacturing and selling regulated PV29 and EPA has identified a single importer of regulated PV29, and assumes the importer uses the PV29 and does not resell PV29. Twenty firms are estimated to use but not resell regulated PV29. Therefore, EPA estimates that only one firm would be subject to the requirement to label products and provide downstream notification. Additionally, EPA estimates that approximately 50,000 firms undertake activities that fall under conditions of use subject to requirements but do not manufacture (including import), process, or use regulated PV29 when performing those activities. While these firms are not estimated to be subject to the proposed requirements because they are not expected to use dry powder PV29, they should read the proposal in order to make that determination. Information on the development of estimates of

affected facilities can be found in Section 3 of the Economic Analysis.

EPA estimates that approximately five small entities using regulated PV29 would be subject to the requirements of the proposed rule. Additionally, EPA estimates that approximately 50,000 small businesses that may be involved in activities in affected conditions of use do not use regulated PV29 but would, nevertheless, need to familiarize themselves with the rule to determine whether there is a need to comply with specific requirements. EPA found impacts under 1% of annual revenues for all but one of the small entities.

Chronic exposure to dry powder C.I. Pigment Violet 29 may 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 C.I. Pigment Violet 29 dust overwhelms the lung clearance mechanisms over time. The inhalation toxicity data on the analogue carbon black demonstrated increased lung burden, alveolar hyperplasia, and inflammatory and morphological changes in the lower respiratory tract. These endpoints are not monetizable themselves, however there are occupational studies on carbon black that have found significant relationships between inhalable carbon black dust exposure and respiratory effects, including chronic bronchitis. Therefore, EPA's Economic Analysis provides estimates to understand the magnitude of potential chronic bronchitis cases avoided from exposure reduction to PV29 as a result of the proposed rule. The estimated monetized benefit of the proposed regulatory action ranges from approximately $271,000 to $629,000 per year annualized over 15-years at a 2% discount rate.

II. Background

A. Overview of C.I. Pigment Violet 29

PV29 is a perylene pigment that is reddish-purple in color and is currently manufactured as a powder, slurry, or paste. It is used to dye products, such as plastics and paints, and is commonly used in automobile paints and coatings. Though PV29 was first produced in 1913, its commercialization did not occur until the late 1950s (Ref. 1). It has been recognized for its high color strength, weather fastness and heat stability. The reasons for these high-performance characteristics have been attributed to the organizational structure of the molecule (Ref. 1).

EPA has identified alveolar hyperplasia (increased number of cells in the lungs where oxygen transfer occurs), inflammatory and morphological changes in the lungs from chronic inhalation exposure to PV29 in the workplace as the basis for the unreasonable risk for PV29 (Ref. 1). This proposed rule is specifically intended to address the unreasonable risk of injury to health that EPA has identified in the 2021 Risk Evaluation for PV29 and the September 2022 revised unreasonable risk determination, as described in Unit III.B.

According to data collected in EPA's 2016 Chemical Data Reporting (CDR) Rule, approximately 603,500 lbs. (exclusive of imports) were manufactured in the United States in Reporting Year 2015 (Refs. 1, 6). EPA assumes that regulated PV29 is expected to be imported at unknown minor volumes under 25,000 lbs (Ref. 6). The exact production volume, including domestic manufacture and import, in the 2020 CDR was reported as confidential business information (CBI) but is estimated to be less than 1,000,000 lbs. PV29's use as a pigment in the colorant industry is described in Unit III.B.1., with a description of proposed requirements to address the unreasonable risk in Units III.B.3, and IV.A.

B. Regulatory Actions Pertaining to C.I. Pigment Violet 29

PV29 is on multiple countries' chemical inventories but is not subject to chemical-specific statutory or regulatory restrictions in other countries and/or international treaties and/or agreements. In the United States, PV29 is regulated under the OSH Act as a Particulate Not Otherwise Regulated (PNOR) and is subject to OSHA's respirable dust requirements (29 CFR 1910.1000 Table Z–1), as there are no chemical specific requirements for PV29 (*https://www.osha.gov/chemicaldata/801*). PNOR substances include dust, nuisance dust, and inert dust; they are described as ''dusts from solid substances'' without reference to a specific CASRN (*https://www.osha.gov/chemicaldata/801*). Additionally, under the Federal Food, Drug, and Cosmetics Act, PV29 is approved for use as a colorant for polymers in food-related articles, such as food packaging, at or below 1 percent by weight of polymers and should follow specific conditions of use (21 CFR 178.3297). PV29 is not listed as an approved food additive (Ref. 1). PV29 is subject to CDR reporting requirements under TSCA.

EPA did not identify information indicating that PV29 is subject to chemical-specific restrictions under state statutes or regulations implemented by state agencies or departments. A summary of the regulatory actions pertaining to PV29 can be found in Appendix A.1 of the 2021 PV29 Risk Evaluation (Ref. 1).

C. Summary of EPA's Risk Evaluation Activities on PV29

EPA published the scope of the PV29 risk evaluation (82 FR 6545, January 19, 2017 (FRL–9958–33)), and, after receiving public comments, published the problem formulation in June 2018 (83 FR 26998, June 11, 2018 (FRL–9978–40)). In November 2018, EPA published a draft risk evaluation (83 FR 57473, November 15, 2018 (FRL–9986–45)), a revised draft risk evaluation in October 2020 (85 FR 68873, October 30, 2020 (FRL–10015–96)), and after public comment and peer review by the Science Advisory Committee on Chemicals (SACC), EPA issued the Final Risk Evaluation for C.I. Pigment Violet 29 in January 2021 in accordance with TSCA section 6(b) (86 FR 6322, January 21, 2021 (FRL–10017–50)). EPA subsequently issued a draft Revised Unreasonable Risk Determination for PV29 (87 FR 12690, March 7, 2022 (FRL–9403–01–OCSPP)), and after public notice and receipt of comments, published the Final Revised Unreasonable Risk Determination for C.I Pigment Violet 29 in September 2022 (87 FR 54491, September 6, 2022 (FRL–9403–02–OCSPP)). The 2021 Risk Evaluation for C.I. Pigment Violet 29 and supplemental materials are in docket EPA–HQ–OPPT–2018–0604, with the September 2022 revised unreasonable risk determination and additional materials supporting the risk evaluation process in docket EPA–HQ–OPPT–2016–0725, on *https://www.regulations.gov.*

1. 2021 Risk Evaluation

In the 2021 Risk Evaluation for C.I. Pigment Violet 29, EPA evaluated risks associated with 14 conditions of use within the following life cycle stages: manufacture (including import), processing, distribution in commerce, industrial and commercial use, consumer use, and disposal (Ref. 1). Descriptions of the conditions of use that contribute to the unreasonable risk are in Unit III.B.1. The 2021 Risk Evaluation for C.I. Pigment Violet 29 identified significant adverse human health effects associated with long-term exposure to PV29, specifically alveolar hyperplasia, inflammatory and morphological changes in the lungs from chronic inhalation exposures. A further discussion of the unreasonable risk of PV29 is in Unit III.B.3.

2. 2022 Revised Unreasonable Risk Determination

EPA revisited specific aspects of its first 10 TSCA existing chemical risk evaluations, including the PV29 risk evaluation, to ensure that the risk evaluations upon which risk management decisions are made were better aligned with TSCA's objective of protecting health and the environment. For PV29, EPA revised the original unreasonable risk determination based on the 2021 Risk Evaluation and issued a final revised unreasonable risk determination in September 2022 (Ref. 2). EPA revised the risk determination for the 2021 Risk Evaluation for C.I. Pigment Violet 29 pursuant to TSCA section 6(b) and consistent with Executive Order 13990, (''Protecting Public Health and the Environment and Restoring Science to Tackle the Climate Crisis'') and other Biden-Harris Administration priorities (Refs. 7, 8, 9). The revisions consisted of making a single risk determination for the chemical substance instead of by individual conditions of use (which resulted in the revised risk determination superseding the prior ''no unreasonable risk'' determinations and the withdrawal of the associated TSCA section 6(i)(1) ''no unreasonable risk'' orders); and revising the risk determination to no longer reflect an assumption that all workers are always provided and appropriately wear PPE (Ref. 2).

In determining whether PV29 presents unreasonable risk under the conditions of use, EPA considered relevant risk-related factors, including, but not limited to: the effects of the chemical substance on health (including non-cancer risks) and human exposure to the substance under the conditions of use (including duration, magnitude and frequency of exposure); the effects of the chemical substance on the environment and environmental exposure under the conditions of use; the population exposed (including any potentially exposed or susceptible subpopulations); the severity of hazard (including the nature of the hazard, the irreversibility of the hazard); and uncertainties.

EPA determined that PV29 presents an unreasonable risk of injury to human health. Inhalation exposure under 10 conditions of use contribute to the unreasonable risk of injury to health for workers and occupational non-users (ONUs, or workers who do not directly handle PV29 but perform work in an area where PV29 is present) from occupational exposures (*i.e.,* during manufacture, processing, industrial and commercial uses, disposal). EPA did not identify risks of injury to the environment that contribute to the unreasonable risk for PV29. The PV29 conditions of use that contribute to EPA's determination that the chemical substance poses unreasonable risk of injury to health are listed in the unreasonable risk determination (Ref. 2) and in Unit III.B.1., with descriptions to aid chemical manufacturers, processors, and users in determining how their particular use or activity would be addressed under the proposed regulatory provisions.

3. Additional Information Received During Risk Management

Following the publication of the 2021 Risk Evaluation for C.I. Pigment Violet 29, the Agency received information from stakeholders during the public comment period after publication of the draft revised risk determination, the SBAR process, and through additional meetings with stakeholders (Ref. 10, 3, 11). This information was considered as part of the development of the proposed and primary alternative regulatory actions and was used to further identify where occupational worker and ONU exposure to dry powder PV29 occurs.

As part of this rulemaking, EPA would like to clarify that the unreasonable risk is due to inhalation exposure to dry powder PV29 and not to PV29 already incorporated into a liquid mixture, such as wet paint or ink. This clarification is needed in part due to a more robust understanding of the PV29 downstream uses through information provided by small entity representatives and through EPA analysis as noted in EPA's memorandum described in this document (Ref. 5) and further consideration of the listing of carbon black under Proposition 65 in California (Ref. 4). In the response to comments for the 2021 Risk Evaluation for C.I. Pigment Violet 29, EPA stated that the risk of injury to health was present for PV29 in its dry powder form and when in solution or a mixture, such as wet or dry paint (Ref. 12). This included potential risk of injury to health from inhalation exposure to paint containing PV29 during automotive spray painting, sanding, grinding, and repair service activities (Ref. 12). This assertion was repeated in the response to comments for the 2022 Draft Revised Unreasonable Risk Determination in reference to automotive paint, where the Agency explained its belief 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 and that these exposures are drivers of the unreasonable risk presented by PV29 (Ref. 10, p. 28).

In the 2021 Risk Evaluation for C.I. Pigment Violet 29, EPA stated that PV29 present in dried paint and plastic products is expected to be encapsulated and available physical and chemical property information indicates that due to a low solubility in water and octanol, it is not expected to leach out (Ref. 1, p. 59). EPA also stated in the TSCA risk evaluation for PV29 that PV29 is not expected to be reactive or leachable either as a neat material or encapsulated in plastics or paint resins (Ref. 1, p. 65). The statements in the risk evaluation support the conclusion that, pigments with a dry powder form like PV29, including carbon black, do not present the same inhalation exposure risk after they are mixed into solution and encapsulated such that PV29 particles cannot be released. Carbon black was the analogue used for PV29's toxicity in the 2021 PV29 risk evaluation. Commenters during the SBAR Panel meeting specifically mentioned the Proposition 65 regulation in California, where carbon black is listed as a carcinogen specifically for airborne, unbound particles of respirable size (Ref. 3, 4). Similar to the statements about encapsulation of PV29 in the TSCA risk evaluation, the Carbon Black Proposition 65 Listing Notice stated that exposure to carbon black, per se, does not occur when it remains bound within a product matrix, such as rubber, ink or paint (Ref. 4).

EPA has issued a memo (Ref. 5), in which the Agency provides clarity about exposure-related statements made since the publication of the risk evaluation. This memo states that the risk assessed in the 2021 Risk Evaluation for C.I. Pigment Violet 29 is based on the analogue carbon black and is associated with inhalation exposures of PV29 in manufacturing and processing as particles in the dry powder form. Exposure to paint aerosols containing PV29 was not assessed in the risk evaluation. The conclusions of the memo are supported by the following sections of the risk evaluation which note that PV29 encapsulated in plastics, paints, and inks are not expected to be reactive or leachable, and therefore, not likely to be biologically available when not in dry powder form:

- Section 1.1 addresses the physical-chemical properties of PV29 and states that the chemical is extremely insoluble in water or other organic solvents and has a very low vapor pressure.
- Section 1.4.1.3 cites information provided by a stakeholder about the

encapsulation of PV29 in plastic resins due to its low solubility in water and octanol.

- Section 1.4.1.4 states that inhalation is not identified as a route of exposure for commercially available watercolor or acrylic paints due to low vapor pressure of PV29.
- Section 2.3.2 states that inhalation is not an expected route of exposure for commercially available watercolor and acrylic paints and that dermal and oral absorption is expected to be limited from the same source due to low water solubility.

Taken together, the information and statements in the memo clarify that EPA agrees when PV29 is incorporated into the matrix of paint and other liquid media, such as ink, it does not retain the original dry particle properties of its original form. This information applies to automotive spray painting, sanding, grinding and repair services, since they involve use of dried paint containing PV29. In these instances, PV29 has been used within a mixture and is no longer bioavailable in its dry powder form. EPA is requesting comment on the interpretations of risk when it is in other forms including bound in a matrix like paint or liquid, and if uses, *e.g.* aerosol spraying, sanding or grinding dry paint, could render PV29 biologically available or possibly pose an inhalation exposure risk.

III. Regulatory Approach

A. Background

Under TSCA section 6(a), if the Administrator determines through a TSCA section 6(b) risk evaluation that the manufacture (including import), processing, distribution in commerce, use, or disposal of a chemical substance or mixture, or any combination of such activities, presents an unreasonable risk of injury to health or the environment, EPA must by rule apply one or more of the following requirements to the extent necessary so that the chemical substance or mixture no longer presents such risk.

- Prohibit or otherwise restrict the manufacturing (including import), processing, or distribution in commerce of the substance or mixture, or limit the amount of such substance or mixture which may be manufactured, processed, or distributed in commerce (TSCA section 6(a)(1)).
- Prohibit or otherwise restrict the manufacturing, processing, or distribution in commerce of the substance or mixture for a particular use or above a specific concentration for a particular use (TSCA section 6(a)(2)).
- Limit the amount of the substance or mixture which may be manufactured, processed, or distributed in commerce for a particular use or above a specific concentration for a particular use specified (TSCA section 6(a)(2)).
- Require clear and adequate minimum warnings and instructions with respect to the substance or mixture's use, distribution in commerce, or disposal, or any combination of those activities, to be marked on or accompanying the substance or mixture (TSCA section 6(a)(3)).
- Require manufacturers and processors of the substance or mixture to make and retain certain records, or conduct certain monitoring or testing (TSCA section 6(a)(4)).
- Prohibit or otherwise regulate any manner or method of commercial use of the substance or mixture (TSCA section 6(a)(5)).
- Prohibit or otherwise regulate any manner or method of disposal of the substance or mixture, or any article containing such substance or mixture, by its manufacturer or processor or by any person who uses or disposes of it for commercial purposes (TSCA section 6(a)(6)).
- Direct manufacturers or processors of the substance or mixture to give notice of the unreasonable risk determination to distributors, certain other persons, and the public, and to replace or repurchase the substance or mixture (TSCA section 6(a)(7)).

As described in Unit III.B., EPA assessed how the TSCA section 6(a) requirements could be applied to address the unreasonable risk identified in the 2021 Risk Evaluation for C.I. Pigment Violet 29 and the final revised unreasonable risk determination, so that PV29 no longer presents such unreasonable risk. EPA's proposed regulatory action and a primary alternative regulatory action are described in Unit IV. EPA is requesting public comment on all elements of the proposed regulatory action and the primary alternative regulatory action and is providing notice that, based on consideration of comments and any new information submitted to EPA during the comment period on this proposed rule, EPA may in the final rule modify elements of the proposed regulatory action. The public should understand that the Agency's consideration of public comments could result in changes to elements of the proposed and alternative regulatory actions when this rule is finalized. For example, elements such as timelines for implementation could be lengthened or shortened, downstream notification could have requirements added or eliminated, or elements of the primary alternative regulatory action could be incorporated.

Under the authority of TSCA section 6(g), EPA may consider granting a time-limited exemption from a requirement of a TSCA section 6(a) rule for a specific condition of use if EPA finds that: (1) The specific condition of use is a critical or essential use for which no technically and economically feasible, safer alternative is available, taking into consideration hazard and exposure; (2) compliance with the requirement, as applied with respect to the specific condition of use, would significantly disrupt the national economy, national security, or critical infrastructure; or (3) the specific condition of use of the chemical substance, as compared to reasonably available alternatives, provides a substantial benefit to health, the environment, or public safety. Based on reasonably available information, EPA has analyzed the need for an exemption and is not proposing to grant an exemption from the rule requirements at this time. EPA is requesting public comment regarding the need for exemptions from the rule (and under what specific circumstances) pursuant to the provisions of TSCA section 6(g). EPA is also requesting comment on, in lieu of proposing a 6(g) exemption in a separate regulatory action, whether any elements of the primary alternative regulatory action should be considered in combination with elements of the proposed regulatory action as EPA develops the final regulatory action.

TSCA section 6(c)(2)(C) requires that, in deciding whether to prohibit or restrict in a manner that substantially prevents a specific condition of use and in setting an appropriate transition period for such action, EPA consider, to the extent practicable, whether technically and economically feasible alternatives that benefit health or the environment will be reasonably available as a substitute when the proposed prohibition or restriction takes effect. As neither the proposed regulatory action nor the primary alternative regulation action would prohibit or restrict in a manner that substantially prevents activities for any conditions of use of PV29, an alternatives assessment was not conducted.

Section 6(c)(2)(A) of TSCA requires EPA, in proposing and promulgating TSCA section 6(a) rules, to consider and include a statement of effects addressing certain factors such as the effects of the chemical substance on health or the environment and the magnitude of exposure, the benefits of the chemical, and the economic consequences of the

rule, including the cost and benefits and the cost effectiveness of the proposed regulatory action and of the one or more primary alternative regulatory actions considered. TSCA section 6(c)(2) considerations are discussed in Unit VI. EPA's proposed regulatory action and a primary alternative regulatory action are fully discussed in Unit IV. EPA is requesting public comment on the proposed regulatory action and the alternative regulatory action.

EPA carried out required consultations as described in this unit and also considered impacts on children's environmental health as part of its approach to developing this TSCA section 6 regulatory action.

1. Consultations

EPA conducted consultations and outreach as part of development of this proposed regulatory action. The Agency held a federalism consultation on May 13, 2021, as part of this rulemaking process and pursuant to Executive Order 13132. During the consultation, EPA met with State and local officials early in the process of developing the proposed action in order to receive meaningful and timely input into its development (Ref. 13). During the consultation, participants and EPA discussed preemption, EPA's authority under TSCA section 6 to regulate identified unreasonable risk, what activities would be potentially regulated in the proposed rule, and the relationship between TSCA and existing statutes (Ref. 13). EPA received no written comments as part of this consultation.

PV29 is not manufactured (including imported), processed, distributed in commerce, or regulated by tribes. However, EPA consulted with tribal officials during the development of this proposed action. The Agency held a Tribal consultation on May 24 and June 3, 2021. Tribal officials were given the opportunity to meaningfully interact with EPA risk managers concerning the current status of risk management. During the consultation, EPA discussed risk management under TSCA section 6(a), findings from the 2021 Risk Evaluation for C.I. Pigment Violet 29, types of information that would be helpful to inform risk management, principles for transparency during the risk management process, and types of information EPA is seeking from tribes (Ref. 14). EPA received no written comments as part of this consultation.

In addition to the formal consultations, EPA also conducted outreach to advocates for communities that might be subject to disproportionate exposure to PV29, such as minority populations, low-income populations, and indigenous peoples. EPA's Environmental Justice (EJ) consultation occurred on June 1 and 9, 2021. EPA held public meetings as part of this consultation which were held pursuant to and in compliance with Executive Orders 12898 and 14008 (Ref. 15). EPA received no written comments following the EJ meeting.

EPA convened a SBAR Panel to obtain advice and recommendations from SERs that potentially would be subject to this proposed rule's requirements (Ref. 3). EPA met with SERs before and during Panel proceedings, on January 25, 2022, and September 14, 2023. Panel recommendations are in Unit V.A.5.; the Panel report is in the docket (Ref. 3). Additional requests for comment based on Panel recommendations are in Unit VIII.

Units X.C., X.E., X.F. and X.J. provide more information regarding the consultations.

2. Other Stakeholder Consultations

In addition to the formal consultations described in Unit X., EPA held a public webinar on February 23, 2021, and attended a Small Business Administration (SBA) Roundtable on February 26, 2021. At both events EPA staff provided an overview of the TSCA risk management process and the findings in the 2021 Risk Evaluation for C.I. Pigment Violet 29 (Refs. 16, 17). Attendees of these meetings were given an opportunity to voice their concerns on both the risk evaluation and risk management.

Furthermore, EPA has engaged in discussions with representatives from different industries, technical experts, and users of PV29. A list of external meetings held during the development of this proposed rule is in the docket (Ref. 11); meeting materials and summaries are also in the docket. The purpose of these discussions was to hear from importers, processors, distributors, and users about the conditions of use evaluated for PV29; substitute chemicals or alternative methods; engineering control measures and personal protective equipment currently in use or potentially feasible for adoption; and other risk reduction approaches that may have already been adopted or considered for the evaluated conditions of use.

3. Children's Environmental Health

The Agency's 2021 Policy on Children's Health (Ref. 18) articulates EPA's policy of protecting children from environmental exposures by consistently and explicitly considering early life exposures (from conception, infancy, early childhood and through adolescence until 21 years of age) and lifelong health in all human health decisions through identifying and integrating children's health data and information when conducting risk assessments. TSCA section 6(b)(4)(A) also requires EPA to conduct risk evaluations to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment, 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. Infants, children, and pregnant women are listed as examples of subpopulations that may be considered relevant ''potentially exposed or susceptible subpopulations'' in the TSCA section 3(12) definition of that term. In addition, TSCA section 6(a) requires EPA to apply one or more risk management requirements under TSCA section 6(a) so that PV29 no longer presents an unreasonable risk (including unreasonable risk to potentially exposed or susceptible subpopulations).

The Risk Evaluation for C.I. Pigment Violet 29 released in January 2021 considered impacts on both children and adults from occupational use from inhalation and dermal exposures, as applicable. The risk evaluation considered males (>16 years of age) and females of reproductive age (>16 years of age) for inhalation exposure. While risks to children are not disproportionate, effects observed in studies include alveolar hyperplasia, inflammatory, and morphological changes in the lungs from chronic inhalation exposure. The effects related to the endpoint used for PV29 risk evaluation were alveolar hyperplasia, inflammatory, and morphological changes in the lungs, which are not associated with disproportionate effects to children. The risks identified in this section would be addressed by both the proposed regulatory action and primary alternative action described in Unit IV.

B. Regulatory Assessment of C.I. Pigment Violet 29

1. Description of Conditions of Use That Contribute to the Unreasonable Risk

This unit describes the TSCA conditions of use that contribute to EPA's unreasonable risk determination for the chemical substance PV29. Condition of use descriptions were obtained from EPA sources such as the 2021 Risk Evaluation for C.I. Pigment Violet 29 and related documents, and include clarifications based on the CDR use codes, as well as the Organisation

for Economic Co-operation and Development (OECD) harmonized use codes and feedback from stakeholders regarding how they describe their uses. For additional description of the conditions of use, including process descriptions and worker activities considered in the risk evaluation, see the 2021 Risk Evaluation for C.I. Pigment Violet 29, and supplemental files (Refs. 1, 19). EPA acknowledges that some of the terms used in this unit may also be defined under other statutes; however, the descriptions in this unit are intended to provide clarity to the regulated entities subject to the provisions of this rule under TSCA section 6(a).

a. Manufacturing

i. Domestic Manufacture

Domestic manufacturing means to manufacture or produce PV29 within the United States. For purposes of PV29 risk management, this includes the complex combination of chemical substances to form PV29 and loading and repackaging (but not transport) associated with the manufacturing and production of PV29.

Based on the reasonably available information before the Agency, EPA believes PV29 is currently manufactured within the United States by one company. EPA received information regarding the bagging and pack out process at the end of manufacturing (Ref. 3). The chemical reaction for PV29 production is well-established, PV29 is obtained by reacting naphthalimide (CASRN 81–83–4) with molten potassium hydroxide, causing the potassium salt of the leuco form of perylenetetracarboxylic diimide to be formed, and followed by atmosphere oxidation (Ref. 1).

This domestic manufacturer of PV29 reports that it produces PV29 as a powder that is used within its own plant to produce other pigments or is sold to other manufacturers and processers in bags (Ref. 1). In addition, powder PV29 can be sold to other manufacturers in a pelleted or slurry form in addition to powder form (Ref. 3). Approximately 80% of PV29 produced in the U.S. is used to make other pigments and the remaining 20% produced is shipped out of the facility to customers or exported (Ref. 3). The paint and coatings trade organization which represents PV29's current domestic manufacturer stated that PV29 powder is produced 12 times a year over the course of one 12-hour shift by 2 workers (Ref. 3).

ii. Import

Import refers to the import of PV29 into the customs territory of the United States and loading and repackaging (but not transport) associated with the import of PV29. In general, chemicals may be imported into the United States in bulk via water, air, land, and intermodal shipments. These shipments take the form of oceangoing chemical tankers, railcars, tank trucks, and intermodal tank containers. PV29 can be imported as a powder and liquid, including as a tint paste (Ref. 1). EPA expects that PV29 and products containing PV29 are often stored in warehouses prior to distribution for further processing and use. Only one company has been identified as an importer of PV29 (Ref. 1). This company reported to EPA's Chemical Data Rule (CDR) that it imports PV29 as a ''liquid, other solid,'' which, based on the Agency's knowledge of forms of PV29, is likely a paste (Ref. 6). Additionally, information provided to EPA by the company also suggests that they import both a tint paste and dry powder form PV29 in volumes less than 25,000 lbs./yr. (Ref. 19). It is possible that there are other companies importing volumes at less than 25,000 lbs/yr that EPA is not able to identify.

b. Processing

i. Processing: Incorporation Into Formulation, Mixture, or Reaction Products in Paints and Coatings

This condition of use (COU) refers to the preparation of a product, *i.e.,* the incorporation of dry powder PV29 into formulation, mixture, or a reaction product which occurs when a chemical substance is added to a product (or product mixture), after its manufacture, for distribution in commerce. In this case, ''processing'' refers to the mixing of dry powder PV29 into paints and coatings. Processors of PV29 for paint and coating manufacturing receive the chemical at 80% concentration in powder in bags that are manually opened and dumped into a mixer where it is milled and formulated into a tint paste. The paste is added to a wide variety of liquid base coats for the automobile industry (Ref. 20). EPA estimates that 14 facilities would process dry powder PV29 into paints and coatings (Ref. 6).

ii. Processing: Incorporation Into Formulation, Mixture, or Reaction Products in Plastic and Rubber Products

This COU refers to the preparation of a product, *i.e.,* the incorporation of dry powder PV29 into formulation, mixture, or a reaction product which occurs when a chemical substance is added to a product (or product mixture), after its manufacture, for distribution in commerce. In this case, ''processing'' refers to the mixing of dry powder PV29 into plastic and rubber products. A processor of PV29 for plastic manufacturing receives the chemical in bags that are manually opened and added to a vessel for weighing and dry blending with polymers and other additives. This preparation is then extruded via a continuous and closed process involving encapsulation into pellets (Ref. 20). EPA estimates that six facilities process dry powder PV29 into plastics (Ref. 6).

iii. Processing: Intermediate in the Creation or Adjustment of Color of Other Perylene Pigments

This COU refers to the use of the dry powder PV29 in a chemical reaction for the manufacturing of another chemical substance or product. In this case, ''processing'' refers to the use of dry powder PV29 in the manufacturing of perylene pigment. According to information provided to EPA by the manufacturer of PV29, the production of PV29 is the starting point for the synthesis of all other perylene pigments at the manufacturing facility and other perylenes produced at the manufacturing facility may contain an estimated 0–5% residual C.I. Pigment Violet 29 in the finished pigment. (Ref. 19).

iv. Processing: Recycling

This COU refers to the process of treating generated waste streams (*i.e.,* which would otherwise be disposed of as waste) containing PV29 that are collected, either on-site or transported to a third-party site, for commercial purpose. PV29 is primarily recycled commercially in the form of PV29-containing articles, including plastics and auto parts. EPA did not find PV29-specific information for recycling, including specific worker activities and commonly recycled materials (Ref 1).

c. Industrial and Commercial Use

i. Industrial and Commercial Use in Automobile Paints and Coatings (Original Equipment Manufacturing and Refinishing)

This COU refers to the industrial and commercial use of industrial or commercial automobile paints and coating products, including primers, topcoats, and basecoats containing PV29. Activities where these types of automobile paint and coatings products are used could include mixing and spray applications, including use of a spray gun, after the original

manufacturing process for automobiles and as part of refinishing operations. These products could also be sanded after curing during automotive refinishing operations (Ref. 1).

ii. Industrial and Commercial Use in Coatings and Basecoats for Paints and Coatings

This COU refers to the industrial and commercial use of industrial or commercial coating and basecoat products that are not specifically used as part of automobile manufacturing and refinishing operations. PV29 could be present in pigment dispersions in waterborne and solventborne systems, waterborne and solventborne basecoats, and as a colorant in solventborne coating (Ref. 21).

iii. Industrial and Commercial Use in Merchant Ink for Commercial Printing

This COU refers to the industrial and commercial use of industrial or commercial printing ink. Public comments during the risk evaluation state PV29 could be used in inkjet ink (Ref. 1). It is estimated that about 1% of PV29 produced within the domestic market is used in merchant ink for commercial printing and packaging, especially where lightfastness and color stability are important (Ref. 22).

In the risk evaluation, this COU included the use of PV29 in merchant ink; however, information provided since the publication of the risk evaluation indicates that PV29 use in merchant ink is uncommon (Ref. 3), and that PV29 is not used in any ink formulation for any of the following print processes in the graphics arts industry: screen, digital, offset lithographic, letterpress, rotogravure, or flexographic (Ref. 3).

d. Disposal

Each of the conditions of use of PV29 may generate waste streams of the chemical. This COU refers to PV29 in a waste stream that is collected and transported to third-party sites for disposal or treatment. This COU also encompasses PV29 contained in wastewater discharged to publicly owned treatment works or other, non-public treatment works for treatment, and other wastes. Recycling of PV29 and PV29 containing products is considered a different COU.

e. Terminology in This Proposed Rule

For the purposes of this proposed rulemaking, ''occupational conditions of use'' refers to the TSCA conditions of use described in Units III.B.1.a. through d. Although EPA identified both industrial and commercial uses in the 2021 Risk Evaluation for C.I. Pigment Violet 29 for purposes of distinguishing exposure scenarios, the Agency clarified then and clarifies now that EPA interprets the authority over ''any manner or method of commercial use'' under TSCA section 6(a)(5) to include both. In the 2021 Risk Evaluation for C.I. Pigment Violet 29, EPA identified and assessed all known, intended, and reasonably foreseen uses of PV29.

EPA is not proposing to incorporate the descriptions of known, intended or reasonably foreseen conditions of use of PV29 presented and described in Unit III.B.1.a. through d. as definitions in the regulatory text. However, EPA requests comment on whether EPA should promulgate definitions for those conditions of use evaluated in the 2021 Risk Evaluation for C.I. Pigment Violet 29, and, if so, whether the descriptions in this unit are consistent with the conditions of use evaluated in the 2021 Risk Evaluation for C.I. Pigment Violet 29 and whether they provide a sufficient level of detail to improve the clarity and readability of the regulation if EPA were to promulgate a regulation that contains a list of all regulated industrial and commercial conditions of use.

EPA further notes that this proposed rule would not apply to any substance excluded from the definition of ''chemical substance'' under TSCA section 3(2)(B)(ii) through (vi). Those exclusions include, but are not limited to, any pesticide (as defined by the Federal Insecticide, Fungicide, and Rodenticide Act) when manufactured, processed, or distributed in commerce for use as a pesticide; and any food, food additive, drug, cosmetic, or device, as defined in section 201 of the Federal Food, Drug, and Cosmetic Act (FFDCA), when manufactured, processed, or distributed in commerce for use as a food, food additive, drug, cosmetic or device.

2. Description of Unreasonable Risk Under the Conditions of Use

EPA has determined that PV29 presents an unreasonable risk of injury to human health under the conditions of use based on chronic toxicity for non-cancer effects. As described in the 2021 Risk Evaluation for C.I. Pigment Violet 29, EPA identified lung toxicity adverse effects from chronic non-cancer inhalation exposures to PV29. Unit VI.A. summarizes the health effects and the magnitude of the exposures in more detail (Ref. 1).

To make the unreasonable risk determination for PV29, EPA evaluated exposures to human receptors, including workers (which includes occupational non-users (ONUs)), using reasonably available monitoring and modeling data for inhalation exposures. EPA did not quantitatively evaluate risks to consumers or bystanders of consumer use because PV29 is not expected to volatilize from consumer paints due to its low vapor pressure (Ref. 1).

For the 2021 Risk Evaluation for C.I. Pigment Violet 29, EPA considered potentially exposed or susceptible subpopulations (PESS) identified as relevant to the risk evaluation by the Agency. Groups of individuals with greater exposure to PV29 relative to the general population include: (1) workers of either sex (>16 years old), including pregnant women, (2) individuals who do not use PV29 but may be indirectly exposed due to their proximity to the user who is directly handling PV29 (ONUs), and (3) consumer users and bystanders associated with consumer use (Ref. 1). All PESS are included in the quantitative and qualitative analyses described in the 2021 Risk Evaluation for C.I. Pigment Violet 29 and were considered in the determination of unreasonable risk for PV29. The 2021 Risk Evaluation for C.I. Pigment Violet 29 did not quantitatively assess the air and water exposure pathways in the published risk evaluation due to PV29's low vapor pressure, volatility, and solubility in water.

3. Description of TSCA Section 6 Requirements for Risk Management

EPA considered the TSCA section 6(a) requirements (listed in Unit III.A.) to identify which ones have the potential to eliminate the unreasonable risk for PV29.

As required, EPA developed a proposed regulatory action and one primary alternative regulatory action, which are described in Units IV.A. and IV.B., respectively. To identify and select a regulatory action, EPA considered the route of exposure driving the unreasonable risk, inhalation, and the exposed populations. For occupational conditions of use (see Unit III.B.1), EPA considered how it could directly regulate manufacturing (including import), processing, distribution in commerce, industrial and commercial use, or disposal to address the unreasonable risk.

As required by TSCA section 6(c)(2), EPA considered several factors, in addition to identified unreasonable risk, when selecting among possible TSCA section 6(a) requirements. To the extent practicable, EPA factored into its decisions: (i) the effects of PV29 on health and the magnitude of exposure of human beings to PV29, (ii) the effects of PV29 on the environment and the

magnitude of exposure of the environment to PV29, (iii) the benefits of PV29 for various uses, and (iv) the reasonably ascertainable economic consequences of the rule. In evaluating the reasonably ascertainable economic consequences of the rule, EPA considered (i) the likely effect of the rule on the national economy, small business, technological innovation, the environment, and public health, (ii) the costs and benefits of the proposed regulatory action and of the primary alternative regulatory action considered, and (iii) the cost effectiveness of the proposed regulatory action and of the primary alternative regulatory action considered. See Unit VI. for further discussion related to TSCA section 6(c)(2)(A) considerations, including the statement of effects of the proposed rule with respect to these considerations.

EPA also considered the regulatory authorities under statutes administered by other agencies such as OSHA's implementation of the OSH Act, as well as other EPA-administered statutes to examine: (1) whether there are opportunities for all or part of this risk management action to be addressed under other statutes, such that a referral may be warranted under TSCA sections 9(a) or 9(b); or (2) whether TSCA section 6(a) regulation could include alignment of requirements and definitions in and under existing statutes and regulations to minimize confusion to the regulated entities and the general public.

In addition, EPA followed other TSCA requirements such as setting proposed compliance dates in accordance with the requirements in TSCA section 6(d)(1)(B) (described in the proposed and alternative regulatory action in Units IV.A and IV.B.).

To the extent information was reasonably available, EPA considered pollution prevention strategies and the hierarchy of controls adopted by OSHA and NIOSH when selecting regulatory actions, with the goal of identifying risk management control methods that are permanent, feasible, and effective (Ref. 23). EPA also considered how to address the unreasonable risk while providing flexibility to the regulated entity where appropriate and took into account the information presented in the 2021 Risk Evaluation for C.I. Pigment Violet 29, as well as additional input from stakeholders (as described in Unit III.A.), and anticipated compliance strategies from regulated entities.

Taken together, these considerations led EPA to the proposed regulatory action and primary alternative regulatory action described in Unit IV. Additional details related to how the requirements in this unit were incorporated into development of those actions are in Unit V.

IV. Proposed Regulatory and Alternative Regulatory Actions

This unit describes the proposed regulatory action by EPA so that PV29 will no longer present an unreasonable risk of injury to health. In addition, as indicated by TSCA section 6(c)(2)(A), EPA must consider the costs and benefits and the cost-effectiveness of the proposed regulatory action and one or more primary alternative regulatory actions. In the case of PV29, the proposed regulatory action is described in Unit IV.A. and the primary alternative regulatory action considered is described in Unit IV.B. The rationale for the proposed and alternative regulatory actions and associated compliance timeframes are discussed in this unit and in more detail in Unit V.A. EPA is requesting public comment on the proposed regulatory action and alternative regulatory action, including whether EPA should have more prescriptive requirements for the cleaning plan.

A. Proposed Regulatory Action

EPA is proposing under TSCA section 6(a) to require specific workplace protections, including respiratory protection and equipment and area cleaning, for certain manufacturing, processing, industrial, and commercial conditions of use. EPA is also proposing to require recordkeeping and to require manufacturers (including importers), processors, and distributors of PV29 for any use to provide downstream notification of requirements.

1. Administrative and Prescriptive Controls

a. Overview

As described in Unit III.B.3, under TSCA section 6(a), EPA is required to issue a regulation applying one or more of the TSCA section 6(a) requirements to the extent necessary so that the unreasonable risk of injury to human health or the environment from the chemical substance is no longer present. The TSCA section 6(a) requirements provide EPA the authority to limit or prohibit a number of activities, including, but not limited to, restricting or regulating the manufacture, processing, distribution in commerce, commercial use, or disposal of the chemical substance. Given this statutory authority, EPA may find it appropriate in certain circumstances to propose respiratory protection requirements for certain occupational conditions of use where dry powder PV29 would be present (*i.e.,* manufacturing, processing, industrial and commercial use, or disposal). This unit describes the proposed prescriptive respiratory protection requirements.

EPA uses the term ''potentially exposed person'' as defined in 40 CFR 751.5 in this unit and in the regulatory text to include workers (including occupational non-users), employees, independent contractors, employers, and all other persons in the work area where PV29 is present and who may be exposed to PV29 under the conditions of use for which the proposed respiratory protection requirements would apply. EPA's proposed respiratory protection requirement would address the unreasonable risk from PV29 to potentially exposed persons directly handling the chemical or in the work area where the chemical is being used. Similarly, the 2021 PV29 risk evaluation did not distinguish between employers, contractors, or other legal entities or businesses that manufacture, process, distribute in commerce, use, or dispose of PV29. For this reason, EPA uses the term ''owner or operator'' as defined in 40 CFR 751.5 to describe the entity responsible for implementing the respiratory protection requirements in any workplace where the proposed respiratory protection requirements would apply. The term includes any person who owns, leases, operates, controls, or supervises such a workplace.

EPA also uses the term ''regulated PV29'' in the proposed regulatory action to describe PV29 in a dry powder form or in dry powder form when mixed with other types of dry powder pigments. Additional discussion is found in Unit V.

EPA is proposing respiratory protection requirements and equipment and area cleaning requirements for the following conditions of use in cases in which regulated PV29 is manufactured, processed, used, or disposed of:

- Domestic manufacture.
- Import.
- Processing: Incorporation into formulation, mixture, or reaction products in paints and coatings.
- Processing: Incorporation into formulation, mixture, or reaction products in plastic and rubber products.
- Processing: intermediate in the creation or adjustment of color of other perylene pigments.
- Processing: recycling.
- Industrial and commercial use in automobile paints and coatings (original equipment manufacturing and refinishing).
- Industrial and commercial use in coatings and basecoats for paints and coatings.

• Industrial and commercial use in merchant ink for commercial printing.
• Disposal.

b. PV29 Regulated Area

EPA is proposing to require that owners or operators of workplaces subject to regulated PV29 respiratory protection or cleaning requirements demarcate any area where regulated PV29 exposures can reasonably be expected to occur, meaning that where a regulated PV29 container is open or in use, equipment containing regulated PV29 is in use or has not yet been cleaned, the area where equipment for regulated PV29 has not yet been cleaned since equipment usage has ceased, or cleaning activities are occurring. PV29 regulated areas would be demarcated using administrative controls, such as warning signs or highly visible signifiers, in multiple languages as appropriate (*e.g.,* based on languages spoken by potentially exposed persons), placed in conspicuous areas, and documented through training and recordkeeping. The owner or operator would be required to restrict access to the PV29 regulated area from any potentially exposed person that lacks proper training, is not wearing required respiratory protection as described in this unit or is otherwise unauthorized to enter. EPA is proposing to require owners and operators demarcate a PV29 regulated area beginning 180 days after the date of publication of the final rule. EPA is soliciting comment on requiring warning signs to demarcate PV29 regulated areas, such as the requirements found in OSHA's General Industry Standard for Beryllium (29 CFR 1910.1024(m)(2)).

c. Respiratory Protection Requirements

EPA is proposing to require the use of respirators with a minimum assigned protection factor (APF) of 50, in general alignment with OSHA's *Respiratory Protection Standard* at 29 CFR 1910.134. Owners and operators would be required to provide respiratory protection selected in accordance with the guidelines described in this unit, that is of safe design and construction for the work to be performed. EPA is proposing to require that owners and operators (1) provide respirators to each potentially exposed person, (2) ensure respirator use, and (3) maintain respirators in a sanitary, reliable, and undamaged condition. Owners and operators would be required to select and provide a respirator that properly fits and communicate respirators selections each potentially exposed person.

EPA is proposing to require respiratory protection with worksite-specific procedures and elements for required respirator use. The proposed respiratory protection requirements would be required when dry powder PV29 is present in the workplace as described in this unit. EPA is proposing to require each owner or operator to select respiratory protection in accordance with the requirements described in this unit and also to comply with OSHA's *Respiratory Protection Standard* at 29 CFR 1910.134 (a) through (l), with the exception of (d) and (a)(1), for selection, proper use, maintenance, fit-testing, medical evaluation, and training when using respirators. The respiratory protection requirements must be administered by a suitably trained administrator, in accordance with OSHA's *Respiratory Protection Standard* at 29 CFR 1910.134(c). This administrator would need to be qualified by appropriate training or experience that is commensurate with the complexity of the program to administer or oversee the respiratory protection program and conduct the required evaluations of program effectiveness. EPA is proposing that owners and operators would provide respirator training to each potentially exposed person who is required by this unit to wear respirators prior to or at the time of initial assignment to a job involving potential exposure to PV29. Owners and operators would also have to re-train each affected person at least once annually or whenever the owner or operator has reason to believe that a previously trained person does not have the required understanding and skill to properly use respirators, or when changes in the workplace or in the respirator to be used render the previous training obsolete.

EPA is proposing to require each owner or operator supply a respirator, in accordance with the APF 50 requirements explained in this unit, to each potentially exposed person who enters an area with regulated PV29 present within six months after publication of the final rule and to ensure that all potentially exposed persons are using the provided respirators whenever dry powder PV29 exposures are expected. EPA recognizes that implementing respiratory protection requirements may require different compliance timeframes depending on existing health and safety programs at various facilities. EPA is soliciting comment on whether six months is a reasonable timeframe to implement respiratory protection requirements or if a different timeframe is appropriate. Additionally, EPA is proposing that the owner or operator must ensure that all filters, cartridges, and canisters associated with respiratory protection used in the workplace are labeled and color coded with the NIOSH approval label and that the label is not removed and remains legible. EPA is requesting comment on whether there should be a requirement for a minimum service life of non-powered air-purifying respirators such as the requirements found in OSHA's General Industry Standard for Benzene (29 CFR 1910.1028(g)(3)(D)).

EPA is proposing to establish minimum respiratory protection requirements, with the requirement for the use of at least an APF 50 respirator, such that any respirator affording a higher degree of protection than the following proposed requirements may be used. EPA does not anticipate that respirators beyond APF 50 will be widely or regularly used to address unreasonable risk. APF 50 respirators that can be used to mitigate the unreasonable risk of injury to health were provided in the risk evaluation in Table 2–7 (Ref. 1) and include: any NIOSH-certified half-mask power air-purifying respirator; any NIOSH-certified half-mask supplied-air respirator or airline respirator in continuous flow mode or pressure-demand or other positive pressure mode; any NIOSH-certified full facepiece air-purifying respirator; any NIOSH-certified full facepiece supplied air respirator or airline respirator (demand mode); any NIOSH-certified full facepiece self-contained breathing apparatus (demand mode); or any NIOSH-certified helmet/hood self-contained breathing apparatus (demand mode). Negative-pressure respirators are acceptable for use if they meet the APF 50 requirement.

d. Workplace Information and Training

EPA is proposing that the implementation of the respiratory protection requirements be done in compliance with the training and information requirements in OSHAs *Respiratory Protection Standard* at 29 CFR 1910.134(k). EPA is requesting comment on whether to require owners or operators to provide additional workplace training in areas where regulated PV29 is present.

e. Equipment and Area Cleaning Requirements

EPA is proposing that each owner or operator create and implement a cleaning plan for equipment and area cleaning where regulated PV29 has been

manufactured, processed, used, or disposed of. As part of the cleaning plan, owners and operators would be required to describe the cleaning method, materials, and procedure to be used for cleaning activities and would be required to clean the equipment and area, as well as the procedure to be used to assess the effectiveness of the cleaning activities. The cleaning method, materials, and procedure would be determined by the owner or operator.

As part of the equipment and area cleaning requirements, EPA is proposing to require equipment and the area in which the equipment is housed to be cleaned within 24 hours following manufacturing, processing, use or disposal of regulated PV29. Surfaces of the equipment that have contact with regulated PV29 as part of operation or the area where the equipment is located would need to be free of residue, meaning that no residue is left on surfaces in the area, such as the outer housing of equipment and places where dust-like particles typically settle, such as the floor; for example, a wet, white cloth, swab, or other similar cleaning fabric will not have visible color after contact with the surface.

EPA is proposing to require each owner or operator to provide information and instructions for the cleaning plan to each person prior to or at the time of initial assignment to a job involving potential exposure to equipment or an area in which regulated PV29 is manufactured, processed, used, or disposed of within six months after the date of publication of the final rule in the **Federal Register**.

f. Compliance Timeframes

EPA is proposing that each owner or operator must provide respiratory protection of at least AFF 50 to all potentially exposed persons in areas where regulated PV29 is present and develop and implement a cleaning plan for equipment and area cleaning where regulated PV29 has been manufactured, processed, used, or disposed of, within six months after the date of publication of the final rule in the **Federal Register**. EPA is also proposing to require each owner or operator to provide information and training for each person prior to or at the time of initial assignment to a job involving potential exposure to regulated PV29 within six months after the date of publication of the final rule in the **Federal Register**. EPA will consider compliance timeframes that may be substantially longer or shorter than the proposed timeframes for owners or operators for procedural adjustments needed to comply with the requirements outlined in this unit and is requesting comment on the feasibility of the proposed compliance timeframes, as well as longer or shorter timeframes.

2. Other Requirements

a. Recordkeeping

EPA is proposing that manufacturers, processors, distributors, and industrial and commercial users of regulated PV29 maintain ordinary business records, such as invoices and bills-of-lading, that demonstrate compliance with the restrictions and other provisions of this proposed regulation; and maintain such records for a period of five years from the date the record is generated. EPA is proposing that this requirement begin at the effective date of the final rule. Recordkeeping requirements would ensure that owners or operators can demonstrate compliance with the regulations if necessary.

Additionally, to support and demonstrate compliance, EPA is proposing that owners and operators of a workplace subject to the respiratory protection requirements and/or the area and equipment cleaning requirements retain compliance records for five years. These proposed requirements are not intended to supersede or otherwise relieve regulated entities from any recordkeeping requirement imposed by other federal laws or regulations. EPA is proposing to require records to include:

(A) Implementation of the respiratory protection requirements and documentation, including as necessary, respiratory protection used and related training;

(B) Information and training provided to each person prior to or at the time of initial assignment and any retraining;

(C) Cleaning plan implementation and documentation, including as necessary, related instructions; and

(D) Information and instructions provided to each person prior to or at the time of initial assignment and any updates to the information and instructions received.

The owners and operators, upon request by EPA, would be required to make such records available to EPA for examination and copying. All records required to be maintained under this proposed rule could be kept in the most administratively convenient form (electronic or paper).

b. Downstream Notification and Labeling

EPA is proposing that manufacturers (including importers), processors, and distributors of regulated PV29 provide downstream notification through Safety Data Sheets (SDSs) by adding the language set forth in proposed 40 CFR 751.907(b) to sections 1(c) and 15 of the SDS. Additionally, EPA is proposing that every regulated PV29 product bear a label that appears on or is securely attached to the immediate container of the PV29 product, and that the contents of a label must show clearly and prominently the language set forth in proposed 40 CFR 751.907(c). In order to provide adequate time to undertake the changes to the SDS and ensure that all processors and distributors of regulated PV29 in the supply chain receive the revised SDS, EPA is proposing a 6-month period for manufacturers, processors, and distributors to implement the proposed SDS changes following publication of the final rule. EPA is also proposing a 6-month period for manufacturers, processors, and distributors to implement the labeling requirement following publication of the final rule.

EPA requests comment on the timeframes for recordkeeping and downstream notification requirements described in this Unit.

B. Primary Alternative Regulatory Action

As indicated by TSCA section 6(c)(2)(A)(iv)(II) and (III), EPA must consider the cost and benefits and the cost effectiveness of the proposed regulatory action and one or more primary alternative regulatory actions considered by the Agency.

The primary alternative regulatory action uses prescriptive workplace controls to address the unreasonable risk from PV29 contributed to by the various conditions of use. EPA requests comment on this primary alternative regulatory action and whether any elements of the primary alternative regulatory action described in this Unit should be considered as EPA develops the final regulatory action.

1. Requirements for Manufacturing and Processing Conditions of Use, Other Than Recycling

a. Overview

The primary alternative regulatory action considered by the EPA would require workplace controls, including engineering controls and respiratory protection for the following conditions of use in cases in which regulated PV29 is manufactured or processed:

- Domestic manufacture;
- Import;
- Processing: Incorporation into formulation, mixture, or reaction products in paints and coatings;
- Processing: Incorporation into formulation, mixture, or reaction

products in plastic and rubber products; and

• Processing: intermediate in the creation or adjustment of color of other perylene pigments.

b. Engineering Controls

The proposed alternative regulatory action would include the use of engineering controls to mitigate the unreasonable risk of injury to health. Engineering controls, such as HEPA filters and other forms of air filtration, would be required to reduce the concentration of regulated PV29 in workplace air. As part of this effort, EPA would adopt OSHA's general monitoring method for respirable dust under 29 CFR 1910.1000 for PNORs, *i.e.,* NIOSH 0600, as the workplace air monitoring method in the proposed alternative regulatory action to confirm that the air concentration of regulated PV29 is at or the NIOSH 0600 limit of detection (LOD, 0.5 mg/m^3). Under the proposed alternative regulatory action, EPA would use NIOSH method 0600 in place of a chemical-specific monitoring method because no analytical monitoring method currently exists for PV29. The respirable dust method would be used in place of a chemical-specific monitoring method to have a way of measuring airborne regulated PV29 workplace exposure. Monitoring would be required to occur at least once every 3 months during when regulated PV29 is manufactured or is in use. If the concentration of airborne dust is above the NIOSH 0600 LOD, monitoring would need to occur at least once every 3 months. If the concentration of airborne dust is below the LOD, monitoring would need to occur at least once every 6 months.

c. PV29 Regulated Area

Similar to the proposed regulatory action, under the primary alternative regulatory action EPA would require that owners or operators of workplaces subject to regulated PV29 respiratory protection or cleaning requirements demarcate any area where regulated PV29 exposures can reasonably be expected to occur, meaning where a regulated PV29 container is open or in use, equipment containing regulated PV29 is in use or has not yet been cleaned, the area where equipment for regulated PV29 has not yet been cleaned since equipment usage has ceased, or cleaning activities are occurring. Regulated areas would be demarcated using administrative controls, such as warning signs or highly visible signifiers, in multiple languages as appropriate (*e.g.,* based on languages spoken by potentially exposed persons), placed in conspicuous areas, and documented through training and recordkeeping. The owner or operator would be required to restrict access to the regulated area from any potentially exposed person that lacks proper training, is not wearing required respiratory protection as described in this unit or is otherwise unauthorized to enter. EPA would propose to require owners and operators demarcate a regulated area beginning 180 days after the date of publication of the final rule. EPA is soliciting comment on requiring warning signs to demarcate regulated areas, such as the requirements found in OSHA's General Industry Standard for Beryllium (29 CFR 1910.1024(m)(2)).

d. Respiratory Protection Requirements

As shown in Unit IV.A.1, the proposed regulatory action would include the requirement for potentially exposed persons to wear an APF 50 respirator in the PV29 regulated area. Under the primary alternative regulatory action, potentially exposed persons would be required to wear an APF 10 respirator. Even though there would be workplace air monitoring performed under the primary alternative regulatory action, EPA is uncertain if the concentration of regulated PV29 in workplace air would be low enough to not result in unreasonable risk of injury to health. Therefore, respirator use would be required as a safeguard to ensure that the unreasonable risk is mitigated for potentially exposed persons. EPA requests comment on the approach of using respirators and engineering controls in tandem to mitigate the unreasonable risk of injury to health.

e. Equipment and Area Cleaning Requirements

The primary alternative regulatory action equipment and area cleaning requirements would be the same as those for the proposed regulatory action. This would ensure that the concentration of regulated PV29 in workplace air is as low as possible.

f. Recordkeeping and Labeling

The primary alternative regulatory action recordkeeping requirements would be different from those for the proposed regulatory action. The alternative regulatory action would require recordkeeping for the engineering controls implemented. The respiratory protection and equipment and area cleaning requirements for recordkeeping would be the same, as owners and operators would be required to maintain respiratory protection and equipment and area cleaning records. However, unlike the proposed regulatory action, the primary alternative regulatory action would not include a labeling requirement for containers storing regulated PV29.

2. Requirements for Recycling, Industrial and Commercial Conditions of Use

The primary alternative regulatory action EPA considered would require respiratory protection and equipment and area cleaning, with different recordkeeping requirements, for the following conditions of use in cases in which PV29 is processed, used, or disposed as a dry powder pigment:

• Processing: recycling;

• Industrial and commercial use in automobile paints and coatings (original equipment manufacturing and refinishing);

• Industrial and commercial use in coatings and basecoats for paints and coatings;

• Industrial and commercial use in merchant ink for commercial printing; and

• Disposal;

The primary alternative regulatory action respiratory protection requirements would be the same as those for the proposed regulatory action. This would include the requirement for potentially exposed persons to use AFP 50 respirators in PV29 regulated areas. It would also include the requirement for a PV29 regulated area as described in the proposed regulatory action.

The primary alternative regulatory action equipment and area cleaning requirements would be the same as those for the proposed regulatory action. This would ensure that the concentration of regulated PV29 in workplace air is as low as possible.

The primary alternative regulatory action recordkeeping requirements would be different from those for the proposed regulatory action. The respiratory protection and equipment and area cleaning requirements for recordkeeping would be the same, as owners and operators would be required to maintain records of the respiratory protection and equipment and area cleaning records. However, unlike the proposed regulatory action, the primary alternative regulatory action would not include a recordkeeping requirement to collect and retain records of regulated PV29 purchase for a period of five years. The Agency would not require a recordkeeping requirement under the primary alternative regulatory action because the respiratory protection requirements and equipment and area cleaning requirements in cases when regulated PV29 is present would

provide sufficient information to indicate that regulated PV29 was purchased.

V. Rationale for the Proposed Regulatory and Primary Alternative Regulatory Actions

This unit describes how the considerations described in Unit III.B.3 were applied when selecting among the TSCA section 6(a) requirements to arrive at the proposed and primary alternative regulatory actions described in Unit IV.A and IV.B.

A. Consideration of Risk Management Requirements Available Under TSCA Section 6(a)

1. Prescriptive Controls

An option EPA considered was requiring specific, prescribed controls—such as engineering controls, administrative controls, and PPE (including respiratory protection)—to reduce exposures to PV29 in occupational settings. Prescriptive controls could include respirators. The Agency identified that respiratory protection could reduce exposures to PV29 to where it no longer presents unreasonable risk. However, for all conditions of use, EPA understands that the use of prescriptive respiratory protection is the lowest on the hierarchy of controls, which is in the following order of greatest to least effectiveness: elimination, substitution, engineering controls, administrative controls, and PPE (Ref. 23). EPA also understands that workplaces have unique processes and equipment in place and that varying types of respiratory protection may be needed for different workplaces. However, due to the lack of an available chemical specific monitoring method for PV29, EPA proposes the use of respiratory protection, specifically APF 50 respirators. APF 50 respirators were found to be the minimum level of respiratory protection that could mitigate the unreasonable risk of injury to health (Ref. 1).

During risk management, the Agency worked to understand the industries that could be potentially impacted by EPA regulatory requirements and considered their use of PV29 and PV29-containing products compared to the inhalation exposure human health risks presented in the 2021 Risk Evaluation for C.I. Pigment Violet 29 and the 2022 Revised Unreasonable Risk Determination. The 2022 Revised Unreasonable Risk Determination for PV29 states that EPA's unreasonable risk determination for PV29 is driven by risks of injury to health associated with 10 conditions of use, including manufacturing (including import), processing, and some industrial and commercial conditions of use. Five downstream conditions of use that contribute to the unreasonable risk of injury to health of PV29—processing: recycling; industrial and commercial use: paints and coatings—automobile (original equipment manufacturing and refinishing); industrial and commercial use: paints and coatings—coatings and basecoats; industrial and commercial use: merchant ink for commercial printing; and disposal—involve the use or breakdown, in the case of recycling and disposal, of products containing PV29, such as paint and plastics.

During the SBAR Panel process, SERs were represented for each of the five downstream conditions of use as well as the other conditions of use that were found to contribute to the unreasonable risk of injury to health. SERs commented about how they could be impacted by a potential PV29 rulemaking in their industries, including their use of PV29, engineering controls and PPE already used, and how they use and handle PV29 (dry powder, paint, plastic, etc.). As part of the SBAR Panel meeting, SERs were asked if PV29 was used in a dry powder or non-dry powder form, such as a slurry or paste, and when after being mixed into paint, what types of equipment and PPE were used for PV29-containing paint application activities. The questions included potential risk of injury to health from inhalation exposure to paint containing PV29 during automotive spray painting, sanding, grinding, and repair service activities (Ref. 3). SERs in the automotive industry stated that they do not use dry powder PV29 and do not mix their own pigments; the paints they use for automotive refinishing activities are provided from automotive and paint and coating manufacturers (Ref. 3). Additionally, SERs in the printing ink manufacturing and graphic arts industries stated that, to their knowledge, PV29 is not used in their industries (Ref. 3). Written comments submitted to the SBAR Panel by a paint and coatings SER specifically mentioned the Proposition 65 regulation in California, where crystalline silica and titanium dioxide are listed as carcinogens specifically for airborne particles of respirable size and airborne, unbound particles of respirable size, respectively (Refs. 3, 4). Carbon black, the analog used for PV29's toxicity, is also listed in the Proposition 65 regulation under a similar description to titanium dioxide, as a carcinogen specifically when as airborne, unbound particles of respirable size.

Notably, the risk evaluation and revised risk determination state that two conditions of use, industrial and commercial uses in finished plastic and rubber products for automobile plastics and industrial carpeting, do not contribute to the unreasonable risk of injury to health of PV29 because the Agency assumed that PV29 powder was incorporated into the materials under these conditions of use and there would be no exposure to PV29 as a dust (Refs. 1, 2). These two conditions of use have similar types of materials compared to the five downstream conditions of use mentioned previously: processing: recycling; industrial and commercial use: paints and coatings—automobile (original equipment manufacturing and refinishing); industrial and commercial use: paints and coatings—coatings and basecoats; industrial and commercial use: merchant ink for commercial printing; and disposal. Additionally, in the 2021 Risk Evaluation for C.I. Pigment Violet 29, where EPA stated that PV29 present in dried paint and plastic products is expected to be encapsulated and available physical and chemical property information indicates that due to a low solubility in water and octanol, it is not expected to leach out (Ref. 1, p. 59). EPA also stated in the risk evaluation that PV29 is not expected to be reactive or leachable either as a neat material or encapsulated in plastics or paint resins (Ref. 1, p. 65). Taken together, the statements in the risk evaluation support information received as part of the SBAR Panel process during the development of this proposed rule, where commenters stated that, in their experience, pigments with a dry powder form like PV29, including carbon black, do not present the same inhalation exposure risk after they are mixed into solution and encapsulated (Ref. 3).

The Agency considered the information in the risk evaluation and the comments provided as part of SBAR during stakeholder meetings and in public comments during the development of this rule. The comments showed that these conditions of use may not result in occupational exposures to dry powder PV29. As stated in Unit II.B.3, EPA has issued a memo (Ref. 5), in which the Agency intended to provide clarity about exposure-related statements made since the publication of the risk evaluation. This memo states that the risk assessed in the 2021 Risk Evaluation for C.I. Pigment Violet 29 is associated with inhalation exposures of C.I. Pigment Violet 29 in manufacturing and processing as particles in the dry powder form. Exposure to paint aerosols

containing PV29 was not assessed in the risk evaluation. The conclusions of the memo are supported by the following sections of the risk evaluation which note that PV29 encapsulated in plastics, paints, and inks are not expected to be reactive or leachable, and therefore, not likely to be biologically available when not in dry powder form:

- Section 1.1 addresses the physical-chemical properties of PV29 and states it is extremely insoluble in water or other organic solvents and has a very low vapor pressure.
- Section 1.4.1.3 cites information provided by a stakeholder about the encapsulation of PV29 in plastic resins due to its low solubility in water and octanol.
- Section 1.4.1.4 states inhalation is not identified as a route of exposure for commercially available watercolor or acrylic paints due to low vapor pressure of PV29.
- Section 2.3.2 states inhalation is not an expected route of exposure for commercially available watercolor and acrylic paints and that dermal and oral absorption is expected to be limited from the same source due to low water solubility.

Taken together, the information and statements in the memo clarify that EPA agrees when PV29 is incorporated into the matrix of paint and other liquid media, such as ink, it does not retain the original dry particle properties of its original form. This information applies to automotive spray painting, sanding, grinding and repair services, since they involve use of dried paint containing PV29. In these instances, PV29 has been used within a mixture and is no longer bioavailable in its dry powder form.

Per the SBAR Panel's recommendation, the Agency also considered tailoring the applicability of requirements for entities that can demonstrate they do not use dry powder PV29, if the requirements are sufficient so that PV29 no longer presents unreasonable risk.

The risk evaluation states inhalation exposure to dry powder PV29 is not expected for two conditions of use in which PV29 has been incorporated into a product, similar to the five downstream conditions of use. Given that (1) unreasonable risk is dependent on exposure to a chemical substance and (2) the products used in the five downstream conditions of use are unlikely to be dry powder PV29 based on public comment and SBAR feedback, the Agency acknowledges that the likelihood of exposure to dry powder PV29 may be low for five conditions of use—processing: recycling; industrial and commercial use: paints and coatings—automobile (original equipment manufacturing and refinishing); industrial and commercial use: paints and coatings—coatings and basecoats; industrial and commercial use: merchant ink for commercial printing; and disposal. However, as there would still be unreasonable risk of injury to health if dry powder PV29 is used, the proposed regulatory requirements would be triggered only when dry powder PV29 is present. Per the SBAR Panel's recommendation, EPA is requesting comment on this approach, specifically how to mitigate the exposure to dry powder PV29, by entities that could, based on demonstrated ability through recordkeeping and utilization of a combination of controls (including engineering controls, administrative controls, and PPE requirements), eliminate inhalation exposure to PV29 to address the unreasonable risk.

2. Equipment and Area Cleaning Requirements

Prescriptive controls that the EPA could require include administrative controls. The use of cleaning requirements is proposed with administrative controls in mind, with the goal of reducing overall exposure to regulated PV29 in a holistic way by using multiple controls on the hierarchy of controls in place of engineering controls. The Agency acknowledges that administrative controls, in the form of a cleaning of the equipment and the area where regulated PV29 is handled, are only one step higher on the hierarchy of controls than respiratory protection but believes that their implementation would be complementary with the use of respiratory protection to address the unreasonable risk. In particular, the Agency chose this path in part because it is difficult to verify the effectiveness of engineering controls for mitigating the unreasonable risk regarding regulated PV29 because a chemical-specific air monitoring method does not currently exist. The Agency also chose this path because, as part of SBAR comments, the Agency learned that the manufacturer of regulated PV29 produces regulated PV29 infrequently over the course of twelve 12-hour shifts per year with 2 workers.

3. Primary Alternative Regulatory Action

EPA acknowledges that for all conditions of use in which it is proposing to require the use of respirators, the types of facilities that would use regulated PV29 may be able to implement engineering controls and respiratory protection, as these conditions of use occur in industrial settings. Therefore, for EPA's primary alternative regulatory action, described in Unit IV.B., EPA is requesting comment on whether any of the uses the Agency is proposing to implement respiratory protection requirements for could be better served by requiring exposure controls in accordance with the hierarchy of controls, including but not limited to engineering controls in tandem with respiratory protection.

As discussed in this unit, in the PV29 Risk Evaluation, EPA identified that respiratory protection could reduce exposures in support of risk management efforts for PV29 and is proposing prescriptive controls, specifically respirators, as part of the primary regulatory option. EPA recognizes the potential for there to be other forms of controls to prevent inhalation exposure to regulated PV29. Therefore, as part of the alternative regulatory action, EPA considered requiring use of engineering controls for five conditions of use that contribute to the unreasonable risk of injury to health where the Agency believes regulated PV29 is commonly present—manufacturing (including import and domestic manufacturing), processing: incorporation into formulation, mixture or reaction products in paints and coatings and in plastic and rubber products, and processing: intermediate in the creation or adjustment of color of other perylene pigments.

For the primary alternative regulatory action, for the conditions of use where the Agency does not believe dry powder PV29 is commonly present—processing: recycling; industrial and commercial use: paints and coatings—automobile (original equipment manufacturing and refinishing); industrial and commercial use: paints and coatings—coatings and basecoats; industrial and commercial use: merchant ink for commercial printing; and disposal—the Agency would require owners and operators to follow the respiratory protection and equipment and area cleaning requirements outlined in the proposed action for these conditions of use when regulated PV29 is purchased. This includes the use of APF 50 respirators and implementation of a cleaning plan. Stakeholder feedback indicated that there could be varying workplace conditions and settings where it would be possible to use regulated PV29, so the Agency believes that respiratory protection and a cleaning plan would be more feasible to require and implement compared to engineering controls. A key difference between the primary alternative regulatory action and the proposed action is the requirement to

implement respiratory protection and cleaning requirements if PV29 is manufactured or purchased. Under the primary alternative regulatory action, respiratory protection and a cleaning plan would always be required regardless of whether an entity under the condition of use manufactures or purchases regulated PV29.

4. Risk Management Requirements Considered but Not Proposed

EPA considered a prohibition as a regulatory option but has found that a different regulatory action would address the unreasonable risk. In addition, EPA considered the information provided regarding alternatives for the use of PV29 as a pigment in paints and coatings. Industry described their efforts to explore alternatives but have not been successful in finding a suitable replacement (Ref. 3).

EPA also considered the option of establishing a Workplace Chemical Protection Program (WCPP) for occupational conditions of use, which would have included a combination of restrictions to address unreasonable risk contributed to by inhalation exposures in the workplace. A WCPP for PV29 would have encompassed restrictions on certain occupational conditions of use and could have included provisions for an Existing Chemical Exposure Limit (ECEL), an airborne concentration generally calculated as an eight (8)-hour time-weighted average (TWA), and ancillary requirements to support implementation of these restrictions. The WCPP requirement for PV29 would have been a non-prescriptive, performance-based exposure limit that would enable owners or operators to determine how to most effectively meet the exposure limits based on conditions at their workplace following the hierarchy of controls. However, EPA was unable to identify an existing chemical-specific inhalation exposure monitoring method for PV29. Additionally, EPA was also unable to identify an existing general workplace dust inhalation exposure monitoring method with a limit of detection lower than the calculated ECEL (0.014 mg/m^3 for inhalation exposures as an 8-hour Time Weighted Average in workplace settings) to ensure that there would be no unreasonable risk of injury to health for potentially exposed persons. EPA is requesting comment on monitoring for inhalation exposures to PV29, including the amount of time needed to develop an inhalation exposure monitoring method or how to use existing monitoring methods for other chemicals (See Unit V.5).

5. Additional Considerations

After considering the different regulatory options under TSCA section 6(a), lack of alternatives (described in Unit V.B.), compliance dates, and other requirements under TSCA section 6(c), EPA developed the proposed regulatory action described in Unit IV.A. to address the unreasonable risk from PV29. To ensure successful implementation of this proposed regulatory action, EPA considered other requirements to support compliance with the proposed regulations, such as requiring respirators and recordkeeping to demonstrate compliance with the respirator requirement, or downstream notification regarding the respirator requirements for use of dry powder PV29 in manufacturing, processing, and distribution in commerce. These proposed requirements are described in Unit IV.A.

Based on reasonably available information, EPA has found that a TSCA section 6(g) exemption is not warranted at this time. Therefore, EPA is not proposing to grant exemptions from the rule requirements under TSCA section 6(g).

As required under TSCA section 6(d), any rule under TSCA section 6(a) must specify mandatory compliance dates, which shall be as soon as practicable with a reasonable transition period, but no later than five years after the date of promulgation of the rule (except in the case of a use exempted under TSCA section 6(g) or for full implementation of ban or phase-out requirements). These compliance dates are detailed in Unit IV.A. and IV.B.

SBAR Panel Recommendations. SBAR Panel information, including Panel's recommendations, was considered throughout the rulemaking process. The Panel's seven recommendations are specifically reflected in this document.

Recommendation 1. The Panel recommends that the EPA consider and request comment on how to mitigate the exposure to PV29, in particular the pure, dry/powder PV29, by entities that could, based on demonstrated ability through recordkeeping and utilization of a combination of controls (including engineering controls, administrative controls, and PPE requirements), eliminate inhalation exposure to PV29 to address the unreasonable risk.

EPA considered the recommendation and the Agency has considered and requests comment on how to mitigate the exposure to PV29, in particular the pure, dry/powder PV29, by entities that could, based on demonstrated ability through recordkeeping and utilization of a combination of controls (including engineering controls, administrative controls, and PPE requirements), eliminate inhalation exposure to PV29 to address the unreasonable risk.

Recommendation 2. The Panel recommends that the EPA consider not prohibiting the use of PV29. Instead, the Panel recommends that the EPA consider the assumptions in the Risk Evaluation to identify requirements that focus on the exposures that are contributing to the unreasonable risk, in particular the pure, dry/powder PV29, as compared to PV29 embedded in a matrix. Additionally, as part of this effort, the Panel recommends that the EPA provide and request comment in the Notice of Proposed Rulemaking (NPRM) on reasonable compliance timeframes for small businesses, with emphasis on comment about how to provide longer compliance timeframes for transitioning to uses requiring reformulation.

EPA considered the recommendation and the Agency is not proposing to prohibit the use of PV29 in any fashion under the conditions of use that contribute to the unreasonable risk of injury to health. Additionally, as part of this panel recommendation, EPA considered the assumptions in the Risk Evaluation to identify requirements that focus on the exposures that are contributing to the unreasonable risk, in particular the pure, dry/powder PV29, as compared to PV29 embedded in a matrix. The Agency's consideration of these points is reflected in the proposed and alternative regulatory options, as described in Unit IV and with additional rationale provided in Unit V.

Recommendation 3. The Panel recommends that the EPA provide readily available information on potential costs that could be incurred using strategies to meet requirements for any proposed exposure controls, such as engineering, administrative, or prescriptive controls e.g., use of specialized systems, cost of new equipment, PPE use), or concentration limit, as they apply to each relevant COU. The Agency should also provide its analysis on whether it is feasible to implement these strategies for the regulated entities.

EPA considered the recommendation and the Agency has provided readily available information on potential costs that could be incurred using strategies to meet requirements for any proposed exposure controls, such as engineering, administrative, or prescriptive controls (*e.g.,* use of specialized systems, cost of new equipment, PPE use), or concentration limit, as they apply to each relevant COU, in the Economic Analysis (Ref. 6).

Recommendation 4. Based on SER comments providing diverse perspectives on preferences for exposure control technologies and methods, the Panel recommends that the EPA consider and request comment on a regulatory approach for those conditions of use where the EPA has confidence that exposures to PV29 can be effectively controlled, and what flexibility could be provided to regulated entities to incorporate the hierarchy of controls to reduce exposures so that the unreasonable risk is no longer present.

EPA considered the recommendation and the Agency also requests comment on a regulatory approach for those conditions of use where the EPA has confidence that exposures to PV29 can be effectively controlled, and what flexibility could be provided to regulated entities to incorporate the hierarchy of controls to reduce exposures so that the unreasonable risk is no longer present. The Agency's consideration of these points is reflected in the proposed and alternative regulatory options, as described in Unit IV and with additional rationale provided in Unit V.

Recommendation 5. The Panel recommends that the EPA provide an overview of information reasonably available regarding engineering or administrative controls that could address inhalation exposures expected for PV29. The panel recommends that the EPA seek comment on state-of-the-art equipment, engineering and administrative controls, and monitoring for inhalation exposures.

EPA considered the recommendation and the Agency has provided an overview of information reasonably available regarding engineering that could address inhalation exposures expected for PV29 as part of the Economic Analysis (Ref. 6). Some administrative controls are mentioned in the Economic Analysis, such as training for respirator usage, and were incorporated into the proposed and alternative proposed options as requirements for signage for regulated areas and respirator fit testing. Additionally, the EPA requests comment on state-of-the-art equipment, engineering and administrative controls, and monitoring for inhalation exposures, including the amount of time needed to develop an inhalation exposure monitoring method or how to use existing monitoring methods for other chemicals.

Recommendation 6. The Panel recommends that the EPA consider tailoring the applicability of requirements for entities that can demonstrate they do not use pure, dry/powder PV29 as long as the requirements are sufficient so that PV29 no longer presents unreasonable risk.

EPA has considered the recommendation and the Agency has tailored the applicability of requirements for entities that can demonstrate they do not use pure, dry/powder PV29 as long as the requirements are sufficient so that PV29 no longer presents unreasonable risk. The Agency's consideration of this point is reflected in the reference to and definition of ''regulated PV29'' in the proposed and alternative regulatory options, as described in Unit IV and with additional rationale provided in Unit V.

Recommendation 7. The Panel recommends that the EPA consider, in accordance with the scientific standards and the weight of scientific evidence required by TSCA, the data submitted after publication of the final risk evaluation for PV29 in the development of risk management options.

EPA has considered the recommendation and has considered, in accordance with the scientific standards and the weight of scientific evidence required by TSCA, the data submitted after publication of the final risk evaluation for PV29 in the development of risk management options. EPA assessed the quality of the particle size data in the study performed in 2020 by the current manufacturer of regulated PV29. This assessment can be found in the docket (Refs. 3, 24).

B. Consideration of Alternatives in Deciding Whether To Prohibit or Substantially Restrict PV29

Under TSCA section 6(c)(2)(C), in deciding whether to prohibit or restrict in a manner that substantially prevents a specific condition of use of a chemical substance or mixture, and in setting an appropriate transition period for such action, EPA must consider, to the extent practicable, whether technically and economically feasible alternatives that benefit human health or the environment will be reasonably available as a substitute when the proposed prohibition or other restriction takes effect. Because EPA is not proposing to prohibit or restrict in a manner that substantially prevents any conditions of use of PV29, formal consideration of alternatives was not necessary.

VI. TSCA Section 6(c)(2) Considerations

A. C.I. Pigment Violet 29: Health Effects and the Magnitude of Human Exposure

For assessment of risks associated with inhalation exposures to workers for PV29, EPA used an analogue, carbon black, to estimate toxicity. EPA used an analogue because no data were available for PV29 for inhalation exposure. 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. Populations exposed to PV29 include individuals age 16 to 19, men and women of reproductive age (16 to 54 years old), and the elderly (55+ years old), including pregnant women and individuals who do not use PV29 but may be indirectly exposed due to their proximity to the user who is directly handling PV29 (ONUs). EPA estimates that, annually, there are approximately between 57 and 77 workers and 78 ONUs at 22 facilities either manufacturing, processing, or using regulated PV29 for industrial and commercial conditions of use (Ref. 6).

B. C.I. Pigment Violet 29: Environmental Effects and the Magnitude of Environmental Exposure

EPA identified and evaluated PV29 environmental hazard data for fish, aquatic invertebrates, amphibians, and aquatic plants across acute and chronic exposure durations. No effects were observed in acute toxicity testing with fish, aquatic invertebrates, and aquatic plants up to the limit of solubility of PV29. As a result, no concentrations of concern (COC) can be calculated for this chemical, as it is not possible to dissolve enough quantities of PV29 in water to elicit a response in aquatic organisms.

EPA determined that environmental exposures of PV29 for the conditions of use are expected to be limited as a result of a qualitative consideration of reasonably available physical and chemical, environmental fate, manufacturing and release, and exposure data. Considering the limited nature of the environmental exposures resulting from the conditions of use of PV29 and the lack of effects observed in the available environmental hazard studies, environmental concentrations

of PV29 are not expected to reach a level where adverse effects to environmental receptors could occur.

C. Benefits of C.I. Pigment Violet 29 for Various Uses

Leading applications for PV29 include use as an intermediate to create or adjust color of other perylene pigments, incorporation into paints and coatings used primarily in the automobile industry, incorporation into plastic and rubber products used primarily in automobiles and industrial carpeting, use in merchant ink for commercial printing, and use in consumer watercolors and artistic color (Ref. 1).

According to data collected in EPA's 2016 Chemical Data Reporting (CDR) database, 603,420 pounds of PV29 were manufactured in the U.S. in 2015. EPA has identified one domestic manufacturer and one importer of PV29 in the United States (Ref. 1). Stakeholder feedback during SBAR Panel proceedings indicated that industry has not been able to find a suitable alternative for PV29, which is used in automotive paints and coatings (Ref. 3).

D. Reasonably Ascertainable Economic Consequences of the Proposed Rule

1. Likely Effect of the Rule on the National Economy, Small Business, Technological Innovation, the Environment, and Public Health

With respect to the anticipated effects of this rule on the national economy, the economic impact of a regulation on the national economy generally only becomes measurable if the economic impact of the regulation reaches 0.25 percent to 0.5 percent of Gross Domestic Product (GDP) (Ref. 25). Given the current GDP this is equivalent to a cost of $69 billion to $139 billion. Therefore, because EPA has estimated that the monetized costs of the rule to range from $1.6 to $1.7 million annualized over 15 years at a 2% discount rate, EPA has concluded that this action is highly unlikely to have any measurable effect on the national economy (Ref. 6). EPA considered the number of businesses, facilities, and workers that would be affected and the costs and benefits to those businesses and workers and society at large and did not find that there would be a measurable effect on the national economy.

In addition, EPA considered the employment impacts of this proposal. While EPA does not have data to quantify employment impacts of the proposed rule. However, EPA expects the short-term and longer-term employment effects to be small. Of the approximately 50,000 small businesses estimated to be potentially impacted by this rule, greater than 99% of firms are estimated to have impacts less than 1% of revenues. Only a single firm is estimated to have impacts between 1 and 3% to their firm revenues, and no firms are expected to have impacts greater than 3% to their firm revenues.

2. Costs and Benefits of the Proposed Regulatory Action and of the 1 or More Primary Alternative Regulatory Actions Considered by the Administrator

The costs and benefits that can be monetized for this rule are described at length in in the Economic Analysis (Ref. 6). The monetized costs for this rule are estimated to range from $1.6 million to $1.7 million annualized over 15 years at a 2% discount rate.

EPA considered the estimated costs to regulated entities as well as the cost to administer alternative regulatory actions. The primary alternative regulatory action is described in detail in Unit IV.B. The estimated annualized costs of the alternative regulatory action are $.9 million at a 2% discount rate over 15 years (Ref. 6).

The proposed rule is expected to achieve health benefits for the American public. Human health hazards for regulated PV29 were assessed in the Risk Evaluation [Ref X] using carbon black as an analogue. Effects of carbon black exposure include increased lung burden, alveolar hyperplasia, and inflammatory and morphological changes in the lower respiratory tract. These endpoints are not monetizable themselves, however there are occupational studies on carbon black that have found significant relationships between inhalable carbon black dust exposure and respiratory effects, including chronic bronchitis. EPA estimates that the monetized benefits of reducing chronic bronchitis cases due to the proposed rule are estimated to range from $271 to $629 thousand annualized over 15 years at a 2% discount rate. The monetized benefits of this alternative regulatory action are estimated to range from $168 to $375 thousand annualized over 15 years at 2% (Ref. 6).

Cost effectiveness of the proposed regulatory action and of the 1 or more primary alternative regulatory actions considered by the Administrator. Cost effectiveness is a method of comparing certain actions in terms of the expense per item of interest or goal. The proposed rule costs an estimated $1.9–$4.3 million per potential bronchitis case avoided while the alternative option costs an estimated $1.8–$3.9 million per potential bronchitis case avoided using annualized costs for the 2 percent discount rate. Thus, the alternative option has a slightly lower cost per case of chronic bronchitis avoided compared to the proposed option, making it the most cost-effective of the two options considered based on estimated costs and benefits. The primary differences between the proposal and alternative option are that the alternative would require engineering controls, such as HEPA filters, to control the regulated PV29 air concentration in addition to PPE and monitoring requirements to measure air concentrations for respirable dust. However, the costs of engineering controls are not monetized in the Economic Analysis.

3. Request for Comments Regarding the Reasonably Ascertainable Economic Consequences of the Proposed Rule

EPA requests comment on its analyses of the number of affected firms, facilities, and occupational users and non-users. EPA requests comment on current PPE practices within affected facilities using regulated PV29 in any of the conditions of use. Finally, EPA requests comment on the costs firms would incur as a result of the proposed rule, as well as information that the Agency could use to improve these estimates.

VII. TSCA Section 9 Analysis and Section 26 Considerations

A. TSCA Section 9(a) Analysis

TSCA section 9(a) provides that, if the Administrator determines, in the Administrator's discretion, that an unreasonable risk may be prevented or reduced to a sufficient extent by an action taken under a Federal law not administered by EPA, the Administrator must submit a report to the agency administering that other law that describes the risk and the activities that present such risk. TSCA section 9(a) describes additional procedures and requirements to be followed by EPA and the other Federal agency following submission of any such report. As discussed in this unit, for this proposed rule, the Administrator proposes to exercise his discretion not to determine that the unreasonable risk from PV29 under the conditions of use may be prevented or reduced to a sufficient extent by an action taken under a Federal law not administered by EPA.

TSCA section 9(d) instructs the Administrator to consult and coordinate TSCA activities with other Federal agencies for the purpose of achieving the maximum enforcement of TSCA while imposing the least burden of duplicative requirements. For this

proposed rule, EPA has coordinated with appropriate Federal executive departments and agencies, to, among other things, identify their respective authorities, jurisdictions, and existing laws with regard to risk evaluation and risk management of PV29, which are summarized in this Unit, and in Unit II. B.

OSHA requires that employers provide safe and healthful working conditions by setting and enforcing standards and by providing training, outreach, education, and assistance. Gaps exist between OSHA's authority to set workplace standards under the OSH Act and EPA's obligations under TSCA section 6 to eliminate unreasonable risk presented by chemical substances under the conditions of use. Health standards issued under section 6(b)(5) of the OSH Act must reduce significant risk only ''to the extent feasible.'' 29 U.S.C. 655(b)(5). To set PELs for chemical exposure, OSHA must first establish that the new standards are economically and technologically feasible (79 FR 61384, 61387, Oct. 10, 2014). OSHA also does not have direct authority over self-employed individuals and public sector workers who are not covered by a State Plan under 29 U.S.C. 667.

The 2016 amendments to TSCA altered both the manner of identifying unreasonable risk and EPA's authority to address unreasonable risk, such that risk management is increasingly distinct from provisions of the OSH Act. EPA risk evaluations under TSCA section 6(b) must determine, without consideration of costs or other nonrisk factors, whether an unreasonable risk of injury to health or the environment is presented, including an unreasonable risk to a relevant potentially exposed or susceptible subpopulation. In a TSCA section 6 risk management rule, following such an unreasonable risk determination, EPA must apply risk management requirements to the extent necessary so that the chemical no longer presents unreasonable risk and only consider costs and benefits of the regulatory action to the extent practicable, 15 U.S.C. 2605(a), (c)(2). EPA's substantive burden under TSCA section 6(a) is to apply requirements to the extent necessary so that the chemical substance no longer presents the unreasonable risk that was determined in accordance with TSCA section 6(b)(4)(A) without consideration of cost or other nonrisk factors.

EPA therefore concludes that TSCA is the only regulatory authority able to prevent or reduce unreasonable risk of PV29 to a sufficient extent across the conditions of use, exposures, and populations of concern. The timeframe and any exposure reduction as a result of updating OSHA regulations cannot be estimated, while TSCA imposes a much more accelerated statutory timeframe for proposing and finalizing requirements to address unreasonable risk. Further, there are key differences between the finding requirements of TSCA and those of the OSH Act. For these reasons, in the Administrator's discretion, the Administrator has analyzed this issue and does not determine that unreasonable risk presented by PV29 may be prevented or reduced to a sufficient extent by an action taken under a Federal law not administered by EPA.

B. TSCA Section 9(b) Analysis

If EPA determines that actions under other Federal laws administered in whole or in part by EPA could eliminate or sufficiently reduce a risk to health or the environment, TSCA section 9(b) instructs EPA to use these other authorities to protect against that risk unless the Administrator determines, in the Administrator's discretion, that it is in the public interest to protect against such risk under TSCA. In making such a public interest finding, TSCA section 9(b)(2) requires EPA to consider, based on the reasonably available information, all relevant aspects of the risk and a comparison of the estimated costs and efficiencies of the action to be taken under TSCA and an action to be taken under another law administered by the Agency to protect against such risk.

The primary exposures and unreasonable risk to workers and occupational non-users would be addressed by EPA's proposed prohibitions and restrictions under TSCA section 6(a). There are no EPA statutes or other regulations for PV29 that would result in reduced exposure to PV29 in occupational settings. EPA therefore concludes that TSCA is the most appropriate regulatory authority able to prevent or reduce risks of PV29 to a sufficient extent across the conditions of use, exposures, and populations of concern.

For these reasons, the Administrator does not determine that unreasonable risk from PV29 under its conditions of use, as evaluated in the 2021 Risk Evaluation for C.I. Pigment Violet 29, could be eliminated or reduced to a sufficient extent by actions taken under other Federal laws administered in whole or in part by EPA.

C. TSCA Section 26 Considerations

In accordance with TSCA section 26(h), EPA has used scientific information, technical procedures, measures, methods, protocols, methodologies, and models consistent with the best available science. As in the case of the unreasonable risk determination, risk management decisions for this proposed rule, as discussed in Units III.B.3. and V., were based on a risk evaluation that was subject to public comment and independent, expert peer review, and was developed in a manner consistent with the best available science and based on the weight of the scientific evidence as required by TSCA sections 26(h) and (i) and 40 CFR 702.43 and 702.45.

The extent to which the various information, procedures, measures, methods, protocols, methodologies, or models, as applicable, used in EPA's decisions have been subject to independent verification or peer review is adequate to justify their use, collectively, in the record for this rule. Additional information on the peer review and public comment process, such as the peer review plan, the peer review report, and the Agency's response to public comments, can be found at EPA's risk evaluation dockets (Docket ID No. EPA–HQ–OPPT–2016–0725 and EPA–HQ–OPPT–2018–0604).

VIII. Requests for Comment

While EPA is requesting public comment on all aspects of this proposal, the Agency is soliciting feedback from the public on specific issues throughout this proposed rule. This section summarizes those specific requests for comments.

1. EPA is requesting public comment on the proposed regulatory action and alternative regulatory action, including whether EPA should have more prescriptive requirements for the cleaning plan. (Unit IV.)

2. EPA is requesting comment on whether to require owners or operators to provide additional workplace training related to PV29 where regulated PV29 is present. (Unit IV.)

3. EPA is requesting public comment on EPA's proposal to not grant a TSCA section 6(g) exemption.

4. EPA requests public comments regarding the number of small businesses subject to the rule and the potential impacts of the rule on these small businesses.

5. EPA is requesting comment on the proposed rule's rationale, including the definition of regulated PV29. (Unit V.)

6. EPA requests comment on whether EPA should promulgate definitions for those conditions of use evaluated in the 2021 Risk Evaluation for C.I. Pigment Violet 29, and, if so, whether the descriptions in this unit are consistent with the conditions of use evaluated in

the 2021 Risk Evaluation for C.I. Pigment Violet 29 and whether they provide a sufficient level of detail to improve the clarity and readability of the regulation if EPA were to promulgate a regulation that contains a list of all prohibited or otherwise regulated industrial and commercial conditions of use. (Unit III.)

7. EPA is soliciting comment on whether six months is a reasonable timeframe to implement respiratory protection requirements or if a different timeframe is needed. (Unit IV.)

8. EPA is requesting comment on whether there should be a requirement for a minimum service life of non-powered air-purifying respirators such as the requirements found in OSHA's General Industry Standard for Benzene (29 CFR 1910.1028(g)(3)(D)). (Unit IV.)

9. EPA will consider compliance timeframes that may be substantially longer or shorter than the proposed timeframes for owners or operators for procedural adjustments needed to comply with the requirements outlined in this unit (Unit IV.) and is requesting comment on the feasibility of the proposed compliance timeframes, as well as longer or shorter timeframes. (Unit IV.)

10. Per the SBAR Panel's recommendation, EPA is requesting comment on this approach, specifically how to mitigate the exposure to dry powder PV29, by entities that could, based on demonstrated ability through recordkeeping and utilization of a combination of controls (including engineering controls, administrative controls, and PPE requirements), eliminate inhalation exposure to PV29 to address the unreasonable risk. (Unit V.)

11. For EPA's primary alternative regulatory action, described in Unit IV.B., EPA is requesting comment on whether any of the uses the Agency is proposing to implement respiratory protection requirements for could be better served by requiring exposure controls in accordance with the hierarchy of controls, including but not limited to engineering controls in tandem with respiratory protection. (Unit V.)

12. Per the SBAR Panel's recommendation, EPA requests comment on reasonable compliance timeframes for small businesses, with emphasis on comment about how to provide longer compliance timeframes for transitioning to uses requiring reformulation. (Unit V.)

13. Per the SBAR Panel's recommendation, EPA requests comment on a regulatory approach for those conditions of use where the EPA has confidence that exposures to PV29 can be effectively controlled, and what flexibility could be provided to regulated entities to incorporate the hierarchy of controls to reduce exposures so that the unreasonable risk is no longer present. (Unit V.)

14. Per the SBAR Panel's recommendation, EPA requests comment on state-of-the-art equipment, engineering and administrative controls, and monitoring for inhalation exposures, including the amount of time needed to develop an inhalation exposure monitoring method or how to use existing monitoring methods for other chemicals. (Unit V.)

15. EPA requests comment on its analyses of the number of affected firms, facilities, and occupational users and non-users. (Unit VI.)

16. EPA requests comment on current PPE practices within affected facilities using regulated PV29 in any of the conditions of use. (Unit VI.)

17. EPA requests comment on the costs firms would incur as a result of the proposed rule, as well as information that the Agency could use to improve these estimates. (Unit VI.)

18. EPA is requesting public comment on the interpretations of risk when it is in other forms including bound in a matrix like paint or liquid, and if uses, *e.g.* aerosol spraying, sanding or grinding dry paint, could render PV29 biologically available or possibly pose an inhalation exposure risk. (Unit II.)

IX. References

The following is a listing of the documents that are specifically referenced in this document. The docket includes these documents and other information considered by EPA, including documents that are referenced within the documents that are included in the docket, even if the referenced document is not physically located in the docket. For assistance in locating these other documents, please consult the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

1. EPA. 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). EPA Document #740–R–18–015. January 2021.
2. EPA. Colour Index Pigment Violet 29 (PV29); Revision to the Toxic Substances Control Act (TSCA) Risk Determination. September 2022.
3. Small Business Advocacy Review Panel. Small Business Advocacy Review Panel on EPA's Planned Proposed Rule under the Toxic Substances Control Act (TSCA) Section 6(a) for C.I. Pigment Violet 29 (PV29). September 14, 2023.
4. California Office of Environmental Health Hazard Assessment. Carbon Black Proposition 65 Listing Notice. *https://oehha.ca.gov/proposition-65/crnr/chemical-listed-effective-february-21-2003-known-state-california-cause-cancer* (accessed November 5, 2024).
5. EPA. Memorandum for ECRAD Response to CPMA Comments Following Small Business Advocacy Review Panel Outreach Meeting on Proposed PV29 Risk Management Rulemaking. March 20, 2024.
6 EPA. C.I. Pigment Violet 29 (PV29); Regulation Under the Toxic Substances Control Act (TSCA); Economic Analysis. December 2024.
7. Executive Order 13985. Advancing Racial Equity and Support for Underserved Communities Through the Federal Government. **Federal Register** (86 FR 7009, January 25, 2021).
8. Executive Order 13990. Protecting Public Health and the Environment and Restoring Science to Tackle the Climate Crisis. **Federal Register** (86 FR 7037, January 25, 2021).
9. Executive Order 14008. Tackling the Climate Crisis at Home and Abroad. **Federal Register** (86 FR 7619, February 1, 2021).
10. EPA. Colour Index Pigment Violet 29 (PV29): Revision to Toxic Substances Control Act (TSCA) Risk Determination Response to Public Comments. August 2022.
11. EPA. Stakeholder Meeting List for Rulemaking for C.I. Pigment Violet 29 under TSCA Section 6(a).
12. EPA. Summary of External Peer Review and Public Comments and Disposition for C.I. Pigment Violet 29 (PV29) (Anthra[2,1,9-def:6,5,10-d′e′f′]diisoquinoline-1,3,8,10(2H,9H)-tetrone), Response to Support the Final Risk Evaluation of C.I. Pigment Violet 29. January 2021.
13. EPA. Federalism Consultation on Forthcoming Proposed Rulemakings under TSCA Section 6(a) for Asbestos, Part 1: Chrysotile Asbestos and C.I. Pigment Violet 29. May 13, 2021.
14. EPA. Tribal Consultations on Risk Management Rulemakings for Asbestos, Part 1: Chrysotile Asbestos and C.I. Pigment Violet 29. May 24, 2021 and June 3, 2021.
15. EPA. Environmental Justice Consultations Risk Management Rulemakings for Asbestos, Part 1: Chrysotile Asbestos and C.I. Pigment Violet 29. June 1, 2021 and June 9, 2021.
16. EPA. Public Webinar on Asbestos, Part 1: Chrysotile Asbestos and C.I. Pigment Violet 29: Risk Evaluation and Risk Management under TSCA Section 6. February 23, 2021.
17. EPA. Small Business Administration Small Business Environmental Roundtable Risk Evaluation and Risk Management under TSCA Section 6 for C.I. Pigment Violet 29. February 26, 2021.
18. EPA. EPA's Policy on Children's Health. October 5, 2021. *https://www.epa.gov/children/childrens-health-policy-and-plan#A1.*
19. EPA. Final Risk Evaluation for C.I. Pigment Violet 29 (PV29) Supplemental

File: Information Received from Manufacturing Stakeholders. January 2021.
20. EPA. Chemical Risk Evaluation Meeting with Sun Chemical Corporation, Color Pigments Manufacturers Association and EPA to Discuss the Downstream Processors of C.I. Pigment Violet 29 (PV29). October 16, 2020.
21. Raleigh Davis; American Coatings Association. Comments to the U.S. Environmental Protection Agency in Response to the TSCA Chemical Use Dossiers on Pigment Violet 29. March 15, 2017.
22. David Wawer; Color Pigment Manufacturers Association, Inc. Comment to the EPA about the Toxicological Properties, Chemical Use (and Other) Information Relevant to EPA's Risk Evaluation of C.I. Pigment Violet 29. March 13, 2017.
23. National Institute for Occupational Safety and Health. Hierarchy of Controls. Page last reviewed: April 10, 2024. *https://www.cdc.gov/niosh/hierarchy-of-controls/about/.*
24. EPA. ECRAD Review of Ramboll's Airborne Particle Size Characterization of C.I. Pigment Violet 29 (PV29) Study and Risk Management Related-Issues. March 13, 2024.
25. Office of Management and Budget. Memorandum for the Heads of Executive Departments and Agencies. Guidance for Implementing Title II of S. 1. March 31, 1995. *https://www.whitehouse.gov/wp-content/uploads/legacy_drupal_files/omb/memoranda/1995-1998/m95-09.pdf.*
26. EPA. Supporting Statement for an Information Collection Request (ICR) Under the Paperwork Reduction Act (PRA); Regulation of C.I. Pigment Violet 29 under TSCA Section 6(a) (Proposed Rule; RIN 2070–AK87). December 2024.

X. Statutory and Executive Order Reviews

Additional information about these statutes and Executive Orders can be found at *https://www.epa.gov/laws-regulations/laws-and-executive-orders.*

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review

This action is not a significant regulatory action as defined in Executive Order 12866 (58 FR 51735, October 4, 1993), as amended by Executive Order 14094 (88 FR 21879, April 11, 2023), and was therefore not subject to a requirement for Executive Order 12866 review.

B. Paperwork Reduction Act (PRA)

The information collection activities in this proposed rule have been submitted to OMB for review and comment under the PRA, 44 U.S.C. 3501 *et seq.* The Information Collection Request (ICR) document that EPA prepared has been assigned EPA ICR No. 7797.01 (Ref. 26). You can find a copy of the ICR in the docket, and it is briefly summarized here.

The information collection requirements contained in the proposed rule are:

- The preparation and retention of records related to respiratory protection requirements in accordance with proposed 40 CFR 751.909(b)(2);
- The preparation and retention of records related to the equipment and area cleaning in accordance with proposed 40 CFR 751.909(b)(1);
- Third-party downstream notifications in accordance with proposed 40 CFR 751.907 from companies that ship PV29 to companies downstream in the supply chain through the SDS to communicate the proposed prohibitions; and
- The preparation and retention of related records in accordance with proposed 40 CFR 751.909, including ordinary business records, such as invoices and bills-of-lading related to the continued distribution of PV29 in commerce.

Respondents/affected entities: Manufacturers (including importers), processors, distributors, and industrial and commercial users of C.I. Pigment Violet 29. See Unit I.A. and the ICR for more details.

Respondent's obligation to respond: Mandatory (15 U.S.C. 2605).

Estimated number of respondents: 49,670.

Frequency of response: On occasion.

Total estimated burden: 16,976 hours (per year). Burden is defined at 5 CFR 1320.3(b).

Total estimated cost: $1,646,584 (per year), includes $200 annualized capital or operation and maintenance costs.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. After display in the **Federal Register** when approved, the OMB control numbers for EPA regulations in 40 CFR are listed in 40 CFR part 9 and displayed on the form and instructions or collection portal, as applicable.

Submit your comments on the Agency's need for this information, the accuracy of the provided burden estimates and any suggested methods for minimizing respondent burden to the EPA using the docket identified at the beginning of this rule. EPA will respond to any ICR-related comments in the final rule. You may also send your ICR-related comments to OMB's Office of Information and Regulatory Affairs using the interface at *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. OMB must receive comments no later than February 13, 2025.

C. Regulatory Flexibility Act (RFA)

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA, 5 U.S.C. 601 *et seq.* The small entities subject to the requirements of this action are small businesses that manufacture/import, process or use the chemical subject to this proposed rule. The estimated annualized costs of this rule are less than $2 million at a 2% discount over 15 years. Only 22 firms are estimated to incur compliance costs associated with rule requirements and five of those are small businesses, however EPA expects that four would be impacted only at less than 1% of revenues and only a single firm would be impacted at between 1% and 3% of revenues. Approximately 50,000 small businesses firms are expected to only incur costs associated with becoming familiar with the proposed requirements and determining that they would not subject to the proposed requirements. EPA does not expect that the costs associated with simply reading and becoming familiar with the proposed requirements would result in direct costs at 1 percent of annual revenues or greater. Details of this analysis are presented in the Economic Analysis (Ref. 6).

Although not required by the RFA to convene a Small Business Advocacy Review (SBAR) Panel because the EPA has now determined that this proposal would not have a significant economic impact on a substantial number of small entities, the EPA originally convened a panel to obtain advice and recommendations from small entity representatives potentially subject to this rule's requirements. A copy of the SBAR Panel Report is included in the docket for this rulemaking.

D. Unfunded Mandates Reform Act (UMRA)

This action does not contain an unfunded mandate of $100 million (in 1995 dollars and adjusted annually for inflation) or more as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. The costs involved in this action are estimated not to exceed $183 million in 2023$ ($100 million in 1995$, adjusted for inflation using the

GDP implicit price deflator) or more in any one year.

E. Executive Order 13132: Federalism

EPA has concluded that this action has federalism implications, as specified in Executive Order 131312 (64 FR 43255, August 10, 1999), because regulation under TSCA section 6(a) may preempt State law. As set forth in TSCA section 18(a)(1)(B), the issuance of rules under TSCA section 6(a) to address the unreasonable risk presented by a chemical substance or mixture has the potential to trigger preemption of State laws, criminal penalties, or administrative action by a State or political subdivison of a State that: (1) is applicable to the same chemical substance or mixture as the rule under TSCA section 6(a); and (2) is to prohibit or otherwise restrict the manufacture, processing, or distribution in commerce or use of that same chemical. TSCA section 18(c)(3) applies that preemption only to the hazards, exposures, risks, and uses or conditions of use of such chemical included in the final TSCA section 6(a) rule.

EPA provides the following federalism summary impact statement. The Agency consulted with State and local officials early in the process of developing the proposed action to permit them to have meaningful and timely input into its development. This included a consultation meeting on May 13, 2021. EPA invited the following national organizations representing State and local elected officials to this meeting: National Association of Attorneys General, Western States Water Council, National Water Resources Association, Association of State Drinking Water Administrators, Association of Clean Water Administrators, Association of Metropolitan Water Agencies, American Water Works Association, National Governors Association; National Conference of State Legislatures, National League of Cities, U.S. Conference of Mayors, National Association of Counties, County Executives of America, and Environmental Council of States. A summary of the meeting with these organizations, including the views that they expressed, is available in the docket (Ref. 13). EPA provided an opportunity for these organizations to provide follow-up comments in writing but did not receive any such comments.

F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

This action does not have tribal implications as specified in Executive Order 13175 (65 FR 67249, November 9, 2000). This rulemaking would not have substantial direct effects on tribal governments because PV29 is not manufactured, processed, or distributed in commerce by tribes and would not impose substantial direct compliance costs on tribal governments. Thus, Executive Order 13175 does not apply to this action.

Notwithstanding the lack of Tribal implications as specified by Executive Order 13175, EPA consulted with Tribal officials during the development of this action, consistent with the EPA Policy on Consultation and Coordination with Indian Tribes, which EPA applies more broadly than Executive Order 13175. The Agency held a Tribal consultation from June 3, 2021, to August 20, 2021, with meetings on May 24 and June 3, 2021. Tribal officials were given the opportunity to meaningfully interact with EPA risk managers concerning the current status of risk management. During the consultation, EPA discussed risk management under TSCA section 6(a), findings from the 2021 Risk Evaluation for C.I. Pigment Violet 29, types of information that would be helpful to inform risk management, principles for transparency during the risk management process, and types of information EPA is seeking from tribes (Ref. 14). EPA received no written comments as part of this consultation.

G. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks

Executive Order 13045 (62 FR 19885, April 23, 1997) directs Federal agencies to include an evaluation of the health and safety effects of the planned regulation on children in Federal health and safety standards and explain why the regulation is preferable to potentially effective and reasonably feasible alternatives. This action is not subject to Executive Order 13045 because it is not a significant regulatory action under section 3(f)(1) of Executive Order 12866, and because the EPA does not believe the environmental health or safety risks addressed by this action present a disproportionate risk to children. Accordingly, we have evaluated associated health impacts of PV29 exposure on children and adults of reproductive age. The effects related to the endpoint used for PV29 risk evaluation were alveolar hyperplasia, inflammatory, and morphological changes in the lungs, which are not associated with disproportionate effects to children. EPA did not find evidence of reproductive and developmental toxicity as a result of exposure to PV29. This action's health and risk assessments and impacts on both children and adults from occupational use from inhalation and dermal exposures are described in Units III.A.3, III.B.3, VI.A., and the 2021 Risk Evaluation for C.I. Pigment Violet 29 (Ref. 1). However, EPA's *Policy on Children's Health* applies to this action. Information on how the Policy was applied is available in Unit III.A.3.

H. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution or Use

This action is not subject to Executive Order 13211 (66 FR 28355, May 22, 2001) because it is not a significant regulatory action under Executive Order 12866.

I. National Technology Transfer and Advancement Act (NTTAA)

This action does not involve technical standards under the NTTAA section 12(d), 15 U.S.C. 272.

J. Executive Orders 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations and Executive Order 14096: Revitalizing Our Nation's Commitment to Environmental Justice for All

EPA believes that the human health and environmental conditions that exist prior to this action result in or have the potential to result in disproportionate and adverse human health or environmental effects on communities with EJ concerns in accordance with Executive Order 14096 (88 FR 25251, April 26, 2023) (building on and supplementing Executive Order 12898 (59 FR 7629, February 16, 1994)). As described more fully in the Economic Analysis for this rulemaking (Ref. 6), EPA conducted an analysis to characterize the baseline conditions faced by workers affected by the proposed regulation to identify the potential for disproportionate impacts on communities with affected by the proposed regulatory option under current conditions, before the regulation would go into effect. The analysis drew on publicly available data provided by EPA and the U.S. Census Bureau, including data from the American Community Survey (ACS) and the Quarterly Workforce Indicators (QWI). The baseline characterization suggests that workers in affected industries are more likely to be people of color than the general population in affected areas (Ref. 6). Therefore, based on reasonably available information, EPA determined that there are potential environmental justice concerns in communities

surrounding facilities subject to this regulation (Ref. 6).

EPA believes that it is not practicable to assess whether this action is likely to reduce or result in new disproportionate and adverse effects on communities with environmental justice concerns. While this proposed regulatory action applies requirements to the extent necessary so that PV29 no longer presents an unreasonable risk, EPA is not able to quantify the distribution of the change in risk for affected populations. Data limitations that prevent EPA from conducting a more comprehensive analysis are summarized in the Economic Analysis (Ref. 6).

EPA additionally identified and addressed potential EJ concerns by conducting outreach to advocates of communities that might be subject to disproportionate exposure to PV29. On June 1, 2021, and June 9, 2021, EPA held public meetings as part of this consultation (Ref. 15). See also Unit II.D. These meetings were held pursuant to Executive Order 12898 and Executive Order 14008, Tackling the Climate Crisis at Home and Abroad (86 FR 7619, February 1, 2021). EPA received no written comments following the EJ meetings, in addition to oral comments provided during the consultations (Refs. 13, 14, 15).

The information supporting this Executive Order review is contained in Unit II.D., as well as in the Economic Analysis (Ref. 6). EPA's presentations, a summary of EPA's presentation and public comments made, and fact sheets for the EJ consultations related to this rulemaking are available at *https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/materials-june-2021-environmental-justice-consultations.* These materials are also available in the docket for this rulemaking.

List of Subjects in 40 CFR Part 751

Environmental protection, Chemicals, Export notification, Hazardous substances, Import certification, reporting and recordkeeping.

Michael S. Regan,

Administrator.

Therefore, for the reasons stated in the preamble, EPA proposes to amend 40 CFR part 751 as follows:

PART 751–REGULATION OF CERTAIN CHEMICAL SUBSTANCES AND MIXTURES UNDER SECTION 6 OF THE TOXIC SUBSTANCES CONTROL ACT

■ 1. The authority citation for part 751 continues to read as follows:

Authority: 15 U.S.C. 2605, 15 U.S.C. 2625(*l*)(4).

■ 2. Add new Subpart J to read as follows:

Subpart J—Color Index Pigment Violet 29

Sec.

§ 751.901 General.

This Subpart sets certain requirements on the manufacture (including import), processing, distribution in commerce, use, and disposal of Color Index Pigment Violet 29 (CASRN 81–33–4), also referred to as PV29, to prevent unreasonable risk of injury to health.

§ 751.903 Definitions.

In addition to the definitions that apply to this part established in § 751.5, the following definitions apply to this subpart:

PV29 regulated area means an area where a regulated PV29 container is open or in use, an area where equipment containing regulated PV29 is in use or has not yet been cleaned, or an area where cleaning activities are occurring.

Regulated PV29 means neat PV29 in a dry powder form or in dry powder form when mixed with other types of dry powder pigments.

Residue means crumbly, powdery, or otherwise particulate material that can be dusted or swabbed off a surface.

§ 751.905 Workplace requirements.

(a) *Applicability.* The provisions of this section apply to workplaces engaged in the following conditions of use of regulated PV29:

(1) Domestic manufacture.

(2) Import.

(3) Processing: Incorporation into formulation, mixture, or reaction products in paints and coatings.

(4) Processing: Incorporation into formulation, mixture, or reaction products in plastic and rubber products.

(5) Processing: intermediate in the creation or adjustment of color of other perylene pigments.

(6) Processing: recycling.

(7) Industrial and commercial use in automobile paints and coatings (original equipment manufacturing and refinishing).

(8) Industrial and commercial use in coatings and basecoats for paints and coatings.

(9) Industrial and commercial use in merchant ink for commercial printing.

(10) Disposal.

(b) *PV29 regulated area.* (1) Beginning [DATE 180 DAYS AFTER DATE OF PUBLICATION OF THE FINAL RULE IN THE **FEDERAL REGISTER**], the owner or operator must establish, maintain, and demarcate a PV29 regulated areas where exposure to regulated PV29 can reasonably be expected to occur.

(2) The owner or operator must limit access to PV29 regulated areas to authorized persons.

(3) The owner or operator must demarcate PV29 regulated areas from the rest of the workplace in a manner that adequately establishes and alerts persons to the boundaries of the area and minimizes the number of authorized persons exposed to regulated PV29 within the PV29 regulated area.

(4) The owner or operator must supply a respirator that complies with the requirements of paragraph (c) of this section and must ensure that all persons within the PV29 regulated area are using the provided respirators whenever exposure to regulated PV29 can reasonably be expected to occur.

(5) An owner or operator who has established a PV29 regulated area as required by paragraph (b)(1) of this section where regulated PV29 exposure can reasonably be expected to occur only on certain days (for example, because of work or process schedule) must have persons use respirators in that regulated area on those days.

(6) The owner or operator must ensure that, within a PV29 regulated area, persons do not engage in non-work activities which may increase regulated PV29 exposure.

(7) The owner or operator must ensure that while persons are wearing respirators in the PV29 regulated area, they do not engage in activities which interfere with respirator seal or performance.

(c) *Respiratory protection.* (1) Beginning [DATE 180 DAYS AFTER DATE OF PUBLICATION OF THE FINAL RULE IN THE **FEDERAL REGISTER**], owners and operators must supply a respirator selected in accordance with this section and 29 CFR 1910.134(a) through (l), with the exception of paragraphs (a)(1) and (d) of that section, to each potentially exposed person. Owners and operators must ensure that all potentially exposed persons are using the provided respirators whenever regulated PV29 exposures can reasonably be expected to occur, meaning in any PV29 regulated area. For purposes of this paragraph:

(i) Any provision applying to ''employee'' in 29 CFR 1910.134 also

applies equally to potentially exposed persons; and

(ii) Any provision applying to ''employer'' in 29 CFR 1910.134 also applies equally to any owner or operator for the regulated area.

(2) Respiratory protection that is of safe design and construction for the work to be performed must be provided, used, and maintained in a sanitary, reliable, and undamaged condition. Owners and operators must select respiratory protection that properly fits each affected person and communicate respiratory protection selections to each affected person.

(i) Owners or operators must select and provide to potentially exposed persons appropriate respirators as follows:

(A) If there is no regulated PV29 expected to be present in an area: no respiratory protection is required.

(B) If there is regulated PV29 present or expected to be in an area, meaning that a regulated PV29 container is open or in use; equipment containing regulated PV29 is in use or has not yet been cleaned; the area where equipment for regulated PV29 is used has not yet been cleaned since equipment usage has ceased; or cleaning activities are occurring: Any NIOSH-certified half-mask power air-purifying respirator; any NIOSH-certified half-mask supplied-air respirator or airline respirator in continuous flow mode or pressure-demand or other positive pressure mode; any NIOSH-certified full facepiece air-purifying respirator; any NIOSH-certified full facepiece supplied air respirator or airline respirator in demand mode; any NIOSH-certified full facepiece self-contained breathing apparatus in demand mode; or any NIOSH-certified helmet/hood self-contained breathing apparatus in demand mode (APF 50). Negative-pressure respirators are acceptable for use if they meet the requirements stated in this paragraph.

(ii) The respiratory protection requirements in paragraph (c)(2)(i) of this section represent the minimum respiratory protection requirements, such that any respirator affording a higher degree of protection than the required respirator may be used.

(iii) When a potentially exposed person requires the use of a respirator and cannot use a negative-pressure respirator, the owner or operator must provide that person with a respirator that has less breathing resistance than the negative-pressure respirator, such as a powered air-purifying respirator or supplied-air respirator, when the person is able to use it and if it provides the person with adequate protection.

(d) *Equipment and area cleaning.* (1) Owners or operators must ensure that any equipment and area where regulated PV29 has been manufactured, processed, used, or disposed is cleaned in accordance with a written cleaning plan established beginning on [DATE 180 DAYS AFTER DATE OF PUBLICATION OF FINAL RULE IN THE **FEDERAL REGISTER**]. The exact cleaning method, materials, and procedure may be determined by the owner or operator and must meet the requirements outlined in paragraph (d)(2) of this section.

(2) Owners or operators must meet the following requirements as part of the equipment and area cleaning:

(i) Equipment and the area in which the equipment is housed must be cleaned within 24 hours after regulated PV29 has been manufactured, processed, used, or disposed.

(ii) Surfaces of the equipment that have contact with regulated PV29 as part of operation and the area where the equipment is located must be free of residue. This requirement includes ensuring that no residue is left on surfaces in the area, such as the outer housing of equipment and places where dust-like particles typically settle, such as the floor; for example, a wet, white cloth, swab, or other similar cleaning fabric will not have visible color after contact with the surface.

(iii) The cleaning plan must describe the cleaning methods, materials, and procedures to be used, as well as the procedure to be used to assess the effectiveness of the cleaning activities, as determined by the owner or operator, to meet the requirements of this section.

(iv) The owner or operator must ensure that each potentially exposed person is instructed on the requirements of the regulated PV29 cleaning plan prior to performing work related to implementation of the regulated PV29 cleaning plan.

(v) The cleaning plan must be documented in the facility with records easily accessible for review and reference by potentially exposed persons and regulatory officials. Records include a copy of the cleaning plan, implementation records required under § 751.909(b)(1), and documentation that instruction has been provided to potentially exposed persons whose job function includes cleaning plan implementation or whose job function requires them to be present in a regulated area where a cleaning plan could be executed.

§ 751.907 Labeling and downstream notification.

(a) Beginning on [DATE 180 DAYS AFTER DATE OF PUBLICATION OF FINAL RULE IN THE **FEDERAL REGISTER**], each person who manufactures (including imports), processes, and distributes in commerce regulated PV29 for any use must, prior to or concurrent with the shipment, notify persons to whom regulated PV29 is shipped, in writing, of the restrictions described in this subpart in accordance with paragraphs (b) and (c) of this section.

(b) The following text must be inserted in Sections 1(c) and 15 of the Safety Data Sheet (SDS):

Color Index Pigment Violet 29 (regulated PV29) is subject to additional respiratory protection and cleaning requirements under 40 CFR part 751, subpart J. Please review the requirements before opening this container and using this product.

(c) Every regulated PV29 product shall bear a label. The label shall appear on or be securely attached to the immediate container of the regulated PV29 product. The contents of a label must show clearly and prominently the following:

Color Index Pigment Violet 29 (PV29) is stored within this container. Regulated PV29 is subject to additional respiratory protection and cleaning requirements under 40 CFR part 751, subpart J. Please review the requirements before opening this container and using this product.

§ 751.909 Recordkeeping requirements.

(a) *General records.* After [DATE 60 DAYS AFTER DATE OF PUBLICATION OF FINAL RULE IN THE **FEDERAL REGISTER**], all persons who manufacture, process, distribute in commerce, or engage in industrial or commercial use of regulated PV29 must maintain ordinary business records, such as downstream notifications, invoices, and bills-of-lading related to compliance with the restrictions and other provisions of this subpart.

(b) *Respiratory protection records.* Owners or operators subject to respiratory protection requirements described in § 751.905(c) must retain records of:

(1) Respiratory protection used and implementation; and

(2) Information and training provided by the regulated entity to each person prior to or at the time of initial assignment to a job involving potential inhalation exposure to regulated PV29.

(c) *Equipment and area cleaning records.* Owners or operators subject to the requirements described in § 751.905(b) must maintain records of:

(1) A copy of the current cleaning plan and previous versions;

(2) The dates, duration, and completion status of equipment and area cleaning each time a cleaning plan is executed;

(3) Implementation records documenting the initial date of cleaning plan implementation; and

(4) Documentation that instruction has been provided to potentially exposed persons whose job function includes cleaning plan implementation or whose job function requires them to be present in a regulated area where a cleaning plan could be executed.

(d) *Retention.* Owners or operators must retain the records required in paragraphs (a) through (c) of this section for five years from the date that such records were generated.

[FR Doc. 2024–30931 Filed 1–13–25; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

45 CFR Parts 205, 260, 261, and 263

RIN 0970–AC97

Strengthening Temporary Assistance for Needy Families (TANF) as a Safety Net and Work Program; Withdrawal

AGENCY: Administration for Children and Families (ACF), HHS.

ACTION: Proposed rule; withdrawal.

SUMMARY: This document withdraws a proposed rule that was published in the **Federal Register** on October 2, 2023. The proposed rule would have amended the Temporary Assistance for Needy Families (TANF) program regulations to strengthen the safety net and reduce administrative burden.

DATES: The Administration for Children and Families is withdrawing the proposed rule published October 2, 2023 (88 FR 67697) as of January 14, 2025.

FOR FURTHER INFORMATION CONTACT: The Office of Family Assistance, ACF, at *TANFquestions@acf.hhs.gov or 202–401–9275.* Deaf and hard of hearing individuals may call 202–401–9275 through their chosen relay service or 711 between 8 a.m. and 7 p.m. Eastern Time.

SUPPLEMENTARY INFORMATION: The Administration for Children and Families (ACF) published a notice of proposed rulemaking (NPRM) related to the administration of TANF in the **Federal Register** on October 2, 2023 (88 FR 67697). The NPRM proposed to (1) establish a ceiling on the term ''needy''; (2) clarify when an expenditure is ''reasonably calculated to accomplish a TANF purpose''; (3) exclude as an allowable TANF maintenance-of-effort (MOE) expenditures cash donations from non-governmental third parties and the value of third-party in-kind contributions; (4) ensure that excused holidays match the number of Federal holidays, following the recognition of Juneteenth as a Federal holiday; (5) develop new criteria to allow States to use alternative Income and Eligibility Verification System (IEVS) measures; (6) clarify the ''significant progress'' criteria following a work participation rate corrective compliance plan; and (7) clarify the existing regulatory text about the allowability of costs associated with disseminating program information.

However, upon further consideration, the Department has elected to withdraw the Strengthening TANF as a Safety Net and Work Program Notice of Proposed Rulemaking published in the **Federal Register** on 10/02/2023, effective January 14, 2025. The Department appreciates the more than 7,000 comments received from State agencies, advocates and a broad range of additional stakeholders. In making the decision to withdraw the NPRM, the Department continues to recognize the importance of rulemaking to ensure that TANF funds are used in a manner consistent with statutory requirements. However, the Department has determined that it could benefit from additional public input and consideration on a set of issues relating to allowable TANF spending before adopting a final rule. With the time left in this Administration, the Department is focusing on other matters, including implementing the TANF provisions of the Fiscal Responsibility Act of 2023, and it is not feasible to solicit additional public comments. The Department has concluded that withdrawing the NPRM will assure agency flexibility in re-examining and exploring options and alternatives with stakeholders in the future prior to developing an NPRM that could draw from this additional stakeholder engagement. For these independently sufficient reasons, the Department is withdrawing this NPRM.

The NPRM published on October 2, 2023, is hereby withdrawn.

Dated: January 7, 2025.

Xavier Becerra,

Secretary, Department of Health and Human Services.

[FR Doc. 2025–00537 Filed 1–13–25; 8:45 am]

BILLING CODE 4184–36–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

[Docket No. FWS–R4–ES–2024–0050; FXES1111090FEDR–256–FF09E21000]

RIN 1018–BH60

Endangered and Threatened Wildlife and Plants; Threatened Status for the Florida Manatee and Endangered Status for the Antillean Manatee

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Proposed rule.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), propose to list the two subspecies of the West Indian manatee, the Florida manatee (*Trichechus manatus latirostris*) and the Antillean manatee (*Trichechus manatus manatus*), under the Endangered Species Act of 1973, as amended (Act). We have conducted status reviews for the two subspecies, and, as a result, we are proposing to list the Florida manatee as a threatened species with protective regulations under section 4(d) of the Act (''4(d) rule''), and the Antillean manatee as an endangered species, under the Act. These two listings would replace the current threatened species listing of the West Indian manatee (*Trichechus manatus*). This determination also serves as our 12-month findings on two petitions and as our completed 5-year review of the West Indian manatee. If we finalize this rule as proposed, it would remove the West Indian manatee from the Federal List of Endangered and Threatened Wildlife (List), add the Florida manatee and Antillean manatee to the List, and extend the Act's protections to the Florida manatee and Antillean manatee.

DATES: We will accept comments received or postmarked on or before March 17, 2025. Comments submitted electronically using the Federal eRulemaking Portal (see **ADDRESSES**, below) must be received by 11:59 p.m. eastern time on the closing date. We must receive requests for an additional public hearing, in writing, at the address shown in **FOR FURTHER INFORMATION CONTACT** by February 28, 2025.

Public informational meeting and public hearing: On February 26, 2025, we will hold a public informational meeting followed by a public hearing from 5 p.m. to 7 p.m., Eastern-Standard time (6 p.m. to 8 p.m., Atlantic-Standard time). For more information, see *Public Hearing,* below.