INITIATION OF PRIORITIZATION UNDER THE TOXIC SUBSTANCES CONTROL ACT (TSCA)

PRE-PRIORITIZATION OF EXISTING CHEMICAL SUBSTANCES UNDER THE TOXIC SUBSTANCES CONTROL ACT (TSCA)

Office of Pollution Prevention and Toxics
United States Environmental Protection Agency

AMERICAN FUEL & PETROCHEMICAL MANUFACTURERS COMMENTS

Attention: EPA–HQ–OPPT–2023-0606

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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, "Initiation of Prioritization Under the Toxic Substances Control Act (TSCA)," to the reopened docket for EPA's "Pre-Prioritization of Existing Chemical Substances Under the Toxic Substances Control Act (TSCA)" ("Proposed Pre-Prioritization"). EPA has reopened the docket and is seeking comment on a list of 22 chemical substances for consideration as candidates for prioritization and subsequent risk evaluation and risk management.[1] These comments address a subset of the list of 22 chemicals, five of which are petrochemicals (aka "petrochemical intermediates") and one, hydrogen fluoride ("HF"), a critical catalyst used in the manufacture of high-octane gasoline.

Specifically, these comments address the following chemical substances' conditions of use by refiners and petrochemical manufacturers: petrochemical intermediates (bisphenol A, m-xylene, o-xylene, p-xylene, and bisphenol S) as well as the catalyst critical to the high-octane component of gasoline (HF).[2] For the reasons set forth below, AFPM urges EPA to consider these six chemicals as low priorities under TSCA section 6(b):

- The five petrochemical intermediates listed above are primarily used as building blocks in closed-loop systems by chemical companies, subject to comprehensive regulations under the Occupational Safety and Health Administration ("OSHA"), Department of Transportation ("DOT"), and other EPA offices, such as the Office of Air and Radiation and the Office of Land and Emergency Management;
- The petrochemical intermediates are consumed through chemical reactions and do not exist in any appreciable amount in downstream products;
- HF is also used in closed systems by petroleum refineries, and is subject to comprehensive regulations under the OSHA, DOT, and other EPA offices;
- The 2014 TSCA Work Plan, High Priority Chemicals Data System ("HPCDS") and other data sources that EPA relied upon for use information in the previous prioritization of these chemicals were technically flawed and incorrect.

II. AFPM Interest in the Proposal

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

[1] *See 89 Fed. Reg. 102903*, "Initiation of Prioritization Under the Toxic Substances Control Act (TSCA); Notice of Availability." EPA–HQ–OPPT–2023–0601; FRL–11581–06–OCSPP, published December 18, 2024.

[2] The xylenes listed as potential high priorities are not the same as mixed xylenes and have different conditions of use. The separated xylenes (i.e., meta-xylene, ortho-xylene, and para-xylene) are value added products used to make synthetic fibers, fiber-reinforced polymers, and other specialized materials. Mixed xylenes can be found as ingredients in formulated mixtures, but the separated xylenes generally are not.

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. In applying TSCA, EPA must analyze the prioritization criteria and use the most accurate information regarding the uses of and potential exposures to chemicals it considers during the pre-prioritization process.

EPA cannot meet its statutory obligations for using the best available science under TSCA section 26(h)(2) unless the Agency considers "the extent to which the information is relevant for the Administrator's use in making a decision about a chemical substance or mixture."[3] EPA must also take into account "the ***likely*** duration, intensity, frequency, and number of exposures under the conditions of use" (emphasis added).[4] If the fundamental information the Agency considers to identify a chemical substance's conditions of use is flawed, then any derivative analyses, such as exposure assessments and risk evaluations, will also be flawed.

EPA must also consider the "best available science" under TSCA section 26(h) in assessing the presence of an unreasonable risk, which means acknowledging the fundamental chemistry involved with petrochemical intermediates. That is, that the petrochemical intermediates do not exist, except in trace quantities, after processing and do not present significant potential for exposure and, therefore, cannot pose an unreasonable risk to human health or the environment.

III. Comments on the Pre-Prioritization for the Petrochemical Intermediates

A. Chemical intermediates generally do not meet the statutory criteria for prioritization.

TSCA requires EPA to "include a consideration of the hazard and exposure potential of a chemical" when prioritizing substances that may be subject to a risk evaluation, but requires assignment of a high priority designation and the start of a risk evaluation only if EPA finds 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."[5] In turn, TSCA defines "conditions of use" to include the "circumstances, as determined by the Administrator, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of."[6]

As AFPM discusses further below, there are no unreasonable risks because there are no reasonably foreseeable routes of exposure. Intermediate chemicals are used in closed-loop processes where they are consumed when transformed into another chemical substance. In all cases, petrochemical intermediates should be considered a low priority under the statute.

[3] See 15 USC § 2625(h)(2).
[4] See 15 USC § 2605(b)(4)(F)(iv).
[5] See 15 USC § 2605(b)(1)(A) and 15 USC § 2605(b)(1)(B)(i).
[6] See 15 USC § 2602.

B. Petrochemical intermediates are critical to American manufacturing.

Petrochemical intermediates are near the top of the manufacturing supply chain and a critical first step for thousands of different products. Most manufacturing processes depend on chemical reactions and start with one or more of a very small number of chemical substances called base petrochemicals. AFPM members manufacture six base chemicals, including: ethylene, propylene, butylenes (also known as olefins) and benzene, toluene, xylenes (also known as aromatics).

From these base petrochemicals, literally thousands of other chemical substances and products can be made through a series of chemical reactions. For example, in the petrochemical derivative manufacturing process, take p-xylene (a base petrochemical) and react it with oxygen to make terephthalic acid. React that terephthalic acid with ethylene glycol (made from ethylene and water) creating polyethylene terephthalate ("PET"). The original base chemicals are transformed into new materials in this process. PET is a polyester, like the fiber found in fleece jackets, golf shirts, and running shoes. PET is also used to make water bottles. PET is fully recyclable, and chemists can actually use advanced recycling techniques to return PET to its original building blocks so it can be recycled over and over again with little degradation.

Of course, the chemistry is technically more complex than this simplified version, but it all starts with base petrochemicals that serve as the building blocks to make thousands of products we see and use every day. Just about everything that isn't glass, rock, or steel starts with one or more of these six base petrochemicals.

Base petrochemicals and their first derivatives are primarily used as intermediates to make other chemical substances and are typically not seen outside of a closed container or process unit in a tightly controlled manufacturing facility. Many second derivatives are also intermediates. Those petrochemicals and derivatives may have other uses, but those other uses typically represent fractions of the total production volumes.

Petrochemical intermediates are used in chemical reactions to attach functional groups of atoms to another molecule, or they serve as monomers (molecules that can link up like a chain) to make a polymer (*i.e.*, plastic material). In either case, the original petrochemical intermediate is consumed in the process to make the other molecule or to make the polymer. When this happens, the petrochemical intermediate no longer exists when it is transformed into the new substance, so it is only present in trace amounts in any of the subsequent chemical substances, polymers, or downstream products that result from the chemical reactions or other manufacturing processes. Importantly, the concentration levels of these petrochemical intermediates are negligible in terms of risk, which is why EPA has traditionally provided exemptions for *de minimis* levels.

To be clear, the term "intermediate" does not apply to ingredients or material components of products because only trace amounts of the original molecule (*i.e.*, the intermediate) exist after it is transformed during the chemical reaction.

C. *Accidental releases of chemical intermediates should not be considered in TSCA risk evaluations.*

Intermediates are used to make other chemical substances, and they are stored in closed containers and transferred by attached hoses or pipes from the closed container to a closed process unit. This creates a closed-loop system, so in these scenarios the intermediates are also referred to as "closed-system" intermediates. The only way that a person could be exposed to a closed-system intermediate is from an accidental release or spill of the substance which is not a condition of use to be considered under TSCA.

AFPM is not alone in this view. EPA stated, on May 3, 2024, "where exposures from future releases of a chemical substance are unsubstantiated, speculative or otherwise not likely to occur (e.g., a future one-time accident involving the chemical substance that could be caused by an atypical one-time set of circumstances), EPA would generally not assess them as part of a risk evaluation."[7] This statement by EPA, coupled with the facts of petrochemical intermediate manufacturing and use practices, should render these substances low priorities under TSCA.

Accidental releases should not be considered in TSCA risk evaluations, let alone prioritizations, because the risk equation under TSCA does not contain the required probability functions (*i.e.*, frequency, duration, and magnitude of accidental release). Risk under TSCA is derived from the margin of exposure ("MOE"), expressed as the ratio of the no-observed-adverse-effect level ("NOAEL") obtained from animal toxicology studies to the dose given or an estimate of concentration from an exposure model. The models used to evaluate the risks of accidents, like under EPA's Risk Management Program ("RMP") are totally different than the models used to do risk evaluations under TSCA. Additionally, the duration and magnitude of exposure in accident scenarios varies from scenario to scenario and are not predictable without a rigorous analysis of past releases that are germane to the scenario under study. The MOE equation and risk evaluation methods used for TSCA Sec. 6 do not fully account for these parameters and functions. For all these reasons EPA should not consider accidental releases in TSCA risk evaluations.

D. *The sources EPA depended on for exposure information during the previous pre-prioritization and prioritization are misleading and, in some cases, incorrect.*

EPA relied on two primary sources of use information for the previous pre-prioritization and prioritization of chemicals for risk evaluation under TSCA: (1) data reported under the Chemical Data Reporting ("CDR") regulations, which forms the basis of the uses identified in the 2014 TSCA Work Plan, and (2) the HPCDS. Both of these sources are flawed when applied to petrochemical intermediates because they do not often discern between an intermediate used to **make** a product and an ingredient or material component made from the intermediate that is **used in** a product -- there are also cases where those sources do not distinguish between a monomer and a polymer. In addition, and maybe more importantly, EPA disclaims the reliability

[7] Docket (EPA-HQ-OPPT-2023-0496)

of the CDR as a valid information source due to troubles with the information collected in those years.

For example, the 2020 CDR data reports styrene in the following manner:[8]

- Type of Process or Use Operation: Processing-incorporation into formulation, mixture, or reaction product
- Industrial Sector: Adhesive Manufacturing
- Industrial Function Category: Adhesives and sealant chemicals

Styrene block copolymers, which are polymers made with alternating monomer units (like styrene and butadiene), are used in adhesives, not styrene itself. Styrene is very reactive and is only used as a monomer to make the block copolymers found in adhesives. Styrene block copolymers are not styrene.

The same 2020 CDR data also report styrene in the following manner:[9]

- Type of Process or Use Operation: Processing-incorporation into formulation, mixture, or reaction product
- Industrial Sector: Plastics Material and Resin Manufacturing
- Industrial Function Category: Paint additives and coating additives not described by other categories

This example also demonstrates the limitations of CDR information because styrene is used to make styrene/acrylic copolymer binders for paint. Styrene/acrylic copolymers are not styrene.

To further highlight the limitations of CDR information used for the most recent prioritization designations, below is an example found in EPA's supporting document for the designation of vinyl chloride as a high-priority substance:

> "*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.*"[10]

The CDR lists a category of use for vinyl chloride as "Incorporating into formulation, mixture or reaction product" and the corresponding subcategory as "Binder in plastics material

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[8] *See* EPA's ChemView database for CDR information.
[9] *Id.*
[10] *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. 17.

and resin manufacturing."[11] 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 different molecular structures than vinyl chloride.

The CDR also lists a category of "Incorporating into articles" with a subcategory of "Wire and cable in primary metal manufacturing."[12] In addition, the CDR has a category of "Building/construction materials not covered elsewhere" and subcategory of "Cable and wire manufacturing."[13] Polyvinyl chloride ("PVC") is used in coatings for wire and cable, not vinyl chloride. Vinyl chloride is a gas and will not coat metal. The CDR lists vinyl chloride as a binder under the category "Plastic and rubber products not covered elsewhere."[14] As mentioned above, vinyl chloride is used to **make** binders, but it is not a binder itself.

Another example can be found in EPA's supporting document for designation of acetaldehyde as a high-priority substance.[15] In the case of acetaldehyde's relationship to glue and adhesives highlighted in the document, it is an intermediate used to make polyvinyl acetate ("PVA"). PVA is what is used in the glue and adhesives CDR category, not acetaldehyde. The acetaldehyde is consumed in the process that makes the PVA, so acetaldehyde is not "used" in the glue and adhesives. To further complicate the matter, polyvinyl acetate is used to make polyvinyl alcohol (via hydrolysis of the acetate), both of which use "PVA" as an acronym. Polyvinyl alcohol is what is used in certain paper manufacturing processes, not polyvinyl acetate, and certainly not acetaldehyde.[16]

As with vinyl chloride, EPA also acknowledges the shortcomings of CDR data for designation of acetaldehyde as a high-priority chemical. In the Agency's supporting document, EPA acknowledges that the functional use of a chemical wasn't even reported to the CDR until 2020.[17]

EPA did incorporate subcategories of use (*i.e.*, functions) and revise its CDR reporting guidance between the 2016 and 2020 reporting periods, but it appears that the guidance is still confusing to some reporters because instead of acetaldehyde being "used" in "paint and coatings," as reported in 2016, it is now reportedly being "used" in "construction and building materials covering large surfaces" (*i.e.*, paint and coatings).[18] The CDR also lists acetaldehyde as an "intermediate in single component glue and adhesives," in "food, beverage, and tobacco product manufacturing," and in "packaging…including paper articles."[19] The intermediate is not found in those products in any appreciable amounts because it is transformed into PVA, which is

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[11] *Id.* at 18.
[12] *Id.*
[13] *Id.*
[14] *Id.*
[15] *See* "Proposed Designation of Acetaldehyde as a High-Priority Substance for Risk Evaluation." EPA-740-P-24-003, July 2024.
[16] *Id.* at 15.
[17] *Id.* at 16.
[18] *Id.*
[19] *Id.* at 17.

a totally different chemical substance. Acetaldehyde is consumed in the process to make PVA. In other words, PVA is used in those products, not acetaldehyde.

These are just three examples that demonstrate the limitations and potential inaccuracies of the CDR as a source of exposure information that the Agency used to create its 2014 TSCA Work Plan and currently uses to designate chemicals as high priorities for risk evaluation under TSCA. These same limitations would apply to the five chemicals AFPM has identified as essential petrochemical intermediates.

The HPCDS is a database of children's products that purportedly "contain" chemicals 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. For example, the HPCDS categorizes Acrylonitrile among "Synthetic Polymers" and "Textiles." Acrylonitrile is not a synthetic polymer; in fact, it is not a polymer at all. Similarly, in EPA's supporting document for designation of acrylonitrile as a high-priority chemical, the Agency relied on the HPCDS to claim that acrylonitrile is used in consumer products, including those intended for children.[20] One of the categories of uses for acetaldehyde that the HPCDS lists is "toys, games, blankets, jewelry, and clothing."[21] Again, the HPCDS uses generic descriptions for acetaldehyde, such as "Synthetic Polymers" or "Textiles." Acetaldehyde is not a synthetic or any other kind of polymer.

The HPCDS does not acknowledge the difference between a monomer and polymer or intermediate and ingredient. Therefore, the HPCDS cannot be considered a valid source for chemicals found in products. These same limitations would apply to the five chemicals AFPM has identified as essential petrochemical intermediates.

IV. Comments on Hydrogen Fluoride

AFPM notes that, due to its inherent properties, unmitigated HF exposure may cause immediate, adverse effects, which is why AFPM members use it in closed systems that are tightly regulated under EPA, OSHA, and DOT. In fact, EPA already regulates accidental releases of HF under RMP Part 68.[22]

HF is used by AFPM members as a catalyst in the alkylation processes at petroleum refineries, allowing them to make the high-octane components of cleaner burning gasoline. The alkylation processing units, storage units, and transfer units employ engineering controls to negate an unreasonable risk of injury from being present under its foreseeable conditions of use.

Baker Risk, a globally recognized risk management company, recently quantified the lifetime risk of sustaining a life-threatening injury from HF use at refineries at 1 in 52 million (this was using a similar methodology to the National Safety Council).[23] Besides federal

[20] *See* "Proposed Designation of Acrylonitrile as a High-Priority Substance for Risk Evaluation." EPA Document # EPA-740-P-24-004, July 2024. p. 17.
[21] *Id.*
[22] *See* 40 CFR Part 68.
[23] Refinery Provision in House Energy Bill Makes Good Safety Sense | RealClearEnergy

requirements, AFPM members properly manage the risk of HF acid through industry recommended practices such as API 751. Even though the publication of the 4^{th} Edition[24] resulted in the number of HF incidents decreasing by one-third of the previous rate, the 5th Edition in 2021 included a special-emphasis inspection program to inspect all carbon steel components for five HF corrosion zones.

Due to its conditions of use as a catalyst in closed-loop alkylation units and the comprehensive regulatory and other regimes that prevent exposure (and reduces the potential of accidental release), EPA should categorize HF as a low priority for risk evaluation under TSCA.

V. Conclusion

AFPM appreciates the opportunity to comment on this Proposed Pre-Prioritization. Petrochemical intermediates are not ingredients or material components of products; rather, they are used in closed systems to make other chemicals and are consumed in the process when they are transformed into another chemical substance. There is negligible potential for exposure. HF is also a chemical used in closed systems with negligible potential for exposure. AFPM strongly urges EPA to designate petrochemical intermediates and HF as low priorities for risk evaluation under TSCA.

Sincerely,

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[24] API 751 – 4^{th} Edition (2013) – Safe Operation of Hydrofluoric Acid Alkylation Units, Section 6.2 Mitigation Systems.