



Inspiring Generations of Play

1200 G Street NW • Suite 200 • Washington, DC 20005
t. 202.459.0354 • e. info@toyassociation.org

May 4, 2022

Ms. Lanelle Wiggins

RFA/SBREFEA Team Leader
Office of Policy
U.S. Environmental Protection Agency
1201 Constitution Avenue NW
Washington, DC 20004

VIA Email: wiggins.lanelle@epa.gov

RE: TSCA Section 8(a)(7) Reporting and Recordkeeping Requirements for Perfluoroalkyl and Polyfluoroalkyl Substances; Proposed Rule, 86 Fed. Reg. 33,926 (Jun. 28, 2021)

Dear Ms. Wiggins:

I provide these comments as a Small Business Representative providing input to the Small Business Advocacy Review Panel considering the above-referenced rule. These comments are provided on behalf of small business members of The Toy Association. We appreciate this opportunity to provide the perspective of small toy producers on this rule.

The Toy Association is the North American based trade association for the toy trade; our membership includes more than 900 businesses – from inventors and designers of toys to toy manufacturers and importers, retailers and safety testing labs – all involved in bringing safe, fun toys and games to children. The toy sector is a global industry of more than US\$90 billion annually, and our members account for more than half this amount. Approximately 80% of our members are small entities as the SBA defines them, and these small members are overwhelmingly importers of articles sourced from factories offshore.

Toy safety, including chemical safety, has been the top priority for The Toy Association and its members since the 1930s, and we have continued to lead global toy safety efforts; in the 1970s we helped to create the first comprehensive toy safety standard, which was later adopted under the auspices of ASTM International as ASTM F963. The ASTM F963 Toy Safety Standard has been recognized in the United States and internationally as an effective safety standard, and it serves as a model for other countries looking to protect the health and safety of their citizens with protective standards for children.

THE PROPOSED RULE

The 2020 National Defense Authorization Act added a new section 8(a)(7) to TSCA, directing EPA to promulgate an information collection rule applicable to manufacturers of “PFAS”:

(7) PFAS DATA.—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).

The amendment does not expand EPA’s reporting authorities, it merely directs EPA to use them. The statute requires EPA to promulgate the final reporting rule by January 2023 but does not specify a deadline for the reporting itself. Nor does the amendment identify any intended purpose or object for the reporting. The details of the reporting are left to EPA’s discretion, but EPA’s discretion to set reporting obligations under section 8(a)(7) is not unlimited.

TSCA section 8(a)(2) subparagraphs (A) through (G), referred to by the amendment, describe the full range of information for which EPA can require reporting under section 8(a).

PFAS Reporting is Subject to TSCA section 8(a) Prudential Limits.

The statutory text carefully included words to assure that all existing burden mitigation provisions of TSCA section 8(a) were made applicable to this new information collection, just as they are for all other TSCA section 8(a) rules. Congress specifically directed that the new section 8(a)(7) PFAS rule should be promulgated in accordance with the other provisions of subsection 8(a):

Not later than January 1, 2023, the Administrator shall promulgate a rule *in accordance with this subsection*

TSCA § 8(a)(7) (emphasis added). As used in TSCA, “subsection” refers to the first rank subdivision below the numbered section level. Accordingly, this cross reference in TSCA section

8(a)(7) refers to TSCA subsection 8(a) and requires that EPA promulgate this PFAS rule “in accordance with” that subsection.

Subsection 8(a) has several limits that require EPA to use skill and good judgment in the exercise of its broad information collection authorities to require others to expend resources. These prudential limits closely parallel but are more restrictive than the 5 CFR § 1320.5(d) standards for ICR approval under the PRA:

- a) EPA may only require reporting that is “reasonable” [§8(a)(1)(A)];
- b) “small manufacturers and processors” are exempt from section 8(a) reporting in most circumstances [§ 8(a)(1)];
- c) reporting is required only to the extent that the information sought is “known or reasonably ascertainable” [§ 8(a)(2)]; to the extent feasible, EPA must not require reporting that is unnecessary [§ 8(a)(5)(A)];
- d) to the extent feasible, EPA must not require reporting that is duplicative [§ 8(a)(5)(A)];
- e) to the extent feasible, EPA must minimize the cost of compliance with section 8(a) reporting rules to small manufacturers and processors [§ 8(a)(5)(B)]; and

- f) to the extent feasible, EPA must direct any reporting obligations to those likely to have the information relevant to the effective implementation of TSCA (and avoid burdening those that do not) [§ 8(a)(5)(C)].

OUR COMMENTS

We generally support collecting existing PFAS health, exposure and use information from industry to support good public policy and meet well defined information needs. However, in this case, the information collection program outlined in EPA's proposed rule was not designed to meet specific unmet information needs and, in our view, is needlessly burdensome. As discussed herein, this flaw arises from a mistaken view of the extent of EPA's discretion under the statute to tailor the rule to its actual information needs. EPA has viewed its discretion too narrowly. In fact, EPA has both the discretion and the time to design a practicable information collection rule that will generate useful information for policy making, without undue burden on the entire regulated community.

As discussed more fully below:

1. EPA is required to issue a PFAS reporting rule in accordance with the information collection planning and burden limiting provisions of the Paperwork Reduction Act (PRA) and TSCA section 8(a). EPA is mistaken to the extent it concludes that it has no discretion to create exemptions and tailor the reporting rule to its current information needs. The reporting rule must be tailored to:

a) avoid duplication to the extent feasible;

b) avoid unnecessary reporting to the extent feasible;

c) limit reporting to information that will be of practical utility to EPA (in substance and in a format) to address particular needs;

d) use the least burdensome approach necessary for the proper performance of the Agency's function;

e) exempt qualifying small businesses; and;

f) to distinguish to the extent feasible among classes of persons and direct reporting obligations to those likely to have useful, responsive information *reasonably ascertainable by those entities*.

Congress directed EPA to promulgate a reporting rule in accordance with these guidelines. Failure to do so would be a violation of TSCA and the Administrative Procedures Act.

2. Given its past interpretation of section 8(a)(7), EPA has never assessed its specific PFAS information objectives that might be addressed by TSCA section 8(a)(7) reporting. At this stage, EPA should redraft the rule based on a principled assessment of its unmet information needs, and articulate a clear plan that will allow it to make practical use of the collected information. The rule then can be tailored to generate the required information while also avoiding unnecessary, duplicative, or needlessly burdensome requests.

3. EPA has grossly underestimated the practical scope and burden associated with the proposed reporting and EPA's PRA ICR should be rejected in its current form. As mentioned previously, 80% of our members are small enterprises, and most import articles only from complex offshore supply chains in multiple countries. They do not intentionally add PFAS (with the rare exception being use of fluoropolymers for internal gears, mechanisms, etc.), but non-polymeric PFAS may be present as contaminants at *de minimis* amounts, so they would need to undertake due diligence to determine

whether this is the case. These are businesses that are in many cases struggling to survive the effects of the pandemic, supply chain snarls, and inflation, and this rule imposes an unwelcome burden atop those. In many cases, their suppliers have not survived the past two years, thus data gathering may include testing of stock rather than supply chain surveys.

EPA has grossly underestimated the number of affected businesses and the cost that small entities would incur. EPA has estimated costs based on sales volume, but in a consumer-responsive industry like toys, the more appropriate measure is stock keeping units ("SKUs"); even small companies may carry up to 10,000 SKUs, each requiring investigation at approximately five hours per SKU @ \$50.00/hr, or as much as \$2.5 million. You can imagine what a burden this is for a company with \$10 million in annual sales. Adding to the cost and difficulty is that toys are popular one month, and not so much the next, so an average toy company replaces 50% of its line offerings every year. Multiply this by the 10-year reporting period, and the problem becomes enormous, especially for entities with scant expertise and bandwidth. It is likely outside consultants and product testing will often be necessary, adding to the costs involved.

These small entities not only would be unduly burdened by the costs involved but are unlikely to be able to provide meaningful data to the Agency, despite having expended enormous sums. This is because the information is in most cases not reasonably ascertainable by them. Add to this the fact that most PFAS in toys will be *de minimis* contaminants within a solid matrix, and the cost/benefit ratio becomes difficult to rationalize.

4. There are techniques available to EPA to tailor the reporting rule that balance EPA's reasonable information needs, differences in the kind and extent of information available to companies in the value chain and burden on the regulated community. These include establishing different response obligations corresponding to a respondent's expected level of knowledge and using tiered and phased approaches to focus reporting on the most relevant and reliable information and to defer or make conditional reporting on information that is less useful, less reliable, or significantly more difficult to obtain.

5. We respectfully request that EPA narrow the scope of required reporting with additional proper exclusions as follow:

- a) exclude importers of articles;
- b) exclude small businesses to the extent they are importers of articles;
- c) exempt materials imported in quantities of less than 2,500 lbs. per year;
- d) exempt *de minimis* amounts in articles;
- e) materials for which EPA has not listed a specific chemical identity;
- f) exempt most fluoropolymers, consistent with EPA's approach in its TSCA Chemical Data Reporting rule.

6. We respectfully request that EPA also modify or narrow individual reporting elements to avoid unnecessary, duplicative, or unduly burdensome reporting:

May 4, 2022

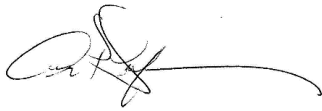
Page 5 of 5

- a) clarify the scope of the “reasonably ascertainable” standard to reasonably limit the extent of required investigation, particularly to entities outside the reporting organization;
- b) define data quality standards for reporting quantitative estimates;
- c) extend the reporting period to at least one year, and preferably 18 months;
- d) provide alternative reporting mechanisms (other than CDR) for entities who do not normally report.

We again thank EPA for this opportunity to provide comments. Please do not hesitate to contact me if you have questions or would like further information. I can be reached at

akaufman@toyassociation.org.

Sincerely,

A handwritten signature in black ink, appearing to read 'Alan P. Kaufman', with a long horizontal flourish extending to the right.

Alan P. Kaufman
Senior Vice President, Technical Affairs