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The Honorable Morgan Griffith
Chairman
Subcommittee on the Environment
U.S. House of Representatives
2125 Rayburn House Office Building
Washington, DC 20515

The Honorable Paul Tonko
Ranking Member
Subcommittee on the Environment
U.S. House of Representatives
2322A Rayburn House Office Building
Washington, DC 20515

Dear Chairman Griffith and Ranking Member Tonko,

AFPM appreciates the opportunity to have testified at the January 22, 2025, Energy and Commerce Subcommittee on the Environment hearing entitled: "*A Decade Later: Assessing the Legacy and Impact of the Frank R. Lautenberg Chemical Safety for the 21st Century Act."* We appreciate the Committee's efforts to review implementation of the 2016 reforms to the Toxic Substances Control Act (TSCA) and look forward to working with Congress and other stakeholders to make TSCA a more practical and workable law. AFPM supports a TSCA statute that remains anchored to science-based risk analysis and decision-making, prioritizes substances for review based on the likelihood of meaningful exposure, and reasonably manages the unreasonable risks of injury presented by the substance's normal conditions of use.

AFPM is pleased to provide the following responses to the Subcommittee's Questions for the Record.

Responses to Questions from the Honorable H. Morgan Griffith

1. **Could you briefly summarize an example of a new or existing chemical review application, involving one of your members, and dating from the beginning of 2016 to the present day, where the applicant believed that the EPA overly relied upon a single study when making its risk assessment? You do not have to name the specific applicant, a specific chemical, or a specific chemical use.**

In relation to existing chemicals, the risk management rule for perchloroethylene (PCE) is an example where EPA relied heavily on a limited data set. For PCE, EPA disregarded measured data from laboratory studies to set the Existing Chemical Exposure Limit (ECEL), which is a new workplace exposure threshold. EPA stated that the ECEL for PCE (0.14 ppm) is based primarily on two studies[1],

[1] Cavalerri et al., 1994, and Echeverria et al., 1995

both of which are epidemiological studies with very small sample sizes and subjective endpoints, such as "color confusion, impaired pattern recognition, and reaction time in pattern memory."[2] Neither study quantified the actual level of PCE in the study subjects; rather, both used air sampling as a surrogate for actual dosages. PCE, though, has a robust data set and toxicological profile. In the Proposed Rule EPA did not adequately compare the study designs or weight the studies, as instructed by Congress in TSCA Sec. 26, to provide an indication of why the Agency chose those two as the primary drivers for such a dramatic shift in workplace exposure thresholds.

2. How would you suggest the EPA weigh evaluation studies of new and existing chemicals?

TSCA professionals and scientists generally agree that there is a hierarchy of preference with respect to weighing the quality of scientific studies used to make conclusions about chemical risk. Among these groups there is a general consensus that measured data is favored over modeled data because, according to EPA, "measured data obtained under realistic conditions are generally more accurate than modeled estimates."[3] Equally important, though, individuals analyzing risk should use a system to objectively judge the quality of the studies and provide the results of the data quality analysis and rationale in the risk evaluation itself. EPA's data quality analyses have been insufficient in many of its risk evaluations to date.

a. Should evaluation studies and statistical models with different methodologies be used for new chemicals and new conditions of use as opposed to other types of studies for existing chemicals?

All scientific studies should be relevant for their purpose, use validated methods, and follow good laboratory practices. Because of a lack of empirical evidence regarding the use of a new chemical, EPA depends on models with conservative default assumptions to evaluate potential exposures. Those models do not reflect realistic use scenarios that may assure resulting values can be assumed to be protective. Existing chemicals, on the other hand, often have actual monitoring and other measured data from the chemical's use, so EPA need not rely on conservative, hypothetical scenarios to estimate exposures. EPA should use measured data in evaluations for existing chemicals. As stated above, EPA should weigh all studies according to quality and report the results when using those studies to support conclusions in a risk evaluation.

Responses to Questions from the Honorable Brett Guthrie

1. What challenges have applicants faced when attempting to communicate with the Environmental Protection Agency (EPA) during the new chemical review process?

AFPM members commonly point to lack of clarity from EPA in the pre-section 5 process as particularly challenging. In the period before the company submits its section 5 notice for review, EPA is generally unclear as to what data – and the level of specificity required for such data – for a notice to be considered "complete." A company then submits the information relevant for the chemical notice and

[2] See *88 Fed. Reg.* 39652. "Perchloroethylene; Regulation Under the Toxic Substances Control Act (TSCA)." EPA-HQ-OPPT-2020-0720; FRL-8329-02-OCSPP, published June 16, 2023. pp. 39655 and 39659.
[3] See EPA's webpage on exposure and fate modeling. Accessed February 27, 2025.

the uses of the chemical, but EPA often holds up review (claiming the notice is incomplete) until the company produces information on irrelevant use cases. EPA previously had a program, entitled "Sustainable Futures," that established a common baseline of understanding for submitters, reviews, engineers. Now, instead of preassessment meetings or technical workshops, companies report EPA's operation of the program is reviewer-dependent. This creates uncertainty for companies submitting multiple chemicals for reviews, as they are unable to ascertain what is expected before entering the process.

Once the company submits the notice to EPA, AFPM understands that EPA is opaque about how it uses the data provided to it. Actual data submitted by the applicant company is sometimes ignored in favor of less relevant modeling data. Moreover, because the opportunity to engage with EPA on its use of modeling data is reviewer-dependent, that adds to existing review delays. GAO reports[4] EPA has not for standardized the pre-manufacturing notice (PMN) process, a 2023 recommendation of its Office of Inspector General.[5]

Finally, AFPM is aware that EPA does not have an easy way for an applicant to determine the status of their PMN – and one AFPM member told us EPA employees sometimes do not even seem to be aware of the status of the PMN assigned to that staff. EPA also has considerable technological issues related to PMN and this exacerbates these issues. AFPM members have experienced repeated technology challenges presented by the operation of the TSCA program's main computer portal – discussed in the answer to Question #2.

2. **On January 22, 2025, as some of my colleagues mentioned at the hearing, the Government Accountability Office (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 programs. (citation omitted). 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?**

Better communication, transparency, and understanding between EPA and regulated companies is always welcome.

AFPM does not support a requirement for companies to generate a minimum data set for new chemicals manufactured in the United States. This is because a hazard-based approach does not consider the potential for exposure when setting testing requirements. The minimum data set concept was thoroughly discussed, analyzed, and rejected during the drafting of the 2016 amendments to TSCA.

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[4] https://www.gao.gov/assets/gao-25-106839.pdf

[5] The EPA Lacks Complete Guidance for the New Chemicals Program to Ensure Consistency and Transparency in Decisions and GAO-25-106839, NEW CHEMICALS PROGRAM: EPA Needs a Systematic Process to Better Manage and Assess Performance

A tiered, targeted, and risk-based approach, which is fundamental to TSCA, uses the potential for exposure to efficiently and effectively drive toxicity data needs, starting at a less involved screening level, then moving up the tiers to more extensive testing as the results from hazard and exposure screening demonstrate whether there is a need for more definitive testing. There is no reason to conduct a toxicity test for an exposure that is unlikely to occur.

There is inconsistency in our members' experience when going through the new chemicals process. EPA's computer portal (CDX) is out of date and inefficient (due to repeated crashes and out-of-service periods). It has been an unreliable system and does not provide the status of the review. To further complicate matters, our members have expressed inconsistency with the PMN case managers as well. The case manager has a great deal of discretion and can affect the outcome of the PMN review.

EPA should continue its prenotice consultations, where a PMN submitter can meet with EPA technical staff and go over a draft PMN before it is submitted. EPA scientists can go over their expectations and provide valuable guidance to the submitting company. AFPM also supports a return of the Sustainable Futures program that instructs PMN submitters in the use of the models EPA utilizes to conduct screening-level risk evaluations on new chemicals.

3. **During the hearing there was discussion about whether the Toxic Substances Control Act (TSCA) should be "opened up." Your written testimony states that American Fuel & Petrochemical Manufacturers (AFPM) supports a combination of administrative and regulatory actions and statutory changes to TSCA.**

    a. **Is implementation the only problem with the current regulatory framework?**

Improved implementation and targeted statutory changes are both necessary to accomplish TSCA's objectives. AFPM believes further clarifying the statutory text will improve outcomes, provide additional predictability, and help focus EPA resources on the highest-risk chemicals. AFPM's testimony highlights some initial examples of suggested targeted statutory changes and we look forward to working with Congress and other stakeholders to make TSCA a more workable and practical law.

    b. **Why does your organization support a multi-pronged strategy, and can you please provide some examples of statutory changes you believe are needed?**

AFPM is convinced targeted statutory improvements in various sections are needed in addition to a few administrative improvements to create meaningful and durable reforms. In light of the Supreme Court's decision in Loper Bright v. Raimondo (2024), AFPM supports administrative changes where the statute clearly gives EPA the ability to improve effectiveness and efficiency of the program – like having section 26(h) science quality criteria apply early in the review process to prevent entire reviews and decisions from being informed by information of low scientific quality or bias.

In places where TSCA has gaps, is unclear, or the law drives adverse outcomes – statutory change is essential. We recommend Congress consider changes such as preventing EPA from (1) regulating chemicals without a risk concern simply because they're made in large quantities, (2) disregarding the creation of risk transfers when deciding unreasonable risk, (3) considering impurities and byproducts as chemicals themselves, and (4) insisting on regulating de minimis levels of a chemical.

The Committee should also consider how to ensure TSCA section 21 does not allow circumvention or truncation of careful review of a chemical's risk.

c. Do you support a regime for TSCA like that of the Pesticide Registration Improvement Act?

AFPM does not support using PRIA as a model for TSCA or turning TSCA into and federal licensing program. The statutes seek to address fundamentally different applications– one is for poisons intended to kill plants or insects and the other is for industrial chemicals. More specifically, PRIA requires that the deadlines and fees of every pesticide be included in the legislation. Such a model would be disastrous for innovators whose chemicals would be available for every global competitor to see and would make Congress the arbiter of what customers want. Equally important, EPA has consistently failed to meet the decision deadlines in PRIA – which would not make it a net improvement over what is happening in TSCA.

4. Please discuss the scope of the regulated entities covered by TSCA and describe which entities make up the larger chemical industry.

The reach of TSCA Title I is unique among all Federal laws. To address identified "unreasonable risks of injury" posed to health or the environment by chemical substances, TSCA gives the EPA broad and comprehensive authority to regulate the entire chain of commerce (including supply chains) for chemicals, mixtures of chemicals, and articles containing chemicals.

Based on its regulatory scope and the extremely broad definition of chemical substance, TSCA does not just apply to chemical companies and the chemical industry is not a monolith – and only a part of it was represented at this hearing. Regulated businesses include not just upstream producers – whether large "bulk" chemical makers (who are represented by AFPM) or smaller "batch" or specialty chemical manufacturers; but also, midstream processors, blenders, and distributors; and downstream manufacturers that are chemical users, like major equipment manufacturers, toy, and semiconductor manufacturers, or "big box" stores.

5. Some argue that without TSCA there is no workplace safety with chemicals, that the areas around chemical facilities will not be protected, and people will be exposed to unreasonable risks. Do you agree that it is "TSCA or bust" for these concerns?

TSCA is not the only, or even best, way to achieve workplace safety. AFPM members have no higher priority than the protection of our workforce and to this end AFPM members not only comply with all relevant worker safety regulations but also participate in voluntary industry occupational and process safety programs.

In addition to our industry's commitment to safety regardless of regulatory responsibilities, both the Clean Air Act and the Occupational Safety and Health Act (OSH Act) have general duty clauses requiring employers to provide a workplace free from recognized hazards that can cause death or serious physical harm. In addition, there would be federal efforts by the Occupational Safety and Health Administration through process safety management and permissible exposure limits, Department of Transportation loading standards, efforts by States under their own versions of OSH Act, and there are industry and third-party consensus standards for best practices. To the extent that EPA's TSCA office believes further regulation is necessary and appropriate, it should make recommendations to other EPA offices or OSHA, pursuant to TSCA section 9.

6. Do you believe courts place more emphasis on statutory language or legislative intent when deciding cases?

The Supreme Court has long held that statutory interpretation begins with actual text of laws adopted by Congress and signed by the President. In recent years, the Court has further refined its jurisprudence to limit federal courts' deference to agency interpretations of statutes, particularly in cases of "economic and political significance."

7. Some have argued that an affirmative "safety" finding is required under TSCA. Would you agree that this is the case?

TSCA does not require an affirmative "safety" finding. Instead, TSCA requires EPA to make determinations concerning "unreasonable risks of injury." Safety is a concept that implies freedom from risks. Risk is a function of inherent hazards **and** the likelihood of exposure (e.g., duration, frequency, and magnitude). In addition, the use of "unreasonable risk" in TSCA not only suggests Congress accepted the presence of some risks as being okay, but that a risk must also cause significant injury to merit management in some fashion. To argue that TSCA requires an affirmative "safety" finding reads the term "unreasonable" out of the statute altogether.

In addition, in TSCA, title I, the word "safety" appears in only three contexts: (1) when naming the title of the legislation amending TSCA, title I in 2016, (2) in identifying the Occupational Safety and Health Administration, and (3) in defining and referencing a "health and safety study." It never defines or modifies any findings or determinations.

8. Do you believe that the source of data provided to EPA should prejudice EPA's use of it, or should the high quality and relevance of the information be the driving factor?

Government should not discriminate against the use of information based on its source. Using such criteria biases decision-making and undermines confidence in the very science and program. Rather, the government should objectively evaluate each piece of information with the same skepticism and high-quality standards. This is what TSCA sections 26(h) and 26(i) call for when science is used to make decisions in TSCA sections 4, 5, and 6: use of the best available science and decisions based on the weight of the scientific evidence.

9. You discussed minimal risks from closed loop systems and intermediates. Could you please explain again why that is a critical point for the Committee to consider?

Since risk is a function of hazard and exposure, and hazards are inherent in most manufacturing processes, the key to managing risk is by adequately addressing exposures. AFPM members know their chemicals are highly reactive, which makes them hazardous. Our members take very seriously their responsibilities to deal with those hazards. That is why they engineer their systems in closed loops: to prevent or minimize exposures.

It is equally important to understand the chemistry definition of "intermediate." It is simply a chemical that is used to make another, unique, chemical. The intermediate chemical is consumed in the process that transforms it into a different substance. For example, adding styrene and acrylonitrile to butadiene (all 3 are intermediates) makes an engineering plastic called ABS. ABS is not butadiene; it is not styrene; and it is not acrylonitrile. It is a different molecule (i.e., a different chemical substance) with different physical and chemical properties than the three intermediates that are used to create ABS.

In sum, a chemical intermediate used in closed-loop systems, consumed in the process, has little chance of exposure and, hence, manageable risk. TSCA acknowledges and allows for manageable risk so America can have a strong manufacturing base. Manufacturing cannot exist without accepting and managing risk.

10. The Occupational Safety and Health Safety and Health Administration (OSHA) has not regulated industry as stringently as some of my colleagues would like.

a. Should EPA use TSCA to compensate for OSHA's perceived lack of more stringent activity?

AFPM does not support EPA substituting its regulatory judgement and actions for those of OSHA, National Institute of Occupational Safety and Health (NIOSH) or other agencies for that matter. Federal agencies are created to carry out specific purposes defined by laws and statutes. AFPM does support EPA sharing information with OSHA and NIOSH about unreasonable risks in the workplace, but EPA does not have the same expertise nor the experience to manage workplace risks as OSHA, NIOSH, and the American Conference of Government Industrial Hygienists.

b. If TSCA does not regulate workplace exposures, would there be no effort to control risks in this area?

No, as there are clear regulatory requirements outside of TSCA (e.g., the Clean Air Act, the OSH Act, and state standards) in this space, as well as voluntary industry efforts to elevate safety beyond those regulatory standards. The refining and petrochemical industries work to control risk regardless of regulatory requirements, including through industry and third-party consensus standards.

c. Should TSCA function as an omnibus law to cover every conceivable circumstance that might involve a chemical? Why or why not?

TSCA is not, and should not act as, an omnibus law. Besides TSCA, the federal government currently has bodies of law in the environmental, labor, and consumer protection spaces that intersect with chemical production and usage. These laws were created by Congress – some after TSCA was originally enacted – to foster technical expertise and tailor regulatory authority to the challenges specific to each sector.

AFPM supports clarifying TSCA to prevent EPA from taking regulatory action in areas where Congress has authorized and funded other agencies to handle those issues.

11. There has been discussion about the definition of "unreasonable risk of injury," or the lack thereof in TSCA. Should the statute clarify that risk transfer should be an acceptable consideration in a risk evaluation?

Yes, without such a clarification, EPA's current approach could create new risks or transfer risk. A failure by EPA to consider risks being transferred skews the risk evaluation (including what might be considered as unreasonable) and can lead to the creation of a final rule with less room to meaningfully address the regulatory decision's newly created risk.

12. The issue of red dye came up in the hearing and its impact as a food ingredient.

a. Are food ingredients regulated under TSCA?

No, TSCA section 3(2)(B)(vi) excludes "any food, food additive, drug, cosmetic, or device (as such terms are defined in section 201 of the Federal Food, Drug, and Cosmetic Act) when manufactured, processed, or distributed in commerce for use as a food, food additive, drug, cosmetic, or device" from the definition of a "chemical substance" under TSCA. Exclusion from the definition of "chemical substance" removes these items from regulatory coverage under TSCA.

b. If a chemical may present risks as a food ingredient, should it be prohibited from being used in any other application, such as industrial uses?

No, a chemical that is regulated by FDA as something that humans ingest is fundamentally different than an industrial use-case. And then, each case is unique and the type, frequency, magnitude, and duration of exposure matter. For instance, industrial usage presents different exposure pathways that, in addition to other mitigating practices, could significantly limit risks of injury to health and make production and usage of an otherwise hazardous chemical quite beneficial to society. One example would be ascorbic acid, vitamin C but also used in water treatment and photographic processing.

13. 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?

In addition to the dramatic decrease in domestic research and development spending and capacity that Dr. Engler mentioned, AFPM members highlight that the current system is impacting innovation in several ways, which directly affects employment and the economy. Two examples are:

1. **Reduction in PMN Filings**: The number of PMNs filed has decreased due to high costs, lengthy and uncertain turnaround times, stringent restrictions, and challenges in bringing these products to market.

2. **Increase in LVE Submissions**: There is a rise in Low Volume Exemption (LVE) submissions[6] as they are more cost-effective, have quicker turnaround times, and face fewer restrictions.

Due to the unpredictability of the new chemicals review process, companies have developed other strategies to address the impacts of EPA's delays. For instance, once chemical efficacy and customer demand have been established, based on a successful LVE, companies then need to resubmit a new TSCA section 5 notice to EPA for review (*i.e.*, essentially duplicating their original LVE submission in the form of a PMN). This burdensome practice results in higher company costs and delays, as well as a greater backlog for EPA to process.

EPA's restrictions on new substances that result from TSCA's provisions also make prospective new chemicals buyers hesitant to transition to newer and safer materials. Significant New Use Rules (SNURs), including when a chemical is not posing a risk but could be made in large quantities, harm the business case for sustainable chemicals where downstream customers (even large, sophisticated ones) do not buy chemicals with a SNUR. The uncertainty in predicting product reception makes introducing new chemicals to the market inherently riskier and more costly. Consequently, this increased resource risk for companies, including costs, results in fewer new chemicals being developed for use in the United States.

Fewer new chemicals lead to lower profitability and slower growth, which in turn means fewer new chemical plants and processes are constructed. This directly impacts innovation, job creation, employment, and the velocity of capital in the economy that is necessary for modern life.

While unreasonable risks need to be adequately managed, TSCA's overreach makes domestic production of innovative and better new chemicals incompatible with market realities for commercial production and acceptance. TSCA gives EPA no more than 180 days to decide on a new chemical submission, yet the time-to-market under TSCA is about 2-5 years (from pre-manufacturing notice submission to commercialization). As part of that timeline, EPA requires a new chemical manufacturer (PMN submitter) to first sign a Consent Order, that often has a clause that restricts distribution until a final SNUR on that new chemical is published in the Federal Register (just because EPA finally approves a PMN does not mean the new chemical can be commercialized), and it often takes 1-3 years for the

[6] LVEs are certain categories of new low-volume chemical substances (typically 10,000 kg/year or less) that are exempt from full PMN review under TSCA section 5. LVE substances undergo a 30-day review.

SNUR to be published in the Federal Register to allow for full commercialization. This framework is killing many projects.

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AFPM appreciates the opportunity to provide its views and looks forward to working with the Committee as it continues its work.

Sincerely,

Geoff Moody