July 28, 2021

Submitted via OIRA_Submissions@omb.eop.gov

Sharon Block
Acting Administrator
Office of Information and Regulatory Affairs
Office of Management and Budget
262 Old Executive Office Building
Washington, DC 20503

Re: ICR Reference No: 202106-2070-002, 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 Ms. Block:

The Alliance for Automotive Innovation[1] (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 Polyfluoralkyl Substances"[2] (hereafter, "the proposed rule"). Two comment deadlines were included in this proposal: July 28, 2021, for comments to the Office of Management and Budget, and August 27, 2021, for comments to EPA. Auto Innovators is submitting these comments to OMB today, focused on the Information Collect Request (ICR) estimates developed by EPA, as required by the Paperwork Reduction Act. Auto Innovators supports the comments submitted by the ad-hoc Downstream Users Coalition as well, and we will be submitting comments to EPA on the entirety of the proposal by the August deadline.

Auto Innovators represents the auto manufacturing sector, including automakers that produce and sell about 99% of the new light-duty vehicles in the U.S. The auto industry plays an important and critical role to our nation's economy, accounting for 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 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 supports EPA's continuing implementation of the Lautenberg Chemical Safety Act and its goals of protecting the environment and human health. 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

[1] 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.
[2] 86 FR 33926, June 28, 2021. https://www.regulations.gov/docket/EPA-HQ-OPPT-2020-0549.

experience to date with regulating industries that assemble products, such as automobiles, has led to a significant underestimation in:

- The feasibility to collect the article-based data;
- The costs associated with data collection efforts and reporting; and
- 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 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, for example. In such cases, it could take months or possibly even years to acquire data at the levels of minutiae that EPA proposes to require. Further, EPA appears to suggest 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.

Our comments on this proposed rule and ICR focus on the estimated burden for TSCA Section 8 requirements but are also applicable to EPA TSCA rules under development. 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.

Our comments cover the following:

A. Application of TSCA Section 8 to Imported Articles
B. Burden of Collecting Data
C. EPA's Estimates for Compliance
D. Benefit or Utility of the Information to be Gathered
E. Timeframe
F. EPA's Ability to Collect and Manage the Volume of Submitted Data
G. Classification of the Rule as "Significant"

A. 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, requiring importers of articles to identify the presence of a chemical or chemicals in the tens of thousands of articles that move through the auto industry's 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.[3]

EPA's No Action Assurance Letter acknowledges the challenges and extreme 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.

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

EPA has routinely chosen to exempt 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.**[4] [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.

[3] 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.
[4] 48 FR 21726, May 13, 1983.

- In EPA's December 23, 1977, Federal Register notice[5] finalizing the Inventory Reporting Requirements, the agency discussed its position on the need to evaluate and collect data regarding 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….[6]

- In an earlier Federal Register notice,[7] EPA also explained its rationale for this exemption:

> As was discussed in the preamble to these reproposed 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.**[8] [emphasis added] (1977 dollars)

- EPA's Inventory Update Reporting Rule[9] exempts articles:

> § 710.50 Activities for which reporting is not required.[10]
> 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.

[5] 42 FR 64572, December 23, 1977.
[6] 42 FR at 64587.
[7] 42 FR 53804, October 3, 1977.
[8] 42 FR at 53805.
[9] 76 FR 54933, Sept. 6, 2011.
[10] 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.

2. Synopsis of EPA's Rationale for Exempting Articles

As reflected in EPA's policy of articles exemptions, including but not limited to the exemptions provided for under TSCA Section 5(d) and Section 8, requiring importers of articles to reach down through a complex, multi-tiered, and global supply chain to collect data on *de minimis* quantities of a chemical that may or may not be embedded in an article imposes a notable burden with very little benefit.

To review EPA's own rationale for exemptions:

- "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."[11]

- "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."[12]

The rationale behind EPA's historical treatment of articles has not changed. In fact, 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, both for resources required by industry and EPA. Since 1983, when EPA issued this policy statement, the global supply chain has become even more complex. For the automotive industry specifically, a vehicle contains thousands of complex components, with multiple subcomponents (~30,000 at the lowest component level), across a global supply chain, which encompasses thousands of tiered suppliers. The automotive Original Equipment Manufacturers (OEMs) is seven to ten level removed from the raw material supplier.

EPA has also acknowledged that the risk associated with a substance embedded in an article was significantly less than a chemical substance or mixture imported in bulk. That statement remains legitimate. With advances in technology, an ongoing focus on substituting out many problematic chemicals, and the majority of chemicals bound into the structure of an article, articles continue to reduce their environmental impact. Due to these two fundamental and compelling realities, 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 is in keeping with EPA's own thinking: "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."[13]

Exempting articles from TSCA Section 8 in no way precludes EPA from any necessary risk management of an article, as appropriately noted by EPA as follows:

[11] 48 FR at 21726 (48 FR 21513, May 13, 1983).
[12] 42 FR at 53805.
[13] 48 FR at 21726.

> 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.[14]

Further, we recognize that this rule is being developed in response to language in the 2020 National Defense Authorization Act (NDAA), which requires EPA to issue a final rule no later than January 2023. This statutorily mandated language, however, focuses on the manufacture of the chemical substance: "requiring each person who has manufactured a chemical substance that is a perfluoroalkyl or polyfluoroalkyl substance."[15] It does not require EPA to deviate from its previous policies of considering the impact, cost, and burden associated with removing the long-standing treatment associated with articles, small businesses, byproducts, reaction wastes, etc. The inclusion of all these previously exempted categories adds substantially to the ICR burden, which EPA's current burden estimates neglect to reflect. Consequently, EPA's ICR estimates grossly underestimate the impact of this proposed rule.

B. 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)"[16] 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;[17] this recommendation was in the context of a limited number of chemicals and a single industry. To date, EPA has not acted on that recommendation, and the burden hours and costs reflected in this current economic assessment continue to significantly underestimate the costs associated with rule familiarization, article identification, outreach to suppliers, data collection, Central Data Exchange (CDX) access, and reporting.

In the absence of an EPA survey or a more formal federal process to evaluate the true 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. Given the short amount of time provided by the 30-day comment period for OMB, our survey was designed to collect the basic of 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.

This data is important to understand the process and the realities of collecting data on imported articles from our industry alone. The expansive and all-inclusive scope of this 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.

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[14] 42 FR at 53805.
[15] SEC. 7351. PFAS DATA CALL. https://www.congress.gov/bill/116th-congress/senate-bill/1790/text.
[16] 86 FR 14904, March 19, 2021.
[17] Comment submitted by Alliance for Automotive Innovation, EPA-HQ-OPPT-2020-0616-0007, https://www.regulations.gov/comment/EPA-HQ-OPPT-2020-0616-0007.

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 an estimate of over 3,500 PFAS chemicals that may or may not be present in small or *de minimis* quantities in all the imported articles. EPA has also expanded the scope of 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, research and development (R&D) chemicals, and reaction products be reported.

In the auto industry alone, vehicles are composed of tens of thousands of components, and there are millions of replacement parts in commerce used to maintain and repair in-service vehicles. In addition, parts domestically manufactured in the U.S. result in importation as well, 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. 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.

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 $100,000.00 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. In fact, EPA's estimates of reports to be received is 1,369 reports, a number that we expect falls far short of what would be required by this rule.

OEMs have invested billions of dollars to develop, maintain, and optimize the International Material Data System (IMDS). 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, 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. The rest have been identified only by Low Volume Exemption (LVE) notation or a structural definition of PFAS.

Further, IMDS has over 13,000 basic substances on the automotive basic substance list, but only a small percentage (about 27%) of the PFAS chemicals that have a delineated CAS numbers are available in IMDS. In addition, IMDS utilizes a default *de minimis* 0.1% reporting threshold, unless otherwise specified. For instance, for PFOA, the IMDS *de minimis* threshold was set at 25 ppb based on restrictions under the European Union's Persistent Organic Pollutants regulations. 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 ruling. 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 and without CAS numbers, simply identifying a PFAS chemical not currently included in the automotive basic substance list could take years to acquire, based on the 15+ years that the OEMs have experience in tracking similar data.

We urge OMB to discuss these issues with EPA and determine why they have not included CAS numbers for all chemicals to be addressed; why it has not included a *de minimis* level below which reporting is not required; why EPA presumes that all individual PFAS chemicals all present the same concerns of risk, and why it has included byproducts. Before EPA moves forward with this rule, we ask that OMB be sure that EPA has the infrastructure in place to collect, process and analyze the real number of reports that this rule will generate to CDX. If EPA is required to develop an accurate economic assessment of the costs imposed by this rule, then EPA needs to fully assess the impact of including new categories previously not included, the resources needed to ensure informative and quality data is submitted by parties that have not previously submitted data, and the extremely high level of resources required to develop a whole new reporting requirement for thousands of chemicals at one time. As our data below shows, the costs will certainly outweigh the benefits and will move this rule into an "economically significant" rulemaking that would be classified as "major" and subject to Congressional review.

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. The global supply chain for the automotive sector has a very complex structure, often up to six or more tiers. For the reasons outlined above, IMDS will not be an effective tool to meet the reporting requirements outlined 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 at least nine months to 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.

C. EPA's Estimates for Compliance

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 Office of Chemical Safety and Pollution Prevention (OCSPP) 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.

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 $161.00 to $1,932.00 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 that is also included in the list of substances required to be reported in IMDS. For the 500+ PFAS chemicals with CAS numbers, only a small percentage are available in IMDS (approximately 27%). For the majority of the substances outlined in EPA's proposed ruling, OEMs will be required to survey their Tier-1 supply base, which is not only time consuming but also extremely complex. 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. 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 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 $6.00 to $664.00 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, additional e-mails, conference calls for further explanation on the data request, and how to manage 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 2nd, 3rd, and lower tiers and material suppliers. For suppliers, it is not currently possible to estimate their burden hours. However, it is clear that it would likely exceed that of an OEM.

5. Reporting to CDX

EPA estimates that each firm (company) will incur costs of $231.00 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, 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 number 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 estimated.

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

	EPA		**Auto Industry***	
Compliance Activity	**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.

D. Benefits of Data Collection on Articles

EPA's rule fails to articulate any benefit from the collection of article-based data for PFAS. As cited earlier in these comments, and as EPA itself has recognized, "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."[18] If, as stated in the 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," then collection of data on the *de minimis* quantities of PFAS in articles 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 a component or article used in an automobile is minute 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.

E. 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, and suggests that a larger, more formal process to access and evaluate EPA's current reporting systems, expansion of users and data submitted, and EPA money needed to update and ensure capacity with CDX.

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 by EPA, 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. EPA has failed to recognize that manufacturers of appliances, toys, textiles, apparel, and aerospace industries, 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 any of 3,500 or more PFAS substances, review, and report, as needed.

F. Classification of the Rule as Significant

The definition of a "significant" rule, found in E.O. 12866, is a rule:

[18] 42 FR 53804 -53806, October 3, 1977.

> …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 is required to do a thorough and 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) and exceed the $100 million threshold and have a significant impact on a 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.

G. Closing Recommendations

The scope of this proposed rule is unprecedented and will likely have far reaching, cross-cutting economic impacts on commerce and jobs and will surely disrupt a complex supply chain that is already struggling to recover after the COVID pandemic. 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.

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.[19]

As demonstrated by Auto Innovators' survey, 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). The time to survey 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:

1) *Remove Articles from Reporting Requirements.*

   The NDAA-specified requirements may be appropriate for bulk chemicals but do not reflect the type of information that is available or useful for articles. Inclusion of articles creates an unprecedented imposition of cost and burden, with little benefit. EPA also lacks analysis and 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. EPA has not even made an initial effort to screen the PFAS universe it is proposing to identify PFAS chemicals of concern from those with little to no concern. As EPA has itself recognized, chemicals bound up in articles are unlikely to contribute in any significant way to exposure.

2) *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, 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.

3) *Limit the Scope of the Rule.*

   If EPA decides to include articles, narrow the scope:

   - Define all applicable CAS numbers;
   - Set a *de minimis* threshold value;
   - Exclude byproducts;
   - Set only a prospective date for articles-based reporting;
   - Ensure that EPA allows adequate time from the effective date of the rule to the data submission deadline to collect the information required; and
   - Require that EPA develop a realistic estimate of costs and burden to be used for this and future TSCA rulemakings that may address articles.

[19] 86 FR 33926, June 28, 2021.

Thank you in advance for your consideration of these comments. Auto Innovators welcomes the opportunity to meet with OIRA, OMB, and 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,

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