December 11, 2017

Dr. Jeff Morris
Acting Director, Office of Pollution Prevention and Toxics
Office of Chemical Safety and Pollution Prevention
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington DC 20460

Re: Serious Concerns about EPA Plans to Weaken the New Chemicals Program and Request to Halt Implementation

Dear Dr. Morris:

The undersigned groups are writing to reinforce our deep concerns about the "framework" for new chemical review that EPA presented at its December 6 public meeting and to request that the Agency halt implementation of the framework while it reviews and addresses public comments and reexamines the framework's legality. As explained below, we believe the framework is contrary to the Toxic Substances Control Act (TSCA) and urge EPA to withdraw it after further analysis and consideration of public comments.

The premanufacture notice (PMN) program for new chemicals is one of the bedrock elements of TSCA. Its purpose is to ensure that protections of health and the environment are in place before new chemicals that may pose an unreasonable risk of harm or lack sufficient information for a reasoned determination of safety enter the marketplace. Careful reviews of new chemicals, accompanied by necessary restrictions on exposure, release, and use and testing requirements, are vital to prevent the widespread presence in the economy, products and the environment of substances later linked to cancer, learning disabilities, reproductive impacts and other health and environmental harms. The dangerous chemicals that escaped review before enactment of TSCA (PCBs, dioxin, asbestos, lead and vinyl chloride) and slipped through the review process under the previous version of the law (brominated flame retardants and perfluorinated compounds) underscore the importance of a strong and effective PMN program.

Rather than strengthen the program, however, the framework EPA outlined on December 6 would reverse recent progress, dismantle a long-standing PMN review process that is securely grounded in TSCA, and replace it with one that is legally dubious, poorly conceived and a major step backward in protecting health and the environment.

EPA ostensibly convened the December 6 public meeting to obtain feedback on the framework and has provided until January 28 for submission of written comments. Yet EPA revealed at the meeting that, rather than reviewing and considering public input, it is instead pushing ahead to implement the framework even though it raises many basic unanswered legal and policy questions under TSCA. To proceed with implementation under these circumstances reflects an alarming indifference to

public input and a reckless rush to judgment in the face of serious concerns about the Agency's approach.

We urge EPA to suspend implementation of the framework indefinitely and instead to review and respond to the public comments and reevaluate the far-reaching changes in the PMN program under consideration. We expect this analysis will demonstrate that EPA is required to issue 5(e) orders whenever it has concerns with intended or reasonably foreseen conditions of use of a PMN chemical and cannot address these concerns solely by issuance of Significant New Use Rules (SNURs). If EPA nonetheless decides to proceed with such SNURs despite the statutory requirement to issue section 5(e) orders, it must conduct a full notice-and-comment rulemaking on each SNUR so the public has an adequate opportunity to present its views, as required by the Administrative Procedure Act (APA) and EPA's SNUR regulations.

**TSCA Does Not Authorize EPA to Forego Section 5(e) Orders When Intended or Reasonably Foreseen Conditions of Use May Present an Unreasonable Risk or cannot be Evaluated Because of Insufficient Information**

In the 2016 Frank H. Lautenberg Chemical Safety for the 21st Century Act (LCSA) amending TSCA, Congress strengthened the PMN program significantly, requiring EPA to make an *affirmative determination of the potential risks of* every new chemical. Thus, EPA can no longer allow the PMN review period to expire without explicitly addressing the chemical's safety. If it concludes that the new chemical may present an unreasonable risk, the Agency lacks sufficient information for an informed risk evaluation, or the chemical has or may have substantial production volume and exposure, EPA *must issue an order under section 5(e)* to restrict activities involving the chemical and/or require testing. This obligation is non-discretionary. The only occasion where no action is required is when EPA determines that the chemical *is not likely to present an unreasonable risk, including to workers and other vulnerable populations.* Thus, EPA cannot simply allow production to begin by default: if it does not regulate the chemical under section 5(e), it has an *obligation to demonstrate by credible evidence that the chemical is unlikely to harm health or the environment.*

For the first several months following enactment of LCSA, EPA staff diligently worked toward the goals of the new law. After careful review, the agency found that in many cases it either had insufficient information to permit a reasoned evaluation and/or that under known, intended, or reasonably foreseen conditions of use, the PMN substance may present unreasonable risks. As a result, it subjected many more new chemicals to section 5(e) orders, placing limits on human exposure and environmental release and increasing the amount of testing required to better understand the potential hazards posed by the chemicals under review. But chemical manufacturers mounted relentless and misleading attacks on EPA's supposed "overreaching," based on a distorted view of the requirements of the new law. In response, the political leadership of EPA (which includes a former official of the American Chemistry Council, Dr. Nancy Beck) intervened to roll back the program improvements that the staff had adopted to comply with LCSA.

The framework presented on December 6 reflects this effort to radically deconstruct the PMN program to appease industry at the expense of public health. It seeks to turn the new law on its

head by dramatically reducing the use of section 5(e) orders, the principal tool under the old and new laws to address the risks of new chemicals of concern.

As the first step in curtailing the use of orders, EPA plans to evaluate the PMN substance based only on the "intended" use conditions identified in the PMN. Where these activities raise human health or environmental concerns that may present an unreasonable risk of injury, EPA would recommend limits on exposure and release that were not identified in the PMN and encourage the submitter to amend its PMN to incorporate them. Although the controls would be strictly voluntary, EPA would then rely on them to make a determination that the chemical is "unlikely to present an unreasonable risk." Such an approach is wholly inadequate to protect the public, or comply with the law, since the conditions of use described in PMNs have no binding effect and are unenforceable unless they are formalized in a section 5(e) order. By contrast, EPA previously made "may present an unreasonable risk" findings on chemicals with potential health and environmental concerns and then used section 5(e) orders to impose enforceable restrictions that protect against the potential unreasonable risk. This is plainly the path that Congress directed EPA to follow.

As an additional basis for avoiding section 5(e) orders in these cases, EPA would presume that the available information on the PMN substance is "sufficient" for a determination of unreasonable risk even though its recommended controls are based on similarities to other chemicals that may be less hazardous than the PMN substance. In the past, section 5(e) orders have required both exposure controls and testing so that EPA can assess whether additional protections are needed based on fuller information. However, EPA's new approach necessarily bypasses the important new requirement in amended TSCA to determine the sufficiency of information and to require testing under section 5(e) to fill critical information gaps while exposure and release are controlled.

Under EPA's framework, a further step in avoiding section 5(e) orders is eliminating their use to address future uses of the PMN substance that "may present an unreasonable risk" and/or lack "sufficient information" for a reasoned evaluation of risk. This change in approach, too, is contrary to TSCA. EPA's safety determinations and regulatory actions under section 5 are expressly required to address risks presented by a new chemical under its "conditions of use." This term is defined under section 3(4) of TSCA to include the circumstances under which a chemical is "*reasonably foreseen* to be manufactured, processed, distributed in commerce, or disposed of" (emphasis added). If EPA identifies a reasonably foreseeable future use of the PMN substance raising concerns that meet the criteria for action under section 5(e), the law states that the Agency "shall" issue an order under that provision, whether the use is intended by the PMN submitter or not.

**SNURs Are Not a Lawful or Adequately Protective Substitute for Section 5(e) Orders**

Instead of complying with the plain terms of TSCA, EPA plans to substitute SNURs for section 5(e) orders both where the submitter amends its PMN to include additional exposure controls and where EPA identifies "reasonably foreseen" future uses of the new chemical that raise health or environmental concerns. But SNURs were never intended to be the primary mechanism for restricting and reducing the risks of new chemicals of concern, nor are they an effective means of doing so. Rather, when EPA determines that it lacks sufficient information to make a reasoned evaluation or the substance may present an unreasonable risk, "the Administrator *shall issue* an

order" pursuant to section 5(e) (emphasis added). In section 5(f)(4), TSCA as amended expressly recognizes that the role of SNURs is to build on section 5(e) orders by extending their requirements to other manufacturers and processors – not to substitute for these orders in the first instance. Indeed, this was EPA's explicit understanding when it issued SNUR regulations in 1989 and throughout its implementation of the PMN program under the old law.

Not only are 5(e) orders legally required, they serve key protective functions in addressing new chemical risks that are not served by SNURs. Except where a section 5(e) order is in place, EPA has no legal obligation to issue SNURs for new chemicals. Accordingly, in contrast to orders, there is no requirement to put SNURs in place before a new chemical raising concerns is commercialized. Orders must be based on and incorporate explicit conclusions about the nature and magnitude of the new chemical's risks but no such risk findings are required in SNURs. As a result, the level of protection that SNURs must afford is not defined in the law. By contrast, section 5(e) orders must prohibit or limit activities involving the restricted chemical "to the extent necessary to protect against an unreasonable risk of injury to health or the environment." EPA can thus make SNUR provisions as weak or strong as it chooses. For this reason, the Agency has no obligation to include in SNURs all the protections now included in section 5(e) orders. For example, as EPA acknowledged at the public meeting, SNURs would **not** include the triggered testing requirements that are now an essential feature of many orders. An across-the-board shift from section 5(e) orders to SNURs would therefore mean much less protection and testing for new chemicals of concern.

**EPA Should Halt Issuance of SNURs in Lieu of Section 5(e) Orders while It Considers Public Comments and Reexamines Whether There Is a Defensible Basis for Its Framework under TSCA**

Given the sweeping and fundamental changes it would make in the TSCA new chemicals program, it is troubling that the only paper EPA has released describing the framework is a mere five pages in length. It contains no legal analysis, despite the seeming conflict between EPA's approach and the text and goals of LCSA. It avoids basic and unresolved issues, such as the timing of SNURs in relation to the end of the PMN review period and the commencement of production of the new chemical, a subject that EPA acknowledged at the public meeting remains under debate. And nowhere does the paper discuss the provisions that SNURs will contain and whether and how they will assure that the protections that would be required under section 5(e) orders will be effectively implemented throughout the new chemical's life-cycle and supply chain.

Despite the many concerns and questions raised at the public meeting, EPA acknowledged after being pressed by stakeholders that it is not waiting for public comments to implement the new framework but is in fact is currently working on a number of SNURs to be used in lieu of 5(e) consent orders and may issue them imminently. Promulgating these SNURs in the middle of the comment process would be irresponsible and make a mockery of EPA's purported commitment to transparency and meaningful public engagement. As emphasized above, EPA should instead put the SNURs on hold indefinitely, review and respond to the public comments and reexamine whether the framework is defensible and lawful in light of the express language and goals of amended TSCA. We believe this process will result in withdrawal of the framework.

**To Comply with its Regulations, EPA Must Conduct a Full Notice-and-Comment Rulemaking on Any SNURs it Issues Based on the Framework**

Although we believe EPA should halt work on SNURs intended to substitute for section 5(e) orders, a meaningful notice-and-comment process is essential under the APA and EPA's SNUR regulations should EPA nonetheless begin issuing such SNURs precipitously.

Distressingly, we understand that EPA instead intends to truncate the rulemaking process by publishing the SNURs as direct final rules and allow only 15 days for interested parties to signify their intent to comment and submit the comments themselves. This is contrary to the commitment to full rulemaking procedures for controversial new chemical SNURs that EPA made in the preamble to its 1989 SNUR regulations:

> "EPA expects to follow notice and comment rulemaking procedures to issue SNURs in cases where it expects adverse or critical public comments on a SNUR. While this option maximizes the period during which a person may engage in the activity EPA intends to regulate under a SNUR, it also gives maximum public notice, and ensures a full period to address any significant issues." 54 Federal Register 31298, 31299 (July 27, 1989).

Clearly, EPA has every reason to expect that its first SNURs under the new framework will engender "adverse or critical public comments" and raise "significant issues." A full rulemaking process under the APA is thus required.

Even if "direct final rulemaking" were appropriate, the SNUR regulations prescribe a very specific process that EPA must follow. 40 CFR 721.170(d)(4)(i)(B) describes this process as follows:

> "The Federal Register document will state that, unless written notice is received by EPA within 30 days after the date of publication that someone wishes to submit adverse or critical comments, the SNUR will be effective 60 days from date of publication. The written notice of intent to submit adverse or critical comments should state which SNUR(s) will be the subject of the adverse or critical comments, if several SNURs are established through the direct final rule. If notice is received within 30 days after the date of publication that someone wishes to submit adverse or critical comments, the section(s) of the direct final rule containing the SNUR(s) for which a notice of intent to comment was received will be withdrawn by EPA issuing a document in the final rule section of the Federal Register, and EPA will issue a proposed rule in the proposed rule section of the Federal Register. The proposed rule will establish a 30-day comment period."

EPA is thus precluded by its own regulations from collapsing the two-step process for direct final rules into a single step and allowing only 15 days for comments instead of the 60 required by the regulations. It must instead provide 30 days for interested parties to signify an intent to submit comments, withdraw the direct final rule and publish a proposed rule in the Federal Register, allow 30 additional days for submission of comments, and then either withdraw or finalize the SNUR together with a response to the comments received. It will be unlawful if EPA deviates from this process.

In sum, we urge EPA to put implementation of the new framework on hold indefinitely, review and respond to comments and reexamine whether the framework can be reconciled with the language and goals of TSCA. If it does nonetheless proceed with SNURs despite the illegality of the framework under TSCA, EPA should conduct a full notice-and-comment rulemaking for these rules in accordance with its SNUR regulations for new chemicals.

We ask that you respond in writing to the issues raised by this letter as soon as possible.

Please contact SCHF counsel Bob Sussman with any questions at bobsussman1@comcast.net.

Sincerely yours,

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