

# Congress of the United States

Washington, DC 20515

December 6, 2023

The Honorable Michael S. Regan  
Administrator  
Environmental Protection Agency  
1200 Pennsylvania Avenue, N.W.  
Washington, DC 20460

Dear Administrator Regan:

America's economic competitiveness and national security depend on a supply chain that is dependable and durable. At the start of this supply chain are chemistries that are needed to manufacture a wide range of critical products from semiconductors to medical devices. Sound and predictable chemical management policies are fundamental to promoting American innovation and strengthening our economy.

Ensuring all the Environmental Protection Agency's (EPA's) risk reviews and risk management decisions for chemicals are timely, practical, tailored, and based on the best available science is critical to meeting America's needs for energy, national security, health care, infrastructure, and more.

Unfortunately, the EPA's implementation of the reforms Congress made to the Toxic Substances Control Act (TSCA) in 2016 has caused delays and undermined American manufacturers' ability to lead. Some of the most serious adverse effects were discussed at an October 18, 2023, hearing before the House Energy and Commerce Committee's Subcommittee on Environment, Manufacturing, and Critical Materials.

In addition, the Government Accountability Office (GAO) recently reported<sup>1</sup> on the worsening output of the New Chemicals Division.<sup>2</sup> Specifically, GAO pointed to a backlog of 399 pre-manufacturing applications still awaiting a risk determination (93 percent of which had been pending longer than the statutory deadline of 90 days). In addition, we note that explanations of underfunding do not square with this backsliding in performance as the EPA's budget and staffing numbers for this office have generally remained constant between multiple Administrations. We believe that these persistent problems need to be addressed expeditiously, including the implementation of serious efforts to meet statutory deadlines, greater transparency, communication and accountability with new chemicals applicants and the public, and improved efficiency and assignment of relevant and appropriate expertise within the program. The EPA also needs to implement a plan to meet its statutory deadlines.

Today, however, we are focusing your attention on resolving challenges with TSCA implementation for chemicals already on the market. These substances are the foundation of several supply chains and are

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<sup>1</sup> *EPA Chemical Reviews: Workforce Planning Gaps Contributed to Missed Deadlines*, Government Accountability Office, 2/23/23, <https://www.gao.gov/products/gao-23-105728>

<sup>2</sup> The New Chemicals Division is part of the Office of Pollution Prevention and Toxics, the area within the EPA's Office of Chemical Safety and Pollution and Prevention that is charged with TSCA activities.

the building blocks of several chemistries important to our high standard of living. Under TSCA, the EPA is required to make risk-based decisions that are based on a chemical's hazard, use, and real-world exposure.

TSCA is not a tool to extinguish American manufacturing or control growth. Rather, as TSCA section 2 makes clear, the policy of the United States is to exercise authority over chemical substances and mixtures in a manner that does “not impede unduly or create unnecessary economic barriers to technological innovation” but also reasonably controls actual risks of injury to health and the environment.

Despite that explicit statutory text, the EPA's TSCA risk evaluations of existing chemicals to date have fallen into the trap of continuing to emphasize hazards and overestimate the risks of uses of chemicals; this leads to bias and exaggeration of chemicals' risks. Such unscientific decision-making not only exacerbates the regulatory burden created by TSCA, but it can lead to market de-selection of safe chemical uses and supply chain disruptions. At its extreme, this is promoting a “ban first, then exempt” approach, which is not reflected in the text of TSCA or committee reports issued at the time of its update in 2016.

TSCA section 6(a) only permits regulation of an existing, high priority chemical if the EPA first makes an “unreasonable risk” determination pursuant to TSCA section 6(b)(4)(A) and the scientific quality criteria in subsections (h) and (i) of TSCA section 26. That “unreasonable risk” determination though, is limited by TSCA section 6(b)(4)(A) to only those “hazards, exposures, conditions of use, and potentially exposed or susceptible populations” affirmatively identified by the EPA under TSCA section 6(b)(4)(D) as within the scope of the evaluation for a chemical the EPA determines is a high priority. We are concerned that the EPA is acting outside of its statutory authority, specifically with respect to the EPA's “Whole Chemical” evaluation and regulatory practices. Efforts to arbitrarily require that every “use” of a chemical be in scope for a risk evaluation defeats the entire purpose of deliberate and mandatory prioritization and scoping requirements.

Moreover, we are concerned that the EPA is using TSCA section 6 in a way that both subverts and supplants the statutory responsibilities of the Occupational Safety and Health Administration (OSHA). For example, OSHA sets enforceable, permissible exposure limits (PELs) to protect workers against the health effects of exposure to hazardous substances, including limits on the airborne concentrations of hazardous chemicals in the air. Yet, the EPA has construed its authority so broadly through the creation of Existing Chemical Exposure Limits (ECELs) that it is – for the first time – claiming the authority to regulate indoor air and is usurping OSHA's PEL authority on a chemical-by-chemical basis.

To better understand this matter, please provide responses to the following questions by December 15th, 2023:

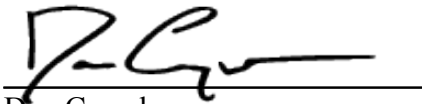
1. Regarding the prioritization, scoping, and risk evaluation provisions in TSCA section 6(b), for chemicals already subject to commercial manufacture for an established use:
  - a. How does the EPA's current practice align with its statutory requirements for each of these activities?

- b. Under the EPA's current practices, please identify any differences in treatment or consideration of a chemical substance or mixture between these activities.
2. How will the EPA conduct scoping activities under TSCA section 6(b)(4)(d) that will transparently, discriminately, and unquestionably identify those matters that are within scope for a risk evaluation and those that are not?
3. Please provide copies of all the reports provided to OSHA under TSCA section (9)(a)(1).
4. Please provide documentation of all meetings and communications that occurred with OSHA, pursuant to TSCA section 9(a)(6), to ascertain whether the EPA was duplicating efforts for any ECELS EPA proposed?
5. Please identify all the EPA's efforts, whether in conjunction with OSHA or another entity, to review and consider the adoption of globally acceptable occupational exposure limits for those chemicals for which the EPA is proposing an ECEL under TSCA section (6)(a). In particular, please identify the following:
  - a. Parties with which the EPA consulted.
  - b. All analyses, including those pursuant to TSCA section 6(c), that indicate whether and to what extent the EPA considered an ECEL that made domestic production for a chemical less globally competitive AND resulted in no corresponding health benefit.
  - c. ECELS subject to peer review by industrial hygienists and provide the recommendations of those industrial hygienists.
  - d. ECELS that received a public comment period of at least 60 days.
6. If a proposed ECEL was not subject to peer review by industrial hygienists or did not receive at least 60 days for public comment, please explain the reasons for such a decision.
7. Regarding TSCA section 6 rulemakings, for chemicals already subject to commercial manufacture for an established use:
  - a. Are all draft TSCA risk evaluations undergoing a full and meaningful rulemaking process that involves engagement from other agencies and adequate time for the public, including the potentially regulated entities, to comment given the complexity of the proposals?
  - b. Does TSCA preclude the EPA from engaging in adequate notice and public comment on draft risk evaluations?
  - c. Has the EPA denied requests for extension of the public comment period of at least another 30 days, but not more than another 60 days. If so, why?
  - d. Have all draft and final TSCA risk evaluations and risk management rules undergone a complete and thorough interagency review process? If not, please identify those that have not and the reasons.
  - e. Have all draft and final TSCA risk evaluations and risk management rules been subject to review under the Small Business Regulatory Enforcement Fairness Act (SBREFA)?
    - i. If so, what was the EPA's response to the SBREFA recommendations?
    - ii. If not, how did the EPA determine that the evaluations and rules did not have a significant impact on a substantial number of small entities?

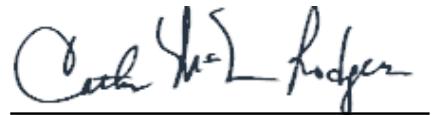
For America to be a leader in the 21<sup>st</sup> Century economy, we must create a regulatory process that balances serious human health and environmental concerns, with the needs of our society and economy, including supporting our manufacturers' ability to innovate, improving our standard of living, and competing globally. Chemical management policies are intrinsically linked to this. The future of energy, transportation, health care, technology, and virtually every sector of the economy depends on getting these policies right.

We appreciate your attention to these vital issues and look forward to a prompt and detailed response to our requests.

Sincerely,



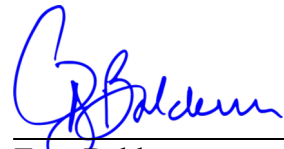
Dan Crenshaw  
Member of Congress



Cathy McMorris Rodgers  
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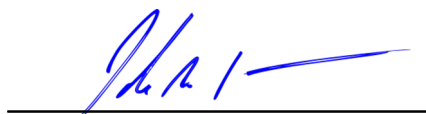
Troy Balderson  
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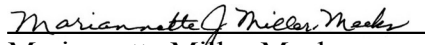
Larry Bucshon, M.D.  
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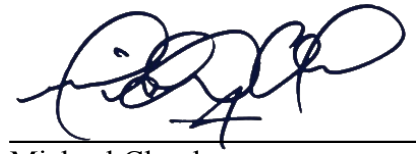


John R. Curtis  
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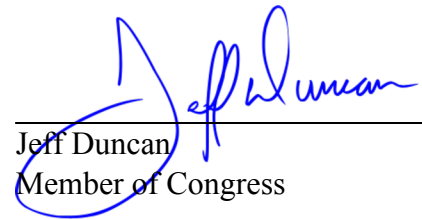
Randy K. Weber, Sr.  
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Mariannette Miller-Meeks,  
M.D.  
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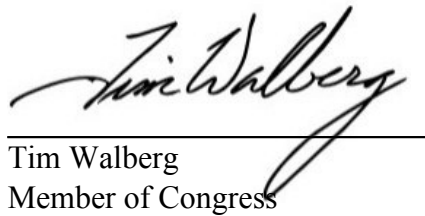


Michael Cloud  
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Russ Fulcher  
Member of Congress



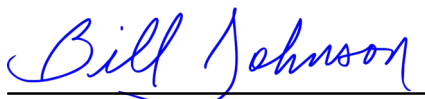
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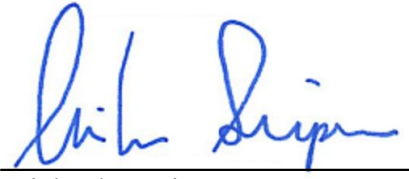


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Neal P. Dunn, M.D.  
Member of Congress



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Michael K. Simpson  
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Kat Cammack  
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Guy Reschenthaler  
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Gus M. Bilirakis  
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Glenn Grothman  
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Kay Granger  
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August Pfluger  
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Gary J. Palmer  
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Michael Guest  
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Lance Gooden  
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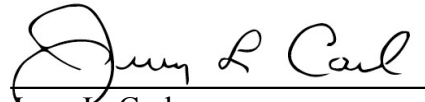
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James R. Baird, PhD  
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Greg Pence  
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Jerry L. Carl  
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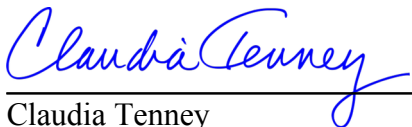
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Alex X. Mooney  
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Bryan Steil  
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Claudia Tenney  
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Jenniffer González-Colón  
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William R. Timmons, IV  
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Kelly Armstrong  
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Debbie Lesko  
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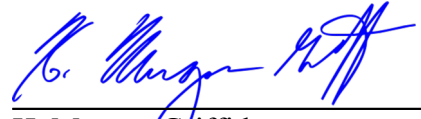
Mike Carey  
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Rich McCormick, MD, MBA  
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H. Morgan Griffith  
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Wesley Hunt  
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Beth Van Duyne  
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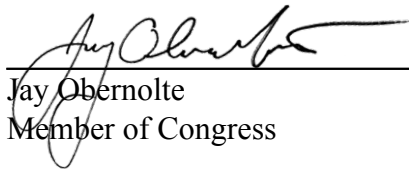
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John Joyce, M.D.  
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Diana Harshbarger  
Member of Congress



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Jay Obernolte  
Member of Congress



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Charles J. "Chuck" Fleischmann  
Member of Congress



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Julia Letlow, Ph.D.  
Member of Congress



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Ryan K. Zinke  
Member of Congress

A handwritten signature in black ink, appearing to read "Max L. Miller", written over a horizontal line.

Max L. Miller  
Member of Congress