Environmental Justice Consultation on Forthcoming Proposed Rulemakings under TSCA Section 6(a)

Asbestos, Part 1: Chrysotile Asbestos and C.I. Pigment Violet 29

June 1 and 9, 2021

Office of Pollution Prevention and Toxics

U.S. Environmental Protection Agency

Opening Remarks and Consultation Overview

Today's Consultation

- Welcome
- Purpose of today's consultation
- Risk management under TSCA section 6(a)
- Proposed rulemaking for Asbestos, Part 1: Chrysotile Asbestos
  - Questions and discussion
- Proposed rulemaking for C.I. Pigment Violet 29
  - Questions and discussion
- Next Steps

E.O. 12898: Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations

- The purpose of E.O. 12898 is to focus federal attention on the environmental and human health effects of federal actions on minority and low-income populations with the goal of achieving environmental protection for all communities
- Under E.O. 12898, EPA is seeking input from stakeholders interested in environmental justice issues during this consultation and encourages participation and comments to inform EPA's upcoming proposed regulation

Impact of Biden-Harris Executive Order on Protecting Public Health and the Environment

- As the Biden-Harris Administration works to advance EPA's mission of protecting human health and the environment, the agency is committed to ensuring the safety of chemicals used by all Americans
- To that end, EPA will follow the science and law, while reviewing TSCA implementation and take any needed steps to ensure that actions protect human health and the environment
- This review is being done in accordance with the Administration's Executive Orders and other directives, including those on environmental justice, scientific integrity, and regulatory review
- The agency will keep stakeholders updated as decisions are made, and next steps are determined

Risk Management under TSCA Section 6(a)

Risk Management Requirements

- Under TSCA, EPA is required to take action to address chemicals that pose unreasonable risks to human health or the environment
- Following a determination of unreasonable risk, EPA must issue a TSCA section 6(a) rule so that the chemical no longer presents an unreasonable risk, within two years:
  - Proposed rule one year after risk evaluation
  - Final rule two years after risk evaluation
- Specific requirements regarding consideration of alternatives depending on the options selected, and a statement of effects for each risk management rule
- Input from stakeholders is critical to the process

TSCA Section 6(a) Regulatory Options

- Prohibit, limit or otherwise restrict manufacture, processing or distribution in commerce
- Prohibit, limit or otherwise restrict manufacture, processing or distribution in commerce for particular use or for use above a set concentration
- Require minimum warnings and instructions with respect to use, distribution, and/or disposal
- Require recordkeeping, monitoring or testing
- Prohibit or regulate manner or method of commercial use
- Prohibit or regulate manner or method of disposal by certain persons
- Direct manufacturers/processors to give notice of the unreasonable risk determination to distributors, users, and the public and replace or repurchase

TSCA Section 6(a)

- TSCA provides EPA with authority to address unreasonable risks in occupational settings, and to regulate entities including:
  - Manufacturers and processors (e.g., formulators)
  - Distributors
  - Commercial users (workplaces and workers)
  - Entities disposing of chemicals for commercial purposes
- TSCA also requires EPA to address unreasonable risks to consumers
  - EPA has authority to regulate at the manufacturing, processing or distribution level in the supply chain to address unreasonable risks from consumer use
  - These authorities allow EPA to regulate at key points in the supply chain to effectively address unreasonable risks to consumers

Principles for Transparency During Risk Management

- Transparent, proactive, and meaningful engagement
- One-on-one meetings, public webinars, and required consultations with state and local governments, Tribes, environmental justice communities, and small businesses
- Extensive dialogue about the findings in the risk evaluations, the risk management process required by TSCA, and the options available for managing unreasonable risks
- Seeking input from stakeholders on potential risk management approaches, their effectiveness, and impacts those approaches might have on businesses, workers, and consumers
- Input can help the Agency develop regulations that are practical and protective

Your Comments

- Please provide specific comments on:
  - Do you have any concerns related to environmental justice about these uses of Asbestos (Part 1) or C.I. Pigment Violet 29?
  - How do you anticipate these rulemakings would have an environmental justice impact?
  - Other thoughts on the rulemakings?

Your Advice for EPA

- Please provide specific examples of:
  - Any experience with the conditions of use for Asbestos, Part 1 or C.I. Pigment Violet 29
  - Any experience with regulation of the conditions of use for Asbestos, Part 1 or C.I. Pigment Violet 29
  - Any risk management experience with specific conditions of use for Asbestos, Part 1 or C.I. Pigment Violet 29

Asbestos, Part 1: Chrysotile Asbestos Topics

- Background on risk evaluation and findings for Part 1
- Focused discussion
- Consultation comments
- Your advice for EPA

Overview of Risk Evaluation for Asbestos, Part 1: Chrysotile Asbestos

- Final risk evaluation for Part 1 published December 30, 2020
- There are six categories of use: 1) Asbestos diaphragms; 2) Sheet gaskets; 3) Oilfield brake blocks; 4) Aftermarket automotive brakes/linings; 5) Other vehicle friction products; and 6) Other gaskets
  - Final risk evaluation follows a series of risk evaluation activities
  - Draft risk evaluation: April 2020; Problem Formulation: May 2018; Scope Document: June 2017
- Public comments and external scientific peer review informed the final risk evaluation for Part 1:
  - 92 public comments received on the draft risk evaluation (comment period closed June 2, 2020)
  - Peer review: EPA's Science Advisory Committee on Chemicals (SACC) met to review the draft evaluation (June 8-11, 2020)
- The final risk evaluation and supplemental materials are in docket EPA-HQ-OPPT-2019-0501, with additional materials supporting the risk evaluation process in docket EPA-HQ-OPPT-2016-0736, at www.regulations.gov

Conditions of Use

- There are six categories of use:
    1) Asbestos diaphragms
    2) Sheet gaskets
    3) Oilfield brake blocks
    4) Aftermarket automotive brakes/linings
    5) Other vehicle friction products
    6) Other gaskets

Unreasonable Risk Determinations

- Among the six categories of conditions of use identified for chrysotile asbestos, EPA determined that chrysotile asbestos presents an unreasonable risk of injury to health
- EPA's unreasonable risk determination for chrysotile asbestos is based on the following conditions of use:
  - Processing and Industrial Use of Chrysotile Asbestos Diaphragms in the Chlor-alkali Industry
  - Processing and Industrial Use of Chrysotile Asbestos-Containing Sheet Gaskets in Chemical Production
  - Industrial Use and Disposal of Chrysotile Asbestos-Containing Brake Blocks in Oil Industry
  - Commercial Use, Consumer Use and Disposal of Aftermarket Automotive Chrysotile Asbestos-Containing Brakes/Linings
  - Commercial Use and Disposal of Other Chrysotile Asbestos-Containing Vehicle Friction Products
  - Commercial Use, Consumer Use and Disposal of Other Chrysotile Asbestos-Containing Gaskets
- EPA's risk evaluation identified unreasonable risks for cancer from chronic inhalation exposure to chrysotile asbestos to workers, occupational non-users (ONUs), consumers and bystanders

Basis for Unreasonable Risk Determination: Workers, ONUs, Consumers and Bystanders

- The unreasonable risk determinations are based on the following health hazards for workers and ONUs during occupational exposures, and consumers and bystanders during do-it-yourself scenarios of chrysotile asbestos:
  - Cancer effects from chronic inhalation
  - Non-cancer effects from chronic inhalation

In-Depth Discussion

Examples of Regulatory Options

- Prohibit manufacturing, processing and distribution of the chemical
- Prohibit manufacturing, processing and distribution for particular conditions of use with unreasonable risks
- Mandate specific engineering controls, ventilation requirements, and personal protective equipment (PPE) at occupational sites
- Provide a prominent label securely attached to each container with specific directions, limitations, and precautions, or that describe the health endpoints

Examples of Regulatory Options

- Require manufacturers, processors, and distributors to maintain ordinary business records
- Require manufacturers, processors and distributors to provide downstream notification to help ensure regulatory information reaches all users in the supply chain
- Set an occupational air exposure limit, for example, establish an Existing Chemical Exposure Limit (ECEL)
- Restrict distribution of a chemical or product only to certain users, under a limited access program that could require training and certification

Examples of Regulatory Options

- Redesign import containers to prevent release to the environment
- Require engineering controls or equipment to contain releases to outside air from facilities that import, process, or recycle
- Require work practices that reduce dust emissions at construction and demolition sites
- Prohibit or regulate manner of commercial disposal

Your Comments

- Please provide specific examples of:
  - Any experience with the conditions of use for Asbestos, Part 1
  - Any experience with regulation of the conditions of use for Asbestos, Part 1
  - Any risk management experience with specific conditions of use for Asbestos, Part 1
- Please provide specific comments:
  - Do you have any concerns related to environmental justice about these conditions of use for Asbestos, Part 1?
  - How do you anticipate this rulemaking would have an environmental justice impact?
  - Other thoughts on the rulemaking?

Additional Information

- General TSCA: https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/frank-r-lautenberg-chemical-safety-21st-century-act
- Current Chemical Risk Management Activities: https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/current-chemical-risk-management-activities
- Asbestos, Part 1: Chrysotile Asbestos: Alie Muneer (muneer.alie@epa.gov, 202-564-6369), https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/final-risk-evaluation-asbestos-part-1-chrysotile
- General risk management outreach: Douglas Parsons (parsons.douglas@epa.gov, 202-564-0341)

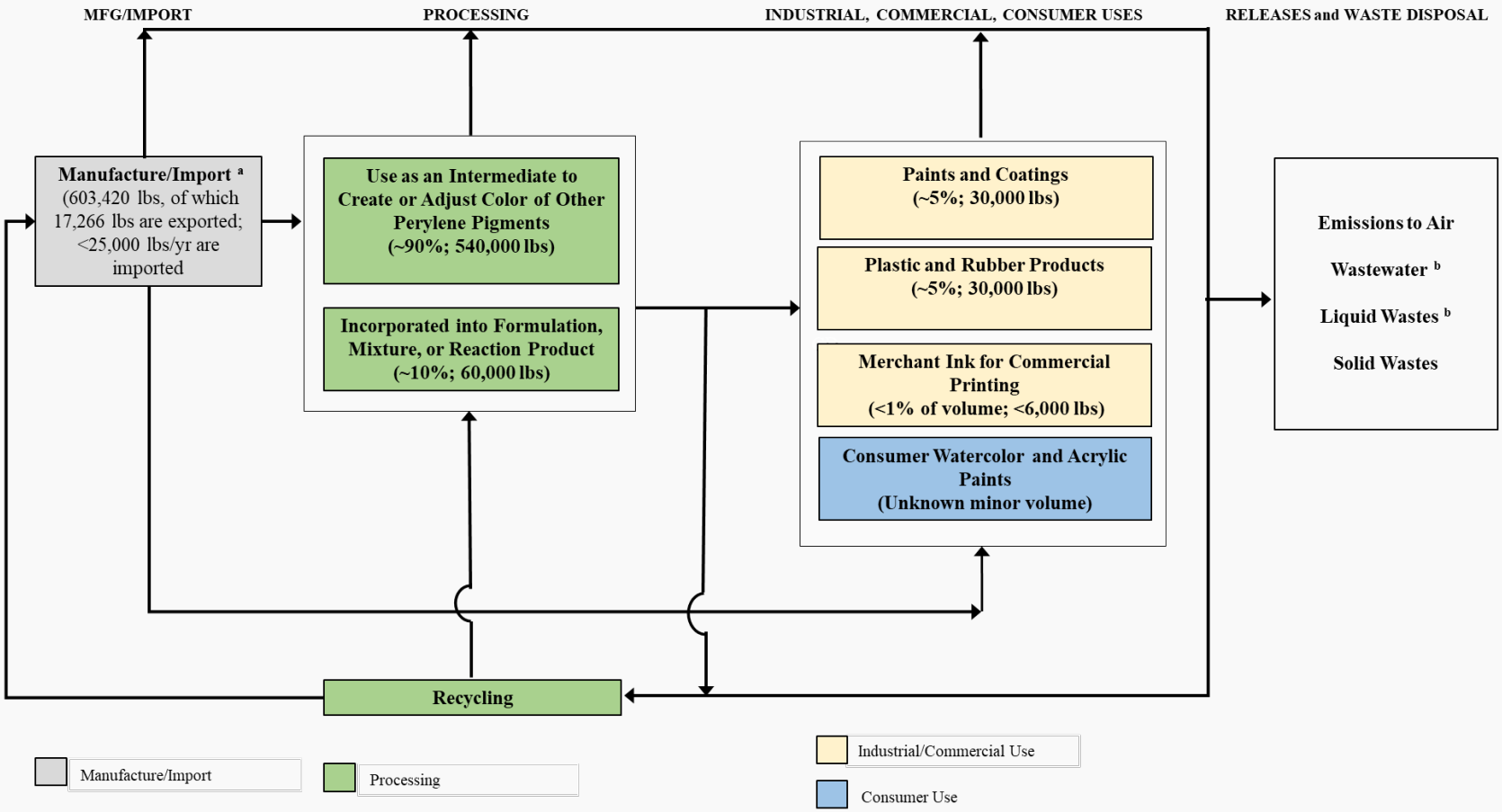
Overview of Risk Evaluation for PV29

- Final risk evaluation published January 2021
  - 14 conditions of use were evaluated
  - Final risk evaluation follows a series of risk evaluation activities
  - PV29 draft risk evaluation: December 2018; PV29 revised draft risk evaluation October 2020; PV29 problem formulation: June 2018; PV29 scope document: June 2017
- Public comments and external scientific peer review informed the final risk evaluation
  - 49 public comments received on the draft and revised draft risk evaluation (revised draft comment period closed December 19, 2020)
  - Peer review: EPA's Science Advisory Committee on Chemicals (SACC) met to review the draft risk evaluation (June 2019) and participated in a letter peer review for the revised draft risk evaluation (December 2020)
- The final risk evaluation and supplemental materials are in docket EPA-HQ-OPPT-2018-0604, with additional materials supporting the risk evaluation process in docket EPA-HQ-OPPT-2016-0725, on www.regulations.gov

General Information on PV29

- C.I. Pigment Violet 29 is a Colour Index (C.I.) name used in sales of products containing anthra[2,1,9-def:6,5,10-d'e'f']diisoquinoline-1,3,8,10(2H,9H)-tetrone, CASRN 81-33-4
- The name "C.I. Pigment Violet 29" is assigned, copyrighted and maintained by the Society of Dyers and Colourists and the American Association of Textile Colorists and Chemists
- It is both produced in and imported into the United States
- EPA identified conditions of use during various life cycle stages of PV29, such as manufacturing (including import), processing, distribution in commerce, use (industrial, commercial and consumer), recycling, and disposal
- PV29 has a wide range of uses, including processing into paints, coatings, plastic, and rubber products; use as an intermediate in perylene pigments, and use in inks and consumer acrylic/watercolor paints
- The total aggregate production volume was 603,420 pounds in 2015

PV29 Life Cycle Diagram



Unreasonable Risk Determinations

- EPA found unreasonable risk to health for PV 29 based on the following conditions of use:
  - Domestic manufacturing or import of the chemical; incorporation into formulation, mixture or reaction products in paints, coatings, plastic and rubber products; use as an intermediate for other perlyene pigments; use in paintings and coatings in the automobile sector, and merchant ink for commercial printing; recycling; and disposal
  - Risks to workers and occupational non-users can come from long-term inhalation exposure
- EPA's unreasonable risk determination for PV 29 is based on:
  - Workers and occupational non-users (ONUs) during occupational exposures
- EPA's risk evaluation evaluated alveolar hyperplasia (an adverse increased number of cells in the lungs where oxygen transfer occurs), inflammatory and morphological changes in the lower respiratory tract from chronic inhalation exposures
- EPA did not evaluate cancer effects from chronic exposure because PV29 is not likely to be carcinogenic via genotoxic mechanisms

Basis for Unreasonable Risk Determination: Workers and ONUs

- The unreasonable risk determination is based on the following health hazards during occupational exposures of PV29:
  - Long term inhalation exposure which would cause alveolar hyperplasia, inflammatory and morphological changes in the lower respiratory tract

Your Comments

- Please provide specific comments on:
  - Do you have any concerns related to environmental justice about these uses of PV 29?
  - How do you anticipate this rulemaking would have an environmental justice impact?
  - Other thoughts on the rulemaking?

Your Advice for EPA

- Please provide specific examples of:
  - Any experience with use of PV 29
  - Any experience with regulation of PV 29
  - Any risk management experience with specific conditions of use of PV 29

Additional Information

- General TSCA: https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/frank-r-lautenberg-chemical-safety-21st-century-act
- Current Chemical Risk Management Activities: https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/current-chemical-risk-management-activities
- PV29: Todd Coleman (coleman.todd@epa.gov, 202-564-1209) https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/risk-management-ci-pigment-violet-29
- General risk management outreach: Douglas Parsons (parsons.douglas@epa.gov, 202-564-0341)

Next Steps

- Please send written comments by August 13th to Amanda Hauff at hauff.amanda@epa.gov with a cc: to muneer.alie@epa.gov for Part 1 or coleman.todd@epa.gov for C.I. Pigment Violet 29