Comments of the American Chemistry Council on the New Chemicals Review Program Under TSCA as Amended

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TABLE OF CONTENTS

Page

EXECUTIVE SUMMARY iii

INTRODUCTION 1

DISCUSSION 2

1. EPA's Implementation of Amended Section 5 Is Creating Structural Problems, Not Just a Temporary Backlog 2

   a. The Backlog Is Large and Growing 2

   b. The Backlog Reflects Structural Changes in EPA's Review of PMNs 3

   c. The Backlog Has Serious Implications 5

   d. The Backlog Contravenes the Congressional Intent That EPA Make PMN Determinations in 90 Days or Less 6

2. Congress Intended the Affirmative Determination Requirement to Promote Transparency 7

3. EPA Should Broaden Its Interpretation of "Not Likely to Present an Unreasonable Risk" 8

   a. EPA's Interpretation Discounts the Exposure Controls in the PMN 8

   b. EPA Should Rely on the Exposure Controls in the PMN 10

4. EPA Should Recognize That the "Not Likely to Present an Unreasonable Risk" Standard Differs Little From What Applied Prior to Enactment 11

5. EPA Should Revise Its Interpretation of the Phrase "Reasonably Foreseen" 12

   a. EPA Erroneously Considers "Reasonably Foreseen" to Expand the Scope of PMN Review 12

   b. Section 5(e) Consent Orders Based on Foreseen Uses by Third Parties Serve No Function 13

   c. "Reasonably Foreseen" Does Not Appear in Section 5(a)(3)(B), Pertaining to Determinations to Issue Section 5(e) Consent

ED_001529_00001066-00002

Orders 14

d. Congress Intended That "Reasonably Foreseen" as Used in Section 5 Refers to Conditions of Use Related to the PMN Itself, Not to Those of Third Parties 15

e. Nothing in the Legislative History Indicates that "Conditions of Use" Alters EPA's Substantive Review of PMNs 18

6. EPA Should Pursue Alternatives to Section 5(e) Consent Orders 19

a. EPA Should Discuss Options with the PMN Submitter Immediately After the Focus Meeting 19

b. EPA Should Encourage Use of the "Binding Option" Without Requiring a Section 5(e) Consent Order, or by Using an Expedited Consent Order Process 20

c. EPA Should Resume Issuance of Non-Section 5(e) SNURs 21

CONCLUSION 23

APPENDIX 1 – ACC Member Company Experiences Under the New Chemicals Review Program Since Enactment

APPENDIX 2 –Unofficial Transcript of the December 14, 2016 Public Meeting on the New Chemicals Review Program Under the Amended Toxic Substances Control Act

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EXECUTIVE SUMMARY

The American Chemistry Council (ACC)[1] welcomes the opportunity to provide comments on the New Chemicals Review Program under the Toxic Substances Control Act (TSCA) as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act (LCSA).[2] ACC submits these comments in response to EPA's notice announcing the December 14, 2016, public meeting on this subject and an opportunity to comment, 81 Fed. Reg. 86713 (Dec. 1, 2016).

These comments make the following points:

- The LCSA enhanced EPA's ability to scrutinize PMN submissions by codifying attention to potentially exposed populations, ensuring that EPA had sufficient information to make decisions, and to provide more transparency in decisions on PMNs. Congress left the standards for New Chemical review and decision-making fundamentally intact, retaining the unreasonable risk standard.

- Notwithstanding Congressional intention to leave the mechanics of this well-run program fundamentally intact, EPA has significantly changed its previous implementation of the New Chemicals Review Program since enactment of the LCSA in a manner inconsistent with congressional intent.

- The changes have created a substantial and growing backlog in the review of premanufacture notices (PMNs) for new chemicals, blocking the ability of businesses to manufacture and bring new chemistries to market in the United States.

- The changes have also introduced substantial structural problems to the operation of the new chemicals program. These include a sharply increased rate of section 5(e) consent orders; a corresponding sharp decline in the rate at which EPA allows PMN substances to be commercialized without a section 5(e) consent order; delays well beyond the 90 days allotted for PMN review -- even for chemicals that do not receive a section 5(e) consent order; and agency requests that submitters allow EPA more time than the 90 days allotted for review, which undercuts Congress' expectation that the review period will be prompt and the review efficient.

- The legislative history does not support EPA's heightened scrutiny of PMNs to explain

[1] The American Chemistry Council (ACC) represents the leading companies engaged in the business of chemistry. ACC members apply the science of chemistry to make innovative products and services that make people's lives better, healthier and safer. ACC is committed to improved environmental, health and safety performance through Responsible Care®, common sense advocacy designed to address major public policy issues, and health and environmental research and product testing. The business of chemistry is an $812 billion enterprise and a key element of the nation's economy. It is the nation's largest exporter, accounting for twelve percent of all U.S. exports. Chemistry companies are among the largest investors in research and development. Safety and security have always been primary concerns of ACC members, and they have intensified their efforts, working closely with government agencies to improve security and to defend against any threat to the nation's critical infrastructure.
[2] Public Law 114-182 (June 22, 2016). References to TSCA in these comments are to TSCA as amended by the LCSA unless otherwise indicated.

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decisions that a PMN substance is not likely to present an unreasonable risk. The LCSA made important changes to EPA's review of new chemicals, but did not change the legal standard applied in PMN reviews.

- EPA should expand its criteria for making a determination that a PMN substance is "not likely to present an unreasonable risk," since its current criteria are too limited. EPA apparently does not regard identification of exposure controls in the PMN to be sufficient for making that finding where it is possible, even though unlikely, that the PMN submitter would not actually impose those controls. This practice reduces the extent to which EPA reviews for risk rather than hazard and is not appropriate.

- The "not likely to present an unreasonable risk" standard is equivalent to the standard that EPA used for 35 years prior to enactment to decide that a section 5(e) consent order was not necessary. There is no statutory justification for EPA to use a more stringent standard post-enactment.

- EPA should reconsider its understanding of the term "conditions of use." It does not require EPA to consider uses of manufacturers or processors other than the PMN submitter and its direct customers. Both the language of section 5 and the LCSA legislative history direct EPA to consider only the uses of the PMN submitter and its direct customers. Consideration of other manufacturers and processors should be addressed through promulgation of significant new use rules (SNURs), as EPA has done for decades.

- EPA should pursue alternatives to section 5(e) consent orders. As an initial matter, immediately after the focus meeting, it should discuss with the PMN submitter what initial concerns EPA has; what additional information would be useful to resolve those concerns; and options for addressing those concerns, where the options include alternatives to a section 5(e) consent order.

- EPA should consider how the PMN "binding option" for controls can be used as an option to address controls that EPA considers critical to resolving its concerns and to avoid the need for a section 5(e) consent order. EPA should provide a simple mechanism for approving potential future changes to controls.

- EPA should resume promulgation of non-section 5(e) SNURs to avoid issuing unnecessary section 5(e) consent orders.

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INTRODUCTION

ACC strongly supported enactment of the LCSA, including the limited amendments to section 5. Its members are committed to successful implementation of TSCA as amended. These comments are offered in that spirit.

The New Chemicals Review Program, set out in section 5 of TSCA, is the entry gate that allows new chemicals to be manufactured and used to make U.S. products. EPA has long had and exercised authority under TSCA to review chemicals for safety before they enter commerce. The basis for its decision-making, however, was not readily apparent to the general public.

ACC supports a robust review of new chemical substances under section 5. The LCSA changes to section 5 codify EPA's prior practice to assess potentially exposed populations, ensure that EPA has sufficient information to make section 5 decisions, and provide for more transparency in EPA's decision-making. The LCSA changes to section 5 do not fundamentally change how EPA was reviewing new chemicals for safety prior to entry into commerce; the safety standard of unreasonable risk with respect to health and safety considerations has not changed.[3]

Companies that research and develop new chemistries depend on a functioning, reliable New Chemicals Review Program to be able to bring these innovations to market. So do companies that want to use these new chemistries to build new products and deliver market solutions. Many new chemistries are developed specifically to deliver better performance or improved health or environmental attributes. A predictable and functioning New Chemicals Program is thus often explained as critical to U.S. innovation; it incentivizes development of new chemistries, which in turn make possible new product and technology applications, upgrades, and even breakthroughs.

Some stakeholders at the December 14 public meeting on section 5 seemed to suggest that industry support for a functioning and efficient program – necessarily one that protects and promotes U.S. innovation – means that industry puts profits ahead of health and environmental considerations. This is disappointing, has no basis in evidence, and is unfair. Like many stakeholders, ACC believes that the New Chemicals Review Program as it existed prior to enactment of the LCSA worked well. Importantly, Congress intended to preserve the fundamental operation of this program. It retained the review standards, codified EPA's practice of reviewing potential impacts of exposures on certain populations, and included new requirements for EPA to be more transparent about the basis for its decision making.

[3] At the December 14 meeting, EPA indicted that even before the LCSA was enacted, EPA had been conducting an internal assessment of the New Chemicals Review Program. EPA staff stated that this internal review has led to multiple changes in assumptions used in the PMN review process. This is the first time that EPA has suggested it is changing the way that it conducts scientific evaluations under saection 5. We note that the LSCA does, in fact, now require under section 26 that EPA use best available science and weight of the evidence in carrying out its reviews under section 5 of the statute. It is imperative that EPA explain the methods and assumptions used to conduct section 5 reviews under thesSection 26 scientific criteria. We urge EPA to do so as expeditiously as possible in light of Congress' expectation, under the LCSA, that the bases for EPA's determinations be transparent. Promptly updated guidance documents could help discharge this obligation.

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Despite a rocky start since enactment of the LCSA, the section 5 program can work well again.

These comments are intended to assist EPA in adapting the program in a manner that is consistent with the statute and its legislative history; maintains EPA's high scientific standards; and successfully protects health and the environment while enabling innovative chemistry to reach the market after appropriate review.

DISCUSSION

1. EPA's Implementation of Amended Section 5 Is Creating Structural Problems, Not Just a Temporary Backlog

At the December 14 meeting, many participants complained about the large and increasing backlog of unresolved PMNs.[4] EPA responded that the backlog was merely temporary, due mainly to EPA's "resetting" the review clock for PMNs that were in the review process as of June 22, 2016, the date of enactment of the LCSA. ACC is concerned that the backlog and resulting delays are not temporary, but rather the result of structural problems in how EPA is interpreting amended section 5. The backlog is having serious adverse impacts on EPA, PMN submitters, and the public. It directly contravenes the Congressional intent that EPA should complete its review of PMNs in 90 days or less.

a. The Backlog Is Large and Growing

It is clear that there is a backlog, and it is growing, not shrinking, despite EPA having had over 6 months since June 22 to adjust to the statutory changes.

On June 22, EPA reset the review period for about 331 PMNs pending as of the day before enactment,[5] some of which had been pending since FY 2009.[6] Since then, the backlog has effectively doubled. During the period from June 22 through November 30, EPA received 327 PMNs that were not originally submitted prior to June 22, for a total of 658 PMNs.[7] (EPA has characterized the backlog as being about 500 PMNs.)[8] During the more than 6 months since June 22, EPA has completed its review of only 29 of those 658 PMNs.

At the December 14 meeting, Jeff Morris, Acting Director Office of Pollution Prevention and

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[4] Additional comments about how the New Chemicals Review Program is no longer working well appear in Appendix 1. These are recent problems experienced by ACC members.

[5] See 81 Fed. Reg. 74784 (Oct. 27, 2016) (349 PMNs "received" during the period June 22 through June 30; 18 of these were new submissions, per the earlier report for June 2016, 81 Fed. Reg. 49976 (July 29, 2016)). At the December 14 meeting, Jeff Morris reported that 308 PMNs had their review periods reset on June 22.

[6] The PMNs whose review periods were "reset" include 2 from FY 2009, 3 from FY 2010, 3 from FY 2011, 15 from FY 2012, 11 from FY 2013, 26 from FY 2014, 62 from FY 2015, and the remainder from FY 2016.

[7] See 81 Fed. Reg. 49976 (July 29, 2016) (18 PMNs received between June 22 and June 30); 81 Fed. Reg. 57903 (Aug. 24, 2016) (48 PMNs received in July); 81 Fed. Reg. 79013 (Nov. 10, 2016) (41 PMNs received in August); 81 Fed. Reg. 79020 (Nov. 19, 2016) (43 PMNs received in September); 81 Fed. Reg. 85556 (Nov. 28, 2016) (36 PMNs received in October); 81 Fed. Reg. 91162 (Dec. 16, 2016) (141 PMNs received in November).

[8] At the December 14 meeting, Jeff Morris said that since June 22 "we have received about 200 more cases. So since enactment there have been 500 cases that we needed to evaluate under the new requirements of the law."

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Toxics, reported:

> Of those 500, about 120, about one quarter of those are undergoing further review. And for the remainder, for hundreds of cases, we made preliminary determinations and action letters, over 100, now have gone out to companies identifying our preliminary determination ....[9]

In other words, in more than 6 months EPA has determined that close to half of the pending PMNs either will receive section 5(e) consent orders or are likely to do so, but it apparently has not completed its review of any of those PMNs.

During that same 6-month period, EPA has apparently made final determinations of "not likely to present an unreasonable risk" for only 29 PMNs. EPA now posts a log on its website identifying PMN substances determined to be "not likely to present an unreasonable risk." According to that log, from June 22, 2016 through January 10, 2017 (the date of the latest update), EPA has posted identification of only 29 such PMN substances (along with 26 microbial commercial activity notices (MCANs)).[10] Of those 29 PMNs, 12 were among those whose review periods were "reset," and 17 were submitted since enactment.

Thus, during a period of about 6 months, while the backlog doubled from 331 PMNs to 658 PMNs, EPA has completed its review of only 29 PMNs. Clearly, the backlog is large and it continues to grow.

b. The Backlog Reflects Structural Changes in EPA's Review of PMNs

One indicator that the backlog is not temporary is EPA's extraordinarily slow progress in identifying PMN substances that are not likely to present an unreasonable risk. Another is that EPA has substantially changed the previous ratio of the number of PMNs that receive a section 5(e) consent order to those that do not.

Prior to enactment of the LCSA, EPA typically "dropped" substances for which it did not plan to issue a section 5(e) consent order before Day 21 of the review period, during the focus meeting. "Dropping" a chemical was analogous to making a determination of "not likely to present an unreasonable risk," since the most commonly used basis for issuing a section 5(e) consent order before enactment was a determination that the PMN substance "may present an unreasonable risk." ACC and its members agreed, however, that there was an important lack of public information on the reason substances were "dropped" from additional review. The LCSA amendments address that transparency element.

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[9] This and other quotations from EPA staff at the December 14 meeting are from an unofficial transcript of the meeting prepared by ACC from the close captioning provided by the software for those attending the meeting remotely (Transcript). ACC has corrected some obvious errors and added paragraph breaks. Additional errors likely remain. The transcript appears in Appendix 2. This quotation appears at page 3 of the Transcript.

[10] EPA Pre-Manufacture Notice Review Determinations under Amended TSCA, https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/epa-pre-manufacture-notice-review (last updated Jan. 10, 2017). The results show 7 determinations in July, 0 in August, 7 in September, 1 in October, 7 in November, and 7 in December.

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Unfortunately, a total of 29 final PMN determinations that a substance is "not likely to present an unreasonable risk" in nearly 6 months is an astonishingly slow pace. Since EPA has no intention of issuing section 5(e) consent orders for these substances, the slow pace cannot be attributed to the time needed to develop, negotiate, and issue section 5(e) consent orders. Instead, EPA is simply taking much more time to review PMNs than before enactment, even for PMN substances of low concern.

Moreover, the time required to make an individual "not likely to present an unreasonable risk" determination is unacceptably long even as EPA gains experience under amended section 5. For the 29 PMNs whose review EPA has completed since June 22, the review periods ranged from 49 to 143 days, for an average of 90 days, i.e., the entire 90-day period allowed in the statute.[11] This is a worrisome situation, particularly since Congress was insistent that EPA complete its PMN reviews within 90 days or less, to the extent practicable, and presumably these are relatively simple reviews. The average of 55 days for decisions made in December is a welcome improvement, but is unclear of that pace can be sustained; the average in November was 91 days.

As for PMNs for which EPA is probably going to make a determination other than "not likely to present an unreasonable risk," since enactment, EPA has substantially increased the percentage of PMNs for which it expects to issue section 5(e) consent orders. Prior to enactment, EPA issued section 5(e) consent orders for about 4% of PMNs received and "dropped" (no further review) about 90% of the PMNs received; the rest were withdrawn by the submitter.[12] At the December 14 meeting, Jeff Morris indicated that about 120 PMNs are undergoing further review, with a section 5(e) consent order likely; that more than 100 action letters have been sent; and that EPA has made "hundreds" of "preliminary determinations" apparently indicating that a section 5(e) consent order is coming.[13] This suggests that EPA is considering issuance of section 5(e) consent orders for about half or more of all pending PMNs, an increase of over 1500% compared to past practice.

Significantly, EPA appears to have largely shifted its review of PMNs from an analysis of potential unreasonable risk to one of potential hazard. This change is not authorized by statute.

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[11] For the 7 final PMN decisions made in July, all of which were for PMNs originally submitted prior to June 22, the average review period was 97 days (including the days prior to June 22). No final decisions were made in August. For the 7 final decisions made in September, of which 6 were for PMNs originally submitted prior to June 22, the average review period was 117 days (including the days prior to June 22). For the 1 final decision made in October, the review period was 89 days. For the 7 final decisions made in November, the average was 91 days. For the 7 final decisions made in December, the average was 55 days.

[12] According to EPA statistics, during fiscal years 1979 through 2015, EPA received 39,962 PMNs, of which 1,710 (4%) received section 5(e) consent orders and 2,068 (6%) were withdrawn by the submitter in the face of EPA action. That means that 36,194 (90%) of PMNs were neither withdrawn nor received a section 5(e) consent order. EPA, "Statistics for the New Chemicals Review Program under TSCA" (last updated Aug. 4, 2016), https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/statistics-new-chemicals-review.

[13] Maria Doa, Director of OPPT's Chemical Control Division, confirmed at the meeting what is now obvious: "As Jeff mentioned, the number of [section 5(e) consent] orders will or have been increasing because they are issued for cases other than the not likely to present." Transcript at 8.

In many cases EPA has indicated that it will require a section 5(e) consent order to ensure that the PMN submitter actually uses the exposure controls addressed in the PMN, so that it places no weight on submitter assurances in the PMN. In many other cases, EPA has indicated that it will require a section 5(e) consent order based on concern about the possible lack of exposure controls implemented by potential manufacturers other than the PMN submitter and their customers, after the substance is added to the Inventory. Since the PMN submitter usually cannot provide information on the exposure controls that such persons would use, EPA gives no weight to the exposure controls that they might use. The result is that many or most PMNs are effectively being regulated through section 5(e) consent orders on the basis of hazard, without regard to the exposure controls described in the PMN. This is substantial change from past practice and is a major cause of the backlog.

In short, EPA is taking an increasingly long time to make a "not likely to present an unreasonable risk" determination and is doing so in fewer cases, down from 90% of cases to perhaps less than 50% of cases. It is increasing the number of PMNs likely to receive a section 5(e) consent order, up from 4% of cases to perhaps more than 50% of cases, if not more. These are radical shifts in how EPA makes decisions under the New Chemicals Review Program. They have nothing to do with the fact that EPA "reset" the review period for then-pending PMNs on June 22. They strongly suggest that over time the current backlog will continue to grow, and grow substantially.

ACC accepts that the LCSA amendments to section 5 provide the Agency more authority to carefully scrutinize new chemical submissions. But the amendments also make clear Congress' intent that PMN review occur within the statutorily-mandated 90-day period. The changes EPA has made in the program strongly suggest that the 90-day review period will be met in only a minority of cases.

c. <u>The Backlog Has Serious Implications</u>

A large and growing backlog has serious implications for EPA, PMN submitters, and the public.

Having many more PMNs to address than before enactment increases the burden on EPA staff. The burden is exacerbated by EPA's apparent view that the majority of these are likely to require development, initiation, and issuance of section 5(e) consent orders. EPA has many new responsibilities under the amended TSCA. It needs to allocate its limited resources to those new responsibilities rather than double the New Chemicals Program staff to address the doubled, and growing, PMN backlog. The backlog means that the New Chemicals Program, previously widely regarded as both effective and efficient, is largely paralyzed. That was not the intent of Congress in amending section 5.

The delays mean that PMN submitters cannot get their new chemicals onto the market for extended periods, and often then only under onerous conditions set in a section 5(e) consent order. In some cases, those conditions may preclude commercialization, as unproven new chemicals burdened by a section 5(e) consent order cannot compete with existing chemicals that have no such burden, even though the new chemicals may have an improved health or

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environmental profile, or be more effective. This can have a significant impact on U.S. innovation in the chemicals area.

Finally, the delays also mean that the public and the environment cannot benefit in a timely manner from the economic, health, and/or environmental advantages that new chemicals held up in the PMN backlog would provide if they were allowed to enter the market.

The current situation does not meet the requirements of section 2(c) that EPA must "carry out this Act in a reasonable and prudent manner" and "shall consider the environmental, economic, and social impact of any action the Administrator takes or proposes as provided under this Act."

d. The Backlog Contravenes Congressional Intent that EPA Make PMN Determinations in 90 Days or Less

The current situation is not what Congress intended. The changes to section 5 – particularly the ability for the agency to identify those PMNs for which insufficient information exists to make a decision – indicate an enhanced ability to scrutinize new chemicals. But in amending section 5, Congress also emphasized the need for EPA to complete its work in 90 days or less.

Although Congress recognized in section 5(c) that EPA may occasionally need more time than 90 days to complete its review of a PMN, such delays are to the be exception, not the rule. Congress added an incentive for EPA to stay on schedule with a mandatory refund in section 5(a)(4):

> If the Administrator fails to make a determination on a notice under paragraph (3) by the end of the applicable review period and the notice has not been withdrawn by the submitter, the Administrator shall refund to the submitter all applicable fees charged to the submitter for review of the notice pursuant to section 26(b), and the Administrator shall not be relieved of any requirement to make such determination.

Similarly, in section 5(a)(3)(C) it actually curtailed the 90-day period where EPA makes a "not likely to present an unreasonable risk" determination by eliminating the previous requirement that PMN submitters wait the full 90 days before commencing non-exempt commercial manufacture.

Moreover, the Senate Report directed EPA to meet the 90-day target whenever it can:

> The Committee notes that ... consistent with current law, the Agency should continue the practice of completing new chemical reviews within 90 days to the maximum extent practicable.[14]

In summary, the growing backlog is a serious concern for all stakeholders. It is also contrary to what Congress intended when it amended TSCA. We offer a number of suggestions below as to how EPA should address the problem.

[14] S. Rep. No. 114-67, 114th Cong., 1st Sess. (June 18, 2015) (Senate Report) at 14-15.

2. Congress Intended the Affirmative Determination Requirement to Promote Transparency

EPA's approach to the obligation to determine that a PMN substance is "not likely to present an unreasonable risk" is based on an interpretation that LCSA mandates a stronger evidentiary base, and a different legal standard, than it used in "dropping" a PMN substance prior to enactment.

EPA should recognize that although the affirmative determination requirement does provide an enhanced basis for review, it did not change the legal standard for review. Importantly, the change serves an important policy objective of increasing transparency.

Congress did not regard the affirmative determination requirement as changing the review criteria for PMNs in a meaningful way. Indeed, the affirmative determination is a mechanism for transparency about the decisions that EPA had been making all along, but without explanation. Additional transparency will give stakeholders other than the PMN submitter insights into EPA's actions and the reasons for those actions. Stakeholders who question those actions will have several opportunities to raise objections, including through comments on a proposed SNUR for the PMN substance; requesting EPA to identify the PMN substance as a high-priority substance under section 6; and filing a section 21 petition or a petition under the Administrative Procedure Act asking EPA to undertake specified activities. Thus, greater transparency provides a check on EPA's actions under the New Chemicals Review Program.

Pre-enactment, whenever EPA decided not to regulate a PMN substance, it offered no explanation of that decision; it simply took no action. In many cases, the decision to "drop" a PMN occurred as early as 15-20 days into the 90-day review period, at the focus meeting. EPA informed the PMN submitter of that decision, but gave no explanation of the reasoning for the decision. The PMN submitter then waited until the 90-day review period expired, after which it could commence non-exempt commercial manufacture of the PMN substance. When EPA published a notice in the Federal Register providing the receipt dates and 90-day due dates for PMNs, it gave the public some sense of that decision, but again, no explanation. In contrast, where EPA did issue a section 5(e) consent order, it provided an explanation of its decision to the PMN submitter (and to the public through FOIA, subject to section 14).

Section 5(a)(3) mandates that EPA make an affirmative determination about each PMN found to be "not likely to present an unreasonable risk." Under section 5(g), EPA must publish in the Federal Register a summary of each determination that a PMN substance is "not likely to present an unreasonable risk," thus giving transparency to those determinations. There was no need to require publication of an explanation of other determinations regarding unreasonable risk, since they would be made in the resulting section 5(e) consent order or rulemaking.

The Senate Report on S. 697 identified the lack of transparency in EPA's reviews of PMNs as a key problem to be addressed:

> Despite the completion of many reviews of new chemicals under section 5, concerns have been raised that it does not require EPA to make an affirmative finding that a new chemical or significant new use is not likely to present an unreasonable risk.[15]

The Senate Report then observed that the requirement in the legislation for an affirmative determination would enhance transparency:

> As with other provisions of S. 697, the section ensures transparency in all EPA decisions on new chemicals or significant new uses.[16]

Nowhere does the legislative history suggest that EPA should change the substantive criteria used for making decisions under section 5.

This added transparency may lead some stakeholders to question EPA's decisions not to restrict particular PMN substances. The purpose of transparency is to allow the public to understand and, at times, question EPA's decisions. Nevertheless, EPA should have been making defensible decisions not to restrict PMN substances during the entire history of the New Chemicals Review Program. Defensible decisions, of course, require sufficient information. The Agency should be making defensible decisions post-enactment as well, without the need for more intense, time-consuming scrutiny. Accordingly, aside from the administrative task of publishing its decisions not to restrict PMN substances, there is no reason for delays in completing PMN reviews for those substances determined to be "not likely to present an unreasonable risk" despite the affirmative determination requirement.

3. EPA Should Broaden Its Interpretation of "Not Likely to Present an Unreasonable Risk"

a. EPA's Interpretation Discounts the Exposure Controls in the PMN

The time-consuming scrutiny that EPA is giving PMNs before finding that they are "not likely to present an unreasonable risk," and the much higher rate at which it is planning to issue section 5(e) consent orders, both mean that EPA has effectively adopted stringent new criteria for a finding that a PMN substance is "not likely to present an unreasonable risk." It has effectively transmuted the concept of risk to one of hazard only, by disregarding exposure controls.

That provision on "not likely to present an unreasonable risk" appears in section 5(a)(3)(C), which provides that EPA may determine:

> that the relevant chemical substance or significant new use is not likely to present an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by the Administrator under the conditions

[15] Senate Report at 3.
[16] Senate Report at 14.

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> of use, in which case the submitter of the notice may commence manufacture of the chemical substance or manufacture or processing for a significant new use.

At the December 14 hearing, Maria Doa described EPA's standards for making a "not likely to present an unreasonable risk" determination:

> So the considerations for the "not likely to present," generally, what you will have is there are a couple of different scenarios that we have been looking at. One is that the chemical has low potential for human health and environmental toxicity. It is not both persistent and bioaccumulative. It may be persistent, but not bioaccumulative or vice-versa, and exposure is considered but that consideration of exposure, we do not anticipate that there will be risks. A second type of scenario is where the toxicity is higher, but the information on all the exposure scenarios that we have considered do not present unreasonable risk. And this includes foreseen uses. The third scenario would be you have the potential for higher toxicity, but the exposure is self-limiting, such as physical/chemical property, something that would impede the potential for exposure.[17]

Those appear to be the only scenarios that EPA would accept as establishing that a PMN substance is "not likely to present an unreasonable risk." While those scenarios are unobjectionable, they exclude other scenarios that should also qualify as "not likely to present and unreasonable risk."

For example, in many cases, there may be potential for toxicity, but the exposure controls in the PMN would be sufficient to prevent exposure, resulting in low risk. EPA does not appear to regard this scenario as sufficient to establish "not likely to present an unreasonable risk." ACC members and speakers at the December 14 meeting indicated that EPA is insisting on section 5(e) consent orders that would require the PMN submitter to implement the controls it described in its PMN.

EPA may be discounting the exposure controls described in PMNs because they are not enforceable through a section 5(e) consent order. It is also requiring section 5(e) consent orders where those enforcement controls would, if implemented, be sufficient to address concerns from the activities of the PMN submitter and its direct customers, but would not necessarily be followed by other manufacturers of the PMN substance after it is added to the Inventory and their customers. This puts the PMN submitter in an impossible situation, since it cannot commit other manufacturers to use particular exposure controls. The end result is that EPA is largely disregarding the exposure side of the risk equation, and requiring section 5(e) consent orders based primarily on concerns about hazard.

This is not what Congress had in mind with respect to the term "unreasonable risk" and its variations in the statute. Congress wanted EPA to consider exposure, and exposure controls, as well as hazard – the elements that together constitute an enhanced level of review for PMNs. By insisting in many cases that any exposure controls be enforced by a section 5(e) consent order, EPA is veering dangerously into a hazard-based regulatory system under section 5.

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[17] Transcript at 6.

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b. EPA Should Rely on the Exposure Controls in the PMN

For the first 35 years of the New Chemicals Review Program, EPA was usually satisfied that a PMN submitter would indeed implement the controls that it had described. Where implementation of the described controls would preclude a finding of "may present an unreasonable risk," the possibility that a PMN submitter would not implement the controls was not sufficient to support a section 5(e) consent order based on a finding of "may present an unreasonable risk." Now, although Congress did not mandate such a change in the legislation, EPA has apparently – and without explanation – changed its approach.

The explanation may be that EPA considers that it is "reasonably foreseeable" that the PMN submitter would not implement those controls, and it feels that that possibility precludes a determination that a PMN substance is "not likely to present an unreasonable risk."

According to Merriam-Webster, definitions for "likely" include "having a high probability of occurring or being true" and "very probable."[18] In contrast, "possible" implies a much lower probability, with a definition of "being within the limits of ability, capacity, or realization."[19]

In other words, to find that a PMN substance is "not likely to present an unreasonable risk," EPA must find that there is not a "high probability" of the risk occurring, or that such a risk is not "very probable." Often, a PMN submitter describes exposure controls in its PMN that it intends to implement prior to commercialization and which, if implemented, would preclude a "may present an unreasonable risk" determination. In that case, it is certainly not "highly probable" or "very probable" that the PMN submitter will not implement those controls, unless EPA has clear evidence to the contrary. EPA should find there that the PMN substance is "not likely to present an unreasonable risk."

At one point during the Congressional consideration of the LCSA, some stakeholders advocated for a different standard: "likely not to present an unreasonable risk." Their sense was that it would be more difficult for EPA to make that finding, and accordingly there would be more section 5(e) consent orders. Under that language, arguably EPA would have had to find that it was likely, i.e., there was a "high probability" that the PMN substance would not present an unreasonable risk.

That wording was not accepted, however. The language that was accepted, "not likely to present an unreasonable risk," implies the absence of sufficient evidence to establish that occurrence of an unreasonable risk has a "high probability" or is "very probable." Thus, EPA should not regard "not likely to present an unreasonable risk" as though it had that more restrictive wording.

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[18] See https://www.merriam-webster.com/dictionary/likely.
[19] See https://www.merriam-webster.com/dictionary/possible.

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4. EPA Should Recognize That the "Not Likely to Present an Unreasonable Risk" Standard Differs Little From What Applied Prior to Enactment

When EPA decides that a PMN substance is "not likely to present an unreasonable risk," it is effectively deciding that a section 5(e) consent order (or a rule under section 5(f) based on a finding that the substance "presents an unreasonable risk") is not appropriate.

It is not necessary for EPA to define new scenarios that will allow it to make a "not likely to present an unreasonable risk" determination. That standard is essentially the same as that which EPA used in deciding to "drop" PMNs prior to enactment. That standard was that the PMN substance did not meet the standards for issuance of a section 5(e) consent order (or a rule under section 5(f) based on a finding that the PMN substance "presents an unreasonable risk").

The LCSA did amend the relevant language for issuing section 5(e) consent orders. Prior to June 22, the relevant language was that in section 5(e)(1)(A), where EPA issued consent orders based on the following:

> (i) the information available to the Administrator is insufficient to permit a reasoned evaluation of the health and environmental effects of a chemical substance with respect to which notice is required by subsection (a); and
>
> (ii) (I) in the absence of sufficient information to permit the Administrator to make such an evaluation, the manufacture, processing, distribution in commerce, use, or disposal of such substance, or any combination of such activities, may present an unreasonable risk of injury to health or the environment ....

Thus, the key standard was, and remains, "may present an unreasonable risk." In about 90% of cases, EPA was able to find that a PMN substance did not meet that standard, and it allowed commercialization without a section 5(e) consent order.

Under section 5(a)(3)(B)(i) of TSCA as amended, the "insufficient information" provision is now an independent basis for a section 5(e) consent order. Otherwise, section 5(a)(3)(B)(ii)(I) is now the key provision, and it is clearly modeled on section 5(e)(1)(A)(ii)(I):

> (ii) (I) in the absence of sufficient information to permit the Administrator to make such an evaluation, the manufacture, processing, distribution in commerce, use, or disposal of such substance, or any combination of such activities, may present an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by the Administrator ....

"May present an unreasonable risk" has not changed. Only the following changes have been made:

- The reasonableness of the risk is to be determined "without consideration of costs or other nonrisk factors"

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- The determination must consider the risks to "a potentially exposed or susceptible subpopulation identified as relevant by the Administrator"

These factors are also included in EPA determinations that a PMN substance is "not likely to present an unreasonable risk" under section 5(a)(3)(C).

As amended, section 5 now requires EPA to make its "may present an unreasonable risk" determinations on the basis of risks to health or the environment, without considering economic or other factors. ACC understands that such factors were never a significant part of EPA's assessment of PMNs during the 35 years of the New Chemicals Review Program prior to June 22. Those factors were critical in determinations under section 6 of whether a chemical such as asbestos "presents an unreasonable risk," but not under section 5.[20]

EPA now has an express requirement to consider the risks to workers or other potentially exposed or susceptible subpopulations. This requirement codifies the practice EPA had certainly adopted under TSCA before amendment. It would be startling to learn that EPA had not been doing that throughout the New Chemicals Review Program prior to the LCSA. Indeed, many section 5(e) consent orders issued prior to LCSA contain provisions addressing workplace protections or effectively prohibiting distribution to consumers. Likewise, EPA must have been considering potential exposures to children in the past, and it would be similarly startling if EPA had not done that in the past. Congress' decision to articulate the considerations that EPA has been using all along should not trigger a change to EPA's decision-making about "may present an unreasonable risk."

In short, nothing in new section 5(a)(3)(B)(ii)(I) justifies the abrupt and dramatic increase in the number of section 5(e) consent orders now under consideration by EPA, or EPA's corresponding refusal to allow commercialization without a consent order where, prior to enactment, it would have allowed such commercialization.

5. EPA Should Revise Its Interpretation of the Phrase "Reasonably Foreseen"

EPA regards the "reasonably foreseen" phrase in the definition of "conditions of use" (as that term is used in amended section 5), as a mandate for a much-expanded scope of review of a PMN substance. That expanded scope of review is apparently leading to many more section 5(e) consent orders than was the case pre-enactment. All those section 5(e) consent orders are contributing substantially to the backlog of PMN reviews. EPA is misapplying that term in its review of PMNs.

a. EPA Erroneously Considers "Reasonably Foreseen" to Expand the Scope of PMN Review

The term "reasonably foreseen" appears in the definition of the term "conditions of use" in section 3(4), which provides:

[20] In his congressional testimony on TSCA legislation, Assistant Administrator Jim Jones lamented the requirement in section 6 to balance costs and benefits. In contrast, he had few, if any, criticisms of section 5.

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> The term "conditions of use" means the circumstances, as determined by the Administrator, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of.

At the December 14 hearing, Jeff Morris commented on the phrase "reasonably foreseen":

> Also the new element to the law is that, as we have interpreted the statute, the conditions of use around which we evaluate a new substance include not only the use of identified in the premanufacture notice, but also any reasonably foreseen uses.[21]

Maria Doa even provided an example of where EPA would issue a section 5(e) consent order based solely on the uses which someone other than the PMN submitter might use in manufacturing the substance after it is added to the Inventory:

> The PMN substance is made [by the PMN submitter] in a way in which there is no free reactive moiety in the chemical substance. However, once it's on the inventory, it can be made in a way such that there will be this reactive moiety in the chemical substance. And from what we know about the chemical and the reactive moiety, we know a lot about the foreseen uses and there will be a potential for both worker and consumer exposure from the uses of these chemicals. So the chemical here may present an unreasonable risk to health based on the foreseeable uses.[22]

EPA's reasoning appears to be that "reasonably foreseen" requires it to consider conditions of use not intended by the PMN submitter nor reasonably to be anticipated from the conditions of use that are described in the PMN. Instead, it apparently believes that it is now required to consider conditions of use that reasonably may be foreseen from activities by persons other than the PMN submitter and its direct customers,[23] such as other manufacturers and their downstream customers, once the PMN substance is added to the Inventory.

b. <u>Section 5(e) Consent Orders Based on Foreseen Uses by Third Parties Serve No Function</u>

EPA's reasoning is flawed, as explained below. But before critiquing the reasoning, ACC must point out a practical problem for which EPA appears to have no response: a section 5(e) consent order issued to a PMN submitter based on foreseen uses by persons other than the PMN submitter and its direct customers has no regulatory effect – thus, it serves no purpose.

Consider the example presented in the preceding section. The PMN submitter there proposes to manufacture the PMN substance in a manner that does not create a free reactive moiety, the

[21] Transcript at 2.
[22] Transcript at 9.
[23] Only EPA and the PMN submitter sign a section 5(e) consent order, so the PMN submitter's direct customers are not signatories. Some consent orders contain provisions prohibiting the PMN submitter from distributing the PMN substance to its direct customers who do not agree in writing to comply with certain of the consent order provisions. Thus, the direct customers may become contractually bound to comply with the specified provisions.

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subject of EPA's concern. A section 5(e) consent order prohibiting the PMN submitter from manufacturing the substance in a manner that does create the free reactive moiety would have no practical effect, since the PMN submitter was not going to do that anyway. In addition, a section 5(e) consent order would have no effect on subsequent manufacturers who might begin to manufacture the substance after it is added to the Inventory in a manner that does create the free reactive moiety. They are the persons whom EPA wants to restrict. Yet they are not signatories to the consent order. They remain unaffected by it. EPA must still promulgate a SNUR in order to restrict their manner of manufacture. EPA has accomplished nothing useful by prohibiting the PMN submitter from doing what it had no intention of doing. However, it has delayed completion of the PMN review process by months while developing, negotiating, and then issuing the consent order.

ACC understands from its members that many of the backlogged PMN substances are facing section 5(e) consent orders due solely to uses that EPA foresees on the part of persons other than the PMN submitter and its direct customers. The futility of EPA's insistence on section 5(e) consent orders in this situation is causing major disruptions of the New Chemicals Review Program. It is certain that Congress intended no such change in the program. In legal parlance, such orders may be regarded as "arbitrary or capricious" since they do not effectuate any protection of health or the environment.

c. "Reasonably Foreseen" Does Not Appear in Section 5(a)(3)(B), Pertaining to Determinations to Issue Section 5(e) Consent Orders

Significantly, the phrase "conditions of use" (with its "reasonably foreseen" language) is not applicable to determinations triggering the issuance of section 5(e) consent orders as provided in section 5(a)(3)(B).

That provision directs EPA to issue section 5(e) consent orders if it makes certain determinations.[24] That provision identifies three determinations that can trigger a section 5(e) consent order:

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[24] For reference, section 5(a)(3) provides:

> REVIEW AND DETERMINATION.—Within the applicable review period, subject to section 18, the Administrator shall review such notice and determine—
>
> (A) that the relevant chemical substance or significant new use presents an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by the Administrator under the conditions of use, in which case the Administrator shall take the actions required under subsection (f);
>
> (B) that—
>
> > (i) the information available to the Administrator is insufficient to permit a reasoned evaluation of the health and environmental effects of the relevant chemical substance or significant new use; or
> >
> > (ii) (I) in the absence of sufficient information to permit the Administrator to make such an evaluation, the manufacture, processing, distribution in commerce, use, or disposal of such substance, or any combination of such activities, may present an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by the Administrator; or

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- The first, under section 5(a)(3)(B)(i), is that there is "insufficient information" available to make a reasoned evaluation. That provision does not include the phrase "conditions of use."[25]

- The second, under section 5(a)(3)(B)(ii)(I), is that the PMN substance "may present an unreasonable risk." That provision does not include the phrase "conditions of use" either, although its restatement in section 5(e)(1)(A)(II) does.[26]

- The third, under section 5(a)(3)(B)(ii)(II), is that the PMN substance will be produced in "substantial quantities" and that there will be "substantial or significant" exposure to the PMN substance. Like the other determinations triggering a section 5(e) consent order, that provision does not contain the phrase "conditions of use." [27]

Accordingly, EPA should not apply any interpretation of "reasonably foreseen" to a determination to issue a section 5(e) consent order.

The phrase "conditions of use" appears twice in section 5(a)(3). It is part of section 5(a)(3)(A), which directs EPA to conduct rulemaking if it determines that a PMN substance presents an unreasonable risk. EPA is likely to make that determination rarely, if ever. Thus, that provision may be disregarded for present purposes.

The other place "conditions of use" appears is in section 5(a)(3)(C), where EPA determines that a PMN substance is "not likely to present an unreasonable risk" under the "conditions of use." It is in this context that EPA's interpretation of "reasonably foreseen" should be examined.

d. Congress Intended That "Reasonably Foreseen" as Used in Section 5 Refers to Conditions of Use Related to the PMN Itself, Not to Those of Third Parties

EPA has erred in concluding that, in the PMN context, "reasonably foreseen" can refer to persons other than the PMN submitter and its direct customers. It has erred in construing that

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(II) such substance is or will be produced in substantial quantities, and such substance either enters or may reasonably be anticipated to enter the environment in substantial quantities or there is or may be significant or substantial human exposure to the substance, in which case the Administrator shall take the actions required under subsection (e); or

(C) that the relevant chemical substance or significant new use is not likely to present an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by the Administrator under the conditions of use, in which case the submitter of the notice may commence manufacture of the chemical substance or manufacture or processing for a significant new use.

[25] Similarly, where that provision is restated in section 5(e)(1)(A)(i) that restatement does not include the term "conditions of use."

[26] The inconsistency between the two provisions creates ambiguity indicating that Congress did not consider that "conditions of use" be a critical factor in deciding whether to issue a section 5(e) consent order.

[27] Where that provision is restated in section 5(e)(1)(A)(ii)(II), that restatement does not include the term "conditions of use."

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phrase to mean that it must speculate about the conditions of use that may occur once a PMN substance is added to the Inventory and anyone can manufacture or process it.

On the contrary, the Senate Report emphasized that "reasonably anticipated" (a clear reference to "reasonably foreseen") exposures should be considered "consistent with existing law" and that the PMN submitter (who has no knowledge of the conditions of use of anyone besides itself and its direct customers) must submit the information on those exposures:

> Consistent with existing law, the PMN submitter must provide EPA all available relevant information, including information on the intended conditions of use and reasonably anticipated exposures. The Committee intends that the review of the PMN should be conducted in that context.[28]

It is clear from this statement that Congress expected that the current PMN regulations would govern the information that EPA is to consider in reviewing PMNs. Those regulations require a PMN submitter to provide exposure-related information both for sites controlled by the submitter and for sites not controlled by the submitter, including the "categories of use."[29] Yet EPA has never interpreted those long-standing regulations to require information about uses by other manufacturers of the PMN substance after it is added to the Inventory, as EPA is now demanding. In LCSA, Congress considered that "reasonably anticipated exposures" would be those resulting from the activities of the PMN submitter and, possibly, those of its direct customers. Congress did not require speculation about what might occur once third parties can manufacture the PMN substance following its addition to the Inventory.

What does "reasonably foreseen" mean in the context of section 5(a)(3)(C)? As noted above, "conditions of use" refers to "the circumstances … under which a chemical is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of." The phrase "reasonably foreseen" thus modifies "intended" and "known."

In H.R. 2576 as passed by the House in 2015, the phrase was "intended conditions of use."[30] Similarly, in the original bipartisan bill introduced by Senator Lautenberg and Senator Vitter and others in 2013, S. 1009, the term was "intended conditions of use."[31] That was later changed to "conditions of use" in the subsequent Senate bill and the final legislation in recognition that there could be reasonably foreseeable uses that are neither intended nor known. Nevertheless, the emphasis remained on "intended, known" conditions of use (those described in the PMN) and any conditions of use which may be "reasonably foreseen" from those uses.

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[28] Senate Report at 15.
[29] 40 C.F.R. § 720.45(f)-(h).
[30] H.R. 2576, 114th Cong., 1st Sess. (July 28, 2015), § 3 ("The term 'intended conditions of use' means the circumstances under which a chemical substance is intended, known, or reasonably foreseeable to be manufactured, processed, distributed in commerce, used, and disposed of.").
[31] S. 1009, 113th Cong., 1st Sess. (May 22, 2013), § 3. Even that version included the concept of reasonable foreseeability. The definition of "intended conditions of use" read, "The term 'intended conditions of use' means the circumstances under which a chemical substance is intended or reasonably anticipated to be manufactured, processed, distributed in commerce, used, and disposed of."

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Under section 6, where many people may use a chemical substance, it may be appropriate to consider a broad range of reasonably foreseeable occurrences. As explained by the House Report on H.R. 2576, which did not propose to amend section 5:

> The Committee expects that the Agency will generally interpret this [phrase, "intended conditions of use"] to mean intended by the manufacturer, known by the manufacturer or the public, or reasonably foreseeable by the manufacturer or the Administrator.[32]

Under section 5(a)(1), which focuses just on PMNs, however, it is only appropriate to consider just what is reasonably foreseeable from the intended uses defined in the PMN, and which relate to the PMN submitter and its direct customers.

Insight should come from the Consumer Product Safety Act. Case law has established that the risks to be evaluated under that statute include "reasonably foreseeable misuse."[33] Similarly, in tort law, the manufacturer must warn against "reasonably foreseeable misuse."[34] For PMNs substances, spills by the PMN submitter or its direct customers may be "reasonably foreseen" misuse that EPA should consider.

Thus, in the PMN context, EPA may consider the potential, "reasonably foreseen," misuse by the PMN submitter or its direct customers, such as the potential for spills. For example, where the PMN indicates that the PMN submitter or its direct customers will handle the PMN substance in open (rather than closed) processes, EPA may reasonably expect that spills may occasionally occur. EPA should evaluate whether the potential for spills from the intended uses prevents EPA from making a "not likely to present an unreasonable risk" finding under section 5(a)(3)(C).

However, in the PMN context, it is not reasonable for EPA to consider whether spills or other reasonably foreseeable uses by persons other than the PMN submitter and its direct customers after the PMN substance is added to the Inventory prevent EPA from making a "not likely to present an unreasonable risk" finding under section 5(a)(3)(C).

This is apparent from the text of section 5(a)(2)(D). One of the enumerated factors that EPA must consider before promulgating a SNUR is:

> the reasonably anticipated manner and methods of manufacturing, processing, distribution in commerce, and disposal of a chemical substance.

That factor well captures the idea behind the term "conditions of use" as applied to persons other than the PMN submitter and its direct customers. "Reasonably anticipated" is essentially

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[32] H.R. Rep. No. 114-176 (June 23, 2015), at 22.

[33] See, e.g., *Southland Mower Co. v. CPSC*, 619 F.2d 499 (5th Cir. 1980) ("Congress intended for injuries resulting from foreseeable misuse of a product to be counted in assessing risk. *Aqua Slide*, 569 F.2d at 841. See S. Rep.No.92-749, 92d Cong., 2d Sess. 14, 92 Cong. Rec. 36198 (1972) (remarks of Sen. Moss) (risk of injury "associated with" consumer products, 15 U.S.C. § 2052(a)(3), to be regulated by CPSC includes risks of injury resulting from "exposure to or reasonably foreseeable misuse of a consumer product.").

[34] See, e.g., *Stults v. International Flavors & Fragrances, Inc.*, 31 F. Supp. 3d 1015 (N.D. Iowa 2014) (citing cases).

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synonymous with "reasonably foreseen."[35] Unlike EPA's review of PMNs, however, a SNUR is not limited to the "manner and methods" of the PMN submitter and its direct customers. Instead, in the SNUR context, EPA should consider (and apparently has, since the inception of the New Chemicals Review Program) the "manner and methods" of anyone who may manufacture, process, distribute, or dispose of the chemical substance.

Thus, Congress effectively directed EPA in promulgating SNURs to consider the "reasonably foreseen" conditions of use of persons other than, or in addition to, the PMN submitter and its direct customers. With that understanding, it is unsupportable for EPA to conclude that it must consider exactly the same thing in evaluating PMNs, or that it must issue section 5(e) consent orders where a SNUR would be appropriate based on that factor.

e. Nothing in the Legislative History Indicates that "Conditions of Use" Alters EPA's Substantive Review of PMNs

As noted earlier, ACC agrees that LCSA enhanced EPA's PMN review authority, particularly to assure that sufficient information existed to make a determination whether a new chemical poses an unreasonable risk or not. Notably, however, Congress provided no indication that the term "conditions of use" should be interpreted to change the review standard for new chemicals. If Congress had intended the term "conditions of use" to substantially alter EPA's evaluation of PMNs, it surely would have indicated that. Congress expressed no concern with EPA's evaluation of PMNs or an intention that EPA should change its approach to that evaluation.

For example, Congress did not express concern that EPA had been allowing unsafe chemical substances to enter the marketplace without restriction. Indeed, EPA's historical implementation of section 5 was widely praised by witnesses at both the Senate and the House hearings. Several stakeholders urged Congress not to amend section 5 at all, since that was one part of TSCA that was working extremely well. EPA itself believes that section 5 as implemented pre-enactment was very effective at keeping unsafe new chemical substances off the market.[36]

The House bill, H.R. 2576, reflected that viewpoint. As passed by the House of Representatives in 2015, it had no provision amending section 5.[37]

The Senate bill, S. 697, did include language amending section 5. However, the Senate Report on that bill had no criticism of EPA decisions not to restrict PMN substances, other than the fact that EPA provided no explanation of those decisions:

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[35] "Foreseeability" and related terms are commonly defined as "reasonably anticipated." See, e.g., West's Encyclopedia of American Law, edition 2 (2008) ("Foreseeability" means "The facility to perceive, know in advance, or reasonably anticipate that damage or injury will probably ensue from acts or omissions.").

[36] See, e.g., EPA, Fiscal Year 2017, Justification of Appropriation (Feb. 2016), https://www.epa.gov/sites/production/files/2016-02/documents/fy17-congressional-justification.pdf, at 517 (consistently high marks on EPA's own metric, "Percent of new chemicals or organisms introduced into commerce that do not pose unreasonable risks to workers, consumers, or the environment").

[37] H.R. 2576 (as passed by the House on June 23, 2015 by a vote of 398-1).

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> Despite the completion of many reviews of new chemicals under section 5, concerns have been raised that it does not require EPA to make an affirmative finding that a new chemical or significant new use is not likely to present an unreasonable risk.[38]

It is not clear that Congress even gave much thought to the application of the term "conditions of use" to PMN reviews. This may be reflected in the omission of references to the term in section 5(a)(3)(B), as discussed above. The Senate Report focused instead on use of the term in section 6:

> "Conditions of Use" is a term used throughout S. 697 to describe the context in which EPA will apply the safety standard in safety assessments and determinations. The term means the "intended, known, or reasonably foreseeable circumstances" under which a chemical substance is manufactured, processed, distributed in commerce, used or disposed of. The term is not intended to include "intentional misuse" of chemicals.[39]

The phrase "safety assessments and determinations" corresponds to the phrase "risk evaluations" in the final legislation. Thus, Congress saw the term as primarily intended to affect risk evaluations under section 6.[40] There is no evidence that it gave any consideration to how referring to "conditions of use" in section 5 might affect EPA's review of PMNs. Certainly, Congress expressed no intention to upend the New Chemicals Review Program by mandating a much more expansive scope to PMN reviews.

6. EPA Should Pursue Alternatives to Section 5(e) Consent Orders

a. EPA Should Discuss Options with the PMN Submitter Immediately After the Focus Meeting

With EPA setting a very challenging standard for "not likely to present an unreasonable risk," EPA's default approach has been to presume that a section 5(e) consent order will be necessary in most cases. This is an unnecessarily narrow approach that is contributing to the backlog.

One practical option available to EPA is to discuss its initial concerns with the PMN submitter immediately after the focus meeting, which typically held on Days 15-20 of the PMN review period. This discussion may identify paths to avoid the need for a section 5(e) consent order.

In the discussion, EPA should explain to the PMN submitter its initial concerns. This may allow the PMN submitter to respond to questions underlying those initial concerns; to correct misimpressions; and to offer information or changes to exposure controls which may effectively resolve those initial concerns.

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[38] Senate Report at 3.
[39] Senate Report at 7.
[40] See also Cong. Rec. S3519 (June 7, 2016) (remarks of Sen. Vitter responding to a question on how "conditions of use" should be applied by EPA in risk evaluations under section 6).

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For example, the PMN submitter may not have recognized that EPA may regard "disposal" of wastes to include disposal to a regular landfill, whereas the PMN submitter had planned to dispose of wastes only in a hazardous waste landfill. Alternatively, the PMN submitter could offer to amend its planned practices to send wastes to a hazardous waste landfill.

The discussion could identify information that would help EPA resolve its concerns. This is particularly useful where EPA may be considering a section 5(e) consent order based on "insufficient information." While PMN submitters are required to submit all available health and safety studies, a concern about hydrolysis, for example, may trigger a more detailed search that uncovers an existing hydrolysis study (e.g., as submitted to a foreign regulatory body). Alternatively, the PMN submitter may volunteer to conduct a hydrolysis study.

The PMN submitter may be able to refer EPA to previous evaluations of the PMN substance by EPA's foreign counterparts, e.g., in China or under REACH. Although those evaluations would not be binding on EPA, they may be influential.

Such discussions can develop a variety of alternatives to a section 5(e) consent order. They should take place as early in the review period as possible, preferably immediately after the focus meeting.

b. EPA Should Encourage Use of the "Binding Option" Without Requiring a Section 5(e) Consent Order, or by Using an Expedited Consent Order Process

Where EPA would otherwise plan to issue a consent order based on concern that the PMN submitter would not implement the described controls, EPA should simply ask the submitter to amend its PMN to select the "binding option" for the relevant controls. In that way, the PMN submitter will commit to implement those controls, and EPA can proceed to make a determination of "not likely to present an unreasonable risk."

Heretofore, EPA has considered selection of a "binding option" to be an invitation to agree to a section 5(e) consent order, because it did not regard a "binding option" to be binding in the absence of such an order.[41] However, EPA should regard selection of a "binding option" to be a commitment by the PMN submitter. Page 2 of the PMN form requires the submitter to make the following certification:

[41] See EPA PMN Instruction Manual (2015) at 16-17 ("Indicating a willingness to be bound by the terms of your PMN notice does not by itself prohibit the submitter from deviating after the end of the review from the information (except chemical identity) which had been reported in EPA Form 7710-25 (unless the submitter and the Agency enter into a binding TSCA section 5(e) Consent Order), but it does provide a starting point for discussions between EPA and the submitter. A checked box can help EPA and the PMN submitter negotiate efficiently in the development of 5(e) consent orders and help the Agency promulgate Significant New Use Rules (SNURs) for those new chemical substances that the Agency determines may present an unreasonable risk if certain control actions are not implemented. The purpose of the binding box is to reduce delays that can slow the development of consent orders absent such prior agreement."). ACC notes, however, that a section 5(e) consent order need not be necessary in many cases involving binding options.

> I hereby certify to the best of my knowledge and belief that all information entered on this form is complete and accurate ....
>
> Any knowing and willful misrepresentation is subject to criminal penalty pursuant to 18 U.S.C. § 1001.

That certification may include selection of a "binding option" for particular controls. EPA has significant remedies if the PMN submitter makes a "binding option" selection and does not meet that commitment, including criminal prosecution for knowing and willful misrepresentation.

PMN submitters are often reluctant to select the "binding option" because of concern that in the future alternative controls may become available that provide equal or greater protection to health and the environment, yet they would be unable to make changes to controls for which "binding option" was selected. EPA could facilitate selection of "binding option" by revising the PMN Manual to explain that a "binding option" is a commitment of the PMN submitter for which it may be held accountable, and to indicate that if, after commercialization, the PMN submitter would prefer to change controls, it may simply send EPA a letter explaining the basis for the change and requesting EPA's approval. EPA could respond by letter approving the change, disapproving it, or suggesting alternative approaches. In this way, the "binding option" process could be made more effective and could be a much more efficient approach than requiring a section 5(e) consent order.

Alternatively, if EPA does insist on a section 5(e) consent order to ensure that a "binding option" selection is indeed binding, it could revise the current cumbersome process with an expedited one. A section 5(e) consent order in this context could be quite brief, a few pages at most, committing the PMN submitter to use the exposure controls for which it has selected a "binding option." Such consent orders could also have an expedited process for amendments based on a satisfactory showing by the PMN submitter that different controls would provide equal or greater protection. ACC believes, however, that superimposing a section 5(e) order on top of a binding option commitment is substantially more cumbersome than needed to provide EPA compliance assurance. Again, this result would be in sharp distinction to pre-LCSA practice.

c. <u>EPA Should Resume Issuance of Non-Section 5(e) SNURs</u>

EPA's SNUR authority in section 5(a)(2) complements its PMN authority in section 5(a)(1). Congress recognized this by directing in section 5(f)(4) that after issuing a section 5(e) consent order for a PMN substance, EPA must, within 90 days, consider promulgating a SNUR for that substance. EPA has an expedited process for issuing such section 5(e) SNURs in 40 C.F.R. § 721.160.

Sometimes the uses described in a PMN do not raise a substantial concern, but potential uses by others after the PMN substance is added to the Inventory do. Historically, EPA has used a SNUR to address those concerns. In those contexts it has not also issued a section 5(e) consent order, since the PMN submitter's actions did not raise those concerns, and a section 5(e) consent order would have done nothing to redress those concerns. EPA has an expedited process for issuing such non-section 5(e) SNURs in 40 C.F.R. § 721.170.

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Since enactment, EPA has halted issuance of non-section 5(e) SNURs. Instead, in every instance where previously it would have issued a non-section 5(e) SNUR, it is planning to issue a section 5(e) consent order to be followed by a SNUR. This abandonment of the non-section 5(e) SNUR mechanism has contributed to the backlog by driving EPA to develop, negotiate, and issue section 5(e) consent orders that previously would have been unnecessary.

Non-section 5(e) SNURs serve an important function. EPA adopted the expedited process for promulgating non-section 5(e) SNURs that appears in 40 C.F.R. § 721.170 because "a non-section 5(e) SNUR may be the least burdensome regulatory alternative for the Agency to pursue."[42] In doing so, it advanced the policies of section 2(b)(3), that "authority over chemical substances and mixtures should be exercised in such a manner as not to impede unduly or create unnecessary economic barriers to technological innovation while fulfilling the primary purpose of this Act to assure that such innovation and commerce in such chemical substances and mixtures do not present an unreasonable risk of injury to health or the environment." As explained in the 1995 preamble adopting that regulation:

> A non-section 5(e) SNUR is typically appropriate for PMNs on chemical substances expected to be toxic but where the PMN indicates the submitter's intention to limit activities, implement control measures, or otherwise adequately mitigate human exposures and environmental releases. **Activities described in such PMNs may not present an unreasonable risk of injury** to human health or the environment so as to warrant the issuance of an Order under section 5(e) of TSCA [followed by promulgation of a section 5(e) SNUR], but deviations from the described activities may present an unreasonable risk warranting the imposition of regulatory controls via a section 5(e) Order. In those cases, **a non-section 5(e) SNUR may be the least burdensome regulatory alternative** for the Agency to pursue, as it will allow the PMN submitter to proceed with planned activities while requiring notification to, and review by, EPA for activities which have not been reviewed.[43]

EPA concluded that the use of non-section 5(e) SNURs would "eliminate unnecessary section 5(e) Orders" then being issued to PMN submitters:

> Thus, this rule amendment is intended to eliminate unnecessary section 5(e) Orders and should not itself increase the number of new chemical substances regulated by EPA via SNURs under section 5 of TSCA. Rather, substances that would formerly have been regulated by 5(e)-SNURs may now be regulated by non-section 5(e) SNURs.[44]

EPA's new refusal to promulgate non-section 5(e) SNURs returns the Agency to the exact situation that the adoption of § 721.170 in 1995 was designed to avoid: issuance of unnecessary section 5(e) consent orders.

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[42] See footnote 43.
[43] 60 Fed. Reg. 16311, 16313 (Mar. 29, 1995) (emphasis added).
[44] 60 Fed. Reg. at 16313.

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Unnecessary section 5(e) consent orders hurt all parties. EPA is burdened with the additional work of drafting, negotiating, and adopting those unnecessary orders. PMN submitters are burdened by the delay of waiting for EPA to draft the orders, negotiating them with EPA, and then waiting for EPA to issue the orders. The public and the environment are burdened from the same delay, as innovative technology and greener chemicals are kept from the market for sometimes extended periods.

If EPA continues to refuse to promulgate non-section 5(e) SNURs, at a minimum it should explain why section 5(e) consent orders are not "unnecessary," and how the new policy advances the policies of section 2(b)(3).

Yet that is the situation EPA is embracing by declining to issue any more non-section 5(e) SNURs. EPA has many demands on its scarce resources with implementation of TSCA as amended. It should not needlessly divert resources to issue unnecessary section 5(e) consent orders.

The futility of issuing "unnecessary" section 5(e) consent orders is manifest. Such orders only apply to PMN submitters and, perhaps, their direct customers. Whereas a non-section 5(e) SNUR would efficiently address concerns raised by persons other than the PMN submitter and its direct customers, a section 5(e) consent order in that context would have no helpful effect at all.

EPA has not explained why it has abandoned the non-section 5(e) SNUR mechanism. Presumably, it is because its interpretation of "reasonably foreseen" has convinced it that it must issue a section 5(e) consent order even when the concerns that it foresees are not raised by the PMN itself, but instead by others after the PMN substance is added to the Inventory. As discussed above, EPA is misinterpreting "reasonably foreseen" in the PMN context. It should recognize that issuing a section 5(e) consent order in this context is meaningless and only slows down the review process, to the detriment of all stakeholders.

CONCLUSION

ACC agrees that the LCSA made some important changes to section 5 of TSCA. EPA now has a mandate to ensure that sufficient information exists to make a decision. EPA must explicitly account for potential exposures to humans, codifying EPA's past practice. EPA must be more transparent about how it reaches decisions in the New Chemicals Program. But the changes in section 5 were clearly not intended to have a significant negative impact on the operation of the program as a whole. EPA's implementation of its new section 5 authority has created a large and growing backlog of PMNs awaiting final determinations. The problem is getting worse, not better. EPA should take the following steps to redress the problem:

- It should acknowledge that the current delays are not a temporary phenomenon that will pass as EPA works through the backlog of PMNs for which it "reset" their review periods. Instead, it should take responsibility for the current situation and take steps to redress it.

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- It should recognize that the affirmative determination requirement for PMN substances found to be "not likely to present an unreasonable risk" does not affect the substantive standard for review..

- It should acknowledge that the standard of "not likely to present an unreasonable risk" is not significantly different from the standard it used pre-enactment to determine that no section 5(e) consent order or other restriction was necessary.

- It should consider exposure controls, and ensure that PMN decisions are made on the basis of risk, not hazards.

- It should stop requiring a section 5(e) consent order in situations where the PMN submitter's uses described in the PMN would adequately control the risk if implemented, unless EPA has a clear basis for believing that they are unlikely to be implemented.

- It should stop requiring a section 5(e) consent order in situations where uses described in the PMN do not create a substantial concern, but uses by others after the PMN substance is added to the Inventory do create such a concern.

- It should meet with PMN submitters immediately after the focus meeting to discuss its initial concerns and address options for resolving those concerns, options that may include but would not be limited to a section 5(e) consent order.

- It should encourage PMN submitters to select the "binding option" for critical exposure controls, then rely on that commitment without requiring a section 5(e) consent order. It should provide a simple mechanism for approval of future changes to those controls if needed.

It should resume issuing non-section 5(e) SNURs.

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APPENDIX 1

ACC Member Experiences Under the New Chemicals Review Program Since Enactment

Requesting Information Beyond the Scope of the PMN

- Company A received multiple onerous requests for more information that, in some cases, appear to have minimal technical value. Some requests were for downstream information that may be unavailable due to CBI protections.

  For example, EPA requested information on the potential for the new substance to contaminate wastewater effluent during processing and monitoring of these streams. It is difficult to understand the rationale for this request based on following:

  - The new substance is a solid material;
  - The new substance is hydrophobic;
  - Based on similar analogues, the new substance is expected to be immiscible in water;
  - Water is not used during the manufacturing process.

- Company B received a request for downstream processing information of the PMN substance. EPA has essentially requested completion of PMN pages 10/10A concerning industrial sites controlled by others. Since this is a new chemical substance, the downstream customer has not purchased the substance for commercial use and has not fully developed and optimized its process; therefore, the data EPA is requesting does not exist or is not attainable, and proprietary business concerns may limit the PMN submitter's access to such data. EPA does not appear to be considering that:

  - The new substance is a chemical intermediate and is intended to be completely consumed in downstream derivations and synthesis;
  - Company B cannot provide data on downstream user's processing efficiency to consume all of new substance;
  - Company B cannot provide data on downstream user's processing waste streams and clean-outs to ensure new substance is not in these effluent streams;
  - These requests could greatly extend the lead time necessary for filing a PMN if confidentiality agreements are required with downstream users to attain such information.

- Company C received a request for sales price data for EPA's economic analysis. It is not clear why this was requested, but it may be used to set a threshold volume calculation in the section 5(e) consent order. It appears that EPA may be trying to determine volume based on the cost of the studies it is requiring in a consent order. Company C has yet to receive a request in writing from EPA and Company C has not supplied EPA with this information to date.

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Policy Shifts without Notice

- Company D submitted an LVE in which the precursors are imported and are PBTs. This substance has a very small use in the U.S. and that use is very controlled. It is then shipped out of the country. For years, Company D has been in this business and has never had a problem with any similar LVEs. The previous LVEs had always been approved. This is the first time in Company D's experience that an LVE has been denied. This is a huge problem for this chemistry. It has a short development cycle of 12-16 months, so it is almost impossible to meet the PMN requirements. The business line impacted by EPA's change in approach threatens a $10 million business that employs 45+ people. Company D is considering whether to move the business overseas.

PMNs Dropped Prior to Enactment Subject to New Review

- Company E has a PMN that has been under review for more than 6 months. It was dropped before enactment of the LCSA. After enactment, EPA re-reviewed the PMN and said it has identified a high concentration of concern (COC) for ecotoxicity. Before submission of its PMN, Company E engaged the Consortium for Environmental Risk Management (CERM) – a Sustainable Futures Program (SFP) partner – to conduct a risk assessment consistent with the a SFP's screening tools. The results were included in the PMN. EPA notified Company E that it received different results than those in the PMN, i.e., a COC 100 times greater than that shown in the risk assessment results provided in the PMN. The EPA ecotoxicity review group apparently decided without notice to industry or EPA's SFP partners that it will no longer accept nitrogen mitigation in association with ecotoxicity assessments. Therefore, Company E wasted resources on the risk assessment performed ahead of submitting the PMN. EPA is now requiring a 90-day inhalation test with a 60-day hold before beginning the test (5-month waiting period).

- Company F submitted a PMN to EPA before enactment of the LCSA, but EPA dropped the PMN from further review before enactment. The business unit was set to launch and had to pull back (wasting resources) because after enactment of the LCSA, EPA notified Company F that its PMN review period had been reset (effectively, extended 90 days to September 22). The PMN is now the subject of a section 5(e) consent order that is under negotiation. EPA told Company F that it will be weeks before the draft consent order arrives because EPA is backlogged drafting consent orders.

- Company G submitted a PMN in April 2016. EPA dropped the PMN from further review in April. Like other PMNs pending on the date of enactment, the review period was reset on June 22. In late July, EPA contacted Company G to inform it that the PMN had been scheduled for a Focus Group Meeting in early August. After the Focus Group Meeting, the program manager informed Company G that the PMN substance was assessed as not likely to present an unreasonable risk. In September, Company G received a call inquiring about downstream customers and the potential for inhalable dust. Later in September, Company G received an "URGENT NEED TO COMMUNICATE" message. Company G was informed that the PMN went to another final Focus Group Meeting and the "not likely to present an unreasonable risk" determination had been revised to an

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"insufficient information" determination and that the PMN substance will be subject to a section 5(e) consent order, and that Company G must await the consent order letter to be informed of the terms. Company G is still awaiting receipt of that letter.

Testing Requirements That Are Not Justified

- Company H submitted a PMN prior to enactment of the LCSA. EPA dropped it from further review prior to enactment. After enactment, EPA notified Company H that its PMN review period had been reset as of June 22. EPA is now requiring an up-front test that is not scientifically justified under the circumstances. The substance is water soluble in a roller application – its intended use. EPA is demanding the testing based on the fact that EPA cannot assess the inhalation potential from the roller. Company H does not understand why EPA is concerned about inhalation because the chemical is not being sprayed. The substance is not a VOC, and there is no analytical method to measure and provide EPA with the data it seeks. Company H is moving to contingency plans until it decides how to proceed in this new climate that is thwarting innovation.

- Company I has a vendor that submitted an LVE for a material that Company H wants to use (with the goal of protecting CBI), so Company H filed a proprietary use document with EPA as a supporting document to the vendor's LVE. Company I received three calls from EPA's engineer to have Company I explain what a "10% weight solids in a pre-mixture tank" contained in the PMN means in reference to a particular application that no one had identified as an intended application.

- Company J has been notified verbally that EPA intends to issue an "insufficient information" finding for a PMN on an intermediate. Prior to enactment of the LCSA, Company I discussed with EPA reviewers some potential ecotoxicity concerns that were resolved and the PMN was going to be dropped. EPA recently informed Company J that on re-review of the PMN, it had identified potential reproductive/developmental toxicity risks. EPA will issue a section 5(e) consent order requiring a reproductive and developmental study prior to manufacturing. In addition, EPA expects to add triggered ecotoxicity testing to the consent order and that the conditions of the consent order are subject to change as it goes through the approval process. Company J finds EPA's initial conclusions unexpected and unreasonable, for the following reasons:

    - The reproductive and developmental hazards had not been raised during previous risk assessment discussions; only the ecotoxicity concerns had been raised. Company J understood that those concerns had been adequately addressed.
    - The intended use of this substance is as an intermediate at Company J's manufacturing plants, where exposure and environmental releases are controlled. EPA does not appear to be considering exposure controls (or a non-section 5(e) SNUR to control uses) to mitigate potential risks in place of testing.
    - The proposed testing requirements are onerous – including lengthy and expensive studies prior to commencement of non-exempt manufacture.

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- Multiple companies are reporting that EPA is frequently requiring 90-day inhalation studies on PMN substances without any use-based justification, i.e., the product as used is does not have potential inhalation exposure.

PPE No Longer Considered When Evaluating PMNs

- Program managers have reported to ACC members that PPE can no longer be considered to mitigate exposure and lower risk when there is potential for human health hazards. The risk has to be determined assuming there is no PPE. Because of data gaps, especially for chronic endpoints, this is often yielding the determination that EPA has "insufficient information" to assess risk and it will require up-front testing. Program managers have stated that this will impact significantly higher molecular weight polymers, as frequently EPA lacks information on them.

- Company K reported that EPA was about to issue a non-section 5(e) SNUR with a release to water trigger the day after enactment of the LCSA. EPA then re-evaluated the PMN and revised its finding to find an ecotoxicity concern and make an "insufficient information" determination regarding mutagenicity. The program manager mentioned that, in the past, EPA would require PPE to mitigate the risk since the concentration was low and exposure was low, but that the Agency has now changed its approach. Rather than issue a SNUR and moving on, up-front mutagenicity testing will be required. This chemical is very low volume and is used in UV curable inks, coatings, adhesives at a maximum concentration of ~5%.

Strict Requirements on Polymers and Consent Orders on Polymers Meeting the Polymer Exemption Criteria

- Company L submitted a PMN for an acrylate polymer. EPA called to request a suspension of the review period so that it can prepare an "insufficient information" section 5(e) consent order that would prohibit releases to water. EPA would consider removing that requirement if Company L completes testing, which has yet to be determined. While the average molecular weight of the polymer is at the low end of the Polymer Exemption criteria, it is surprising that EPA is interested in regulating it when it likely meets the low-risk criteria of the Polymer Exemption.

- Company M's PMN on a polymer had its review period reset on June 22. EPA then requested a suspension to complete a section 5(e) consent order. Company M requested the Action Letter and was told it cannot be provided until finalized and signed. Company M requested the engineering report, but it has not yet been received. The program manager has informed Company M that the consent order will be very different from anything it has seen in prior SNURs for this chemistry.

- Company N has 16 PMNs (a number of which are polymers) and 2 LVEs in review. Of these, one PMN has received a "not likely to present an unreasonable risk" determination. The review periods for the other 15 PMNs and the 2 LVEs have been suspended. Seven of these have pending section 5(e) consent orders. The outcomes of the remaining 10 are

currently not known. Two of the PMNs had been submitted prior to enactment and had been dropped prior to enactment, but are now subject to consent orders.

- Company O expects a section 5(e) consent order on a polymer that meets the polymer exemption criteria. Company O does not understand the explanation provided by EPA as to what it is about the polymer that EPA is trying to control.

- Company P has several examples of EPA trying to control the molecular weight of prepolymers and polymers. While there may be some justification for this approach, manufacturers need practical flexibility. EPA should not force manufacturers to adhere to exact values because the molecular weight may be reported in the PMN from lab samples, but when a company scales up to a commercial run, the molecular weight can change slightly.

- Company Q filed a PMN in May on a polymer with a high molecular weight. The PMN was dropped from further review before enactment of the LCSA. After enactment, EPA reset the review period. This material is site-limited and completely consumed onsite. EPA informed Company Q that it was concerned about inhalation issues/lung overload and it wanted a 90-day inhalation test with a 60-day holding period (totaling 5 months). Company Q explained that the material would never be respirable, which was reflected in the shaking test in the PMN. EPA has nevertheless requested another 15-day review and asked Company Q to send in more written material, which it is providing.

Philosophical Change in Approach

- Multiple companies report a marked change in philosophy and approach at EPA. Whereas EPA used to work more collaboratively with PMN submitters to work through issues and concerns, since enactment of the LCSA, EPA is issuing unwarranted demands, and requiring unjustified section 5(e) consent orders without adequately consulting with PMN submitters. EPA is requiring information on potential conditions of use downstream, requiring up-front testing for those uses, and requiring companies to provide a compelling argument regarding its proposed use of the chemical to get approval. The consent orders are requiring companies to commit to only the use identified in the PMN and no releases to water.

Consistent Refusal to Issue Non-Section 5(e) SNURs

- Many companies report being told that EPA can no longer issue non-section 5(e) SNURs.

- EPA representatives told the U.S.-Canada Regulatory Cooperation Council (RCC) in September that non-section 5(e) SNURs "are not really a thing and never were . . . ." When pressed on this point, EPA said they would double check and clarify. EPA sent ACC an email citing the following Q&A from the FAQs and asked if this responded to the inquiry:

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Q14. Does EPA still see a continuing role for non-section 5(e) significant new use rules (SNUR) under the new law?

A: The Agency's authority to issue SNURs derives from section 5(a)(2) – not section 5(e). Section 5(a)(2) was not changed under the recent amendments to TSCA. The Agency fully expects to continue to exercise its SNUR authority, as appropriate, in the context of both new and existing chemicals.

Unfortunately, this Q&A does not address this question.

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