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March 15, 2017

Wendy Cleland-Hamnett
Acting Assistant Administrator
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-2016-0735**

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

**Re: Environmental Protection Agency's "Risk Evaluation Scoping Efforts Under TSCA for Ten Chemical Substances; Reopening of Comment Period; Cyclic Aliphatic Bromide Cluster (Hexabromocyclododecane or HBCD"**

Dear Ms. Cleland-Hamnett:

The American Fuel & Petrochemical Manufacturers (AFPM) respectfully submits these comments on the Environmental Protection Agency's (EPA's or the Agency's) "Risk Evaluation Scoping Efforts Under TSCA for Ten Chemical Substances; Reopening of Comment Period" at 82 FR 12589 (March 6, 2017), for cyclic aliphatic bromide cluster (hexabromocyclododecane or HBCD.

AFPM is a national trade association representing nearly 400 companies that encompass 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).

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

# AFPM Comments on the Notice – Risk Evaluation Scoping Efforts Under TSCA for Ten Chemical Substances; Reopening of Comment Period; Cyclic Aliphatic Bromide Cluster (Hexabromocyclododecane or HBCD"

**March 15, 2017**

**Docket ID No. EPA-HQ-OPPT-2016-0735**

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# COMMENTS BY TOPIC

The following comments are organized by general topic.

## 1.0 GENERAL COMMENTS ON EPA'S DETERMINATION OF SCOPE FOR RISK EVALUATIONS

### 1.1 AFPM understands that EPA is on a tight schedule for the first 10 chemicals.

AFPM fully appreciates the efforts of EPA to begin the risk evaluation process for the first 10 Work Plan chemicals on such short notice. AFPM understands that certain factors and methods used for the first 10 substances will likely not be used for subsequent determinations of scope. These comments are offered in a spirit of cooperation and are intended to provide suggestions moving forward. AFPM does not expect EPA to abandon its current work; rather, the expectation is for the Agency to refine its processes moving forward.

### 1.2 Conditions of use should be limited only to those uses that are intended by the manufacturer.

Manufacturers have limited control over how their products are used after the point of sale. The scope of risk evaluations should be limited to the conditions of use intended by the manufacturer and should not include use scenarios outside of what is intended. The whole spirit of TSCA begins with a manufacturer's intent, which is to sell a substance into commerce for a commercial purpose. From the new chemical review process to reporting under Section 8, persons are subject to TSCA based on their intent to manufacture chemicals for distribution in commerce.

Some stakeholders have suggested that EPA include accidents and other activities or scenarios outside of the intended uses. AFPM strongly opposes the inclusion of activities outside of intended uses because toxicological risk assessment that compares hazard and exposure is not an appropriate method to evaluate the potential of an accident or misuse, whether intentional or unintentional. Probabilistic approaches are typically used to evaluate the risk of accidents. Misuse is not even predictable and should never be included in toxicological risk assessment.

EPA should not consider non-TSCA uses to be within the scope of a TSCA risk evaluation. When crafting the LCSA, Congress did not intend for EPA to become an agency supplanting or overseeing other federal laws and agencies. The uses covered by other laws are outside of the scope of TSCA and are already overseen by other federal agencies. There is no valid reason to duplicate or second guess those efforts.

There have been suggestions by a small number of stakeholders to disregard personal protective equipment, labeling and other protective measures when considering the potential for exposure to a substance. AFPM strongly disagrees with these suggestions and does not share the position that people will not read and follow label instructions and safety information on safety data sheets. Furthermore, disregarding personal protective equipment would unjustifiably bias any exposure risk determination. Protective measures such as clear labeling and PPE are well-established means of minimizing exposure risks and ensuring safe use and handling of chemicals. Disregarding these measures will only overestimate true exposure risks and drive unnecessary controls or storage and use limitations.

There are no provisions in the LCSA requiring EPA to consider all conditions of use, nor was that the intent of Congress. In fact, at Section 6(b)(4)(F)(ii) the statute explicitly mentions "sentinel exposures"

when requiring EPA to describe its consideration of exposures. AFPM interprets the inclusion of "sentinel exposures" as a clear message to the Agency that it should not include every conceivable use as part of the scope of a risk evaluation. The intent of Congress was to allow EPA flexibility in its approach to risk evaluation so that the Agency could maximize the efficient use of resources.

### 1.3 EPA should only include validated scientific methods when determining the scope of a risk evaluation.

AFPM has noticed an increased call for cumulative exposure and risk considerations, including the potential for synergistic reactions, by a small number of stakeholders. AFPM believes that the science for this type of assessment is far from established and many of the methods to conduct cumulative assessments have not been scientifically validated. AFPM does support more research into the area of cumulative risk assessment, but does not think this practice is appropriate for regulatory risk evaluations at this time.

### 1.4 EPA should immediately implement the sound science provisions found in TSCA Section 26 as part of these risk evaluations.

EPA should increase the scientific transparency of risk evaluations throughout the entire process, including when determining the scope of the evaluation. Congress was clear in its intent and has directed the Agency to consider the best available science and use a weight-of-the-evidence approach when prioritizing chemicals, determining the scope of a risk evaluation and when conducting the evaluation itself.

Currently, there are lists of uses found in the dockets for the first 10 chemicals EPA has selected; however, the criteria and weight given to each relevant factor the Agency considered is far from clear. AFPM questions the validity of some internet-based sources EPA employed to identify the intended uses to determine the scope of the evaluation. Web sites such as Google, Wikipedia and Amazon are not considered to be reliable scientific sources. Worse yet are unverifiable and miscellaneous accounts of uses found on random internet postings. AFPM supports EPA's current efforts to verify the accuracy of the information it found during the scoping exercise, by consulting with experts who know the substances and how they are used. In the future, EPA should increase scientific transparency by identifying specific factors it will consider when determining the scope of a risk evaluation and assigning appropriate weights to those factors.

### 1.5 EPA should use a tiered approach for each risk evaluation and define the tiers when publishing the scope for comment.

A small number of stakeholders has suggested that EPA evaluate all uses, whether intended or not, all subpopulations, accident scenarios, legacy contamination, and other activities, when determining the scope of a risk evaluation. EPA does not have the resources or time to include all of these considerations in each risk evaluation; furthermore, this one-size-fits-all approach to risk evaluation lacks focus, would be wasteful, and would be terribly inefficient.

AFPM strongly urges EPA to employ a tiered approach to risk evaluations. Congress has given EPA full discretion and flexibility to use a variety of tools at different levels to maximize efficiencies during the risk evaluation process. EPA must work under statutory deadlines, so the Agency must use a tiered approach beginning with the prioritization process, refine the tiers during the scoping exercise, and continue on the tiered path through the full risk evaluation.

EPA should begin with a semi-quantitative look at hazards and exposures, using modeling and other scientifically valid approaches to prioritize which substances and which intended uses of those substances it will consider for risk evaluations. EPA should focus its resources on the intended uses that present the greatest likelihood of exposure (i.e., sentinel exposures) and subsequent risk. EPA can qualitatively outline the uses it does not intend to quantify and provide a simple scientific justification behind those decisions in the scoping documentation.

### 1.6 EPA should consult with industry and other technically qualified experts earlier in the process, before publishing a scoping document.

To avoid the use of inappropriate or inaccurate information when determining the scope of a risk evaluation, EPA should actively consult with industry and other experts technically qualified to identify the intended uses of a substance. Downstream processors and users are in a unique position to contribute significantly during the scoping exercise and ensure that the information used by EPA is valid, relevant and accurate.

## 2.0 CONCLUSION

AFPM supports EPA's efforts to refine the use information that determines the scope of the risk evaluation for the first 10 chemicals. AFPM urges EPA to consider the recommendations outlined in these comments moving forward in its LCSA implementation efforts.