

**INITIATION OF PRIORITIZATION UNDER THE  
TOXIC SUBSTANCES CONTROL ACT (TSCA);  
REQUEST FOR COMMENT  
ACETALDEHYDE**

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Office of Pollution Prevention and Toxics  
United States Environmental Protection Agency

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**AMERICAN FUEL & PETROCHEMICAL MANUFACTURERS  
COMMENTS**

**Attention: EPA-HQ-OPPT-2018-0497-0002**

March 18, 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, “Initiation of Prioritization Under the Toxic Substances Control Act (TSCA); Request for Comment” (“Proposed Prioritization” or “Proposal”). EPA proposes to categorize 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 acetaldehyde as a candidate for high-priority designation. AFPM’s comments highlight the following concerns that the Proposed Prioritization:

- Focuses on acetaldehyde, which is naturally occurring and primarily used as a chemical intermediate with extremely low potential for exposure,
- Depends on the flawed 2014 TSCA Work Plan that falsely claims acetaldehyde is used as an ingredient in consumers goods; and,
- Moves 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 and focus on chemicals that present the greatest potential for exposure, such as those found in 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.

Acetaldehyde is a petrochemical building block (i.e., intermediate) used to make acetic acid, a derivative used in the manufacture of polyvinyl acetate (“PVA”). PVA is one of the most prevalent and safe adhesives on the market. PVA is used to make Elmer’s Glue<sup>®</sup> and is the adhesive for envelopes and other packaging. Acetaldehyde is an intermediate; it is not PVA. Put simply, this intermediate 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.

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

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<sup>1</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.

minimal risks of exposure associated with intermediates, diverts limited resources away from substances more suited for TSCA prioritization.

### III. Comments on the Prioritization Proposal for Acetaldehyde

*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> Acetaldehyde has a persistence and bioaccumulation score of only 1. EPA points to a general hazard category score in Unit III.B., but this general hazard score does not specify that acetaldehyde is a known human carcinogen *and* has high acute *and* chronic toxicity.<sup>5</sup> On the contrary, EPA’s own fact sheet on acetaldehyde states that it is a “probable human carcinogen (Group B2).”<sup>6</sup> The lowest LC<sub>50</sub> for a rat is 13,000 ppm.<sup>7</sup> The classification of high toxicity is below 100 ppm, so clearly acetaldehyde does not have high acute toxicity.<sup>8</sup>

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>9</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>10</sup> “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.”<sup>11</sup> Acetaldehyde, like other intermediates, is consumed in the chemical reaction process. Since acetaldehyde is “ubiquitous in the ambient environment,” the background exposures dwarf any exposure from its use as an intermediate in a closed system.<sup>12</sup> In this Proposal, EPA is disregarding 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.

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<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 EPA’s [fact sheet on acetaldehyde](#).

<sup>7</sup> See CDC/NIOSH [fact sheet on acetaldehyde](#).

<sup>8</sup> See the International Labour Organization for [toxicity classifications](#).

<sup>9</sup> See [TSCA Sec. 6\(b\)\(1\)\(A\)](#).

<sup>10</sup> See [TSCA Sec. 6\(b\)\(1\)\(B\)\(i\)](#).

<sup>11</sup> See EPA’s [fact sheet on acetaldehyde](#).

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

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

Acetaldehyde has a robust hazard dataset. In Unit III.A., 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 chemicals just because they possess more full hazard datasets.<sup>13</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 whole intent of TSCA. Congress intended TSCA to be a risk-based approach, which is evident throughout the entire statute. EPA should abandon its attempt to focus on hazards and fully consider the potential for exposure, or in this case the lack thereof, and prioritize chemicals the way that Congress intended.

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

As noted earlier, acetaldehyde is ubiquitous in nature. In Unit III.B. of the Proposal, EPA generally notes that acetaldehyde was reported in 2020 under the Chemical Data Reporting (“CDR”) rule but the Agency does not provide any information on what it found in the CDR to support its claim that the conditions of use for acetaldehyde could lead to a significant potential for exposure beyond the exposures from natural sources.<sup>14</sup> Information reported under the CDR rule is general usage information and there is no legitimate reason that EPA cannot aggregate it to support its assertions in the proposed rule.

#### **IV. Conclusion**

AFPM has serious concerns about EPA selecting acetaldehyde for consideration as a high priority. The Agency has provided no information to support a finding of significant potential exposure beyond that which is due to acetaldehyde found in nature. Acetaldehyde is a petrochemical intermediate mostly 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,



James Cooper  
Senior Petrochemical Advisor

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<sup>13</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>14</sup> *Id.* at 87425.