Responses to Questions for the Record, 1/22/25 Environment Subcommittee Hearing

Chris Jahn, President & CEO, American Chemistry Council

The Honorable Brett Guthrie

1. ***As discussed at the hearing, innovators who want to bring new chemicals or new uses of chemicals to the market have encountered major delays in receiving a decision from the Environmental Protection Agency (EPA) on whether and how they can proceed. The Lautenberg Act changed what must happen before an applicant who submits a new chemical or new use to EPA for review may proceed with processing or manufacturing that chemical. Previously, if EPA did not act within a specified time, the chemical could proceed to market. Now, applicants cannot proceed until they receive a determination from EPA.***

   Currently, EPA has 90 days to issue a determination on an application. In 2023, the Government Accountability Office (GAO) concluded that of all pre-manufacture reviews that EPA completed from 2017 through 2022, the agency typically completed less than ten percent of those reviews within statutory 90-day period.

   As of January 17, 2025, of the 407 new chemicals under review, only 22 are still within that 90-day review period.

   a) ***What happens if EPA does not issue a determination within the statutory timeframe? What recourse does an applicant have realistically?***

      The data shows that EPA has consistently failed to meet its statutory requirement to make a determination within 90 days. The delays and uncertainty around new chemical reviews have a profound effect on innovation and American manufacturing and must be addressed by Congress and the EPA.

      In practice, the EPA will ask the submitter to voluntarily "suspend" the application as the 90-day deadline approaches. The manufacturer has little recourse at this point. If they refuse to suspend, the agency would likely reject the application and the submitter would go to the back of the line. With time and money already invested in the Premanufacture Notice (PMN) application, manufacturers typically will agree to suspend and go beyond the 90-day deadline. In some cases, the reviews drag out over the course of several years.

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This is an area of the statute that should be examined as the Committee considers reauthorization of fees under the Lautenberg Act. The 90-day statutory deadline should mean something, and the EPA should be held accountable for meeting it.

b) The prior Administration has blamed lack of resources and an increased workload under the Lautenberg Act for this delay. Your organization has tracked the pace of new chemical reviews and collected data on this. Does this explain the backlog, or are there other factors to consider?

Lack of resources is not the main driver in causing delays in reviews. If anything, EPA has done less with more in recent years.

The fees for new chemical applications have more than doubled since 2016 and now cost $37,000. Total funding for the Office of Pollution Prevention and Toxics (OPPT), including appropriations and fees, has increased more than 40% since FY17, while the number of PMN determinations has decreased by 55%. This is not simply a problem of resources.

The issue that is driving the delays is the type of review the agency is conducting. Rather than following the intent of the law and focusing on what the chemical will actually be used for, EPA is considering hypothetical and unlikely future uses. The statute says EPA should make a determination based on whether a chemical is "not likely to present unreasonable risk." It does not say no risk.

Congress has the opportunity to clarify the original intent of the Lautenberg Act by directing EPA to evaluate the reasonably foreseen conditions of use for submitted chemicals. This would help cut down the time needed for reviews of PMNs.

EPA should be clear that it has two goals:

- Protecting human health and environment safety; and
- Fulfilling its their statutory responsibility to promptly review new chemicals submissions and make determinations in a timely manner.

2. On January 22, 2025, as some of my colleagues mentioned at the hearing, GAO released a report on EPA's New Chemicals Program, concluding that EPA does not follow most key management practices for assessing the results of this program.

a) GAO has developed key practices that can help federal agencies better manage and evaluate their programs. One key practice is to involve stakeholders, which, in this case, includes manufacturers and organizations that address environmental protection. GAO

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notes that the New Chemicals Division at EPA drafted a plan to address strategic goals in August 2024 but did not consult with stakeholders in doing so. Do you believe that EPA could more effectively engage manufacturers and other stakeholders in developing improvements to the New Chemicals Program to try to address some of the delays and concerns discussed at the hearing?

More consistent and effective engagement with stakeholders would certainly help improve the New Chemicals Program. ACC and our members need TSCA to work. We are eager to work constructively with the EPA to suggest ways to improve efficiency, streamline processes and ensure timely reviews of new chemicals.

b) ***As part of this review, GAO interviewed 19 manufacturers, and, unsurprisingly, 16 of the 19 reported that they experienced review delays. Of these manufacturers several reported frustrations about not knowing where their submissions stood in the review process. Is this an issue some of your members have experienced as well?***

We hear from our members about the lack of communication between the EPA and submitters all the time. There are very basic steps EPA can take to ensure better communication, including more regular check-ins between EPA staff handling the PMN and the submitter.

Congress has already expressed concern about this issue. Language included in the final FY24 Interior Appropriations bill and proposed FY25 Interior bills highlights the need for improved communications and directs the EPA to take steps to improve.

c) ***Most manufacturers GAO interviewed reported a need for increased transparency in new chemicals reviews. Several manufacturers recommended that EPA clarify requirements for the new chemicals review process. One suggestion included establishing updated, publicly accessible protocols on minimum likely testing requirements. Do you feel that manufacturers have a clear picture of what information will be required of them and what they will need to provide to EPA during the new chemicals review process? If not, do you have any suggestions for how EPA could address this concern or provide more helpful guidance?***

The lack of clarity on what data the EPA needs to conduct its review is a significant factor in causing delays. It is in the submitter's interest to provide the data and information necessary to ensure a timely review and having a clear understanding upfront of these data needs would improve the process. In some cases, EPA requests additional data and information from

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submitters only to ignore this information and rely on models and defaults. This inconsistency causes unnecessary delays.

EPA has made some effort to provide more direction for submitters, but there is more work that needs to be done.

2. ***Given the ongoing concerns around delays, lack of transparency, and the need for more stakeholder engagement, what effects have you seen these issues have on jobs, innovation, and the economy? How might improving the New Chemicals Program help foster growth in these areas?***

National defense, energy independence, modern healthcare, technology, innovation and a resilient supply chain all depend on chemistry. Supporting more domestic chemical production will help make America stronger and more affordable.

The health of American manufacturing depends on new chemicals coming to market in a timely and predictable fashion. New chemistry is essential to supporting American innovation.

Problems and delays with EPA's new chemical reviews are having a real-world impact. Since 2016, when the Lautenberg Act was passed, the number of PMNs has declined by more than half. Manufacturers are simply developing and submitting fewer new chemicals in America.

Companies are either a) not innovating and bringing new products to market, or b) are commercializing new chemicals overseas. Neither of these outcomes are desirable. It means the loss of innovation, the loss of American R&D, and fewer American manufacturing jobs.

Fixing EPA's broken New Chemicals Program would help our manufacturing sector thrive, encourage innovation, incentivize more R&D, and support more jobs.

EPA's evaluations of critical chemicals already in commerce should also be examined by the Committee. Regulations must put sound science first, promote innovation, and ensure resilient supply chains. However, in recent years EPA has made unrealistic assumptions about exposures to chemicals, resulting in overregulation that will disrupt vital supply chains. The Committee should ensure EPA's implementation of TSCA reflects the risk-based program that Congress intended.

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ACC and our members look forward to working together with Congress to improve TSCA.

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