May 28, 2021

Via Regulations.gov
Dr. Michal Freedhoff
Principal Deputy Assistant Administrator
Office of Chemical Safety and Pollution Prevention
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460

Re: **Agency Information Collection Activities; Recordkeeping and Reporting Requirements for Allegations of Significant Adverse Reactions to Human Health or the Environment, Docket No. EPA-HQ-OPPT-2015-0688**

Dear Dr. Freedhoff:

Earthjustice, Environmental Defense Fund, Environmental Working Group and Natural Resources Defense Council submit these comments on the Environmental Protection Agency's ("EPA") Information Collection Request for Recordkeeping and Reporting Requirements for Allegations of Significant Adverse Reactions to Human Health or the Environment (the "ICR").[1]

The ICR solicits comment on EPA's information gathering under Section 8(c) of the Toxic Substance Control Act ("TSCA"), which authorizes EPA to collect from "[a]ny person who manufactures, processes, or distributes in commerce any chemical substance or mixture … records of significant adverse reactions to health or the environment … alleged to have been caused by the substance or mixture."[2] Such records include, but are not limited to, "records of consumer allegations of personal injury or harm to health, reports of occupational disease or injury, and reports or complaints of injury to the environment submitted to the manufacturer, processor, or distributor in commerce from any source."[3] Congress enacted Section 8(c) to provide EPA with access to information—including worker and consumer complaints about a chemical's harmful effects—that is often not publicly available and might otherwise escape EPA's notice. This information is particularly important for EPA's TSCA prioritization decisions, risk evaluations, and risk management rules, each of which calls for a robust understanding of a chemical's effects on human health and the environment.

However, EPA has rarely used its Section 8(c) data gathering authority in the past, and, according to the ICR, the Agency only intends to issue "one additional [8(c)] notice per year during the three year ICR collection period"[4]—a period in which EPA must complete at least 23 TSCA risk evaluations, issue 10 risk management rules, and designate at least one new high-

[1] *Agency Information Collection Activities; Proposed Renewal of an Existing Collection and Request for Comment; Recordkeeping and Reporting Requirements for Allegations of Significant Adverse Reactions to Human Health or the Environment*, 86 Fed. Reg. 16,347 (Mar. 29, 2021).
[2] 15 U.S.C. § 2607(c).
[3] *Id.*
[4] EPA, *Supporting Statement for an Information Collection Request (ICR) Under the Paperwork Reduction Act (PRA)* ("ICR Supporting Statement") at 8–9 (Mar. 16, 2021), https://www.regulations.gov/document/EPA-HQ-OPPT-2015-0688-0009.

priority substance for each risk evaluation it completes. EPA's decision not to collect 8(c) data is misguided and inconsistent with EPA's statutory obligation to consider "reasonably available information" when preparing prioritization decisions, risk evaluations and risk management rules.[5] We urge EPA to issue 8(c) data requests for every chemical undergoing risk evaluation and risk management, as well as for per- and polyfluoroalkyl substances ("PFAS") and for any chemicals identified as a candidate or proposed for high-priority designation under TSCA in the future.

The benefits of collecting 8(c) data far outweigh the costs to reporting entities and EPA. Under Section 8(c), companies are already required to maintain "[r]ecords of … adverse reactions to the health of employees … for a period of 30 years from the date such reactions were first reported … ."[6] All other 8(c) records, including consumer complaints, must be "retained for a period of five years from the date the information contained in the record was first reported."[7] Those records are thus readily accessible, and EPA can compel their production with a Federal Register Notice or a letter to the reporting entity; EPA does not need to undergo rulemaking procedures or issue an order.[8] In the ICR, EPA conservatively estimates that a company's response to an 8(c) data request would take of total of eight hours, or approximately $600 of staff time, per report:

> EPA estimates that a management level company official will spend one hour reviewing the Federal Register notice or letter from EPA to determine whether the company manufactures (including imports) or processes substances subject to the reporting requirement. Technical personnel would then spend an estimated two hours conducting a search of the company's TSCA section 8(c) files for any relevant allegation records. Once the file search is complete, EPA estimates that a managerial employee would spend two hours preparing a transmittal letter and other explanatory material to accompany the allegation records. An upper-level management official would spend an additional two hours reviewing these materials. One hour of clerical labor would be required to prepare and mail the response. A total of eight hours is expended per report (five managerial hours, two technical hours and one clerical hour). The unit cost for reporting, per report, is $605.53.[9]

Section 8(c) records are particularly relevant to TSCA prioritization decisions, risk evaluations, and risk management rules, three processes in which EPA is statutorily required to consider "reasonably available information" related to a chemical's hazards and exposures.[10] According to EPA, Section 8(c) "provides a mechanism to identify previously unknown chemical hazards" by "reveal[ing] patterns of adverse effects which otherwise may not be otherwise noticed or detected."[11] While 8(c) reports may not be sufficient, standing alone, to

---

[5] *See, e.g.*, 15 U.S.C. § 2625(k) (requiring EPA to consider "reasonably available information" when conducting risk evaluations and issuing risk management rules).
[6] *Id.* § 2607(c).
[7] *Id.*
[8] 40 C.F.R. § 717.17(b).
[9] ICR Supporting Statement at 10, *supra* note 4.
[10] 15 U.S.C. § 2625(k).
[11] EPA, "Data Development and Information Collection to Assess Risks" (last updated Feb. 17, 2021), https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/data-development-and-information-collection-

measure a chemical's risks, they can identify effects that warrant additional analysis and potential regulation, and can also help EPA identify facilities, materials, or products that use or release the chemical, and populations that have been harmed by it. Moreover, EPA's TSCA regulations define "reasonably available information" as "information that EPA possesses *or can reasonably generate, obtain, and synthesize* for use in risk evaluations, considering the deadlines specified in TSCA."[12] Under this definition, 8(c) records are "reasonably available," because they can be reasonably obtained by EPA within the statutory deadline for a risk evaluation or risk management rule.

Despite the benefits of Section 8(c) reporting, and TSCA's mandate to consider reasonably available information, EPA has hardly ever used its 8(c) authority. Since finalizing regulations implementing Section 8(c) in 1983, EPA has issued only two data requests under that Section, covering two chemicals and two chemical categories.[13] In contrast, EPA estimates that companies receive more than 5,500 reports of adverse reactions under Section 8(c) each year, which would total more than 200,000 total reports over that period.[14] EPA lacks access to the overwhelming majority of that data, solely because it never asked for it. Under the ICR, EPA intends to maintain this hands-off approach over the years ahead, with plans to issue only "one additional [8(c)] notice per year," despite EPA's heightened need for chemical safety data during that period.[15]

We urge EPA to make greater use of its Section 8(c) data collection authority, and to issue requests for 8(c) reports covering the following groups of chemicals:

- All chemicals currently undergoing TSCA risk evaluations: EPA is currently conducting 23 risk evaluations, which are designed "to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment."[16] Section 8(c) records can identify previously unknown chemical uses, hazards, and exposures, and call attention to health effects that may warrant further analysis in a risk evaluation.
- All chemicals for which EPA is developing risk management rules: EPA is also preparing risk management rules for the 10 chemicals that underwent risk evaluations in the last administration. Those rules require the consideration of "the effects of the chemical substance … on health and the magnitude of the exposure of human beings," both of which would be informed by available information in 8(c) records.[17]

---

assess-risks. The scope of recordkeeping under Section 8(c) is broader than reporting under TSCA Section 8(e), which covers only information that reflects "*substantial* risk of injury to health or the environment." 15 U.S.C. § 2607(e) (emphasis added); *see also* EPA, *Questions and Answers Concerning the TSCA Section 8(c) Rule* at 24 (July 1984), https://www.complywithtsca.com/pdf%20files/previews/1dQandA.pdf ("Section 8(c) allegations … can also report lesser effects experienced by a group, or repeatedly by an individual," which would not be reported under Section 8(e).).

[12] 40 C.F.R. § 702.33.

[13] ICR Support Statement at 8, *supra* note 4.

[14] *Id.*

[15] *Id.* at 9.

[16] 15 U.S.C. § 2605(b)(4)(A).

[17] *Id.* § 2605(c)(2)(A)(i).

- All chemicals that are identified as candidates or proposed for a "high priority" designation in the future: EPA reports that it intends to conduct "preliminary analyses of prioritization candidates for pre-prioritization phase" over the coming year.[18] The "pre-prioritization" process will identify chemicals that may be subject to "high priority" designations and TSCA risk evaluations in the future. Once EPA identifies a potential high priority chemical through the pre-prioritization or prioritization process, EPA should immediately use its 8(c) authority to collect relevant information about that chemical.
- PFAS chemicals: According to EPA, "[u]nderstanding the scope of PFAS exposure including sources, pathways, populations exposed, and levels of exposure is critical to effectively characterizing the potential human health and environmental risks associated with these compounds."[19] In addition, while all PFAS are persistent and many of the PFAS that have been studied share common health effects, "for most PFAS there is limited or no toxicity information."[20] A Section 8(c) records request could help to fill that data gap and provide information that could inform EPA's broader efforts to prioritize, evaluate, regulate, or remediate PFAS.[21] Notably, some of the earliest indications of PFAS toxicity came from the impacts on workers in PFAS manufacturing plans, the very type of information covered by Section 8(c).

In short, Section 8(c) is an important but underutilized tool that can assist EPA in its TSCA implementation efforts. We encourage EPA to make greater use of its 8(c) authority in the future, and we appreciate the opportunity to submit the foregoing comments. For additional information about the issues raised in these comments, please contact Jonathan Kalmuss-Katz at jkalmusskatz@earthjustice.org.

Respectfully submitted,

Earthjustice
Environmental Defense Fund
Environmental Working Group
Natural Resources Defense Council

[18] EPA Office of Pollution Prevention & Toxics, *Strategic Plan FY 2021 – FY 2023* at 22 (May 2021), https://insideepa.com/sites/insideepa.com/files/documents/2021/may/epa2021_1033.pdf.
[19] EPA, *EPA's Per- and Polyfluoroalkyl Substances (PFAS) Action Plan* at 10 (Feb. 2019), https://www.epa.gov/sites/production/files/2020-01/documents/pfas_action_plan_feb2020.pdf.
[20] *Id.*
[21] Because TSCA provides that "any action authorized or required to be taken by the Administrator under any provision of this [Act] with respect to a chemical substance or mixture may be taken … with respect to a category of chemical substances or mixtures," EPA may issue a single request all Section 8(c) records for the class of PFAS, as opposed to for individual PFAS chemicals. 15 U.S.C. § 2625(c).