UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Comments of Safer Chemicals Healthy Families, Natural Resources Defense Council and Environmental Health Strategy Center on EPA's Working Approach for Making New Chemical Determinations under Section 5 of the Toxic Substances Control Act

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INTRODUCTON AND SUMMARY

Safer Chemicals Healthy Families (SCHF), Natural Resources Defense Council and Environmental Health Strategy Center submit these comments on the Environmental Protection Agency (EPA) December 2019 document "TSCA New Chemical Determinations: A Working Approach for Making Determinations" under section 5 of the Toxic Substances Control Act (TSCA)."[1] These organizations are 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.

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. EPA evaluates new chemicals by reviewing a premanufacture notice (PMN) submitted at least 90 days before the anticipated start of production. Where these chemicals raise concerns, section 5 requires EPA to use its broad authority to control their risks before they harm people and natural systems. In the absence of effective protections before the start of commercial production, unsafe new chemicals may cause significant harm that cannot be reversed once they are pervasive in the environment and embedded in the economy.

In 2016, Congress enacted the Frank R. Lautenberg Chemical Safety for the 21st Century Act (LCSA) amending TSCA. LCSA strengthened the section 5 program significantly following serious concerns about its effectiveness. The amendments require EPA to make an *affirmative determination of the potential risks of* every chemical for which a PMN is required 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. If EPA cannot make a determination that a new chemical is unlikely to present an unreasonable risk of injury under section 5(a)(3)(C), the new law requires EPA to restrict the chemical. These restrictions can be based on a finding that the new chemical presents or may present an unreasonable risk of injury, has the potential for substantial human exposure or environmental release and/or lacks sufficient information to permit a reasoned evaluation of its health and

[1] https://www.epa.gov/sites/production/files/2019-12/documents/new_chems_working_approach_-_12.20.19_final.pdf; 85 Federal Register 99 (January 2, 2020).

environmental effects. As under the original law, the vehicle for restricting chemical use and exposure in response to these findings is a legally enforceable order under TSCA section 5(e) or 5(f).

For the first 18 months after LCSA's enactment, EPA staff diligently implemented the new law, issuing numerous enforceable orders resulting in more thorough evaluations of new chemicals, greater protection against these chemicals' potential risks and increased testing to determine their health and environmental effects. However, in late 2017, EPA began to reverse this progress, replacing a review process grounded in TSCA and longstanding EPA policies with one that is legally dubious and that takes a major step backward in protecting health and the environment.

EPA's rollbacks were reflected in the New Chemicals Decision-Making Framework (Framework) issued in November 2017.[2] Our groups and others raised serious concerns about the Framework at EPA's December 6, 2017 public meeting and in written comments.[3] However, in the ensuing two years, EPA has not only continued to implement the Framework but adopted new policies that further erode the effectiveness of the new chemical program. The Working Approach retains the basic elements of the Framework and adds new elements that reduce protections against unsafe new chemicals. A key thrust of the Working Approach is to greatly scale back enforceable orders under TSCA section 5(e) and instead rely on voluntary actions by PMN submitters that provide no assurance of meaningful protection against known and suspected risks.

To measure the steady trend toward less meaningful scrutiny of new chemical risks, we looked at PMN dispositions that took effect in 2019. We found that during this year, EPA determined that 161 new chemicals were not likely to present unreasonable risks and did not warrant any restriction. By contrast, only 46 new chemicals – or 22 percent of the total – were regulated under section 5(e) orders. This is a complete reversal from the first 21 months following enactment of the new law, during which section 5(e) orders accounted for 74 percent of all PMNs. The result has been a dramatic reduction in restrictions on new chemical use, exposure and environmental release and a sharp decline in new chemical testing.

In these comments, we first examine the need for a robust review process for new chemicals that identifies and protects against their harmful effects before they become pervasive in the environment and economy. We then describe how Congress strengthened section 5 of TSCA in 2016 to enhance protections against unsafe new chemicals and increase testing.

The bulk of the comments explain how EPA, after initially implementing the new law effectively, has subverted the intent of Congress by eliminating meaningful review and control of all but a few new chemicals. As we explain more fully below, EPA has accomplished this rollback through a flawed framework for PMN review that departs from the letter and intent of TSCA:

Circumventing TSCA Requirements to Issue Section 5(e) Orders

As amended, TSCA requires EPA to evaluate new chemical risks under "conditions of use." TSCA defines this term to encompass "intended" uses described in a PMN, other "known" uses of the new chemical, and uses outside the PMN that are "reasonably foreseen." Previously, EPA would have issued a section 5(e) order

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

[3] Comments of Safer Chemicals Healthy Families, et al. on Progress Implementing the New Chemicals Review Program under the Amended Toxic Substances Control Act, January 20, 2018.

whenever it determined that the intended or reasonably foreseen uses of the new chemical may present an unreasonable risk. Now, however, EPA bypasses the need for an order using the following stratagems:

- When the intended conditions of use in the PMN raise health or environmental concerns, EPA encourages the submitter to amend the PMN by adding voluntary controls on exposure. Based on these PMN amendments, EPA then determines that the new chemical is "not likely to present an unreasonable risk" under TSCA section 5(a)(3)(C). Thus, EPA exempts the new chemical from 5(e) requirements by limiting its PMN review to changes in use conditions that the submitter did not initially propose and is under no legal obligation to implement.

- As TSCA expressly requires, EPA initially issued section 5(e) orders when it identified "reasonably foreseen" conditions of use of the PMN chemical, beyond the "intended" use conditions in the PMN, that would result in increases in exposure that may present an unreasonable risk of injury. However, even where "reasonably foreseen" future uses present potential risks, EPA now makes a "not likely to present an unreasonable risk" determination on the ground that these risks can be addressed under 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, TSCA is explicit that when EPA determines that a "reasonably foreseen" future use may present an unreasonable risk, "the Administrator *shall issue* an order" pursuant to section 5(e) (emphasis added). In section 5(f)(4), TSCA 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.

- EPA has further limited the scope of regulation under section 5 by narrowly defining the scope of "reasonably foreseen" uses to exclude future use scenarios that are plausible and foreseeable based on professional judgment and expert knowledge but may not be highly probable. This narrow definition enables EPA to exempt from any restriction future changes in use that could increase exposure and risk, either under a section 5(e) order or SNUR.

- In some cases, EPA has proposed SNURs for changes in use which it does not consider "reasonably foreseen" well after the expiration of the PMN review period, creating a time gap in which the PMN submitter or other manufacturers and processors can initiate the new use without any restriction. Since EPA has identified and is concerned about the change in use, it is hard to understand why it is not treating the new use as "reasonably foreseen." By avoiding this designation, EPA is weakening section 5 protections by increasing the likelihood that the new use is not controlled under a section 5(e) order or timely SNUR.

Eliminating Protections for At-Risk Workers

Enforceable protections for workers exposed to serious health risks from new chemicals have virtually disappeared from the PMN program, departing from EPA's longstanding reliance on section 5(e) orders requiring comprehensive worker protection programs for unsafe chemicals.

Since October 2018, EPA has issued 160 "not likely" determinations for new chemicals present in the workplace that its scientists have found may cause serious health effects, including developmental and reproductive harm, cancer, lung overload and neurotoxicity. In many of these cases, the Agency has acknowledged that worker exposure levels for these chemicals do not provide adequate protection under

the conditions of use described in PMNs. However, it has determined that unreasonable risks to workers are "not likely" because workers "are expected" to voluntarily use personal protective equipment (PPE), such as respirators and gloves, recommended in the PMN submitters' Safety Data Sheets (SDSs).

This "expectation" is undercut by EPA's own recognition in section 6 risk evaluations that PPE use is at best uneven and ineffective even when legally required and the advice of its Science Advisory Committee on Chemicals (SAAC) that determinations of unreasonable risk should not be based on the disproven assumption that PPE will reliably protect workers. Although EPA claims that employers must require use of PPE under OSHA regulations in the absence of any requirement under TSCA, this is a misinterpretation of OSHA policy. In reality, EPA's approach leaves workers vulnerable and unprotected under both TSCA and the Occupational Safety and Health (OSH) Act.

Requiring Virtually No Testing of New Chemicals

Although data included in PMNs submitted by industry remain extremely limited, the amount of new chemical testing underway is almost non-existent because EPA is taking virtually no steps to fill data gaps in PMNs. This violates EPA's obligation under section 5(a)(3)(B)(i) to restrict new chemicals and require testing where available information is insufficient to determine the chemicals' health and environmental effects. Although the PMN program uses modeling and other predictive tools to evaluate new chemicals in the absence of data, these tools are often less sensitive and precise than actual testing and either miss concerns for certain endpoints entirely or understate the level of potential risk. Thus, EPA's failure to require testing is greatly reducing the likelihood that harmful properties of new chemicals will be identified and addressed under section 5.

EPA is compounding the absence of testing by failing to apply the long-standing uncertainty factor (UF) of 10X that the Agency normally uses to account for database uncertainty in its assessment of chemical risks. Failure to apply this UF is resulting in benchmark Margins of Exposure (MOE) that provide inadequate protection and that understate the risks on which EPA bases its safety determinations under section 5(a)(3).

Lack of Transparency

EPA has taken useful steps to increase the availability of information about the PMN program on its website. However, important identifying information for PMNs and section 5(e) orders is still not readily searchable. In addition, the opportunity for public scrutiny of the basis for EPA's safety determinations remains very limited and informed oversight of the Agency's decisions on new chemicals is virtually impossible. For example, the EPA "not likely" determinations are largely boilerplate and provide little chemical-specific information that would shed light on EPA's conclusions about hazard and exposure and its methodology for assessing risk under conditions of use. What little information is contained in these determinations is frequently redacted as Confidential Business Information (CBI), creating large gaps in public understanding. EPA needs to enhance the depth and quality of its "not likely" determinations and reduce redaction of CBI consistent with TSCA transparency requirements. Otherwise, these determinations will be uninformative and thus fail to provide the accountability to the public that Congress required for EPA decisions not to regulate new chemicals.

I. 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 for 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, as well as requirements for testing, 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.[4]

When TSCA was enacted in 1976, Congress recognized that "none of the [existing] statutes provide the means for discovering adverse effects on health and environment before manufacture of new chemical substances." S. Rep. No. 94-698, at 5 (1976). As emphasized in the Senate report, "[t]he most effective and efficient time to prevent unreasonable risks to public health or the environment is prior to first manufacture. It is at this point that the costs of regulation in terms of human suffering, jobs lost, wasted capital expenditures, and other costs are lowest." Id.

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 PFAS 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 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."[5]

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).[6] 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.

[4] Since the inception of the PMN program in 1979, over 20,000 new chemicals have been reviewed by EPA.
[5] S. Rep. No. 114-67, 114th Cong., 1st Sess. (June 18, 2015) at 3.
[6] 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.

II. The 2016 TSCA Amendments Significantly Enhanced 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 for 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* . . ." (emphasis added) [7]

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

(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)).

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

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).[8] 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:[9]

> "[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 that do not reliably identify potential risks. 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."[10]

III. EPA Has Subverted the Intent of Congress by Circumventing the Need for Section 5(e) Orders for Most New Chemicals

For the 18 months 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 the great majority of new chemicals to section 5(e) orders, placing limits on human exposure and environmental release and increasing the amount of testing to better understand new chemical hazards.

[8] 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.
[9] See note 7.
[10] S. Rep. No. 114-67, supra, at 15.

Through April 2018, EPA issued section 5(e) orders for 352 PMN substances under the new law.[11] This represented 74 percent of all the chemicals completing PMN review following enactment of LCSA. The Agency determined that a much smaller number of new chemicals – 122 or 26 percent of the total completing review – were "not likely to present unreasonable risks" under section 5(a)(3)(C) and could be commercialized without restriction.

But even though EPA staff was doing exactly what Congress intended, the chemical industry mounted relentless and misleading attacks on EPA "overreaching." In response, the political leadership of EPA intervened to roll back the program improvements that the staff had adopted to comply with LCSA.

The 2017 Framework and now the 2019 Working Approach demonstrate the methods by which the Agency management has carried out this agenda. At the heart of this effort is the goal of 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. The flawed and legally dubious mechanisms EPA has used for this purpose are described below.

A. EPA Encourages Submitters to Modify the Intended Conditions of Use in the PMN and then Determines that the New Chemical Is Not Likely to Present an Unreasonable Risk Even Though the Submitter Is Not Legally Bound by the Modified Conditions of Use

As the first step in curtailing the use of orders, the Working Approach provides that EPA will evaluate the PMN substance based on the "intended" use conditions identified in the PMN. As explained in the Framework, where EPA identifies potential risks to health or the environment, it will ask PMN submitters to provide "written amendments to their submissions addressing those concerns" and will then "consider the conditions of use in those amended submissions to be the intended conditions of use."[12] Since its concerns would be "adequately addressed through amendment of the PMN," EPA would determine that the chemical is "not likely to present an unreasonable risk" under section 5(a)(3)(C) and can be manufactured and used without any restriction.[13]

Under this logic, the processing and use conditions that the manufacturer originally "intended" would be replaced by different measures recommended by the Agency. Once reflected in the amended PMN, these EPA-recommended measures would become the only "intended" conditions of use and would be deemed sufficient to avoid enforceable restrictions even though the commitments in the PMN are voluntary and non-binding.[14] Given the clear intent of original and amended TSCA to protect against new

[11] https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/statistics-new-chemicals-review (accessed on April 28, 2018)

[12] Framework at 2. As the Working Approach states at 9, "[w]here the submitters provide written amendments to the PMN, EPA generally identifies the conditions of use in these amended submissions to be the new conditions of use, where appropriate."

[13] Framework, at 4.

[14] EPA's long-standing position is that the statements submitters make in PMNs are not binding and enforceable. For example, EPA's standard PMN form provides that the "statements you make in this notice should reflect your best prediction of the anticipated facts regarding the chemical substance described herein." The form also contains boxes that give submitters the option to designate certain portions of the form as "binding." However, EPA's instructions for the form explain that checking these boxes is simply intended to help EPA craft a section 5(e) order or SNUR expeditiously and that "checking a 'binding' box in a PMN does not by itself prohibit the submitter from later deviating from the information (except chemical identity) reported in the form." USEPA. Premanufacture Notice for New Chemical Substances,

chemical risks through mandatory requirements under section 5(e), the fiction that voluntary EPA-devised measures are "intended" conditions of use and render these risks "not likely" defeats the purpose of the PMN program and turns the statute on its head.[15] By contrast, EPA previously made "may present an unreasonable risk" findings where the initial PMN submission raised health and environmental concerns and then used section 5(e) orders to impose enforceable restrictions that protect against the potential unreasonable risk.[16] This is plainly the path that Congress directed EPA to follow and EPA's failure to do so violates TSCA.

B. EPA Is Using SNURs, Not Section 5(e) Orders, For Reasonably Foreseen Conditions of Use that May Present Unreasonable Risks

EPA further reduces the issuance of section 5(e) orders by eliminating their application to "reasonably foreseen" conditions of use 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."

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

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https://www.epa.gov/sites/production/files/2012/documents/pmnviewonly.pdf. Obviously, if information designated "binding" does not preclude deviations by the submitter, all other information in the PMN is likewise subject to revision after the new chemical enters production.

[15] As discussed more fully below, the original "intended" conditions of use in the PMN, even if modified, should still be considered "reasonably foreseen" and trigger a section 5(e) order but EPA now makes "not likely" determinations in these instances because it believes SNURs are the correct vehicle for addressing "reasonably foreseen" uses that raise concern.

[16] Virtually all of the orders issued under the old and initially under the new law were based on the underlying methods of manufacture and processing and anticipated patterns of distribution and use described in the initial PMN. Where EPA then determined that additional controls were needed to reduce worker exposure, discharges to water or other exposure pathways, EPA's practice was to formalize them in an enforceable order. EPA's examples of section 5(e) orders at the December 14, 2016 public meeting on the new LCSA PMN requirements illustrate this approach. EPA Public Presentation on Reviewing New Chemicals Under the Toxic Substances Control Act, December 14, 2016. at 29-35. However, the Working Approach indicates (p. 3) that "[r]isk mitigating practices and controls identified in the submission . . . .are generally considered to be part of the intended conditions of use" and therefore will not be considered in determining the need for new chemical restrictions even though they are voluntary and unenforceable. To now consider voluntary risk management measures a basis for foregoing regulation of an unsafe chemical is contrary to the long-standing premise that has guided the PMN program.

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).[17]

Thus, if EPA identifies a 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 is "reasonably foreseen."

In comments filed with EPA on January 17, 2017, 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.[18]

For the 18 months 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 foreseen future uses and then issued section 5(e) orders restricting these uses where they may present unreasonable risks. Although compelled by the plain language of the law, EPA has now abandoned this approach.

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

[17] 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.

[18] 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 January 17, 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."

As reflected in the Working Approach, EPA's practice is to promulgate SNURs in lieu of section 5(e) orders where EPA identifies "reasonably foreseen" future uses of the new chemical that raise health or environmental concerns. Under EPA's approach, promulgation of a SNUR during the PMN review period enables the Agency to determine that a PMN chemical is "not likely" to present an unreasonable risk, and to forego a section 5(e) order, on the theory that the SNUR adequately addresses "reasonably foreseen" uses that otherwise would require a determination of potential unreasonable risk or insufficient information under section 5(a)(3)(B).

However, 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 that 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 disposal of such substance or to prohibit or limit any combination of such activities . . . under the *conditions of use* . . ."(emphasis added). Since "reasonably foreseen" uses are conditions of use, they must be addressed under a section 5(e) order if they raise health or environmental concerns.

By their terms, the SNUR provisions in section 5(a)(2) of TSCA do not apply to "new chemical substances" and thus come into play after a chemical has completed PMN review. In fact, in section 5(f)(4),[19] 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.[20]

Section 5(e) orders 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

[19] 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.

[20] EPA regulations provide a mechanism for issuing SNURs for section 5(e) and non-5(e) chemicals that have completed PMN review. 40 C.F.R. Part 721., 40 C.F.R. 721.170, which governs non-5(e) SNURs, is clear that they may only apply to "new chemical substances that have completed premanufacture review." EPA's current approach departs from this approach -- and thus is contrary to the SNUR regulations -- because it contemplates issuing a SNUR before the completion of PMN review.

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 promulgate a SNUR if it has issued a section 5(e) order, that deadline does not apply in the absence of an order. As a result, 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." However, in the absence of a 5(e) order, there is no required timetable in the law for promulgating a SNUR. 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.

- 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." 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. By contrast, no risk findings are required for SNURs and the level of protection that SNURs must afford is not defined in the law or EPA's Part 721 SNUR regulations. [21]

- 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). 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.[22] In the absence of a section 5(e) 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) order 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 EPA has determined that SNUR

[21] 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."

[22] 40 CFR Part 721, Subpart B

chemicals "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 "potentially exposed or susceptible subpopulations." However, protection of these vulnerable subpopulations is not expressly identified as a consideration in developing SNURs under section 5(a)(2).

- Amended TSCA explicitly provides that EPA determinations under section 5(a)(3) must be made "without consideration of costs or other nonrisk factors." However, the SNUR provisions in section 5(a)(2) do not rule out consideration of costs and other nonrisk factors.

- 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), the Agency would have no obligation to include testing provisions in SNURs and in fact none of the SNURs EPA has issued to-date for new chemicals include testing requirements.[23]

- 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.[24] 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.

- 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.[25] 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.

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.

D. EPA's Narrow Definition of "Reasonably Foreseen" Further Limits Meaningful Protection Against New Chemical Risks

The Working Approach explains that "[r]easonably foreseen conditions of use are future circumstances under which the Administrator *might expect* the new chemical to be manufactured, processed, distributed, used or disposed of" (emphasis added).[26] However, in practice, EPA defines "reasonably foreseen" more narrowly than this description would suggest.

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[23] 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.
[24] 40 CFR § 721.170(c)(2)
[25] https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/new-chemicals-program-boilerplates
[26] Working Approach at 4.

The Agency's "not likely" determinations consistently state that EPA in fact only considers future use conditions that the "Administrator expects" as opposed to those he "might expect."[27] This difference in wording is significant and indicates that EPA equates "reasonably foreseen" with "highly probable" and therefore excludes changes in use conditions that are plausible and reasonably anticipated based on professional judgment and experience but not certain to occur. Confirming this narrow approach, the "not likely" determinations further explain that:[28]

> The identification of 'reasonably foreseen' conditions of use will necessarily be a case-by-case determination and will be highly fact-specific. Reasonably foreseen conditions of use will not be based on hypotheticals or conjecture. EPA's identification of conditions of use includes the expectation of compliance with federal and state laws, such as worker protection standards or disposal restrictions, unless case-specific facts indicate otherwise. Accordingly, EPA will apply its professional judgment, experience, and discretion when considering such factors as evidence of current use of the new chemical substance outside the United States, evidence that the PMN substance is sufficiently likely to be used for the same purposes as existing chemical substances that are structurally analogous to the new chemical substance, and conditions of use identified in an initial PMN submission that the submitter omits in a revised PMN.

Thus, EPA demands actual evidence that the future use either exists already (because it is occurring outside the United States) or is highly probable (because it is an existing use for an analogue to the PMN substance and the new chemical is "likely to be used for the same purposes" since it already has uses in common with the analogue).[29] This approach greatly narrows the universe of "reasonably foreseen" uses by excluding uses that are plausible because of the new chemical's properties, the range of known uses for the chemical class to which it belongs, or the processing methods and environmental release controls common in the industry sector where the new chemical will be manufactured and used.[30]

The consequence of EPA's approach is that the great majority of "not likely" determinations state that "EPA evaluated whether there are reasonably foreseen conditions of use and found none." Of the 479 determinations since enactment of the new law, only 68 SNURs (or 14 percent) have been issued based on "reasonably foreseen" future uses.[31] This underscores how EPA has defined "reasonably foreseen"

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[27] See, e.g. TSCA Section 5(a)(3) Determination for Premanufacture Notice (PMN) P-18-0328, https://www.epa.gov/sites/production/files/2020-01/documents/p-18-0328_determination_non-cbi_final.pdf

[28] Id.

[29] The Working Approach states (at 8) that "[w]hen there is at least one use in common with an intended condition of use for the new chemical, EPA may determine that it is reasonable to foresee that the new chemical substance will be used in the same additional way(s) as the associated analogue."

[30] EPA also indicates in the Working Approach (at. 9) that "conditions of use that were identified in an initial notice and later omitted in an amended submission may be determined to be reasonably foreseen conditions of use." However, EPA has infrequently used this approach. For example, where EPA recommends that the SDS for a new chemical specify use of PPE and the submitter amends the PMN accordingly, it would be "reasonably foreseen" that other manufacturers of the new chemical or downstream users would not make similar PPE recommendations in their SDSs. However, EPA has never issued a SNUR defining failure to amend an SDSs to recommend PPE as a significant new use.

[31] As shown in a recent blog by EDF, the great bulk of these SNURs were proposed *after* the "not likely" determination despite EPA's statement in the Working Approach (p. 6) that "[i} the absence of the SNUR, such a determination by EPA would not be possible." EDF also shows that very few of these SNURs have been finalized. http://blogs.edf.org/health/2020/01/10/the-trump-epa-says-precede-means-

far more narrowly than its natural meaning. EPA must broaden the definition so that future uses of the new chemical raising environmental or health concerns don't fall between the cracks.

E. SNURs Proposed Long After "Not Likely" Determinations and the Expiration of the PMN Review Period Do Not Provide Adequate Protection Against New Uses That May be Unsafe

The Working Approach indicates (p. 7) that EPA is also proposing SNURs after it has issued "not likely" determinations and the PMN review period has expired "where EPA has identified other circumstances that – should they occur in the future, even if not reasonably foreseen – may present risk concerns." According to EDF,[32] such SNURs have been proposed for 84 PMN substances. Because these SNUR proposals often are issued many months after the completion of PMN review, there is a time gap in which the PMN submitter or other manufacturers and processors can initiate the new use without any restriction and would then be exempt from the SNUR once it is finally proposed.[33] Since EPA has identified and is concerned about the change in use that the SNUR would address, it seems obvious that the use is "reasonably foreseen." EPA's reluctance to treat the use as such may reflect a desire to conserve resources, but this does not justify putting the public at risk by allowing the commercialization of the new chemical without a section 5(e) order.

In sum, EPA's abandonment of 5(e) orders in favor of "not likely" determinations and SNURs violates TSCA and weakens protection of public health and the environment. EPA should revise the Working Approach to restore section 5(e) orders to their primary role in addressing the risks of new chemicals, as Congress intended.

IV. EPA's Many "Not Likely" Determinations for Chemicals Posing Risks to Workers Violate TSCA and Accepted Workplace Protection Policies

A. EPA Has Replaced Section 5(e) Orders Imposing Enforceable Workplace Controls with Reliance on Voluntary PPE Use Based on Unenforceable Recommendations in Safety Data Sheets

Starting in October 2018, EPA greatly reduced the level of protection it provides to workers exposed to new chemicals subject to section 5. This change in approach eliminated the enforceable worker safeguards that EPA had previously required for hundreds of new chemicals of concern under the TSCA PMN program and left workers exposed to new chemicals at risk of harmful health effects.

Following enactment of the new law and for the first 18 months, EPA made "not likely" determinations only for chemicals it believed had low toxicity to humans and the environment based on test data on the

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[32] Id.

[33] As the Working Approach notes at 6, once a final SNUR is issued, the date on which the SNUR was proposed determines whether a new use is subject to the SNUR. That's one reason why EPA has emphasized the need to propose SNURs for reasonably foreseen uses *before* making a "not likely" determination. The longer EPA waits to propose a SNUR, the greater the possibility that either the PMN submitter or another company will initiate the use, making it no longer "new" and therefore beyond the reach of the SNUR.

PMN substance or analogues. Where EPA identified the potential for serious health effects, it determined that the new chemical "may present an unreasonable risk" under section 5(a)(3)(B)(ii) and then imposed restrictions on the chemical's use through an order issued under TSCA section 5(e).

For chemicals posing health risks to workers, these orders contained detailed "standard" provisions that were developed before TSCA was amended in 2016 and have long been incorporated in EPA's "boilerplate" section 5(e) order.[34] These provisions require worker exposures to be reduced through a combination of engineering controls, the use of Personal Protective Equipment (PPE), and training, labeling and hazard communication programs. These measures must be implemented throughout the new chemical's supply chain, i.e. during both manufacturing and downstream processing and use. The orders also frequently require testing to better characterize the potential adverse effects of the new chemical and provide more reliable data for assessing worker risks. By including these requirements in a section 5(e) order, EPA made them enforceable under sections 15, 16 and 17 of TSCA.

In contrast to its earlier approach, EPA is now making "not likely" determinations for numerous chemicals *that its scientists have found may cause serious adverse health effects to workers*. EPA principally identifies these potential effects on the basis of data on structural analogues since very few PMNs include data on the new chemical itself. EPA's "not likely" determinations cite numerous endpoints of concern, including reproductive and developmental toxicity, sensitization, liver, bladder, blood and kidney toxicity, lung overload and carcinogenicity.

To assess the level of risk for these endpoints, EPA's determinations typically calculate a Margin of Exposure (MOE) between anticipated worker exposure levels and concentrations at which the chemical is expected to have adverse effects. To make this comparison, EPA calculates a "benchmark" MOE that it considers adequately protective, taking into account uncertainty factors. If the actual MOE is smaller than the benchmark MOE, EPA concludes that workers are at risk-- i.e. potentially exposed to levels of the substance that cause adverse health effects.

In these instances, EPA previously would have issued a section 5(e) order based on a finding that the new substance does or may present an unreasonable risk, and the order would have required the PMN submitter to reduce exposure to levels that protect against that risk. Now, however, EPA finds that workers will be protected from adverse health effects based on the unsupported assumption that all workers will use PPE (gloves, goggles and respirators) that it claims will prevent exposure. Based on these anticipated protections, EPA then concludes that the chemical is "not likely" to present an unreasonable risk to worker health.

Between October 5, 2018 and January 31, 2020, EPA issued 160 "not likely" determinations for new substances with worker exposure that were found to have the potential for serious health effects.[35] A majority of these determinations also concluded that MOEs for workers were insufficiently protective

[34] These provisions are reflected in EPA's "boilerplate" section 5(e) order, available at https://www.epa.gov/sites/production/files/2016-09/documents/co_all_purpose_preamble_and_consent_order_combined_9-1-2016_clean.pdf.

[35] Some of these determinations are also subject to SNURs but these SNURs do not address the risks to workers' health identified in the "not likely" determinations. Over this timeframe, EPA has also proposed SNURs for other PMN chemicals for which it has made "not likely" determinations but these SNURs and determinations are based on different health and environmental concerns and do not directly involve unsafe worker exposures to chemicals with the potential to cause serious health effects.

but that voluntary use of PPE would prevent harm. In some cases, the MOEs were significantly below EPA benchmarks.

In contrast to previous section 5(e) orders obligating PMN submitters to require use of PPE, these "not likely" determinations rely on the assumption of voluntary action by employers. EPA "expects" effective use of PPE based on PMN submitters' commitments to amend their SDSs so they recommend use of gloves and/or respirators. Several of the determinations state that:[36]

> "EPA expects that workers will use appropriate personal protective equipment (i.e., impervious gloves, respirator), consistent with the Safety Data Sheet prepared by the PMN submitter, in a manner adequate to protect them."

Although EPA relies on the SDS to ensure that workers use adequate and protective PPE, these SDSs are not included or described in the "not likely" determinations. As a result, the determination does not enable the public to judge whether the SDSs effectively describe the hazards of the PMN substance and the recommended measures to reduce exposure.[37] Nor is there any assurance that the "approved" SDS will remain in use. Because the SDS is not enforceable under TSCA, the PMN submitter can change it to remove any reference to PPE without incurring any penalty or risking EPA enforcement action. Similarly, other companies are free to manufacture or process the PMN substance using different SDSs.

Moreover, in the absence of a section 5(e) order, the submitter has no obligation under TSCA to ensure that its employees in fact use PPE at its own facilities or to communicate the hazards of the PMN substance and recommended precautions to downstream users and ensure that they implement PPE. Thus, if PPE are not consistently and effectively used and workers are at risk, no remedy is available to EPA under TSCA. This will unavoidably mean that more workers – who are identified in TSCA as a potentially exposed or susceptible subpopulation warranting protection against unreasonable risks -- will suffer from disease and illness as a result of avoidable workplace exposure to chemicals that EPA scientists recognize are likely unsafe.

B. Contrary to EPA, OSHA Regulations Place no Obligation on Employers to Implement PPE that Are Not Required by a Chemical-Specific OSHA Standard

EPA claims in the Working Approach that the "requirements set forth by the Occupational Safety and Health Administration (OSHA), including OSHA's worker protection standard, require employers to provide and have affected employees use PPE wherever it is necessary by reason of hazards present in the workplace."[38] Apparently EPA believes that, although PPE is not legally required under TSCA, employers are obligated by OSHA regulations to implement any PPE recommended in the PMN submitter's SDS. On this basis, EPA misleadingly suggests, OSHA regulations provide sufficient assurance

[36] See, e.g., TSCA Section 5(a)(3) Determination for Premanufacture Notice (PMN) P-17-0233, https://www.epa.gov/sites/production/files/2020-01/documents/p-17-0233_determination_non-cbi_final.pdf

[37] In theory, the revised SDS is available through Chem View as an attachment to the amended PMN. However, many SDSs have been claimed to be Confidential Business Information (CBI) and are not part of the public PMN file. In addition, searching through the PMN submission and various amendments and attachments is confusing and identifying the final revised SDS can be difficult. Where SDSs are publicly available, their contents often raise concerns. In some cases, we have found SDSs that mention the need for PPE but fail to provide a meaningful description of the potential hazards of the PMN substance that would highlight to users why use of the PPE is important and the health consequences that might follow if PPE is not used effectively or at all.

[38] Working Approach, at 8.

of worker protection to conclude that the new chemical is "not likely to present an unreasonable risk" under section 5. Unfortunately, EPA misreads OSHA regulations and overstates their requirements.

To begin with, OSHA is only authorized to regulate 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."[39] Further, OSHA may impose only economically and technologically feasible limits on exposure.[40] The term "unreasonable risk" under TSCA does not demand the same demonstration of harm and does not require or even allow EPA to consider costs and other nonrisk factors.[41] Indeed, under section 5, new chemicals are reviewed based on limited data and similarities to other chemicals. OSHA could not adopt a workplace standard based on this level of evidence. Accordingly, workplace concerns for new chemicals 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.

In the absence of an applicable workplace standard, OSHA regulations give employers wide latitude to interpret evidence of workplace risks and to select worker protection measures they deem appropriate. Thus, OSHA's worker protection standard requires employers to assess the hazards workers face but to provide PPE only when the employer deems such measures "necessary." [42] This is also true for the OSHA Respiratory Protection Standard (29 CFR 1910.134), which likewise applies only "where respirators are necessary to protect the health of the employee." Should the PMN submitter or downstream users conclude that PPE are unnecessary because the hazards of the PMN substance are not documented or for other reasons, OSHA will have no recourse against the employer under these standards.

Nor could OSHA require the PMN submitter and downstream users to implement PPE because they are recommended in a voluntary SDS included in the PMN. OSHA regulations do not require employers to follow the recommendations in an SDS, and the preamble to OSHA's hazard communication rule expressly states that "there is no requirement for employers to implement the recommended controls."[43]

The OSH Act "General Duty Clause" (29 U.S.C. § 654) similarly would not require employers to address new chemical risks identified by EPA in the absence of a section 5(e) order. The Clause 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

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

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

[41] 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).

[42] 29 C.F.R. § 1910.132(a).

[43] Hazard Communication, 77 Fed. Reg. 17574, 17693 (Mar. 26, 2012).

required to meet as a precondition for regulation, and that the risk is generally recognized by the employer or its industry.[44] 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.

Most importantly, both OSHA and NIOSH, for almost 50 years, have repeatedly taken the position that PPE are worker exposure controls of last resort because of their limited effectiveness. OSHA and NIOSH manage chemical risks using the "hierarchy of controls," under which hazard elimination, substitution, engineering and administrative controls are all prioritized over the use of PPE.[45] As explained by NIOSH, "[t]he hierarchy of controls normally leads to the implementation of inherently safer systems" because chemical regulation and substitution are "more effective and protective" than PPE.[46] EPA's own draft risk evaluation for 1,4-dioxane under section 6(b) of TSCA likewise recognizes that "[t]he most effective controls are elimination, substitution, or engineering controls [and that] "[r]espirators, and any other personal protective equipment. . . , should only be considered when process design and engineering controls cannot reduce workplace exposure to an acceptable level."[47]

Although the hierarchy of controls would dictate that EPA first address workplace risks through process design and engineering controls, EPA's focus upon identifying such risks is solely on "whether the risks would be mitigated by the use of PPE."[48] EPA's 5(e) orders previously imposed enforceable process controls and use restrictions along with PPE requirements but in the "not likely" determinations, EPA is now relying entirely on PPE, which OSHA and NIOSH consider the least preferred and protective means of preventing harmful worker exposure.

C. EPA's Risk Evaluations under Section 6 of TSCA Acknowledge the Absence of Evidence that Workers Consistently Wear Respirators and Gloves

In the initial risk evaluations EPA is conducting on commercially established existing chemicals under section 6(b) of TSCA, EPA likewise concludes that unsafe occupational exposures do not present an unreasonable risk because use of PPE will adequately protect workers. EPA bases this conclusion on the

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

[45] OSH, Ctrs. for Disease Control & Prevention, updated Jan. 13, 2015, https://www.cdc.gov/niosh/topics/hierarchy/.

[46] See also, e.g., 29 C.F.R. § 1926.55 (to prevent employee exposure to inhalation, ingestion, skin absorption or contact with substances above safe levels, "engineering controls must first be implemented whenever feasible. When such controls are not feasible to achieve full compliance, protective equipment or other protective measures shall be used . . . ."); Id. § 1910.134(a)(1) (to control occupational disease due to contaminated air, "the primary objective shall be to prevent atmospheric contamination. This shall be accomplished as far as feasible by accepted engineering control measures (for example, enclosure or confinement of the operation, general and local ventilation, and substitution of less toxic materials). When effective engineering controls are not feasible, or while they are being instituted, appropriate respirators shall be used . . . .")

[47] Draft Risk Evaluation for 1,4-Dioxane, June 2019, at 52, available at https://www.epa.gov/sites/production/files/2019-06/documents/1_14-dioxane_draft_risk_evaluation_06-27-2019.pdf.

[48] Working Approach, at 8.

assumptions that that "workers and occupational non-users wear respirators for the entire duration of the work activity throughout their career" and "are properly trained and fitted on respirator use." According to EPA, "similar assumptions apply to the use of gloves and their expected elimination of any dermal exposure."[49]

However, the draft evaluations repeatedly acknowledge that EPA has no real-world evidence to support these assumptions. Thus, in the methylene chloride (MC) draft evaluation,[50] it admits that:

- "[N]o data were found about the overall prevalence of the use of respirators to reduce DCM exposures and it was not possible to estimate the numbers of workers who have reduced exposures due to the use of respirators."
- "Regarding glove use, data about the frequency of effective glove use – that is, the proper use of effective gloves – is very limited in industrial settings. Initial literature review suggests that there is unlikely to be sufficient data to justify a specific probability distribution for effective glove use for a chemical or industry."

The 1-Bromopropane (1-BP) draft risk evaluation[51] similarly acknowledges that "[f]ew literature sources indicate the use of respirators in 1-BP conditions of use." Along the same lines, the 1,4-dioxane evaluation[52] recognizes that "[t]he use of a respirator would not necessarily resolve inhalation exposures since it cannot be assumed that employers have or will implement comprehensive respiratory protection programs for their employees."[53] It adds that gloves provide effective protection only "if proven impervious to the hazardous chemical, and if worn on clean hands and replaced when contaminated or compromised."[54]

As EPA further explained in its draft evaluation for N-methylpyrrolidone (NMP):[55]

> Overall, EPA understands that workers may potentially wear gloves but does not know the likelihood that workers wear gloves of the proper type and have training on the proper usage of gloves. Some sources indicate that workers wear chemical-resistant gloves (Meier et al., 2013; OECD, 2009a; NICNAS, 2001), while others indicate that workers likely wear gloves that are more permeable than chemical-resistant gloves (RIVM, 2013). No information on employee

[49] Draft Risk Evaluation for HBCD, June 2019, available at https://www.epa.gov/sites/production/files/2019-07/documents/hbcd_draft_risk_evaluation_062719_hero_link_0.pdf, at 381.
[50] Draft Risk Evaluation for Methylene Chloride, October 2019, at 690, 110, available at https://www.epa.gov/sites/production/files/2019-10/documents/1_methylene_chloride_risk_evaluation_peer_review_draft_heronet_public.pdf. (MC Risk Evaluation).
[51] Draft Risk Evaluation for 1-Bromopropane, August 2019 at 57, available at https://www.epa.gov/sites/production/files/2019-08/documents/01._1-bp_draft_risk_evaluation_hero_links_external.pdf.
[52] https://www.epa.gov/sites/production/files/2019-06/documents/1_14-dioxane_draft_risk_evaluation_06-27-2019.pdf
[53] Note 47, at 53.
[54] Id at 180.
[55] Draft Risk Evaluation for N-methylpyrrolidone, October 2019, at 68, available at https://www.epa.gov/sites/production/files/2019-11/documents/1_draft_risk_evaluation_for_n-methylpyrrolidone_110419_public.pdf.

> training was found. Data on the prevalence of glove use is not available for most uses of NMP. One anecdotal survey of glove usage among workers performing graffiti removal indicates that 87% of workers wear gloves, although the glove materials varied and were sometimes not protective; only a small fraction of these workers used gloves made of optimal material for protection against NMP and some used cloth or leather gloves (Anundi et al., 2000).

EPA has previously rejected reliance on respirators as a basis for protecting workers against unreasonable risks under section 6 of TSCA. In its January 2017 proposed ban on MC paint removers under section 6(a), EPA acknowledged that "not all workers may be able to wear respirators . . . Individuals with impaired lung function due to asthma, emphysema, or chronic obstructive pulmonary disease, for example, may be physically unable to wear a respirator."[56] EPA further observed that "individuals with facial hair, like beards or sideburns that interfere with a proper face-to-respirator seal, cannot wear tight fitting respirators," and "respirators may also present communication problems, vision problems, worker fatigue, and reduced work efficiency."[57] For these reasons, EPA concluded that it would not impose a respirator requirement in lieu of a ban on MC paint removers since respirators would not eliminate the unreasonable risk presented by these products.

Consistent with EPA's analysis, in a 2016 letter to the Agency, the Assistant Secretary responsible for OSHA wrote that respirators are the "least satisfactory approach to exposure control," explaining that:

> ". . . to be effective, respirators must be individually selected, fitted and periodically
>
> refitted, conscientiously and properly worn, regularly maintained, and replaced as necessary. The absence of any one of these conditions can reduce or eliminate the protection the respirator provides.
>
> Respirator effectiveness ultimately relies on the practices of individual workers who must wear them. . . Furthermore, respirators can impose substantial physiological burdens on workers, including the burden imposed by the weight of the respirator; increased breathing resistance during operation; limitations on auditory, visual, and olfactory sensations; and isolation from the workplace environment."[58]

NIOSH has found that respirator programs often provide inadequate protection even where respirator use is legally required. As cited in EPA's draft risk evaluation for carbon tetrachloride (p.63), a NIOSH survey found that establishments subject to respirator requirements had the following program deficiencies:[59]

- 59% provided training to workers on respirator use;
- 34% had a written respiratory protection program;

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[56] 82 Fed. Reg. 7464, 7479 (January 19, 2017).
[57] *Id.*
[58] Letter from David Michaels, PhD, MPH, Assistant Secretary, U.S. Dep't of Labor, Occupational Safety & Health Admin., to James J. Jones, Assistant Administrator, U.S. EPA, Office of Chem. Safety & Pollution Prevention (Oct. 25, 2016), found at https://www.regulations.gov/document?D=EPA-HQ-OPPT-2014-0650-0041
[59] NIOSH, Respirator Usage in Private Sector Firms, 2001, https://www.cdc.gov/niosh/docs/respsurv/

- 47% performed an assessment of the employees' medical fitness to wear respirators;
- 24% included air sampling to determine respirator selection.

As these findings demonstrate, effective use of PPE requires clear and understandable hazard warnings and directions for safe use together with adequate employee training, monitoring and testing. Although earlier EPA section 5(e) orders and SNURS required these measures as part of comprehensive worker protection programs, the EPA "not likely" determinations place sole reliance on voluntary SDSs to compel use of PPE. Without a comprehensive worker protection program to ensure that gloves and respirators are used when necessary and in fact provide effective protection, it is highly doubtful that recommending PPE in SDSs will in itself result in reliable and consistent PPE use.

As described above, the hierarchy of controls should provide the framework for protecting workers under the PMN program. Under this framework, engineering controls, chemical substitution and other measures should be the primary approach for eliminating unreasonable risks and PPE should be required as a last resort if these measures are not feasible. However, where PPE are necessary, their use should be mandatory, not voluntary, and should be one element of a comprehensive training, monitoring, and hazard communication program required under a section 5(e) order. The absence of such a legally enforceable worker protection program is a further reason why EPA's "not likely" determinations for new chemicals putting workers at risk are unjustified.

D. SACC Has Consistently Questioned EPA's Assumption of Universal PPE Use

In each of its reviews of draft evaluations, EPA's Science Advisory Committee on Chemicals (SAAC) has repeatedly raised concerns about EPA's undue reliance on voluntary PPE use to determine that chemicals of concern do not present unreasonable risks to workers. The SAAC's concerns are directly relevant to EPA's "not likely" determinations for new chemicals posing risks to workers.

In its report on the Pigment Violet 29 (PV29) draft, the SAAC noted that "the analysis in the Evaluation does not discuss or account for the fact that downstream commercial users may be oblivious to chemical risks and lack even rudimentary industrial hygiene measures."[60] Similarly, in reviewing the 1,4-dioxane evaluation, the SACC concluded that the "consensus of the Committee believes that PPE may not be consistently and properly worn, as EPA assumed"[61] and noted that "[g]love use should not always be assumed to be protective" and, if worn improperly, gloves "could actually lead to higher exposures."[62] The SACC emphasized that, "[b]ecause respirators are inherently uncomfortable and potentially unreliable for long-term use, the use of respirators for more than relatively short terms is not considered appropriate in typical industrial hygiene practice." As it concluded, "8-hour use of PPE should not be used in the risk characterization of inhaled 1,4-Dioxane. Risk estimates should be presented without the use of PPE as reasonable worst case."[63]

[60] SACC Report on PV29 at 37.
[61] SACC Report on 1,4-dioxane and HBCD, at 86. These "heighted exposures" could occur as a result of "contamination of the interior of the glove" (if workers were not properly trained in glove use and replacement) or by "acting as a reservoir" for contaminants (if the gloves were not impermeable).
[62] SACC Report on 1,4-dioxane and HBCD, at 55.
[63] Id. at 53.

In the case of HBCD, the SACC noted that "it was unreasonable to assume workers would wear PPE for entire 8-hour shifts due to underlying medical conditions, facial hair, discomfort, and other issues" and added that:[64]

> [M]any members of the Committee believed EPA should place more emphasis on the limited likelihood that respiratory protection will be adopted without specific occupational exposure guidelines for HBCD . . . Dust exposures in the construction trades (especially residential construction) continue to represent an occupational health concern because of the many small-to-medium size operators and the use of temporary (and, not infrequently, undocumented) workers. Workers in these small-to-medium enterprises may not be likely to adopt personal protective equipment (PPE) controls, so EPA's characterization of reasonable risk relying on use of PPE is not sufficiently supported by the practical realities of many workplaces.

The SACC report on 1-BP provides further amplification of these concerns:[65]

> The DRE document utilizes respirator protection factor (APF) values and assumes that respirators will be used by workers. The Committee observed that while this may be accurate for larger professional organizations with resources, awareness, and knowledge, it is very likely that smaller establishments and family owned businesses (e.g., dry cleaners) will not likely use or properly utilize personal protective equipment (PPE). One Committee member highlighted the Blando et al., 2010 article, where dry cleaners did not use PPE or if a respirator was available, it was not the properly assigned respirator. The CDC MMWR study from 2008 (CDC, 2008) demonstrated that the dry cleaning index case and the case from the wave solder room in Pennsylvania did not properly operate its PPE. The wave solder case did not use respiratory protection and had a non-working cooling coil at the top of the open top batch degreaser. These experiences documented in the published papers demonstrate the difficulty of relying on PPE use for employee protection.
>
> One member noted that the Committee has now received public testimony from two former highly distinguished Occupational Safety and Health Administration (OSHA) administrators expressing concerns regarding EPA's reliance upon non-regulatory guidance and PPE to reduce risks to reasonable levels. Persons familiar with PPE use realize that nominal protection factors may not be achieved in actual practice. The most recent of these comments also noted that compounds with high vapor pressures (such as 1-BP) may "breakthrough" cartridge type respirators in time frames much shorter than a work shift. Since respirators do not have real-time indicators of remaining capacity, respiratory protection failure is more likely for high vapor pressure compounds. 1-Bromopropane also is known to penetrate many glove types. This increases the likelihood of failure to select an appropriate glove.

The SACC concluded that EPA "[a]ssumptions about PPE use are likely unrealistic for many of the scenarios and so the determination of whether a condition of use results in an acceptable or unacceptable risk should be based on no PPE use, with the possible exception of in a manufacturing facility."[66]

[64] Id at 118.
[65] SACC Report on 1-BP, at 30-31.
[66] Id at 66.

In sum, while EPA may "expect" that workers will voluntarily use PPE "in a manner adequate to protect them," the lack of any enforceable requirement to use PPE under TSCA or the OSH Act, coupled with the inherent limitations of PPE in preventing exposure, call this expectation into serious question. With no justification to conclude that exposed workers will be adequately protected, a determination that these workers are "not likely" to be at risk of harmful health effects is without any basis. Where EPA finds that a chemical is potentially hazardous to workers, TSCA obligates EPA to determine that the chemical "may present an unreasonable risk of injury" – thereby triggering a section 5(e) order imposing the mandatory workplace controls that EPA has historically included in such orders. EPA's failure to follow this course violates TSCA.

V. EPA Is Failing to Use Its Expanded Authority under TSCA to Require Testing of New Chemicals for Which Insufficient Information Is Available

Concerned about the minimal amount of testing on new chemicals, Congress strengthened TSCA in 2016 by requiring EPA to issue section 5(e) orders where it determines that available information is "insufficient to permit a reasoned evaluation of the health and environmental effects" of the PMN substance under section 5(a)(3)(B)(i). Because EPA no longer must find that the new chemical "may present an unreasonable risk" in order to justify testing, this new authority enables EPA to require development of data whenever data gaps prevent a full and informed determination of the chemical's adverse effects. In such cases, the section 5(e) order issued by EPA would require testing and limit exposure while data are being developed.

However, the shift away from section 5(e) orders and marked increase in "not likely" determinations under recent EPA policies have been accompanied by a significant reduction in required testing on new chemicals. Not only do these determinations find that the new chemical lacks the potential for unreasonable risk under its conditions of use, but they also effectively conclude that sufficient information is available to support this determination. The determinations do not describe the basis for this conclusion. Either they ignore the sufficiency of the available data entirely or they contain the conclusory statements like the following:[67]

> the information available to EPA is sufficient to permit the Agency to conduct a reasoned evaluation of the health and environmental effects of the chemical substance under the conditions of use . . . in order to determine that the chemical substance is not likely to present an unreasonable risk under those conditions of use. As such, EPA does not need to impose testing requirements to conduct this evaluation.

Moreover, where EPA decides to issue a SNUR because it has identified "reasonably foreseen" conditions of use that may present an unreasonable risk, the SNUR need not require testing. As stated in some "not likely" determinations, "[t]o the extent that testing may be necessary to conduct a reasoned evaluation of the health or environmental effects of the reasonably foreseen conditions of use that are

[67] See, e.g., TSCA Section 5(a)(3)(C) Determination for Premanufacture Number (PMN) P-18-0236, https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/tsca-section-5a3c-determination-360

subject to the proposed SNUR, EPA will make the appropriate determination if a SNUN is submitted following finalization of the SNUR."[68]

Previously, section 5(e) orders imposed the level of protection warranted by information available at the time of PMN review but required the submitter to conduct additional testing to support a more definitive risk evaluation. This approach recognized that further testing could demonstrate more serious or different hazards than EPA initially identified and thus call into question EPA's initial assumptions about the level of protection and accompanying control measures necessary to prevent risks to workers and other exposed populations. However, EPA's recent "not likely" determinations abandon this approach, instead assuming without explanation that available information is sufficient and no further data is needed. EPA's across-the-board dismissal of the need for testing for nearly all new chemicals effectively makes the expanded authority in section 5(a)(3)(B)(i) a dead letter.[69]

The Working Approach states that "[t]est data can reduce uncertainty in the risk assessment . . . [but] EPA does not believe that a single definition [of sufficient information] would be appropriate . . . [g]iven the case-by-case nature of the hazard and exposure scenarios, and the variability in what could be considered 'sufficient' information for a particular assessment." EPA further maintains that "'[s]ufficient information does not necessarily mean complete or perfect information . . . [and] need not necessarily be data on the actual chemical substance" as opposed to an analogue.[70]

These statements indicate when EPA will not require testing, but they shed no light on the criteria EPA would use in identifying PMNs that lack sufficient information and do warrant testing. EPA may not need a single definition of "sufficiency," but the Working Approach should at a minimum provide concrete examples of situations where more data are needed for a reasoned evaluation of the PMN substance's health and environmental effects. Without these examples, the Working Approach, like EPA's many "not likely" determinations, conveys the message that additional testing will be the rare exception and not the norm.

For many PMNs, the case for further testing will be a strong one. For example, EPA's "not likely" determinations often rely on data on analogues and not the PMN substance itself. However, the relevance of analogues to the PMN substance may be uncertain. Some analogues may be "weak" predictors of the new chemical's toxicity because of differences in molecular structure that could result in different modes of biological activity. Other analogues, while seemingly better surrogates for the new chemical, may not cause adverse health or environmental effects in the same species or target organs or at the same doses. In these cases, reliance on studies on the analogue may result in assessments that overlook effects of concern or determine "safe" levels of exposure that would be unprotective based on actual data on the PMN substance. In other cases, studies on the analogue may be of limited duration (i.e., a reproductive toxicity screening study or 28 day repeat dose study) and therefore poor predictors of the chemical's effects over a longer period of exposure. To the extent that EPA relies on "structural alerts" that identify molecular characteristics known to be associated with certain health effects, these

[68] Id.

[69] Although hard to determine from EPA's website, it seems that some section 5(e) orders do require testing. The extent of this testing is difficult to determine because EPA does not provide overall statistics on how many chemicals are being tested and what types of studies are being conducted.

[70] Working Approach at 4-5.

indicators of concern cannot substitute for studies determining actual toxicity and dose response – their role is to trigger closer review, including testing.

The "not likely" determinations also reveal that EPA's assessments generally focus on a small group of endpoints, selected because the analogue to the new chemical has been tested for the endpoint and has demonstrated toxicity. For example, the assessment might address developmental toxicity but not neurotoxicity or carcinogenicity. The absence of these endpoints could mean that studies on the analogue are negative and do not raise health concerns. Or it could mean that there are no studies on the analogue addressing the endpoint and thus no basis to reach conclusions about the effects of the PMN substance one way or the other. In the latter event, EPA could not reasonably conclude that, by identifying a "safe" exposure level for one endpoint, exposed workers and consumers would necessarily be protected from all other adverse effects; the untested endpoints could in fact prove to be *more* sensitive to the substance's effects if testing is conducted. Thus, the lack of data for significant endpoints would be a clear case of insufficient information to make a "reasoned evaluation" of the health or environmental effects of the new chemical. EPA would therefore be obligated to make a determination under section 5(a)(3)(B)(i) and issue a section 5(e) order requiring testing.

Another example is the lack of information on toxicokinetics in most "not likely" determinations. Often, the determinations include statements such as "[a]bsorption of the new chemical substance is expected to be poor through the skin and lungs and moderate from the GI tract based on physical-chemical properties" or that "[a]bsorption of the new chemical substance is expected to be nil to poor via all routes based on physicochemical properties."[71] However, predictions of absorption based on physical-chemical properties are known to be inexact and actual absorption studies are considered more reliable. Indeed, in reviewing the draft risk evaluation for Pigment Violet 29, the SACC criticized EPA for lacking a sound basis to assume an absence of absorption and emphasized the need for actual absorption studies.[72] EPA's use of similar assumptions in its "not likely" determinations is another area where the Agency lacks information for a reasoned evaluation of the new chemical and should be requiring testing.

The negligible amount of testing being required under section 5 is compounded by EPA's failure to account for data gaps in assessing new chemical risks. EPA guidance calls for application of a UF where the absence of adequate data creates uncertainty in determining a chemical's health effects:[73]

> The database UF is intended to account for the potential for deriving an underprotective RfD/RfC as a result of an incomplete characterization of the chemical's toxicity. In addition to identifying toxicity information that is lacking, review of existing data may also suggest that a lower reference value might result if additional data were available. Consequently, in deciding to apply this factor to account for deficiencies in the available data set and in identifying its magnitude, the assessor should consider both the data lacking and the data available for particular organ systems as well as life stages.

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[71] See, e.g. TSCA Section 5(a)(3) Determination for Premanufacture Notice (PMN) P-18-0176, https://www.epa.gov/sites/production/files/2020-01/documents/p-18-0176_determination_non-cbi_final.pdf

[72] SACC Peer Review Report for EPA Draft Risk Evaluation of C.I. Pigment Violet 29, at 17-18,https://www.epa.gov/tsca-peer-review/peer-review-draft-risk-evaluation-pigment-violet-29

[73] EPA-630-P02-002F, A Review of the Reference Dose and Reference Concentration Processes, at 4-44 (Dec. 2002) https://www.epa.gov/risk/review-reference-dose-and-reference-concentration-processes-document. (RD and RC Review).

The size of this UF can vary between 3 and 10. EPA guidance advises that "the size of the database factor to be applied will depend on other information in the database and on how much impact the missing data may have on determining the toxicity of a chemical and, consequently, the POD."[74]

None of the risk assessments in EPA's "not likely" determinations account for database deficiencies in setting benchmark MOEs and comparing them to actual MOEs. As a result, the benchmark MOEs EPA is using provide inadequate protection and understate risks.

In sum, EPA is now going out of its way to avoid requiring new chemical testing and is ignoring its obligation under section 5(a)(3)(B)(i) to ensure that it has sufficient information for sound, evidence-based evaluations of new chemical risks. EPA should revise the Working Approach so it demonstrates a commitment to using its authority to fill data gaps and describes the circumstances in which the Agency will determine that available information is insufficient and testing is needed.

VI. EPA Needs to Enhance Public Review and Understanding of Its Decisions on individual New Chemicals

EPA has made some recent progress in posting PNNs and related information on its website. However, the availability of these materials is incomplete and searching the EPA website can be difficult and time-consuming.

In addition, public scrutiny of the basis for EPA's safety determinations remains limited and informed oversight of the Agency's decisions on new chemicals is virtually impossible. 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, EPA is now issuing far fewer orders and a much larger number of "not likely" determinations under section 5(a)(3)(C). Section 5(g) requires EPA to publish in the Federal Register a statement of its findings when issuing such determinations.[75] However, these statements are generally conclusory and contain large amounts of boilerplate language that offer limited insights into EPA's evaluation of the PMN at hand.

Thus, the determinations generally do not identify the new chemical manufacturer or the sites where it will be manufactured and processed, the process steps and equipment used to produce the chemical, the number of downstream sites using the chemical, the number of exposed workers and the nature and extent of worker exposure. Similarly, the determinations provide minimal information about EPA's risk evaluations and MOE analyses. For example, many do not identify the analogues EPA is using to determine the new chemical's adverse effects or reference the studies for these analogues on which EPA is relying. The determinations also fail to describe how EPA has estimated the levels of worker exposure it uses to calculate MOEs. Representative monitoring of breathing zones of exposed employees is generally necessary to

[74] Id. at 4-45.

[75] To ensure timely public notice, Section 5(g) requires these statements 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.

estimate worker exposure levels, but the determinations do not provide monitoring data where it is available or describe the exposure modeling conducted in its absence.

We recognize that CBI claims may limit the disclosure of some PMN information. However, under section 14(b)(2) of TSCA, EPA must disclose all health and safety information on chemicals "for which notification is required under section 5."[76] Under EPA regulations, "not only is information which arises as a result of a formal, disciplined study included [in the definition of health and safety study], but other information relating to the effects of a chemical substance or mixture on health or the environment is also included. Any data that bear on the effects of a chemical substance on health or the environment would be included."[77] In addition, section 14(b)(3) broadly requires disclosure of general production volume information and general descriptions of the processes used in manufacture and processing and the "industrial, commercial or consumer functions and uses of a chemical substance."[78]

In light of these provisions, there is a considerable amount of information in PMNs that must be in the public domain. Thus, EPA should be able to make its "not likely" determinations considerably more detailed and explanatory by including additional non-CBI data and analysis. We urge EPA to make enhancing the informativeness of its section 5(a)(3)(C) determinations a top priority so the public can conduct meaningful review and oversight of EPA's new chemical safety determinations.

EPA should also track additional trends in PMN reviews and dispositions and provide data on these trends in its ongoing statistical summaries of the PMN program. This should include, for example, breakdowns of the number and types of health and safety studies submitted in PMNs or required under section 5(e) orders, the range of restrictions on new chemical manufacture and use required under section 5(e) and the different categories of conditions of use (consumer, industrial and commercial) within the PMN universe. Such breakdowns will be valuable to the public in assessing the overall performance of the PMN program and its impacts on health and environment.

CONCLUSION

We appreciate the opportunity to comment on EPA's Working Approach 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 under TSCA.

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

[76] The only exceptions to this disclosure requirement are for information "that discloses processes used in the manufacturing or processing of a chemical substance or mixture or, in the case of a mixture, the portion of the mixture comprised by any of the chemical substances in the mixture."

[77] 40 C.F.R. § 720.3(k)(1)

[78] In connection with its December 10, 2019 public meeting on the Working Approach, EPA released a number of CBI "determinations" for PMN information. 84 Fed. Reg. 64063, 64063 (November 20, 2019). However, these determinations were incomplete and also failed to reject CBI claims for information required to be disclosed under section 14(b).

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