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

Office of Pollution Prevention and Toxics United States Environmental Protection Agency

AMERICAN FUEL & PETROCHEMICAL MANUFACTURERS COMMENTS

Attention: EPA-HQ-OPPT-2018-0449

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 "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. These comments address the Proposed Designation of acrylonitrile as a high-priority substance for risk evaluation and potential risk management. AFPM's comments highlight the following concerns that the Proposed Designation:

- It is technically flawed and fails to recognize the difference between a chemical intermediate and an ingredient or material component of a product;
- It relies on the flawed 2014 TSCA Work Plan and other incorrect data sources that erroneously conclude acrylonitrile is used in commercial, consumer, and other finished goods; and
- It shifts from the Congressionally mandated risk-based approach to a hazard-based approach to prioritization by selecting acrylonitrile because it has a robust hazard dataset

Based on the concerns raised in these comments, EPA should withdraw acrylonitrile from consideration as a high priority and focus on chemicals that present the greatest potential for exposure, such as those found in consumer and commercial 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, it appears EPA's disregard of acrylonitrile'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.

AFPM members produce acrylonitrile, which is a petrochemical building block (i.e., intermediate) used to make polyacrylonitrile ("PAN") fiber. PAN is the fiber used in carbon fiber-reinforced composites. Fiber-reinforced composites make modern wind turbine blades

¹ 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-OCSPP, published July 25, 2024.

possible. These important composites also make automobiles more lightweight, saving fuel and making electric vehicles more energy efficient. Fiber-reinforced composites are also used in aircraft bodies to make jet planes more fuel efficient. They are also used to make sporting equipment, from bicycle frames to tennis rackets and skis. In addition to its criticality in carbon fiber, acrylonitrile is also used with other monomers to make copolymers, such as the acrylonitrile-butadiene-styrene ("ABS") engineering plastic used for computer keyboards, car parts, and Lego® blocks. Acrylonitrile is also used to make acrylic fiber that goes into rugs and clothing, in addition to its use to make adiponitrile for the production of nylon.

Acrylonitrile is critical to manufacturing of American products that we use every day. It is produced, used, and consumed in closed systems and highly regulated in industrial and manufacturing settings. These manufacturing processes transform intermediates like acrylonitrile into new molecules that have proven safe in commerce. It is very important to note that acrylonitrile is not PAN, nor is it ABS, acrylic fiber, or nylon.

III. Comments on the Proposed High-Priority Designation for Acrylonitrile

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." 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." Acrylonitrile has a persistence and bioaccumulation score of only 1. EPA points to a general hazard category score in Unit III.B. of its "Initiation of Prioritization Under the Toxic Substances Control Act (TSCA); Request for Comment," ("Priority Initiation Notice") but this general hazard score does not specify that acrylonitrile is a known human carcinogen and has high acute and chronic toxicity. On the contrary, EPA's own fact sheet on acrylonitrile states that it is a "probable human carcinogen (Group B1)," and that classification is just based EPA's own internal assessment. The lowest LC50 (rat) for acrylonitrile is 425 ppm. The classification of high toxicity is below 100 ppm, so clearly acrylonitrile does not have high acute toxicity.

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." 8 Sec.

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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 EPA's fact sheet on acrylonitrile.

⁷ See CDC/NIOSH <u>fact sheet on acrylonitrile</u>. An LC50 is a routine measurement of lethal concentration, in parts per million, that is used to determine the level of acute toxicity for a given substance. Also see the International Labour Organization for toxicity classifications.

⁸ See TSCA Sec. 6(b)(1)(A).

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 acrylonitrile is "used in" consumer products, which is not supported by current knowledge of this product. EPA acknowledges that acrylonitrile is used as an intermediate to make other chemicals on its own fact sheet. 11

Like most intermediates, acrylonitrile is used in closed systems and is highly regulated in industrial and manufacturing settings. These processes transform acrylonitrile into new molecules that have proven safe in commerce. After processing in the closed system, the acrylonitrile no longer exists. Its use as a chemical intermediate does not present an unreasonable risk in downstream products if it no longer exists. Clearly, acrylonitrile does not meet the statutory criteria for persistence, bioaccumulation, carcinogenicity, or acute toxicity, nor does it meet the criteria for exposure potential.

B. EPA fails to demonstrate that the conditions of use for acrylonitrile present a significant potential for exposure.

In Sec. 2.2 of EPA's supporting document for acrylonitrile, EPA states that the production volume presents "a consistent potential source of exposure." Production volume is not an appropriate surrogate for exposure. Exposure is determined through the scenarios under which a chemical is used (*i.e.*, conditions of use). AFPM acknowledges that the Agency is required to consider production volume but cautions against giving it much weight in the exposure part of the risk equation.

Table 2-2 of the supporting document correctly characterizes the use of acrylonitrile as an intermediate or monomer to make polymers and other chemicals for a variety of finished goods manufacturing. One clarification needed is for the entry "Adhesive and sealant chemical in all other basic chemical manufacturing." Acrylonitrile is a "hard monomer" used in copolymeric adhesives, which means that it is consumed in the process of making the polymer. The polymer molecule is not acrylonitrile.

Another needed clarification is the entry "Incorporating into formulation, mixture or reaction product." This category is confusing because incorporation into a formulation, mixture, or reaction product implies that acrylonitrile is an ingredient, which it is not. The only function acrylonitrile serves in those products is as an intermediate or as a monomer.

Table 2-3 of the supporting document does not have the utility of Table 2-2. The use categories listed in the table do not distinguish between ingredients and intermediates and just

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⁹ See TSCA Sec. 6(b)(1)(B)(i).

¹⁰ See 2014 update of the TSCA Work Plan for Chemical Assessments.

¹¹ See EPA fact sheet for acrylonitrile.

¹² See "Proposed Designation of Acrylonitrile as a High-Priority Substance for Risk Evaluation." EPA Document # EPA-740-P-24-004, July 2024. p. 16.

¹³ *Id*. at 18.

¹⁴ *Id*.

use manufacturing sectors, polymeric references, or references to finished goods. The links go to a database to search for anything from air emissions to product contamination websites.

In Table 2-3, EPA uses comments from AFPM on the notice for Initiation of Prioritization for Acrylonitrile.¹⁵ In those comments, AFPM was careful to point out that acrylonitrile is not "used in" any of those products it identified; rather, it is an intermediate to make other chemical substances, such as PAN and ABS, that are "used in" those products. Comments from the Acrylonitrile Group, a consortium representing manufacturers of acrylonitrile, were also careful in their language. The comments use the term "used to make" rather than "used in," because the former describes an intermediate and the latter describes an ingredient or material component.¹⁶ Table 2-3 is inadequate to demonstrate exposures to acrylonitrile and should not be relied upon for a high-priority designation.

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 acknowledges that according to the CDR data, there are no consumer or commercial uses of acrylonitrile.¹⁷ Rather than accepting the fact that acrylonitrile is an intermediate to make other chemical substances, EPA turned to the technically flawed and incorrect High Priority Chemicals Data System ("HPCDS") to justify its inclusion of children as a PESS. 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." Acrylonitrile is not a synthetic polymer; in fact, it is not a polymer at all. Therefore, 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 and epidemiology data sources that document reproductive and/or developmental effects following exposure." 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 acrylonitrile. 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. Since acrylonitrile is an industrial intermediate used in closed systems and is transformed in those processes into a totally different chemical substance, the probability of exposure to acrylonitrile of any woman of reproductive age is highly unlikely.

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¹⁵ See <u>AFPM comments</u> on "Initiation of Prioritization Under the Toxic Substances Control Act ("TSCA"); Request for Comment," submitted to docket EPA–HQ–OPPT–2018–0449-0002 on March 18, 2024.

¹⁶ See Acrylonitrile Group comments on "Initiation of Prioritization Under the Toxic Substances Control Act ("TSCA"); Request for Comment," submitted to docket EPA–HQ–OPPT–2018–0449-0002 on March 18, 2024.

¹⁷ See "Proposed Designation of Acrylonitrile as a High-Priority Substance for Risk Evaluation." EPA Document # EPA-740-P-24-004, July 2024. p. 22.

¹⁸ *Id.* at 23.

¹⁹ *Id*.

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

Acrylonitrile has a robust hazard dataset. In Unit III.A. of its Priority Initiation Notice, 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." This approach penalizes acrylonitrile simply because there are hazard data for the substance.²⁰

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, as is evident throughout the entire 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 acrylonitrile for consideration as a high priority. Clearly, acrylonitrile fails to meet the statutory criteria for designation as a high-priority chemical. In this Proposal, EPA disregards the exposure component of the risk equation and appears to be moving toward a hazard-based approach to prioritization, which runs counter to Congressional intent.

The Agency has provided no evidence of significant potential exposure. In fact, EPA's main data source to identify uses under TSCA contains no known commercial or consumer uses. Acrylonitrile 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 could lead to an unreasonable risk. Acrylonitrile also does not have the required persistence, bioaccumulation, and toxicity levels that TSCA requires for consideration as a high-priority chemical. EPA must remove acrylonitrile from further consideration so it can concentrate on substances that may actually present an unreasonable risk.

Sincerely,

James Cooper

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²⁰ 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.