INITIATION OF PRIORITIZATION UNDER THE TOXIC SUBSTANCES CONTROL ACT (TSCA); REQUEST FOR COMMENT VINYL CHLORIDE

Office of Pollution Prevention and Toxics
United States Environmental Protection Agency

AMERICAN FUEL & PETROCHEMICAL MANUFACTURERS COMMENTS

Attention: EPA–HQ–OPPT–2018–0448-0002

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I. Introduction

The American Fuel & Petrochemical Manufacturers ("AFPM") respectfully submits these comments on the Environmental Protection Agency's ("EPA" or "the Agency") Federal Register notice titled, "Initiation of Prioritization Under the Toxic Substances Control Act (TSCA); Request for Comment" ("Proposed Prioritization" or "Proposal"). EPA proposes to categorize five chemicals as high priorities for risk evaluation and potential risk management under TSCA Sec. 6.[1] These comments address the selection of vinyl chloride as a candidate for high-priority designation. AFPM's comments highlight the following concerns that the Proposed Prioritization:

- Focuses on vinyl chloride, which is a chemical intermediate with extremely low potential for exposure,
- Depends on the flawed 2014 TSCA Work Plan that falsely claims vinyl chloride is used as an ingredient in consumers goods; and,
- Moves from the Congressionally mandated risk-based approach to a hazard-based approach to prioritization by selecting vinyl chloride because it has a robust hazard dataset

Based on the concerns raised in these comments, EPA should withdraw vinyl chloride from consideration and focus on chemicals that present the greatest potential for exposure, such as those found in consumer products.

II. AFPM Interest in the Proposed Framework

AFPM is the leading trade association representing the manufacturers of the fuels that keep America moving and petrochemicals that are the essential building blocks for organic chemistry, including plastic products that improve the health, safety, and living conditions of humankind and make modern life possible. AFPM members are committed to sustainably manufacturing safe, high-performing fuels and the petrochemicals and derivatives that growing global populations and economies need to thrive.

AFPM members produce vinyl chloride. Vinyl chloride is a petrochemical building block (i.e., intermediate) used to make polyvinyl chloride ("PVC") and other vinyl products. PVC is critical to many supply chains, especially housing and construction products, such as PVC pipes, vinyl siding, vinyl windows, vinyl soffits, waterproof plank flooring, car seats, and many other valuable, long-lasting products. This intermediate is produced and used in closed-systems and is highly regulated in industrial and manufacturing settings. These processes transform vinyl chloride into new molecules that have proven safe in commerce. PVC is not vinyl chloride.

AFPM member companies are regulated under TSCA, and their products have been and will continue to be subject to TSCA risk evaluations. If properly implemented, TSCA can be a critical statute to ensure sound chemical management. Unfortunately, in this case, EPA is using TCSA to target industrial chemicals used to make plastics as a means to limit plastic products.

[1] See *88 Fed. Reg. 87423*, "Initiation of Prioritization Under the Toxic Substances Control Act (TSCA); Request for Comment." EPA–HQ–OPPT–2023–0601; FRL–11581–01–OCSPP, published December 18, 2023.

These efforts under TSCA appear to be designed to disrupt critical plastics supply chains despite these chemicals being used in industrial settings and in closed processes that are highly regulated.

III. Comments on the Prioritization Proposal for Vinyl Chloride

EPA is not meeting its statutory obligations for designation of high-priority substances.

EPA is required under TSCA Sec. 6(b)(3)(C) to "designate at least one high-priority substance upon the completion of each risk evaluation."[2] TSCA Sec. 6(b)(2)(D) directs the Agency to give preference to chemicals "that are listed in the 2014 update of the TSCA Work Plan for Chemical Assessments ["2014 TSCA Work Plan"] as having a Persistence and Bioaccumulation Score of 3," and "are known human carcinogens and have high acute and chronic toxicity."[3,4] Vinyl chloride has a persistence and bioaccumulation score of only 2. AFPM questions how a very reactive gas could possibly persist in the environment and bioaccumulate in mammals. EPA points to a general hazard category score in Unit III.B., but this general hazard score does not specify that vinyl chloride is a known human carcinogen ***and*** has high acute ***and*** chronic toxicity.[5] Vinyl chloride is a known human carcinogen according to the International Agency for Research on Cancer ("IARC"), which is why exposures to vinyl chloride are tightly controlled in petrochemical plants through advanced engineering. The oral LD_{50} for vinyl chloride is greater than 4,000 milligrams per kilogram body weight ("mg/kg") and the inhalation LC_{50} is 390,000 milligrams per cubic meter or 152,573 parts per million ("ppm").[6] Clearly, vinyl chloride is not acutely toxic.

TSCA Sec. 6(b)(1)(A) stipulates that the "process to designate the priority of chemical substances shall include a consideration of the hazard and exposure potential."[7] Sec. 6(b)(1)(B)(i) reiterates Congressional direction when it requires EPA to prioritize substances that "may present an unreasonable risk of injury to health or the environment because of a potential hazard and a potential route of exposure under the conditions of use."[8] In the 2014 TSCA Work Plan, the Agency claims that vinyl chloride is used as an ingredient in consumer products, which is not supported by current knowledge of this product.[9] EPA acknowledges that vinyl chloride is used primarily as an intermediate to make polyvinyl chloride ("PVC") and vinyl copolymers on its own fact sheet.[10] Vinyl chloride, like other intermediates, is used in closed systems employing a process that totally consumes the substance. Any residual vinyl chloride in PVC or vinyl copolymers is negligible. In fact, EPA already regulates how much residual vinyl chloride is allowed to leach from PVC pipes, setting the maximum concentration level at 0.002 ppm, far

[2] See TSCA Sec. 6(b)(3)(C).
[3] See TSCA Sec. 6(b)(2)(D).
[4] See 2014 update of the TSCA Work Plan for Chemical Assessments.
[5] See *88 Fed. Reg. 87423*, "Initiation of Prioritization Under the Toxic Substances Control Act (TSCA); Request for Comment." EPA–HQ–OPPT–2023–0601; FRL–11581–01–OCSPP, published December 18, 2023. p. 87425.
[6] See OECD SIDS dossier for vinyl chloride.
[7] See TSCA Sec. 6(b)(1)(A).
[8] See TSCA Sec. 6(b)(1)(B)(i).
[9] See 2014 update of the TSCA Work Plan for Chemical Assessments.
[10] See EPA fact sheet for vinyl chloride.

below a level at which it could do any harm.[11] Furthermore, the PVC pipe industry follows the NSF/ANSI Standard 61, which sets the concentration limit at 0.0002 ppm, which even more strict than the EPA level.[12] Vinyl chloride in the air around manufacturing facilities is usually less than 0.0001 ppm and water less than 0.001 ppm, both of which are below analytical detection limits and far below levels considered to be toxic.[13] There are simply no exposures to vinyl chloride that would qualify it as a candidate for high-priority designation.

EPA focuses mostly on hazard, not risk, as a determining factor for prioritization.

Vinyl chloride has a robust hazard dataset and has been through the Organisation for Economic Cooperation and Development ("OECD") Screening Information Data Set ("SIDS") Programme. The OECD concluded that no further work was necessary. In Unit III.A. of the Proposal, EPA notes that "data availability was a significant driver of the Agency's selections" and that "chemicals ultimately designated as High-Priority Substances for risk evaluation should have a robust data landscape," which penalizes vinyl chloride just because it possesses a more full hazard dataset.[14] There are no provisions in TSCA Sec. 6 that direct or authorize EPA to use completeness of hazard data as a criterion for high-priority designation. Focusing on hazard data is a hazard-based approach to chemicals management and contradicts the whole intent of TSCA. Congress intended TSCA to be a risk-based approach, which is evident throughout the entire statute. EPA should abandon its attempt to focus on hazards and fully consider the potential for exposure, or in this case the lack thereof, and prioritize chemicals the way that Congress intended.

EPA does not demonstrate that the conditions of use for vinyl chloride present a significant potential for exposure.

In Unit III.B., EPA generally notes that vinyl chloride was reported in 2020 under the Chemical Data Reporting ("CDR") rule but the Agency does not provide any information on what it found in the CDR to support its claim that the conditions of use for vinyl chloride could lead to a significant potential for exposure.[15] Information reported under the CDR rule is general usage information and there is no legitimate reason that EPA cannot aggregate it to support its assertions in the proposed rule.

IV. Conclusion

AFPM has serious concerns about EPA selecting vinyl chloride for consideration as a high priority. EPA sponsored vinyl chloride for the OECD SIDS process in 2001 and the OECD determined that no further work was necessary.[16] EPA already regulates the levels of vinyl

[11] See PVC Pipe Association Technical Brief.
[12] *Id.*
[13] See OECD SIDS dossier for vinyl chloride.
[14] See *88 Fed. Reg. 87423,* "Initiation of Prioritization Under the Toxic Substances Control Act (TSCA); Request for Comment." EPA–HQ–OPPT–2023–0601; FRL–11581–01–OCSPP, published December 18, 2023. p. 87424.
[15] *Id*. at 87425.
[16] See OECD SIDS dossier for vinyl chloride.

chloride that can be in air and water, including the potential for leaching trace amounts from PVC pipe.

The Agency has provided no information to support the finding of significant potential exposure. Vinyl chloride is a petrochemical intermediate used in closed systems to make other chemicals and is consumed in those chemical processes. The TSCA statutory language is very clear that EPA must demonstrate a potential for exposure that may lead to an unreasonable risk. Vinyl chloride also does not have the required persistence, bioaccumulation, and acute toxicity levels that TSCA requires for consideration as a high-priority chemical. EPA must remove vinyl chloride from further consideration so it can concentrate on substances that may actually present an unreasonable risk.

Sincerely,

James Cooper
Senior Petrochemical Advisor