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

Office of Pollution Prevention and Toxics
United States Environmental Protection Agency

AMERICAN FUEL & PETROCHEMICAL MANUFACTURERS COMMENTS

Attention: EPA–HQ–OPPT–2018–0497

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U.S. Environmental Protection Agency
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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, "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.[1] These comments address the Proposed Designation of acetaldehyde as a high-priority substance for risk evaluation and potential risk management. AFPM's comments highlight the following concerns with the Proposed Designation:

- It is technically flawed and fails to recognize the difference between a chemical intermediate and an ingredient or component of a product;
- It relies on the flawed 2014 TSCA Work Plan and other incorrect data sources that erroneously conclude acetaldehyde 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 acetaldehyde because it has a robust hazard dataset.

Based on the concerns raised in these comments, EPA should withdraw acetaldehyde 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, in this case, it appears EPA's disregard of acetaldehyde'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.

Acetaldehyde is a petrochemical building block (i.e., intermediate) used to make acetic acid, a derivative used in the manufacture of polyvinyl acetate ("PVA") and other derivatives. PVA is one of the most prevalent and safe adhesives on the market. PVA is used to make

[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.

Elmer's Glue® and is the adhesive for envelopes and other packaging. Acetaldehyde is an intermediate; it is not PVA.

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

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."[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] Acetaldehyde 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," but that general hazard score does not specify that acetaldehyde is a known human carcinogen ***and*** has high acute ***and*** chronic toxicity."[5] On the contrary, EPA's own fact sheet on acetaldehyde states that it is only a "probable human carcinogen (Group B2)."[6] The lowest LC_{50} for acetaldehyde (rat) is 13,000 ppm.[7] The classification of high toxicity is below 100 ppm, so clearly acetaldehyde does not have high acute toxicity.[8]

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."[9] 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."[10] According to EPA, "Acetaldehyde is mainly used as an intermediate in the synthesis of other chemicals. It is ubiquitous in the environment, found naturally in foods, and may be formed in the body from the breakdown of ethanol."[11]

Like most intermediates, acetaldehyde is used in closed systems and is highly regulated in industrial and manufacturing settings. These processes transform acetaldehyde into new molecules that have proven safe in commerce. After processing in the closed system, the acetaldehyde no longer exists. Its use as a chemical intermediate does not present an unreasonable risk in downstream products if it no longer exists. Clearly, acetaldehyde does not

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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 acetaldehyde.
[7] *See* CDC/NIOSH fact sheet on acetaldehyde.
[8] *See* the International Labour Organization for toxicity classifications.
[9] *See* TSCA Sec. 6(b)(1)(A).
[10] *See* TSCA Sec. 6(b)(1)(B)(i).
[11] *See* EPA's fact sheet on acetaldehyde.

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 acetaldehyde present a significant potential for exposure.*

In Sec. 2.2 of EPA's supporting document for acetaldehyde, EPA states that the production volume presents "a consistent potential source of exposure."[12] 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.

The use categories reported under the Chemical Data Reporting ("CDR") rule are not adequate to capture the scientific realities of chemical intermediates. In the case of acetaldehyde's relationship to glue and adhesives, for example, it is an intermediate used to make PVA. PVA is what is used in glue and adhesives, 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.

EPA acknowledges the shortcomings of CDR data and is seeking comment to clarify reported uses. In the Agency's supporting document, EPA acknowledges that the functional use of a chemical wasn't even reported to the CDR until 2020.[13] Furthermore, EPA states that "guidance regarding the reporting of categories and subcategory information was updated" between 2016 and 2020, so this may have led to further discrepancies in the reported uses.[14]

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).[15] The way Table 2-2 itself lists the subcategories of uses is also misleading. For example, under the subcategory column it lists acetaldehyde as an "intermediate in single component glue and adhesives," in "food, beverage, and tobacco product manufacturing," and in "packaging…including paper articles."[16] The intermediate is not found in those products because it is used to make a totally different chemical substance and is consumed in the process. In other words, PVA is used in those products, not acetaldehyde. Table 2-2 in the supporting document should not even list what was reported in

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

2016 under the old guidance because the use categories did not distinguish between an ingredient or component and an intermediate.[17] Table 2-2 is confusing and technically incorrect.

EPA states that in 2016, acetaldehyde was reported to have commercial uses for "golf and sports turfs, as well as in both commercial and consumer use in plastic and rubber products and paint and coatings," but not in 2020.[18] In addition, EPA states that in 2020 acetaldehyde "was identified in commercial use for construction and building materials covering large surfaces and agricultural non-pesticidal products, as well as commercial and consumer packaging."[19] The Agency goes on to say that these uses could be new, or now meet the CDR reporting threshold, or are reporting discrepancies. Acetaldehyde is a gas above 68.4° F. It is not a component found in artificial turf, plastic, or rubber, which are all solids. Nor is it an ingredient in paint or coating mixtures. Rather, it is a building block (i.e., intermediate) that is used to make resins that are used as binders in paints and coatings. Those resins are not acetaldehyde; they are totally different molecules that are made from acetaldehyde. The CDR and other information sources used by EPA do not adequately acknowledge the difference.

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

Regarding children as a PESS, EPA says it did not find any uses of acetaldehyde in products intended for children reported to the CDR is 2016 or 2020.[20] Yet it lists "toys, games, blankets, jewelry, and clothing" as products for which acetaldehyde is used because of a reference in the High Priority Chemicals Data System ("HPCDS").[21] 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, like the CDR before 2020, 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." Acetaldehyde 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."[22] 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 acetaldehyde. 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.[23] Since acetaldehyde is an industrial intermediate used in closed systems and is transformed in those

[17] *Id.* at 17.
[18] *Id.* at 16.
[19] *Id.*
[20] *Id.* at 21.
[21] *Id.*
[22] *Id.* at 22.
[23] *Id.*

processes into a totally different chemical substance, the probability of exposure to acetaldehyde of any woman of reproductive age is highly unlikely.

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

Acetaldehyde has a robust hazard dataset. In Unit III.A. of its Initiation of Prioritization 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 chemicals simply because they possess more full hazard datasets.[24]

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 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 acetaldehyde for consideration as a high priority. Clearly, acetaldehyde 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 beyond that which is due to acetaldehyde found in nature. Acetaldehyde 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. Acetaldehyde also does not have the required persistence, bioaccumulation, and toxicity levels that TSCA requires for consideration as a high-priority chemical. EPA must remove acetaldehyde from further consideration so it can concentrate on substances that may actually present an unreasonable risk.

Sincerely,

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[24] *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.