UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Comments of Safer Chemicals Healthy Families, et al. on Progress Implementing the New Chemicals Review Program under the Amended Toxic Substances Control Act

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INTRODUCTON AND SUMMARY

Safer Chemicals Healthy Families (SCHF) and the undersigned groups submit these comments on the Environmental Protection Agency (EPA) program to review and address the risks of new chemicals under section 5 of the recently amended Toxic Substances Control Act (TSCA). Our comments supplement our statements at the December 6, 2017 public meeting on new chemicals and the December 11, 2017 letter to Dr. Jeff Morris, Director of the EPA Office of Pollution Prevention and Toxics (OPPT) submitted by several of our organizations.

The signatory organizations listed below are national and grassroots groups committed to ensuring the safety of chemicals used in our homes, workplaces and the many products to which our families and children are exposed each day. Our organizations took a leadership role during the TSCA legislative process, advocating the most protective and effective legislation possible to reduce the risks of toxic chemicals in use today.

Safer Chemicals Healthy Families
Alaska Community Action on Toxics
Alliance of Nurses for Healthy Environments
Asbestos Disease Awareness Organization
Breast Cancer Prevention Partners
Center for Environmental Health
Clean and Healthy New York
Connecticut Clean Water Action
Earthjustice
Ecology Center
Environmental Health Strategy Center
Health Care Without Harm
Learning Disabilities Association of America
Natural Resources Defense Council
Physicians for Social Responsibility
Science and Environmental Health Network
Union of Concerned Scientists
U.S. Public Interest Research Group
Vermont Public Interest Research Group
WE ACT for Environmental Justice

Section 5 of TSCA performs the core function of ensuring that the hundreds of new chemicals introduced each year do not enter commerce without a careful evaluation to ensure that they do not pose an unreasonable risk to public health and the environment. Where these chemicals raise concerns, section 5 requires EPA to use its essential authority to control their risks before they harm people and natural systems.

In the 2016 Frank R. Lautenberg Chemical Safety for the 21st Century Act (LCSA) amendments to TSCA, Congress strengthened the section 5 program significantly. These amendments require EPA to make an *affirmative determination of the potential risks of* every new chemical before it can enter commerce. They

also increase EPA's authority to protect against risks of new chemicals and to require industry to conduct testing to better understand how new chemicals affect people and the environment. For over a year after LCSA's enactment, EPA staff diligently implemented the new law, resulting in more thorough evaluations of new chemicals, greater protection against their potential risks and increased testing to determine their health and environmental effects.

In the face of industry opposition to a strong new chemicals program, however, EPA management is now reversing recent progress, dismantling a long-standing review process that is securely grounded in TSCA, and replacing it with one that is legally dubious, poorly conceived and a major step backward in protecting health and the environment. EPA's rollback of the program is reflected in the New Chemicals Decision-Making Framework (Framework) that the Agency released in advance of the December 6 public meeting and presented at the meeting. [1]

While it ostensibly convened the December 6 public meeting to obtain feedback on the Framework, EPA revealed at the meeting that it is pushing ahead to implement the Framework without waiting for comments on the many legal and policy questions it raises under TSCA. To begin applying the Framework 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.

In our December 11 letter, we urged EPA to suspend implementation of the Framework indefinitely and instead to review and respond to the public comments it receives. We reiterate this request in these comments. As we show below, the new chemical review process established by the Framework is unlawful under LCSA and puts public health and the environment at serious risk. We strongly believe that, after reevaluating the many legal and policy concerns the Framework raises, EPA must withdraw the Framework and reinstate the new chemical review process it initially established after enactment of LCSA.

We also strongly urge EPA to increase the transparency of the new chemical review process, including by complying fully with LCSA requirements that have not been adequately implemented. And we urge EPA to reject the chemical industry's irresponsible and unwarranted proposal to reverse the longstanding role of the section 5 program in safeguarding workers, thereby putting American workers at risk by deferring all workplace protections for new chemicals to the Occupational Safety and Health Administration (OSHA), which lacks the resources and legal authority to address these chemicals effectively.

The key points in these comments are summarized below:

- **Why the Framework Must be Withdrawn**

  Following Congress' strengthening of section 5, EPA staff initially worked diligently toward the goals of the new law, subjecting many more new chemicals to orders placing limits on human exposure and environmental release and increasing the amount of testing required. Although EPA staff was doing exactly what Congress intended, the chemical industry mounted relentless and misleading attacks on EPA "overreach" and the political leadership of EPA (which now features a former official of the American Chemistry Council, Dr. Nancy Beck) intervened to roll back the protections the staff had put in place.

[1] https://www.epa.gov/sites/production/files/2017-11/documents/new_chemicals_decision_framework_7_november_2017.pdf

The Framework reflects this effort to radically deconstruct the new chemicals program. It seeks to turn the new law on its head and reduce health protections by dramatically curtailing 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.

To avoid section 5(e) orders, the Framework would limit premanufacture notice (PMN) review to the "intended uses" of the new chemical even though the law requires EPA to evaluate "reasonably foreseen" uses as well. Where the new chemical raises health or environmental concerns under intended conditions of use, EPA would not protect against these risks by imposing mandatory controls under a section 5(e) order but would instead request that the submitter amend its PMN to provide for implementation of these controls on a voluntary and unenforceable basis. On the basis of the amended PMN, EPA would then determine that the new chemical is "not likely to present an unreasonable risk" under TSCA section 5(a)(3)(C) even though it has found that the chemical is likely to be hazardous and the submitter is under no legal obligation to protect against the risk. Where anticipated future uses of the new chemical present potential risks that warrant control, EPA would similarly make a "not likely to present an unreasonable risk" determination on the ground that these risks need not be addressed under section 5(e). This approach is directly contrary to LCSA's mandate to address all "reasonably foreseen" conditions of use that raise concerns under a section 5(e) order.

Under the Framework, EPA would replace section 5(e) orders with Significant New Use Rules (SNURs) under TSCA section 5(a)(2). 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 that 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 proper 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.

Not only are 5(e) orders legally required, they perform 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 promulgate SNURs 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. They must then 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." By contrast, no risk findings are required for SNURs and the level of protection that SNURs must afford is not defined in the law. 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.

At the December 6 public meeting, OPPT Director Jeff Morris repeatedly asserted that, by bypassing section 5(e) orders and proceeding directly with SNURs, the premanufacture notification (PMN) process would become more "efficient." However, achieving greater efficiency in reviewing new

chemicals is not EPA's mandate from Congress. The Agency is obligated to implement the PMN program, consistent with the law's requirements, to protect public health and the environment. The desire of chemical manufacturers for a speedy review (and rubber stamp) of their products is irrelevant to the proper implementation of TSCA.

Moreover, the claim that PMN reviews will become more efficient under the Framework is not in fact correct. Because it will add additional steps, the new review process will likely increase the expenditure of time and resources rather than conserve them. Since "greater efficiency" cannot explain the new process, the only plausible motivation for that process is to enable industry to falsely claim that its chemicals are "safe" because EPA has determined that they are "not likely to present an unreasonable risk," a conclusion reached by distorting the requirements of the law. EPA's willingness to be a party to this deception is deeply troubling but not surprising under a leadership that has consistently put public health at risk in order to advance industry's commercial agenda.

- **Enhancing Public Review and Understanding of the PMN Program**

At the same time as it implements troubling changes in the PMN process that reduce protections against new chemical risks, EPA has moved backward in providing timely and meaningful information about the PMN program, despite repeated requests by our groups for greater transparency and LCSA's mandate for greater disclosure of PMN information. This has added to the difficulty of tracking the progress of individual new chemicals through the review process, the basis for EPA's new chemical evaluations, and the actions it takes (or doesn't take) on particular PMNs. As a result, it is essentially impossible for the public to provide meaningful input to EPA while PMNs are under review, and even after-the fact, EPA's findings and conclusions are extremely difficult to reconstruct. The erection of new barriers to public participation in the new chemical review process is directly contrary to Congress' explicit goal of increased transparency when it recently amended TSCA and imposed requirements on EPA for that express purpose.

To increase transparency and opportunities for public participation, EPA must take the following steps: (1) publish timely notices of the receipt and status of PMNs in accordance with sections 5(d)(2) and (3); (2) issue statements for "not likely to present" determinations before the end of the PMN review period as required by section 5(g) and expand these statements so they provide a meaningful rationale for EPA's determinations; (3) restore descriptions on EPA's website of the interim status of PMNs under review, including the "focus meeting" recommendations of EPA staff; (4) make available the expert analyses of hazard and exposure underlying EPA's PMN reviews; and (5) aggressively review and weed out unjustified CBI claims that block access to PMNs and related information submitted by manufacturers.

- **Preserving EPA's Essential Role in Protecting Workers from New Chemical Risks**

The industry "New Chemicals Coalition" (NCC) – comprised of 20 unnamed chemical manufacturers – has called on EPA to "consult" with OSHA on each new chemical raising workplace protection issues. NCC proposes that during these consultations, EPA would bring its workplace concerns to the attention of OSHA but thereafter rely on the employer's responsibilities under the Occupational Safety and Health Act (OSH Act) and OSHA's expertise and regulatory program to ensure that workers are protected from occupational risks presented by new chemicals.

The NCC proposal would reverse and sweep away nearly forty years of precedent under the new chemicals program. From the inception of the program, EPA has addressed workplace risks during PMN reviews and used section 5(e) orders and SNURs to protect workers. LCSA provides no remotely plausible basis for eliminating these protections and instead deferring to an agency that has neither the resources nor the legal tools to assume the responsibilities that EPA has performed.

TSCA enables and, in fact, requires EPA to fill a critical gap in worker protection that OSHA cannot effectively address. Thus, the work of the two agencies is complementary, not conflicting. EPA's role in addressing the workplace risks of new chemicals is one that Congress, industry and OSHA itself have accepted for nearly forty years and that LCSA in fact strengthened just 18 months ago by defining workers as a "potentially exposed or susceptible population" requiring explicit protection under TSCA. To eliminate EPA's role would be irresponsible, dangerous to workers and contrary to law.

I. THE PMN REVIEW PROCESS ESTABLISHED BY THE FRAMEWORK IS UNLAWFUL UNDER LCSA AND PUTS PUBLIC HEALTH AND THE ENVIRONMENT AT SERIOUS RISK

A. An Effective Chemical Safety Program Must Include Strong Mechanisms to Review New Chemicals Before They Enter Commerce and Protect People and the Environment Against any Unreasonable Risks They may Present

The 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. This precautionary goal is now more important than ever as new chemicals in products continue to replace existing substances in large numbers and account for an ever-increasing portion of public exposure to chemicals.[2]

Since EPA can only evaluate and restrict a small portion of the existing chemical universe, the safeguards provided by the PMN program are uniquely important and may be the only opportunity in the life cycle of many chemicals to provide protection against harm. 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 and the dangers of allowing unsafe new chemicals to fall between the cracks.

While an improvement to the status quo, the PMN program established under the original TSCA suffered from several shortcomings that limited its effectiveness. The Senate report on TSCA reform legislation noted that "concerns have been raised that [the original law] does not require EPA to make an affirmative finding that a new chemical or a significant new use is not likely to present an

[2] Since the inception of the PMN program in 1979, over 20,000 new chemicals have been reviewed by EPA

unreasonable risk." The report added that EPA's limited authority "constrains the Agency's ability to mandate new testing when necessary to support review of a new chemical or significant new use."[3]

Reflecting these shortcomings, only 10 percent of PMN submissions under the old law were subject to controls on human exposure and environmental release or testing requirements under section 5(e).[4] The great bulk of new chemicals entered manufacture without restriction or additional testing since EPA had no obligation to make a safety determination and could only take action on the basis of an affirmative finding of risk. To compensate for the absence of data in nearly all PMNs, EPA screened most new chemicals on the basis of possible similarities in molecular structure to better characterize existing substances. However, the benefits of using Structure-Activity Relationships (SARs) and other read-across and predictive toxicity approaches were limited by the lack of a full suite of acute and chronic hazard data on the analogue chemical and the inability to determine whether the PMN substance was more hazardous than the analogue and therefore required a higher level of protection.

B. The 2016 TSCA Amendments Significantly Enhance the Effectiveness of the PMN Program

In LCSA, Congress significantly strengthened the tools for reviewing the risks of new chemicals and ensuring that health and environmental protections are in place when they are introduced into commerce. The most important change in the law is that, under section 5(a)(3), EPA now must make an affirmative determination of safety for every new chemical on which a PMN is submitted. Thus, EPA can no longer allow the PMN review period to expire without explicitly addressing the chemical's risks but must make a considered judgment about these risks and then take action as prescribed in the law.

The June 7, 2016 statement of several Democratic Senators on the final TSCA legislation underscores the importance of making a safety determination for every PMN:

> While existing TSCA does not preclude EPA from reviewing new chemicals and significant new uses following notification by the manufacturer or processor, it does not require EPA to do so or to reach conclusions on the potential risks of all such chemicals before they enter the marketplace. EPA has authority to issue orders blocking or limiting production or other activities if it finds that available information is inadequate and the chemical may present an unreasonable risk, but the burden is on EPA to invoke this authority; if it fails to do so within the 90– 180 day review period, manufacture of the new chemical can automatically commence. *This bill makes significant changes to this passive approach under current law: For the first time, EPA will be required to review all new chemicals and significant new uses and make an affirmative finding regarding the chemical's or significant new use's potential risks as a condition for commencement of manufacture for commercial purposes* . . .[5]

LCSA provides that EPA's safety determination must fall into one of five categories:

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[3] S. Rep. No. 114-67, 114th Cong., 1st Sess. (June 18, 2015) at 3.

[4] EPA, Statistics for the New Chemicals Review Program under TSCA, updated through September 30, 2015. https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/statistics-new-chemicals-review.

[5] Congressional Record – Senate, S3516 (June 7, 2016).

(1) The chemical "presents an unreasonable risk of injury to health or the environment" ((a)(3)(A));
(2) The available information "is insufficient to permit a reasoned evaluation of the health and environmental effects" of the chemical ((a)(3)(B)(i));
(3) In the absence of sufficient information, 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"((a)(3)(B)(ii)(I));
(4) The substance "is or will be produced in substantial quantities" and either will or may "enter the environment in substantial quantities" or will or may result in "significant or substantial human exposure" ((a)(3)(B)(ii)(II)); or
(5) The substance "is not likely to present an unreasonable risk of injury to health or the environment" ((a)(3)(C)).

If EPA makes any of the first four determinations, it is *obligated* to issue an order restricting the chemical under sections 5(e) or 5(f).[6] The order *must* prohibit or limit manufacture or other commercial activities "to the extent necessary to protect against unreasonable risk."

EPA is only allowed to authorize manufacture of the new chemical without any restrictions where it makes the fifth finding -- that the chemical is not likely to present an unreasonable risk. As the statement of Democratic Senators explains:

> [I]n the absence of a finding that the chemical or significant new use is not likely to present an unreasonable risk, manufacture will not be allowed to occur. . . . Only chemicals . . . that EPA finds are not likely to present an unreasonable risk can enter production without restriction. This affirmative approach to better ensuring the safety of new chemicals entering the market is essential to restoring the public's confidence in our chemical safety system.

Under this approach, unlike the original law, the burden of producing sufficient information to support a finding of likely safety rests with the Agency. 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.*

Necessarily, EPA cannot determine that the new chemical is unlikely to present an unreasonable risk where it concludes that available data "is insufficient to permit a reasoned evaluation of the health and environmental effects" of the chemical under section 5(a)(3)(B)(i). This expanded authority to regulate new chemicals was intended to increase testing and reduce reliance on uncertain and imprecise predictive tools like SAR. As the Senate report notes, "new chemicals may not have as robust a data set as existing chemicals [and] the testing authority provided to EPA under section 5 of S. 697 is intended to ensure EPA can obtain necessary information to review a PMN application . . . without having to demonstrate potential risk to require testing."[7]

[6] The original law provided that, upon making risk findings, EPA "may" issue an order regulating the new chemical but, as amended, section 5(e) states that EPA "shall" issue such orders.
[7] S. Rep. No. 114-67, supra, at 15.

C. 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

For the first year following enactment of LCSA, EPA staff diligently worked toward the goals of the new law. After careful review of individual PMNs, the Agency found that in many cases it either had insufficient information to permit a reasoned evaluation of health or environmental effects and/or that the PMN substance may present an unreasonable risk under known, intended, or reasonably foreseen conditions of use. 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. As a result, 291 section 5(e) orders have been issued since the new law took effect.

But even though EPA staff was doing exactly what Congress intended, the chemical industry mounted relentless and misleading attacks on EPA "overreaching" and distorted the requirements of the new law. In response, the political leadership of EPA (which now features 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 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 versions of the law to address the risks of new chemicals of concern.

As the first step in curtailing the use of orders, the Framework provides that EPA will 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, under the Framework, 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. By requiring even less testing than under the old law, EPA's new approach is directly contrary to Congress' goal of

improving the basis for new chemical review by *increasing* the amount of test data to inform decision-making.

The EPA Framework further reduces the issuance of section 5(e) orders by eliminating their application to 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.

Throughout TSCA as amended, EPA's risk evaluations and regulatory actions are expressly required to address health and environmental concerns presented by chemicals under their "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). Thus, future uses or methods of manufacturing and processing PMN chemicals that can be reasonably anticipated based on their properties or the functions of similar existing substances qualify as "conditions of use."[8]

The law is clear that EPA's obligations to review and, as appropriate, restrict new chemicals under section 5 must be based on an evaluation of their "conditions of use." For example, section 5(a)(3)(C) specifies that a determination that a substance is not likely to present an unreasonable risk of injury must be "under the conditions of use." Similarly, section 5(e)(1)(A), which describes the orders that EPA must issue where it makes one of the determinations in sections 5(a)(3)(B), requires that such orders "shall" –

> prohibit or limit the manufacture, processing, distribution in commerce, use, or disposal of such substance or . . . prohibit or limit any combination of such activities to the extent necessary to protect against an unreasonable risk of injury to health or the environment . . . *under the conditions of use* (emphasis added).[9]

Thus, if EPA identifies a reasonably foreseeable future use of the PMN substance raising health or environmental concerns that meet the criteria for action under section 5(e), the law is explicit that the Agency "shall" issue an order under that provision, whether the use is "intended" by the PMN submitter or not. This approach is not only required by LCSA but provides necessary protections against changes in use and exposure that could present significantly increased risks to health or the environment or warrant additional testing to ensure an informed evaluation of safety. If these changes in use are not addressed effectively under section 5, it is likely they will never be meaningfully controlled under TSCA once the chemical is listed on the Inventory.

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[8] Although industry has complained that EPA determinations of reasonably foreseeable future uses are speculative and remote, EPA uses a well-defined methodology to identify such uses, as explained by EPA staff at its December 14, 2016 public meeting.

[9] While the corresponding provision of section 5(a) – paragraph (3)(B) – does not expressly mention conditions of use, the presence of this phrase in the order language in section 5(e) is clear evidence that Congress intended conditions of use to be within the scope of "may present" determinations. Nor is it logical to assert – as some stakeholders have done – that conditions of use are only relevant to potentially exposed or susceptible subpopulations but not to the general population. This tortured reading of the statutory text is based on the omission of a comma in section 5(a)(3) that appears in identical language found in section 6(b)(4)(A). All indications are that the comma omission was a drafting error without any substantive intent. Clearly, there is no rational risk-based justification for why Congress might limit the role of "conditions of use" to vulnerable populations in section 5 but not section 6.

In comments filed with EPA on January 17, 2017, the three Senate negotiators of the final version of LCSA explicitly rejected EPA's assertion that reasonably foreseeable conditions of use are outside the scope of PMN reviews:

> Congress clearly intended for EPA to assess *all* conditions of use for new chemicals. Doing otherwise would be antithetical to the goal of providing the assurance that a new chemical proposed for manufacture is not likely to pose an unreasonable risk, whether that risk is presented by the use(s) the first manufacturer intends to commercialize or by a future use commercialized by that or any other manufacturer. The definition of "conditions of use" clearly requires EPA to contemplate such potential future (reasonably foreseen) uses. If EPA makes a determination that any condition of use, including a reasonably foreseen use, presents or may present an unreasonable risk, or if there is insufficient information with which to make such a determination, sections 5(e) and 5(f) require EPA to issue an order to mitigate the risks from all such uses.[10]

For the first year after enactment of LCSA, EPA staff assessed new chemicals under section 5(a)(3) based not just on intended or known uses described in the PMN but on reasonably foreseeable additional uses. It then issued orders restricting these reasonably foreseeable uses, along with intended and known uses, where warranted by the Agency's determinations of safety. These orders frequently imposed testing requirements triggered by changes in use and exposure. Although EPA's approach was compelled by the plain language of the law, EPA has now abandoned it in the face of industry opposition. This is a clear violation of law.

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

Instead of complying with the plain terms of TSCA, the Framework indicates that EPA plans to promulgate SNURs in lieu of section 5(e) orders where: (1) EPA identifies health or environmental concerns that would normally trigger a "may present an unreasonable risk" finding but the submitter amends its PMN to include additional exposure controls voluntarily addressing these concerns, and (2) EPA identifies "reasonably foreseen" future uses of the new chemical that likewise raise health or environmental concerns but these uses are not "intended" by the PMN submitter. For individual new chemicals, bypassing section 5(e) orders in these circumstances would be contrary to the requirements of the statute. If EPA applies this approach across the board, SNURs will become the principal tool for addressing the risks of new chemicals and section 5(e) orders will be the rare exception.

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 of risk or the substance may present an unreasonable risk, section 5(e)(1)(A) expressly states that "the Administrator *shall issue* an order" under that provision "to prohibit or limit the manufacture, processing, distribution in commerce, use, or

[10] Senators Markey, Udall and Merkley Comments on "New Chemicals Review Program under the Amended Toxic Substances Control Act" Docket EPA-HQ-OPPT-2016-0658, Submitted Friday January 13, 2017. The Senators' comments also note that "as we negotiated the final bill provisions, we considered – and rejected – language that would have limited EPA's consideration of the potential for an unreasonable risk to be posed by a chemical substance for which a pre-manufacturing notice was submitted to the specific uses identified by the manufacturer in that notice."

disposal of such substance or to prohibit or limit any combination of such activities . . . under the *conditions of use* . . ."(emphasis added). There is no indication in the law that EPA could proceed with SNURs without first restricting chemicals of concern under section 5(e). In fact, in section 5(f)(4),[11] 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 for the new chemical program in 1989 and throughout its implementation of the PMN program under the old law.[12]

Section 5(e) orders are not only legally required for PMNs that raise health or environmental concerns, but also perform key protective functions in addressing new chemical risks that are not served by SNURs. Thus, a PMN program primarily utilizing SNURs will fall far short in achieving the goals of the TSCA new chemical requirements.

A comparison of SNURs and section 5(e) orders underscores the inadequacies of SNURs in protecting against new chemical risks:

- SNURs are fundamentally notification requirements. The activities they define as "significant new uses" are not prohibited: companies seeking to conduct these activities must notify EPA and the Agency may or may not choose to restrict them. By contrast, the requirements imposed by section 5(e) orders are binding on the submitter until and unless EPA decides to modify the order.

- Section 5(e) orders are mandatory if EPA makes the triggering determinations in section 5(a)(3)(B). While section 5(f)(4) sets a deadline for deciding whether to promulgating a SNUR if it has issued a section 5(e) order, that deadline does not apply in the absence of an order and, in this circumstance, EPA has no legal obligation to issue a SNUR.

- By the explicit terms of Section 5(e), orders must "take effect upon the expiration of the applicable review period" and thus will impose restrictions on the PMN submitter as of the date it is eligible to begin manufacture. However, unless a 5(e) order has been issued, there is no required timetable in the law for promulgating a SNUR. Accordingly, there is no assurance that SNURs will be in place at the time manufacture commences (or even subsequently). Should the SNUR be delayed or never issued, the new chemical could be manufactured without any controls or restrictions, for an extended period and maybe forever.

- EPA has already failed dismally to initiate SNUR rulemakings on section 5(e) chemicals or provide its reasons for failing to do so within 90 days of issuance of an order, as required by section 5(f)(4) of TSCA. Of the 291 section 5(e) orders issued since LCSA was enacted, EPA has

[11] Section 5(f)(4) provides that, within 90 days after issuing an order under section 5(e), EPA "shall consider" promulgating a SNUR that "identifies as a significant new use any manufacturing, processing, use, distribution in commerce, or disposal of the chemical substance that does not conform to the restrictions imposed by the . . .order." By the 90 day deadline, EPA must either "initiate . . . a [SNUR] rulemaking or publish a statement describing the reasons of the Administrator for not initiating such a rulemaking." Significantly, section 5(f) does not mention – let alone set a deadline for – SNURs on new chemicals that are not subject to section 5(e) orders.

[12] See 40 CFR Part 721.

begun the SNUR rulemaking process on only 29.[13] Given EPA's poor track record of issuing timely SNURs even where it has a statutory obligation to do so, there is no reason to expect EPA to issue SNURs expeditiously in the absence of a statutory deadline.

- While EPA claims that it intends to expedite SNURs through direct final rules, under the Administrative Procedures Act and the Part 721 regulations,[14] a notice that interested parties plan to submit comments will convert the final rule to a proposal that will trigger a comment period and require a notice of final rulemaking before taking effect. This may delay the final SNUR by several months. There is no similar potential for delay with section 5(e) orders because they do not entail rulemaking and must take effect before the expiration of the PMN review period.

- The required level of protection under section 5(e) orders is defined in the statute: orders must prohibit or limit activities involving the subject chemical "to the extent necessary to protect against an unreasonable risk of injury to health or the environment." Under this standard, where the order is based on a determination under section 5(a)(3) that the chemical may present an unreasonable risk, lacks data sufficient for such a determination, or will have substantial production volume and exposure/release, the restrictions in the order must take into account these determinations and then require controls on exposure and/or testing sufficient to protect against any unreasonable risk that the chemical may present. In contrast to this precautionary approach, neither the statute nor the Part 721 regulations prescribe the level of protection that EPA must afford in designating activities as "significant new uses." Rather, the criteria for SNURs in section 5(a)(2) are general and flexible and give EPA broad discretion in determining which activities will be subject to SNURs and to what extent they will be restricted.[15]

- Where EPA has issued a section 5(e) order, the follow-up SNUR must incorporate the requirements of that order. Under TSCA section 5(f)(4), SNURs on section 5(e) chemicals must designate as significant new uses "any manufacturing, processing, use, distribution in commerce or disposal of the chemical substance that does not conform to the restrictions imposed by the . . . order." However, there are no such guideposts on how to frame SNURs where a section 5(e) order has not been issued.

- The Part 721 SNUR regulations provide a lengthy menu of restrictions from which EPA chooses in designing SNUR requirements for individual chemicals.[16] In the absence of a section 5(e)

[13] 82 Federal Register 48637 (October 19, 2017).

[14] 40 CFR § 721.160

[15] Section 5(a)(2) of TSCA states that EPA's determination that a use of a chemical substance is a significant new use must be made "after consideration of all relevant factors, including:

- The projected volume of manufacturing and processing of a chemical substance.
- The extent to which a use changes the type or form of exposure of human beings or the environment to a chemical substance.
- The extent to which a use increases the magnitude and duration of exposure of human beings or the environment to a chemical substance.
- The reasonably anticipated manner and methods of manufacturing, processing, distribution in commerce, and disposal of a chemical substance."

[16] 40 CFR Part 721, Subpart B

order, EPA has discretion in determining which of these restrictions to include in a SNUR. By contrast, EPA's selection of requirements for a section 5(e) is dictated by its determinations of safety under section 5(a)(3) and its obligation to protect against potential unreasonable risks as required by these determinations. Since under the Framework, EPA would be developing SNURs for chemicals that it has determined "are unlikely to present an unreasonable risk of injury" under section 5(a)(3)(C), there would be no comparable risk findings to shape the selection of control measures.

- EPA's determinations of potential unreasonable risk under section 5(a)(3)(A)-(B) must explicitly address risks to "potential exposed or susceptible subpopulations." Under section 5(e)(1)(A), where a section 5(e) order is warranted, its requirements must protect against "an unreasonable risk to a potentially exposed or susceptible subpopulation" However, protection of these vulnerable subpopulations is not a relevant consideration in developing SNURs under section 5(a)(2) and can be ignored in selecting SNUR requirements on substances in the absence of an order under section 5(e).

- Amended TSCA explicitly provides that EPA determinations under section 5(a)(3) must be made "without consideration of costs or other nonrisk factors" and these factors are likewise specifically precluded in selecting control measures under section 5(e)(1)(A) sufficient to protect against unreasonable risks. However, the SNUR provisions in section 5(a)(2) do not rule out consideration of costs and other nonrisk factors and thus EPA would have discretion to weaken SNUR provisions in order to reduce costs to industry.

- Section 5(e) orders have typically imposed both controls on exposure and requirements to conduct testing, consistent with determinations under section 5(a)(3)(B) that the information available to the Agency is "insufficient to permit a reasoned evaluation of the health and environmental effects of the" new substance. However, when it bypasses section 5(e) by making an "unlikely to present" determination for a new chemical under section 5(a)(3)(C), the Agency would have no obligation to include testing provisions in SNURs. Thus, as OPPT Director Jeff Morris acknowledged at the December 6 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 testing for new chemicals of concern, despite the intent of LCSA to increase such testing.[17]

- The EPA regulations are clear that, where EPA does not issue a 5(e) order, EPA "may designate as a significant new use only those activities that . . . are different from those" described in the PMN.[18] Thus, consistent with its regulations, EPA could not use a SNUR to require a PMN submitter to adhere to the conditions of use in its PMN if these conditions are not incorporated in a section 5(e) order. If EPA tries to use SNURs for this purpose, it would be violating its own regulations. If it adheres to those regulations, the SNUR could not require the PMN submitter to implement the controls in the PMN (e.g. respirator use) that EPA deems necessary to protect against an unreasonable risk. Thus, these controls would be voluntary and unenforceable.

[17] EPA could address this gap by issuing a section 4 order or rule in conjunction with the SNUR, as it has done previously. However, this EPA has thus far shown no inclination to use its section 4 testing authority.
[18] 40 CFR § 721.170(c)(2)

- EPA's "boilerplate" section 5(e) order allows it to impose additional restrictions and controls based on new evidence of risk, with little recourse by the submitter to resist these more stringent requirements.[19] No comparable mechanism exists for SNURs. Instead, if EPA wants to tighten the restrictions in a SNUR, it must conduct a rulemaking to amend the SNUR. Moreover, where the activity to be restricted by the amended SNUR is already occurring, it cannot be designated a new use and the Agency would lack authority to restrict it under the SNUR.

In short, the differences between section 5(e) orders and SNURs are not mere formalities but go to the heart of the level of protection that EPA affords against the health and environmental risks of new chemicals.

E. Despite EPA's Claims, the Review Process Established by the Framework Will be Less Efficient than the Current Process and its True Motivation is to Misrepresent the Risks of New Chemicals to the Public

At the December 6 public meeting, OPPT Director Jeff Morris repeatedly asserted that, by bypassing section 5(e) orders and proceeding directly with SNURs, the PMN process would become more "efficient." However, "efficiency" is not a relevant consideration under the law and cannot justify circumventing the process that Congress prescribed for reviewing and restricting new chemicals.

Moreover, it is highly doubtful that the new process described in the Framework will in fact conserve time and resources and it more likely would add to both (without even factoring in the legal challenges to EPA's approach that are likely to ensue). As before, EPA would need to review the PMN to identify any health or environmental concerns, examine processing conditions and exposure and release pathways, and select controls necessary to mitigate potential risks. It would then need to present its recommended control measures to the submitter, request submission of an amended PMN and then review this amended submission. These activities could well require more effort than drafting a section 5(e) order, a straightforward task in which the Agency simply "cuts and pastes" the relevant provisions in its "boilerplate" order that are applicable to the PMN.[20] Moreover, where EPA foregoes an order, it would still need to devote time and resources to developing a "not likely to present" determination under section 5(a)(3)(C) and publishing that determination in the Federal Register under section 5(g). The development of a follow-up SNUR would likewise be more resource-intensive than under the old process because EPA would need to decide what requirements to include in the SNUR, as opposed to simply incorporating the provisions in the applicable section 5(e) order.

In sum, EPA's new process adds steps absent from the current process that will offset and likely exceed any resource savings, and the end result will be an equivalent or greater expenditure of time and effort by the Agency and PMN submitters.

Since "greater efficiency" cannot explain the new process, what is its true motivation? It's hard to escape the conclusion that, by eliminating section 5(e) orders and substituting "not likely to present" determinations, industry seeks to convey the misleading message to customers and the general public

[19] https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/new-chemicals-program-boilerplates

[20] Indeed, as we understand the new process, EPA in fact still develops draft orders and presents these orders to the submitter with a request to choose between the order or a SNUR.

that EPA has declared its chemicals "safe." EPA's willingness to be a party to this deception is deeply troubling but not surprising under a leadership that has consistently put public health at risk in order to advance industry's commercial agenda.

II. EPA HAS FRUSTRATED PUBLIC REVIEW AND UNDERSTANDING OF THE PMN PROGRAM BY FAILING TO IMPLEMENT IMPORTANT TRANSPARENCY REQUIREMENTS IN THE LAW

At the same time as it implements troubling changes in the PMN process that reduce protections against new chemical risks, EPA has moved backward in providing timely and meaningful information about the PMN program, despite repeated requests by our groups for greater transparency. This has added to the difficulty of tracking the progress of individual new chemicals through the review process, the basis for EPA's new chemical evaluations and the actions it takes (or doesn't take) on particular PMNs. As a result, it is essentially impossible for the public to provide meaningful input to EPA while PMNs are under review, and even after the fact, EPA's findings and conclusions are extremely difficult to reconstruct. EPA has erected these increased barriers to transparency despite Congress' recent efforts in LCSA to *enhance* timely public understanding of the PMN process.

EPA's failure to provide transparency is evident in several aspects of the PMN review process and in many cases represents a violation of the clear requirements of the amended law:

- Section 5(d)(2) requires that EPA publish a notice in the Federal Register *within 5 business days of receipt of a PMN* providing basic identifying information, including the identity of the new chemical, the uses described in the PMN and any test data provided by the submitter. In addition, section 5(d)(3) requires that EPA publish in the Federal Register at the beginning of each month a list showing each substance for which a PMN has been received and for which the review period has not expired, and each substance for which the review period has expired since publication of the last list.

  EPA is routinely violating both of these provisions. The Agency has failed to publish any notices of the receipt of individual PMNs and thus has not complied with the 5-day publication deadline in section 5(d)(2). The only Federal Register notices published in the last year relating to PMNs are the monthly publications called "Certain New Chemicals; Receipt and Status Information." However, these publications cover PMNs submitted 2-3 months earlier (publication in January for October, in December for September, and so on), not in the prior month. Thus, they are insufficient to satisfy section 5(d)(3). Because these monthly notices are not timely, the 90-day period will be nearly complete before the public learns of a PMN and has an opportunity to review it and comment.

- EPA does publish a table on its website showing the status of PMNs.[21] However, this table does not contain the information required under sections 5(d)(2) and (3) and seems to be 3-4 months out-of-date in recording PMN dispositions. Of additional concern, the table has recently been revised to delete any description of the recommendations of EPA staff at PMN "focus meetings." Thus, it is no longer possible to ascertain what determinations under section 5(a)(3) the staff

[21] https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/premanufacture-notices-pmns-and

proposed at these meetings and whether the staff recommended a section 5(e) order. EPA acknowledged these deletions at the December 6 public meeting but offered no explanation other than that the previous "interim status" descriptions were "confusing." EPA has been providing this information to the public on its website for years. Since when did it suddenly become "confusing"? In fact, a more likely explanation is that EPA and chemical manufacturers recognized that, under the new Framework, management is now rejecting staff recommendations to issue section 5(e) orders and directing the staff to make "not likely to present" determinations instead.[22] Thus, EPA leadership is attempting to conceal the divergence between the recommended staff disposition of the PMN and the Agency's final action, further blocking public understanding of EPA's evaluations of individual PMNs.

- Section 5(g) requires EPA to publish a statement of its findings when it has concluded that a new chemical is not likely to present an unreasonable risk of injury under section 5(a)(3)(C). As EPA issues a far larger number of "not likely to present" determinations under the Framework, these statements will be increasingly important in tracking implementation of the PMN program. To ensure timely public notice, Section 5(g) requires them to "be submitted for publication in the Federal Register as soon as practicable before the expiration of the [PMN review] period." However, Federal Register publication of section 5(g) notices is not occurring on this timetable but has been delayed for several weeks after the "not likely to present" determination has been made and commercial production of the chemical has been initiated.

  More significantly, the statements themselves are uninformative about EPA's analysis of the new chemical's hazards and pathways of exposure and release. Instead, they simply recite EPA's general conclusions using boilerplate language that offers no insight into its evaluation of the specific chemical. Thus, it is impossible to ascertain how EPA arrived at its "unlikely to present" determination, rendering the determination arbitrary and capricious.

- Section 5(e) orders typically provide a detailed description of use and exposure conditions for the PMN substance, environmental releases, worker and general population exposure, EPA's toxicity findings, and the nature and magnitude of its concerns about potential risks to health and the environment. However, as EPA issues far fewer orders under the Framework, this critical documentation will disappear. EPA thus has an even greater responsibility than before to provide the public with the underlying analyses of Agency scientists and engineers that form the basis for its determinations on individual new chemicals.

- Finally, the inordinate number of CBI claims for PMN information by submitters has greatly impeded informed public review of PMNs: while redacted versions of PMNs are publicly available, they contain extensive deletions of essential information. Reduction of unwarranted CBI claims would greatly enhance the public's ability to track the health and environmental impacts of new chemical production and use and the basis for the Agency's safety determinations.

  Section 14 of LCSA was intended to accomplish this objective. It imposes new requirements for submitters to "substantiate" information at the time of PMN filing and provides that general use

[22] An initial review of table entries for "not likely to present" determinations revealed several instances where staff recommendations to issue section 5(e) orders were rejected.

and processing information and health and safety data cannot be withheld from disclosure. We have previously asked EPA to describe the steps it is taking to review CBI claims against the new requirements and disallow claims that lack substance.[23] However, EPA not provided meaningful assurance that it is expeditiously winnowing out CBI claims for PMN information that cannot be defended under the new law. EPA must step up to its responsibilities under section 14.

III. EPA SHOULD REJECT INDUSTRY RECOMMENDATIONS TO STOP IMPOSING WORKER PROTECTION REQUIREMENTS UNDER SECTION 5 AND INSTEAD DEFER TO OSHA

On December 1, 2017, an industry group described as the "New Chemicals Coalition" (NCC) called on EPA to implement an "appropriately robust and ongoing consultation process" with OSHA on each new chemical raising workplace protection issues.[24] The NCC recommended that, during these consultations, EPA bring its workplace concerns to the attention of OSHA but thereafter rely on the employer's responsibilities under the OSH Act and OSHA's expertise and regulatory program to assure that workers are protected from occupational risks. Thus, EPA would no longer consider workplace concerns in determining whether a new chemical "may present an unreasonable risk" under section 5(a)(3), in issuing orders to address such risks under section 5(e) or in promulgating SNURs under section 5(a)(2).

The NCC proposal would reverse and sweep away nearly forty years of precedent under the new chemicals program. From the inception of the program, EPA has addressed workplace risks during PMN reviews and used section 5(e) orders and SNURs to protect workers. Under EPA's 1979 PMN regulations, PMNs have been required to characterize employee exposure and describe workplace conditions. [25] Based on EPA's review of this information, hundreds of section 5(e) orders have required implementation of engineering controls, Personal Protective Equipment (PPE), and hazard labels and warnings. These worker protections have been carried over into SNURs applicable to all other manufacturers and processors of the PMN chemical. Both EPA's "boilerplate" section 5(e) order and its new chemical SNUR regulations codify in painstaking detail the range of worker protection requirements EPA may impose based on the nature and magnitude of the workplace risks it identifies.[26]

As the basis for dismantling these core elements of the PMN program, NCC points to a brief provision added to TSCA by LCSA and found in section 5(f)(5) of the amended law. This provision requires EPA to "consult" with OSHA "to the extent practicable" before adopting prohibitions or restrictions on new chemicals to "address workplace exposures." Nowhere does section 5(f)(5) say that EPA must defer to OSHA and stop regulating workplace exposures – a far-reaching policy change that would have been highlighted during the legislative process. And nowhere does it require EPA to "consult" OSHA on *every* new chemical – a burdensome and time-consuming undertaking – rather than simply engaging with OSHA periodically on its general approach to workplace protection under section 5.

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[23] October 16, 2017 Letter to Jeffrey Morris, OPPT Director, from SCHF, NRDC, Earthjustice and Environmental Health Strategy Center.

[24] December 1, 2017 Letter to Jeffrey Morris, OPPT Director, from Kathleen Roberts of the NCC. The letter indicates that NCC has 20 members but does not identify them.

[25] 40 CFR § 720.45

[26] 40 CFR § 721.63 and § 721.72

NCC recognizes that "EPA has an obligation to review and make determinations regarding worker exposure issues and to formulate and adopt TSCA Section 5(e) that include measures to protect workers."[27] It does not dispute that Congress strengthened this obligation in enacting LCSA by including workers in the definition of "potentially exposed or susceptible subpopulation" in section 3(12) and then directing EPA to ensure that these populations are protected from unreasonable risks in safety determinations under section 5(a)(3) and orders under sections 5(e) and (f). Yet NCC nonetheless argues that EPA should refuse to perform these obligations because the "OSHA regulatory scheme" will be adequate to address any unreasonable risks to workers that EPA identifies during PMN review.

The NCC proposal should be rejected both because it flies in the face of TSCA and because it rests on a distortion of OSHA's core authorities over new chemicals as compared to EPA's and a misleading understanding of how OSHA and employers interact in the real world.

To begin with, OSHA is only authorized to adopt workplace standards for chemicals presenting "significant risks of harm," a term interpreted by the Supreme Court's *Benzene* decision as requiring OSHA to demonstrate by substantial evidence that "it is at least more likely than not that long-term exposure to [a chemical] presents a significant risk of material health impairment."[28] Further, OSHA may impose only economically and technologically feasible limits on exposure.[29] The term "unreasonable risk" under TSCA does not demand the same demonstration of harm that OSHA must make and, as interpreted in LCSA, does not require or even allow EPA to consider costs and other nonrisk factors.[30] Indeed, under section 5, the standard for regulation under section 5(e) is whether a new chemical "may present" an unreasonable risk or lack sufficient information for a reasoned determination of risk. Thus, EPA is obligated to act on the basis of suggestive but inconclusive similarities between a new chemical and related substances known to be hazardous and even where there is no known risk but simply an absence of data. OSHA could not adopt a workplace standard based on this level of evidence.

Accordingly, workplace concerns for new chemicals that EPA is required to address under section 5 will generally not meet the criteria for action under the OSH Act. Not surprisingly, no PMN chemical has ever been subject to an OSHA workplace standard and, indeed, many existing chemicals posing demonstrated risks have avoided OSHA regulation because of the agency's limited resources and the time and effort required by the OSH Act's cumbersome rulemaking procedures.[31]

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[27] December 1, 2017 Letter at 3.

[28] *Industrial Union Department, AFL-CIO v. American Petroleum Institute,* 448 U.S. 607 (1980)

[29] *American Textile Manufacturers Institute, Inc. v. Donovan*, 452 U.S. 490, 508-11 (1981).

[30] Based on these considerations, EPA decided against referring to OSHA workplace risks from exposure to trichloroethylene (TCE) under section 9(a) of TSCA, even though OSHA had earlier promulgated a workplace standard for TCE. In deciding to address risks to workers through a section 6(a) rulemaking instead, EPA compared its authority under TSCA to eliminate these risks to that of OSHA, concluding that "there is no other federal law that provides authority to prevent or sufficiently reduce these . . . exposures." It further concluded that risks that EPA found to be "unreasonable" under TSCA might not be deemed "significant" by OSHA. 82 Federal Register 7432, 7454 (January 19, 2017).

[31] Since 1970, OSHA has promulgated complete occupational health standards including new permissible exposure limits (PELs) for 16 agents, and standards without PELs for 13 carcinogens. OSHA enforces PELs for an additional 500 or so agents. Many of these PELs date to the 1960s, or before, but OSHA has been unsuccessful in updating them. According to the Government Accountability Office, the average time that it takes OSHA to set a new standard is greater than seven years, and the promulgation of PELs takes considerably longer (https://www.gao.gov/assets/590/589825.pdf).

NCC suggests that, in the absence of an OSHA workplace standard, the OSH Act "General Duty Clause" would still require employers to address new chemical risks identified by EPA, making requirements to protect against these risks under section 5 redundant. However, the Clause (29 U.S.C. § 654) is extremely general. It requires employers to provide a workplace "free from recognized hazards that are causing or are likely to cause death or serious physical harm." The Occupational Safety & Health Review Commission has interpreted this provision, in the face of citations for chemical exposures, to require that OSHA demonstrate both that employees are exposed to a "significant risk of harm," the same evidentiary standard OSHA is required to meet as a precondition for regulation, and that the risk is generally recognized by the employer or its industry.[32] Because its burden of proof is so high in chemical exposure cases, OSHA has issued virtually no citations under this provision to protect against chemical exposures. What is more, citations bind only the cited employer to implement protections; they do not impose a rule of general applicability. With its resource constraints, OSHA has no practical ability to assess significant risks for the hundreds of new chemicals reviewed by EPA under TSCA, let alone to enforce the Clause against the many employers who have failed to implement workplace controls for these chemicals. Thus, "deferring" to OSHA will simply mean that workers are exposed to unsafe workplace conditions.

This is equally true for the OSHA Respiratory Protection Standard (29 CFR 1910.134), which NCC also argues should result in effective PPE requirements for new chemicals raising workplace concerns during PMN review. First, effective protection of workers from chemical exposures requires reliance on engineering controls; respirators should be the protection of last resort. Moreover, the Standard applies "In any workplace where respirators are necessary to protect the health of the employee." Thus, in the absence of a section 5(e) order, the Respirator Standard leaves it up to employer discretion to determine whether worker protections are necessary; the Standard imposes no independent duty to provide PPE for new chemicals in the absence of express EPA requirements. Again, the practical result will be that neither engineering controls nor respiratory protection will be afforded to workers breathing new chemicals that present potentially serious inhalation risks if EPA fails to require these protections under TSCA.

NCC warns of "overlapping authority . . . and duplicative, if not conflicting, requirements for workplace exposures" if EPA does not defer to OSHA. This is a red herring. There is in fact no "overlap" between OSHA and EPA for the simple reason that OSHA has not, and likely could not, regulate new chemicals. Nor is there a danger of "overlapping" and "conflicting" requirements" because EPA and OSHA regulate distinct categories of chemicals that do not overlap. On the contrary, TSCA enables and, in fact, requires EPA to fill a critical gap in worker protection that OSHA has not been able to, and likely could not, effectively address. EPA's role in addressing the workplace risks of new chemicals is one that Congress, industry and OSHA itself have accepted for nearly forty years and that LCSA in fact strengthened just 18 months ago. To eliminate that role would be irresponsible, dangerous to workers and contrary to law. It would be unlawful for EPA to re-write TSCA in the manner suggested by the NCC and it should reject the coalition's proposal without additional consideration.

We appreciate the opportunity to comment on EPA's new chemicals program and strongly urge EPA to reexamine its implementation of the PMN program and return to an approach that is both lawful and protective of public health and the environment.

[32] *Kastalon, Inc.* 12 OSH Cases (BNA) 1928 (Rev. Comm'n 1986).

If you have any questions about these comments, please contact SCHF counsel, Bob Sussman, at bobsussman1@comcast.net.

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