



September 27, 2021

VIA ELECTRONIC SUBMISSION

The Honorable Michael S. Regan  
Administrator  
Environmental Protection Agency  
Washington, DC 20460

**Re: TSCA Section 8(a)(7) Reporting and Recordkeeping Requirements for Perfluoroalkyl and Polyfluoroalkyl Substances (Docket ID No. EPA-HQ-OPPT-2020-0549)**

Dear Administrator Regan:

On June 28, 2021, the Environmental Protection Agency (EPA) published the above-referenced proposed rulemaking on reporting and recordkeeping requirements for Perfluoroalkyl and Polyfluoroalkyl Substances (PFAS).<sup>1</sup> This proposed rule would require any person who manufactures or has manufactured PFAS since January 1, 2011 to electronically report information regarding PFAS uses, production volumes, disposal, exposures, and hazards.

Advocacy is concerned that the agency has improperly certified that this rule will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (RFA).<sup>2</sup> Advocacy is further concerned with small businesses' ability to comply with the rule due to its broad scope and applicability. Therefore, Advocacy believes that EPA must conduct a small business advocacy review panel, as required by Section 609 of the RFA<sup>3</sup> to assess the impact of the proposed rule on small entities, and to consider less burdensome alternatives. Advocacy supports EPA's goal of effective information sharing and communication about PFAS under the Toxic Substance Control Act (TSCA)<sup>4</sup> and hopes to work with the agency to identify a more effective and less burdensome means to achieve this goal.

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<sup>1</sup> TSCA Section 8(a)(7) Reporting and Recordkeeping Requirements for Perfluoroalkyl and Polyfluoroalkyl Substances, 86 Fed. Reg. 33926 (June 28, 2021).

<sup>2</sup> 5 U.S.C. § 601 et seq.

<sup>3</sup> 5 U.S.C. § 609(d)(2).

<sup>4</sup> 15 U.S.C. § 2601 et. seq.

## I. Background

### A. The Office of Advocacy

Congress established Advocacy under Pub. L. 94-305 to represent the views of small entities before Federal agencies and Congress. Advocacy is an independent office within the U.S. Small Business Administration (SBA); as such the views expressed by Advocacy do not necessarily reflect the views of the SBA or the Administration. The RFA, as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA),<sup>5</sup> gives small entities a voice in the rulemaking process. For all rules that are expected to have a significant economic impact on a substantial number of small entities, the RFA requires federal agencies to assess the impact of the proposed rule on small entities and to consider less burdensome alternatives.

The Small Business Jobs Act of 2010 requires agencies to give every appropriate consideration to comments provided by Advocacy.<sup>6</sup> The agency must include, in any explanation or discussion accompanying the final rule's publication in the *Federal Register*, the agency's response to these written comments submitted by Advocacy on the proposed rule, unless the agency certifies that the public interest is not served by doing so.<sup>7</sup>

Advocacy's comments are consistent with Congressional intent underlying the RFA, that “[w]hen adopting regulations to protect the health, safety, and economic welfare of the nation, federal agencies should seek to achieve statutory goals as effectively and efficiently as possible without imposing unnecessary burdens on the public.”<sup>8</sup>

### B. The Proposed Rule

On June 28, 2021, EPA proposed reporting and recordkeeping requirements, under TSCA Section 8(a)(7), to require any person who manufactures or has manufactured PFAS to electronically report information regarding its chemical identity, uses, production volumes, disposal, exposures, disposal, and hazards, retrospectively dating back to January 1, 2011. This section was recently added to TSCA by the National Defense Authorization Act for Fiscal Year 2020.<sup>9</sup> The statutory requirement is limited to the collection of detailed information on PFAS, as described above. EPA anticipates that a potential benefit of this information collection is that it could satisfy EPA's research need to better understand potential routes of exposure to PFAS and potential human health and environmental impacts of certain PFAS.

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<sup>5</sup> Pub. L. 104-121, Title II, 110 Stat. 857 (1996) (codified in various sections of 5 U.S.C. §601 et seq.).

<sup>6</sup> Small Business Jobs Act of 2010 (PL. 111-240) §1601.

<sup>7</sup> *Id.*

<sup>8</sup> 5 U.S.C. § 601 note.

<sup>9</sup> Pub. L. 116-92, Section 7351. “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's interpretation of the statute includes 1,346 listed PFAS and an unknown number of unlisted chemicals that meet a structural definition provided by the agency. In addition, the agency is requiring all manufacturers and importers of PFAS, including importers of articles and other commonly excluded entities such as manufacturers of impurities and byproducts, to report on PFAS.

EPA is proposing to require the reporting of information "known to or reasonably ascertainable by" manufacturers of PFAS. The agency explains that "known to or reasonably ascertainable by" is defined to include "all information in a person's possession or control, plus all information that a reasonable person similarly situated might be expected to possess, control, or know." The agency interprets this standard to require affected entities to evaluate their current level of knowledge of their manufactured products, including imports, as well as to evaluate whether there is additional information that a reasonable person, similarly situated, would be expected to know, possess, or control.

The agency provides a six-month submission period, which would begin six months following the effective date of the final rule, essentially allowing one year to collect and submit all required information to EPA.

EPA has certified that the rule will not have a significant economic impact on a substantial number of small entities under the RFA.

## **II. EPA Has Improperly Certified the Rule under the Regulatory Flexibility Act.**

If, after conducting an analysis for a proposed or final rule, an agency determines that a rule will not have a significant economic impact on a substantial number of small entities, section 605(b) provides that the head of the agency may so certify. The certification must include a statement providing the factual basis for this determination, and the certification must be published in the *Federal Register* at the time the proposed or final rule is published for public comment. Agency certifications of final rules are subject to judicial review<sup>10</sup> and courts evaluate them by determining whether the statement of basis and purpose accompanying the rule identifies a "factual basis" to support the certification.<sup>11</sup>

However, if an agency covered by Section 609 of the RFA, such as EPA,<sup>12</sup> is unable to certify then the agency must conduct a SBREFA panel, to assess the impact of the proposed rule on small entities, and to consider less burdensome alternatives.<sup>13</sup> In addition, the agency must produce an initial regulatory flexibility analysis (IRFA) in the *Federal Register* at the same time it publishes the proposed rulemaking. The IRFA is required to include discussion of specific elements including a description of any significant alternatives to the proposed rule that

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<sup>10</sup> 5 U.S.C. § 611.

<sup>11</sup> 5 U.S.C. § 605(b).

<sup>12</sup> 5 U.S.C. § 609(d)(2).

<sup>13</sup> *Id.*

minimize significant economic impacts on small entities while accomplishing the agency's objectives.<sup>14</sup>

Advocacy believes that EPA cannot certify the proposed rule under the RFA because EPA has underestimated the impacts of the rule and underestimated the number of small entities subject to the rule, and has not included the impacts on small business importers of articles that will be subject to the proposed rule. Moreover, EPA's factual basis does not meet the standard set by the agency's own guidance for how to conduct a threshold analysis under the RFA.

#### **A. EPA Underestimates the Impact of Compliance Costs Associated with the Proposed Reporting Requirements.**

Small businesses representatives have expressed concerns that the agency has grossly underestimated the compliance costs for the proposed rule given the broad scope of the rule for PFAS and the retrospective nature of the reporting required for years dating back to 2011. For instance, as referenced above, the rule requires reporting on 1,346 known PFAS plus an unknown number of chemicals, potentially thousands, according to small business representatives, that would be within the scope of reporting for this rule. In addition, even though it is a one-time reporting rule, it requires one-time reporting for each instance of manufacture that occurred in the past ten plus years.

Furthermore, although the agency provides estimates for the compliance burden for importers of articles, this information was not included in the analysis to support its RFA certification. EPA's estimates include that article importers may incur a range of costs depending on the number of articles they import, their level of knowledge of their imported articles, the complexity of supply chains, and whether PFAS is present in their articles.<sup>15</sup> Small business representatives have expressed concerns that these compliance burdens are also severely underestimated.

Finally, in presenting the impacts of the rule for small businesses across a range of industries, EPA includes revenues for businesses of all sizes, resulting in the minimization of the scale of the impacts of this regulation on small businesses. For this reason, Advocacy believes the percentages for the impacted small entities provided in the agency's certification are misrepresented. In EPA's economic analysis, Table 7-6 appears to provide the estimated revenue distribution for all firms within the identified industries; it does not appear to be restricted to small firms in those industries.<sup>16</sup> Since the purpose is to calculate the percentage of small firms that incur costs above certain thresholds, only small firms should be included in the distribution. Because large firms have higher revenues, including them increases the estimated

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<sup>14</sup> See 5 U.S.C. § 603(b)-(c).

<sup>15</sup> 86 Fed. Reg. at 33935. "Importers of articles that contain PFAS may incur costs for rule familiarization (\$69.79 per firm); identifying the type of imported articles that potentially use PFAS (\$1,641-\$1,932 per firm); identifying suppliers involved (\$1,185 per firm); collecting data from suppliers (\$0-644 per article); and recordkeeping (\$12 per firm)."

<sup>16</sup> Economic Analysis for the Proposed TSCA Section 8(a) Reporting and Recordkeeping Requirements for Perfluoroalkyl and Polyfluoroalkyl Substances, (May 2021) (hereinafter "Economic Analysis"), pg. 7-6.

revenue at each percentile, and this subsequently decreases the calculated percent of firms that fall below each revenue threshold. This suggests that in Table 7-7,<sup>17</sup> the numbers and percentages in the “>3 percent” column are underestimated and the number and percentages in the “<1 percent” column are overestimated.

### **B. EPA Underestimates the Number of Small Entities Subject to the Rule.**

Advocacy is also concerned the agency underestimated the number of impacted small entities and their costs because the agency’s estimates are based on limited data. EPA extrapolated its estimate for the number of small businesses impacted based on the Chemical Data Reporting (CDR) requirements as the source of its data.<sup>18</sup> The CDR rule provides exemptions for articles, byproducts, impurities, non-isolated intermediates, research and development, and small manufacturers and importers<sup>19</sup> and certain polymers.<sup>20</sup> The CDR rule also exempts materials manufactured in quantities of less than 2,500 pounds.<sup>21</sup> In addition, EPA notes that it is using information from a subset of the entities reporting for CDR, PFAS manufacturers consisting of only those considered to be submitting non-confidential business information.<sup>22</sup> The agency specifically states that it has not attempted to describe all the entities that could be affected by the proposal.<sup>23</sup> For these reasons, the agency’s estimate for the number of small businesses impacted cannot be considered to provide a true representation of those small entities that would be subject to the reporting requirements.

More importantly, EPA admittedly did not include an entire class of small business importers of articles among those that would be subject to the rule, nor did the agency include the cost of compliance for these small businesses in its RFA certification, as described above.<sup>24</sup> EPA explains that it does not have this information because it has not previously imposed reporting requirements on these entities.<sup>25</sup> Without an estimate of the total number of impacted small entities (and their estimated costs) that are importers of articles, EPA does not have sufficient information to constitute a factual basis for certification under the RFA.

Moreover, EPA is requiring compliance under its “known to or reasonably ascertainable by” standard to report information required in this rulemaking. EPA confirms that while the reporting rule requirements only apply to importers who know that their products contain PFAS, any importers that do not know will still need to engage in some form of information collection

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<sup>17</sup> Economic Analysis at 7-6.

<sup>18</sup> *Id.* at 7-2.

<sup>19</sup> 40 C.F.R. § 704.5.

<sup>20</sup> 40 C.F.R. § 711.6.

<sup>21</sup> *See*, 40 C.F.R. § 711.15.

<sup>22</sup> Economic Analysis at 7-2.

<sup>23</sup> 86 Fed. Reg. at 33927.

<sup>24</sup> *Id.* at 33935.

<sup>25</sup> *Id.*

to determine whether the potential presence of PFAS in their imported products meets the “known to or reasonably ascertainable by” standard.<sup>26</sup> Based on this explanation, the proposed rule imposes a legal obligation to investigate on every single importer of articles to determine whether their product is PFAS-free.

EPA acknowledges that manufacturers, wholesalers, and retailers that import articles may be affected.<sup>27</sup> For these reasons, it is reasonable to assume that *all* manufacturers, wholesalers, and retailers that import articles will be affected by this rule to some degree. In 2019, importing U.S. businesses included 29,132 manufacturers with fewer than 500 employees (small business size standards for manufacturers range from 500-1500 employees), 55,519 wholesalers with fewer than 100 employees (small business size standards range from 100-250 employees), and 37,104 small- and medium-sized retailers.<sup>28</sup> Though these are not exact counts of small importing businesses in these industries, they illustrate that many affected small businesses were omitted from EPA’s analysis. The universe of affected importers also likely extends beyond just manufacturers, wholesalers, and retailers.

**C. EPA’s certification does not meet the standard set by the agency’s own guidance for how to conduct a threshold analysis under the RFA.**

Based on the agency’s own guidance on compliance with the RFA<sup>29</sup> and the estimates included in the agency’s factual basis, the agency cannot justify an RFA certification without further analysis into small business impacts. Since the RFA does not define the terms significant or substantial as they pertain to the extent of economic impact and the number of small entities affected, EPA’s guidance provides that the agency consider certain numerical thresholds to determine whether a rule can be certified under the RFA.<sup>30</sup> These include: “(1) magnitude of economic impact that may be experienced by regulated small entities; (2) total number of regulated small entities that may experience the economic impact; and (3) percentage of regulated small entities that may experience the economic impact.”<sup>31</sup> The first numerical threshold relates to significance of the economic impact.<sup>32</sup> The second and third numerical thresholds relate to the substantial number of small entities impacted.<sup>33</sup>

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<sup>26</sup> 86 Fed. Reg. at 33928.

<sup>27</sup> *Id.* at 33958.

<sup>28</sup> Profile of U.S. Importing and Exporting Companies (2018-2019), U.S. Census Bureau (April 7, 2021), *available at*: <https://www.census.gov/foreign-trade/Press-Release/edb/2019/index.html#Tables>

<sup>29</sup> *Regulatory Management Division, EPA Office of Policy, EPA’s Action Development Process: Final Guidance for EPA Rulewriters: Regulatory Flexibility Act, as amended by the Small Business Regulatory Enforcement Fairness Act*, (November 2006) (hereinafter “EPA Rule Guidance for RFA”).

<sup>30</sup> *Id.* at pg. 23.

<sup>31</sup> *Id.*

<sup>32</sup> EPA Rule Guidance for RFA at pg. 23.

<sup>33</sup> *Id.*

In applying these thresholds, EPA explains that with fewer than 100 small entities impacted, an impact of three percent of revenue or greater for twenty percent of the impacted entities does not support a presumption for certification under RFA because it is considered to be uncertain.<sup>34</sup> EPA's certification for this rule provides that thirty-five percent of the estimated fifty-nine impacted small entities will have an impact of three percent of revenue or greater.<sup>35</sup> Based on EPA's guidance, this rule falls into the "Uncertain - No Presumption" of significant economic impact on a substantial number of small entities category.<sup>36</sup> In this case, the agency directs itself to conduct additional analysis such as an analysis of cost pass-through, use of or examination of profits or profit margins, measurement of the financial health of entities, or comparing the relative impacts on small entities versus large entities.<sup>37</sup> For this proposal, the agency did not conduct or provide any such additional analyses, per its own guidance, to account for the uncertainty regarding its presumption for a significant economic impact on a substantial number of small entities. For this reason, the agency should not have certified the rule under the RFA.

### **III. Advocacy Recommends EPA Convene a SBREFA Panel and Consider Burden-reducing Compliance Flexibilities for Small Businesses.**

For the reasons provided above, EPA's RFA certification based on the factual basis provided does not support a conclusion that the rule will not impose significant economic impact for a substantial number of small entities. Therefore, EPA should have convened a SBREFA panel for this proposed rulemaking, Advocacy urges the agency to do so. A SBREFA panel will allow the agency to get information on the number of small entities that would be impacted, assess the impacts of the proposed rule on all the relevant small entities and consider less burdensome alternatives.

Advocacy urges the agency to include the following compliance flexibilities for small businesses:

1. Exemptions for small businesses who are not likely to produce responsive, reliable or any information at all;
2. A tiered and phased approach for compliance based on the small businesses' abilities to provide required information; and
3. Tailored guidance on the application of the "reasonably ascertainable" standard for reporting on articles.

#### **A. EPA should provide exemptions for small business entities that are least likely to provide responsive, reliable or any information at all.**

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<sup>34</sup> EPA Rule Guidance for RFA at pg. 24.

<sup>35</sup> 86 Fed. Reg. at 33935.

<sup>36</sup> EPA Rule Guidance for RFA at pg. 24.

<sup>37</sup> *Id.* at 28.

Although EPA states otherwise,<sup>38</sup> EPA has the statutory discretion under TSCA to provide exemptions for this reporting rule. EPA has already provided exemptions for other reporting rules under TSCA Section 8 that include similar language in requiring “any person” to report.<sup>39</sup> For example, as mentioned above, EPA provides exemption to various entities under its CDR requirements.<sup>40</sup> CDR is also a section 8 reporting rule. The statute uses similar language in defining the scope for the corresponding regulations, which is “each person.”<sup>41</sup> Therefore, a statutory requirement to impose reporting obligation on every person, does not preclude the agency from providing exemptions under a similar provision under TSCA 8(a)(7).

Moreover, EPA has an affirmative duty to provide exemptions for this reporting rule under TSCA when certain factors are present. TSCA 8(a)(7) requires the agency to promulgate a rule “in accordance with this subsection,” which includes the requirements, “to the extent feasible, that EPA: (A) Not require reporting which is unnecessary or duplicative; (B) Minimize the cost of compliance with TSCA section 8 and the rules issued thereunder on small manufacturers and processors; and (C) Apply any reporting obligations to those persons likely to have information relevant to the effective implementation of this subchapter.”<sup>42</sup>

The agency provides consideration for the first factor by providing proposed exceptions to reporting for unnecessary and duplicative reporting but does not perform any analysis for the two other factors. Under both the RFA and TSCA the agency should have considered minimizing the cost of compliance with the rule for small entities by limiting the application of reporting obligations to only those entities that are likely to have relevant information. The agency can still satisfy this provision of TSCA by providing an exemption for small business entities who will not be able to provide the agency any responsive and reliable information. Here, EPA specifically acknowledges that article importers may not have the information being requested and requests comments on whether articles of importers should be included in the scope of the rule.<sup>43</sup> This demonstrates the agency recognizes that it has discretion in providing this type of flexibility.

Small business importers of articles who likely do not have the information being requested should be exempt from the reporting requirement because the rule would impose an unjustifiable and costly burden on these entities to conduct due diligence under the agency’s broad standard without providing any benefit under the rule. Imported articles frequently involve complex supply chains that span multiple continents and contain many layers of suppliers. According to small business representatives, gathering information about whether (and what) PFAS are contained in articles, and for what purpose, would be a cost- and time-intensive exercise for

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<sup>38</sup> 86 Fed. Reg. at 33929.

<sup>39</sup> See 15 U.S.C. § 2607(a)(1).

<sup>40</sup> See 40 C.F.R. §§ 704.5, 711.6, 711.15.

<sup>41</sup> See 15 U.S.C. § 2607(a)(7).

<sup>42</sup> 86 Fed. Reg. 33929, *citing* 15 U.S.C § 2607(a)(5).

<sup>43</sup> *Id.* at 33930.



article manufacturers and importers, particularly because of the low utility of the information to EPA.

Most recently, when EPA issued the TSCA Fees Rule<sup>44</sup> to require reporting for the 20 chemicals contained in imported articles, byproducts and impurities, the agency had to subsequently issue a “No Action Assurance” granting relief to these entities from having to undertake “significant and expensive product testing efforts to find out what chemical substances may be present even in very small amounts in the articles they import.”<sup>45</sup> These concerns are directly relevant to the PFAS rulemaking. However, the difference is that in requiring reporting for PFAS for these entities, EPA should anticipate an exponential increase in the difficulty in compliance given the large scope of rule that will require reporting for over 1300 chemicals, including countless number of unlisted PFAS looking back over an extended period.

For these reasons, the agency should reevaluate its need to impose the reporting requirement on importer of articles, and manufacturers of byproducts, impurities, including any other unintentional manufacture of PFAS and consider providing an exemption for these entities to the extent that the agency can make a determination that these entities will be unable to provide any information, or reliable and responsive information. If the agency convenes a SBREFA panel as required by the RFA, the agency would be able to get direct feedback on the impacts of the rule on these entities, including their ability to provide the required information and consider regulatory flexibilities such as exemption from the proposed requirements.

**B. EPA should use a tiered and phased approach for compliance based on the small business entities’ abilities to provide required information.**

The statute does not prescribe a single reporting deadline for all entities; therefore, EPA should allow for different compliance timelines based on the small business entities’ abilities to provide the required information. For tiered reporting under this rule, EPA should consider a system of tiered reporting over an extended period, beginning with manufacturers and importers of bulk chemicals. As part of the first effort to implement the rule, all except those considered to be small manufactures and importers could be required to report. The agency could then provide additional time for the small business entities to report given their limited resources and the likelihood that they are going to be first-time reporters since they are currently exempt from reporting under CDR. Prior to imposing the reporting requirements on the remaining entities as part of the second tier, the agency should evaluate the information received and determine the extent to which it is necessary to obtain additional information from the other entities including manufacturers (and importers) of articles, byproducts, impurities, etc. Based on EPA’s assessment of its information needs, the agency could require reporting for these entities in different phases within reasonable timeframes.

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<sup>44</sup> See 40 C.F.R. § 700.40.

<sup>45</sup> Memorandum re: Request for No Action Assurance Regarding Self-Identification for Certain “Manufacturers” Subject to the TSCA Fees Rule at 2 (March 18, 2020). See, Memorandum re: No Action Assurance Regarding Self-Identification Requirement for Certain “Manufacturers” Subject to the TSCA Fees Rule at 1 (March 24, 2020).

In addition, the agency should consider a phased approach by limiting the scope of the rulemaking to the listed or known PFAS, especially for importer of articles. Small businesses representatives have expressed concerns about the ability to comply with the rule, which includes unknown chemicals as defined by a structural diagram. Small business representatives note that smaller companies will not know that a substance in their product is subject to reporting if it contains a PFAS that is only identifiable by a structural diagram. These small business entities have limited resources and limited knowledge about specific chemicals being imported. Advocacy recommends that the agency consider excluding reporting for PFAS that are not listed as a specific chemical identity, at least in the first phase of reporting.

Most recently, to address the issues raised by importer of articles in trying to locate the presence of one chemical, phenol, isopropylated phosphate (3:1)(PIP 3:1), under a deadline,<sup>46</sup> the agency issued a “No Action Assurance” Memorandum,<sup>47</sup> followed by a direct final rule,<sup>48</sup> to extend the compliance deadline. The same concerns would apply here for any compliance timelines provided for article importers, except that it would include thousands of chemicals instead of just one. For this reason, Advocacy urges the agency to provide additional time for importer of articles to comply with any reporting requirements for this rule.

The agency should provide tiered or phase-in compliance for the different entities according to their abilities to report the required information. If EPA convenes a SBREFA panel as required by the RFA, the agency would be able to get direct feedback on small businesses’ abilities to comply with the rule and any appropriate regulatory flexibilities such as delayed compliance or alternative compliance timeframes for small businesses.

**C. EPA should provide tailored guidance to importers of articles on its “known to or reasonably ascertainable by” standard for their reporting obligations under the proposed rule.**

The issues raised above regarding the broad scope of the rule and collecting information on the unknown and vast number of PFAS is compounded for importers of articles under EPA’s “known to or reasonable ascertainable by” standard. The agency should provide more guidance to importers of articles on the specific activities that would be considered sufficient for complying with the agency’s due diligence standard and how frequently importers must undertake these activities. EPA uses the same due diligence standard for other reporting rules such as CDR.<sup>49</sup> In fact, the agency refers the potentially regulated entities, specifically the

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<sup>46</sup> See 40 C.F.R. § 751.407.

<sup>47</sup> Memorandum re: No Action Assurance Regarding Prohibition of Processing and Distribution of Phenol Isopropylated Phosphate (3:1), PIP (3:1) for Use in Articles, and PIP (3:1)-containing Articles under 40 CFR 751.407(a)(1), (March 8, 2021).

<sup>48</sup> See Regulation of Persistent, Bioaccumulative, and Toxic Chemicals Under TSCA Section 6(h); Phenol, Isopropylated Phosphate (3:1); Compliance Date Extension, 86 Fed. Reg. 51823 (September 17, 2021).

<sup>49</sup> 40 C.F.R. § 711.15.

importer of articles, to guidance provided for this standard under its CDR rules.<sup>50</sup> As mentioned above, CDR rules do not apply to importers of articles. In other words, CDR applies to manufacturers and importers of actual PFAS and to those who intentionally produce PFAS to introduce into commerce. Entities such as manufacturers and importers of the chemical are in the best position to be able to provide the requested information on these chemicals. However, under this rulemaking EPA is imposing the same reporting standard on entities such as importers of articles, who are often end users of an imported product, far removed from any handling of chemical substances. EPA acknowledges this unique position of the importer of articles and the difficulties anticipated in not only obtaining the information to be able to report but also the ability to obtain information to determine if they are required to report (i.e., whether their article contains PFAS).<sup>51</sup>

As previously emphasized, importers of articles do not typically have first-hand knowledge of the actual chemical used in the product they import. They must rely on foreign suppliers for this information. There is no guarantee that these communication requests will be fruitful as they move through layers of entities throughout the supply chain for countless PFAS—and accounting for the use of each PFAS for the past ten or more years. Small business representatives have also cautioned that complying with the rule’s requirements under this standard will translate into different obligations for small businesses with limited resources in contrast with large businesses who may already have dedicated in-house resources to collect information and track their supply chains. Advocacy urges the agency to provide the regulated entities, particularly importers of articles in this case, more clarity on how to satisfy the “known to or reasonably ascertainable by” standard by providing additional guidance. If the agency convenes a SBREFA panel as required by the RFA, the agency would be able to get direct feedback from small businesses on how to address these concerns.

#### **IV. Conclusion**

Advocacy is concerned that the agency has improperly certified that this rule will not have a significant economic impact on a substantial number of small entities under the RFA. Advocacy is further concerned with small businesses’ ability to comply with the rule due to its broad scope and applicability. Therefore, Advocacy believes that EPA must conduct a small business advocacy review panel, as required by Section 609 of the RFA to assess the impact of the proposed rule on small entities, and to consider less burdensome alternatives.

Advocacy urges EPA to give full consideration to the above issues and recommendations. We look forward to working with you to reduce the regulatory burden on small businesses. If you have any questions or require additional information, please contact me or Assistant Chief Counsel Tayyaba Zeb at (202) 205-6790 or by email at [tayyaba.zeb@sba.gov](mailto:tayyaba.zeb@sba.gov).

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<sup>50</sup> 86 Fed. Reg. at 33928.

<sup>51</sup> *Id.*

Sincerely,

/s/

Major L. Clark, III  
Acting Chief Counsel  
Office of Advocacy  
U.S. Small Business Administration

/s/

Tayyaba Zeb  
Assistant Chief Counsel  
Office of Advocacy  
U.S. Small Business Administration

Copy to: Sharon Block, Acting Administrator  
Office of Information and Regulatory Affairs  
Office of Management and Budget