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Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency
1200 Pennsylvania Ave. NW
Washington, DC 20460-0001
Docket No.: EPA-HQ-OPPT-2017-0586; EPA-HQ-OPPT-2018-0659

Via Regulations.gov submission

RE: A Working Approach for Identifying Potential Candidate Chemicals for Prioritization; Notice of Availability

The Society of Chemical Manufacturers & Affiliates (SOCMA) appreciates the opportunity to provide comments on EPA's near- and long-term approaches for identifying potential candidate chemicals for prioritization.¹

SOCMA is the only U.S.-based trade association solely dedicated to the specialty and fine chemical industry. Our members play an indispensable role in the global chemical supply chain, providing specialty chemicals to companies in markets ranging from aerospace and electronics to pharmaceuticals and agriculture.

SOCMA commends EPA in its development of a working approach for pre-prioritization and supports the Agency's efforts to collect feedback on the 73 remaining chemicals on the 2014 TSCA Work Plan while a strategy is developed to evaluate the universe of active chemicals on the TSCA inventory. SOCMA provides these comments to further assist and add clarity to EPA's approach to ensure that the program developed is scientifically robust, effective, and consistent with statutory requirements.

I. Dockets for Potential Candidate Chemicals

As part of the Agency's first steps in identifying the next group of chemicals that will be subject to risk evaluation under TSCA, public docket have been opened on the [73 chemicals](#) that remain on the 2014 TSCA Work Plan. EPA has also opened a general docket that will allow for the public to provide relevant information on other chemicals listed active on the TSCA Inventory. SOCMA supports this approach and

¹ 83 FR 50366 (October 5, 2018).

believes it is in conformance with stakeholder recommendations made in January 2018 calling for EPA to establish clear procedures for transparency, data gathering, and public participation.²

EPA's Working Approach document notes, though, that "EPA may will [*sic*] also open dockets for other potential candidate chemicals for those not on the Work Plan."³ The Agency's Response to Comments Summary additionally does not address the use and applicability of dockets for chemicals not on the TSCA Work Plan.⁴ SOCMA recommends that EPA state unambiguously that it will always establish dockets for the pre-prioritization of individual chemical substances (or chemical categories) before any enter the statutory prioritization phase. SOCMA foresees that once EPA has completed "binning" the active TSCA inventory, the Agency will use the risk-based pools thus created to inform EPA's identification of batches of future pre-prioritization candidates. EPA should then establish additional dockets for each chemical in such a batch and provide sufficient time (e.g., six months) for stakeholders to generate information, as needed, and otherwise provide EPA with a more adequate data landscape. SOCMA also recommends that EPA not indicate, at the time it opens such dockets, whether it anticipates prioritizing an individual chemical as either high or low, as discussed below.

II. Risk Characterizations of Work Plan Chemicals

As noted above, EPA's near-term approach will consist of developing a data landscape for each of the 73 remaining substances on the TSCA Work Plan. While SOCMA agrees that EPA has the statutory obligation to make at least 50% of its High-Priority designations from the Work Plan, it does not necessarily agree that EPA should pre-suppose all work plan chemicals will all be candidates for high prioritization. EPA's Working Approach document notes though that EPA "is to primarily look to the 2014 Work Plan for high-priority potential candidates."⁵ EPA further iterates in its Response to Public Comments document that it intends to select all High-Priority candidates from the Work Plan and all Low-Priority candidates from the Safer Chemical Ingredients List (SCIL).⁶ While the Agency states that taking this course will minimize stigmatization of the candidate chemicals, it in fact pre-judges the candidate substances before they have undergone prioritization.

As SOCMA has noted in prior comments, the 2014 Work Plan update had a number of shortcomings at the time it was published including a lack of most currently available data and models. Data references and scientific assumptions from the 2014 Work Plan are increasingly out-of-date, which increases the uncertainty regarding risk potential. These shortcomings reinforce the point that EPA should not pre-determine that all Work Plan Chemicals will become candidates for high-priority designations. Instead, these substances must be regarded like all other relevant candidates and undergo EPA evaluation based on the best available science, without bias. This will conform with the science policy mandate of the 2016 Lautenberg Chemical Safety Act and ensure that EPA does not expend unnecessary resources devoted to the risk evaluation of substances that might have avoided inclusion on the 2014 Work Plan using information available today.⁷

² 82 FR 51415 (November 6, 2017).

³ See "A Working Approach for Identifying Potential Candidate Chemicals for Prioritization," pg. 9.

⁴ See "Summary of Public Comments by Topic," pgs. 13-14.

⁵ See "A Working Approach for Identifying Potential Candidate Chemicals for Prioritization; Notice of Availability," pg. 6.

⁶ See "Summary of Public Comments by Topic," pgs. 10-12.

⁷ See 15 U.S.C. § 2605(b)(1)(A) and 40 C.F.R. § 702.1(a).

III. The Agency's Long-Term Approach

SOCMA is pleased that EPA has proposed a “binning” approach that, longer-term, will categorize the active Inventory in a finite number of groups based on potential risk and data availability. While this approach does not exactly track the Canadian Chemicals Management Plan, it does “build upon it,” as EPA noted.⁸ In particular, it shares the principal virtue of the CMP’s approach, which was to evaluate and express at least an initial view regarding the risks posed by all chemicals in commerce. It has already become clear that, under amended TSCA, there will be approximately 40,000 chemicals on the active Inventory and no realistic prospect that more than a small percentage will be prioritized or evaluated within the coming decades. Accordingly, it is important for EPA to have some objective basis for stating that the great bulk of Inventory chemicals are a low priority for prioritization. The Agency’s proposed long-term approach would accomplish that task.

Conclusion

SOCMA appreciates the opportunity to comment on EPA’s working approach for identifying candidate chemical substances for prioritization. SOCMA supports the Agency’s ongoing efforts to implement amended TSCA and believes its near- and long-term approaches for pre-prioritization will provide for risk-based characterizations of candidate substances that are robust, transparent, and defensible.

SOCMA looks forward to continued collaboration with EPA on these and other matters in the future.

Respectfully submitted,



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⁸ “Working Approach,” pg. 16.