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Hearing
"A Decade Later: Assessing the Legacy and Impact of the Frank R. Lautenberg Chemical Safety for the 21st Century Act"

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Summary of Written Testimony of Richard E. Engler, Ph.D.

EPA has for decades reviewed new chemical notices under TSCA using a variety of data sources, including data on the new chemical, data on analogs, and models. EPA evaluates the hazards of the chemical (*e.g.*, how toxic it is) and the potential exposures to workers, the general public, consumers, and releases to the environment. This remains true today. As a result of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, EPA is now required to restrict the conditions of use for a chemical if EPA finds that the substance may or will present an unreasonable risk. If EPA finds that unreasonable risk is not likely to occur, EPA does not restrict the chemical.

In my considered judgment, EPA's New Chemicals Program has departed from the statutory requirement for EPA to evaluate unreasonable risk under the reasonably foreseen conditions of use. EPA now instead imposes restrictions whenever it finds that the chemical has any hazard other than "low hazard" for health and "low hazard" for the environment, regardless of how attenuated that hazard is or whether that hazard is or can be adequately controlled by other means. EPA does so even when the new chemical notice submitter provides robust toxicity data on the substance, including measured workplace exposures and/or facility release monitoring. This approach results in EPA restricting the vast majority of new chemicals. EPA issues these restrictions even to green and sustainable chemicals, including chemicals that are listed on EPA's Safer Choice ingredient list.

The imposition of restrictions is a significant barrier to market entry. EPA's restrictions come with significant compliance obligations, including recordkeeping and reporting for exports. Even if a company complies with the restrictions, the lack of records documenting compliance can be prosecuted as a TSCA violation and fines can be substantial. The record shows that this enforcement risk leads to market deselection by potential customers.

EPA's insistence on issuing restrictions for all chemicals that are not low hazard for both health and ecotoxicity reflects EPA's hazard-based approach to new chemical review that does not align with TSCA's clear statutory language. It is also proving to be a significant barrier to the adoption of green and sustainable chemicals, chemicals that have been fully commercialized around the world, including in the European Union, Canada, and Asia-Pacific countries. This is not to say that no new chemicals should be restricted. It is to say EPA's review of new chemicals often impermissibly restricts chemicals for modest, common hazards. Under its current policies, EPA would likely restrict vinegar and not allow its use by consumers as a descaler for coffee makers.

Congress must act to clarify its intent that TSCA requires EPA to ensure that only *unreasonable risk* is not likely to occur under the *reasonably foreseen conditions of use*, and not chemical hazards or risks not reasonably likely to occur.

Written Testimony of Richard E. Engler, Ph.D.

Good morning, Chairman Griffith, Ranking Member Tonko, Chairman Guthrie, Ranking Member Pallone, and members of the Subcommittee on Environment. Thank you for inviting me to testify before the Subcommittee today about the Toxic Substances Control Act (TSCA) and the Frank R. Lautenberg Chemical Safety for the 21st Century Act (Lautenberg amendments).

My testimony this morning highlights three key points : (1) the TSCA New Chemicals Program, since enactment of the Lautenberg amendments, has led to reduced innovation, hampered the adoption of sustainable chemistry, and is hastening commercialization of new and innovative chemistry outside the United States; (2) properly administered, the TSCA New Chemicals Program can promote innovation and spur adoption of new and more sustainable chemistry here in the United States; and (3) Congress should respond to these challenges by providing clear direction to the U.S. Environmental Protection Agency (EPA) and conducting appropriate oversight to ensure that TSCA's New Chemicals Program is implemented in a predictable, reliable, and transparent manner.

Education and Experience with TSCA

My name is Richard E. Engler. I am here today to speak about my experience with TSCA as a former EPA employee and, for the past ten years, as the Director of Chemistry for The Acta Group (Acta®). My testimony today focuses on the TSCA New Chemicals Program. I would be pleased to address any aspect of TSCA as I work in all aspects of the law.

I earned a Ph.D. from the University of California, San Diego. I taught introductory organic chemistry and other classes before joining EPA's Headquarters office in 1997 as a staff chemist. During my 17-year career at EPA, I participated in the review of thousands of premanufacture notices and low volume exemptions. My primary role was reviewing the identity and properties of the chemicals so that the other EPA assessors had the key information needed to perform a complete assessment. I also participated in hazard assessment meetings and decision-making meetings. While at EPA, I also ran the Green Chemistry Program, including the Presidential Green Chemistry Challenge Award. I left EPA in 2015 to join The Acta Group and am now the Director of Chemistry.

The Acta Group is a chemical regulatory and scientific consulting firm. Acta supports clients with chemical registrations in the United States and around the world. Acta assists with TSCA, the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), the Federal Food Drug and Cosmetic Act (FFDCA), the Canadian Environmental Protection Act, 1999 (CEPA), the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), UK-REACH, Korea REACH (K-REACH), and other global chemical control statutes. Acta also assists companies with Globally Harmonized System of Classification and Labeling of Chemicals (GHS)/Occupational Safety and Health Administration (OSHA) compliance. I provide chemistry support across those statutes and am particularly expert in TSCA. During my ten years with Acta, I have assisted clients with hundreds of new chemical notifications, referred to as Premanufacture Notifications (PMN), and exemption requests, known as Low Volume Exemptions (LVE), both

before and after the enactment of Lautenberg, and am intimately familiar with how EPA now is conducting review of new chemicals.

I wish to describe how, since enactment of the 2016 Lautenberg amendments, EPA's approach to new chemicals has stifled innovation, inhibited the adoption of sustainable chemistry, and is improperly evaluating chemicals using a hazard-based approach, rather than a risk-based approach, as mandated by TSCA. According to EPA's website, "*Under the Toxic Substances Control Act (TSCA), as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act, EPA evaluates potential risks from new and existing chemicals and acts to address any unreasonable risks chemicals may have on human health and the environment*." EPA acknowledges here it is required to evaluate and regulate using a risk-based standard that considers both hazard and potential exposures. In practice, however, EPA employs a hazard-based approach that perversely inhibits greener chemicals from entering the market and discourages chemical innovation at a time we most need next generation chemical products.

Risk vs. Hazard

A first step to understanding how Congress intended EPA to implement TSCA is to understand the difference between risk and hazard. These terms are sometimes used interchangeably but are quite fundamentally different. Here is an example to illustrate the point.

A shark in the ocean is a hazard, but it is not a risk if a swimmer is not also in the ocean near the shark. In this analogy, one would not prohibit sharks because they are hazardous to people, nor would EPA prohibit swimming anywhere in the ocean because a shark is also in the ocean, but when sharks are or are likely to be where people swim, we might mitigate the shark presence with underwater nets, or we might warn swimmers or even prohibit swimming. We also consider the size and aggressiveness of the shark. A small, docile shark is not likely to lead to injury unless a swimmer behaves aggressively toward the shark; in that case, we might not need any risk mitigation measures. This is how Congress intended TSCA to work. EPA evaluates the hazard of the shark, the likelihood of exposure of the swimmer to the shark, and, if warranted, implements risk mitigation measures to keep the swimmer (and the shark) safe.

TSCA New Chemicals

Under TSCA Section 5, EPA must review each PMN and make one of several determinations. EPA must determine whether a substance

1. is ***not likely to present*** unreasonable risk to health or the environment, including to potentially exposed and susceptible subpopulations, under the intended, known, and reasonably foreseen conditions of use;

2. ***may present*** unreasonable risk; or

3. ***will present*** an unreasonable risk.

In its determination, EPA is prohibited from considering cost or other non-risk factors.

If EPA determines that the substance may or will present unreasonable risk, EPA must issue a restriction in the form of an order and Significant New Use Rule (SNUR) to protect against the potential unreasonable risk identified.

If EPA determines that the substance is not likely to present unreasonable risk, the substance can proceed to market without restriction.

A key to determining whether a substance presents or may present an unreasonable risk is whether a condition of use is reasonably foreseen. When it enacted the Lautenberg amendments, Congress did not define "reasonably foreseen" or "not likely." Nor has EPA published its interpretation of either term. What I describe here is EPA's course of conduct and how EPA's New Chemicals Program is interpreting those terms, even if EPA has not expressed its interpretation of these terms in writing. First, allow me to explain how the new chemicals review process works, and has worked for decades.

When a manufacturer submits a PMN, EPA carefully reviews the chemistry, hazards, releases and exposures, and fate in the environment, and considers all relevant factors in its risk determination. When EPA conducts hazard review, it considers test data on the substance, test data for analogs, and predictive models. As currently practiced, if EPA finds there is any hazard other than "low hazard," a term of art, EPA imposes restrictions.

How low does the hazard have to be to avoid a restriction? Lemon juice would probably be hazardous enough for EPA to seek some controls. Based on EPA's current policies and practices, if vinegar were to be submitted in a PMN as a descaler for coffee makers, EPA would very likely not allow it to be used by consumers.

Vinegar definitely has hazards. It is irritating to skin, eyes, and mucous membranes and, if left on the skin, it will cause chemical burns. If inhaled, it will damage the tissues of the respiratory tract. EPA's current policy is that any corrosive substance may not be present in a consumer product above 3 percent. Acetic acid (the "active ingredient" in vinegar) is corrosive and most vinegar contains about 5 percent acetic acid, so EPA would prohibit vinegar as a descaler or other consumer use.

It is likely that EPA would allow vinegar to be used in industrial and commercial settings but would issue a restriction that it not be sprayed and that workers be required to use appropriate dermal

personal protective equipment (PPE). I question whether this is what Congress intended in the Lautenberg amendments. Nevertheless, it is EPA's standard practice.

Since enactment of the Lautenberg amendments, EPA has acted as though *any* uncertainty about any potential exposure, however improbable, is sufficient to conclude that the substance "may present" an unreasonable risk. Returning to the shark analogy, EPA would likely prohibit swimming because there might be a shark in the water, even if years of observations document that sharks do not inhabit the water or are only rarely present. Only if a submitter can prove that releases or exposures cannot possibly exceed EPA's concern levels (that is, we know to a scientific certainty that the shark will never be present) will EPA not require restrictions. Even when EPA does not find any exceedances of its concern levels for health or the environment using its worst-case analyses, EPA still issues a restriction. Restrictions can range from volume limits, import-only limits, required PPE, water release limits and/or prohibitions, such as no consumer use, or limit to a specified use, or some combination. The result is that EPA is implementing a hazard-based standard and not a risk-based standard as required by the statute.

EPA appears to be using the hazard-based standard because the identification of *any* hazard leads EPA to issue a restriction. EPA's implementation ignores any consideration of the statutory terms "not likely" and "reasonably foreseen." You may wonder "Is that not what society should want? For EPA to protect against all hazards?" In my view, that is not the standard in TSCA Section 5 and not what Congress intended with the Lautenberg amendments. Some hazards are familiar and

routine, and the public can be trusted to not misuse the substances and harm themselves or the environment.

There are other statutes to protect workers, consumers, and the environment. I know there is considerable debate on the effectiveness of the Occupational Safety and Health Act (OSH Act), but there is a clear duty to protect workers from the hazards like those posed by vinegar. The Federal Hazardous Substances Act (FHSA) prohibits sale of some products and requires warnings on other consumer products. There are federal, state, and local ordinances that prohibit improper disposal or dumping of spent chemical substances. EPA improperly assumes that none of these protective measures has any effect when it evaluates conditions of use. There is no support in the law or its legislative history that Congress intended for EPA to duplicate efforts to protect consumers from corrosive substances or to assume none of these measures exist or is followed. For an agency as resource-strained as EPA often claims to be, these efforts are not a good use of its resources or taxpayer dollars.

One of the drivers for TSCA reform that led to the Lautenberg amendments' enactment was EPA's need for data on chemical substances. Unfortunately, the practice of EPA has been that even if a submitter submits a robust set of toxicity data, if those toxicity data do not show the substance is low hazard for both health and ecotoxicity, EPA will issue a restriction. That makes the other foundation of risk assessment -- exposure -- irrelevant. If the data show that there is any chance that the shark can bite at all, under any circumstance, however improbable, EPA will impose a restriction. EPA often solicits specific data, finds those data acceptable, and still issues a restriction.

The problem is even worse for release and exposure data. Regardless of the data that submitters provide about workplace exposures or environmental releases, EPA as a matter of practice assumes that someone, somewhere, however improbable, might not take precautions. This practice negates entirely the value of release and exposure data, and ignores the all-important phrase under reasonably foreseen conditions of use. The time, expense, and animal use may refine EPA's concern level, but EPA will still issue a restriction. When asked about the why EPA is imposing restrictions, even duplicative restrictions, EPA often responds, "The restriction allows you [the submitter] to do what you wanted to do, so what is the big deal?" The thinking is, for example, you will protect your workers with gloves anyway, why is a TSCA requirement to use gloves a problem?

Bias against New Chemicals

EPA's practice has led EPA to issue restrictions on about 85 percent of PMNs since 2016 (*see* Table 1). Recently, that percentage has risen to more than 90 percent. The "big deal" is the effect this has on the supply chain for that chemical. TSCA restrictions require the specified protections, but they also trigger other TSCA requirements. Each company in the supply chain must follow the restrictions, each must document compliance with the restrictions, and each must satisfy other reporting requirements, such as export notices and the loss of exemptions for Chemical Data Reporting under TSCA Section 8.

Even if a company in the supply chain complies with all the prescribed protective measures, the lack of records documenting compliance can be prosecuted as a TSCA violation. EPA violations can be substantial, over $50,000 per day, per chemical. As many of you may know, TSCA enforcement actions have resulted in some of the largest fines imposed by EPA.

The potential of enforcement actions resulting from a paperwork violation is sufficient for many companies to decide not to purchase or use chemicals subject to these restrictions -- EVEN IF that chemical is less hazardous, more sustainable, performs better, or has other more positive characteristics compared to a chemical currently in use. The specter of enforcement has a commercially chilling effect. The financial implications are significant as are the consequences of damage to a company's brand and reputation.

The following example explains how a company could be found in violation. If a company that manufactures or uses a chemical has a new employee that performs all the required protective measures but fails to produce a record, each day without the paperwork record could be a $50,000 fine. That is $250,000 for a five-day workweek.

If a supervisor only reviews the records after six months, that could be $6.5 million of fines -- again not for failing to take the protective measures but failing to produce the paperwork. Add on top of that potential violations if the product is shipped to another country without notifying EPA in advance of the export. To make matters worse, EPA (justifiably) prioritizes enforcement of chemicals with restrictions.

Customers, especially customers that are not as familiar with TSCA, often do not want to take such a risk. They do not want to take the financial risk or risk being named in a press release from EPA's enforcement office and the reputational damage. The Acta Group has been working with its clients to help their customers better understand how to document compliance and to build systems to automate recordkeeping, but it is a significant undertaking for customers. It is often far easier to avoid the enforcement risk by not using the chemical, despite the obvious benefits of the new chemical. This is the essence of the bias against new chemicals.

Consider this more familiar scenario: if the chemical is a car, EPA would review the new car and find that performing routine maintenance reduces the risk of accidents. As a result, EPA would require routine maintenance and require that you keep records documenting that maintenance was performed on time. An alternative, older car does not have the recordkeeping requirement.

You, as a responsible car owner, do routine maintenance, but you worry that you might not be able to find a record of every visit to the mechanic or you might go a bit over the mileage that triggers the maintenance. In either case, it would be viewed as a violation. In addition, the police, when they see your model car, are more likely to pull you over to review your maintenance records. Wouldn't you hesitate to buy that car? Would you hesitate to buy that car for a novice driver that might not be as assiduous with maintenance and recordkeeping? It is this fear that leads customers to avoid substances with restrictions. An easier way to avoid the violation is to simply buy a different car that is not burdened by the recordkeeping requirement and associated enforcement risk. That's what happens to new chemicals with restriction.

Effects on Green/Sustainable Chemicals

EPA's approach to new chemicals is, unfortunately, stifling innovation. PMN submissions are way down. Before 2016, EPA received about 600 PMNs per year. After 2016, PMN submissions dropped to about 400 per year. For the past three years, companies have submitted fewer than 200 PMNs per year.

Some PMNs need to impose restrictions. Others, in my view, do not. Let me give you some examples.

There are several examples of chemicals that are listed on EPA's Safer Choice ingredient list -- EPA's list of the best-of-the-best chemicals for various products like laundry, dish detergent, car care, and spray cleaners -- being evaluated as PMNs.

In three cases, when substances that are nearly identical to full-circle-green ingredients -- those that were found to meet the Safer Choice criteria based on measured data -- were submitted as new chemicals, EPA determined that the new chemicals ***were too hazardous to be allowed in consumer products*** and imposed other restrictions, such as water release restrictions. One of these, a biobased-biodegradable detergent, has the lowest hazard profile of any detergent I have seen, but EPA insists it is still too hazardous to be allowed in commerce without restriction.

I expect that if all the ingredients on the Safer Choice list were run through the New Chemicals Program, the majority would be restricted in some way and many would be prohibited in consumer products. EPA has determined that other chemicals that were identified as a "Safer Choice" were also found to be too hazardous to be allowed in consumer products. This makes no sense—how can it be "safer" but also too hazardous to be allowed?

These are examples of why and how EPA is taking the wrong approach to the difference between "not likely" and "may" present an unreasonable risk. EPA is simply looking for certainty of no risk. In meetings, EPA has noted that it is not stating that it seeks certainty of no risk, only confidence. As a practical matter, however, the result is the same. Experience has shown that if EPA finds even the smallest hazard, EPA issues restrictions. This is, in effect, a hazard-based approach.

The result of EPA's approach is that great sustainable products -- ***products that have been thoroughly tested for safety and far surpass others in their category*** -- are being restricted in ways that make them undesirable or, in some cases, impermissible in products that would benefit consumers and the environment.

Many more sustainable products have been commercialized in all the other major markets outside of the United States. Unfortunately, consumers cannot benefit from these innovations because they cannot get through EPA's New Chemicals Program without restrictions that offer no environmental or human health benefit while making the chemical commercially uncompetitive.

The Need for Change

The Acta Group, on behalf of its many clients, has been discussing these issues with EPA since 2016. We have offered countless proposals to align better EPA's practices with the law as written. Unfortunately, EPA's practice has not changed across three Administrations. EPA's interpretation and implementation appears to be fully embraced in the program's operations and, in my view, is not going to change unless Congress acts to clarify its intent for the standard of review for new chemicals under TSCA. Let me be clear: new chemicals can pose risk sufficient to justify some restrictions, but those restrictions should be premised on a reasonably foreseen likelihood of risk, not the presence of any hazard under any condition, however improbable.

TSCA is the gateway to new products coming to market. If the United States is to be the leader in more sustainable chemistry, Congress needs to enact changes to TSCA to provide clear direction to EPA so that EPA is making determinations based on the best available science and rational, reasonable predictions and assumptions. If TSCA is not amended, then adoption of more sustainable chemistry will continue to lag. Americans will miss out on the economic, environmental, and health benefits of newer, innovative, sustainable products.

Other publications on this topic:

- Mark J. Washko and Richard E. Engler, Ph.D., How DOGE Can Help EPA: Proposing a Fourth Reform — Improving Agency Efficiency.

- Bergeson & Campbell, P.C. and The Acta Group, Forecast for U.S. Federal and International Chemical Regulatory Policy 2025.

- Lynn L. Bergeson and Richard E. Engler, Ph.D., "Optimizing the Toxic Substances Control Act to Achieve Greener Chemicals," American Bar Association *NR&E*, Summer 2022.

- Richard E. Engler, Ph.D. and Jeffery T. Morris, 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*, February 22, 2021.

- 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.

Determination Year	Number of PMN Determinations	Percentage of PMN Determinations that Include Restrictions	Percentage of Withdrawn Cases
2016	37	22%	34%
2017	324	88%	25%
2018	206	88%	23%
2019	293	81%	12%
2020	235	90%	14%
2021	87	68%	36%
2022	96	95%	14%
2023	101	90%	24%
2024	135	92%	13%
2025	1	100%	0%
Total	**1515**	**85%**	**17%**

Table 1: Table of PMN determinations made in each calendar year and the percent of those determinations that include restrictions of some kind. Withdrawn cases are instances in which the submitter withdrew the PMN; this is often, but not always, in the face of EPA's proposal of commercially unacceptable restrictions.

Source: EPA. Premanufacture Notices (PMNs) and Significant New Use Notices (SNUNs) Table. https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/premanufacture-notices-pmns-and as of December 12, 2024, supplemented with *Federal Register* notices for Significant New Use Rules.