Coalition for Chemical Innovations (CCI)

EPA Needs to Consider Explicitly Risk Reduction in Assessing New Chemicals

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Introduction

This white paper explains why the U.S. Environmental Protection Agency (EPA) must consider explicitly risk reduction when performing risk assessments on new chemical substances and making risk determinations under Section 5 of the Toxic Substances Control Act (TSCA).

TSCA, as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act (Lautenberg Act), is the nation's primary chemical management law that authorizes EPA to regulate new and existing chemical substances, primarily under Sections 5 and 6, respectively. The distinction between new and existing chemicals is that the former are not on the TSCA Inventory and require EPA review prior to manufacture (including import) for a non-exempt commercial purpose, whereas the latter listed substances are considered "existing" and permitted in U.S. commerce (if not prohibited by regulation). As shown in Figure 1, EPA is required under TSCA to make risk findings for all new chemical substances[1] and for existing chemical substances that EPA identifies as "high-priority substances" for risk evaluation under its TSCA Section 6(b) prioritization process.

TSCA Section 5	TSCA Section 6
New Chemical Substances (NCS)	Existing Chemical Substances (ECS)
↓	↓
Determination that the NCS:	Prioritization of the ECS as:
1. "presents", 2. "may present", or 3. "not likely to present"	1. "low-priority substance", or 2. "high-priority substance" (HPS)
"an unreasonable risk of injury to health or the environment"	Risk evaluation on HPS and determination whether it presents: "an unreasonable risk of injury to health or the environment"

Figure 1. Regulatory determinations for new and existing chemical substances under TSCA.

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EPA is required to implement risk management where EPA identifies the statutory threshold (*e.g.*, "may present" or "presents" unreasonable risk) for triggering risk management. In these cases, EPA is required to impose restrictions "to the extent necessary" to protect against an unreasonable risk "under the conditions of use." TSCA also requires EPA to perform these duties "in such a manner as not to impede unduly or create unnecessary economic barriers to technological innovation."[2]

Technological innovation primarily occurs in the industrial chemicals market when new chemicals are developed to improve upon existing chemical applications. These improvements may relate to various chemical attributes, including performance, reduced hazards, reduced exposure, and/or pollution prevention. EPA states on the new chemical substance notification form that "[t]o the extent known, information about the technology being replaced will assist EPA in its relative risk determination" and requests submitters to describe the improvements to "the extent to which the new chemical substance may be a substitute for an existing substance that poses a greater overall risk to human health or the environment."[3] Under EPA's current practice, no consideration is given to these improvements, and they do not factor in EPA's risk assessments or determinations on new chemicals.

Since the Lautenberg Act was enacted on June 22, 2016, EPA has been reviewing new chemical substance notifications and, in the vast majority of cases, if EPA identifies hazards other than low hazard to human health or the environment, EPA has imposed restrictions through a TSCA Section 5 order (usually a consent order) and/or a significant new use rule (SNUR). Either of these risk mitigation strategies imposes burdens on manufacturers and downstream users and results in market deselection because of the stigma of the regulation (implying that the new chemical is more hazardous than the existing one, whether valid or not) or the avoidance of enforcement risk, or both.

EPA Does Not Currently Consider Risk Reduction in Evaluating New Chemicals

Unfortunately, EPA does not consider the benefits of risk reduction that are typically available with new chemicals. For example, suppose a new chemical is corrosive to skin, but is a replacement for an existing chemical that has cancer concerns from dermal exposures. EPA will typically require risk mitigation *via* a consent order and/or SNUR on the new, corrosive substance despite a clear reduction in potential risk to the market alternative. EPA places the onerous requirements on the new chemical compared to the less restricted but more toxic alternative (a phenomenon called the "new chemicals bias").

Failure to Consider Risk Reduction Prevents Innovative Chemistry from Replacing Existing Riskier Chemicals

Within the context of risk reduction, EPA's current practice privileges unevaluated existing chemicals over the EPA-evaluated new chemicals, irrespective of the health or environmental gains that could be achieved through the introduction of the new chemical in commerce. While it is true that EPA is required to evaluate all existing chemicals, the sheer volume of existing chemicals to be reviewed (*e.g.*, >42,000 as of February 2022)[4] will effectively limit the number of existing chemicals that EPA will be able to review in a meaningful time period. This creates market disincentives for transitioning to new chemicals that may include risk reduction benefits yet carry excessive risk management burdens compared to the alternative unregulated existing chemicals that may take EPA decades to evaluate.

TSCA requires EPA to implement risk management on those risks that EPA determines are unreasonable. TSCA does not, however, provide a definition for "unreasonable risk." Rather, EPA applies standard risk assessment practices for making its determination by evaluating the hazard and exposure potential of each new chemical in isolation and to the exclusion of risks posed by incumbent existing chemicals. This is an important consideration because the potential health or environmental benefits of commercializing a new chemical are not "costs or other nonrisk factors" that EPA is prohibited to consider in TSCA risk determinations; they are risk-related considerations that are integral to the full meaning of unreasonable risk. Therefore, determining whether a new chemical presents or may present unreasonable risk should include an analysis of whether the introduction of the new chemical in commerce has the potential to prevent pollution, lower chemical-related hazard (acknowledging differences in hazard profiles between substitute chemicals), or reduce exposure (likewise, acknowledging different exposure pathways or chemical properties between substitute chemicals) associated with the conditions of use described in the new chemical notification.

EPA Should Embrace the Statutory Authority Granted under Section 5 to Consider Risk Reduction in New Chemical Reviews

To resolve this bias against new chemicals, EPA must reassess how it evaluates risks, including opportunities for risk reduction. One option for doing so would be for EPA to perform a tiered evaluation, whereby if EPA determines that a new chemical "may present an unreasonable risk," it would then perform a comparative risk assessment to the existing chemical incumbent identified by the submitter and/or EPA. EPA would then evaluate the potential risk reduction benefits of the new chemical and include that in its risk management decision. This option is consistent with the types of considerations for net benefits that EPA allows submitters to provide with new chemical notifications[5] and is consistent with comparative risk approaches used

by EPA for conventional reduced risk pesticides,[6] the language of the Pollution Prevention Act, and the language of the Sustainable Chemistry Research and Development (R&D) Act.

EPA must reevaluate its policies and procedures to ensure that risk reduction is explicitly factored into its determinations of unreasonable risk. EPA should acknowledge and reward submitters that develop data to support comparative risk assessments on new chemicals versus existing chemical incumbents. EPA's current practice of quantifying risks in isolation and to the exclusion of information on the potential reduced risk benefits is inconsistent with the scientific standards under TSCA and with the policies from other EPA offices that recognize the benefits of reduced risk to public health. As currently practiced, EPA is foregoing environmental and health benefits by regulating lower risk chemicals more stringently than the higher risk existing chemicals they are designed to replace. That the new chemical does not meet EPA's low-hazard thresholds should not automatically lead to EPA issuing regulatory restrictions, especially when there are environmental and health benefits to be gained by the commercialization of the lower risk chemical.

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[1] For new chemical reviews under Section 5, EPA may also determine that the "information … is insufficient" to make a determination of risk or that the new chemical will be produced in "substantial quantities" and is "anticipated to enter the environment in substantial quantities" or "there is or may be significant or substantial human exposure" to the chemical.

[2] *See* TSCA § 2(b)(3), 15 U.S.C. § 2601(b)(3).

[3] EPA Form 7710-25 (Rev. 12-19), Premanufacture Notice for New Chemical Substances, at 11 (PDF p. 16), available at https://www.epa.gov/sites/default/files/2020-02/documents/section_5_main_form_updated_omb_and_expiration_01142020.pdf.

[4] EPA (2022a) How to Access the TSCA Inventory, available at https://www.epa.gov/tsca-inventory/how-access-tsca-inventory.

[5] EPA, *supra* note 3.

[6] EPA (2022b), Conventional Reduced Risk Pesticide Program, Pesticide Registration, Office of Pesticide Programs, available at https://www.epa.gov/pesticide-registration/conventional-reduced-risk-pesticide-program.