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A DECADE LATER: ASSESSING THE LEGACY AND IMPACT OF THE FRANK R. LAUTENBERG CHEMICAL SAFETY FOR THE 21ST CENTURY ACT

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Testimony Summary

The American Fuel & Petrochemical Manufacturers ("AFPM") is the leading trade association representing the U.S. fuel refining industry, which supplies gasoline, diesel, jet fuel, sustainable aviation fuel, and renewable diesel around the country and the world; the petrochemical industry, which manufactures the essential building blocks for modern life; and the midstream energy industry, which makes it possible to transport energy feedstocks and products where they need to go.

The Toxic Substance Control Act ("TSCA") provides the Environmental Protection Agency ("EPA") unique authorities to regulate the production and use of chemicals. In practical terms, this gives EPA authority over the manufacture and use of much of what Americans rely on in their daily lives. Recognizing the potential impacts on the U.S. economy, Congress attempted to write a balanced statute that ensures chemical risks are appropriately managed for their conditions of use without needlessly impeding the manufacturing economy. In other words, they sought reasonable regulations to control unreasonable risks of injury. This concept of risk is critical. It is a term that accounts for both the hazards of a chemical, but importantly also the exposure to the hazard.

AFPM supports a TSCA statute that stays true to these objectives. The law must remain anchored to science-based risk analysis, prioritize those substances based on likelihood of exposure, and reasonably manages the unreasonable risks of injury that come through the substance's normal conditions of use in a manner that supports a high and affordable American standard of living.

AFPM is concerned EPA's implementation of TSCA is inconsistent with the statute and principles of risk management. In the existing chemicals program, EPA's approach to prioritization and risk management is rooted in a hazard analysis focused on all uses of a chemical, rather than exposures through normal conditions of use. Under this hazard-based approach, EPA is regulating conditions of use that pose no unreasonable risk of injury (i.e., if evaluated separately, those uses would pose no unreasonable risk) and industry is left without any ascertainable certainty about how EPA will regulate risk.

EPA's hazard-based approach to prioritization and risk analysis is further complicated by EPA's implementation of the scientific and coordination provisions in TSCA that require the "best available science" and "weight of the evidence." For example, EPA's risk evaluations assume industry workers do not wear personal protective equipment and make erroneous assumptions about worker exposure to chemicals. EPA is also failing to adequately coordinate with other agencies, particularly OSHA, and ignoring TSCA's directives to defer to other agencies designed to manage particular risk.

EPA's implementation of the New Chemicals Program under Section 5 is hindering new products through a combination of backlogs and a burdensome risk evaluation process.

Finally, AFPM identifies ongoing issues throughout TSCA related to test orders and information collection.

Full Testimony

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AFPM appreciates the opportunity to share its views on the implementation of the 2016 amendments to the Toxic Substances Control Act ("TSCA"). Congress crafted TSCA to address areas that are not addressed other statutes governing environmental media, consumer protection, and safety. The statute provides the Environmental Protection Agency ("EPA") unique authorities to regulate the production and use of chemicals. In practical terms, this gives EPA authority over the manufacture and use of much of what Americans rely on in their daily lives. For example, plastics are essential for applications in healthcare, energy, transportation, home goods, food packaging, cleaning products, and clothing. AFPM companies are likewise innovating new fuels, which are also subject to TSCA. Restrictions on chemical uses can have both intended and unintended consequences for not only products in the market today, but also for the introduction of new and better products tomorrow.

Recognizing the potential impacts on the U.S. economy, Congress attempted to write a balanced statute that ensures chemical risks are appropriately managed for their conditions of use without needlessly impeding the manufacturing economy. In other words, they sought reasonable regulations to control unreasonable risks of injury. This concept of risk is critical. It is a term that accounts for both the hazards

of a chemical, but importantly also the exposure to the hazard. Determining risk is nuanced and complex, but it must start with the use of sound – meaning objective and high quality – science.

AFPM supports a TSCA statute that stays true to these objectives. The law must remain anchored to science-based risk analysis, prioritize those substances based on likelihood of exposure, and reasonably manage the unreasonable risks of injury that come through the substance's normal conditions of use in a manner that supports a high and affordable American standard of living.

I. Implementation of the Existing Chemicals Program (Section 6) is Inconsistent with the Statute and Principles of Risk Management

A. The Current Rationale for Prioritization of Existing Chemical Reviews is Arbitrary

The 2016 amendments to TSCA established a process for EPA to prioritize chemicals on the TSCA Inventory as either "high" or "low" priority for risk evaluation. Then, EPA is required to evaluate the risks associated with certain uses of those high priority chemicals and determine whether there is an unreasonable risk of injury from any of the identified uses. To implement these provisions, in 2017 EPA published rules describing how chemicals would undergo prioritization and subsequent risk evaluations. Those rules focused agency resources on specific uses for each chemical and on those with the greatest potential for exposure. This approach was consistent with the amended TSCA and rightfully focused agency resources on chemicals with the highest potential risk.

Unfortunately, in 2024, EPA revised the risk evaluation methodology and rather than focusing on specific uses with the greatest potential for exposure, it now focuses on the chemical's hazards. EPA is also trying to capture every possible use of a given chemical, even those that are unlikely to occur or to have any appreciable impact on overall risk. This "hazard-based" approach is now yielding high-priority designations for chemicals such as industrial intermediates that are used to make other chemicals and processed in closed-loop systems at highly regulated facilities. To illustrate, the five chemicals that EPA

designated as high priorities for risk evaluation last month all fit this description, as do the next five on which EPA has solicited comment.

B. Current EPA Practices Are Not Based on Established Principles of Risk

Upon establishing a chemical as a high priority for risk evaluation, EPA is now determining risk of injury on the basis of the chemical as a whole even if there are safe uses of that chemical. Previously, EPA's regulatory approach was designed to assess unreasonable risks of injury from potential exposures for each specific condition of use within the scope of the evaluation. As a result of this new approach, EPA does not distinguish between instances where there is high potential for exposure (for example, in consumer products) and where there is minimal potential for exposure (for example, in industrial closed-loop processes or laboratory settings).

This "whole chemical" approach (assigning a single risk to a chemical regardless of it actual uses) results in an unreasonable risk of injury determination driven by whatever use or uses that EPA determines poses an unreasonable risk. And unsurprisingly, EPA has deemed every substance it has evaluated as presenting an unreasonable risk of injury and therefore subjected to stringent risk management measures. Under this hazard-based approach, EPA seeks to regulate conditions of use that pose no unreasonable risk of injury (i.e., if evaluated separately, those uses would pose no unreasonable risk) and industry is left without any ascertainable certainty about how a chemical will be regulated in a subsequent risk management rule.

C. EPA Disregards TSCA's Sound Science and Coordination Provisions

As part of its risk evaluation, EPA is required to use the "best available science" and "weight of the evidence." Unfortunately, EPA has interpreted TSCA to allow the Agency to make arbitrary assumptions about how risk is currently evaluated and managed. For instance, EPA assumes that industry workers do not wear personal protective equipment ("PPE") when handling hazardous chemicals. This is an arbitrary assumption, untethered from the reality of AFPM members' procedures, and, importantly, the

Occupational Safety and Health Administration's ("OSHA") PPE requirements. This false assumption cannot be squared with TSCA's directive to EPA to evaluate "intended, known, or reasonably foreseen" conditions of use. It also disregards TSCA's requirements to coordinate with other federal agencies.

OSHA is the federal agency tasked with regulating the workplace, a fact long acknowledged by EPA. OSHA establishes regulations to protect workers from chemical hazards, including through creating "permissible exposure limits" ("PELs"). OSHA has PELs for approximately 500 chemicals, many of which overlap chemicals under TSCA review. The American Conference of Government Industrial Hygienists ("ACGIH") is another expert body that develops workplace exposure limits through a standards-setting process. Rather than defer to OSHA or ACGIH on such matters, EPA has supplanted established values with its own workplace exposure limits, which are developed in a vacuum with no opportunity for public or expert input and in many cases orders of magnitude lower than OSHA and ACGIH values. Section 9 of TSCA contains a mechanism for EPA to refer risks to other agencies if it determines a risk "may be prevented or reduced to a sufficient extent by action taken under a Federal law not administered by the Administrator." Section 9 then precludes EPA from further consideration of those risks. In other words, EPA's no-PPE assumption is plainly contrary to both the intent and plain language of the statute.

EPA's disregard for TSCA's science quality provisions goes beyond its failure to defer to OSHA. EPA models are riddled with unrealistic assumptions, including low-frequency events like misuse and rare accident scenarios, which distort the potential for exposure and do not stand up to the science quality provisions in Section 26. For instance, AFPM members that are part of a butadiene consortium of manufacturers provided EPA fence line monitoring data, but the Agency disregarded the measured data in the draft risk evaluation in favor of less reliable modeling data. This runs counter to basic scientific quality principles, where measured data is generally favored over modeled data.

In another instance of false assumptions, EPA found an unreasonable risk of injury for a product used by AFPM members on the basis that the product was transferred 250 times per year for 8 hours per transfer, and that there was an accidental release every time, and that a worker got splashed and didn't wash it off for 8 hours. AFPM members met with EPA staff and provided upper bound numbers to challenge the model assumptions, but EPA chose not to use those numbers and stuck with its unrealistic assumptions, resulting in an unreasonable risk of injury finding for workers at petroleum refineries. To be clear, American petroleum refineries are among the most stringently regulated and safest manufacturing sector in the world.

Real world changeouts and potential exposure opportunities are significantly different from those assumed by EPA's models. Consider, according to AFPM members that use perchloroethylene (an important refining catalyst), that on average, the frequency that totes are switched out is 10 to 35 times per year. The duration of each changeout is approximately 15 minutes. The frequency of tank truck changeouts is anywhere from 2 to 12 times per year, with an average duration between 30 and 60 minutes each time. The variability in frequencies is due to each refinery being different in design, layout, and processing capacity. If EPA had used the upper bound values provided by AFPM and not assumed that an accidental release occurred every time, EPA simply could not have found an unreasonable risk of injury.

II. The New Chemicals Program (Section 5) is Hindering New Products and Solutions to Societal Problems

TSCA requires manufacturers to receive affirmative EPA approval before they can introduce a new chemical into commerce or to engage in a significant new use of a chemical already commercially manufactured. Congress established – and in 2016 retained – deadlines for EPA to approve these applications; EPA routinely misses and has avoided accountability when it does so.

The Government Accountability Office ("GAO") found in 2022 that the EPA completed no new chemical reviews within the statutory deadline of 90 days, and only 10 percent of reviews were completed before the statutorily permitted extension of 180 days. These delays is that they hurt manufacturing by creating market uncertainty and prevent new products from coming to market that can help address societal problems.

In one example, EPA proposed a significant new use rule ('SNUR") to regulate the components of pyrolysis oil. Pyrolysis oil is the product made from heating plastic waste in the absence of oxygen (i.e., pyrolysis), a key advanced recycling technique. Pyrolysis is a process that enables manufacturers to break down waste plastics and return them to useful feedstocks that can then be made into new plastics. The process facilitates the ability to recycle a wider variety of plastics than mechanical recycling and also enables the new product to meet standards for virgin plastics without diminished quality or contamination. The components subjected to the proposed SNUR are indistinguishable from chemicals already on the TSCA Inventory and should be deemed equivalent so that a notice and review are not required, and yet the SNUR has been pending since 2023, impeding the ability to scale advanced recycling to meet goals.

In a second example, EPA announced it would subject new renewable fuels to TSCA. When even a small percentage of renewable feedstocks is co-processed with petroleum feedstocks, the EPA considers the resulting fuel products—despite being compositionally identical to those made entirely from petroleum—as new substances subject to lengthy and unpredictable TSCA review and approval. It creates unnecessary barriers and substantially delays bringing renewable fuel products to market in the U.S.

III. Additional Areas for Consideration

In addition to Sections 5 and 6 of TSCA there are important implementation issues with other sections of the statute.

A. Test Orders (Section 4)

The scientific modeling concerns mentioned previously also apply to TSCA section 4. Section 4 gives EPA authority to require manufacturers or processors of a certain chemical or mixture conduct testing to produce new information. Congress broadened this section in 2016 to make it easier for EPA to compel information production. Unfortunately, EPA has made unrealistic assumptions and employed unrealistic practices here too, and has exceeded Congressional intent. For instance, EPA issued test orders for several companies, including an AFPM member, on a volatile chemical. This chemical has known physical/chemical properties that when released into the environment, it rapidly evaporates from water or soil surfaces. Yet, the EPA issued these test orders requiring these companies to conduct both earthworm and avian studies. However, the chemical evaporated rapidly in the soil or avian feed, so the studies, ultimately, could not be conducted. EPA also asked several companies, including an AFPM member, to conduct a consumer exposure study for a chemical that was no longer used in any consumer products.

B. Section 8 (Information Collection)

Section 8 has several provisions related to the reporting and maintenance of information about chemicals actively in use in the United States. Until recently, EPA had historically exempted impurities and byproducts from reporting under Section 8. Instead, EPA has now decided to end those exemptions in order to aggregate those exposures. For example, EPA just finalized a rule requiring companies to extract every study conducted on sixteen chemical substances, including if the substance was just an impurity in a mixture. Unfortunately, many of these studies were conducted before the development of

software to manage such information and making companies find and verify this impurity information will be quite burdensome, and in some cases impossible.

C. Section 26 (Information Usage and Risk Framework)

TSCA requires EPA to use the "best available science" and "weight of evidence" to inform its regulatory approach. It is critical that adherence to sound and objective high-quality science be the foundation of EPA's regulatory work, including evaluations made by the Science Advisory Committee on Chemicals ("SACC"). This is particularly true under TSCA, which concerns not just health and environmental matters, but also economic factors and national security. From AFPM's perspective, if industry and interested stakeholders do not trust the science used by EPA, the TSCA regime falls apart. Restoring trust in the science underpinning TSCA evaluations should draw serious congressional and executive branch attention.

IV. Conclusion

Thriving refining and petrochemical industries are critical for U.S. energy security, national security, and the economy. Maintaining and expanding the U.S. competitive edge as a global leader in innovation and manufacturing requires reasonable and predictable regulations. The Administration and Congress should ensure TSCA strikes a proper balance between reasonable regulations to manage unreasonable risks of injury and the high and affordable stand of living and quality of life in our country. AFPM appreciates the Committee beginning its work to review implementation of the 2016 reforms and looks forward to working with Congress and other stakeholders to make TSCA a more workable and effective law.