Environmental Defense Fund

February 27, 2025

Mr. Calvin Huggins
Legislative Clerk
Committee on Energy and Commerce
2125 Rayburn House Office Building
Washington, DC 20515

Dear Mr. Huggins:

In response to the request by Chairman Griffith in his letter of February 12, 2025, attached please find my responses to the Questions to the Record for the Subcommittee on Environment on Wednesday, January 22, 2025, hearing entitled "A Decade Later: Assessing the Legacy and Impact of the Frank R. Lautenberg Chemical Safety for the 21st Century Act."

Sincerely,

Maria J. Doa, Ph.D.
Senior Director, Chemical Policy
Environmental Defense Fund

Attachment

Questions for the Record
Maria J. Doa, Ph.D.
Environmental Defense Fund

The Honorable Frank Pallone Jr.

1. **TSCA requires EPA to review new chemicals' potential risks to human health and the environment and enact safeguards to eliminate unreasonable risk. Several times throughout the hearing, we heard assertions that EPA's new chemical determinations are hazard-based and, therefore, frequently lead to 'undue restrictions' on new chemicals. Does EPA make new chemical decisions based on hazard or based on risk?**

   EPA takes a risk-based approach to new chemicals consistent with the TSCA requirement that EPA affirmatively determine whether a new chemical poses an unreasonable risk.

   Determining whether a new chemical poses an unreasonable risk requires EPA to assess both the hazard or toxicity of a chemical and the exposure to the chemical from its various uses. Hazard is the health harm a chemical can pose and exposure is how much of the chemical we inhale, absorb or ingest. The level of exposure to the chemical relative to the level at which the chemical can pose a harm indicates the likelihood of harm and determines the risk.

   To determine the risk the chemical presents, EPA must determine the hazard the chemical may present. However, EPA does not equate hazard with risk and stop there. It then compares the level at which the chemical poses harm with the level of exposure to determine if that chemical will pose an unreasonable risk.

   If EPA identifies unreasonable risks from a chemical, it must require steps to reduce exposures – such as discharge limits and workplace controls. By addressing exposure it is addressing the risk.

2. **Exposure estimates help EPA determine the risks of a chemical to the consumers, the environment, and vulnerable subpopulations, like workers and children. Appropriately quantifying exposure estimates is key to evaluating risks and adequately protecting public health. Industry has argued that EPA overestimates risk and therefore overregulates chemicals.**

   a. **Do you agree that EPA is overestimating risk? Why or why not?**

   EPA does not overestimate risks. EPA appropriately considers exposures from all uses of a chemical and all pathways of exposure, e.g., air, water, land. This is a more accurate way to assess risk based on the best available science. When we are exposed to a chemical it can be from different sources - and what is in the body is an aggregate from different sources. To not consider all the sources would underestimate exposures and health risks.

   While EPA does not overestimate risks, it often underestimates risks because it does not consider the TSCA exposure in the context of other exposures of the chemical and it does not take into account that many people, particularly those more highly exposed such as fenceline communities and workers, are more likely to be exposed to multiple chemicals that cause the same harm. This is particularly a concern for those who live near or work at facilities that make or use and release multiple similar chemicals. For example, chemical companies often specialize in chemicals known to cause the same harm such as PFAS or brominated flame retardants.

b. What would be the impact of adopting some of the suggestions by industry stakeholders to mitigate this perceived overestimation?

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. Considering exposures and risks from each use in isolation grossly underestimates a person's risks from a chemical.

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.

Considering the exposures in isolation would be particularly harmful for those subpopulations who are more susceptible to the effects of the chemical, such as infants and pregnant women. Underestimating the exposures to a chemical by artificially isolating the exposures from individual uses may lead to risk management restrictions that do not mitigate the unreasonable risk. Such a decision would leave in place exposures that could significantly harm pregnant women and infants.

3. Witnesses during the hearing testified about delays in new chemical reviews and claimed that EPA provides status updates and/or requests additional information from applicants on day 89 of a 90-day review period.

a. In your experience, is this an accurate depiction of the review process?

No. EPA asks for information that the company has and should have included in the original submission, including how the chemical is made and how it is intended to be used. This is basic information about the company's processes, how much of the chemical will be released to air, water and land, and how many workers will be exposed. The information that industry often fails to include in its original submission is the information needed to determine worker and general population exposure, which is typically determined early in the review process. This is information that is "known or reasonably ascertainable to the company" (the TSCA standard for new chemical submissions). The industry falsely labels this as "new" information requested by EPA even though this is information that should have been included in the initial new chemical submission.

Some information may be needed at the risk management stage, after EPA has made its unreasonable risk determination. Companies will often assert without substantiation that they have the controls in place to mitigate the unreasonable risk. EPA will request that the company provide information that supports these unsubstantiated claims.

b. What factors contribute to delays in the review process?

The industry is responsible for most of the delays in the review of new chemicals. Many cases take longer than 90 days because industry will submit information that should have been included in the initial new chemical submission midway through the process, industry will challenge EPA's risk assessment and industry frequently objects to EPA's finding of unreasonable risk and the restrictions needed to mitigate the unreasonable risk.

Late submission of data

New chemical submitters will 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 (TSCA New Chemical Engineering Initiative to Increase Transparency and Reduce Rework: Analysis of New Chemicals Rework Issues) 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. If the submitter were to follow the law and provide all "known or reasonably ascertainable" information, they would likely avoid such delays.

Challenging EPA's risk assessment

New chemical submitters, who have an economic interest in EPA's determination will challenge EPA's risk assessment. New chemical submitters will challenge EPA's scientists' determination on the toxicity of the new chemical, the level at which it causes harm, the exposures they have calculated and the risk of the chemical. These challenges result in further delays because after EPA defends the challenges to its assessments the new chemical submitters will state they want to provide new information on the new chemical or challenge EPA's scientific analysis from a new angle.

Challenging restrictions needed to mitigate the unreasonable risk

Another 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.

4. **At the hearing, some claimed that EPA has departed from statutory requirements and imposes restrictions on any new chemical that presents more than a "low hazard". They further claim that "safe" chemicals – such as vinegar – would be overregulated if EPA reviewed it under the new chemicals process as implemented by the Biden Administration.**

    a. **Is this an accurate assessment of the new chemicals program?**

No. Most new chemicals are actually toxic and many are highly toxic, such as the metal-based chemicals used for electric vehicle batteries and the persistent and bioaccumulative chemicals, including new PFAS, used to make microchips.

EPA routinely allows these and other toxic chemicals on the market with restrictions to mitigate unreasonable risks. Only where restrictions cannot mitigate the unreasonable risk will the chemical not be commercialized.

There is little incentive for industry to design truly safer chemicals given the risk framework of TSCA. Risk is a combination of hazard (toxicity) and exposure. The regulation of new chemicals is primarily regulation of exposure to the new chemical, e.g., through worker protections, limitations on releases to water, concentration limitations.

b. Is vinegar a reasonable example to use?

No. EPA would not regulate vinegar. Vinegar, which contains only very dilute weak acid, is a poor analogy for the highly corrosive new chemicals EPA reviews that can destroy human tissue.

While vinegar used for food is not subject to TSCA, the component that gives vinegar its tang - acetic acid could have TSCA uses. Vinegar is about 5 parts acetic acid and 95 parts water. Vinegar is that specific ratio; it is not any combination of acetic acid and water. As a result, higher concentrations of acetic acid in water are not vinegar - they would be inedible because they would burn your mouth. More highly concentrated acetic acid in water is corrosive. Inhaling this higher concentration of acetic acid in water or getting it in the eyes could cause chemical burns.

In assessing corrosive chemicals, EPA often puts concentration limits on the use of the chemical, particularly if the chemical could be used in a consumer product where it can be inhaled and get into people's eyes and cause lasting damage. For example, concentrated forms of corrosive chemicals may be used in industrial applications like metal etching, plating, and cleaning, due to their ability to break down materials like metal chemicals. However, this ability to break down metal compounds means that the concentrated forms of corrosive chemicals can also attack living tissue when they come into contact with it. Dilute forms of some of these chemicals are often effective for consumer uses, such as household cleaning products. Where these dilute forms are not harmful, EPA will approve their industrial use and put a concentration limit on their use in consumer products.

c. Why is it important for public health, the environment, and consumer confidence for EPA to adequately regulate new chemicals to eliminate unreasonable risk?

Assessing new chemicals before they enter commercial production and regulating them where they do or may present unreasonable risks is far more effective and much less costly than removing unsafe chemicals from the marketplace after they have caused significant harm.

Further, the public expects and wants assurance that new chemicals are safe prior to introduction. A recent survey shows that 92% of voters agree (63% strongly agree) that the government should require products to be proven safe before they're allowed on the market.

5. In December 2024, EPA finalized amendments concerning the new chemicals review process. The amendments clarified the level of detail needed in submissions and amended EPA's procedures for notices that are incomplete, amongst other updates. How will these changes improve the efficiency of chemical reviews?

These changes will increase efficiency both directly and indirectly. By clarifying the detail required in new chemical submissions, this action is expected to reduce the frequency of the submission of new information during the middle of the review that should been included in the initial review. This should result in a decrease in the number of times EPA must revise or completely redo a risk assessment. This should result in shorter, less resource-intensive new chemical reviews. It will also increase efficiency because the experts in engineering, general population and consumer exposure, ecological risk, and human health risk will no longer be diverted from working on other cases. This should also speed up the review of other cases.

6. In 2023, EPA proposed Significant New Use Rules (SNURs) under TSCA for 18 chemicals made from plastic waste-derived feedstocks, which are used in "advanced" or "chemical

recycling". Industry stakeholders have expressed concern with EPA's approach to plastic waste-derived feedstocks.

a. **Why is it necessary for EPA to review these chemicals before they can be used to produce transportation fuels?**

It is necessary for EPA to review these chemicals because they are unique complex mixtures of chemicals that are different from other fuels, and definitionally new chemicals.

In addition to meeting the requirement for TSCA new chemical review, they should be reviewed given the significant risks they pose. They are highly toxic chemicals that contain toxic byproducts and toxic impurities that are carried along to the fuel and can be released by the burning of the fuel. They are produced by a very inefficient process that in addition to producing toxic byproducts also releases toxic chemicals into the surrounding community.

Further, EPA should review these because of the differences among the new chemicals produced from different waste-plastic feedstocks. The make up of the new chemicals will be dependent upon the complex combination of contaminants from the additives in the original plastics; contaminants from residual materials in plastic containers, such as pesticides; and the dioxins introduced during processing.

b. **Can you speak to the environmental justice concerns of advanced recycling?**

TSCA-regulated facilities pyrolyzing waste plastic or using waste-plastic pyrolysis oils as feedstocks are often located near communities already facing significant industrial pollution burdens. These facilities produce and release carcinogenic combustion products, PFAS, dioxins, and heavy metals among other air toxics. EPA has estimated that air releases into the surrounding community at one facility would result in extremely high cancer risks - up to 100%. These toxic air releases can also lead to other serious health effects to nearby residents, including birth defects, harm to pregnant women, cardiovascular and respiratory impairment, neurological problems, and reproductive system damages.

c. **Industry claims that the chemicals in the proposed SNURs are 'chemically identical' to chemicals already on the TSCA inventory, obviating the need for notice and review. Is that a safe assumption?**

This is incorrect. The chemicals subject to the SNUR are not like chemicals on the TSCA Inventory. These chemicals are produced by the pyrolysis of waste-plastic streams that are often complex mixtures of different types of plastics (e.g., PVC, HDPE). The pyrolysis of waste plastic produces chemicals that are themselves complex mixtures formed during the inefficient and non-specific pyrolysis process.

This is further complicated because even within each general plastic category, there are tens and hundreds of different types with hundreds of different chemical additives (plasticizers, stabilizers, flame retardants). These include heavy metals (arsenic, cadmium, chromium VI, lead, mercury), dioxins, phthalates, PFAS, polybrominated diphenyl ethers, alkylphenols, perchlorates, benzophenone, bisphenol A, organochlorine pesticides, ethyl glycol, methyl glycol, or N-methyl-2-pyrrolidone. It has been estimated that a waste-plastic pyrolysis stream contains up to 1000 different chemicals (Joseph Vaillancourt, Cyclyx. World Petrochemical Conference 2024, Recycling Build Out & Technologies.)

d. Similar concerns have been raised regarding EPA's approach to substances categorized as renewable fuels. Should these chemicals circumvent the new chemicals process?

These chemicals should not circumvent the new chemicals process. The chemicals that are part of renewable fuels are not necessarily less toxic even if the feedstocks are based on renewable materials. Indeed, these renewable fuels can be as or more toxic than their non-renewable counterparts. EPA should review all new chemicals to determine if they may present an unreasonable risk. The Agency should not ignore unreasonable risks just because the feedstocks are claimed to be renewable.

The "advanced recycling" waste-plastic derived new chemicals have been falsely claimed to be renewable. If they were able to circumvent the new chemicals process because they were claimed to be renewable then these toxic fuels with sky-high risks would be on the market.

The Honorable Paul D. Tonko

1. I am very proud of the bipartisan work that this Committee has done in recent years to support Americans suffering from neurological disorders, such as Alzheimer's and Parkinson's. There is mounting scientific evidence that exposure to certain chemicals, like TCE, can be an environmental trigger for Parkinson's, and it is critical that EPA properly assesses all the quantifiable harms a chemical can pose to people.

a. Historically, has the TSCA program sought to quantify a chemical's risk primarily by how often that chemical is linked to causing cancer?

Yes. The TSCA program has expressed cancer risks as probabilities (e.g., 1 in a million risk) based on the assumption that generally there is no exposure level of a chemical without some cancer risk. In contrast, noncancer risks are based on a bright line – a threshold – below which there is no observed effect.

b. Do you believe TSCA chemical reviews are adequately considering and quantifying non-cancer risks, such as correlations to neurological disorders? And if not, what else can EPA be doing to better quantify these potential harms?

The bright-line approach of using a threshold for noncancer effects underestimates both the response and the variability in response across the population. EPA should use the probabilistic approaches recommended by authoritative scientific bodies, especially where the chemical in question produces noncancer effects that are likely to be compounded by exposure to other chemicals that exert similar health effects or to other non-chemical stressors, such as background aging, disease processes, etc.

This approach considers varying susceptibilities based on background exposures or biology, such as the vulnerability of children's developing systems, and does a better job than the threshold/bright line approach in estimating both the response and the variability in responses.

This approach can be used to calculate the risk of noncancer health effects across a range of exposures and how this approach provides more information than what is obtained through the TSCA program's traditional non-probablistic approach. Quantifying health risk above, at, and below threshold values is essential to contextualize population health

impacts for non-cancer effects, incorporate uncertainty and variability consistently and transparently, and allow more thorough assessment of risks.

The Honorable Robert Menendez

1. **On his first day in office, President Trump signed a swath of executive orders, undoing the important work carried out by the Biden Administration. Among these includes the reinstatement of Schedule F, which could result in potentially tens of thousands of career federal employees – many of whom are experts in their specialized fields – to be reclassified and laid off. Schedule F could seriously harm the important work carried out at federal agencies, including at the Environmental Protection Agency. I have concerns about how this policy could impact this important program.**

    a. **How would the reinstatement of Schedule F impact EPA's ability to conduct risk assessments and management rules under TSCA?**

Schedule F (now renamed Schedule Policy/Career) will affect the scientists and engineers who work on new chemical assessments and existing chemical evaluations and thus impact these TSCA assessments.

Because these assessments support regulatory actions, scientific and technical staff could be classified as working on policy and subject to Schedule Policy/Career. This would place significant pressure on the career scientific and technical staff to change their scientific conclusions. This is not just speculation on my part; I can attest to this based on my own experience. I directed the TSCA risk management programs for both new and existing chemicals from 2011 to 2018. In 2017 and 2018, there was constant pressure on the scientists, engineers and career managers to change scientific and technical analyses and risk management decisions to reduce the restrictions on chemicals or to change the decision and not regulate them at all.

    b. **How could the reinstatement of Schedule F impact the scientific integrity of TSCA?**

Making scientists and engineers subject to Schedule Policy/Career will undoubtedly impact the integrity of the TSCA determinations. The scientific and technical staff, who only want to do their scientific work and will follow the policy directions given, will be pressured – at the risk of losing their jobs - to downplay the toxicity of chemicals, to underestimate the exposures that communities, consumers, and workers face leading to fewer determinations of unreasonable risks. Many of these assessments will be compromised, will not represent the risks people and the environment actually face from toxic chemicals and will not be based on the best available science.