

**PROPOSED HIGH-PRIORITY SUBSTANCE  
DESIGNATIONS UNDER THE TOXIC  
SUBSTANCES CONTROL ACT (TSCA);  
NOTICE OF AVAILABILITY  
VINYL CHLORIDE**

---

Office of Pollution Prevention and Toxics  
United States Environmental Protection Agency

---

**AMERICAN FUEL & PETROCHEMICAL MANUFACTURERS  
COMMENTS**

**Attention: EPA-HQ-OPPT-2018-0448**

October 23, 2024  
Dr. Michal Freedhoff  
Assistant Administrator  
Office of Chemical Safety and Pollution Prevention  
U.S. Environmental Protection Agency  
1200 Pennsylvania Avenue, NW  
Washington, DC 20004

## **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, “Proposed High-Priority Substance Designations Under the Toxic Substances Control Act (TSCA); Notice of Availability” (“Proposed Designation” or “Proposal”). EPA proposes to designate five chemicals as high priorities for risk evaluation and potential risk management under TSCA Sec. 6.<sup>1</sup> 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 Designation:

- Vinyl chloride is a chemical intermediate with extremely low potential for exposure;
- The Proposed Designation relies on the flawed 2014 TSCA Work Plan and other incorrect data sources that erroneously claim vinyl chloride is used in consumer goods; and
- The Proposed Designation moves from the Congressionally mandated risk-based approach to a hazard-based approach by selecting vinyl chloride due to its 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 commercial and 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 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, it appears EPA’s disregard of vinyl chloride’s primary use as an intermediate, and failing to acknowledge the minimal risks of exposure associated with intermediates, diverts limited resources away from substances with a much greater potential for exposure. .

Vinyl chloride is used in the production of plastics and these efforts under TSCA will disrupt critical plastics supply chains despite these chemicals being used only in industrial settings and in closed processes that are highly regulated.

---

<sup>1</sup> See 89 *Fed. Reg.* 60420, “[Proposed High-Priority Substance Designations Under the Toxic Substances Control Act \(TSCA\); Notice of Availability](#).” EPA–HQ–OPPT– 2023–0601; FRL–11581–03–OCSP, published July 25, 2024.

AFPM members manufacture 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. Importantly, PVC is not vinyl chloride.

### III. Comments on the Prioritization Proposal for Vinyl Chloride

#### A. *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.”<sup>2</sup> 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.”<sup>3,4</sup> 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.<sup>5</sup> 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<sub>50</sub> for vinyl chloride is greater than 4,000 milligrams per kilogram body weight (“mg/kg”) and the inhalation LC<sub>50</sub> is 390,000 milligrams per cubic meter or 152,573 parts per million (“ppm”).<sup>6</sup> 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.”<sup>7</sup> 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.”<sup>8</sup> In the 2014 TSCA Work Plan, the Agency claims that vinyl chloride is used in consumer products, which is wrong.<sup>9</sup> EPA

---

<sup>2</sup> See [TSCA Sec. 6\(b\)\(3\)\(C\)](#).

<sup>3</sup> See [TSCA Sec. 6\(b\)\(2\)\(D\)](#).

<sup>4</sup> See [2014 update of the TSCA Work Plan for Chemical Assessments](#).

<sup>5</sup> 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.

<sup>6</sup> See OECD SIDS [dossier for vinyl chloride](#).

<sup>7</sup> See [TSCA Sec. 6\(b\)\(1\)\(A\)](#).

<sup>8</sup> See [TSCA Sec. 6\(b\)\(1\)\(B\)\(i\)](#).

<sup>9</sup> See [2014 update of the TSCA Work Plan for Chemical Assessments](#).

acknowledges that vinyl chloride is used primarily as an intermediate to make PVC and vinyl copolymers on its own fact sheet.<sup>10</sup>

Vinyl chloride, like other intermediates, is used in closed systems employing a process that 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 below a level at which it could do any harm.<sup>11</sup> 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.<sup>12</sup> 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.<sup>13</sup> There are simply no exposures to vinyl chloride that would qualify it as a candidate for high-priority designation.

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

In Section 2.2 of the supporting document, titled “Proposed Designation of Vinyl Chloride as a High-Priority Substance for Risk Evaluation,” EPA claims that “production volume has been reported above 10 billion pounds, suggesting a consistent source of potential exposure to vinyl chloride.”<sup>14</sup> Production volume is not a surrogate for exposure, especially in the case of closed-system intermediates. AFPM acknowledges that EPA is required to consider production volume but cautions against giving it much weight in the prioritization process.

The Chemical Data Reporting (“CDR”) information found in Table 2-2 is misleading and in some cases incorrect. EPA admits there are limitations in the data:

“It is difficult to discern whether there are significant changes in conditions of use for vinyl chloride based on reported information to CDR in 2016 and 2020 because guidance regarding the reporting of categories and subcategory information was updated between these periods. This update may have resulted in the use information being reported differently in 2020 compared to 2016, possibly leading to inaccurate implications that some uses may have commenced or ceased in recent years.”<sup>15</sup>

Table 2-2 in the supporting document is outdated and contains errors. All entries under the year 2016 should be disregarded because there was no guidance or even a category option for reporting intermediates, which is the only function that vinyl chloride serves. In the section highlighting the processing lifecycle stage, it lists a category as “Incorporating into formulation,

---

<sup>10</sup> See EPA fact sheet for [vinyl chloride](#).

<sup>11</sup> See PVC Pipe Association [Technical Brief](#).

<sup>12</sup> *Id.*

<sup>13</sup> See OECD SIDS [dossier for vinyl chloride](#).

<sup>14</sup> See “[Proposed Designation of Vinyl Chloride as a High-Priority Substance for Risk Evaluation](#),” EPA Document # EPA-740-P-24-002, published July 2024. p. 16.

<sup>15</sup> *Id.* at 17.

mixture or reaction product” and the subcategory as “Binder in plastics material and resin manufacturing.”<sup>16</sup> Vinyl chloride is a gaseous substance and does not “bind” anything. Vinyl chloride is a monomer used to **make** copolymer binders. Those binders are not vinyl chloride. The vinyl chloride is polymerized with another monomer (hence, the term “copolymer”). The copolymers have totally different molecular structures than vinyl chloride.

Further down the table, it lists a category of “Incorporating into articles” with a subcategory of “Wire and cable in primary metal manufacturing.”<sup>17</sup> Under the lifecycle stage of commercial use, the table also lists a category of “Building/construction materials not covered elsewhere” and subcategory of “Cable and wire manufacturing.”<sup>18</sup> PVC is used in coatings for wire and cable, not vinyl chloride. Vinyl chloride is a gas and will not coat metal. The table also lists vinyl chloride as a binder under the category “Plastic and rubber products not covered elsewhere.”<sup>19</sup> As mentioned above, vinyl chloride is used to **make** binders, but it is not a binder itself. The consumer uses listed in Table 2-3 obviously confuse vinyl chloride with PVC or its copolymers. PVC and copolymers are not vinyl chloride. Again, vinyl chloride is a gas.

*C. EPA does not adequately justify the inclusion of children, woman of reproductive age, and overburdened communities as Potentially Exposed or Susceptible Subpopulations (“PESS”).*

EPA states it “did not identify products intended for children as reported to 2016 and 2020 CDR for vinyl chloride,” so instead the Agency attempts to use other databases like the technically flawed and incorrect High Priority Chemicals Data System (“HPCDS”) to justify categorization of children as a PESS.<sup>20</sup> The HPCDS is a database of children’s products that purportedly “contain” chemicals as reported by manufacturers of children’s products to the states Oregon and Washington. The HPCDS does not distinguish between ingredients and intermediates. It is not a reliable source for information on materials or the chemicals that make those materials because the use categories are very vague, such as “Synthetic Polymers” or “Textiles.”<sup>21</sup> Vinyl chloride is not a synthetic polymer; in fact, it is not a polymer at all. Nor is it a textile. Vinyl chloride is a gas. The HPCDS is wrong and should not be considered a valid source for chemicals found in any products, let alone children’s products.

EPA intends to classify women of reproductive age as a PESS primarily based on “animal toxicity data sources that document reproductive and/or developmental effects following exposure.”<sup>22</sup> That is a hazard-based approach that has nothing whatsoever to do with the likelihood that a woman of reproductive age could be exposed to vinyl chloride. EPA claims that it did consider the potential for exposure “because women of reproductive age can be workers” somewhere along the lifecycle of the substance.<sup>23</sup> Since vinyl chloride is an industrial intermediate used in closed systems and is transformed in those processes into a totally different

---

<sup>16</sup> *Id.* at 18.

<sup>17</sup> *Id.*

<sup>18</sup> *Id.*

<sup>19</sup> *Id.*

<sup>20</sup> *Id.* at 22.

<sup>21</sup> *Id.*

<sup>22</sup> *Id.* at 23.

<sup>23</sup> *Id.*

chemical substance, the probability of exposure to vinyl chloride of any woman of reproductive age is highly unlikely.

*D. 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 Initiation Prioritization document, 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 simply because it possesses a more full hazard dataset.<sup>24</sup>

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 intent of TSCA to be risk-based. Congress intended TSCA to be a risk-based approach, which is evident throughout the statute. EPA should abandon its myopic focus on hazards and fully consider the potential for exposure, or the lack thereof, and prioritize chemicals as Congress intended.

#### **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.<sup>25</sup> EPA already regulates the levels of vinyl 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

---

<sup>24</sup> 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-OCSP, published December 18, 2023. p. 87424.

<sup>25</sup> See OECD SIDS [dossier for vinyl chloride](#).