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Thank you, Chairman Griffith, Ranking Member Tonko and members of the subcommittee for the opportunity to testify today. My name is Maria Doa. I am the Senior Director for Chemical Policy for the Environmental Defense Fund. EDF, one of the world's leading international nonprofit organizations, creates transformational solutions to the most serious environmental problems. To do so, EDF links science, economics, law, and innovative private-sector partnerships. With more than 3 million members and supporters, EDF's experts are working in 28 countries and across the United States to turn our solutions into action.

Overview

Nearly four decades after enactment of the Toxic Substances Control Act (TSCA) in 1976, it was apparent that the tools in the law were ineffective and progress in reducing chemical risks had been disappointing. Thousands of chemicals were being used and released to the environment, but few had been studied, assessed, or regulated and most chemical risks remained either unknown or unaddressed. Many stakeholders and members of Congress agreed that a stronger, more protective system of chemical regulation was needed. In 2016, after a decade long debate, Congress reached a bipartisan agreement, one that industry and health and environmental

organizations largely supported and passed the Frank R. Lautenberg Chemical Safety for the 21st Century Act (Lautenberg Act) with overwhelming bipartisan support. The Lautenberg Act significantly strengthened the once dead-letter law that left Americans unprotected from hazardous chemicals. The Lautenberg Act set a clear directive to protect human health and the environment. That hard-fought bipartisan compromise should not be reopened.

The improvements to TSCA made by the Lautenberg Act are starting to result in real gains in reducing our risks from toxic chemicals and protecting public health. This testimony will focus on two notable areas of the law that have improved chemical safety: first, for new chemicals entering the market, the requirement for an affirmative safety determination prior to market entry; and second, for chemicals already on the market, the regulation of existing chemicals, such as trichloroethylene and methylene chloride, that have been known to be dangerous for many years. Other notable areas of improvement include the requirement that EPA specifically consider more highly exposed and susceptible groups, including fenceline communities, workers, pregnant women and infants. This testimony will focus on the first two.

New Chemicals

Before TSCA was amended there was no requirement that the Environmental Protection Agency (EPA) make an affirmative decision on the safety of a new chemical before it entered the U.S. marketplace. It was up to EPA to determine whether a new chemical may present an unreasonable risk of injury to health or the environment. EPA had statutory authority to regulate chemicals if it had information indicating that the chemical may present an unreasonable risk. However, many chemicals, particularly those new chemicals with little or no data and few close analogs (chemicals with similar attributes), made it onto the market without any restrictions, because of a lack of information about the toxicity of the chemical. Requiring that EPA affirmatively determine the safety of the new chemical was a sea change for the new chemicals

program. Before the Lautenberg Act, EPA was only required to demonstrate that a new chemical may present an unreasonable risk. It was not required to demonstrate that the chemical could safely enter U.S. commerce.

EPA's safety determination now can range from a finding that the new chemical is not likely to present an unreasonable risk to a determination that it presents an unreasonable risk. Where EPA has identified unreasonable risks, it will typically put in place restrictions on the production, distribution in commerce, use and/or the disposal of the chemical to mitigate the unreasonable risks. Even with the range of determinations that EPA can make, it is important to note that almost all new chemicals are approved, including approvals with restrictions to mitigate the unreasonable risks. Indeed, more than 3,600 chemicals have been approved during the first eight years of amended TSCA.

New Chemical Review Period

Despite the fairly expeditious clip of approvals of new chemicals – more than one per day, there have been claims that EPA is holding up the approval of new chemicals and is not completing these reviews in 90 days. However, the delays in the review are most often caused by the new chemical submitters themselves failing to provide sufficient information upfront. This results in the submission of additional information later in the process that slows down the review.

A new chemical notice is only required to include information that is "known or reasonably ascertainable." As a result, EPA must often do its assessment with very little data. EPA will use the information included in a new chemical submission with other available data to conduct a risk assessment for the new chemical, which is then used as the basis of the new chemical safety determination. Submitters sometimes provide additional information after EPA has started or even completed the risk assessment, particularly if EPA has preliminarily identified significant risks. This information often focuses on environmental releases and occupational

exposure. As a result, EPA must revise the risk assessment which adds time to the review period. An EPA analysis indicates that some cases have required the risk assessments to be revised up to five times and could add several months to the review period.[1] If the submitter were to follow the law and provide all "known or reasonably ascertainable" information, they would likely avoid such delays.

Time is also added to the review process when EPA identifies unreasonable risks and works with the company to mitigate the unreasonable risk before the Agency approves the new chemical. Part of the additional time is for the submitting company to consider EPA's suggestions and identify and provide additional information to support its claims that a chemical can be safely used.

A third area that adds time to the review process is when a company disagrees with EPA on the safety determination itself, and the restrictions needed to mitigate unreasonable risks. Where there is a finding of unreasonable risk, companies may seek to minimize the terms of any restrictions as much as possible in order to gain as much market access as possible regardless of the potential risks to humans and the environment. This back and forth between EPA and a company is both time and resource intensive and takes EPA staff away from other cases.

Finally, the 90-day review period is not the determinative factor for new chemical reviews. The determinative factor is the affirmative safety determination that must be made before a new chemical can enter the U.S. marketplace. Before the Lautenberg Act, when the 90-day review period did serve as the determinative factor, far too many unsafe chemicals entered into the U.S. market.

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[1] EPA. TSCA New Chemical Engineering Initiative to Increase Transparency and Reduce Rework, https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/tsca-new-chemical-engineering

There is an easy solution to cut down the time spent on new chemical reviews. If EPA were to simply make a determination and identify restrictions, where warranted, based on the information provided in a company's initial new chemical submission, rather than committing considerable time and resources to help companies get their new chemical submissions approved, the Agency could more expeditiously complete its reviews.

Innovation

Another common complaint from industry is that despite the high rate of approval of new chemicals, EPA's implementation of TSCA impedes innovation because it does not quickly approve chemicals that are claimed to be innovative. Yet innovation by itself should not be the determining factor, as the damage from chemicals such as polychlorinated biphenyls (PCBs) and per-and polyfluoroalkyl (PFAS)—also known as "forever chemicals" clearly demonstrate. In fact, TSCA does not place innovation over health and safety. TSCA explicitly recognizes that innovation cannot occur at the expense of health and the environment.

> It is the policy of the United States that… authority over chemical substances and mixtures should be exercised in such a manner as not to impede unduly or create unnecessary economic barriers to technological innovation while assuring that such innovation and commerce in such chemical substances and mixtures do not present an unreasonable risk of injury to health or the environment.[2]

EPA should never be pressured to approve a new chemical that may present an unreasonable risk, no matter how innovative a company claims the new chemical may be. Unfortunately, companies often provide EPA with very little toxicity data for their chemicals, and

[2] §2601. Findings, policy, and intent

at the same time, pressure the agency to conduct assessments quickly, claiming that the chemicals under review support innovation and should therefore be approved.

Extensive interaction between EPA and companies often occurs with toxic chemicals that are important to key technologies, such as semi-conductors and electric vehicles. Some of these chemicals are quite toxic and EPA scientists and engineers often work with the company to identify process changes and engineering controls to mitigate risks so that these chemicals can be safely used and commercialized.

In addition to the unreasonable risks that can result from the production and intended use of a chemical, the EPA must also consider the potential exposures to a chemical in unanticipated ways, such as when an industrial chemical is also used in consumer products.

We have seen the problems caused by chemicals that were considered innovative when first introduced. We are now paying the costs to clean them up. For example, "innovative" chemicals, like PCBs, which were introduced many years ago, have since been banned because of their toxicity, persistence and presence in the environment, and ability to accumulate in fish and other animals. Today, we are still trying to clean up uses of PCBs from decades ago that continue to contaminate many of our schools. We are doing the same with PFAS that contaminate our drinking water, ground water, and farmland and can cause decreased fertility, developmental delays, and increased risk of some cancers, among other impacts. State and local governments are spending hundreds of millions of dollars to clean the contamination from their production and use.[3]

Some companies have argued that EPA is impeding innovation by putting restrictions on chemicals intended to be used in consumer products that are claimed to be safer than those on the

[3] For example, see Minnesota Pollution Control Agency, Evaluation of Current Alternatives and Estimated Cost Curves for PFAS Removal and Destruction from Municipal Wastewater, Biosolids, Landfill Leachate, and Compost Contact Water, https://www.pca.state.mn.us/sites/default/files/c-pfc1-26.pdf

market. This argument falls short because the TSCA approval for the new chemical does not result in a prohibition on the production and use of the existing chemical. As such, approving a new chemical that might be slightly less hazardous than one already on the market simply results in two harmful chemicals on the market.

We support innovation and true innovation embraces functionality and health and safety. EPA must be given sufficient information to make efficient and expeditious reviews that ensure adequate review and, where necessary, allow for restrictions to protect health and the environment while supporting innovation. The extra time needed to ensure that an innovative chemical can safely enter U.S. commerce is a small percentage of the multi-year process needed to develop a new chemical.

Existing Chemicals

Under the Lautenberg Act, EPA took the first meaningful action in 25 years to address the unreasonable risks of some of the worst of the worst chemicals, starting with asbestos, trichloroethylene, methylene chloride, perchloroethylene and carbon tetrachloride. These chemicals cause harmful effects on our health, including cancer, birth defects, neurological damage, liver and kidney disease, damage to immune system and even death. In the last two years, EPA finalized 5 new risk management rules for these harmful chemicals, banning many unsafe uses, dramatically strengthening worker protections, and providing greater protections for families and children across the United States from dangerous products. For example, EPA final rules on methylene chloride will protect the estimated 15 million consumers who use products that contained methylene chloride and will increase protections for the 900,000 workers.[4] The

[4] EPA. Methylene Chloride; Regulation Under the Toxic Substances Control Act (TSCA), Final Rule, 89 Fed. Reg. 39254, May 8, 2024, https://www.govinfo.gov/content/pkg/FR-2024-05-08/pdf/2024-09606.pdf

regulation for perchloroethylene will produce up to $80 million in economic benefits from reduced cancer rates alone, while allowing the vast majority of the current production to continue.[5] These regulations will also reduce the risk of those who live near the chemical plants that produce and use these harmful chemicals.

A significant improvement the Lautenberg Act made to TSCA that substantially contributed to these health protective regulations was the requirement that EPA use the best available science to determine the risks presented by the real-world exposure to the chemical rather than examining the risk of exposure to a single individual use. Our bodies do not distinguish exposure we experience from a chemical used in an adhesive from exposure by breathing in the same chemical being released by a nearby factory. Nor does our body distinguish releases of the chemical from a nearby facility that makes interior automobile parts from another nearby facility that uses it to make a refrigerant. While chemicals are used for different purposes and in different products, the total production, uses, distribution, and disposal of the chemical contributes to our total exposure. The sum of these exposures together with information on the potential harms caused by the chemical and the levels at which the harms occur informs how much of a risk we actually face from the whole chemical. An accurate evaluation of the risks presented by the chemical cannot be determined by examining exposure to an individual use of a chemical and treating that exposure as if it exists in isolation. By analogy, if someone were intent on limiting their consumption to 2,000 calories per day but only measured their calorie intake at breakfast, lunch and dinner, while ignoring between-meal snacks, they would necessarily understate their true caloric intake and stand a good chance of overconsuming and failing to meet their goal.

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[5] EPA. Perchloroethylene (PCE); Regulation Under the Toxic Substances Control Act (TSCA), 89 Fed. Reg., December 18, 2024, https://www.govinfo.gov/content/pkg/FR-2024-12-18/pdf/2024-30117.pdf

How exposure and risk are considered has real world implications. EPA is likely to come to a different conclusion on whether a chemical presents an unreasonable risk if it were to consider the exposure and risk from each use in isolation from the other uses instead of considering the sum of the exposures and risks from all the uses of the chemical. In addition to being core to the determination of whether a chemical poses an unreasonable risk, an accurate evaluation of risks is fundamental to determining the most effective way to mitigate that risk. TSCA provides EPA with a menu of risk management tools, ranging from banning the chemical or uses of the chemical, to process changes to labeling, to mitigate the unreasonable risk.

Considering the sum of all exposures is especially important for those subpopulations who are more susceptible to the effects of the chemical, such as infants and pregnant women. As an example, take trichloroethylene, a chemical associated with kidney and liver cancer and damage, non-Hodgkin's lymphoma, harm to the immune system and neurotoxicity as well as developmental harms including cardiac malformations and adverse effects on the developing immune and neurological systems. Underestimating the exposures to this chemical by artificially isolating the exposures from individual uses may have led to risk management restrictions that do not mitigate the unreasonable risk. Such a decision would have left in place exposures of trichloroethylene that significantly harm pregnant women and infants.

These five regulations are significant steps in protecting people and the environment from these well-known hazardous chemicals. They impact real people who have been exposed and harmed by these chemicals. EPA should continue to use the whole chemical approach to assess and mitigate the risks for chemicals.

Conclusion

The Lautenberg Act fundamentally improved our nation's approach to chemical safety and is the driver in reducing unreasonable risks from toxic chemicals. Two of the important tools for

these reductions are the requirement of an affirmative safety determination for new chemicals and the evaluation and regulation of the risks of existing chemicals based on our real-world exposures. Maintaining these aspects of the law, along with other key provisions, is essential for safeguarding public health, supporting informed innovation, preventing harmful chemicals from entering commerce and mitigating the risks from highly toxic chemicals on the market.