VINYL CHLORIDE; DRAFT SCOPE OF THE RISK EVALUATION UNDER THE TOXIC SUBSTANCES CONTROL ACT (TSCA); NOTICE OF AVAILABILITY AND REQUEST FOR COMMENT

Office of Pollution Prevention and Toxics
United States Environmental Protection Agency

AMERICAN FUEL & PETROCHEMICAL MANUFACTURERS COMMENTS

Attention: EPA–HQ–OPPT–2018–0448; FRL–12439–01–OCSPP

April 2, 2025
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I. Introduction

The American Fuel & Petrochemical Manufacturers ("AFPM") respectfully submits these comments to the Environmental Protection Agency ("EPA" or "the Agency") on its Federal Register notice titled, "Vinyl Chloride; Draft Scope of the Risk Evaluation Under the Toxic Substances Control Act (TSCA); Notice of Availability and Request for Comment" ("Draft Scope"). EPA is seeking comments on both its Draft Scope for the vinyl chloride risk evaluation as well as the Draft Scope's supporting documents.[1] These comments address the Draft Scope and its supporting documents and assumptions. AFPM is concerned that EPA:

- Selected vinyl chloride, a chemical intermediate used in closed systems and consumed in those processes (i.e., with little chance for exposure), as a high-priority chemical, which is not supported by measured data;
- mischaracterized certain uses of vinyl chloride and the exposure estimates derived from those errors will result in a flawed risk evaluation;
- will misapply its time and resources by focusing on trace amounts of vinyl chloride in polyvinyl chloride ("PVC") products, since there is little chance those molecules have an appreciable effect on risk;[2] and,
- will exceed its authority by planning to include possible byproducts and residual feedstocks in the risk evaluation.

Based on the concerns raised within these comments, EPA should scale back the Draft Scope and, instead, focus the risk evaluation only on conditions of use that pertain directly to vinyl chloride. Specifically, EPA should not include the vinyl chloride derivative, polyvinyl chloride ("PVC") in the scope. Further, EPA should, because vinyl chloride is a gas, delete all references that incorrectly identify vinyl chloride as an ingredient or component in a formulation or end product or its incorporation into articles, as there would be no reasonable chance of exposure in these instances and their evaluation would waste the agency's and industry's limited resources.

II. AFPM Interest in the Draft Scope

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.

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[1] See *90 Fed. Reg.* 4738, "Vinyl Chloride; Draft Scope of the Risk Evaluation Under the Toxic Substances Control Act (TSCA); Notice of Availability and Request for Comment." EPA–HQ–OPPT–2018–0448; FRL–12439–01–OCSPP, published January 16, 2025.

[2] EPA acknowledges that due to its physical properties, "the residual vinyl chloride in PVC resin and products is expected to be entrapped within the matrix of PVC polymer." See "Draft Scope of the Risk Evaluation for Vinyl Chloride." EPA-740-D-25-001, January 2025. p. 25.

AFPM member companies are among the most highly regulated facilities in all manufacturing, and their products have been and will continue to be subject to TSCA. AFPM believes TSCA, properly applied, can be a critical statute for obtaining sound chemical management. Unfortunately, in this case, it appears EPA's disregard of vinyl chloride's primary use as an intermediate (i.e., a monomer that is consumed in the polymerization process), and EPA's failure to acknowledge the infinitesimal exposure potential associated with closed-system intermediates (i.e., limited risk presented), divert EPA resources away from substances with far greater potential for exposure. Furthermore, as detailed in these comments, EPA's Draft Scope does not, as required by TSCA section 26(h), "use scientific information, technical procedures, measures, methods, protocols, methodologies, or models, employed in a manner consistent with the best available science."[3]

Vinyl chloride is a petrochemical building block (i.e., intermediate) used to make 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, doors, and tough, waterproof plank flooring. PVC is the material preferred by hospitals for medical tubing and IV bags. PVC is also found in car seats, advertising banners, wire and cable insulation, inflatable rafts and water toys, and many other valuable, long-lasting products.

Vinyl chloride is produced and used in closed systems and is highly regulated in industrial and manufacturing settings. These processes transform vinyl chloride into new molecules (i.e., PVC) that have proven safe in commerce. The vinyl chloride is consumed in the chemical reaction. Importantly, PVC is not vinyl chloride. Moreover, the workspaces and loading/unloading areas at petrochemical facilities are regulated by the Occupational Safety and Health Administration ("OSHA") and Department of Transportation ("DOT"). Compliance with those regulations makes exposure to vinyl chloride during everyday use very rare.

This flawed Draft Scope, and any subsequent risk evaluation based on it will risk EPA wrongly finding that vinyl chloride presents an unreasonable risk. Such a decision may result in inappropriate regulations that will disrupt critical supply chains, including a significant portion of the construction industry, the coatings industry, the furniture industry, toy industry and even medical applications. Moreover, this result also invites judicial challenge under TSCA Sec. 19 of subsequent risk management actions.

III. AFPM Comments on the Draft Scope for the Vinyl Chloride Risk Evaluation and Supporting Documents

EPA has issued this draft scope of the risk evaluation pursuant to TSCA section 6(b)(4)(D), 15 U.S.C. 2605(b)(4)(D), and EPA's implementing regulations at 40 CFR 702.39(b). This Draft Scope is a foundational part of the TSCA risk evaluation process. As such, AFPM appreciates the opportunity to provide comments as part of this process and stresses our concerns that flaws with the Draft Scope will undermine any derived evaluation of risks and subsequent actions.

[3] See 15 U.S. Code § 2625(h).

A. Vinyl chloride should not have been designated as a "high priority" in the first place.

AFPM submitted comments on EPA's proposed designation of vinyl chloride as a high priority for risk evaluation, pointing out that the Agency failed to meet the statutory requirements for high-priority substances. In those comments AFPM highlighted that 1) vinyl chloride does not have the preferential physical or toxicological properties outlined in the statute, 2) the Agency conflated vinyl chloride with PVC, and 3) ignores the existing regulations and standards that limit vinyl chloride monomer concentrations in PVC products. AFPM's specific concerns are reiterated below and remain:

> "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." 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." 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. 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 LD50 for vinyl chloride is greater than 4,000 milligrams per kilogram body weight ("mg/kg") and the inhalation LC50 is 390,000 milligrams per cubic meter or 152,573 parts per million ("ppm"). Clearly, vinyl chloride is not acutely toxic.
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> 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." 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." In the 2014 TSCA Work Plan, the Agency claims that vinyl chloride is used in consumer products, which is wrong. EPA acknowledges that vinyl chloride is used primarily as an intermediate to make PVC and vinyl copolymers on its own fact sheet.
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> 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. Furthermore, the PVC

> pipe industry follows the NSF/ANSI Standard 61, which sets the concentration limit at 0.0002 ppm, which is even more strict than the EPA level. 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. There are simply no exposures to vinyl chloride that would qualify it as a candidate for high-priority designation."[4,5]

AFPM has concerns that EPA's prioritization process unfairly selects data-rich chemicals and isn't a true measure of risk. The Agency noted 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 distorts the prioritization factors for vinyl chloride simply because it possesses a more complete hazard dataset. Ultimately, the agency must focus on risk (i.e., exposure and hazard) not just an abundance of data.[6]

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 and contradicts the plain language of TSCA that prioritization be risk-based.[7] 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 stipulated in TSCA section 6(b)(1).

In its response to comments document in the docket, however, EPA disregards AFPM's comments and simply states, "sufficient information was available to demonstrate both potential exposure and hazard, therefore contributing to the risk-based approach used to substantiate the designation as High-Priority Substances," but provides no further documentation on the exposure potential, outside its own conclusions or rationale, to support EPA's position or to counter AFPM's assertions.[8] The rest of EPA's response simply restates TSCA statutory language generally outlining the prioritization process and requiring that half the high-priorities come from the 2014 TSCA Work Plan. EPA did not, however, explain how a reactive flammable gas could possibly be present in commercial or consumer products. Nor did it provide examples of the "sufficient information" on exposure data that it claims to dismiss AFPM's concerns. EPA has not supported its claims in its prioritization publications, and in so doing constructed this Draft Scope on a flawed designation.

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[4] See AFPM comments on "Proposed High-Priority Substance Designations Under the Toxic Substances Control Act (TSCA); Notice of Availability" for vinyl chloride, submitted October 23, 2024. pp. 3-4.
[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.
[6] *Id.* at p. 87424.
[7] TSCA Sec. 6(b)(1) (see 15 U.S.C. 2605(b)(1)) requires EPA to "establish, by rule, a risk-based screening process, including criteria for designating chemical substances as high priority substances for risk evaluations or low-priority substances for which risk evaluations are not warranted at this time."
[8] See "EPA Response to Public Comments Received on the 'Initiation of Prioritization Under the Toxic Substances Control Act' and 'Proposed High-Priority Substances Designations Under the Toxic Substances Control Act'," published December 2024. p. 8.

B. Use and exposure data from the 2016 CDR reporting for vinyl chloride is flawed and should be discarded.

In the Draft Scope, EPA admits that "[a]ll of the identified industrial, commercial, and consumer uses are related to vinyl chloride serving as a monomer in plastics—primarily polyvinyl chloride (PVC) and other polymers," meaning the conditions of use identified by the Agency are mostly for polymers and not vinyl chloride, which is a monomer.[9] Also, in section 2.2.1 of the Draft Scope, EPA says it "identified COUs based on Chemical Data Reporting (CDR) provided in 2016 and 2020," in addition to other sources.[10] Any reference to vinyl chloride that came from 2016 CDR reporting, though, is unreliable because in 2016, the CDR codes did not distinguish between monomers and polymers. Instead, 2016 CDR submitters were forced to use erroneous codes for the monomers in downstream uses because there were no options for polymers that were made from those monomers. EPA willingly admits chemical uses may have been "reported differently in 2020 compared to 2016, possibly leading to inaccurate implications that some uses may have commenced or ceased in recent years."[11] AFPM pointed this discrepancy out in its comments on EPA's proposal to designate vinyl chloride as a high priority for risk evaluation.[12] AFPM strongly urges EPA – again – to disregard the 2016 CDR data due to their severe limitations and potential invite for a judicial challenge. Applying the 2016 CDR in these circumstances is bad science.

C. EPA does not distinguish between vinyl chloride (a monomer) and PVC (a polymer) creating fatal flaws in the Draft Scope and Use Report.

In Table 2-2 of the Draft Scope, EPA lists the conditions of use the Agency expects to address in the risk evaluation.[13] The information in Table 2-2, however, is wrong on several counts. It mistakenly lists vinyl chloride as incorporated into articles used in wiring and cable. It also claims vinyl chloride is used in pulp and paper processing, construction and building materials, sewer pipes, automotive components, furniture (plastic and faux leather), adhesives, paint, textiles, and even toys. ***To be clear, vinyl chloride is not an ingredient in any of those products. EPA is confusing vinyl chloride with PVC***. Oddly, as pointed out in Section III.B. of these comments, tables in the Draft Scope are supposed to list uses related to vinyl chloride, but the tables list uses of PVC instead. The risk evaluation is for vinyl chloride, not for PVC. Most of the listed conditions of use in Table 2-2 are irrelevant and should be disregarded. In footnotes to the Table, EPA says if listings are wrong, the Agency will "address them in the preparation of the draft risk evaluation."[14] AFPM finds this unacceptable. The provisions in TSCA Sec. 26(h)(2) are quite clear that EPA must consider the "extent to which the information is relevant for the Administrator's use in making a decision about a chemical substance."[15] ***Products made***

[9] See Draft Scope of the Risk Evaluation for Vinyl Chloride. EPA Document# EPA-740-D-25-001, January 2025. p. 7.
[10] *Id*. at p. 13.
[11] *Id*.
[12] See AFPM comments on "Proposed High-Priority Substance Designations Under the Toxic Substances Control Act (TSCA); Notice of Availability" for vinyl chloride, submitted October 23, 2024.
[13] See Draft Scope of the Risk Evaluation for Vinyl Chloride. EPA Document# EPA-740-D-25-001, January 2025. p. 14.
[14] *Id*. at p. 16.
[15] See 15 U.S. Code § 2625(h)(2).

from PVC are not relevant to a risk evaluation on vinyl chloride. They are two different substances.

In Unit 2.3.1 of its "Use Report for Vinyl Chloride" ("Use Report"), EPA acknowledges that "today the estimated vinyl chloride use for PVC is up to 99%," then goes on to discuss the many different uses of PVC.[16] Table 2-15 of the Use Report, which lists all of the Tier 1 uses of vinyl chloride, actually refers to PVC for all of its commercial and consumer uses.[17] To further confuse uses of vinyl chloride, Table 2-16 provides "a sample of products containing vinyl chloride" and lists adhesives, coatings, construction and building materials, screen printing ink, and other solid and liquid materials.[18] Those products contain PVC or a vinyl chloride copolymer and not vinyl chloride itself. Vinyl chloride is a gas.

In Unit 3.1 of the Use Report, Table 3-2 provides data from the National Emissions Inventory ("NEI") and lists emissions from fuel combustion, oil and gas production, coatings, non-ferrous metals, pulp and paper, cement manufacturing, electrical generation, and degreasing solvents. Since, according to EPA, 99% of vinyl chloride is used to make PVC, it is very doubtful that it is used in any of those sectors. Again, vinyl chloride is a gas. It is not PVC.

In comments on EPA's proposed high-priority designation for vinyl chloride, AFPM pointed out that the Agency's draft lifecycle diagram was wrong, yet EPA includes the same flawed diagram in its Draft Scope.[19] To reiterate, vinyl chloride is not used as a binder in plastic or resin manufacturing; PVC is used as a binder. Nor is vinyl chloride incorporated into articles (i.e., cable and wire).[20] Again, PVC is used as a coating for wire and cable. EPA must correct these errors in its lifecycle diagram and not wait until publication of the draft risk evaluation.

D. Residual vinyl chloride in PVC products does not result in meaningful human exposures and EPA's focus on this is an inefficient use of resources

In Unit 2.3.4 of the Draft Scope, the Agency states, "human populations that EPA expects to be assessed in the vinyl chloride risk evaluation may be exposed to vinyl chloride as a residual monomer in plastics made from PVC and related polymers."[21] However, EPA goes on to explain that "the concentration of residual vinyl chloride monomer in plastic products is expected to be low" and "concentrations of residual vinyl chloride monomer in PVC resin are generally ≤ 3 ppm."[22] Furthermore, the Agency acknowledges that due to its physical properties, "the residual vinyl chloride in PVC resin and products is expected to be entrapped within the matrix of PVC

[16] See Use Report for Vinyl Chloride, Public Release Draft. Economic and Policy Analysis Branch, Existing Chemical Risk Management Division, Office of Pollution, Prevention, and Toxics. Published January 2025. p. 2-16. U.S. Environmental Protection Agency
[17] *Id.* at pp. 2-22 to 2-24.
[18] *Id.* at pp. 2-27 to 2-51.
[19] See AFPM comments on "Proposed High-Priority Substance Designations Under the Toxic Substances Control Act (TSCA); Notice of Availability" for vinyl chloride, submitted October 23, 2024.
[20] See Draft Scope of the Risk Evaluation for Vinyl Chloride. EPA Document# EPA-740-D-25-001, January 2025. p. 19.
[21] *Id.* at p. 25.
[22] *Id.*

polymer."[23] The only rationale EPA puts forth to justify spending time and resources looking at such low exposure (and low risk) scenarios is because the vinyl chloride "might leach out of the material by diffusion over time."[24,25]

The rate of diffusion from a polymeric matrix is key when trying to assess the likelihood that a monomer could result in any appreciable exposures that would contribute to an unreasonable risk of injury. The rate of diffusion over time, which in the case of monomers from polymeric matrices is exceedingly slow, coupled with such a low concentration of residual monomer in PVC to begin with, will result in a very low probability for appreciable (or even measurable) exposure.

In its simplest form, risk is a function of hazard and the probability of exposure to that hazard. For chemicals, hazards are inherent and, therefore, fixed. Exposure, on the other hand, is variable and represents the probability function of the chemical risk equation. The ***possibility*** of diffusion is meaningless in the context of TSCA because possibility is not probability. TSCA Sec. 6(b)(4)(F)(iv) calls for consideration of the "***likely*** duration, intensity, frequency, and number of exposures under the conditions of use of the chemical substance (emphasis added)."

In 1988, the DC Circuit affirmed that exposures under TSCA must be real when it asserted EPA must find a "more-than-theoretical basis" of exposure for TSCA test rules under Sec. 4, which must meet a lower legal standard of "may present" than "presents" under TSCA Sec. 6.[26] The Court also affirmed when "the probability of exposure in the amount found by EPA" is "no more than theoretical or speculative," the Agency must defend its claims and actions.[27] EPA did not do that in its draft designation of vinyl chloride as a high priority, nor has the Agency defended its claims in the Draft Scope.

E. EPA exceeds its authority by planning to include possible byproducts and residual feedstocks in the risk evaluation.

In a footnote for Table 2-2, EPA mentions that it "plans to assess byproducts and residual feedstocks of vinyl chloride manufacture" as part of the risk evaluation.[28] The Agency identifies "1,1-dichloroethane (CASRN 75-34-3); 1,1,2-trichloroethane (79-00-5); trans-1,2-dichloroethylene (156-60-5); trichloroethylene (79-01-6); perchloroethylene (127-18-4); methylene chloride (75-09-2); and carbon tetrachloride (56-23-5)" as possible byproducts and "hydrochloric acid (7647-01-0) and 1,2-dichloroethane (107-06-2)" as potential residual feedstocks.[29] EPA does not provide any evidence or measured data that quantifies the presence of byproducts or residual feedstocks. This "condition of use" is purely hypothetical. Furthermore, according to TSCA Sec. 6(a), risk evaluations pertain to "a chemical substance or

[23] *Id.*
[24] *Id.*
[25] Notably, TSCA does not require EPA to speculate on some future presence of an unreasonable risk of injury as Congress struck "will present" in the 2016 amendments to TSCA.
[26] See Chemical Mfrs. Ass'n v. U.S.E.P.A, No. 86-1718. 859 F.2d 977 (D.C. Cir. 1988).
[27] *Id.*
[28] See Draft Scope of the Risk Evaluation for Vinyl Chloride. EPA Document# EPA-740-D-25-001, January 2025. p. 16.
[29] *Id.*

mixture" designated by the Administrator as a high priority.[30] No such mixture involving vinyl chloride or any of those substances has been identified or designated as a high priority; only vinyl chloride itself has been designated and is the subject of this Draft Scope.

IV. Conclusion

Vinyl chloride is a petrochemical building block used in closed systems (i.e., with little chance for exposure) as an intermediate to make PVC and vinyl copolymers. As a chemical intermediate, vinyl chloride is consumed in those processes, with only trace amounts of residual vinyl chloride in the polymer matrix, which is bound up in the polymer by atomic and molecular forces. The rate of diffusion, for monomers in general from a polymer matrix, is too slow to result in exposures meaningful to overall risk. EPA has failed to consider these facts when designating vinyl chloride as a high priority chemical and subsequently continued to rely on flawed assumptions in this Draft Scope. EPA also confuses vinyl chloride with PVC when listing certain conditions of use as vinyl chloride is not incorporated into articles. Nor is it used in commercial or consumer products. Vinyl chloride is a gas that is used to make PVC – a solid. They are two different chemical substances with totally different physical and chemical properties.

AFPM urges EPA to withdraw the Draft Scope and repropose it with a focus on correcting the flaws identified in these comments. AFPM would appreciate the opportunity to work collaboratively with the Agency and other stakeholders to ensure the continued safe use of vinyl chloride.

Sincerely,

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[30] See 15 U.S. Code § 2605(a).