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Deputy Assistant Administrator
Office of Chemical Safety and Pollution Prevention
Environmental Protection Agency
1200 Pennsylvania Avenue, NW
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Attention: Docket ID Number EPA-HQ-OPPT-2017-0585
Submitted to the Federal eRulemaking Portal (www.regulations.gov)

Re: Environmental Protection Agency's "New Chemicals Review Program Implementation"

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 new chemicals review program at EPA has always been considered a valid, robust model for risk evaluation that covers the entire planned lifecycle of chemicals before they enter commerce. The EPA has worked closely with colleagues from around the world, through the Organization for Economic Cooperation and Development (OECD) and other programs, to help with the challenges associated with evaluating new chemicals. Further, EPA scientists have shared a great deal of their tools and techniques with their Canadian counterparts when Canada was implementing its prioritization of chemicals under the updated Canadian Environmental Protection Act (CEPA). In these comments, AFPM will provide insight into EPA's new chemicals review program prior to enactment of the LCSA, as well as demonstrate that Congress did not envision dramatic changes to the program.

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 – New Chemicals Review Program Implementation

January 20, 2018

Docket ID No. EPA-HQ-OPPT-2017-0585

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COMMENTS BY TOPIC

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

1.0 EPA SHOULD ACKNOWLEDGE THAT IT HAS ALWAYS HAD A ROBUST NEW CHEMICALS REVIEW PROGRAM

1.1 Background

EPA's new chemicals review process is a pragmatic, scientifically sound approach to evaluating the risk of chemicals before they enter commerce. Prior to the LCSA, stakeholders did not identify section 5, governing new chemical review, as a provision in need of revision; in fact, the Agency's new chemicals review program received broad support from a variety of stakeholders (see 1.4 of this document). EPA and one of its committees under the Federal Advisory Committee Act (FACA) had done separate analyses assessing the protectiveness of the new chemicals review program by comparing Sec. 8(e) risk reports and Premanufacture Notices (PMNs) received. Both analyses supported the conclusion that the new chemicals review program has been sufficiently protective, even in the absence of a robust set of measured data.

Over decades, EPA has developed conservative, predictive models and methods to evaluate the risk of chemicals. Those models and methods have been shared widely among government risk assessors around the world.[1] Other programs, such as Design for the Environment, Sustainable Futures and other EPA pollution prevention efforts, also use these tools and approaches.

1.2 EPA has conducted retroactive studies of the effectiveness of its program for its reporting obligations under the Government Performance Review Act.

As part of the program assessment for EPA Chemical Risk Review and Reduction under President Obama's ExpectMore.gov, EPA reported using comparisons of Sec. 8(e) risk notifications and PMN submissions to measure the effectiveness of the new chemicals review program.[2] EPA has conducted annual analyses since establishing a baseline in 2005 and has found the new chemicals review process to be protective of human health and the environment.[3]

1.3 The National Pollution Prevention and Toxics Advisory Committee (NPPTAC) conducted its own analysis to compare Sec. 8(e) reports with PMN submissions.

In the minutes of the NPPTAC meeting, dated July 13-14, 2004, the chair of the Broader Issues Work Group reported to EPA that the Work Group had conducted an analysis of Sec. 8(e) notices and PMNs received in 1999 and 2000. In his report, the chair of the work group concluded that the PMN review process is "robust."

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[1] Canada, in particular, specifically requested advanced training in the use of EPA's new chemicals review tools to assist in its efforts to prioritize existing chemicals in Canadian commerce.
[2] Program Code 10009064, EPA Chemical Risk Review and Reduction, 2007, included the measure "Percent of new chemicals or organisms introduced into commerce that do not pose unreasonable risks to workers, consumers, or the environment."
[3] Ibid.

1.4 The NPPTAC proposed that EPA use the same approach it uses under the new chemicals review program to conduct evaluations of existing chemicals.

A proposal presented by the Broader Issues Work Group of the NPPTAC to EPA officials on October 6, 2005, included an idea to apply the new chemical review process to the review of chemicals that were not part of the High Production Volume Chemical Challenge (HPV Challenge). In the section identifying the benefits of the idea, the Work Group expressed that the "new chemicals review process and associated tools already enjoy broad support among a variety of stakeholders."[4] The Work Group also stated in its proposal that both Denmark and Canada used this type of approach to prioritize all of their chemicals in commerce.

2.0 CONGRESS DID NOT INTEND TO SLOW DOWN THE NEW CHEMICALS PROCESS OR MAKE IT MORE BURDENSOME; EPA MUST COMPLY WITH THE PRESCRIBED REVIEW PERIOD

2.1 When crafting the LCSA, Congress did not make broad, sweeping changes to TSCA Sec. 5 like it did in other TSCA sections.

The changes made to Sec. 5 update the law to conform to EPA's preexisting risk determination practice under the New Chemicals Review Program. As demonstrated below, each of the new provisions in this section simply codify EPA's existing procedures.

The most significant changes to Sec. 5 are found in Sec. 5(a); however, the only substantive additions to Sec. 5(a) are two requirements: (1) for EPA to conduct a review, which it has always done, and (2) for the Agency to make its conclusions and the basis for those conclusions available to the public. Specifically, if the Agency finds that the new chemical is not likely to present an unreasonable risk, EPA must make public that finding or determination and the basis for its determination.

Further, the additions to Sec. 5(a)(B) in the LCSA contain similar information and text to Sec. 5(e) of the original statute. Some stakeholders have mischaracterized these additions as new text. However, Congress simply consolidated text from other sections of the original statute and listed it at the end of Sec. 5(a). Additionally, Sec. 5(f) of the original statute required a risk review and finding by EPA, which as mentioned above, EPA has always conducted. Therefore, the only actual change in the LCSA is that EPA is now required to affirm that a substance did or did not meet the safety standard.

The safety standard itself is mostly intact, but Congress did make it explicit that cost and other non-risk factors cannot be part of the risk determination. Historically, EPA has not included cost or other non-risk considerations when make a finding under Sec. 5, so it is not a change from past practice. In the LCSA, Congress also requires EPA to consider susceptible subpopulations; this requirement, too, is consistent with EPA's past practices. Again, this is no real change from past practice.

Congress also added a new requirement to consider "conditions of use" in the safety standard; however, upon careful reading, it is only in the context of considering potentially exposed subpopulations.

> "…including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by the Administrator under the conditions of use…"

[4] *How Can EPA more efficiently identify potential risks and facilitate risk reduction decisions for non-HPV existing chemicals?* Broader Issues Work Group Proposal, presented to the NPPTAC, October 6, 2005. Page 14

There are no provisions in the LCSA requiring EPA to consider all conditions of use, nor was that the intent of Congress. In fact, Section 6(b)(4)(F)(ii) of 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 possible use when evaluating risk.[5] The intent of Congress was to allow EPA flexibility in its approach to risk evaluation, so the Agency could maximize the efficient use of resources.

Congress also added "orders" and "consent agreements" to Sec. 5(b); but, again, this is consistent with past EPA practices. The intent for most changes to Sec. 5 was to make it more consistent with Sec. 4. Interestingly, one change that Congress made, which is a departure from past practice, was a requirement to refund the fee for a new chemical review if the Agency does not complete the review process within 180 days. This change is a clear signal that Congress did not intend to make the new chemical review process more burdensome or time-consuming.

3.0 EPA SHOULD FOCUS ON THE POTENTIAL FOR EXPOSURE TO THE NEW CHEMICAL UNDER THE USES IDENTIFIED BY THE PMN SUBMITTER

3.1 EPA should not include accident scenarios in the new chemical review process.

Accidental release risks are typically determined using probabilistic methods that are not appropriate for toxicological risk assessment endpoints. A margin of exposure is determined by comparing inherent hazards with predicted exposures, and thus are not expressed as a probabilistic outcome. Further, accidental releases have never been considered part of a use scenario by any toxicological risk assessor. Such releases typically result in acute exposures and, therefore, have little value when determining a margin of exposure. Margins of exposure involve repeat exposure scenarios.

3.2 EPA should focus on the intended uses identified by the PMN submitter and not try to guess other uses of the chemical.

The risk evaluation should be focused on the intended uses identified by the manufacturer on the PMN. The manufacturer of a new chemical should not be held responsible for others' uses or misuses. Inclusion of other potential uses requires speculation on the part of the Agency and exceeds the authority granted to EPA under Sec. 5, effectively leaving the PMN submitter at the whim of Agency assumptions concerning uses. Had Congress intended to change Sec. 5 into a registration scheme, it would have explicitly done so in the legislative language.

4.0 CONCLUSION

AFPM appreciates the opportunity to submit these comments and fully appreciates the efforts of EPA to implement the LCSA. AFPM firmly believes that the new chemicals review program at EPA has been a successful model and that Congress did not intend to make significant changes to it when crafting the LCSA.

[5] 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 monitor other subordinate uses or background source. This approach can save valuable time and resources.