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VIA REGULATIONS.GOV

Re: Request for Information: Deregulation (90 Fed. Reg. 15481, April 11, 2025)

Ms. Kelsi Feltz
Office of Information and Regulatory Affairs
Office of Management and Budget
725 17th Street NW
Washington DC, 20503

Dear Ms. Feltz:

The Chemical Users Coalition (CUC) appreciates the opportunity to provide these comments in response to the Request for Information (RFI) published by the Office of Management and Budget (OMB), soliciting ideas for deregulation.

CUC is an association of companies from diverse industries that typically acquire and use, rather than manufacture, chemical substances.[1] CUC has consistently supported measures that protect health and the environment in a manner that enables the regulated community to pursue technological innovation simultaneously with economic development in the United States. CUC members produce and distribute highly complex materials and products, including critical semiconductor devices to major devices, appliances, aircraft, communications technologies, and other intricate equipment.

To thrive in a competitive global economy, our members depend on the availability of certain existing substances, as well as products that incorporate such substances, which are necessary components of a reliable pipeline for our members' production of

[1] The members of CUC are Airbus S.A.S., The Boeing Company, Carrier Corporation, HP Incorporated, IBM Company, Intel Corporation, Lockheed Martin Corporation, National Electrical Manufacturers Association, RTX Corporation, Sony Electronics Inc., and TDK U.S.A. Corporation.

innovative new products upon which the consumer, commercial, industrial, health care, defense, space, and transportation sectors consistently rely.

Consequently, our members have always encouraged regulatory agencies, when contemplating or promulgating regulations, to develop regulatory approaches that responsibly consider existing (and developing) products and technologies on which the U.S. economy and the departments of the federal government depend. The availability of such products and the development of new technologies could be unintentionally and adversely restricted if agencies do not carefully consider the impact of regulation. Regulations that follow both the letter and spirit of the authorizing law are essential to creating an atmosphere of regulatory transparency and predictability, which can significantly aid industry in their compliance efforts.

In the RFI, OMB specifically requested input on regulations that are "unnecessary, unlawful, unduly burdensome, or unsound." CUC's focus is on chemical regulatory matters; therefore, our comments are directed at rules promulgated by the U.S. Environmental Protection Agency ("EPA" or the "Agency") pursuant to the Toxic Substances Control Act (TSCA).

Reporting and recordkeeping requirements for certain per- and polyfluoroalkyl substances
(PFAS) 40 CFR 705.1 et. seq.

Section 7351 (Subtitle E) of the National Defense Authorization Act for Fiscal Year 2020 (NDAA) amended TSCA by adding Section 8(a)(7).
The amendment states:

> Not later than January 1, 2023, the Administrator shall promulgate a rule in accordance with this subsection requiring each person who has manufactured a chemical substance that is a perfluoroalkyl or polyfluoroalkyl substance in any year since January 1, 2011, to submit to the Administrator a report that includes, for each year since January 1, 2011, the information described in subparagraphs (A) through (G) of paragraph (2).

EPA finalized the rule implementing this provision (the "PFAS Reporting Rule") in October 2023. In CUC's view, the sweeping scope of the PFAS Reporting Rule is not supported by the statutory language; certain provisions impose a significant cost relative to small speculative benefit; and compliance with the rule imposes a significant burden on numerous sectors in the U.S. economy. CUC's concerns regarding specific provisions are described below.

- **Imported Articles**

  CUC believes that manufactured "articles" containing PFAS should not be included within the scope of the PFAS Reporting Rule. The statutory provision above does not require inclusion of articles; rather, it specifically targets manufacturers of the PFAS substances themselves. EPA's regulatory definition of "article" in 40 C.F.R. § 704.3 is not consistent with the PFAS Reporting Rule's inclusion of articles within the scope of chemical substances that must be reported. Based on a direct reading of the statutory language, it is clear the requirement to report PFAS in articles should be rescinded.

- **Reporting Exemptions**

  EPA also failed to include certain standard exemptions from reporting in the PFAS Reporting Rule. Previously, EPA has routinely adopted exemptions for TSCA reporting rules adopted under the relevant provisions in Section 8. Although EPA stated that its basis for refusing to adopt exemption was the use of the term "each person" in the NDAA text (implying that every person must report), there are numerous other instances in the underlying statute where the term "each person" or "any person" was used in connection with reporting requirements and EPA nonetheless provided standard exemptions from reporting.[2] Consequently, EPA should revise the rule to provide for standard TSCA reporting exemptions. The Agency should include exemptions for: PFAS substances in manufactured articles as well as PFAS that are used in small quantities and solely for research and development (R&D) purposes; and, for PFAS generated or present as a byproduct or impurity.

  Failing to provide these exemptions runs afoul of TSCA Section 8(a)(5)'s directives that: EPA not require reporting that is unnecessary or duplicative; minimize the costs of compliance for small businesses; and apply reporting obligations to those persons likely to have information relevant to the effective implementation of TSCA. EPA's information-gathering efforts should be directed to those entities and for those substances for which there is the greatest likelihood

[2] Section 8(a)(1) begins: "The Administrator shall promulgate rules under which—(A) each person (other than a small manufacturer or processor) who manufactures or processes or proposes to manufacture or process a chemical substance (other than a chemical substance described in subparagraph (B)(ii) shall maintain such records, and shall submit to the Administrator such reports, as the Administrator may reasonably require …."

that existing studies and information requested can be economically obtained and would be specifically worthwhile to EPA's regulatory efforts under TSCA.

Procedures for Chemical Risk Evaluation Under TSCA
40 CFR 702.31 et. seq.

CUC believes that the approach to risk evaluations EPA adopted in the rule for Procedures for Chemical Risk Evaluation Under the Toxic Substances Control Act (the "Procedural Rule") is inconsistent with express statutory provisions in TSCA and fails to provide an accurate picture of the risks presented by a chemical substance under the substance's actual conditions of use.

TSCA states:

(4) Risk evaluation process and deadlines

(A) In general

The Administrator shall conduct risk evaluations pursuant to this paragraph to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant to the risk evaluation by the Administrator, under the conditions of use. …

(D) Scope

The Administrator shall, not later than 6 months after the initiation of a risk evaluation, publish the scope of the risk evaluation to be conducted, including the… hazards, exposures, conditions of use, and the potentially exposed or susceptible subpopulations…

Source: 15 U.S.C. § 2605(b)(4)(A), (D) (emphasis added).

- **Singular Risk Determinations**

The Procedural Rule adopts the position that all TSCA Section 6 evaluations must result in a single pronouncement of whether a substance does or does not meet the safety standard; furthermore, such determinations are not to be made on a condition-of-use-by-condition-of-use basis. This approach is at odds with the

structure Congress created in the 2016 TSCA amendments for prioritizing, evaluating, and managing the risks of existing chemical substances.

The statute provides that EPA, to start the actual risk evaluation process, must publish a scope document containing the conditions of use EPA expects to consider in the risk evaluation. The scope document is the opportunity for the EPA to establish what requires evaluation and to seek public comment on the scope determination. It is not simply a ministerial act of compiling use, exposure, and hazard data points. In granting this authority to EPA, Congress clearly intended for EPA to exercise discretion to select what was to be evaluated, on a conditions of use basis.

If Congress had intended EPA to include all conditions of use, it could have specified in the statute that EPA must evaluate all conditions of use and all exposure pathways. Rather, the statute states clearly that the scope must contain those elements that EPA "expects to consider," meaning EPA is to exercise discretion. Furthermore, for all interested parties to know what EPA will be reviewing, EPA must publish a scope. If all uses must be evaluated for all substances, there was no need for Congress to provide the opportunity for public input.

These are substances that have been determined by EPA, after undergoing a screening exercise, to potentially (i.e., "may") present an unreasonable risk. It is therefore inevitable that some conditions of use of a high priority substance will be determined to present an unreasonable risk. Under the current construct, with a single determination of risk for a substance, EPA will never reach a conclusion that a substance does not pose an unreasonable risk, and therefore the provisions in TSCA about how such determinations are finalized, via an order, are rendered meaningless. Only if EPA is able to make determinations on a condition-of-use-by-condition-of-use basis could EPA make determinations that a substance, under a particular condition of use, does not present an unreasonable risk. Accordingly, this approach embodied in the Procedural Rule is not supported by the underlying statute.

- **No Assumption of Use of Personal Protective Equipment**

  Additionally, the rule's requirement that evaluations should not assume use of personal protective equipment (PPE) by those using or handling the subject substance is inconsistent with TSCA's Section 6(b)(4) risk evaluation

requirements relating to "conditions of use." Section 6(b)(4)(A) requires that EPA conduct risk evaluations "to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment … under the conditions of use." TSCA Section 3(4) defines "conditions of use" as "the circumstances, as determined by the Administrator, under which a chemical substance is intended, known or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of."

The structure of the definition of "conditions of use" makes clear that "circumstances" includes more than the fact that a substance is manufactured, imported, processed, etc. Therefore, "circumstances" logically includes aspects of the context in which a chemical substance is manufactured, imported, processed, etc., including whether workers wear PPE. EPA's elimination of the PPE assumption also effectively eliminates "circumstances" from the definition of "conditions of use." Use of PPE is a circumstance that "is intended, known, or reasonably foreseen." PPE use therefore belongs as a component of the conditions of use that the TSCA Section 6 risk evaluations must consider.

Furthermore, Section 26(k) of TSCA specifically requires the EPA to take into consideration all information which is reasonably available to the Agency concerning both hazard and exposure information. By failing to consider the use of PPE, EPA is not considering fully what efforts are being made within facilities that manufacture or process substances undergoing risk evaluations, specifically with the use of PPE. In practice, in the context of TSCA risk management rules EPA has proposed and/or promulgated for specific substances, EPA has repeatedly failed to fully consider the practices in place in facilities and the many methods within the Occupational Safety and Health Administration (OSHA) traditional "hierarchy of controls," (e.g., administrative procedures, employee training, engineering controls, and manufacturing practices) which inherently minimize chemical exposures. By promulgating a risk evaluation Procedural Rule which specifically declines to take these factors into consideration, EPA has deliberately ignored its obligations under Section 26 of TSCA.

Overall, EPA has selected an overly aggressive approach that goes beyond regulating "to the extent necessary[3]." The Procedural Rule, in its current form, has resulted in risk

[3] 15 USC 2605(a): If the Administrator determines in accordance with subsection (b)(4)(A) that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or mixture, or that any combination of such activities, presents an unreasonable risk of injury to health or the environment, the Administrator shall by rule and subject to section 2617 of this title, and in

evaluations that fail to comport with statutory requirements to address risk of substances under their conditions of use, and consequently, the provisions of risk management rules go beyond what is needed, creating needless compliance burdens and negative economic impact.

EPA's risk management proposal for n-methylpyrrolidone (NMP) 89 FR 51134

The consequences of using the approach embodied in EPA's risk evaluation Procedural Rule can be better understood by reviewing EPA's risk management proposal for n-methylpyrrolidone (NMP). When considering the severe impact of the proposal on just one specific sector as an example – the semiconductor industry – it is evident that the proposal is overly burdensome, adds layers of administrative costs to demonstrate compliance, and does not contribute to improved worker health and safety.

EPA has proposed requiring:

- Annual training for workers who use NMP in addition to OSHA Hazard Communication training requirements, OSHA PPE training requirement, and OSHA respiratory protection training requirements;
- A specific NMP written program, in addition to other OSHA administrative documentation requirements for Hazard communication, PPE, and respiratory protection; and,
- NMP use justification evaluations, which require employers to document through assessment why substitution and elimination of NMP use for decisions that may have been made decades ago are not viable pathways, why the use of NMP is still required, and how those uses are controlled.

Furthermore, EPA's proposed compliance responsibility is in inherent conflict with OSHA compliance responsibilities for complex multi-employer work sites, thus raising unnecessary legal, contractual, and conflict of interest issues. EPA should adapt the risk management framework – in this context, and with all TSCA risk management rules – so that risk management mandates are consistent with the preexisting OSHA regulatory compliance framework. This will avoid creating unnecessarily complex, conflicting and expensive compliance frameworks on the part of owner/operator/employers.

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accordance with subsection (c)(2), apply one or more of the following requirements to such substance or mixture **to the extent necessary so that the chemical substance or mixture no longer presents such risk:**

The approach EPA has taken to risk evaluation and risk management to date imposes needless significant administrative costs for compliance, contains numerous elements that may duplicate or conflict with standards and assessments developed by other agencies or industry standard setting organizations, and will not result in better outcomes for workers.

New Chemicals Regulations Under the Toxic Substances Control Act (TSCA)
40 CFR 720.1 et seq

- **Low Volume Exemption Applicability**

  In December 2024, EPA finalized amendments to the regulations that govern the Agency's review of new chemicals under TSCA. These amendments eliminated the ability of manufacturers and importers of PFAS and persistent, bioaccumulative, toxic (PBT) chemical substances to qualify for a low volume exemption (LVE) or low release and exposure exemption (LoREX) from the standard Section 5 New Chemical Review.

  CUC believes that EPA's amendment of the Low Volume Exemption (LVE) regulations to make PFAS and certain PBT chemical substances ineligible for LVEs and LoREXs from the full PMN review process must be rescinded. None of these measures are necessitated by the 2016 amendments to TSCA, nor did the amendments empower EPA to make them.

  LVEs and LoREXs were designed to make the new chemical review process more efficient for scenarios in which a substance is shown (by meeting the terms of the exemption) to have reduced or no human exposure opportunities or material environmental releases. The regulations were specifically written to require the Exemption Holder to be "bound" to follow all of the terms in the submitted application pertaining to the controls and measures which have any bearing on exposures, releases, and risks. See 40 CFR 723.50(j). The regulations for these exemptions make clear that deviations from the application's express terms (without EPA's consent) would constitute a violation of the LVE/LoREX regulations.

  Yet, despite the fact that these substances are indeed regulated, EPA excluded an entire category of substances from eligibility for the exemptions, which serves to create more work for EPA and will further hamstring the new chemicals program. In fact, this requires the entities proposing to manufacture such substances to

submit PMNs which, in turn, will likely require EPA to conduct a detailed risk assessment, to consider (and presumably evaluate) any reasonably foreseeable uses of the same substance, and then to issue a Section 5(e) Order. The categorical exclusion is unnecessarily burdening EPA's already strapped resources and exacerbating the issues which plague an already "underperforming" new chemicals program.

EPA should refocus its attention on the many resource-saving benefits of the LVE and LoREX process, which should continue to be a way for EPA to oversee and limit the total quantities and methods by which chemical substances of potential concern may be produced, and to legally bind the Exemption Holders to those terms indefinitely.

Furthermore, CUC considers such "categorial" exclusions from eligibility to be improper when the statute requires EPA to make risk-based determinations with regard to all new chemical Notifications (and Exemptions) on the basis of the risks presented under the conditions of use described in the Notification submitted to EPA. See Section 5(a)(3) of the amended Act.

LVEs and LoREXs do not present issues with regard to "reasonably foreseen other uses," and they thus permit EPA to make exposure-driven determinations of risk where warranted. EPA's current approach does the opposite as it prejudges what a potential exemption submitter's conditions of use might be without consideration of the information EPA might acquire in an LVE or LoREX application. The 2016 amendments to TSCA require EPA to evaluate chemical substances on the basis of the information available and using the best available science and a "weight of the evidence" approach. See Sections 26(h) through (j).

Global and categorical determinations to exclude potentially thousands of PFAS within the proposed structural definition (and substances that might fit EPA's PBT criteria) from consideration for an exemption ignore the statutory considerations (such as "exposures") that must be taken into account and reduce the "risk" equation (which includes, by definition, assessing both hazard and exposure) to a foregone conclusion in the absence of information or assessment of the science.

- **Completeness Determinations**

  In addition to the LVE provision, the recent amendments also provided that EPA may retroactively determine (in its sole discretion) that a Notification that was submitted is "incomplete" on the basis of new information submitted to EPA that suggests the original submission did not include all information that was reasonably ascertainable. Such determinations would "reset" the 90-day review period to begin again. CUC believes that this presents an opportunity for EPA to abuse its discretion.

  This also will make Notification submitters reluctant to generate and submit any new information or data they might obtain during the course of the Notification review period. This outcome would inhibit, not enhance, a thorough review of a proposed condition of use.

Conclusion

CUC appreciates the opportunity to provide input to OMB on suggested improvements to the U.S. regulatory structure. CUC Members would be pleased to meet and confer with key personnel who are responsible for reviewing this information and making recommendations based on the comments submitted.

Sincerely,

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