

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

Office of Pollution Prevention and Toxics
United States Environmental Protection Agency

**AMERICAN FUEL & PETROCHEMICAL MANUFACTURERS
COMMENTS**

Attention: EPA-HQ-OPPT-2018-0474

October 23, 2024
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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, “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 selection of benzeneamine (“aniline”) as a candidate for high-priority designation. AFPM’s comments highlight the following concerns that the Proposed Designation:

- Is technically flawed and fails to recognize the difference between a chemical intermediate and an ingredient or component of a product;
- The Proposed Designation relies on the flawed 2014 TSCA Work Plan and other incorrect sources that erroneously claim aniline is used in consumers goods; and
- The Proposed Designation moves from the Congressionally mandated risk-based approach to a hazard-based approach by selecting aniline due to its 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 commercial and 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 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 aniline’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.

These efforts under TSCA will disrupt critical plastics supply chains despite these chemicals being used in industrial settings and in closed processes that are highly regulated.

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–OCSP, published July 25, 2024.

AFPM member companies manufacture 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. Another major use of aniline is in the manufacture of indigo dye, specifically 2,2'-bis(2,3-dihydro-3-oxoindolyliden). Indigo is the dye used in blue jeans. Aniline is also used to make acetaminophen. Aniline is produced and used in closed systems and is highly regulated in industrial and manufacturing settings. When making MDI, indigo, acetaminophen, or any other aniline derivative, the aniline is consumed in the process, so afterward the aniline no longer exists. MDI is not aniline, nor is acetaminophen. Aniline is not a dye or brightener; it is used to make a dye or brightener.

III. Comments on the Prioritization Proposal for Aniline

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} 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.⁵ 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.⁶ The oral LD₅₀ (rat) for aniline is 780 mg/kg for females and 930 mg/kg for males.⁷ Furthermore, the dermal LD₅₀ (guinea pig) is 1,316 mg/kg.⁸ 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 and EPA’s designation of aniline as a high-priority substance does not comport with TSCA’s requirements.⁹

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.”¹⁰ Sec. 6(b)(1)(B)(i) reiterates Congressional direction when it requires EPA to prioritize substances that

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 aniline](#).

⁷ See European Chemicals Agency [dossier for aniline](#).

⁸ *Id.*

⁹ See the International Labour Organization for [toxicity classifications](#).

¹⁰ See [TSCA Sec. 6\(b\)\(1\)\(A\)](#).

“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.”¹¹

The 2014 TSCA Work Plan lists aniline as being used in consumer products, which is wrong.¹² EPA correctly acknowledges that aniline is used as an intermediate to make other chemicals on its own fact sheet.¹³ Aniline, like other intermediates, is produced and used in closed processes that consume the intermediate. 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.”¹⁴ 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 (*i.e.*, negligible) 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.

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

In Section 2.2 of the supporting document, titled “Proposed Designation of Benzenamine as a High-Priority Substance for Risk Evaluation,” EPA claims that “production volume...suggests a consistent potential source of exposure to benzenamine.”¹⁵ Production volume is not a surrogate for exposure, especially in the case of closed-system intermediates. AFPM acknowledges that EPA is required to consider production volume but cautions against giving it much weight in the prioritization process.

The Chemical Data Reporting (“CDR”) information found in Table 2-2 is misleading and in some cases incorrect. EPA admits there are limitations in the data:

”It is difficult to discern whether there are significant changes in conditions of use for benzenamine 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.”¹⁶

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

¹² See [2014 update of the TSCA Work Plan for Chemical Assessments](#). Aniline is an intermediate to make precursors (other chemicals) that are used in the manufacture of finished goods. Aniline itself is not found in finished goods.

¹³ See EPA [fact sheet for aniline](#).

¹⁴ *Id.*

¹⁵ See “[Proposed Designation of Benzenamine as a High-Priority Substance for Risk Evaluation](#).” EPA Document # EPA-740-P-24-001. Published July 2024. p. 16.

¹⁶ *Id.* at 17.

In Table 2-2, under the lifecycle stage of processing, EPA lists aniline as a reactant and correctly identifies it as an intermediate in the subcategory. However, the next subcategory in the reactant category lists aniline as a dye in “synthetic dye and pigment manufacturing,” and in “textiles, leather, and apparel manufacturing.”¹⁷ Aniline itself is not a dye; rather, it is used to **make** dyes, specifically 2,2'-bis(2,3-dihydro-3-oxoindolyliden) (aka indigo). In the process of manufacturing dyes, the aniline is consumed and no longer exists, so the aniline is not in the dye. The next subcategory listed under the reactant category lists aniline as a “[b]rightener in paper manufacturing.”¹⁸ Similar to its function in dye manufacturing, aniline is an intermediate to make the reactants (e.g., aniline-2,5-disulphonic acid) for stilbene brighteners but aniline itself is not used as a brightener. It is consumed in the process to make aniline-2,5-disulphonic acid and other building blocks for stilbene brighteners – it is not present in the brightener. The last incorrect entry in the lifecycle stage of processing, under the category of “Incorporating into articles,” lists aniline as an antioxidant in rubber manufacturing.¹⁹ Aniline is an intermediate to make diphenylamine-based antioxidants and antiozonants. Aniline is not an antioxidant or antiozonant; diphenylamines serve those functions.

All the categories and subcategories list under the industrial, commercial, and consumer lifecycle stages of Table 2-2 are wrong.²⁰ Like the other examples outlined thus far, the only function aniline serves in any of the listed categories is as a primary intermediate to make other chemical substances. The other chemicals are the substances used in lubricants, heat transfer fluids, rubber tires, or furniture; not aniline. The consumer use listings in Table 2-3 should be disregarded entirely.²¹ As explained above, aniline is not used in any of those products.

AFPM strongly urges EPA to disregard most of purported uses listed in Table 2-2 and Table 2-3. Most of the information found in those tables is incorrect.

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 depends on CDR data to justify inclusion of children as a PESS, claiming in Table 2-4 that aniline is used in dyes that go on products intended for children.²² As stated earlier, aniline is not a dye; it is used to make dyes. The CDR is wrong. EPA also used the technically flawed and incorrect High Priority Chemicals Data System (“HPCDS”). 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 vague, such as “Synthetic Polymers” or “Textiles.”²³ Aniline is not a synthetic polymer; in fact, it is not a

¹⁷ *Id.* at 18.

¹⁸ *Id.*

¹⁹ *Id.*

²⁰ *Id.* at 18-19.

²¹ *Id.* at 19.

²² *Id.* at 23.

²³ *Id.* at 22.

polymer at all. Nor is it a textile. 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 data sources that document reproductive and/or developmental effects following exposure.”²⁴ 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 aniline. 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.²⁵ Since aniline 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 aniline of any woman of reproductive age is highly unlikely.

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

Aniline has a robust hazard dataset. In Unit III.A. of its initiation of prioritization notice, EPA noted 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 simply because it possesses a more full hazard dataset.²⁶ 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, which 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 aniline for consideration as a high priority. Clearly, aniline 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 sources for uses are incorrect and misleading. 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 could lead to an unreasonable risk. Aniline also does not have the required persistence, bioaccumulation, and toxicity levels that TSCA requires for consideration as a high-priority

²⁴ See [“Proposed Designation of Benzenamine as a High-Priority Substance for Risk Evaluation.”](#) EPA Document # EPA-740-P-24-001. Published July 2024. p. 23.

²⁵ *Id.*

²⁶ 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.

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", written in a cursive style.

James Cooper
Senior Petrochemical Advisor