



June 2, 2022

Via E-Mail

Melanie Buser, Ph.D.
Asst. Director for Environmental Health
Office of Science and Technology Policy
Executive Office of the President
Eisenhower Executive Office Building
1650 Pennsylvania Avenue, N.W.
Washington, DC 20504

Re: Response to Request for Information: Sustainable Chemistry

Dear Dr. Buser:

The Toxic Substances Control Act (TSCA) New Chemicals Coalition (NCC)¹ is pleased to provide comments in response to the Request for Information (RFI) related to Subtitle E of the 2021 National Defense Authorization Act (NDAA), also called the Sustainable Chemistry Research and Development Act. TSCA NCC submits frequently new chemical notices, mostly premanufacture notices (PMN) and low-volume exemption notices (LVE), under TSCA, and it welcomes this opportunity to comment.

Definition of Green Chemistry and Sustainable Chemistry

The RFI requests comments on the definition of sustainable chemistry and how it is similar to or different from green chemistry. In TSCA NCC's view, the two are nearly, if not entirely, synonymous.

According to the U.S. Environmental Protection Agency (EPA), the definition of green chemistry is "the design of chemical products and processes that reduce or eliminate the use or generation of hazardous substances."² EPA lists further the Twelve Principles of Green

¹ TSCA NCC is a group of representatives from over 15 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.

² EPA, Basics of Green Chemistry, available at <https://www.epa.gov/greenchemistry>.

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Chemistry.³ While some may view green chemistry as focusing on only what is made,⁴ neither the definition nor the principles are so limited. In fact, the majority of the principles relate to how chemicals are made. The principles include:

- Designing chemicals to be less hazardous:
 - Design safer chemicals and products;
 - Design for degradation;
 - Minimize the potential for accidents;
- How chemicals are made:
 - Prevent waste;
 - Maximize atom economy;
 - Design less hazardous syntheses;
 - Use safer solvents;
 - Increase energy efficiency;
 - Avoid chemical derivatives;
 - Use catalysts;
 - Analyze in real time;
 - Minimize the potential for accidents; and

³ *Id.*

⁴ 87 Fed. Reg. 19539, 19540 (Apr. 4, 2022).

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- What chemicals are made from:
 - Use renewable feedstocks.

These principles align well with Congress’s goal to “promote efficient use of resources in developing new materials, processes, and technologies that support viable long-term solutions to a significant number of challenges.”⁵ Some have also argued that green chemistry excludes competitiveness (cost or performance). The principle related to designing chemicals specifically states that chemical products should be “fully effective” in addition to having little or no toxicity. Implicit in the definition of green chemistry, “the design of chemical products and processes that reduce or eliminate the use or generation of hazardous substances,” is competitiveness. If a chemical product is not competitive in the marketplace, it is less likely to be purchased and, as a result, will not achieve the specified outcome (to “reduce or eliminate the use or generation of hazardous substances”). Competing successfully in the market on a cost/performance basis is implied in the definition of green chemistry, even if it is not explicitly stated.

Sustainable chemistry has been defined by the Organization for Economic Cooperation and Development (OECD) as follows:⁶

“Sustainable chemistry is a scientific concept that seeks to improve the efficiency with which natural resources are used to meet human needs for chemical products and services. Sustainable chemistry encompasses the design, manufacture and use of efficient, effective, safe and more environmentally benign chemical products and processes.”

Sustainable chemistry is also a process that stimulates innovation across all sectors to design and discover new chemicals, production processes, and product stewardship practices that will provide increased performance and increased value while meeting the goals of protecting and enhancing human health and the environment.

⁵ *Id.* (citation omitted).

⁶ OECD, Sustainable Chemistry, available at <https://www.oecd.org/chemicalsafety/risk-management/sustainablechemistry.htm>.



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OECD does not identify more specific principles, but the definitions are substantially similar. The least evident aspect of sustainability in these definitions is sustainability benefits that may accrue during the use phase. A novel chemistry technology may have some hazards and may be manufactured from extracted materials, but could still have substantial environmental and/or health benefits in the use phase. For example, a mined metal incorporated into a product that improves transportation carbon efficiency by 50 percent could be well worth the potential risks during manufacturing and processing to achieve the benefits during the use phase and, therefore, could be considered green or sustainable chemistry.

A key feature of both terms is that they are relative, not absolute. New technologies should be evaluated relative to incumbent technologies. A key question is whether the new technology is “greener” or “more sustainable” than the technology it seeks to replace. Chemists across the board (academia, industry, government, non-governmental organizations) should aim for the lowest possible hazard from the most easily obtained feedstocks in the most efficient manner, but the reality is that some new chemical technologies may not be entirely non-hazardous and will still be preferable to and more sustainable than existing chemical technologies. Designing for sustainability will be asymptotic with a true sustainable state; chemistry designers and decision-makers need to recognize that greenness/sustainability is not a threshold determination.

Sustainability also requires consideration within a specific use category. For example, all surfactants have properties that are characteristic -- they decrease the surface tension at liquid interfaces. As a result, all surfactants have hazards related to the characteristic (*e.g.*, eye irritation and some aquatic toxicity). Whether one surfactant is more sustainable than another, stakeholders should recognize that there is a limit to whether such a characteristic can be designed out entirely. Instead, one must compare the characteristics between (or among) specific surfactants.

Policy Considerations

TSCA NCC writes primarily to emphasize that, in our view, EPA’s Office of Pollution Prevention and Toxics (OPPT) is implementing the Frank R. Lautenberg Chemical Safety for the 21st Century Act (Lautenberg) in a manner that is inconsistent with the statutory language, Congress’s intent, and stakeholders’ interests of achieving sustainability. As discussed in more detail below, it is TSCA NCC’s view that OPPT’s current policies implementing TSCA Section 5 impose a significant barrier to the commercial launch, implementation, and acceptance of new, more sustainable chemical technologies.



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Specifically, TSCA NCC is concerned that OPPT is misinterpreting the meaning of “not likely to present an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by the Administrator under the conditions of use [including the intended, known, or reasonably foreseen conditions of use].”⁷ Since June 22, 2016, OPPT has been interpreting this term, almost exclusively, to mean that if a new chemical substance has a hazard other than low hazard to both health and the environment (“low/low” hazard), that the substance may present unreasonable risk and therefore must be subject to some restriction through an order and/or a Significant New Use Rule (SNUR).

Essentially, OPPT apparently views any condition of use as reasonably foreseen because “somebody might” exceed EPA’s concern threshold, regardless of the hazard, toxicity, or exposure information in the submission or the output of EPA’s models, and regardless of the improbability of the occurrence. In TSCA NCC’s view this is a hazard-based standard, not a risk-based one, as is specified in Lautenberg. EPA seems to reserve the right to review all future potential conditions of use for unreasonable risk (using orders and SNURs) in an apparent attempt to turn TSCA into a registration statute like the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).

If that had been Congress’s intent, Congress could have and would have modeled Lautenberg on FIFRA and been explicit about the requirement that industry submit and EPA review any changes in intended or known conditions of use. Congress declined to do so. Congress instead required that EPA review the conditions of use that are intended, known, and reasonably foreseen. EPA has stated that “[r]easonably foreseen conditions of use will not be based on hypotheticals or conjecture.”⁸ This language was standard in footnote 1 of TSCA Section 5(a)(2) (“not likely to present unreasonable risk”) determination documents published by EPA. At some point, that language was removed from that standard footnote, apparently after the change in Administration in January 2021.

⁷ TSCA § 5(a)(3)(C) and § 3(4), by reference.

⁸ EPA, Numerous examples in EPA’s determination documents, for example, TSCA Section 5(a)(3) Determination for Premanufacture Notice (PMN) P-19-0135, footnote 1, available at https://www.epa.gov/sites/default/files/2020-01/documents/p-19-0135_determination_non-cbi_final.pdf.



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The meaning of reasonably foreseen is critical in informing EPA's risk management actions on new chemicals. If EPA continues to include any possible condition of use within the meaning of reasonably foreseen, EPA will continue to be implementing TSCA using a hazard-based standard, not a risk-based standard (as required by the statute). EPA will then continue to issue restrictions on all new chemicals that are not low/low for hazard. As a result, EPA will continue to put new chemicals at a significant disadvantage compared to incumbent technologies, regardless of the potential sustainability benefits of the new chemical.

Also troubling is that EPA imposes regulatory restrictions whether or not there are data on the new chemical substance. One of the drivers of TSCA reform was the perception that there is insufficient information to review the safety of chemicals, especially new chemicals. TSCA NCC members agree that information is required to inform a risk assessment, but TSCA NCC's view is that using a combination of models, data on analogs, and data on a substance can provide sufficient information to make a reasoned evaluation. What is especially concerning is that regardless of whether submitters submit robust data sets, if the data do not demonstrate that a substance is "low/low," EPA seems to impose controls in orders and/or SNURs. This seemingly reflexive response is a substantial disincentive to developing data on the substance. EPA's conduct suggests that unless the testing demonstrates "low/low" hazards, EPA will impose a regulation. If that is the case, there is little value to the submitter to develop data on a voluntary basis. For example, EPA might use its aquatic toxicity model to predict a concentration of concern (CoC) of 100 parts per billion (ppb). All actors in the supply chain may be under that threshold for all conditions of use (the intended, known, and worst-case predicted conditions of use), but EPA imposes the CoC as a limit because "somebody might" exceed that limit even though EPA has no basis for that conclusion other than conjecture. A submitter might perform expensive chronic toxicity testing on fish and daphnia to show that the CoC should be 200 ppb instead of 100 ppb, but that is not enough for EPA to forego the surface water restriction. Since no actors in the supply chain were expected to exceed 100 ppb, having the limit be higher does nothing for the supply chain. Therefore, why invest the resources for the testing? As implemented currently, EPA's decision is not based on the extent of the data set for hazard or exposure; EPA's decision is based on whether or not EPA has identified a hazard other than "low/low."

New Chemicals Bias

EPA has and continues to dismiss submitter concerns about the commercial effects of orders and SNURs. While EPA is correct that a SNUR that does not prohibit the intended conditions of use is not a regulatory barrier to commercial implementation, that view ignores the commercial effects of a SNUR (related largely to burdens of a SNUR on the rest of



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the supply chain). SNURs require notification to EPA prior to undertaking a significant new use (SNU), as defined in the SNUR itself,⁹ so EPA concludes that if a company is not undertaking a SNU, a SNUR should not be a burden, but this ignores the other burdens of a SNUR.

TSCA NCC suggests this analogy as a means to help explain the burdens of a SNUR:

Consider an electric vehicle (EV) that is, over its life cycle, 50 percent more carbon efficient than a comparable gasoline-powered vehicle. Because the EV uses a “new engine” under the rules, EPA must review the EV under the reasonably foreseen conditions of use, and EPA finds that, if the EV is not subjected to routine maintenance, the EV has a 1 in 10,000 chance of causing a vehicle fire. As a result EPA issues a SNUR requiring that owners perform scheduled routine maintenance every 5,000 miles. An analysis of the existing gasoline-powered vehicle shows it has the same car fire risk when not maintained properly, but because that car’s engine was “grandfathered in,” it is not subject to a similar SNUR. The SNUR also requires that owners keep records of their compliance with the SNUR and, as is the case for all SNURs, notify EPA prior to driving the vehicle to another state for the first time (an analog of the TSCA Section 12(b) export notice requirement). If you fail to perform the routine maintenance, fail to keep records of that maintenance, or fail to inform EPA prior to the car being driven to a new state for the first time, you are in violation and could be subject to thousands of dollars in fines.

Would you choose the EV? Would you worry what EPA might do if you were 50 or 100 miles late to perform routine maintenance? What if you cannot find the paperwork documenting each required maintenance visit? What if your child takes the car to Ocean City for a summer trip and decides to drive up to Rehoboth Beach for the day without telling you so you can submit the required notice to EPA? Might you be hesitant to take on the enforcement risk? Is it reasonable for another driver to think that the potential penalties are too much of a risk and opt for the traditional engine?

Some companies, especially the large chemical companies, have robust systems to maintain and document compliance with orders and SNURs, but companies further down the supply chain that do not think of themselves as “chemical companies” often specifically avoid substances with SNURs. It is partly because of the perception that a SNUR implies a greater degree of hazard, as is implied in the procedures for SNUR rulemaking at 40 C.F.R. Section

⁹ 40 C.F.R. § 721.5.



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721.170(b), and the fact that SNURs trigger other reporting obligations such as TSCA Section 12(b) export notices and a lower threshold for Chemical Data Reporting (CDR), and partly because those companies do not want to take on the enforcement risk of a potential SNUR violation. EPA's review of new chemicals in isolation of the existing markets and EPA's indifference to the commercial effects of SNURs are the underpinnings of the new chemicals bias. The bias predates TSCA reform, but enactment of Lautenberg and EPA's implementation of the law have greatly exacerbated the problem.

One of the arguments that EPA is not imposing regulatory disadvantage on new chemicals is that EPA will impose similar regulations on existing chemicals as it works through its obligations under TSCA Section 6. Even if EPA is reviewing existing chemicals in the roughly three years allotted for its review of existing chemicals, given that there are over 40,000 substances listed as active on the TSCA Inventory, EPA will not assess any meaningful fraction of existing chemicals any time soon. As a result, new chemicals will continue to be commercialized on an uneven playing field because they are being regulated in ways that pose significant market disadvantages, even when there are sustainability benefits of the new chemical.

Below TSCA NCC suggests two policy changes that could reduce the new chemicals bias and together lower the barriers to commercial acceptance of more sustainable new chemicals.

EPA Must Bound the Meaning of Reasonably Foreseen

It is not reasonable to interpret amended TSCA Section 5 to require that EPA issue protective controls whenever it identifies a hazard other than "low/low" as has been EPA's practice in the vast majority of cases since the enactment of the Lautenberg amendments.¹⁰

¹⁰ Except for determinations in 2019 and 2020 when EPA implemented a policy that, while it may be the case that workers would not use routine personal protective equipment (PPE), such as gloves and goggles, in some cases, because of Occupational Safety and Health Administration (OSHA) requirements and widespread industrial practice, EPA determined that it would not conclude that absence of such PPE was reasonably foreseen. In those cases, if EPA found that routine PPE was sufficient to protect workers and that other measures to protect the general population, consumers, or the environment were not needed, EPA would conclude that such substances were "not likely to present unreasonable risk." This policy was reversed by the Biden Administration.



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Congress opted not to turn TSCA into a registration statute in the model of FIFRA, so EPA should be implementing TSCA in a way that effectively achieves that end through EPA's interpretation of the statutory language.

Bergeson & Campbell, P.C. (B&C[®]), TSCA NCC's Legal Counsel, has been advocating for a wide stakeholder engagement effort in which OPPT would solicit and consider input on the meaning of "reasonably foreseen" and how unlikely a circumstance must be to be considered "not likely." Congress clearly did not intend for EPA to have a high degree of certainty to reach a "not likely" determination because Congress used the term "not likely to present an unreasonable risk under the [reasonably foreseen] condition of use" instead of the alternative "reasonable certainty of no harm" used in other chemical control statutes.

While many submitters view EPA's course of conduct as impermissible under the statute, submitters have been hesitant to challenge EPA in court, because no single new chemical is worth the time, expense, and potential reputational harm of suing EPA over an overly restrictive order or SNUR. Companies simply withdraw the submission and abandon the U.S. TSCA market for that substance.

Reduced Risk Considerations

EPA has long had the authority to consider pollution prevention benefits¹¹ and has, for decades, included an "optional pollution prevention" page in the PMN form. In past years, EPA had recognized new chemicals for Pollution Prevention Recognition.¹² According to EPA's website, EPA has not identified any PMNs for recognition since 2010.¹³ It is not clear if PMN submitters are not providing the information or not seeking recognition, or if EPA is not seeing anything worthy of recognition or simply not operating the program any more.

¹¹ 42 U.S.C. § 13101 *et seq.* (1990).

¹² See EPA, P2 Recognition Project, available at <https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/p2-recognition-project>.

¹³ *Id.*

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B&C professionals have written previously about why consideration of reduced risk is permitted in EPA's consideration of "unreasonable risk."^{14,15} EPA is prohibited from considering "costs or other nonrisk factors"¹⁶ in its evaluation of new chemicals, but reduced risk is, in B&C's view, a risk factor, and therefore can (and should) be considered in risk evaluations and, more importantly, in EPA's new chemical risk management decisions.

Among the questions that EPA needs to explain to submitters is what body of evidence is needed to justify EPA's consideration of reduced risk when evaluating risk or proposing risk management. Existing guidance on what should be provided on the Optional Pollution Prevention (P2) page is general and does not provide sufficient insight into EPA's thinking. EPA is open to information from submitters, including anything on the P2 page, but based on submitter experience and EPA's course of conduct, there appears to be no benefit for providing P2 information, meaning there is little value in investing time or resources into a fulsome P2 statement.

In TSCA NCC's view, EPA should take all potential P2 benefits into account and, if hazards are demonstrably reduced, the substance can be reasonably expected to reduce releases or exposures (*e.g.*, because of reduced volatility), or the substance can be reasonably expected to provide P2 benefits during use or disposal, EPA should consider carefully whether issuing an order and/or a SNUR is in the best interest of protecting against unreasonable risk considering the hazards, potential exposures, and potential P2 benefits during use or disposal. If EPA needs specific information to support its evaluation, EPA should communicate that information to submitters, either prior to or during EPA's evaluation.

¹⁴ See Jeffery T. Morris, Ph.D., and Richard E. Engler, Ph.D. "Why the US EPA can, and should, evaluate the risk-reducing role a new chemical may play if allowed on the market, *Chemical Watch*, available at <https://chemicalwatch.com/220164/guest-column-why-the-us-epa-can-and-should-evaluate-the-risk-reducing-role-a-new-chemical-may-play-if-allowed-on-the-market>.

¹⁵ Lynn L. Bergeson, Richard E. Engler, Charles M. Auer, and Kathleen M. Roberts. "New Chemicals Under New TSCA -- Stalled Commercialization." Bloomberg Environment Insights (September 11-13, 2018), available at <http://www.lawbc.com/uploads/docs/00251156.pdf>.

¹⁶ TSCA § 5(a)(3).



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Advocates frequently identify “regrettable substitution” as a reason to disallow new chemicals to market without a thorough review. The fact is, however, that EPA’s current practice means that even if a new substance has a robust data set supporting the claim that it is less hazardous across many domains, if the data do not support a conclusion of “low/low” for hazard, EPA will impose restrictions, and those restrictions are a disincentive to market adoption.

Summary

New, more sustainable chemical innovations will not reach their full potential if EPA continues to regulate new sustainable chemistry technologies in ways that impose regulatory obligations that do not apply to the incumbent, existing chemical technologies and that disadvantage the more sustainable substances in the marketplace. EPA’s current interpretation of TSCA Section 5 and course of conduct will continue to be barriers to the deployment and commercial adoption of more sustainable technologies and will continue to provide market advantage to existing chemical technologies. This practice will diminish the potential and promise of the Sustainable Chemistry Research and Development Act and will delay the United States and the world from enjoying the sustainability benefits of new greener technologies.

We hope this information is helpful. As always, please call if you have any questions.

Sincerely,

A handwritten signature in black ink, appearing to read "Richard E. Engler", written in a cursive style.

Richard E. Engler, Ph.D.
Director of Chemistry, B&C