



EPA Should Define More Precisely What Is “Reasonably Foreseen” under TSCA Section 5

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Introduction

This white paper explains why the U.S. Environmental Protection Agency’s (EPA) open-ended interpretation of what are “reasonably foreseen” conditions of use (COU) that must be evaluated when a new chemical substance notification is submitted to EPA under the Toxic Substances Control Act (TSCA) should be defined more precisely to reflect Congressional intent and avoid discouraging chemical innovation.

EPA Is Legally Required to Evaluate Chemicals under Reasonably Foreseen COUs

TSCA Section 5(a)(3), as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act (Lautenberg Act), requires EPA to review new chemical notifications (*e.g.*, premanufacture notices or PMN)¹ and to make a determination, including whether the new chemical substance will, may, or is not likely to present an unreasonable risk of injury to health or the environment² under the known, intended, or reasonably foreseen COUs.³

Except where EPA determines that the new chemical is not likely to present an unreasonable risk under the COUs, EPA is required to take further action, including imposing restrictions to the extent necessary to protect against unreasonable risk of the new chemical. If EPA makes a determination that the new chemical is not likely to present an unreasonable risk under the COUs, the submitter is free to commence manufacture of the new chemical without a TSCA restriction.

Key to this evaluation is EPA’s interpretation of what is a “reasonably foreseen” COU. The Senate Committee report states only that “[t]he term is not intended to include ‘intentional misuse’ of chemicals,” but provides no further clarity.⁴ The absence of greater specificity invites considerable uncertainty as to whether there are boundaries of what is “reasonably foreseen” and, if so, what those boundaries are. Clarity is essential to effectuate Congress’s intent and to define a concept by something other than the limits of human imagination. The past six years have proven that the absence of guidance has elicited wildly disparate outcomes and profoundly discouraged innovation in new chemicals.



EPA Should Define More Precisely What Is
“Reasonably Foreseen” under TSCA Section 5
October 2022
Page 2

One perspective that informs the meaning is comparing the term “not likely to present an unreasonable risk under the reasonably foreseen COU” to other statutory thresholds, such as “reasonable certainty that no harm will result” -- the statutory threshold for food use chemicals under the Federal Food, Drug, and Cosmetic Act (FFDCA). By not setting a standard of “reasonable certainty of no harm,” Congress clearly intended to allow a greater degree of uncertainty under TSCA than in regulating food use chemicals under FFDCA.

The absence of guidance facilitates overly broad interpretations of what is “reasonably foreseen,” triggers the imposition of unnecessary use restrictions that stifle innovation, undermines sustainability efforts, constricts supply chain flexibility, hinders economic growth, and undermines environmental justice progress.

EPA Conflates Reasonably Foreseen with “Someone Somewhere Might”

Since the Lautenberg Act was enacted on June 22, 2016, EPA’s current practice is that when reviewing PMNs, if EPA identifies a hazard other than low hazard to health and low hazard for ecotoxicity (“low/low”), EPA imposes a restriction, either in the form of a TSCA Section 5(e) order (usually a consent order) and/or a TSCA Section 5(a)(2) significant new use rule (SNUR). The notable exceptions to this practice are related to EPA changing its assumptions about the use of personal protective equipment (PPE) in 2019 and 2020. During that time, EPA assumed that non-use of routine PPE (*e.g.*, gloves and goggles) was not reasonably foreseeable in view of enforceable worker protection standards established by the U.S. Occupational Safety and Health Administration (OSHA). If EPA concluded that routine PPE would protect against the risks identified during the PMN review, EPA would make a “not likely” determination. Since June 2021,⁵ however, EPA no longer assumes “that workers are adequately protected under OSHA’s worker protection standards and updated Safety Data Sheets (SDS).” Rather, EPA assumes that the “absence of worker safeguards [*e.g.*, no PPE use]” are “reasonably foreseen” COUs.

This means that EPA now assumes that PPE is not worn. EPA points to OSHA’s top violations website,⁶ but neglects to acknowledge that lack of eye and face protection on that page relates to the construction industry, not the chemical industry. OSHA data on violations of the specific eye standard that applies to the chemical manufacturing industry (North American Industry Classification System (NAICS) 325) show that only six citations out of 162 issued in the chemical industry in fiscal year (FY) 2021 were for lack of eye protection.⁷

In addition, the legal standard is whether a substance is not likely to present an unreasonable risk under the reasonably foreseen COUs. In the chemical industry, it is reasonable to assume PPE is provided and required to be used -- even if there are instances in which PPE is not used. The statutory threshold does not require certainty -- the apparent inference in EPA’s rationale in eliminating the assumption.



EPA Should Define More Precisely What Is
“Reasonably Foreseen” under TSCA Section 5
October 2022
Page 3

EPA’s current practice of imposing regulations in all cases except low/low cases impermissibly makes EPA’s reviews on new chemical substances a hazard-based approach instead of a risk-based approach. TSCA requires that EPA perform a risk-based evaluation. EPA’s current approach is inconsistent with the specific language of the statute and renders measured data irrelevant. A submitter might generate workplace exposure and release data demonstrating that exposures and releases are well controlled given actual COUs. EPA nevertheless assumes that another company might not use those same levels of control and instead relies on its standard worst-case models for releases and exposures, thus ignoring the submitted data. If EPA routinely defaults to modeled data, there is no reason for a submitter to measure releases or exposures.

Similarly, if EPA regulates all cases that are not low/low for hazard, there is no reason for a submitter to generate toxicity testing data unless the submitter is confident that testing will demonstrate that the substance meets EPA’s low hazard criteria for both health and environmental effects. Simply put, data on the new chemical rarely, if ever, change the outcome of EPA’s review, embedding a perverse disincentive to chemical testing in the Section 5 review process, the very opposite of what Congress intended.

EPA Needs to Apply Reason to the Foreseeable Uses It Identifies

EPA should reevaluate its TSCA Section 5 policies and procedures and develop guidance on what COUs are reasonably foreseen. EPA’s current practice of speculating that “somebody might” someday exceed EPA’s concern level is a flawed interpretation of “reasonably foreseen” and is contrary to the law and Congressional intent. EPA should acknowledge and reward submitters that develop data to support PMNs rather than treating data-rich and data-poor PMNs the same -- by regulating all that are not low/low cases.

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EPA Should Define More Precisely What Is
“Reasonably Foreseen” under TSCA Section 5
October 2022
Page 4

¹ EPA also reviews microbial commercial activity and Significant New Use Notices under this standard. These cases are omitted for brevity.

² See TSCA § 5(a)(3), 15 U.S.C. § 2604(a)(3).

³ TSCA Section 3 defines COU as “the circumstances, as determined by the Administrator, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of.”

⁴ U.S. Congress (2015), *Frank R. Lautenberg Chemical Safety for the 21st Century Act, Report together with Minority Views*, 114th Congress, 1st Session, Report 114-67, at 7, available at <https://www.congress.gov/114/crpt/srpt67/CRPT-114srpt67.pdf>.

⁵ See EPA’s announcement, “Important Updates on EPA’s TSCA New Chemicals Program,” available at <https://www.epa.gov/chemicals-under-tsca/important-updates-epas-tsca-new-chemicals-program>.

⁶ See OSHA, “Top 10 Most Frequently Cited Standards,” available at <https://www.osha.gov/top10citedstandards>.

⁷ See OSHA, Industry Standard 19100133, Eye and face protection, https://www.osha.gov/pls/imis/industryprofile.stand?p_esize=&p_stand=1910.133&p_state=FEFederal&p_type=3.