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March 20, 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-2016-0654
Submitted to the Federal eRulemaking Portal (www.regulations.gov)

Re: Environmental Protection Agency's "Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act"

Dear Ms. Cleland-Hamnett:

The American Fuel & Petrochemical Manufacturers ("AFPM") respectfully submits the attached comments on the Environmental Protection Agency's ("EPA" or the "Agency") proposed rule entitled "Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act" at 82 FR 7562 (January 19, 2017).

AFPM is a national trade association representing approximately 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).

While these comments focus on the risk evaluation process, AFPM believes that the fundamental principles of sound science, as found in Section 26(h) and 26(i) in particular, apply equally to prioritization and risk evaluation. Further, AFPM views prioritization as the first step in a risk evaluation process; therefore, many of these comments also will be found in the comments submitted to the docket for the prioritization process. Transparency and weight-of-the-evidence will be recurring themes because the science provisions in Section 26 ("Administration of the Act") are explicit. Additionally, the provisions in Section 6 ("Prioritization, Risk Evaluation, and Regulation of Chemical Substances and Mixtures") contain requirements to ensure that both the prioritization and risk evaluation processes are transparent and afford stakeholders opportunities to work with the Agency and help inform decisions through the submission of available information.

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 – Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act

March 20, 2017

Docket ID No. EPA-HQ-OPPT-2016-0654

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COMMENTS BY TOPIC

The following comments are organized by general, overarching comments, then address specific requests for comment by EPA, followed by other recommendations. These comments are offered in a spirit of cooperation and constructiveness.

1.0 TRANPARENCY

1.1 EPA must establish a transparent risk evaluation process, along with opportunities for stakeholder input, to achieve confidence and scientific credibility.

One of the most fundamental principles that must be established when implementing the provisions of the Lautenberg Chemical Safety Act (LCSA) is transparency. Support of this principle is shared by an overwhelming majority of stakeholders, which necessitates its establishment early in the implementation process. Most importantly, stakeholder engagement should be promoted prior to, throughout and after the completion of risk evaluation activities, which begins with risk screening for prioritization. AFPM commends EPA for already beginning the stakeholder dialogue through a public forum.

Section 26(h) states that EPA must use "the best available science" when carrying out Sections 4 ("Industry Testing Requirements"), 5 ("Manufacturing and Processing Notices"), and 6 ("Prioritization, Risk Evaluation, and Regulation of Chemical Substances and Mixtures"). The provisions found in the subparagraphs, such as the requirement for EPA to consider the clarity and completeness of documentation in data reporting, as well as the extent of independent review, readily demonstrate the intent of Congress to ensure that the Agency incorporates science in a transparent manner.

Section 6(b)(4)(F) also outlines requirements placed on EPA to ensure transparency in the process. Section 6(b)(4)(F)(v), in particular, requires EPA to "describe the weight of the scientific evidence," which means that the Agency will need to establish the criteria by which it judges the quality of information it considers for the risk evaluation. This concept is reiterated in Section 26(i), which simply states that EPA must "make decisions under sections 4, 5, and 6 based on the weight of the scientific evidence."

1.2 EPA should make the evaluation methods, information it intends to consider, criteria by which quality will be judged, peer review procedures, and other information pertinent to a risk evaluation publicly available prior to initiation of the risk evaluation.

Transparency will be key for the public credibility of the risk evaluation process. EPA should fully document methods, procedures, criteria considered, and other necessary information to allow stakeholders the opportunity for review and comment. All measured data – sufficient to replicate findings critical to the overall evaluation – and default assumptions used in modeling should be made publicly available to afford stakeholders the opportunity to verify evaluation results.

2.0 CONDITIONS OF USE

2.1 AFPM does not fully agree with EPA's interpretation of "conditions of use."

EPA's interpretation of "conditions of use" is overly broad and goes well beyond what Congress intended when creating the safety standard. In Unit II.C.2., EPA admits that Section 6(b)(4)(D) can be interpreted to mean "EPA does not need to consider all conditions of use." AFPM agrees with that interpretation. If Congress intended for EPA to disregard its long-established practice of focusing on uses and exposures

that are most likely to contribute to high risk, it would have clearly articulated that intent in the statute. EPA also states in Unit II.C.2. its belief that the word "the" calls for "evaluation that considers all conditions of use."

> "The evaluation is on the chemical substance – not individual conditions of use – and it must be based on *the* conditions of use. In this context, EPA believes the word 'the' is best interpreted as calling for evaluation that considers all conditions of use."

AFPM does not subscribe to this interpretation of the word "the." Again, if Congress intended for the Agency to consider all conditions of use, it would have used the clearer word "all" before "conditions of use" in the statute instead of "the."

EPA goes on to provide an example, also in Unit II.C.2., where the Agency could determine that a substance "with 10 known uses" meets the safety standard because it only considers one of the ten uses in the scope. Not only is this example unrealistic, it is also ironic because EPA has publicly stated it will incorrectly determine that a substance does *not* meet the safety standard if only one use is found to present an unreasonable risk, even if the chemical has many different uses that meet the safety standard.

The Agency also attempts to justify its interpretation by claiming the infeasibility of completing a significant number of risk evaluations "if EPA were to continually need to re-evaluate chemical substances based on different subset of uses." AFPM questions why the Agency would feel the need to re-evaluate substances for which it has already determined the relevant scope after examining the known uses. The purpose of the scoping phase is for EPA to qualitatively look at uses and potentials for exposure, then determine which uses it will quantitatively study and which uses it will qualitatively describe and set aside.

EPA also states if the "law is read as allowing EPA to select particular conditions of use," the statute provides no criteria for EPA to follow when selecting which uses to consider. AFPM views this is as an example where Congress intentionally grants EPA discretion. EPA even claims it has discretion when determining the scope of a risk evaluation. Further in Unit II.C.2., the Agency says that a use or activity is considered a condition of use "only if EPA determines that it does."

The Agency is proposing to "lock down" the conditions of use determined in the scope for the risk evaluation. AFPM questions why EPA allows itself discretion to limit the number of uses in this manner, but interprets the law as a requirement to consider all conditions of use. Either way, AFPM does not support the proposal to lock down the uses. There could be a situation where only an end user (not a producer or importer) knows of a particular use, but would not ordinarily read the *Federal Register* or have an understanding of TSCA. If that use becomes known to the manufacturer, the manufacturing company should be afforded the opportunity to include the use as part of the scope, even after the close of the scoping phase, and EPA should still consider that use in the risk evaluation. EPA should not assume that manufacturers are privy to all end uses of a substance.

Another reason that EPA should not lock down the uses in the scope is the potential for erroneous information. It is quite plausible that some conditions of uses will be wrong, which could lead to an evaluation that is viewed as unreliable and of insufficient quality, if that use is included. EPA should allow more flexibility when determining the scope of a risk evaluation and allow for adjustments when new information becomes available or is clarified.

EPA finally states toward the end of Unit II.C.2. that it is proposing a "fit for purpose" approach to risk evaluations, where different uses will require different levels of scrutiny, ranging from qualitative

approaches to quantitative approaches. AFPM supports this type of approach and recommends that the Agency make this more clear and prominent throughout the appropriate parts of the rule.

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 when determining 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.

The move away from EPA's standard risk assessment practices will result in wasted time and resources by not focusing on the uses and exposures that present the greatest risk. Rather, EPA's proposed interpretation will result in an approach that lacks the type of focus that EPA had successfully used conducting reviews in the new chemicals program and in other previous risk assessment activities. AFPM is not suggesting that EPA disregard "known, intended, or reasonably foreseen uses;" rather, the Agency should more clearly articulate its discretion in the risk evaluation process rule to use qualitative, semi-quantitative and other approaches when evaluating hazards, exposures and risk.

3.0 TIERED AND TARGETED APPROACH USING WEIGHT-OF-THE-EVIDENCE

3.1 Each risk evaluation should immediately incorporate a tiered and targeted approach.

First and foremost, AFPM urges EPA to differentiate between an academic approach and a regulatory approach to risk assessment. Chemicals and their intended conditions of use can vary, creating a variety of different risk profiles. In many cases, the risks associated with certain uses can be easily quantified in ranges, without a need to increase precision, because hazards and uses can be characterized using protective approaches and default assumptions. For example, EPA uses conservative approaches to characterize both hazards and exposures during reviews of Premanufacture Notices (PMNs), and has expressed confidence in the conservatism of those approaches. In other cases, the hazards or uses may be more nuanced and require greater precision to adequately characterize risks. A tiered approach allows for both scenarios and leaves a degree of discretion to the Agency. As a general rule, however, measured data should be given preference to modeled data.

The PMN review process at EPA, while perhaps not the exact model for evaluating existing chemicals, could at least inform a tiered approach for the risk evaluation process under the updated TSCA. The process could begin with a look at existing and reasonably available information on hazards and physical properties, including the use of analog chemicals, read-across data and EPA models. Similarly, even though measured data are preferred to modeled data, exposures can be roughly estimated using EPA models and key default assumptions. Adjustments of default values could be accomplished by incorporating targeted, measured data that addresses issues like frequency, duration and quantity of substances used, residue in containers, water treatment efficacy, and other factors that could impact exposures. Stakeholders should be afforded the opportunity to provide information prior to the initial evaluation.

An important thing to remember is that the decision to refine one part of the risk equation (*i.e.*, hazard) should be based on the information in the other component of the risk equation (*i.e.*, exposure). Another way to express this concept is that *the need for higher tiered hazard information should be driven by the potential for exposure and vice versa*. This is what makes a tiered risk evaluation an iterative process, which is what AFPM refers to as a targeted approach. For example, if a chemical is known to be volatile, is bioaccumulative and has the potential for liver toxicity, then priority should be given to certain exposures that are relevant to that endpoint. On the other hand, if a chemical is used in a consumer item

and could be released in amounts that lead to the potential exposure of a sensitive subpopulation, then priority should be given to toxicity endpoints that could affect that subpopulation.

The academic approach to risk evaluation does not usually follow a tiered and targeted approach; rather, this type of evaluation strives for the highest degrees of certainty and precision. The academic approach should be reserved for the upper tiers of a risk evaluation, if necessary, especially evaluations that could result in significant and potentially disruptive risk management action. AFPM acknowledges the value in both tiered and academic approaches, and believes that both share a goal of ultimately reducing uncertainty. The tiered approach, however, can expedite risk-based decisions and allow for the analysis of additional chemicals in a more efficient and effective manner.

3.2 Defining the scope of a risk evaluation will be critical and care must be taken to identify and document the intended conditions of use considered by EPA, even if the information considered are estimates expressed in ranges.

The scoping process should identify intended conditions of use covered by the risk evaluation, including the level of comprehensiveness at which each use will be evaluated. AFPM is advocating a tiered approach; therefore, extra care must be taken to document what was considered throughout the evaluation process, including considerations that rely on estimated ranges. In addition, the general process should include an opportunity for stakeholders to provide EPA with information to assist the Agency in appropriately defining the overall scope of the evaluation. This could be accomplished through voluntary submissions or using Section 8(a) ("Preliminary Assessment and Information Reporting") in a targeted manner to gather use and exposure information.

The scope of a risk evaluation will have a direct impact on what is and what is not preemptive under the updated TSCA. Documentation of all EPA considerations will be critical, even if certain intended conditions of use are not fully quantified. EPA has the discretion to employ a sentinel approach to exposure assessment, which is scientifically legitimate. When the Agency uses a sentinel approach, it still considers other exposures and through that consideration concludes that the magnitude of other exposures is so low that it does not affect the overall risk. Because this is a regulatory risk evaluation, the Agency must carefully document all considerations.

Sentinel exposures are employed to represent broad categories of use so that the assessor does not have to go into each specific subcategory of use. Sentinel exposures represent realistic upper-bound exposures within those broad use categories. The exposures are expected to be much greater than other sources or pathways, so if the margin of exposure is at an acceptable level, there is no need to delve into each and every type of use or background source. This approach can save valuable time and resources.

EPA's definition is not consistent with the common use of the sentinel exposure. Relying on the highest exposure scenario does not mean that the "maximal" exposure is used, rather reasonable values from that highest exposure scenario should instead be used. More appropriate language would include the term "plausible exposure" or "plausible upper bound exposure." It is common to use the 95th percentile under average exposure conditions. Significant revisions are needed to EPA's definition to capture the appropriate use of the sentinel exposure concept.

3.3 EPA should develop clear criteria by which to judge the quality of information it considers for prioritizations in a timely fashion.

AFPM firmly believes that the weight-of-the-evidence approach required by Section 26(i) must be part of the risk evaluation process. The statutory language simply and 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)(4)(F)(v), 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 evaluating a chemical. 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.

In no way should the funding source of any particular scientific study be considered as a factor when using a weight-of-the-evidence approach. Only relevant factors like methods, documentation, sampling, etc., should be considered when EPA establishes quality criteria.

EPA should use consistent quality criteria in a transparent and objective manner when conducting risk evaluations, whether the evaluation was initiated by EPA or by any other stakeholder group. Industry will expect the same treatment during the process when it requests a risk evaluation under Section 6(b)(4)(C)(ii). Any deviation from the quality acceptance criteria established by EPA will run counter to the sound science and weight-of-the-evidence provisions found in Sections 26(h) and 26(i).

3.4 Hazard and exposure characterizations need to be inclusive and incorporate consideration of modes of action, pharmacokinetics, biomonitoring, dose-response (including non-linear approaches for carcinogens), and other pertinent information as applicable, whether for the chemical of interest or an analog.

Critical and relevant information related to the potential hazards of chemicals has been minimized or even excluded from some past risk assessments. A hazard characterization should include an evaluation of the potential to which an exposed person can even be affected. For example, if a chemical is metabolized and excreted rapidly and effectively, that information is pertinent to the overall hazard characterization. If it is excluded, a reviewer will have an incomplete picture of not only the hazard, but also the risk.

Furthermore, dose-response information should be plotted for all relevant non-cancer endpoints, including a distribution of hazard values. Naturally-occurring background levels of chemical substances and the potential for metabolites from naturally-occurring substances should also be considered when evaluating dose-response. Endpoints used in a dose-response assessment should be limited to those that have demonstrated adverse effects and are biologically plausible.

For exposure assessments, EPA should be flexible and use approaches that approximately fit the level of complexity. If the assessment is at a screening level and uses modeling, similar to the approach for new chemicals, then default assumptions and values should be clearly stated such that stakeholders understand the conservatism involved and have an opportunity to provide EPA information to refine the assessment. Additionally, the models themselves, or at least the algorithms, should also be publicly available so that stakeholders can reproduce the results of exposure assessments. Even where models are used, EPA should still consider physical properties and environmental fate to quickly identify where the Agency should allocate its resources in the overall evaluation. In the event that biomonitoring information is used, the data should be of high quality and appropriately characterized by the level at which the substance was detected.

EPA has expressed its intent to aggregate exposures whenever possible. AFPM acknowledges that aggregate exposure assessments can be an appropriate approach in many situations; however, there may be other situations where using a sentinel approach is more appropriate. Sentinel exposures are employed to represent broad categories of use so that the assessor does not have to go into each specific subcategory of use. Sentinel exposures represent realistic upper-bound exposures within those broad use categories. The exposures are expected to be much greater than other sources or pathways, so if the margin of

exposure is at an acceptable level, there is no need to delve into each and every type of use or background source. This approach can save valuable time and resources.

4.0 EPA REQUEST FOR COMMENTS

In Unit IV, EPA specifically requests comments in seven areas. The section below addresses EPA's requests in the order in which they appear in the proposed rule.

4.1 Redefining Scientific Terms

AFPM firmly believes for the sake of clarity and regulatory certainty for all stakeholders, EPA should define the scientific terms common to TSCA risk evaluation. The importance of consistent definitions to enhance communications cannot be overemphasized. The concepts may not be novel, as EPA claims, but the lack of clear, concise definitions continues to confound the objective of greater transparency in regulatory processes and decision-making. The definitions should be relevant to TSCA and reflect the intent of Congress as much as possible. AFPM urges EPA to consult *Key Elements for Judging the Quality of a Risk Assessment*, published in *Environmental Health Perspectives* in February 2016, when developing these critical definitions. AFPM recommends the following specific definitions:

Best Available Science

> Best available science is the information resulting from inquiries conducted in accordance with sound and objective scientific practices, including, when available, peer reviewed science and supporting studies resulting in accurate, reliable and unbiased information.[1] All studies should be evaluated for their quality, relevance and utility of the results using an objective approach that employs predefined criteria.

Weight-of-the-Evidence (WoE)

> A WoE approach is a systematic review method that uses a pre-established protocol to comprehensively, objectively, transparently and consistently identify and evaluate each stream of evidence, including strengths, limitations and relevance of each study, and to integrate evidence as necessary and appropriately based upon strengths, limitations and relevance.

Sufficiency of Information

> The information required to assess the potential for exposure under the conditions of use that present the greatest risk.

Unreasonable Risk

AFPM acknowledges EPA's view that a single definition of unreasonable risk is unrealistic because of the variety of factors considered in an unreasonable risk finding. EPA could, however, list the factors and provide at least some clarity for stakeholders.

> Unreasonable risk is the result when the Administrator has considered relevant factors, including the effects of the chemical substance on health and the magnitude of human exposure to such substance under the conditions of use, and the effects of the chemical

[1] Consistent with EPA/260R-02-008, 2002

> substance on the environment and the magnitude of environmental exposure to such substance under the conditions of use. Factors considered to reach this determination may include: characterization of cancer and non-cancer risks (including margins of exposure for non-cancer risks), the population exposed (including any susceptible populations), the severity of hazard (the nature of the hazard), the irreversibility of hazard, and uncertainties associated with the analysis and data.

In Unit II.C.4., EPA proposes to include "estimates of cumulative exposure" in the determination of unreasonable risk. AFPM strongly opposes this inclusion and 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. Furthermore, the LCSA does not require the consideration of cumulative exposures in the risk evaluation provisions in Section 6. AFPM does, however, support more research into the area of cumulative exposure assessment, but does not think this practice is appropriate for regulatory decision-making at this time.

Reasonable Available Information

> Information that EPA possesses or can reasonably obtain and synthesize for use in risk evaluations, considering the deadlines specified in TSCA Section 6(b)(4)(G) for completing such evaluation. Confidential business information provided to the Agency will be treated as reasonably available information, along with the appropriate protection from disclosure of that information.

4.2 Margin of Exposure (MOE)

AFPM strongly urges EPA to continue its use of MOEs, which includes uncertainty factors, leading to greater transparency than other approaches, such as hazard indices. The MOE approach is consistently employed and considered standard practice both throughout and outside of the federal government.

4.3 Systematic Review

AFPM believes that systematic review should be defined in the regulatory text, especially if EPA is going to use this practice in the future. AFPM recommends the following definition:

> A standardized approach to identifying and analyzing evidence related to clearly formulated questions that proceeds through a sequence of steps that includes formulating a question or problem statement, developing a review protocol, performing a comprehensive literature search, selecting relevant studies, assessing the risk of bias of included studies, extracting and synthesizing the study data, rating the certainty of the findings, and interpreting and summarizing the findings. The outcome of this approach is to minimize subjectivity and enhance transparency, rigor and consistency in the way the review is conducted and reported.

4.4 Manufacturer Requests

EPA is seeking comment on its use of Section 8(a) and (d) authorities to collect existing information on substances. AFPM has consistently called on the Agency to use such authority if voluntary initiatives do not produce the necessary information. In the case of risk evaluations initiated by manufacturers, EPA proposes to require such manufacturers to possess all necessary information for a full risk evaluation. AFPM has two significant concerns with this approach. First, the requesting manufacturer does not have the legal authority to compel other market players to provide information. EPA, on the other hand, does

have that authority under Section 8. Secondly, the requesting manufacturer may sell a chemical into commerce for only one particular use. Since that manufacturer must pay the entire cost (100%) of the risk evaluation, it should not be forced to pay for uses outside of its own intent in commerce.

When Congress introduced the concept of a manufacturer-initiated risk evaluation, its intent was to prevent states from acting on chemicals and provide manufacturers with a method to obtain a federal-level evaluation that could preempt state action. Congress did not intend for the manufacturer-requested evaluation to be exhaustive and cover all conditions of use, or else Congress would have added those provisions in the statute. Rather, Congress provided a pathway for an individual manufacturer or group of manufactures to request that EPA review a chemical for one or more uses that are of interest to the requesting company or consortium.

Requiring a manufacturer to cover and pay for all conditions of use, even those outside of its own intended uses, is overly burdensome and contravenes the intent of Congress when it crafted the provisions for risk evaluations initiated by manufactures. To prevent potential free-rider situations and not unduly penalize individual companies requesting risk evaluations, EPA should limit the considerations of use to those requested by the manufacturer; or, in case where the Agency wants to expand the scope beyond those supported by the requesting company, limit the collected fee to the scope requested by the manufacturer.

4.5 Peer Review

EPA should initiate peer review whenever it finds an unreasonable risk during a risk evaluation, before starting the risk management phase. All supporting science and justification for decisions should be reviewed in a robust manner.

For influential and precedent-setting evaluations, EPA should outline the peer-review process in accordance with the scope and potential impact of the risk evaluation and make it available for public comment before the assessment begins.

Peer-review panels should have appropriate knowledge and expertise. Stakeholder groups should be afforded the opportunity to provide a qualified panelist; however, to ensure a sound scientific approach, it is essential for EPA to verify the qualifications of each panelist. Multiple perspectives and potential biases should be identified and balanced, including potential conflicts of interest. Affiliation with a particular stakeholder group should not be grounds for automatic inclusion or exclusion.

AFPM supports EPA's plan to provide peer-review plans during the publication of draft scopes. Draft materials for the peer review should be made available to panelists and the public at the same time. Peer reviewers should be provided with public comments prior to the panel convening. Peer-review meetings should be open to the public and attendees afforded the opportunity to provide oral comments at the meetings. In cases where consensus is not reached, a minority opinion should be provided. All comments should be addressed in the final report.

4.6 Reliance on Existing Guidance and Procedures for Conducting Risk Evaluations

AFPM supports the premise that EPA should not have to start anew when establishing the processes, policies, procedures and guidance for risk evaluations. AFPM does, however, believe that many documents to which EPA points in the proposed rule are in dire need of updating. The statute clearly states in Section 26(h) what is expected from a scientific perspective when the Agency conducts a risk evaluation. While Section 26(l) gives EPA two years to develop the policies, procedures and guidance necessary to carry out the act, AFPM strongly urges EPA to start updating existing documents as soon as

possible because that deadline is only a year and a half away. As stated in other sections of these comments, EPA should consult *Key Elements for Judging the Quality of a Risk Assessment*, published in *Environmental Health Perspectives* in February 2016, to inform the Agency when updating its policies, procedures and guidance.

The Agency should also clearly state (codify in the rule) that assessments that are being started now should be consistent with these new and updated guidance documents when they are finalized. It is in the interests of all stakeholders that the Agency's guidance be updated to reflect current science and that all assessments initiated after the effective date of the LCSA be developed in compliance with that updated guidance.

4.7 Interagency Collaboration

The importance of interagency coordination cannot be overemphasized. The collaboration should not be limited to any preexisting body; rather, EPA should approach coordination in a flexible, fit-for-purpose manner to ensure that the right agencies are involved in the process. While obvious candidates are OSHA, NIOSH and NIEHS, the Agency should also, when appropriate, include DOD, DOE, NASA and SBA. Further, AFPM recommends the involvement of the Office of Management and Budget (OMB) as a coordinating body for potentially significant and precedent-setting evaluations.

5.0 OTHER RECOMMENDATIONS AND COMMENTS

5.1 EPA should not expand the Congressional definition of potentially exposed or susceptible subpopulations.

In §702.33, EPA proposes to significantly expand the definition of potentially exposed or susceptible subpopulations, even though Congress provided a broad, clear definition. AFPM is adamantly opposed to expanding the Congressional definition and views this part of the proposal as a clear attempt to exceed the authority granted to EPA by Congress. EPA should follow the definition provided in the statute because it was the intent of Congress to provide such definition and not leave it to EPA discretion.

5.2 EPA should adjust the timelines under which industry must submit comments or further information.

EPA has proposed a 30-day comment period after publication of the evaluation scope. Since EPA intends to capture as many conditions of use as possible, 30 days is not enough time to adequately review the scope and supporting documents, let alone provide constructive comments on it. AFPM recommends a minimum 60-day comment period.

EPA has proposed a 30-day comment period for draft risk evaluations. Risk evaluations that cover many different uses will likely be large, complex documents with myriad supporting documents. Reviewing, digesting and developing comments on the draft evaluations will be a significant, burdensome undertaking that will likely involve many different people. AFPM, therefore, recommends a 90-day comment period for draft risk evaluations.

EPA has proposed a 30-day comment period for manufacturer-initiated draft risk evaluations. The comment period for draft risk evaluations should be consistent, whether the draft originated from EPA or industry. AFPM recommends a 60-day comment period with limited opportunities for extensions.

The Agency should provide more time for stakeholders in each of these steps to allow for a proper review and the most informed feedback.

5.3 EPA's risk evaluation should take into consideration controls already in place to control or mitigate risks related to health and environmental exposures, including regulations under other statutes and industry standards.

This is especially relevant as it relates to evaluations that include within their scope exposures to workers or other groups, such as fence line communities. For example, the evaluation of workers or fence line communities in the scope of a risk evaluation should consider that OSHA and EPA have other statutes under which they have issued regulations to prevent or mitigate exposures. These include PPE requirements, engineering and pollution controls, permit limits, etc. In addition, §2608 of LCSA requires that EPA consider whether risks can be prevented or reduced under other laws such as the Occupational Safety & Health Act, the Clean Air Act, the Clear Water Act and the Consumer Product Safety Improvement Act, before taking risk management action under LCSA. EPA must also ensure it avoids duplication of federal action against such risks, as well as "impose the least burdens of duplicative requirements" on the regulated community. It would be a more efficient use of resources to consider this during the scoping phase of the risk evaluation to avoid unnecessary effort to evaluate risks of exposures that are already controlled under another existing statute.

6.0 CONCLUSION

AFPM appreciates the opportunity to submit these comments and fully appreciates the efforts of EPA to implement the LCSA. While there are many aspects of the proposed process that AFPM supports, there are also significant concerns with other parts of the proposal. AFPM will continue its work with EPA in a cooperative and constructive spirit.