

August 8, 2023

*Submitted via Regulations.gov*

Dr. Michal Freedhoff

Assistant Administrator, U.S. Environmental Protection Agency

Office of Chemical Safety and Pollution Prevention

1200 Pennsylvania Ave., N.W.

Washington, DC 20460

Re: Proposed Rule: “Updates to New Chemicals Regulations Under the Toxic Substances Control Act (TSCA),” Docket No. [EPA-HQ-OPPT-2022-0902](https://www.regulations.gov/document/EPA-HQ-OPPT-2022-0902)

Dear Assistant Administrator Freedhoff:

EPA has a major opportunity to improve its TSCA New Chemicals Program by crafting regulations that ensure robust, transparent, and objective reviews of all new chemicals that will fully protect human health and the environment, including for those people at greatest potential risk. The undersigned groups urge the Agency to take this opportunity to strengthen its proposed “Updates to New Chemicals Regulations Under the Toxic Substances Control Act (TSCA).”

With this proposed rule, EPA has suggested limited changes that will make some modest improvements to its reviews of new chemicals.<sup>1</sup> For example, we support EPA’s proposal to end the use, going forward, of new chemical review exemptions for PFAS,<sup>2</sup> and we also encourage the Agency to finalize its proposed requirements for information companies must submit to EPA about the new chemicals they seek to manufacture.

However, EPA’s proposal falls significantly short of implementing the fundamental changes needed to ensure the safety of any new chemicals allowed onto the market. In these comments, we briefly describe the challenges that EPA must address, and discuss some of the major concerns we have with EPA’s proposed rule.

### **The New Chemicals Program Must Confront Fundamental Problems That Threaten Its Integrity**

When reforming TSCA in 2016, Congress made extensive changes to section 5, which governs new chemical reviews. These changes were intended to address problems with how the reviews had been conducted under the original TSCA, enacted in 1976. EPA’s update of its new chemicals regulations should fully reflect the scope, intent, and specifics of the changes Congress made when reforming TSCA. This is especially critical in light of the previous

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<sup>1</sup> 88 Fed. Reg. 34100, May 26, 2023, <https://www.regulations.gov/document/EPA-HQ-OPPT-2022-0902-0001>.

<sup>2</sup> EPA has allowed numerous PFAS, under the “low volume” and “low release and exposure” exemptions, to avoid full new chemicals review before they are manufactured. EPA is now proposing to end that practice for any future new PFAS. We urge EPA also to revoke the hundreds of existing PFAS exemptions that it already granted.

administration's highly flawed initial implementation of the 2016 law, which further exacerbated the structural flaws Congress sought to fix.

As a result, we have seen a severe decline in public confidence in the objectivity and scientific rigor of decisions made under the New Chemicals Program. In our view, this is traceable to long-standing practices that make the program vulnerable *both* to undue industry access and influence and to interference by political appointees during administrations, such as the previous one, that prioritize industry interests over public interests. EPA should alter these long-standing practices through its regulations to ensure this cannot happen again. The primary purpose of TSCA – to ensure that chemicals do not present unreasonable risks to people or the environment – can be thwarted unless these structural problems are addressed. And those most at risk, including workers and fenceline communities, will bear the brunt.

### **EPA's New Chemicals Regulations Must Be Updated to Address These Structural Problems**

Here, we identify several of our largest concerns with the proposed rule that, if finalized, would limit transparency, public engagement, and Agency accountability and would fail to address the core imbalances and vulnerabilities of the program. We also recommend certain changes needed to address these concerns.

**First**, EPA proposes to consider revising regulatory orders it has issued for certain high-risk chemicals only when the Agency gets new information about those substances from their manufacturers (the companies who profit from the chemical's entry onto the market), and not from members of the public or any other stakeholder.<sup>3</sup> Moreover, EPA's proposal indicates that new information from the manufacturer could lead to weakening or revoking of its regulatory orders but does not indicate that it could lead to the strengthening of the initial health and environmental protections.<sup>4</sup> The Agency needs to correct this problematic proposal by making clear in its regulations that EPA has the authority to strengthen protections based on new information obtained from any source.

**Second**, in its proposal EPA fails to put a stop to its practice of sharing with chemical companies – and chemical companies only – its findings about the risks posed by a new chemical, and then allowing only companies to dispute EPA's findings.<sup>5</sup>

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<sup>3</sup> See proposed 40 C.F.R. § 720.75(d)(3); 88 Fed. Reg. at 34124.

<sup>4</sup> *Id.*

<sup>5</sup> “Currently, after EPA completes its risk assessment of a chemical substance, EPA reaches out to the submitter to explain the findings of the risk assessment and any proposed prohibitions or limitations on the manufacturing, processing, distribution in commerce, use, or disposal of the chemical substance. If the submitter disagrees with the potential risks identified in the risk assessment, the submitter may provide additional information intended to demonstrate that risks are lower than EPA estimated.” 88 Fed. Reg. at 34109.

EPA's practice of sharing its risk findings with companies and allowing industry to then dispute Agency findings has no basis in the law and creates serious problems. First, the practice is a major cause of large-scale waste of EPA's limited time and resources. EPA has vividly described the problem as imposing a burden of "rework" on Agency scientists, who must repeatedly redo their risk assessments based on "late" information that companies were required to, but did not, give to EPA when they submitted their new chemical applications.<sup>6</sup> In fact, EPA has acknowledged that the industry, at times, submits late information to EPA specifically in order "to refute EPA's initial risk determination."<sup>7</sup> Yet EPA proposes to continue this damaging practice.

The practice is especially troubling because the process operates entirely out of the public's view. Only the companies have an opportunity to respond and seek to influence EPA's determinations. No such opportunity is made available to any other stakeholders, such as unions, public health groups, or community advocates.

Instead of this back-and-forth between EPA and industry, EPA should put in place a straightforward process that is consistent with TSCA. Specifically, EPA should finalize regulations that require companies to submit all required information before the new chemical review process begins. EPA would then proceed with its review and communicate a final risk determination to the company and the public at the end of the process. If EPA insists that it must share draft risk findings with companies before the completion of the process, its regulations should require that all such documents and communications be made public at the same time so that all interested stakeholders may also review and comment.

**Third**, EPA has not incorporated into its regulations a set of procedures to ensure timely public access to: the industry's new chemical applications, the documents EPA generates during its review of those new chemicals, and the decisions that come out of those reviews. While in recent years EPA has developed and expanded helpful online databases for sharing some of this information, the Agency has not proposed to codify its use of these means of giving public access or committed to specific timelines for making the information accessible. By not codifying the means, procedures, and timelines for public access, future administrations may attempt to halt the current practices without providing the public any recourse or even advanced notice. In contrast, if EPA codifies these changes, any future changes to them would require public notice and comment and could be legally challenged.

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<sup>6</sup> See EPA, "TSCA New Chemical Engineering Initiative to Increase Transparency and Reduce Rework," <https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/tsca-new-chemical-engineering> and "Analysis of Engineering Information Submitted for TSCA Section 5 New Chemicals Submissions," <https://www.epa.gov/system/files/documents/2022-06/Engineering%20Initiative%20Analysis.pdf>.

<sup>7</sup> EPA, "TSCA New Chemical Engineering Outreach Initiative to Increase Transparency and Reduce Rework, Kick-Off Meeting," July 27, 2022, <https://www.epa.gov/system/files/documents/2022-07/TSCA%20New%20Chemical%20Engineering%20Initiative%20C%20Kick%20Off%20Meeting%20Materials.pdf>, at 4.

**Finally**, EPA has not, but needs to, provide a meaningful opportunity for public engagement with the New Chemicals Program, including a formal opportunity to comment on the applications for the new chemicals that industry seeks to commercialize, with sufficient time for the public to develop those comments and for EPA to consider them during its reviews of the new chemicals. EPA's final regulations should include specific provisions to govern this public engagement, which is a vital counterpoint to the extensive opportunities companies are given to seek to influence the outcome of EPA's review of their chemicals.

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Thank you very much for considering these comments. If you have any questions, please contact Samantha Liskow, Lead Counsel, Healthy Communities, at Environmental Defense Fund ([sliskow@edf.org](mailto:sliskow@edf.org)).

Respectfully submitted,

**AFL-CIO**

**American Federation of Teachers**

**BlueGreen Alliance**

**Environmental Defense Fund (EDF)**

**Environmental Working Group (EWG)**

**Moms Clean Air Force**

**National Resources Defense Council (NRDC)**