



September 27, 2021

*Submitted via regulations.gov*

Michal Freedhoff  
Assistant Administrator  
Office of Chemical Safety and Pollution Prevention  
U.S. Environmental Protection Agency  
1200 Pennsylvania Ave. NW  
Washington, DC 20460-0001

Re: **Docket ID No: EPA-HQ-OPPT-2020-0549**  
TSCA Section 8(a)(7) Reporting and Recordkeeping Requirements for Perfluoroalkyl and Polyfluoroalkyl Substances; Proposed Rule, 86 Fed. Reg. 33,926 (June 28, 2021)

Dear Assistant Administrator Freedhoff:

The Alliance for Automotive Innovation<sup>1</sup> (Auto Innovators) appreciates the opportunity to provide comments on the Environmental Protection Agency's (EPA) proposed rule, "Toxic Substances Control Act Reporting and Recordkeeping Requirements for Perfluoroalkyl and Polyfluoroalkyl Substances (PFAS)"<sup>2</sup> (hereafter, "the proposed rule"). Two comment deadlines were included in this proposal: July 28, 2021, for comments to the Office of Management and Budget (OMB), and an extended comment period of September 27, 2021, for comments to EPA. Auto Innovators submitted comments on the draft Information Collection Request (ICR) to OMB and also submitted them to the EPA docket.<sup>3</sup> We are submitting these comments to EPA today, focused on several significant implementation issues and challenges posed by this proposal, as well as comments on EPA's estimate of paperwork and burden associated with the collection of the proposed data elements.<sup>4</sup>

Auto Innovators represents the automotive manufacturing sector, including automakers that produce approximately 99% of the new light-duty vehicles sold in the United States. As such, these comments reflect the very real challenges that EPA's proposal presents to almost the entire U.S. automotive manufacturing sector. The automotive industry plays an important and critical role to our nation's economy, accounting for over 10 million jobs and 5.5% of the annual Gross Domestic Product. Our mission is to work with policymakers to realize a future of cleaner, safer, and smarter personal

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<sup>1</sup> Formed in 2020, the Alliance for Automotive Innovation is the singular, authoritative and respected voice of the automotive industry. Focused on creating a safe and transformative path for sustainable industry growth, the Alliance for Automotive Innovation represents the manufacturers producing nearly 99 percent of cars and light trucks sold in the U.S. The organization, a combination of the Association of Global Automakers and the Alliance of Automobile Manufacturers, is directly involved in regulatory and policy matters impacting the light-duty vehicle market across the country. Members include motor vehicle manufacturers, original equipment suppliers, technology and other automotive-related companies and trade associations. The Alliance for Automotive Innovation is headquartered in Washington, DC, with offices in Detroit, MI and Sacramento, CA. For more information, visit our website <http://www.autosinnovate.org>.

<sup>2</sup> 86 FR 33926, June 28, 2021. <https://www.regulations.gov/docket/EPA-HQ-OPPT-2020-0549>.

<sup>3</sup> Comment submitted by Alliance for Automotive Innovation, [EPA-HQ-OPPT-2020-0549-0030](https://www.regulations.gov/docket/EPA-HQ-OPPT-2020-0549-0030), posted August 19, 2021.

<sup>4</sup> Auto Innovators also supports the comments submitted by the ad-hoc Downstream Users Coalition, and herein incorporates them by reference.

transportation and to work together on policies that further these goals, increase U.S. competitiveness, and ensure sustainable, well-paying jobs for citizens throughout the country.

Auto Innovators continues to collaborate with and support EPA's ongoing implementation of the Lautenberg Chemical Safety Act (LCSA), in addition to EPA's goals of protecting the environment and human health. We understand and support EPA's focus on PFAS chemicals of concern and want to provide as much support as possible for EPA's assessment activities. Our Association and its members have been working closely with staff from EPA's Office of Chemical Safety and Pollution Prevention (OCSPP) since the LCSA was enacted to provide data, where available, on high priority chemicals and to assist staff in understanding the complexities of the automotive supply chain and the very real differences between collecting data from chemical manufacturers and processors compared to importers of articles. While we have been addressing this issue in meetings with EPA and in our comments on TSCA rulemakings, this proposed rule's unprecedented request for data makes clear that we need to ask EPA to recognize and acknowledge that the information that is reasonably available to importers of articles is more limited than that available to a bulk chemical manufacturer or processor.

Thus, our comments focus on:

- A. [Compliance with the NDAA](#)
- B. [Application of TSCA Section 8 to Imported Articles](#)
- C. [Burden of Collecting Data](#)
- D. [Benefit or Utility of the Information to be Gathered](#)
- E. [Focus on PFAS Chemicals of Known Concern](#)
- F. [EPA's Estimates for Compliance](#)
- G. [Timeframe for Reporting](#)
- H. [EPA's Ability to Collect and Manage the Volume of Submitted Data](#)
- I. [Classification of the Rule as "Significant"](#)
- J. [Recommendations to Address Auto Innovators Concerns](#)

#### **A. Compliance with the NDAA**

We recognize that this rule is being developed in response to the 2020 National Defense Authorization Act (NDAA), which requires EPA to issue a final rule on PFAS reporting no later than January 2023 and that collects data from "each person who has manufactured a chemical substance that is a perfluoroalkyl or polyfluoroalkyl substance in any year since January 1, 2011."<sup>5</sup> Based on our reading of this language, EPA must collect data on all manufactured PFAS going back to January 1, 2011, but nowhere is EPA required to extend these requirements beyond the manufacture of the chemical substances, or disregard the other considerations included in TSCA Section 8(a). As proposed, EPA's reporting requirements would extend back to 2011, would include manufacturers, processors, and importers of articles, and would offer no exemptions for byproducts, importers, research and development (R&D), *de minimis* quantities, non-isolated intermediates, substances formed during end use, product aging, or weathering.

It is unclear why EPA has chosen to go beyond the direction of the NDAA to collect data from entities "that have manufactured a chemical substance that is a perfluoroalkyl or polyfluoroalkyl *substance*"<sup>6</sup> (*emphasis added*) by also including importers of articles. Articles are neither a chemical substance nor a perfluoroalkyl or polyfluoroalkyl substance. For purposes of TSCA Section 8, the term article is defined at 40 CFR Section 704 as:

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<sup>5</sup> "National Defense Authorization Act for Fiscal Year 2020," Public Law No: 116-92 (12/20/2019).

<sup>6</sup> Subtitle E, Section 7351, <https://www.govinfo.gov/content/pkg/BILLS-116s1790enr/pdf/BILLS-116s1790enr.pdf>.

Article means a manufactured item (1) which is formed to a specific shape or design during manufacture, (2) which has end use function(s) dependent in whole or in part upon its shape or design during end use, and (3) which has either no change of chemical composition during its end use or only those changes of composition which have no commercial purpose separate from that of the article, and that result from a chemical reaction that occurs upon end use of other chemical substances, mixtures, or articles; except that fluids and particles are not considered articles regardless of shape or design.<sup>7</sup>

It is possible that an article may contain some amount of a PFAS chemical as a result of the manufacturing process, but an article does not meet the intent of the NDAA direction. Further, this statutorily mandated language does not direct EPA to deviate from its previous policies of considering the impact, cost, and burden associated with removing the long-standing exemptions for articles, small businesses, byproducts, R&D chemicals, reaction wastes, etc. The inclusion of all these previously exempted categories adds substantially to implementation challenges. It also adds to the burden of compliance and appears to be beyond the scope intended by the NDAA by extending these requirements beyond the manufacture of chemical substances.

## **B. Application of TSCA Section 8 to Articles**

For the reasons appropriately cited by EPA in its “No Action Assurance Letter” on the TSCA Fees Rule<sup>8</sup>, requiring importers of articles to identify the presence of a chemical or chemicals in the hundreds of thousands of articles that move through the global supply chain is impractical, cost-prohibitive and without significant benefit to EPA:

...the broad scope of the current TSCA Fees Rule unintentionally imposes potentially significant burdens on importers of chemical substances in articles, and manufacturers of byproducts and impurities. Determining whether they may be subject to the TSCA Fee Rule and thus need to self-identify could be difficult or impossible for certain manufacturers across the country. Your request indicates that the inherent uncertainties and difficulties associated with identifying the presence (or not) of one or more of the 20 high-priority chemicals by these stakeholders, especially those that have not previously been subject to a TSCA regulatory requirement, creates a compliance problem and adversely impacts the agency’s implementation of the TSCA Fees Rule.<sup>9</sup>

EPA’s No Action Assurance Letter acknowledges the challenges and burden, if not impossibility, that EPA would have created by requiring importers of articles to identify the presence (or not) of *de minimis* quantities of chemicals that may have been used in the manufacture of articles. This letter also reinforces EPA’s long-standing recognition that requiring importers of articles to identify, collect and submit data from a global supply chain offers little benefit at an overwhelming cost.

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<sup>7</sup> <https://www.govinfo.gov/content/pkg/CFR-2017-title40-vol33/pdf/CFR-2017-title40-vol33-sec704-3.pdf>.

<sup>8</sup> “Fees for the Administration of the Toxic Substances Control Act (TSCA).” 83 FR 52694, October 17, 2018.

<sup>9</sup> EPA “No Action Assurance Regarding Self-Identification Requirement for Certain ‘Manufacturers’ Subject to the TSCA Fees Rule,” *Letter*, March 24, 2020. <https://bit.ly/3BQjD4W>.

1. *Articles Have Historically Been Exempted from TSCA Section 5 and 8 Actions*

EPA has routinely exempted articles when the burden of inclusion would outweigh any benefit derived from collecting data on a chemical embedded in an article. In developing these policy decisions on the collection of articles-based data, EPA recognizes that inclusion of articles in TSCA Section 5 and Section 8 actions imposes an unreasonable and perhaps impossible task on importers of articles. While some of these precedent-setting decisions go back nearly 50 years, the number of imported articles and the depth of a multi-tiered, global supply chain have only increased in complexity and magnitude. Examples from previous EPA decision-points include:

- TSCA Section 5 Exemption:

Under §720.22 [b] of this rule, persons who intend to import a new chemical substance for a commercial purpose are subject to section 5 notice requirements. This includes chemicals imported in bulk or as part of a mixture. **Because it would be enormously difficult for an importer to determine the identity and inventory status of each chemical substance in imported articles (e.g., automobiles), the rule does not require persons to submit notices on new substances imported as part of articles.**<sup>10</sup> (emphasis added)

- Information Gathering Rules (§8) from 40 CFR § 704.5(a):

§ 704.5 Exemptions.

A person who is subject to reporting requirements for a substance identified in this part is exempt from those requirements to the extent that the person and that person's use of the substance is described in this section. This section is superseded by any TSCA section 8(a) rule that adds to, removes, or revises the exemptions described in this section.

(a) *Articles.* A person who imports, processes, or proposes to import or process a substance identified in this part solely as part of an article is exempt from the reporting requirements of this part with regard to that substance.

- In EPA's December 23, 1977, Federal Register notice finalizing the Inventory Reporting Requirements<sup>11</sup>, the agency discussed its position on the need to evaluate and collect data from articles:

Articles defined at §710.2(f) will not be included on the inventory. The inventory is a list of chemical substances manufactured or processed for a commercial purpose in the United States....<sup>12</sup>

- In an earlier Federal Register notice,<sup>13</sup> EPA also explained its rationale for this exemption:

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<sup>10</sup> 48 FR 21726, May 13, 1983.

<sup>11</sup> 42 FR 64572, December 23, 1977.

<sup>12</sup> 42 FR at 64587.

<sup>13</sup> 42 FR 53804, October 3, 1977.

As was discussed in the preamble to these repropoed regulations (42 FR 39185), comments from industry and trade associations argued that it would be extremely burdensome for importers to identify the chemical substances contained in the articles they import. According to estimates from the American Importers Association, the total direct cost would range from \$187 million to about \$437 million... Accordingly, to require an importer of the article to identify its constituent chemical substances would impose a proportionately greater burden. Moreover, EPA does not believe that domestic manufacturers of articles would move their operations abroad or be put at a serious disadvantage if the importer is not required to identify constituent substances in articles. **Finally, because of its form, the health and environmental risk posed by a chemical substance in an imported article may be less than the risk posed by a chemical substance imported in bulk or in a mixture.**<sup>14</sup> (emphasis added) (1977 dollars)

EPA's characterization of burden here is based on the assessment of having to collect and track import data that has not been previously collected or tracked. While the automotive industry maintains the International Material Data System (IMDS) as a way of tracking and collecting chemical substances in articles, it has taken thirty years and tens of billions of dollars to develop this tracking system. Further, given the scope of the current proposed rule, these statements regarding data collection are still applicable for the automotive industry for PFAS without listed CAS numbers, since they cannot be tracked in IMDS, and for any imported manufacturing equipment that may contain PFAS, since it is not tracked by IMDS as it is not an article contained in the vehicle.

- EPA's Inventory Update Reporting Rule<sup>15</sup> exempts articles:

§ 710.50 Activities for which reporting is not required.<sup>16</sup>

A person described in § 710.48 is not subject to the requirements of this subpart with respect to any chemical substance described in § 710.45 that the person solely manufactured or imported under the following circumstances:

(a) The person manufactured or imported the chemical substance described in § 710.45 solely in small quantities for research and development.

(b) The person imported the chemical substance described in § 710.45 as part of an article.

(c) The person manufactured the chemical substance described in § 710.45 in a manner described in § 720.30(g) or (h) of this chapter.

While we recognize that this exemption language provides EPA with the opportunity to redetermine any of these exemptions, EPA has never exercised such authority for articles. As mentioned above, EPA's inclusion of articles in the TSCA Fees Rule, a rule that would have collected several data elements similar to TSCA Section 8 reporting, was ultimately deemed "difficult or impossible". The same issues that prompted that conclusion are relevant here.

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<sup>14</sup> 42 FR at 53805.

<sup>15</sup> 76 FR 54933, Sept. 6, 2011.

<sup>16</sup> Please note that this section of the regulations does not appear to be listed on the eCFR at time, and it is unclear why this might be the case: [https://www.ecfr.gov/cgi-bin/text-idx?SID=c46e234451598d8ad9bb1bf857b708fb&mc=true&tpl=/ecfrbrowse/Title40/40cfr710\\_main\\_02.tpl](https://www.ecfr.gov/cgi-bin/text-idx?SID=c46e234451598d8ad9bb1bf857b708fb&mc=true&tpl=/ecfrbrowse/Title40/40cfr710_main_02.tpl).

## 2. Synopsis of EPA's Rationale for Exempting Articles

As reflected in EPA's long-standing policy of articles exemptions, including but not limited to the exemptions provided for under TSCA Section 5(d) and Section 8, the rationale behind EPA's historical treatment of articles has not changed. EPA has continued to recognize that requiring importers of articles to reach down through a complex, multi-tiered, and global supply chain to collect data on a chemical that may or may not be embedded in an article imposes a notable burden with very little benefit.<sup>17</sup> For purposes of this proposed rule, this justification remains applicable for the automotive industry in all applications where the IMDS tracking systems cannot be implemented (i.e., for which there is no CAS number, no *de minimis* level, or no exclusion of byproducts or impurities).

EPA's rationale for the historical treatment of articles has not changed, and many of the issues recognized by the EPA have in fact become more compelling as the global nature of commerce has expanded and supply chains have become more complex. When EPA stated that it would be "enormously difficult for an importer to identify...", there was a clear recognition that navigating the supply chain for articles would be challenging and costly, because of the resources required of industry and also of EPA. Since 1983, when EPA issued this policy statement, the global supply chain has become even more complex.

EPA has also acknowledged that the risk associated with a substance embedded in an article is typically significantly less than a chemical substance or mixture imported in bulk. We believe that any regulation of articles under TSCA should be addressed through Section 6, which relies on best available scientific data and exposure modeling to correlate risk with the various conditions of use for a chemical. This approach is in keeping with EPA's own thinking: "Because of its form, the health and environmental risk posed by a chemical substance in an imported article may be less than the risk posed by a chemical substance imported in bulk or in a mixture."<sup>18</sup> Exempting articles from TSCA Section 8 in no way precludes EPA from any necessary risk management of an article, as appropriately noted by EPA:

However, the Agency will exercise its authority to regulate the import of chemical substances in bulk, in mixtures and in articles under section 6 of the Act, as necessary to protect against unreasonable risks of injury to health and the environment. This might, for example, include prohibiting, limiting or in other ways restricting the import of such chemical substances.<sup>19</sup>

## C. Burden of Collecting Data

When the "Agency Information Collection Activities; Proposed Renewal of an Existing Collection and Request for Comment; User Fees for the Administration of the Toxic Substances Control Act (TSCA)"<sup>20</sup> was published for comment, Auto Innovators submitted comments recommending that EPA conduct a survey of the automotive sector to ensure a more accurate accounting of the burden associated with collecting data relative to articles and their potential chemical content.<sup>21</sup> To date, EPA has not acted on that recommendation, and the burden hours and costs reflected in this current economic assessment

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<sup>17</sup> As EPA has stated, "[b]ecause it would be enormously difficult for an importer to determine the identity and inventory status of each chemical substance in imported articles (e.g., automobiles), the rule does not require persons to submit notices on new substances imported as part of article." 48 FR at 21726, May 13, 1983.

<sup>18</sup> 42 FR at 53805.

<sup>19</sup> 42 FR at 53805.

<sup>20</sup> 86 FR 14904, March 19, 2021.

<sup>21</sup> Comment submitted by Alliance for Automotive Innovation, EPA-HQ-OPPT-2020-0616-0007, <https://www.regulations.gov/comment/EPA-HQ-OPPT-2020-0616-0007>.

continue to significantly underestimate the costs associated with rule familiarization, article identification, outreach to suppliers, data collection, Central Data Exchange (CDX) access, and reporting.

This proposed rule also ignores the guiding direction provided in TSCA section 8(a)(5):

...in carrying out TSCA section 8, EPA shall, to the extent feasible: (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>22</sup>

As part of our comments to OMB on this proposed rule, Auto Innovators recommended development of a Federal Advisory Committee Act (FACA) process to address the complexity of gathering data on articles. This recommendation is based on EPA's current request for data for this proposed rule, growing requests for data under the TSCA chemical prioritization and risk assessment processes, and the need for an informed approach related to chemical use in articles. Auto Innovators has worked with EPA for years to provide data and explain the system we have in place to provide such information. Our industry, however, is somewhat unique with our chemical database system, and even then, EPA's desired data elements and focus on imported articles remain a challenge for us. Further, articles information requests go beyond EPA's traditional focus on manufacturers of the bulk chemicals, and so it is appropriate to design a process to fully evaluate and scope EPA's resource needs for articles. To the extent EPA determines that articles-based reporting is an end goal, a FACA process will ensure EPA and the regulated parties are appropriately scoping resource needs, assessing readily available data sources, developing a reporting system specific to articles, and taking into consideration lead time, development time, costs to undertake this effort, and a dedicated education program to ensure all regulated parties are informed and engaged. Further, a FACA-led group will have the advantage of pulling from a diverse group of industries to provide expertise and precise information on how best to implement articles-based reporting.

In the absence of an EPA survey or a more formal federal process to evaluate the costs of regulating articles, Auto Innovators has reached out to its membership to gather data that more accurately reflects the time and cost associated with determining what type of compliance is necessary for the rule. Our survey was designed to collect basic information. Since Auto Innovators represents OEMs and domestic suppliers of automotive parts and components, our survey has attempted to differentiate between the burden this rule will place on OEMs and that of suppliers. Additional information on our survey is provided in Section F of these comments.

#### 1. *Number of Chemical and Number of Articles*

EPA is proposing that an importer of articles conduct due diligence down the complex global supply chain to identify and collect, if necessary, data on thousands of PFAS chemicals that may or may not be present in small or *de minimis* quantities in imported articles.<sup>23</sup> EPA has also expanded the scope of

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<sup>22</sup> 86 FR 33926, June 28, 2021.

<sup>23</sup> The proposed rule states: "The requirements of this part apply to all chemical substances and mixtures that are PFAS, consistent with the definition of PFAS at § 705.3. This includes, but is not limited to, all PFAS listed or otherwise described in this section. This section contains 5 listings of examples of chemical substances or mixtures that meet this definition. Paragraph (a) of this section is a list of chemical substances on the TSCA Inventory that have an associated Chemical Abstract Services (CAS) Registry Number. Paragraph (b) of this section is a list of chemical substances that have an associated TSCA Accession Number. Paragraph (c) of this section is a list of chemical substances that have both an associated low-volume exemption (LVE) case number and a non-confidential CASRN. Paragraph (d) of this section is a list of chemical substances with

coverage by prescribing that any reports must be submitted on chemicals that are not even on the TSCA inventory. EPA is also proposing that any byproducts, impurities, waste products, R&D chemicals, and reaction products be reported.

In the automotive industry alone, vehicles are composed of tens of thousands of articles, and there are millions of replacement parts in commerce used to maintain and repair in-service vehicles. In addition, even parts domestically manufactured in the U.S. may end up being imported, since the assembly of many subsystems can cross the border numerous times prior to being assembled into the vehicle. It is also not uncommon for an article to be imported in an “unfinished” state, have additional components or technologies applied, be exported to another tier of the supply chain, and then imported again in a finished state. This could result in double and triple reporting with duplicative information and “over estimation” of PFAS content and PFAS containing articles, to the extent EPA’s proposed data sets and chemicals can be identified. While importation of the fully assembled vehicle can be traced and identified, the sheer challenge of identifying what, when or how a part is considered imported (or that of its subparts) will certainly result in over-reporting to ensure all imported parts, even if domestically manufactured, have been captured by EPA’s reporting requirements. This point assumes that all suppliers in the supply chain can identify the presence of a given PFAS chemical, given that no known system in any industry appears to be available or robust enough to do so based on the chemical identifiers that EPA has provided.

The volume of reporting that would be required of importers of articles will not only overwhelm the automotive sector but most certainly will exceed the capacity of EPA’s CDX system. In EPA’s “Economic Analysis for the Proposed TSCA Section 8(a) Reporting and Recordkeeping Requirements for Perfluoroalkyl and Polyfluoroalkyl Substances,” EPA has estimated a one-time cost of \$100,000 to allow the CDX system to develop the infrastructure to accept templates from Organization for Economic Cooperation and Development (OECD) reports; there is no estimate for the expanded capacity that will be required to accommodate all article submissions. EPA estimates receiving 1,369 reports, a number that falls exceedingly short of what would be submitted to CDX if this proposed rule includes imported articles.

As we have shared with EPA numerous times, OEMs have invested billions of dollars to develop, maintain, and optimize the IMDS. The IMDS is used throughout the global automotive supply chain to collect and analyze all parts and materials on the vehicle at the point of sale, including replacement parts. It provides analysis capabilities of the substances present in vehicles and vehicle components. The automotive sector is unique in having this data system, but IMDS does have some limitations. For instance, the IMDS does not have the ability to track substances without a Chemical Abstract Service (CAS) number. For this proposed rule, however, only a very small number of the PFAS chemicals that EPA has identified have CAS numbers. EPA is placing the burden on importers of articles to evaluate the material / substance composition of each article against EPA’s categorical definition to determine if reporting is required. The rest have been identified only by Low Volume Exemption (LVE) notation or a structural definition of PFAS.

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an LVE case number but no CASRN. Paragraph (e) of this section is a list of structural diagram examples of PFAS and those CASRNs.” (86 FR at 33937).

Based on EPA’s listed examples, Auto Innovators counts 413 PFAS with known CAS numbers, 224 PFAS with TSCA accession numbers, 107 PFAS with LVE case number and CASRNs, 409 PFAS with LVE case number but without CASRNs, and nine structures with CAS numbers (86 FR at 33937-33957). Again, as EPA notes, these are examples, and the inclusion of “confidential chemicals whose generic names contain ‘fluor’ and are identified by Accession number; and confidential chemicals whose generic names do not contain ‘fluor’, and therefore, are not listed by CASRNs, Accession numbers, or low-volume exemptions (LVE) case numbers” (86 FR at 33929) could result in unlimited numbers of covered PFAS beyond the 1,164 listed examples.

Further, the complete list of substances available in IMDS is called the Basic Substance List (BSL). This list is comprised of over 13,000 basic substances contained with the chemical name and associated CAS number. However, only a fraction (~27%) of the PFAS chemicals that EPA has included in the proposed rule have clearly delineated CAS numbers that are available in IMDS. Further, it is also difficult to delineate between imported vs. domestically produced articles in IMDS without outreach to individual suppliers.

Additionally, IMDS utilizes a default *de minimis* 0.1% reporting threshold, unless otherwise specified. For instance, for the PFOA substance category, the *de minimis* threshold in IMDS is 25 ppb, as required under Regulation (EU) No 2019/1021 (Persistent Organic Pollutants – POP). On the other hand, EPA’s proposed rule does not outline any *de minimis* value. After years of engagement with EPA, the proposed rule ignores the criticality of having a defined CAS number and *de minimis* value – both of which are vital for the automotive sector to leverage the use of IMDS to meet the requirements outlined in the proposed rule. It is discouraging that EPA has ignored the automotive sector’s substantial investment into IMDS and proposed a rule that results in the inability to use IMDS. Without use of IMDS, CAS numbers, or a *de minimis* level, simply identifying a PFAS chemical not currently included in the automotive basic substance list could take years.

## 2. *Timely Access to Supplier Information*

EPA’s proposed rule and draft economic assessment make clear that as part of the “reasonably ascertainable” standard, EPA expects that importers of articles will reach down into the supply chain for chemical content information about each article that could potentially contain a PFAS chemical or have PFAS as a byproduct, impurity, etc. There are, however, very real differences between collecting data from chemical manufacturers and processors compared to importers of articles and information throughout the supply chain. Chemical manufacturers have access to the type of data typically requested by EPA in TSCA Section 8 data collection rules; importers of articles do not have access to that same type of data. Specifically, importers of articles do not routinely have access to the volume of the chemical used in the manufacturing process, or the amount of the chemical that may remain, intentionally or unintentionally, in or on the article. Additionally, an importer of a finished article has very limited access to data on chemicals used in the lower tiers of the supply chain and in many cases that information may be seen as proprietary by the supplier. EPA should revise the definition of “reasonably ascertainable” to identify existing data sources more clearly, like IMDS, that would be considered to meet the data collection requirements.

The automotive global supply chain has a very complex structure, often up to seven or more tiers. For the reasons outlined above, IMDS will not be an effective tool to meet the reporting requirements defined in the proposed ruling. Therefore, OEMs will be required to query the Tier 1 supply base for the thousands of components in every vehicle manufactured. The Tier 1 supplier will then need to query their supply chain, until a point at which the raw material supplier is reached. In addition to the tremendous burden on cost and resources associated with this type of activity, the time required to reach out through the supply chain, to collect and verify information would be significant, requiring between nine months and one year to complete for PFAS chemicals with known CAS numbers. For those identified with only a chemical structure notation, it is not clear how this activity could be undertaken, and it could take years to fulfill the basic requirements of due diligence that EPA proposes.

## **D. Benefits of Data Collection for PFAS in Articles**

In the NPRM, EPA states the following about the benefits of collecting data on articles:

...the Agency would benefit from collecting the requested information on PFAS-containing articles (including articles containing PFAS as part of surface coatings) because the information would improve the Agency's knowledge of various products which may contain PFAS, their categories of use, production volumes, and exposure data.<sup>24</sup>

EPA's rule, however, lacks articulation of any benefit from the collection of article-based data for PFAS, other than the identification of which articles may contain PFAS chemicals. EPA has not explained how it might use this data to conduct risk evaluations for individual articles that would be different from the risk evaluation for PFAS chemicals themselves, how EPA will manage the volume of data that will likely be received, why the data request going back 10 years is appropriate for articles that could no longer be in commerce, or why the full breadth of data elements is appropriate to articles versus bulk chemical substances. EPA also does not explain why it has chosen to extend these requirements to articles when the 2020 NDAA statute clearly identifies the manufacture of the chemical substance: "each person who has **manufactured a chemical substance** that is a perfluoroalkyl or polyfluoroalkyl substance in any year since January 1, 2011." (emphasis added)

As noted earlier in these comments, EPA has recognized that "because of its form, the health and environmental risk posed by a chemical substance in an imported article may be less than the risk posed by a chemical substance imported in bulk or in a mixture."<sup>25</sup> If, as stated in the proposed rule's preamble, "[o]ne potential benefit of this action is the information collected may serve as a basis to better understand potential routes of exposure to PFAS and potential human health and environmental impacts of certain PFAS, among other research needs listed in the Agency's PFAS Action Plan,"<sup>26</sup> then collection of such data could also be designed to align with existing data systems, readily available data, or use of well-established practices to reduce burden on the sectors and industries that have never before had to supply data of this extent or for articles to EPA. The inclusion of articles in the proposed rule will do little to enhance EPA's understanding of potential routes of exposure, given that there is little to no exposure for chemicals embedded in articles. The amount of PFAS that may be in an automotive component or article is small when compared to the amount of the PFAS in bulk chemicals. Therefore, it raises the very real question of what benefit can be derived from this insignificant contribution to overall volumes, uses, and potential exposure. Taken together with the huge reporting burden that importers of articles will have to shoulder – and that many will have to develop – it is unlikely that the benefits of including articles will outweigh the burden, particularly given the breadth and scope of chemicals covered by this rulemaking.

While Auto Innovators disagrees with the approach and scope of this proposed rule – it goes well beyond the scope of that required by the statute and creates new costly, burdensome and possibly infeasible requirements for importers of articles – Auto Innovators recognizes and understands EPA's goals of protecting the environment and human health. More importantly, in the context of this proposed rule, we understand and support EPA's focus on PFAS chemicals of concern. Thus, Auto Innovators reiterates our goal of wanting to provide as much support as possible for EPA's assessment activities, to work with the agency to identify appropriate and necessary data for collection, and to be part of a larger process, like a FACA group, that works to properly design a means for articles-based data collection going forward.

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<sup>24</sup> 86 FR at 33930.

<sup>25</sup> 42 FR at 53804-53806, October 3, 1977.

<sup>26</sup> 86 FR at 33926.

## **E. EPA Should Focus on PFAS Chemicals of Known Concern**

In this proposed rule, EPA suggests that thousands of unique chemicals in the broad and diverse category of PFAS all share the same level of risk and concern to humans and the environment. It is imperative that EPA acknowledge the very different physical, chemical, environmental, and biological properties in the broad use of the term PFAS. EPA should prioritize its data collection activities on the PFAS chemicals that are of high concern and exclude those that EPA has determined are of low concern. For example, EPA should consider excluding substances with low exposure potential, such as fluoropolymers.<sup>27</sup> A preliminary investigation appears to indicate that these types of chemicals would be those predominantly found in articles used in the automotive sector. These types of chemicals have high molecular weight, low levels of residual monomer and do not degrade easily under normal conditions of use. Other reporting categories where the potential for exposure is insignificant, such as R&D and low volume service chemicals, should be excluded from the final rule.

## **F. EPA's Estimates for Compliance**

We appreciate EPA's good faith efforts to determine the burden of the proposed collection of information, including the validity of the methodology and assumptions used. We are, however, concerned that the Agency's lack of operational experience to date with regulating industries that assemble products, such as automobiles, has led to a significant underestimation in:

- The feasibility of collecting the article-based data
- The costs associated with data collection efforts and reporting
- Agency resources required to implement new industry-wide compliance practices for the proposed requirements

EPA has traditionally not regulated product manufacturers, and never on the proposed scale of the thousands of substances included in the PFAS family. It is therefore understandable that the time and systems required to comply with the proposed rule, if even practical, are not fully recognized by EPA. An agency-led survey to collect and evaluate this information would be useful in better capturing the impact of the proposed regulations. For instance, a relatively simple component or subassembly of a complex durable good may require evaluation of and communication with dozens of suppliers and their sub-tiers down to the raw material provider level; possibly many times that for an electrical assembly. In such cases, it could take months or possibly even years to acquire data at the levels of minutiae that EPA proposes to require.

Our comments on the burden imposed by this proposed rule focus on the estimated burden for TSCA Section 8 requirements but are also applicable to all EPA TSCA rules under development that may impact the automotive sector. If EPA ultimately diverges from its long-standing practices related to articles and complex durable goods, EPA will need to work across all industry sectors to develop a more reliable estimate model to calculate burden.

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<sup>27</sup> Fluoropolymers are widely used in the economy and including these in the rule will bring in tens of thousands of additional reporting entities importing articles. EPA could significantly reduce the burden of the rule by exempting these from reporting under Section 8(a)(7) as it has from other TSCA rules. For example, the TSCA Chemical Data Reporting rule, 40 CFR Part 711, exempts all polymers from reporting. Similarly, EPA excluded PFAS compounds that are polymers in the initial and amended versions of its TSCA SNUR for long chain perfluoroalkyl carboxylates. As EPA has explained, "there is an exceedingly low probability that potential exposure to high molecular weight water-insoluble polymers, as a class, will result in unreasonable risk or injury to human health or the environment." 60 Fed. Reg. 16316, 16322 (Mar 29, 1995). While the Agency recognizes a specific class of fluoropolymers (defined by a specific structural feature) that may generate degradation products of interest, it could avoid unnecessary reporting by limiting the reportable scope to those materials.

EPA provides several estimates related to rule familiarization, data collection, etc., throughout the proposed rule and analysis. Based on our initial survey results and our association-based experience working with companies to understand EPA's TSCA-related rulemakings, we believe EPA has underestimated these compliance-based activities. Further, Auto Innovators and our member companies have been actively engaged with EPA's OCSPP staff for nearly ten years on TSCA-related rulemakings and have been working closely with OCSPP to provide information and data to the agency (albeit simplistic compared to this rulemaking). Auto Innovators believes the data provided below represents a best-case scenario for industries and companies that are familiar with TSCA requirements. Industries that have not previously been engaged on TSCA-related compliance or rulemakings, or do not have material data systems such as IMDS to leverage, would require additional resources well above our estimates. This data is important to understanding the process and the realities of collecting data on imported articles from the automotive sector. The expansive and all-inclusive scope of this proposed rule – from the number of chemicals to the broad inclusion of all importers of articles – make it one of the most resource-intensive data collections that EPA has issued.

### *1. Rule Familiarization: OEMs and Suppliers*

EPA assumes that each company subject to the rule will spend 0.82 hours becoming familiar with the requirements of the rule and developing an understanding of what actions are necessary to comply with the reporting requirements. This assumption includes reviewing the list of chemicals associated with the rule and is estimated as a one-time burden. EPA's cost estimate is \$68.79 per company, and that 234 companies comprise the potentially affected universe.

The Federal Register publication of the rule is 38 pages in length; the prepublication version was over 100 pages. Supporting documents include the "Draft Economic Analysis", "Examples of PFAS and Structural Diagrams", and data elements included in the proposed rule, which in total add an additional 200-plus pages that require review to fully understand the requirements of the proposed rule. At a minimum then, a company must review approximately 250 pages of regulatory text, technical scientific notation for chemicals, legal requirements, and reporting obligations. Our survey results indicate that a rule such as this is routinely reviewed by legal counsel, company managers, facility or plant managers, and technical staff. As would be expected, our survey indicated a range of resource spend at a low of 10 hours and a high of 80 hours. For OEMs, the average time was 30 hours for rule familiarization, and for suppliers, the average was higher, closer to the high-end estimate of 80 hours. Even using the lower end estimate of the time required for rule familiarization, it is more than 10 times greater than EPA's estimate, and again, these estimates are coming from companies well versed in reviewing and familiarizing themselves with TSCA-related rulemakings.

The assumptions behind EPA's low estimate fail to reflect the real costs of rule familiarization. It is inaccurate to assign rule familiarization costs only to those entities that will ultimately be subject to the rule. Realistically, every entity that manufactures (including imports), processes, or uses a PFAS chemical will need to review the rule to verify if they do or do not potentially have to report on PFAS in their products. It is not until after a review of the rule that any entity will be comfortable deciding about whether it will have to comment or comply.

### *2. Identifying Articles that Potentially Contain PFAS*

EPA estimates that each firm (company) will incur costs ranging from \$161 to \$1,932 to identify any articles they may import that contain PFAS. We believe that EPA's lack of familiarity with the process that would be used to accomplish this task has resulted in an unrealistically low estimate.

The process for identifying articles that may contain PFAS will be different for OEMs and suppliers. As a first step, OEMs will attempt to leverage data available in IMDS, which is only searchable if there is a defined CAS number and a *de minimis* level and which is also included in the list of substances required to be reported in IMDS. For the 500+ examples of PFAS chemicals with CAS numbers provided in the proposed rule,<sup>28</sup> only a small percentage are available in IMDS (approximately 27%). For the majority of the substances outlined in EPA's proposed rule, OEMs will be required to survey their Tier-1 supply base. Based on the Auto Innovators survey, OEMs estimated the average search time to be 54 hours. There is, however, uncertainty in this estimate, because trying to identify chemicals in articles in the absence of a CAS number and a *de minimis* level is not possible with the IMDS. This is further complicated since EPA also proposes to include reporting on byproducts, which are most certainly present in *de minimis* levels in products not tracked or captured by the IMDS. For suppliers, the task will be more resource- and time-intensive, based on the complex multi-tiered supply base that will need to be queried. Based on experience in working with multiple tiers of suppliers across a global market, an educated estimate would be 2,000 hours or more for suppliers to identify any articles they may import that may contain PFAS; use of any formulations as opposed to CAS numbers will further complicate this process and likely add to the estimated 2,000 hours, if even feasible.

### 3. Identifying Suppliers

EPA estimates that each firm (company) will incur costs of \$1185.26 to identify any suppliers they may need to contact to obtain information on any imported articles that may contain PFAS. The hours associated with identifying suppliers that will need to be contacted is dependent on the number of articles that have been identified by the importer. At a minimum, both OEMs and suppliers will need to identify the downstream suppliers that may or may not include PFAS in any of their processes and prepare a survey for their suppliers. For OEMs, survey results indicate it could take up to 120 hours to search production parts and service parts records, as well as purchasing records, in identifying the supplier. The number of articles each OEM will need to verify with suppliers will vary but could reach nearly 5,000. For suppliers, this task is even more complex, because suppliers will have to reach beyond direct suppliers. It is not possible currently to estimate the total hours per supplier.

### 4. Collecting Data from Suppliers

EPA estimates that each firm (company) will incur costs ranging from \$6 to \$664 to collect data from suppliers. In addition to the initial outreach to suppliers, OEMs will spend a significant amount of time following up on their data requests, including but not limited to, e-mails, conference calls for further explanation on the data request, and managing confidential data. For OEMs, estimates encompass a large range, from four hours per article to 4,800 hours for larger companies with multiple suppliers.

Tier 1 suppliers will then need to reach out to 2<sup>nd</sup>, 3<sup>rd</sup>, and lower tiers and material suppliers. For suppliers, it is not currently possible to estimate their burden hours. However, it would likely exceed that of an OEM.

EPA has not addressed the issue of trade secret information or confidentiality regarding collecting data from suppliers. It is quite likely that along the supply chain, there will be suppliers who will want to claim proprietary processes as trade secret and decline to share data that they deem to be confidential.

### 5. Reporting to CDX

EPA estimates that each firm (company) will incur costs of \$231 for all stages of reporting to CDX. While EPA has not been clear as to how article information will be reported (by article, class of product,

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<sup>28</sup> 86 FR at 33937- 33944 and at 33948-33950.

e.g., plastic, or chemical), Auto Innovators estimates that it will take approximately 0.5 hours for each submission to CDX. For companies that have never reported to CDX, this estimate may be higher, since the CDX system is not a particularly user-friendly system, and there is additional time associated with creating log in credentials, familiarization with a database or reporting tool, etc.

6. *EPA’s Wage Rate Estimates*

The wage rates that EPA has used throughout its economic assessment are averaged rates across the nation and across industry sectors. These wage rates are drastically inconsistent with current wage rates in the automotive sector and the seniority of staff required to review and verify all the components associated with reporting. For example, EPA has used a loaded wage rate of \$94.54 for corporate managers and \$80.50 for senior technical staff in the automotive sector. These numbers are twofold lower than actual industry standard billing rates. The estimate of \$107.46 per hour for regulatory attorneys is equally underestimated.

7. *Per Firm Burden Summary*

Table 1 summarizes the information provided above in terms of hours, cost, and burden from EPA’s proposed rule alongside results from Auto Innovators’ survey of our member companies. Auto Innovators’ survey results were generated using a best-case scenario, whereby we have existing knowledge of EPA’s TSCA rulemakings and access to a screening tool, such as IMDS. As outlined above, the use of IMDS will only be effective for a small percentage of substances outlined in the proposed rule, and therefore, Auto Innovators estimates that time and costs will be higher than those estimated.

**Table 1  
Comparative Data of Firm Burden from  
EPA Proposed Rule and Auto Innovators’ Blinded, and Aggregated Survey Results**

Compliance Activity	EPA		Automotive Industry*	
	Estimated Hours Per Firm	Estimated Cost per Firm	Estimated Hours per Company	Estimated Costs** per Company
Rule Familiarization	0.82	\$68.79	OEM & Supplier: 10-80	OEM: \$6,000 Supplier: \$16,000
Identifying Articles that Potentially Contain PFAS	None Provided	\$161.00- \$1,932.00	OEM: 54 Supplier: 2,000	OEM: \$10,800 Supplier: \$400,000
Identifying Suppliers	None Provided	\$1185.26	OEM: 120 Supplier: TBD	OEM: \$24,000
Collecting Data from Suppliers	None Provided	\$6.00 - \$664.00	OEM: 4,800 Supplier: TBD	\$960,000
Reporting to CDX	None Provided	\$231.00	0.5 hrs. per submission (could be as high as 5000 submissions)	\$100 per submission

\* Results aggregated and blinded based on survey of Auto Innovators OEM and supplier member companies.

\*\* Assumes an average wage rate of \$200.00 across all levels of the company.

**G. Timeframe for Reporting**

The proposed rule plans for a reporting period of six months following promulgation. A longer reporting period is more appropriate given the complexity involved in researching and collecting the required information going back more than 10 years. Auto Innovators recommends a minimum of a

one-year reporting period, beginning six months after publication of the final rule. This time would provide impacted parties with time for rule familiarization and necessary time to request, collect and report required information. It also provides EPA with additional time for education and awareness with the regulated parties.

Further, depending on EPA's decision-making on the scope, complexity, and exemptions for the rulemaking, it may also be appropriate for the agency to develop a tiered or phased approach to data collection, where, for example, importers of articles may have additional time for reporting compared to the bulk chemical manufacturers, EPA would defer certain levels of data collection until an initial set of data is collected and reviewed, the requirements for data reporting are streamlined or lessened for the older time periods compared to the newest, etc. A tiered or phased approach would assist in addressing burden, duplication, and ultimately tailoring the Agency's data needs with its intended use for that data.

#### **H. EPA's Ability to Collect and Manage the Volume of Submitted Data**

If EPA continues to require importers of articles to meet the requirements of this rule, at a minimum, it should reflect the true volume of reports that it will receive and reflect in its economic analysis, the costs to increase CDX capacity, and EPA staff hours required to review the reports. Both EPA and industry will need more time than the rule proposes to adequately prepare for compliance with the proposed reporting requirements.

This proposed rule's economic assessment demonstrates that EPA has not considered the volume of information that will be submitted to CDX if importers of articles are required to identify PFAS content and report to EPA. Unfortunately, this underestimation of volume and need for CDX capacity is a repeat of EPA's underestimation of the reports it would receive for the first TSCA Administration of Fees Rule. It suggests that a larger, more formal process to access and evaluate EPA's current reporting systems, expand users and data submitted, and determine EPA money to update and ensure capacity with CDX will all be needed.

For this proposed PFAS reporting rule, EPA estimates that 234 firms would be subject to the reporting requirements. In the list of potentially impacted NAICS codes identified in the proposed rule, EPA has included automobile manufacturers but has failed to identify the myriad of other downstream users, including those producing complex durable goods, that will also be pulled into the reporting. Reaching down through the supply chain will also have an impact on the accuracy of the data that EPA may receive. Lower tier articles are frequently passed back and forth between countries for manufacturing or assembling into bigger components; thus, multiple suppliers will be reporting the same information on the same article multiple times. EPA has also failed to recognize that manufacturers of appliances, toys, textiles, apparel, and aerospace, as well as many other consumer product manufacturers will be subject to the reporting requirements. In effect, the broad reach of this rule could require that all industries importing goods into the U.S. with any quantity of the 1,164+ PFAS substances, review and report, as needed.

## **I. Classification of the Rule as Significant**

The definition of a “significant” rule, found in E.O. 12866, is a rule that:

...is likely to (1) Have an annual effect on the economy of \$100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities; (2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) Raise novel legal or policy issues arising out of legal mandates, the President’s priorities, or the principles set forth in this Executive order.

If EPA updates its economic assessment and reports a realistic estimate of the number of firms that will be subject to this rule (after familiarization and development of knowledge to understand how or if such a firm is subject to the rule) and the burden of this rule on importers of articles, it will certainly meet criteria “(1)”, exceed the \$100 million threshold, and have a significant impact on the economy, as well as have an impact on states and local governments that will be required to report on articles that they import. The initial estimates for our industry – just one of the many impacted industries – for a best-case scenario is nearing \$1 million dollars per company alone, and we believe the time, costs, and compliance requirements with this proposed rule will exceed this estimate given the complexity and breadth of this rulemaking. At a time when the President is looking at ways to strengthen the supply chains of the U.S. economy, this rule undermines this focus in a significant manner.

Further, if a rule is designated as “economically significant,” EPA is required to perform a cost-benefit analysis and assess the costs and benefits of “reasonably feasible alternatives” to the planned rule. Under E.O. 12866, EPA must “propose or adopt a regulation only upon a reasoned determination that the “benefits” of the rule “justify its costs.”

If an accurate economic assessment is required of EPA, it is also likely that this rule would be determined a “major rule”. While similar to the criteria for an “economically significant” determination, a major rule would also require a determination that the benefit or utility of the information to be gathered outweighs the costs and burden of collecting the information. A major rule becomes subject to the Congressional Review Act (CRA), and requires that “major” rules (e.g., those that have a \$100 million effect on the economy) have a delayed effective date of at least 60 days, and that agencies must submit their rules to both houses of Congress and the Government Accountability Office (GAO) before the rules can take effect.

## **J. Closing Recommendations**

The scope of this proposed rule is unprecedented and will likely have far reaching, cross-cutting economic impacts on commerce and jobs. As proposed, this rule will require an unprecedented amount of industry resources to conduct due diligence, develop new systems to identify and report to EPA, and to generally ensure compliance with the reporting requirement. This effort will be required at the very time the Administration is focusing on a stronger, more robust vision for U.S. competitiveness and economy.

As demonstrated by Auto Innovators' survey, provided to OMB and included in these comments as well, which provides an initial estimate of time, cost, and burden under a best-case scenario, this proposed rule exceeds the goals of TSCA section 8(a)(5) to not require unnecessary or duplicative reporting and reduce cost of compliance. The time to collect information through the automotive supply chain based on the thousands of suppliers and components that will require evaluation for thousands of chemicals will take years and roughly 5,000 hours per company to complete. It would also create a complex and vast set of requirements with little to no benefit for the Agency or the environment.

Therefore, Auto Innovators offers the following recommendations:

- *Limit the Scope of Data Collection under the Reporting Requirements*

The NDAA-specified requirements reflect the types of data that EPA has traditionally collected under TSCA 8(a) from the manufacturers of bulk chemicals. EPA has not traditionally collected this type of data from importers of articles, because that data is often not available and is broader than necessary to assess any potential risks from imported articles. Inclusion of articles creates an unprecedented imposition of cost and burden, with little to no benefit for the initial screen that 8(a) data is intended to provide. The proposed rule lacks analysis or detail on how this inclusion would support the stated purpose of the rule to better understand potential routes of exposure to PFAS and potential human health and environmental impacts. The extensive list of PFAS chemicals identified by EPA merges together PFAS chemicals that have demonstrated some level of concern with other PFAS chemicals that have not been shown to be of concern. As EPA has itself recognized, chemicals bound up in articles are unlikely to contribute in any significant way to exposure, and in this case, EPA may be asking for information on chemicals in articles that have not been shown to be of any concern. Therefore, Auto Innovators continues to recommend that EPA exclude articles from the scope of this proposed rule.

- *Develop a Federal Advisory Committee Act (FACA) Process to Address the Complexity of Gathering Data on Articles*

To the extent EPA determines that articles-based reporting is an end goal, EPA should develop a process under FACA to appropriately scope resource needs, readily available data sources, development of a reporting system specific to articles, lead time, development time, costs to undertake this effort, and a dedicated education program. Further, a FACA-led group will have the advantage of pulling a diverse group of industries to provide expertise and precise information on how best to implement articles-based reporting.

- *Redefine "Reasonably Ascertainable" to Limit the Scope of Data Collection for Articles*

If EPA determines to include articles in its final rulemaking, the scope of data collection for articles should be limited to the information that is readily available in existing chemical databases. For the automotive sector, this existing chemical database would be the IMDS, where any PFAS identified by the Global Automotive Declarable Substances List (GADSL) with corresponding CAS numbers and present at levels above specified *de minimis* thresholds, can be tracked, collected, and reported, reflecting ongoing and legacy uses. This dataset, however, will not include PFAS without CAS numbers, byproducts or impurities, or *de minimis* presence of any listed PFAS, and separate investigative efforts would be required to designate domestic versus imported articles. While these data sources may have limitations, the automotive industry could provide EPA with relevant and readily obtainable information from the IMDS about the PFAS used in articles. To accomplish this, EPA would need to clearly articulate that a search of the IMDS system would meet the "reasonably

ascertainable” standard. As explained in detail in comments<sup>29</sup> submitted by our predecessor organizations, the Association of Global Automakers and the Alliance for Automobile Manufacturers, on the “Significant New Use Rule: Long-Chain Perfluoroalkyl Carboxylate (LCPFAC) and Perfluoroalkyl Sulfonate Chemical Substances (PFAS)” [80 FR 2885, January 21, 2015], to search the IMDS EPA would need to provide a CAS number and a *de minimis* threshold consistent with the GADSL listing for each PFAS chemical.

- *Additional Elements to Address in the Scope of the Rule*
  - Limit reporting requirements to PFAS chemicals of known concern
  - Define all reportable chemicals by CAS numbers
  - Set a *de minimis* threshold value or use the current CDR lower reporting threshold of 2,500 lbs.
  - Exempt byproducts and impurities
  - Exempt R&D chemicals
  - Ensure that EPA allows adequate time from the effective date of the rule to the data submission deadline to collect the information required – at least 18 months; consider a tiered or phased approach to data reporting as well
  - Develop a realistic estimate of costs and burden to be used for this and future TSCA rulemakings that may address articles

Thank you in advance for your consideration of these comments. Auto Innovators welcomes the opportunity to meet with EPA to discuss these comments. In addition, Auto Innovators reiterates our goal to work with EPA to find a feasible and appropriate pathway to address articles under TSCA, and we look forward to continuing working together toward this goal.

Sincerely,



Julia M. Rege  
Vice President, Energy & Environment  
(202) 326-5559  
jrege@autosinnovate.org

CC: Stephanie Griffin, EPA Office of Pollution Prevention and Toxics  
Sharon Block, Office of Information and Regulatory Affairs

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<sup>29</sup> EPA-HQ-OPPT-2013-0225-0044, February 20, 2015. Found at: <https://www.regulations.gov/comment/EPA-HQ-OPPT-2013-0225-0044>.

EPA-HQ-OPPT-2013-0225-0078, June 30, 2015. Found at: <https://www.regulations.gov/comment/EPA-HQ-OPPT-2013-0225-0078>.