



February 18, 2020

Via Docket Submission

U.S. Environmental Protection Agency
Office of Pollution Prevention and Toxics
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460

Re: TSCA NCC Comments on December 2019 EPA Document, “TSCA New Chemical Determinations: A Working Approach for Making Determinations under TSCA Section 5”
Docket Number EPA-HQ-OPPT-2019-0684

Dear Sir or Madam:

The Toxic Substances Control Act (TSCA) New Chemicals Coalition (NCC)¹ offers these comments in response to the U.S. Environmental Protection Agency’s (EPA) request for comment on its December 2019 document, “TSCA New Chemical Determinations: A Working Approach for Making Determinations under TSCA Section 5,” ([New Chemicals Working Approach document](#)) (85 Fed. Reg. 99 (January 2, 2020)). The NCC appreciates EPA’s significant effort in being more transparent with its policies and practices, as we believe it will benefit all new chemical stakeholders in understanding better EPA’s approach in reviewing new chemical notifications. The comments below build on the oral comments made on behalf of the TSCA NCC during the December 10, 2019, EPA workshop.

Conditions of Use -- Reasonably Foreseen Conditions of Use

NCC acknowledges and applauds the fact that the New Chemicals Working Approach document includes more information on how EPA determines conditions of use as intended, known, and reasonably foreseeable. This welcome clarification provides more clarity as to EPA’s thinking.

That said, the NCC is disappointed to note that in practice, EPA continues to speculate, often without support, that there might be circumstances that EPA has not evaluated, in which a concern threshold might be exceeded, and as such, a significant new use rule (SNUR) is required.

¹ The TSCA NCC is a group of representatives from about 20 companies that have come together to identify new chemical notification issues under amended TSCA and work collaboratively with EPA and other stakeholders to address them.



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While it may be true that there are conditions of use that EPA has not evaluated, it remains the case that EPA's determination is required by law to be based on and bounded by **reasonably foreseeable conditions of use**. As EPA has stated in a recent response to a comment on a SNUR that suggested that EPA should generally designate as a significant new use any use of a chemical substance other than the uses EPA evaluated in its PMN review and determined are not likely to present an unreasonable risk:

Commenters suggested approach is overly broad. TSCA requires that EPA evaluate new chemicals under their conditions of use, including the intended, known and reasonably foreseen circumstances of manufacture, processing, distribution in commerce, use and disposal. Based upon EPA's review of the relevant PMNs, the Agency identified uses that are appropriate for designation as "significant new uses" in order to ensure that EPA has an opportunity to review those uses in a SNUN submission at a later date and address any unreasonable risks at that time. TSCA § 5(a)(2) does not require EPA to take the catch-all approach advocated by commenters, and EPA believes a more tailored approach is warranted to avoid unduly burdensome regulations.²

We remind EPA that it has stated that "reasonably foreseeable" must be based on "information, knowledge, or experience" and not merely hypothetical conditions of use. EPA's common defense to its current approach is that once listed on the Inventory, a substance could conceivably be used for anything. While this may be hypothetically true, it is certainly not accurate from a chemistry standpoint. An insoluble pigment cannot be used as a solvent. A fragrance cannot be used as a rigid material. A lubricant cannot be used as an adhesive. And although it may seem innocuous to set a SNUR for a use condition that could never occur, the reality is that the imposition of the SNUR must be lawfully based, and the mere existence of the SNUR -- whether that use is achievable or not -- has significant adverse market impacts on the entire value chain for the subject chemical. The NCC recognizes that these market impacts may not be logical, but EPA cannot reasonably dismiss them as irrelevant.

The NCC also reminds EPA that the legal TSCA standard is not likely to present unreasonable risk under the reasonably foreseeable condition of use. It is NOT "will not present unreasonable risk under any conceivable condition of use." Given the adverse market impacts that

² *Federal Register* notice, "Significant New Use Rules on Certain Chemical Substances," April 5, 2019, 84 Fed. Reg. 13531, EPA-HQ-OPPT-2017-0575.



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occur when SNURs are unsupported and inappropriately applied, even if the condition of use would never occur, we urge EPA to follow the law and exercise its judgment in its assessment of what is likely and reasonably foreseeable when deciding on a regulatory action and to reflect this discretionary approach in the final New Chemicals Document.

Conditions of Use Involving Workers

NCC supports fully EPA's approach for worker protection. In the New Chemical Working Approach document, EPA explains that in reviewing a PMN and worker exposures, it first considers engineering controls and calculates potential worker exposures absent personal protective equipment (PPE). If EPA finds potential unreasonable risk without PPE, EPA then evaluates whether PPE would sufficiently mitigate exposures so as to pose no unreasonable risk. EPA then states that it relies upon the Occupational Safety and Health Administration (OSHA) authority that compels employers to inform employees of the hazards, train those employees in proper use of PPE, and require that employees take the steps necessary to protect themselves. As NCC has provided to EPA in past comments, OSHA violations for gloves, goggles, or general dermal protection were quite rare (less than one percent of violations among the 12 million violations that OSHA has issued). This low rate of violations meets the statutory criterion of "not likely to present unreasonable risk under the [reasonably foreseeable] conditions of use." It is not that glove or goggle non-use never happens, but the statutory language does not require that level of certainty and does not permit EPA to take regulatory action if there is only a very limited possibility of unreasonable risk.

Information Sufficiency -- Use and Release Information

The NCC urges EPA to provide additional guidance on what information is required to be submitted in the Section 5 pre-manufacture notice (PMN) for EPA to override its generic scenarios on use and release expectations. Specifically, companies submitting notifications need to know how much release and exposure information is considered sufficient for EPA to move away from its overly conservative scenarios that, in many cases, do not reflect real-life values or practices. EPA has repeatedly stated that submitters should provide detailed information in their PMNs. But in our experience, when NCC members and others have responded to EPA's recommendations to provide details on conditions of use, EPA ignores this information in preference for its generic scenario (GS) models.

The EPA engineering reports on these submissions simply state "GS is more conservative," suggesting that EPA would only use the submitter's release and exposure information if those numbers are considered by EPA reviewers to be worse than the generic scenario. The NCC hopes that this inference is not the case, as it provides no incentive for a submitter to develop and



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submit detailed information on anticipated conditions of use. Indeed, such an inference acts as an affirmative deterrent to new data development.

If EPA requires the level of detail comparable to a scenario from the Organization for Economic Cooperation and Development (OECD) that forms the basis of one of EPA's scenarios, it should so state. The NCC urges EPA to cease its practice of pressing for excessive detail in PMNs and instead engage with industry associations to develop new, robust scenarios that meet EPA's needs to limit what EPA foresees. If this approach is taken, it needs to be implemented immediately so updated scenarios can be available for EPA use quickly.

Risk-Based Approach -- Hazard Assessments

Reliance on Chronic Points of Departure for Acute End Point Assessment Not Scientifically Justified

In the health assessment of the new chemical submission, EPA compares acute doses to chronic points of departure (POD) to derive Margins of Exposure (MOE). This approach is not scientifically justified in instances of chronic systemic or specific target organ toxicity. Instead, EPA must compare acute (or single-exposure) end points to predicted acute doses to calculate an acute MOE and chronic end points to predicted chronic doses.

Approach for Evaluating Lung Overload for Particulates Unfounded

EPA routinely uses the OSHA permissible exposure limit (PEL) of 15 mg/m³ for particulates as an upper limit for respiratory exposure. When evaluating lung overload, however, EPA should be using 5 mg/m³ (the PEL for respirable particles under 10 microns), rather than 15 mg/m³. Only the respirable fraction is available to contribute to lung overload. The remaining 10 mg/m³, representing the larger particles, only affects the upper respiratory tract or may be ingested. The data show that these larger particles simply do not reach the deep lung to contribute to lung overload.

Insufficient Information

NCC generally agrees with the explanation that EPA provides related to its interpretation of "sufficient information." We support the tiered approach that EPA has been using, which follows the standard practice for risk assessments. The NCC also believes EPA's current practice of including "potentially useful" information in orders or SNURs strikes an appropriate balance between EPA's requirement to make a determination on the unreasonable risk for permissible



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conditions of use and EPA's likely need for additional information to inform a determination for the conditions of use prohibited by the order or SNUR.

Although there is general agreement on EPA's discussion on "sufficient information," the NCC raises an important issue that EPA must address related to inconsistent findings of insufficient information on some new chemicals for which nearly identical chemistries are included on the EPA Safer Chemical Ingredient List (SCIL). NCC is aware of circumstances in which EPA has determined there is insufficient information to assess the safety of a new surfactant under the new chemicals program while at the same time, EPA is promoting dozens of nearly identical surfactants on SCIL for use in consumer spray cleaners. While it is true that inhalation hazard is not one of the SCIL criteria, we question EPA's position that a surfactant on the SCIL-listed ingredient is considered by EPA to be "safer," when an equivalent surfactant submitted under Section 5 is found to pose unreasonable risk due to insufficient information. EPA cannot have it both ways. We believe that the decades of use of surfactants in consumer cleaning products, while not quantitative, provide a qualitative basis for EPA to conclude that common surfactants, especially non-ionic and anionic surfactants, are not likely to pose unreasonable risk. EPA should treat both groups of chemicals consistently, and use EPA's history of surfactants' inclusion on SCIL as evidence for accepting PMN surfactants as providing sufficient information for review. To do otherwise sustains an irreconcilable inconsistency in EPA's PMN review process and misrepresents EPA's confidence of the hazards associated with SCIL-listed surfactants.

Finally, the NCC appreciates EPA's need to determine "unreasonable risk of injury to health or the environment" on a case-by-case basis in which they consider severity and/or reversibility of effects of the substance or its degradants, the nature of exposures, and characteristics of the exposed population. As we did in our January 2018 comments on the initial New Chemicals Framework document, NCC again recommends that EPA include example case studies to demonstrate when and how these considerations would come into play as part of a new chemical review.

SNURs That Precede "Not Likely" Determinations

NCC supports EPA's use of SNURs without corresponding orders. EPA's use of a SNUR to prohibit potentially problematic conditions of use is an effective way to limit what is "reasonably foreseeable" and allows EPA and the PMN submitter to proceed to commercialization with the SNUR protections in place. We believe that the questions raised regarding the protectiveness of SNURs versus consent orders are based on a general lack of understanding about how SNURs work, what is required, and what EPA does when a significant new use notice (SNUN) is submitted. NCC urges EPA to retain its current approach on non-order SNURs.



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Feedback on EPA December 10, 2019, Public Meeting

While not part of the New Chemicals Working Approach document review, the NCC feels compelled to take this opportunity to provide feedback to EPA on the December 10, 2019, public meeting. Specifically, our members were very disappointed in the EPA decision to limit oral comments to two minutes. Given the complexity of the issues surrounding new chemicals review, it is impossible accurately and comprehensibly to provide helpful and meaningful feedback in 120 seconds. Moreover, this decision to limit time was made unilaterally and with no notice on the day of the workshop, so parties who planned to attend in person to make comments had virtually no time to refine their prepared comments. If a similar situation were to arise in the future, EPA should obtain an accurate count during a scheduled break and calculate time slots for those remaining. Lastly, if necessary, EPA should limit the number of speakers per organization.

In addition, EPA failed to apply the time limitation consistently. It was clear during the workshop that parties providing input via the conference call line were afforded far more time beyond the two-minute limit. Those commenters who attended in person were held strictly to the two minutes. EPA's failure to apply its unreasonable time limitation consistently was particularly prejudicial and frustrating to our members who took time and resources to travel to the EPA meeting in person.

Finally, while hindsight is always 20/20, EPA's unilateral and unreasonable decision to limit comments to two minutes turned out to be far too conservative, as there was additional time remaining at the end of the workshop. Once EPA made the determination that additional time could be afforded to comments, it should have allowed those parties in the room a chance to add to or clarify the comments made earlier in the day.

The TSCA NCC looks forward to continuing to work with EPA to strengthen the Section 5 program. Thank you for the opportunity to provide these comments.

Sincerely,

A handwritten signature in black ink that reads "Kathleen M. Roberts". The signature is fluid and cursive, with the first letters of the first and last names being capitalized and prominent.

Kathleen M. Roberts
TSCA NCC Manager