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November 15, 2018

Jeffery T. Morris
Director
Office of Pollution Prevention and Toxics
Office of Chemical Safety and Pollution Prevention
Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, DC 20460-0001

Attention: Docket ID Number EPA-HQ-OPPT-2018-0659

Submitted to the Federal eRulemaking Portal (www.regulations.gov)

Re: Environmental Protection Agency's "A Working Approach for Identifying Potential Candidate Chemicals for Prioritization; Notice of Availability"

Dear Dr. Morris:

The American Fuel & Petrochemical Manufacturers ("AFPM") respectfully submits the attached comments on the Environmental Protection Agency's ("EPA" or the "Agency") notice announcing the availability of a White Paper entitled, "A Working Approach for Identifying Potential Candidate Chemicals for Prioritization."[1]

AFPM is a national trade association representing virtually all U.S. refining and petrochemical manufacturing capacity. AFPM refining and petrochemical member companies are subject to the Toxic Substances Control Act ("TSCA") and will be directly impacted as EPA implements the Frank R. Lautenberg Chemical Safety for the 21st Century Act ("LCSA").

EPA has increased the transparency by which it has been developing the prioritization process. The Agency sought initial public comment on the process as a whole (Docket ID Number EPA-HQ-OPPT-2016-0636), then followed up with a separate docket (Docket ID Number EPA-HQ-OPPT-2017-0586) to specifically address the identification of potential candidates for prioritization. AFPM submitted comments to both dockets and appreciates the opportunity to comment on EPA's longer-term approach outlined in its white paper.

AFPM has long supported TSCA modernization and looks forward to working with EPA and other stakeholders throughout the implementation process.

Sincerely,

James Cooper
Senior Petrochemical Advisor

[1] *See* 83 *Federal Register* 50369 (October 5, 2018).

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

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These comments address EPA's longer-term approach to identifying potential chemicals for prioritization.

1.0 TRANSPARENCY

1.1 AFPM supports EPA's efforts to increase transparency in the prioritization process.

Throughout the White Paper, EPA outlines steps it will take to increase transparency in the development of the prioritization process. For example, the Agency intends to hold public meetings to gather more input, open a new docket to solicit comments on its longer-term approach to "bin" chemicals, and open dockets for chemicals on the 2014 Work Plan list. AFPM applauds these efforts and supports EPA's attempts to increase transparency.

2.0 USING WORK DONE UNDER OTHER PRIORITIZATION AND RISK EVALUATION PROGRAMS

2.1 EPA should consider other prioritization and risk evaluation programs when crafting its own approach to selecting chemicals for prioritization, and use work done under those programs to save time and resources.

AFPM is encouraged by references to other programs, such as Canada's Chemical Management Program, the Organization for Economic Cooperation and Development Screening Information Data Set Programme, and its own Chemical Assessment Management Program. AFPM strongly recommends that the Agency use the work done under these other programs to help identify both high and low priority designations.

3.0 BINNING THE ACTIVE INVENTORY

3.1 AFPM supports the longer-term approach to bin chemicals from the active inventory; however, more clarity is needed to understand how chemicals will end up in each bin and which ones will be designated as high and low priorities.

The white paper describes the criteria used to score chemicals for the purpose of placing them into bins, but the paper is deficient in details on how each criterion is scored and weighed. EPA should also make clear the score required for high-priority and low-priority designations. Upon clarification of this process, EPA should seek further comment on the proposed approach.

4.0 CONSIDERATION OF EXPOSURES

4.1 EPA should employ a tiered approach to estimate exposures for the estimate of hazard-to-exposure ratios.

The white paper outlines a method to bin chemicals, building on the process used in the TSCA 2012 Work Plan. EPA states it will "incorporate human hazard relative to exposure" and use the ExpoCast model to estimate exposures (see Section 7.3) to generate a hazard-to-exposure ratio. AFPM strongly recommends the Agency adopt a tiered approach, consistent with the tiered approach to estimate hazards, and incorporate available measured environmental and occupational data. The conservative default assumptions in EPA's exposure models will greatly exaggerate the exposure potential for certain intended uses. Measured data is routinely used to challenge default assumptions in the models used for the new

chemicals program. A tiered approach will incorporate data provided by companies and trade associations, which is consistent with how data will be sought from industry for hazard information. This tiered approach would also be consistent with the Agency's preference for measured data versus modeled data.

4.2 EPA must consider physical properties when using a category approach to group chemicals according to certain uses.

AFPM generally supports the Agency's rationale to group certain chemicals to address resource issues. EPA must consider physical properties when grouping chemicals by general use to avoid inclusion of chemicals that would not result in the same level of potential exposure as others in that category or group. For example, chemicals used as solvents may have widely different vapor pressures that would impact the potential for inhalation exposures. To only look at the general use as a solvent could conceivably include substances for which inhalation exposure is expected to be low.

5.0 DATA LANDSCAPING

5.1 EPA should apply data landscaping to the identification of both high and low priority chemicals.

AFPM supports the data landscaping approach along with the use of weight-of-the-evidence when identifying studies to determine high priority substances. Data landscaping is an efficient way to identify data availability and gaps, and to assess whether the amount of data available is sufficient for prioritization and risk evaluation of candidate chemicals. This approach greatly improves prioritization efficiency and should also be applied to identify low priority substances.

6.0 IDENTIFICATION OF INFORMATION

6.1 EPA should employ a weight-of-the-evidence approach when considering Type 1, Type 2 and Type 3 information sources.

Section 5.2 of the white paper identifies and categorizes different types of information sources. AFPM supports this approach with the caveat that EPA must use a weight-of-the-evidence approach when considering individual studies, and not just rely on its preference for Type 1 data sources. There are many high-quality studies possessed by industry that have not been published. EPA should apply a weight-of-the-evidence approach to all studies so that high-quality studies not found in the literature are appropriately weighted. For example, studies that do not demonstrate a negative effect are rarely published in technical journals; however, when those studies follow well-established protocols and the record-keeping is thorough and transparent, they should be given equal weight to other high-quality studies.

7.0 TECHNICAL CORRECTION

7.1 EPA needs to correct the second bullet on Page 27 (Section 7.10, Intermediate-Term Goals and Improvement) by changing the word "mixtures" to "complex substances."

Mixtures of substances are technically exempt from the TSCA Inventory; therefore, the bullet should read, "…half of the active TSCA inventory are *complex substances* or substances of unknown or variable composition…"

8.0 CONCLUSION

AFPM strongly supports EPA's efforts to increase transparency, not only in the development of the prioritization process, but also when EPA conducts the actual prioritizations. EPA should seek industry input early and often during the prioritization process to solicit data and other information that may not be readily available to the Agency. In addition, AFPM urges EPA to use a weight-of-the-evidence approach throughout the prioritization process, including when the Agency is selecting chemicals for prioritization. Weight-of-the-evidence is explicit throughout the LCSA and is expected whenever EPA conducts prioritizations, risk evaluations and, especially, in regulatory decision-making. AFPM appreciates the opportunity to provide this input and looks forward to working with the Agency to ensure a balanced, scientifically-based TSCA modernization.