



**American
Fuel & Petrochemical
Manufacturers**

1667 K Street, NW
Suite 700
Washington, DC
20006

202.457.0480 office
202.457.0486 fax
afpm.org

January 25, 2018

Nancy Beck
Deputy 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-2017-0586

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

Re: Environmental Protection Agency's "Identifying Potential Candidates for Prioritization for Existing Chemical Risk Evaluations Under the Amended Toxic Substances Control Act (TSCA)"

Dear Dr. Beck:

The American Fuel & Petrochemical Manufacturers ("AFPM") respectfully submits the attached comments on the Environmental Protection Agency's ("EPA" or the "Agency") notice entitled, "New Chemicals Review Program Implementation and Approaches for Identifying Potential Candidates for Prioritization of Existing Chemical Risk Evaluations Under the Amended Toxic Substances Control Act (TSCA); Notice of Public Meetings and Opportunity for Public Comment" at 82 FR 51415 (November 6, 2017).

AFPM is a national trade association whose members comprise 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).

The LCSA requires EPA to prioritize chemicals for risk evaluations, but it does not provide direction on how to select chemicals for prioritization. There are strict deadlines under which EPA must conduct a risk evaluation once a chemical is identified as a high priority. Those deadlines pose a challenge to EPA if it determines that there is insufficient information to conduct the evaluation, because the Agency must issue a test order, consent agreement or rule and collect the information all within the specified timeline dictated by the statute. EPA is seeking public comment regarding its thoughts on how to select chemicals for prioritization.

AFPM has long supported TSCA modernization and applauds the Agency's decision to seek public input in advance of implementing the prioritization process.

Sincerely,

James Cooper
Senior Petrochemical Advisor

**AFPM Comments on the Notice - Identifying
Potential Candidates for Prioritization for
Existing Chemical Risk Evaluations Under the
Amended Toxic Substances Control Act
(TSCA)**

January 25, 2018

Docket ID No. EPA-HQ-OPPT-2017-0586

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COMMENTS BY TOPIC

The following comments on EPA's proposed guidance are organized by general, overarching topics, followed by comments on specific parts of the discussion document. These comments are offered in a spirit of cooperation and constructiveness.

1.0 TRANSPARENCY

1.1 EPA must establish a transparent process for identifying potential candidates for prioritization, along with opportunities for stakeholder input, to achieve stakeholder confidence and scientific credibility.

Transparency is crucial to the implementation of the Frank R. Lautenberg Chemical Safety for the 21st Century Act (LCSA). Support of this principle is shared by an overwhelming majority of stakeholders, which necessitates establishment early in the implementation process. Most importantly, stakeholder engagement should be promoted prior to, throughout and after the completion of prioritization and other risk evaluation activities. AFPM commends EPA for already beginning the stakeholder dialogue through a public forum and continuing to seek input through comments on the discussion document.

Section 6(b)(1) lays out explicit requirements for EPA that will ensure transparency and opportunities for stakeholder involvement in the prioritization process. AFPM firmly believes that the process by which a substance is selected for prioritization is a major component of the overall process. Section 6(b)(1)(C)(ii), in particular, requires EPA to "publish each proposed designation of chemical substance...along with an identification of the information, analysis, and basis used to make the proposed designations." These requirements should apply to pre-prioritization activities and decisions as well.

To enhance transparency, EPA should publish for comment the selection process for prioritization that not only includes the criteria and factors it intends to use for decision-making, but also the relative weight given to each factor. When finalized, this approach or algorithm should be open source and reproducible by interested stakeholders. Finally, this algorithm should be evergreen, with regular reviews and updates to account for changing methodologies and data sources. The Agency should document in its pre-prioritization proposal how it will keep the process evergreen.

1.2 EPA should publish the list of chemicals it is considering for prioritization and provide stakeholders the opportunity to submit existing information before making final prioritization decisions.

One important step toward greater transparency is the publication of chemicals that the Agency is considering for prioritization and an opportunity for stakeholders to voluntarily submit existing information. Any published list, however, could stigmatize the chemicals that appear on that list. Care should be taken to minimize stigmatization (please refer to Part 5.3 for more detail).

Sufficient time should be afforded interested stakeholders to submit information from other programs, including regulatory and voluntary programs that are outside of the United States. There is significant, relevant information from scientific studies conducted under various regulatory programs, such as those found in Canada, the European Union, Asia, and the Screening Information Data Set (SIDS) program under the Organization of Economic Cooperation and Development (OECD). Furthermore, Section 6(b)(1)(C)(ii) explicitly requires EPA to provide stakeholders with the opportunity to provide the Agency with such information, even before a chemical is proposed as either a high or low priority. EPA should notify companies that their chemicals are being considered for prioritization as early as possible. Timely

notification will allow companies to gather pertinent information and work with the Agency in a cooperative and constructive manner.

When proposing chemical substances for prioritization, EPA should make the information upon which its conclusions are based publicly available, including chemicals that come from the TSCA Work Plan List. Sections 6(b)(1) and 26(h) are clear regarding the requirement that EPA make decisions transparent and base those decisions on sound science, which includes decisions to prioritize a particular chemical from the Work Plan List. For example, Section 6(b)(1)(C)(ii) requires EPA to publish the “information, analysis, and basis used to make the proposed designations.”

1.3 When seeking information from stakeholders for prioritization, EPA should accept existing summary formats.

Information provided by stakeholders should not require a new format. EPA should accept existing summary formats, including robust summaries as prepared for other programs, such as the Agency’s High Production Volume (HPV) Program, the OECD SIDS Programme, and those submitted as part of European Union Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) dossiers. The timing for review of submitted information should be clear and reasonable, and anticipate unexpected issues that may arise, so they can be effectively resolved without unduly overburdening the prioritization and risk evaluation processes.

EPA should request voluntary submissions of information to avoid costly rulemaking and to help keep the timing of prioritizations on track. In the event that voluntary submissions are not forthcoming, the Agency can use its authority under Sections 8(a) (“Preliminary Assessment and Information Reporting”) or 8(d) (“Health and Safety Data Reporting”) to collect information it needs to prioritize chemicals. As a last resort, if the Agency still lacks the necessary information, EPA should use its authority under Section 4.

1.4 EPA should make all modelling assumptions and default values used to identify chemicals for prioritization publicly available.

AFPM understands that EPA will use conservative models to predict ranges of toxicity and exposure potential in the absence of measured data when identifying chemicals for prioritization. To achieve EPA’s goals of transparency, the Agency should clearly list the assumptions and default values inherent in the model so stakeholders know what to expect and to allow for reproduction of the modelling results. Additionally, when EPA receives information that results in changes to the assumptions or default values, the Agency should clearly state those changes when publishing its basis for designating a high or low priority.

2.0 TIERED AND TARGETED APPROACH

2.1 Prioritization, including the process by which chemicals are selected for prioritization, and other components of a risk evaluation should immediately incorporate a tiered and targeted approach.

Prioritization should be as simple as possible to achieve the desired result, which is to quickly screen many chemicals to identify only a handful for immediate risk evaluation and those that do not require immediate risk evaluation. Some chemical risk evaluations depend on extensive laboratory testing for hazards and complex mathematical models and distribution functions for the exposure component, but most chemicals do not need such intensive scrutiny. Often, EPA can conservatively predict endpoints of interest through structure-activity relationships or exposure pathways through known use and activity patterns. A tiered approach to hazard, exposure and risk characterization should be used from the very

beginning, which saves time and resources, especially when screening the risks of many different chemicals. A tiered approach starts with a general look at a chemical, its structure and how it is used, then targets and refines certain areas to bring about more clarity or certainty. It is an iterative process during which hazards and exposures are reviewed simultaneously, throughout the entire process. To develop a complete hazard characterization and exposure characterization separately, before comparing the two, could result in wasted work, time and resources, because some conditions of use may not require the same level of detail as others.

Conducting a full suite of toxicity testing or a comprehensive, quantitative exposure assessment is generally unnecessary to prioritize a chemical; and, in many cases even for final decision-making, because EPA scientists can use protective methods to predict toxicity and exposure in ranges. In addition, EPA has exposure-related information available through other programs (please see Part 2.3 for more detail).

Often, existing information is adequate to at least semi-quantitatively characterize the chemical with a simple analysis of hazards and potentials for exposure to yield an estimated measure of risk. The process should begin with a look at the molecular structure, composition (if a formulation), chemical and physical properties, health effects information, hazard ratings, use and activity patterns, etc., using information from readily available sources. If there are gaps for certain endpoints, then conservative modeling based on structure-activity relationships and for potential exposure scenarios should be conducted to fill those gaps.

AFPM believes that pre-prioritization is a risk screening step – the first step – in the overall risk evaluation process. Risk screening is not intended to be an exact science; rather, its primary use is for prioritizing what to address, in what order, and to what initial level of detail. Risk screening allows the placement of resources where the efforts will be most beneficial. When the approach considers hazard and exposure using weight-of-the-evidence, a general risk screening method is appropriate for the first-tier evaluation. If conditions of use exist that require more information, spotting these areas in a tiered, targeted manner will be more efficient than employing a full-blown, academic approach to risk evaluation.

2.2 EPA should develop clear criteria by which to judge the quality of information it considers during the pre-prioritization phase in a timely fashion.

AFPM firmly believes that a weight-of-the-evidence approach is required by Section 26(i) to be part of the pre-prioritization process. The language clearly states that decisions made under Sections 4, 5 and 6 must be “based on the weight of the scientific evidence,” which means that upon enactment, EPA must begin to employ a weight-of-the-evidence approach. In the context of the requirements found in Section 6(b)(1)(C)(ii), EPA also will need to develop and make public the criteria by which it will judge the quality and validity of studies it considers when selecting chemicals for prioritization. AFPM strongly urges EPA to develop the quality criteria as soon as possible and recommends consulting *Key Elements for Judging the Quality of a Risk Assessment*, published in *Environmental Health Perspectives* in February 2016, to help inform the Agency when crafting and proposing the process by which candidates will be selected for prioritization.

The funding source of any scientific study should not be considered a factor when using a weight-of-the-evidence approach. When establishing acceptance quality criteria, EPA should only consider relevant factors such as methods, documentation, sampling, etc.

Finally, EPA should not use IRIS values as part of its pre-prioritization algorithm. The IRIS program has not and currently does not produce hazard assessments in line with the sound science provisions found in

TSCA Section 26. Though the individual components of an IRIS assessment may be useful in a risk evaluation, none of its final conclusions (e.g., slope factors, dose-response curves, hazard endpoints, etc.) hold up to the science standards of TSCA and are therefore not appropriate for regulatory decision-making.

2.3 EPA should consider and appropriately weight readily available public information when selecting chemicals for prioritization.

As conveyed earlier in these comments, the risk screening process to prioritize chemicals should follow a tiered and targeted approach. The Agency should have the flexibility to use analogs, read-across and other surrogates to estimate chemical hazards and exposures when measured data are scarce or not available.

Exposure considerations should include use and volume information submitted under the Chemical Data Reporting (CDR) program, the Toxic Release Inventory (TRI), high-quality biomonitoring data, physical/chemical properties, and other pertinent information that can be used to estimate potential exposures. When it comes to biomonitoring data, the mere detection of a chemical should not be the sole factor in prioritization; rather, the levels at which the chemicals are present and the severity of impact should be the main considerations.

Hazard considerations should include, where available, mechanistic, pharmacokinetic, and other pertinent information related to the body's ability to breakdown and excrete substances. Unpredictable idiopathic effects unique to an individual should not be given the same weight as other well-documented toxic endpoints, because consideration of individual sensitivities is akin to consideration of allergies. There is no way for EPA to predict who will have a reaction to what substance or to reliably predict the amount to which an individual will react.

In cases where EPA has few data, the Agency should solicit the voluntary cooperation and submission of data from interested parties before using its authority under Sections 4 and 8 ("Reporting and Retention of Information"). AFPM member companies have conducted studies and prepared hazard, exposure and risk characterizations under a variety of voluntary and regulatory programs, and are prepared to submit information to help the Agency in the prioritization process.

3.0 DATA OWNERSHIP AND CONFIDENTIAL BUSINESS INFORMATION

3.1 EPA must protect confidential business information (CBI) and respect industry's right to protect its intellectual property.

Protection of CBI will be paramount when making information on chemicals available to the public, including during the prioritization process. EPA must take care to ensure sensitive business information is not inadvertently released during any point in the process. Many companies gain a competitive advantage by not divulging the connection between a molecule and a particular use or function. In fact, many gain an advantage by shielding the identity of a particular chemical from their competitors, especially some overseas competitors that may not share the values of the protection of intellectual property. CBI claims under TSCA must be honored by the Agency as they are critical to industry's right to protect its intellectual property

3.2 EPA must respect the rights of data owners to protect their business investments.

EPA should recognize that study reports and other specific types of information may have significant monetary value. AFPM members have invested vast amounts of time and resources over the years to develop a comprehensive understanding about the safety of their chemicals. The study reports received

from the laboratories are key to a study's value. Those study reports should not be made publicly available for anyone to copy and use; rather, robust summaries, like those already made public on the EPA website, should suffice for technical qualified people to use in assessing the implications of varying chemicals in commerce. Scientists can easily verify the factors that EPA has considered by consulting a robust summary of a study. The appropriate balance must be struck between making information available to the public in a manner that allows them to reasonably and extensively assess the implications of certain chemicals and their uses in commerce and respecting the rights of data owners to protect their property.

4.0 COMMENTS ON THE BACKGROUND OF THE DISCUSSION DOCUMENT

4.1 EPA should clearly articulate specific susceptible subpopulations according to key toxicological or exposure characteristics.

In the second footnote on Page 5, EPA provides the statutory definition for susceptible subpopulation. When selecting chemicals for prioritization, and in subsequent steps in the prioritization and risk evaluation process, EPA should identify specific subpopulations at risk and clearly explain the toxicological and exposure characteristics that place those subpopulations at risk.

4.2 EPA must ensure reproducibility in its decisions.

In its discussion under the "Possible Approaches and Tools" of the background section of the discussion document, the Agency lists six considerations. AFPM does not subscribe to one specific approach from the list. AFPM expects EPA to develop its own approach and use desirable attributes from the six that are listed, as well as parts of other approaches not listed that have proven to be transparent, efficient and reproducible. The priority consideration is ensuring transparency so all stakeholders can follow the Agency's process, including methods and criteria, to allow for a full understanding and reproducibility of EPA's decisions.

4.3 EPA should consider a variety of regulatory approaches when creating its process to identify chemicals for prioritization.

Of the six approaches listed by the Agency, beginning on Page 8, only two are established regulatory approaches to select chemicals for prioritization: EPA's Work Plan Methodology and the approach used under Canada's Chemical Management Plan (CMP). There may be components of other regulatory approaches not found on the list that could be of value. EPA should not limit itself by only looking at its current approach and that used by Canada.

5.0 COMMENTS ON THE OVERARCHING GOAL, MILESTONES, STATUTORY ELEMENTS AND GUIDING PRINCIPLES

5.1 A single approach would result in more consistent and transparent outcomes than a set of approaches.

AFPM cautions the Agency against adopting a variety of different approaches to select chemicals for prioritization. EPA should develop a single approach that allows the Agency flexibility, yet results in transparency, reproducibility and consistency. The approach should be simple, tiered and iterative. Complex approaches may introduce increased demands for precision that are premature, since this phase is simply to identify chemicals for prioritization in a consistent and transparent manner.

5.2 EPA should focus on the Active portion of the TSCA Inventory when identifying candidates for prioritization.

AFPM fully agrees with the Agency's assertion that "active chemicals may have a greater potential for exposure," which is clearly outlined in the seventh guiding principle. While AFPM acknowledges that there may be rare cases of legacy chemicals posing risks, AFPM believes that the Agency has the necessary flexibility and discretion to address those risks.

5.3 EPA needs an effective communications effort to minimize the potential for stigmatization of chemicals on priority and other lists.

AFPM generally supports the guiding principles outlined by EPA in the discussion document and appreciates the Agency's acknowledgement that chemicals on lists can be stigmatized (i.e., black-listed). This stigmatization can lead to potential market deselection, which can be disruptive to producers and users along the manufacturing supply chain, create advantages for replacement chemicals that have not been fully evaluated for risk or efficacy and, ultimately, cause irreparable damage to companies and supply chains.

Stakeholders want transparency; however, with transparency comes responsibility. EPA should clearly state the purpose of each list and what it represents and does not represent. The Agency should also publicly respond to situations intentional misuse or misrepresentation of the lists and other preliminary findings and categorizations.

AFPM urges EPA to take proactive steps and develop clear and concise messages and caveats that describe what the lists are and what they are not. Those messages and caveats should appear prominently wherever the lists appear, whether in print, on electronic files or on the internet.

5.4 EPA can minimize stigmatization by listing both high priority and low priority chemicals together.

Another way that EPA could minimize stigmatization is to identify and list both high priority and low priority chemicals together. Including both on the same list would inherently demonstrate that listing does not indicate any particular hazard or risk. AFPM specifically supports the fifth guiding principle, that EPA will "strive to identify more than the statutory-mandated minimum of 20 low-priority chemicals."

6.0 COMMENTS ON THE OVERVIEW OF EPA'S TSCA WORK PLAN CHEMICALS METHODS DOCUMENT

6.1 AFPM supports a 3-tier labelling approach for pre-prioritization, similar to that used by EPA in Step 2 of the Work Plan method.

EPA is not required to designate chemicals as low or high priority during the pre-prioritization phase. Congress did not address how chemicals would be selected for prioritization or how those chemicals should be labelled. EPA could use labels other than "high, medium or low" to more clearly describe the intent of placing certain substances on each type of list.

For example:

1. Ready for Prioritization
2. Undergoing Information Collection
3. Future Prioritization

AFPM is not necessarily suggesting these specific labels; rather, they are offered as a demonstration that alternatives exist to the traditional “high, medium and low” classification approach. Classifications that are more descriptive of the purpose of the lists could help reduce stigmatization.

6.2 EPA should use the results from Step 2 of the Work Plan to select chemicals for prioritization.

AFPM acknowledges the efforts of the Agency to narrow the list of candidates for risk evaluations under the Work Plan. To go back and repeat those efforts using similar methodologies would not result in a significantly different list from the 345 substances that EPA already identified. Using the results from Step 2 will enhance transparency and certainty, and will facilitate the efficient collection of necessary information to better focus limited resources of all stakeholders. When selecting candidates for prioritization, however, AFPM expects that the Agency will be more transparent as to what specific factors it has considered and what weight was given to each of those factors.

7.0 POSSIBLE APPROACHES AND TOOLS FOR IDENTIFYING POTENTIAL CANDIDATES FOR PRIORITIZATION

7.1 AFPM does not subscribe to any one of the listed approaches and urges EPA to develop its own approach by modifying the TSCA Work Plan methods.

EPA lists six approaches to identifying potential candidates for prioritization in the discussion document and provides detail on each approach. AFPM believes the Agency should use the TSCA Work Plan as a starting point and strive for greater transparency by making public the specific factors it uses, the weight given to each factor and any assumptions used. For example, just listing proximity of storage containers to water as factor will not suffice. For instance, EPA should establish a threshold to define “proximity.” It is also important to assign a weight to that factor so it can be put into context with the other factors.

7.2 Substances that have previously been through the new chemical review process or have been identified as low risk through other regulatory programs should be designated as low priority, unless a change in conditions of use warrant reexamination.

Many substances in commerce have been through the new chemical review process, which is a robust, conservative, screening-level risk evaluation. EPA has already determined that the substances at the time of commencement do not pose an unreasonable risk – if that were not the case, the Agency would have issued a Significant New Use Rule (SNUR) or initiated some other regulatory action. Using the information collected under the CDR should verify if there are significant changes in production volume and potential for exposure. If there are no significant changes, EPA should consider those substances as potential candidates for a low priority designation. Similarly, EPA should consider the findings of regulatory risk evaluation programs in other countries. Many substances have been reviewed under a variety of programs in different countries, and have been found to not present an unreasonable risk. Most programs share the same degree of scientific scrutiny and rigor as TSCA. If domestic conditions of use are different, then the Agency should focus on those specific differences and not concern itself with those already reviewed.

7.3 There should be no difference in approaches to identify high priority and low priority substances.

The LCSA is explicit in its requirements for the use of sound science and transparency throughout the prioritization and risk evaluation process. While the process for identifying chemicals for prioritization is

not articulated in the statute, the principles for all work under Section 6 are clear. Those principles should apply to all substances, without presupposition. The statute calls for a risk-based approach and lists certain criteria that must be considered. It does not, however, direct EPA to use different approaches for high-priority and low-priority substances. The decision to prioritize a chemical should be based on risk, just like the prioritization itself.

Just as there is no limit to the number of high priority substances to be assessed over time, there should be no limit imposed on the number of substances that are designated low priority. Identifying low priority substances should be considered as valuable as identifying high priority substances.

7.4 EPA should fully consider the lessons learned from Canada's Chemical Management Plan (CMP).

AFPM acknowledges that there are differences between TSCA and the chemical control provisions in the Canadian Environmental Protection Act (CEPA). There are also differences in US and Canadian commerce. There is, however, enough consistency in scientific principles and general approaches to risk evaluation that EPA can learn from the experience of Canada as it implemented the CMP.

Canada learned the importance of exposure potential and the use of weight-of-the-evidence. It also learned that an academic approach for each chemical is unnecessary and inefficient, and that streamlining for low-volume substances is necessary. Interestingly, Canada also saw the value in the use of Quantitative Structure-Activity Relationships (QSARs) and other predictive approaches early in the process, especially for prioritization. AFPM appreciates EPA's acknowledgement of Canada's learnings and urges the Agency to consider those lessons learned when developing its own approach to identify chemicals for prioritization.

Canada recognized early in the first phase of its CMP that there was value in the development of rapid screening approaches to evaluate substances expected to be of low concern from a hazard perspective or used in low volumes. Canada was able to identify low-priority substances more quickly and efficiently, and concentrate its resources on high-priority chemicals. At each step, if there were questions regarding the potential for exposure or hazard, Canada categorized the chemical as needing further study and collected the necessary information to refine its evaluation.

Lastly, Canada also identified strong stakeholder involvement as a key to success. AFPM is encouraged by the level of public engagement through public meetings and opportunities to comment on EPA proposals and guidance.

7.5 The Safer Chemical Ingredients List (SCIL) is one starting point for identifying candidates for low-priority designation, but not the only one.

The SCIL is a hazard-based list of substances that meet certain criteria under EPA's Safer Choice program. The SCIL is limited in scope, however, and applies primarily to cleaning products. The criteria for low concern are based on thresholds, and AFPM acknowledges EPA's efforts to be transparent in the use of those criteria. AFPM agrees with EPA that substances with low hazards are not likely to present an unreasonable risk. AFPM urges EPA to give the same consideration to substances with low exposure potential. The LCSA makes clear that prioritization activities must be based on risk and not just hazard. That requirement should prompt the Agency to identify chemicals that are suitable for a low-priority designation based on low exposure potential.

7.6 The functional use approach is a valid method to generally categorize potential exposures, but there should be a distinction between chemicals used in a controlled industrial setting and those used in consumer and commercial settings.

AFPM generally supports the concept of a functional use approach to generally categorize chemicals for potential exposure. AFPM acknowledges the work that EPA and its colleagues around the world have done over the years through the OECD Environment Programme to develop and vet the functional use approach.

In the first step of the process, outlined in the “Functional Category Approach, based on Use and Exposure Potential,” chemicals are placed into one of three tiers. The first tier includes widely used consumer products with a high potential for exposure. AFPM agrees that this should be a top priority with respect to functional uses. The second tier includes consumer, commercial and industrial uses (not necessarily wide-spread) that have a high likelihood for exposure. The third tier contains the remaining functional uses.

AFPM does not believe that substances used in an industrial setting belong in the same tier as consumer and commercial uses. The industrial workplace is well-regulated by OSHA and the requirements for engineering and other controls to limit chemical exposures have been in practice for decades. There is no valid reason to presume that workers are exposed above legally-binding OSHA permissible exposure limits, nor is there reason to presume that workers willfully ignore personal protective equipment recommendations or basic industrial hygiene practices.

If OSHA has a question about the hazards or exposures of a particular chemical, it approaches EPA to have that substance placed on a list for chemical testing under TSCA Section 4. If a chemical is placed on that list, AFPM agrees that it should be categorized as a candidate for further study, but it should not be in the same functional use category as consumer and commercial uses.

7.7 The functional use approach should be limited when used as a surrogate for determining exposure potential.

While AFPM sees potential value in using high-throughput screening in a general sense, it questions the use of this method to determine whether chemicals in a functional use category have sufficient hazard data. This type of generalization will likely result in false-positives, meaning that chemicals with sufficient data would be labelled as insufficient. EPA should limit the functional use approach to exposure potential and use other validated methods to determine hazard data adequacy.

7.8 The functional category approach is useful for predicting toxicity ranges, but EPA should not attempt to identify uses by way of molecular structure.

The fifth approach outlined in the discussion document, “Functional Category Approach, based on Chemical Structure and Function,” appears to be a complicated process that does not fit well into the Work Plan approach. AFPM acknowledges the utility of molecular structures when predicting toxicity ranges; however, the approach outlined in the discussion document goes beyond that and suggests utility in identifying potential uses based on structure. AFPM does not see value in trying to determine uses based on molecular structure as a component of any pre-prioritization approach. There may be instances where one could conceivably predict a use from a structure, but those instances would be the exception, not the rule, and such an approach does not provide an acceptable degree of certainty. Incorporating Approach 5 would make the overall pre-prioritization approach unnecessarily burdensome and prone to misidentification of uses.

7.9 New Approach Methods (NAMs) may be of value, but each must stand on its own scientific merits.

AFPM sees potential value in using high-throughput screening, computational toxicology, *in vitro*, *in silico* and other screening methods, but each method must be scientifically validated for use in a regulatory prioritization scheme or process. AFPM views Approach 6 as a set of tools that could be used to augment EPA's TSCA Work Plan Method, but care must be taken to ensure transparency and scientific validity when using any of the tools. The web-based tool should be made available for public comment before it is used as part of a regulatory program.

8.0 CONCLUSION

AFPM commends EPA for identifying several different approaches to identify chemicals for prioritization, as well as taking comments on those options. AFPM urges EPA to develop its own approach using the TSCA Work Plan Method as a starting point and the experiences and lessons learned by Canada and other countries that are implementing chemical management plans. AFPM does not believe that any single approach listed in the discussion document will suffice; rather, each should be considered when identifying elements that would make the overall pre-prioritization approach risk-based, transparent, efficient and scientifically sound.