

**CHAMBER OF COMMERCE
OF THE
UNITED STATES OF AMERICA**

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November 15, 2018

VIA ELECTRONIC FILING

Ms. Susanna Blair
Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, DC 20460

RE: A Working Approach for Identifying Potential Candidate Chemicals for Prioritization; Notice of Availability, 83 Fed. Reg. 50,366 (Oct. 5, 2018); Docket No. EPA-HQ-OPPT-2018-0659

Dear Ms. Blair:

The U.S. Chamber of Commerce submits these comments to the U.S. Environmental Protection Agency (EPA or Agency) in response to its publication of the document, “A Working Approach for Identifying Potential Candidate Chemicals for Prioritization” (White Paper).¹ The Chamber generally supports EPA’s efforts to prescribe approaches for identifying existing chemicals as potential candidates for prioritization, but urges EPA to reexamine a number of deficiencies included in the White Paper.

I. Background

The Chamber has long supported a high-quality and science-based chemical management and evaluation program. On June 22, 2016, President Obama signed the Frank R. Lautenberg Chemical Safety for the 21st Century Act (LCSA)² into law, which amended the Toxic Substances Control Act (TSCA) for the first time since the statute’s enactment in 1976.³

¹ A Working Approach for Identifying Potential Candidate Chemicals for Prioritization; Notice of Availability, 83 Fed. Reg. 50,366 (Oct. 5, 2018), *available at* https://www.epa.gov/sites/production/files/2018-09/documents/preprioritization_white_paper_9272018.pdf (“White Paper”).

² Pub. L. No. 114-182, 130 Stat. 448 (June 22, 2016).

³ 15 U.S.C. § 2601 et seq. (1976). Hereinafter, all references to TSCA include the LCSA amendments.

Prioritization is the first step in the process prescribed under TSCA for reviewing and managing existing chemical substances. The prioritization process sets the stage for a new chemical management and evaluation program and allows EPA to recognize which substances have the greatest hazard and exposure potential, so that they may go through the risk evaluation process first.

On January 17, 2017, EPA published a proposed rule in the *Federal Register* to establish the formal prioritization process.⁴ This proposal suggested a four-step process to identify chemical substances as either “high priority” or “low priority.” Those four steps are: 1) pre-prioritization; 2) initiation; 3) proposed designation; and 4) final designation.⁵ High priority substances are those that EPA considers to have the greatest hazard and exposure potential and will undergo further risk evaluation.⁶ Conversely, low priority substances will not require risk evaluations at that time.⁷

The Chamber submitted comments in response to the proposal on March 20, 2017.⁸ In its comments, the Chamber suggested that EPA provide further clarity regarding the pre-prioritization phase of the prioritization process, treat high priority and low priority chemicals equally, and provide additional clarity on how it plans to apply the Section 26 standards to the prioritization process.⁹

EPA published the final prioritization rule in the *Federal Register* on July 20, 2017.¹⁰ Notably, EPA chose not to include the pre-prioritization provisions included in the proposal in the final rule. EPA stated that the public generally supported the concept and importance of pre-prioritization activities, but that the “details of implementing pre-prioritization activities were the subject of widely differing, and often irreconcilable views by commenters.”¹¹

⁴ Procedures for Prioritization of Chemicals for Risk Evaluation Under the Toxic Substances Control Act (82 Fed. Reg. 4,825) (January 17, 2017).

⁵ *See id.*

⁶ *Id.*

⁷ *Id.*

⁸ Comments of the Chamber of Commerce of the United States of America on “Procedures for Prioritization of Chemicals for Risk Evaluation Under the Toxic Substances Control Act,” Docket Nos. EPA-HQ-OPPT-2016-0636; FRL-9957-74; RIN: 2070-AK23 (Mar. 20, 2017), available at https://www.uschamber.com/sites/default/files/3.20.17-comments_to_epa_on_proposed_procedures_for_prioritization_of_chemicals_for_risk_evaluation_under_tsc.pdf.

⁹ *See id.*

¹⁰ Procedures for Prioritization of Chemicals for Risk Evaluation Under the Toxic Substances Control Act, 82 Fed. Reg. 33,753 (July 20, 2017).

¹¹ *Id.* at 33,757.

EPA further noted that it would not be appropriate to attempt to finalize a pre-prioritization process without further discussions with interested stakeholders.¹² On December 11, 2017, EPA held a public meeting to gain further input on this matter, and solicited oral and written comments from stakeholders to aid in formulating the content of the White Paper.¹³ EPA's White Paper is the outgrowth of continued conversations with stakeholders regarding such pre-prioritization activities and lays an appropriate foundation for future prioritization activities.

The Chamber supports EPA's prescribed approach to pre-prioritization efforts, including the Agency's decision to open up 74 dockets for public comment, bin active chemicals for routing prioritization process, and notify stakeholders whenever the Agency deems a candidate chemical information-deficient. EPA could improve the White Paper, however, by clearly communicating the process and timeframes associated with the pre-prioritization process and balancing the risks associated with data-rich and data-deficient chemicals.

II. The Chamber Supports EPA's Pre-Prioritization Efforts

The Chamber supports EPA's efforts thus far to develop a sound prioritization process, including the near-term approach for identifying potential chemicals for prioritization and long-term risk-based approach for considering the larger TSCA active chemical universe included in the White Paper. As noted in the Chamber's comments on the proposed prioritization rule, a sound prioritization process is pivotal to not only developing a comprehensive risk evaluation process, but also the success of TSCA as a whole.¹⁴ With that said, the White Paper takes a number of appropriate steps towards meeting that goal.

First, the Chamber applauds EPA for opening public dockets for each of the remaining 73 chemicals on the "2014 Update to the TSCA Work Place for Chemical Assessments," as well as a general docket for other chemicals listed in the TSCA inventory.¹⁵ This will allow stakeholders to plan and provide additional information to EPA well in advance of the Agency taking any action, and encourages information sharing among relevant stakeholders.

Second, the Chamber feels that EPA has improved process certainty by proposing to "bin" the active chemicals on the TSCA Inventory for routine prioritization processing.¹⁶ Specifically, this long-term, risk-based approach, will allow EPA to develop an objective basis for determining which chemicals are low priority and focus on chemicals that are much more likely to be a high priority for risk evaluation. There will likely be close to 40,000 chemicals on the active TSCA Inventory, and

¹² *Id.*

¹³ *See supra* note 1, at 4.

¹⁴ *Supra* note 8 at 2.

¹⁵ White Paper, 83 Fed. Reg. at 50,367-8.

¹⁶ *See supra* note 1, at 6.

adjusting EPA's long-term approach to more proactively address high priority chemicals is a step in the right direction.

On that note, EPA should consider providing additional clarity on the determination process for which chemicals the Agency "bins" as low priority. Exposure is only a factor in one of the five elements included in the "binning" score, and this may ultimately minimize the exposure component of the human hazard-to-exposure ratio score. This could lead to an inaccurate representation of exposure when the Agency makes its determination.

Third, the Chamber supports EPA's use of a systematic review document to establish what information is scientifically sound, specifically the proposed "notice of deficient information" approach.¹⁷ It is imperative that the quantity and quality of information used in the risk evaluation process is strong enough to support a well-reasoned risk determination. However, as further noted below, in regards to the quantity of information available, data-rich chemicals should not necessarily be prioritized over data-deficient chemicals, as they have been around for decades, are likely more regulated, and likely have the best controls in place to minimize exposure.

Using the proposed approach to screen out those candidate chemicals that may initially hinder EPA's ability to perform scientifically sound risk evaluations due to inadequate or deficient information will guarantee that risk evaluations are based on the best available and sound scientific data. Moreover, allowing the public to participate in the information development process for those candidate chemicals that are deemed "information deficient" will allow EPA to further strengthen the quality and quantity of information used in the risk evaluation process.

III. EPA Should Reexamine a Number of Flaws Included in the White Paper

While the Chamber appreciates EPA's efforts to develop a sound process for identifying candidate chemicals for the prioritization process, the Chamber finds that the White Paper contains a number of deficiencies. For example, EPA explains its near-term approach in very general terms. Rather than describe a process or methodology that EPA will follow, the Agency simply includes factors that it will consider, including two that are relatively broad and new – "overarching agency priorities" and "work load and resource constraints." EPA should better describe the process that will be used to determine candidate chemicals and more thoroughly describe the factors used in the process in order to ensure that the process aligns with TSCA's priorities and Congressional intent.

EPA should communicate more transparently the process associated with selecting chemicals and should include time frames for such a process. Specifically, EPA's process should:

1. Include time frames for when work plan chemicals will be reviewed, taking into account exposure risks when making such a determination;
2. Prioritize and complete review of the Work Plan chemicals for which thorough risk evaluation have yet to be conducted by competent regulatory authorities;

¹⁷ *Id.* at 8.

3. Include chemicals that are not on the Work Plan based on the statutory factors included in section 6 of TSCA;¹⁸ and
4. *Consistently* communicate that Agency's selection of candidate chemicals for possible review are not determinations of risk or safety of these chemicals.

The White Paper also ranks data-rich chemicals that may not necessarily pose the greatest risk to human health and the environment over those that are data-deficient. Just because a candidate chemical is data-rich does not necessarily mean that the candidate chemical poses a higher risk than a data-deficient chemical, especially if the candidate chemical is already highly regulated by the states or other mechanisms and has already been thoroughly reviewed by competent regulatory authorities. EPA should ensure that more emphasis is placed on substances for which gaps exist in terms of risk evaluations, rather than duplicative efforts with data-rich chemicals for which number risk assessments already exist. EPA should also seek to more-readily balance the differences in data between chemicals and fill in any apparent gaps in existing regulations.

IV. Conclusion

The Chamber appreciates the opportunity to comment on EPA's White Paper, "A Working Approach for Identifying Potential Candidate Chemicals for Prioritization." It is important that EPA develop an efficient and scientifically-sound process that addresses those substances that pose the greatest risk potential and achieve Congress' vision for a strong federal chemical regulation program.

Sincerely,



Karen A. Harbert

¹⁸ 15 U.S.C. § 2605(b)(1)(A). Those factors are: 1) the chemical's hazard and exposure potential; 2) the chemical substance's persistence and bioaccumulation; 3) potentially exposed or susceptible subpopulations; 4) storage of the chemical substance near significant sources of drinking water; 5) the chemical substance's conditions of use or significant changes in conditions of use; and (6) the chemical substance's production volume or significant changes in production volume.