

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

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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-2018-0474-0002**

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 benzeneamine (“aniline”) as a candidate for high-priority designation. AFPM’s comments highlight the following concerns that the Proposed Prioritization:

- Focuses on aniline, which is a chemical intermediate with extremely low potential for exposure,
- Depends on the flawed 2014 TSCA Work Plan that falsely claims aniline 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 aniline because it has a robust hazard dataset

Based on the concerns raised in these comments, EPA should withdraw aniline 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.

AFPM member companies produce aniline. Aniline is a petrochemical building block (i.e., intermediate) used to make a major component of polyurethane, called methylene diphenyl diisocyanate (“MDI”). MDI is a safer alternative to the component previously used to make polyurethane. Polyurethane is used for memory foam mattresses, car seat cushions, building insulation, and myriad other valuable products. Aniline is also used to make acetaminophen. This intermediate is produced and used in closed-systems and is highly regulated in industrial and manufacturing settings. These processes transform aniline 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. Unfortunately, in this case, EPA is using TSCA

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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.

to target industrial chemicals used to make plastics as a means to limit plastic products. Aniline is used in the production of plastics, among other things. These efforts under TSCA appear to be designed to disrupt critical plastics supply chains despite these chemicals being used in industrial settings and in closed processes that are highly regulated.

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

*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> Aniline 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 aniline is a known human carcinogen *and* has high acute *and* chronic toxicity.<sup>5</sup> On the contrary, EPA’s own fact sheet on aniline states that the Agency “classified aniline as a Group B2, probable human carcinogen,” and that classification is just based EPA’s own internal assessment.<sup>6</sup> The oral LD<sub>50</sub> (rat) for aniline is 780 mg/kg for females and 930 mg/kg for males.<sup>7</sup> Furthermore, the dermal LD<sub>50</sub> (guinea pig) is 1,316 mg/kg.<sup>8</sup> The classification of high toxicity by oral exposure is below 5 mg/kg and the classification for high toxicity by dermal route is 50 mg/kg, so clearly aniline does not have high acute toxicity.<sup>9</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>10</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>11</sup>

In the 2014 TSCA Work Plan, the Agency claims that aniline is used in consumer products, which is not supported by current knowledge of these products.<sup>12</sup> EPA acknowledges that aniline is used as an intermediate to make other chemicals on its own fact sheet.<sup>13</sup> Aniline, like other intermediates, is produced and used in closed processes that totally consume the

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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 aniline](#).

<sup>7</sup> See European Chemicals Agency [dossier for aniline](#).

<sup>8</sup> *Id.*

<sup>9</sup> See the International Labour Organization for [toxicity classifications](#).

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

<sup>11</sup> See [TSCA Sec. 6\(b\)\(1\)\(B\)\(i\)](#).

<sup>12</sup> See [2014 update of the TSCA Work Plan for Chemical Assessments](#).

<sup>13</sup> See EPA [fact sheet for aniline](#).

substance. It can also be a laboratory reagent that is used under tightly controlled regulations. The Agency also states that aniline “may be found in some foods, such as corn, grains, rhubarb, apples, beans, and rapeseed cake (animal feed),” as well as “a volatile component of black tea.”<sup>14</sup> Exposures from food groups are regulated by the U.S. Food and Drug Administration and EPA should exclude those background levels as it has done for other high-priority chemicals. Because aniline is used and consumed in closed processes, the potential for exposure is far less than exposure from natural sources. 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.

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

Aniline 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 aniline just because it possesses a more full hazard dataset.<sup>15</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 the 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 aniline present a significant potential for exposure.*

In Unit III.B. of the Proposal, EPA generally notes that aniline 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 aniline could lead to a significant potential for exposure.<sup>16</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 aniline for consideration as a high priority. The Agency has provided no information to support a finding of significant potential exposure beyond what is found in nature. Aniline 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 may lead to an unreasonable risk. Aniline also does not have the required persistence,

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<sup>14</sup> *Id.*

<sup>15</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>16</sup> *Id.* at 87425.

bioaccumulation, and toxicity levels that TSCA requires for consideration as a high-priority chemical. EPA must remove aniline from further consideration so it can concentrate on substances that may actually present an unreasonable risk.

Sincerely,

A handwritten signature in black ink, appearing to read "James R. Cooper". The signature is fluid and cursive, with the first name "James" and last name "Cooper" clearly distinguishable.

James Cooper  
Senior Petrochemical Advisor