December 27, 2022

Ms. Stephanie Griffin
Data Gathering and Analysis Division (7401M)
Office of Pollution Prevention and Toxics
Environmental Protection Agency
1200 Pennsylvania Ave NW
Washington, DC 20460-0001

Re: Docket ID No: EPA-HQ-OPPT-2020-0549; 87 Fed. Reg. 72,439 (Nov. 25, 2022)

Dear Ms. Griffin:

The Alliance for Automotive Innovation[1] (Auto Innovators) appreciates the opportunity to provide comments on the Environmental Protection Agency's (EPA) "TSCA Section 8(a)(7) Reporting and Recordkeeping Requirements for Perfluoroalkyl and Polyfluoroalkyl Substances; Notice of Data Availability and Request for Comment regarding the Initial Regulatory Flexibility Analysis (IRFA) and Updated Economic Analysis."[2] Auto Innovators represents the auto manufacturing sector, including automakers that produce and sell nearly 98% of the new light-duty vehicles in the United States. These comments reflect the very real challenges that EPA's proposal presents to almost the entire U.S. auto manufacturing sector.

EPA's 2021 TSCA Section 8(a)(7) Reporting and Recordkeeping Requirements for Perfluoroalkyl and Polyfluoroalkyl Substances proposed rule[3] would require all manufacturers of a chemical substance or a mixture containing a chemical substance that is a PFAS (including article manufacturers and importers) in any year since 2011 to report certain information to EPA related to chemical identity, categories of use, volumes manufactured and processed, byproducts, environmental and health effects, worker exposure, and disposal (i.e., the TSCA section 8(a)(2) requirements). EPA also proposed a five-year retention period for all relevant records following the submission period.

Auto Innovators submitted comments to EPA on the proposed TSCA Section 8(a)(7) rule on September 27, 2021, and, as requested, submitted comments on the Information Collection Request (ICR) to the Office of Management and Budget (OMB) on July 28, 2021. We incorporate those comments here by reference.

In our comments to both EPA and OMB, Auto Innovators challenged the assumptions about the hours and associated costs that EPA estimated would be needed to comply with the regulation if finalized as

[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] 87 Fed. Reg. 72,439 (Nov. 25, 2022).
[3] 86 Fed. Reg. 33,926 (Jun. 29, 2021).

proposed. At that time, we questioned EPA's classification of the proposed rule as not meeting the threshold of a "significant" rule.[4]

In this more recent document, we are pleased to see that EPA has updated its economic analyses and has included estimated compliance costs associated with reporting on articles, a component missing from the original economic analyses despite EPA's assertion that articles were to be included in the reporting requirements. We also appreciate EPA's efforts to update hours and costs related to all other components of the analyses. However, we believe that while EPA has made a good faith effort to update the costs to industry and EPA of complying with the proposed TSCA Section 8(a)(7) rule, the revised numbers continue to fall short of actual costs.

Our comments below on this new Notice of Data Availability and Request for Comment focus on:

- EPA's Reassessment of Compliance Costs
- EPA's Rationale for Reversing Exemptions Routinely Associated with TSCA Section 8(a) Rules
- EPA's Consideration of Burden-Reducing Options
- EPA's Interpretation of the Requirements of the National Defense Authorization Act
- EPA's Ability to Collect and Manage the Volume of Submitted Data

## A. EPA's Reassessment of Compliance Costs

EPA updated its estimate of costs for the proposed rule from approximately $10.8 million to $876 million in industry costs, as well as from $948,078 to $1.6 million in agency costs. EPA estimates that importers of articles will incur costs of $865,598,945 for 11,789,809 burden hours.[5] Requiring article importers to report would constitute approximately 99% of the burden potentially imposed by this rule.

Auto Innovators believes that even with this high percentage, EPA continues to significantly underestimate the reporting burden that importers of articles will incur. EPA has applied a base assumption throughout its calculation of burden hours and costs that article importers will file an average of five reports each—implying that each importer files one record for each of five articles.[6] It is not clear in the revised economic analysis how EPA arrived at this assumption. Article importers will have to research many articles to determine whether or not each article contains PFAS; for articles not containing PFAS, no report will be filed, even though effort to research the article was already expended. As we explained in our September 27, 2021, comments on the proposed rule, in the auto industry alone, vehicles contain tens of thousands of individual parts; there are millions of replacement parts in commerce used to maintain and repair in-service vehicles; and equipment for our U.S.-based manufacturing facilities is often imported. Align this number of articles, a majority of which are imported, with the approximately 3,500 PFAS chemicals to be reported, and the industry may need to submit thousands of reports. And this is just the automotive sector. EPA will need to consider that a

[4] The definition of a "significant" rule, found in E.O. 12866, is a rule that may, among other things, "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[.]" 58 Fed. Reg. 51,735, 51,738 (Oct. 4, 1993).

[5] Initial Regulatory Flexibility Analysis and Updated Economic Analysis for TSCA Section 8(a)(7) Reporting and Recordkeeping Requirements for Perfluoroalkyl and Polyfluoroalkyl Substances, *available at* https://www.epa.gov/system/files/documents/2022-11/2070-AK67_TSCA%208a7%20IRFA_11-25-22%20clean.pdf (hereinafter IRFA & UEA).

[6] *Id.*

similar volume of reports may be required from other complex durable goods manufacturers,[7] and separately from manufacturers of other goods as well.

Some specific examples of ways in which costs continue to be underestimated include:

- EPA assumes that importers of articles will spend 6.4 hours of technical labor and 2.85 hours of managerial labor to familiarize themselves with the rule enough to perform a compliance determination. EPA fails to account for review by an attorney(s) even though the Small Business Advisory Panel (SBAP) informed EPA that companies will require a legal review,[8] and Auto Innovators previously submitted comments that also made note of this necessity.

- EPA assumes an average of five reports per firm, resulting in estimated burdens of 8.75 hours of clerical labor, 22.5 hours of technical labor, and 5.0 hours of managerial labor per firm. As stated earlier, the estimate of an average of five reports is a significant underestimate, especially for manufacturers of complex durable goods.

- EPA estimates an average of 2.15 hours of technical burden and 0.54 hours of managerial burden per firm for reporting production volume. EPA anticipates that only the subset of importers who know the concentration of PFAS in their imported articles will be able to report production volume information. These estimates therefore reflect EPA's assumption that only 5% of importers will submit production volume information. It is not clear how EPA derived this 5% estimate. Is EPA assuming that importers of articles will not have access to this information, or is EPA assuming a low compliance rate? In addition to the undercount of reports that will be submitted, we believe this 5% assumption is incorrect and needs to be further assessed.

- EPA acknowledges that firms need to familiarize themselves with the structural definition of PFAS. EPA assumes that manufacturing and importing firms and large article importers will have staff with the technical knowledge to understand a structural definition more easily. Therefore, manufacturing firms and large article importers are assumed to spend 4 hours of technical labor on familiarization with the structural definition of PFAS. Small article importers are assumed to spend seven hours on familiarization with the structural definition of PFAS. EPA also assumes 10% of these small article importer firms will rely on consultant attorneys for help understanding the structural definition. The remaining 90% of firms are assumed to rely on in-house technical staff. EPA provides no data to support its assumption that 90% of reporting companies will have the in-house technical expertise to understand and apply the PFAS structural definition to all their articles and components. Given that EPA itself has estimated that the structural definition could include over 3,5000 individual chemicals,[9] the estimates of familiarization hours are unrealistically low. In fact, many manufacturers of complex durable goods will need to reach out and rely on input from a multi-tiered supply chain. EPA's estimate of four hours for large firms and seven hours for small firms is a significant underestimate of the time it takes to reach into an international multi-tiered supply chain.[10]

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[7] *See* Comments from the Ad Hoc Downstream Users Coalition on PFAS (Sept. 27, 2021), Docket ID No. EPA-HQ-OPPT-2020-0549-0114.
[8] EPA identified and quantified attorney/professional costs only for assistance in understanding the structural definition of PFAS in the rule but seeks comment on whether professional skills would be needed for other aspects of the regulation, including compliance determination, form completion, CBI claim substantiation, and recordkeeping. IRFA & UEA, *supra* note 5.
[9] 86 Fed. Reg, at 33,929.
[10] *See* Comments from Alliance for Automotive Innovation (Sept. 27, 2021), Docket ID No. EPA-HQ-OPPT-2020-0549-0068.

- According to the economic analysis, submitters will spend 4.38 hours on each substantiation type reviewing the information, preparing the response, and submitting the response to EPA (assumed to be 0.36 clerical hours, 2.49 technical hours, and 1.53 managerial hours). EPA assumes that assertion is accomplished via checking a box when completing the form, so the burden is included in the form completion estimate. Again, EPA's assumption of five reports per firm makes this estimate unrealistically low. This estimate fails to account for the vast number of chemicals covered by this rule that will need substantiation, and for the legal review that will be necessary prior to submission.

As a result of EPA's underestimate of the costs associated with requiring reporting from importers of articles, EPA cannot certify the burden values in its Information Collection Request to OMB. In earlier comments, Auto Innovators recommended that EPA survey article importers to get a more realistic estimate of hours and costs.[11] We provided information based on an informal survey of our members that indicated that upwards of 5,000 reports from our industry alone may be triggered by the proposed reporting requirements. Additionally, we believe that if EPA updates its economic assessment and utilizes a realistic estimate of the number of reports and the number of firms that will be subject to this rule to calculate the burden of this rule on importers of articles, it will certainly exceed $100 million 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,[12] and we believe the time, costs, and compliance requirements of this proposed rule will exceed this estimate given the complexity and breadth of the 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 goal in a significant manner. The costs of gathering the proposed information will place an unprecedented burden on U.S. manufacturers that will further hinder their ability to meet consumer needs.

Further, under E.O. 12866, 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.[13] EPA must "propose or adopt a regulation only upon a reasoned determination that the "benefits" of the rule "justify its costs."[14] Also, an accurate economic assessment addressing all of these issues would likely lead to a determination that this is a "major rule" under the Congressional Review Act (CRA)—one that is likely to result in "an annual effect on the economy of $100,000,000 or more," or "a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions."[15] While similar to the criteria for a "significant" designation, 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. Major rules under the CRA have a delayed effective date of at least 60 days, and agencies must submit their rules to both houses of Congress and the Government Accountability Office (GAO) before the rules can take effect.

If EPA accurately accounts for the costs associated with requiring importers of articles to collect and report information on the small amounts, even *de minimis* amounts, of PFAS in articles, it would be obvious that the costs outweigh any meaningful benefit.

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[11] *Id.*
[12] *Id.*
[13] 58 Fed. Reg. at 51,741.
[14] *Id.* at 51,736.
[15] 5 U.S.C. § 804(2).

## B. EPA's Rationale for Reversing Exemptions Routinely Associated with TSCA Section 8(a) Rules

EPA has not provided any compelling rationale for reversing the exemptions traditionally applied to TSCA Section 8(a) reporting. These include exemptions for imported articles, certain byproducts, non-isolated intermediates, small quantities of R&D chemicals, and a minimum production volume reporting threshold of 25,000 lbs./year.

1. *Article Exemption*

For the reasons appropriately cited by EPA in its No Action Assurance memorandum on the TSCA fees rule,[16] 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.

> [T]he 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.[17]

EPA's No Action Assurance memorandum 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 memorandum 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 overwhelming cost.

EPA routinely exempts articles because their inclusion in information-gathering rules outweighs 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 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 since then. Examples from previous EPA decisions include:

- Information Gathering Rules (TSCA Section 8) from 40 C.F.R. § 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*

[16] 83 Fed. Reg. 52,694 (Oct. 17, 2018).
[17] Memorandum from Susan Parker Bodine, Assistant Administrator for Enforcement and Compliance Assurance, to Alexandra Dapolito Dunn, Assistant Administrator, Office of Chemical Safety and Pollution Prevention, March 24, 2020, "No Action Assurance Regarding Self-Identification Requirement for Certain 'Manufacturers' Subject to the TSCA Fees Rule," *available at* https://www.epa.gov/sites/default/files/2020-03/documents/no_action_assurance_regarding_self-identification_requirement_for_certain_manufacturers_subject_to_the_tsca_fees_rule_march_24_2020.pdf.pdf .

> *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.*

While we recognize that this exemption language does provide EPA with the opportunity to void any of these exemptions, EPA has never exercised such authority under Section 8 regarding 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.

- In EPA's December 23, 1977 Federal Register notice finalizing the Inventory Reporting Requirements,[18] the agency discussed its position on the need to evaluate and collect data regarding articles:

> *Articles as 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.*[19]

- In an earlier Federal Register notice,[20] 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 imported in an article may be less than the risk posed by a chemical substance imported in bulk or in a mixture.***[21] *[emphasis added] [1977 dollars]*

In the benefits section of the Initial Regulatory Flexibility Analysis and Updated Economic Analysis, EPA clearly states that "[t]he proposed rule is an information-collecting rule and does not attempt to reduce risks related to PFAS."[22] The benefits of this rule appear to be limited to collecting information on PFAS that may be currently unavailable. However, EPA provides no clarity as to why the information will be beneficial and how it will be used to identify or reduce any potential risks associated with PFAS chemicals.

[18] 42 Fed. Reg. 64,572 (Dec. 23, 1977).
[19] 42 Fed. Reg. at 64,587.
[20] 42 Fed. Reg. 53,804 (Oct. 3, 1977).
[21] 42 FR at 53,805.
[22] IRFA & UEA, *supra* note 5.

In particular with respect to imported articles, Auto Innovators questions how the data required by this proposed TSCA Section 8(a)(7) rule will further inform or benefit EPA's understanding of PFAS chemicals, in light of the following:

- Importers of articles will not have access to any occupational exposure information related to the manufacture of the article.
- As stated by EPA in the Initial Regulatory Flexibility Analysis and Updated Economic Analysis, most importers of articles will not have access to or submit production volume information.
- Importers of articles will rarely have access to or will submit health and safety data.
- Manufacturers of vehicles will have little or no occupational exposure data to submit given that any PFAS chemical will likely be in the *de minimis* range and will be bound up in the article itself.
- Importers of articles will not have data regarding where, when, or how the article may be treated at end of life.

While EPA states that the benefit of the proposed rule is that it "will increase EPA's knowledge by providing the agency with significant exposure-related data on PFAS,"[23] we believe that this is simply not the case for imported articles, and EPA should apply the article exemption to any final rule.

*2. Exemptions for Impurities and Byproducts*

Companies that manufacture and import chemicals solely as impurities or byproducts face the same challenges as importers of articles. The effort needed to ascertain enough information on impurities and byproducts to report under the proposed TSCA Section 8(a)(7) rule greatly outweighs any value that may be derived. As recognized by the No Action Assurance memorandum on the TSCA fees rule as discussed above, many companies do not have supply systems set up to monitor impurity and byproduct levels in their products. Chemicals in these two categories are generally exempt from other regulatory schemes. For example, impurities and byproducts are exempt from PMN reporting.[24] In addition, a byproduct that is not used for a commercial purpose after it is manufactured was not required to be listed on the TSCA Inventory.[25]

Requiring companies to gather information on impurities or byproducts for each year since January 1, 2011, would take substantial resources and a significant amount of time on the part of manufacturers and importers. A good example of this is formaldehyde, a high-priority substance. Formaldehyde is a byproduct of combustion. Without an exemption for such byproducts, every entity in the United States that combusts fuel (such as a company that owns a power plant, manufacturing facility with flares, truck fleet, and building heated by natural gas or oil) would be required to self-identify as a manufacturer of formaldehyde. In addition to the overwhelming burden this would place on manufacturers and importers, the time and cost to EPA to process thousands of additional self-identification responses would overwhelm EPA's staff and needlessly increase implementation costs.

*3. Research and Development Exemption*

Members of Auto Innovators are committed to continuous improvement in their processes and the use of the safest and most effective materials in their products. In order to support a commitment to innovation, our members support state of the art research and development (R&D) programs to

[23] *Id.*
[24] 40 C.F.R. § 720.30(h).
[25] 40 C.F.R. § 710.4(d)(2).

identify opportunities to use green chemistry options where possible and to replace or reduce chemicals of potential concern in our applications. We request that EPA include an R&D exemption in the TSCA Section 8(a)(7) rule that would relieve R&D programs from reporting. Similar to EPA's TSCA Section 5 R&D exemption,[26] the exemption could be narrowly crafted to ensure that activities are limited to "the analysis of the chemical or physical characteristics, the performance, or the production characteristics of a chemical substance, a mixture containing the substance, or an article."[27] An exemption from the reporting requirements would allow our R&D programs to continue their essential work without the time and financial burden imposed by regulation. Such an exemption should focus on small quantities solely for the purposes of scientific experimentation or analysis, or chemical research for the development of a product.

*4. Provide a* De Minimis *Level for Mixtures*

In addition to the traditional TSCA Section 8 exemptions, we request that, consistent with other federal and international regulatory agencies, EPA establish a default *de minimis* level for PFAS in mixtures,[28] below which reporting would be inapplicable. EPA has itself recognized the practicality of a *de minimis* threshold. Most recently, in the EPA's "Long-Chain Perfluoroalkyl Carboxylate and Perfluoroalkyl Sulfonate Chemical Substances; Significant New Use Rule; Supplemental Proposal," EPA put forward sound arguments for establishing a *de minimis* threshold:

> Establishment of a threshold could be based on one or more of the following rationales: (1) below the selected threshold level, there is no "reasonable potential for exposure" within the meaning of § 5(a)(5) (i.e., the risk of exposure is very low); and (2) below the selected threshold level, there is a "reasonable potential for exposure" (or, alternatively, there may be such a potential), but the potential does not "justif[y] notification" (i.e., potential for risk is very low in light of the low level of LCPFAC present in the surface coating).[29]

We support the above rationale for establishing a *de minimis* reporting level and believe it is appropriate for this proposed information gathering rule. It is an approach consistent with other EPA reporting requirements, as well as other federal and international chemical regulatory schemes.

As another example, in the European Union's Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) regulation, "notification" or reporting of chemicals contained in articles has a *de minimis* threshold of 0.1% in product. The EU producers or importers of articles must notify only if their articles contain a substance on their Candidate List and only if the substance is present in those articles in quantities totaling over one ton per producer or importer per year and if the substance is present in those articles above a concentration of 0.1%. This system has proven to be effective in allowing the European Union to focus on chemical manufacturing and use scenarios where the volume of the chemical is significant enough to pose a concern for exposure.

When EPA proposes to regulate articles or mixtures, many automakers use the industry's existing International Material Data System (IMDS) as a first screen to identify potential uses of chemical substances. The IMDS has been adopted as the global standard for reporting material content

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[26] 40 C.F.R. §§ 720.36, 721.47.
[27] *Research and Development Exemption for New Chemical Review Under TSCA,* U.S ENVIRONMENTAL PROTECTION AGENCY, https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/research-and-development-exemption.
[28] Our focus here is on mixtures and the assumption that imported articles would be exempted.
[29] 85 Fed. Reg. 12479, 12482 (Mar. 3, 2020).

throughout the automotive supply chain and for identifying which chemicals of concern to human health and the environment are present in finished materials and components. The automotive industry, throughout its supply chain, has made significant investments in this data system to track compliance with global regulations impacting our products. The default threshold for reporting for this system is 0.1% by weight, a threshold almost universally adopted by international regulatory bodies, including the European Chemicals Agency under REACH, and many states within the United States. The IMDS now has over 15 years of data compiled relying on a *de minimis* level of 0.1%.[30] The presence of any chemical below this threshold is not required to be reported in IMDS. As a result, levels of chemical below a threshold of 0.1% do not appear in IMDS or elsewhere in other global chemical management systems.

### C. EPA's Consideration of Burden-Reducing Options

EPA's Initial Regulatory Flexibility Analysis and Updated Economic Analysis presents several reporting alternatives that would significantly reduce the burden on industry while having little to no detrimental impact on the benefits that EPA hopes to accrue. When analyzing the regulatory flexibility alternatives, EPA is required to consider the factors under TSCA Section 8(a)(5), which require EPA, to the extent feasible, to: (A) not require reporting which is unnecessary or duplicative; (B) minimize the cost of compliance on small manufacturers; and (C) apply any reporting obligations on those persons likely to have information relevant to the effective implementation of TSCA.

Section 609(b) of the Regulatory Flexibility Act, as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA), required EPA to conduct outreach to small entities and convene a SBAP, which it did on April 20, 2022. As a result of that engagement, EPA's Initial Regulatory Flexibility Analysis and Updated Economic Analysis put forward several regulatory flexibility alternatives for the proposed TSCA Section 8(a)(7) rule. Those include: 1) an exemption for article importers with less than $6 million in sales; 2) removing the structural definition of PFAS; 3) a threshold exemption of either 2,500 lbs. per year or 25,000 lbs. per year; and 4) a simplified reporting form for R&D substances manufactured in volumes of less than 10 kg per year. Auto Innovators supports these options and urges EPA to adopt them in its final rulemaking on this topic.

1. *Exemption for article importers with less than $6 million in sales.*

While EPA has presented an option to exempt article importers with less than $6 million in sales, recommendations from the SBAP are applicable for all impacted entities. We believe that EPA should consider an exemption for all article importers. For the reasons presented in section B above, requiring reporting for article importers will provide minimal benefit to EPA, states, or the public. Multiple small entity representatives (SERs) recommended including reporting exemptions for imported articles. Limiting this exemption to importers with less than $6 million in sales would exempt 87% of the affected article importers. EPA provides no justification as to why reporting from the remaining 13% would provide beneficial information.

2. *Removing the structural definition of PFAS.*

The SBAP recommended limiting the scope of chemicals to be reported to a finite list of PFAS subject to the rule. This alternative simplifies rule familiarization for affected entities and removes the cost and

[30] There are, however, instances where an alternative *de minimis* threshold is applied due to a specific regulatory requirements with a smaller threshold.

burden of understanding the structural definition of PFAS. We recommend limiting reporting to PFAS chemicals of known concern and to PFAS chemicals with a searchable CAS number.

For example, EPA should exclude substances with low exposure potential. This would include fluoropolymers. These types of chemicals have high molecular weight, low levels of residual monomer and do not degrade easily under normal conditions of use. Other categories that could be excluded are chemicals used for research and development, *de minimis* levels of PFAS chemicals, low volume service chemicals, and other categories identified as low exposure potential. By providing CAS numbers, EPA will define the universe of chemicals that require notification and further clarify reporting requirements. CAS numbers are critical to ensuring compliance with the notification requirements.

3. *Threshold exemption of either 2,500 lbs. per year or 25,000 lbs. per year.*

EPA considered providing a reporting threshold exemption, as this alternative was recommended by multiple SERs. For this alternative, EPA considered providing an annual reporting threshold exemption of 2,500 lbs. per year and an annual reporting threshold exemption of 25,000 lbs. per year. We support this option and urge EPA to include this exemption in any final rulemaking.

Auto Innovators further recommends that the notification requirement exclude products that contain PFAS equal to or less than 0.1% by weight. A 0.1% by weight threshold is an appropriate threshold for EPA to employ for purposes of the notification requirement, aligning with global *de minimis* and standards reporting practices. It would reasonably limit the volume of notifications, particularly for parts and components, as well as for intentionally added or byproduct chemicals. Otherwise, EPA will be burdened with thousands of notifications related to automotive parts and components that contain only trace concentrations of PFAS, which would be insignificant from a safety and health perspective.

In addition, promulgating a notification rule without a *de minimis* threshold would overly burden the supply chain. All end-product manufacturers would be required, in the absence of a *de minimis* threshold, to spend considerable time and effort to attempt to determine whether any part or component, whether sourced locally or globally, that goes into their end products might contain a trace concentration of PFAS. Such manufacturers would also need to determine whether such PFAS was "intentionally added," which based on the current definition must likely be assumed, and the specific purpose and amount of PFAS. This excessive data gathering would place an enormous burden on manufacturers, requiring them to pursue specific article composition with their suppliers—some of which are second, third, etc. tier suppliers. This information would be difficult, if not impossible, to obtain.

4. *Simplified reporting form for R&D substances manufactured in volumes of less than 10 kg per year.*

Simplified reporting for R&D substances was suggested in the Initial Regulatory Flexibility Analysis and Updated Economic Analysis as an option for reducing compliance burdens; Auto Innovators supports a full exemption for R&D substances as described in section B.3. above.

## D. EPA's Interpretation of the Requirements of the National Defense Authorization Act

The FY2020 National Defense Authorization Act (NDAA) amended TSCA by adding Section 8(a)(7), which obligates EPA to promulgate a rule by January 1, 2023, that requires each person who has manufactured PFAS in any year since 2011 to report and maintain records, for each year, with

information described in TSCA Section 8(a)(2). This information includes a broad range of information, such as information related to chemical identity and structure, production, use, exposure, disposal, and health and environmental effects, categories more typically applied to a bulk chemical manufacturer. In addition, EPA believes that the collected data may help provide more information about PFAS manufacture, and to the extent that new information indicates the presence of negative externalities or data gaps, inform future agency actions and/or legislation governing the manufacture, processing, use, and disposal of PFAS. EPA's proposed rule would require all manufacturers of PFAS in any year since 2011 to report certain information to EPA related to chemical identity, categories of use, volumes manufactured and processed, byproducts, environmental and health effects, worker exposure, and disposal (i.e., the section 8(a)(2) requirements). EPA also proposed a five-year retention period for all relevant records following the submission period.

We recognize that this rule is being developed in response to language in the NDAA. It is, however, unclear as to 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***"[31] (emphasis added) to also include 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 C.F.R. § 704 as:

> "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."

It is possible that an article may contain a trace amount of a PFAS chemical because of the manufacturing process, but an article does not meet the intent of the NDAA. 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 associated with articles, small businesses, byproducts, research and development chemicals, reaction wastes, etc. The inclusion of all these previously exempted categories adds substantially to the implementation challenges and burden of compliance and appears to be beyond the scope intended by the NDAA. Expanding beyond that scope increases costs to both manufacturers and the Agency, as further described below.

### 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, its analyses should reflect the true volume of reports that it will receive; the costs to increase the Chemical Data Exchange (CDX) capacity; and the EPA staff hours required to review the reports. Both EPA and industry will need more time than the rule suggests to adequately prepare for compliance with the proposed reporting requirements.

The proposed rule's preliminary and revised economic assessments demonstrate 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

[31] Pub .L. No. 116-92 § 7531.

CDX capacity is a repeat of EPA's underestimation of the reports it would receive for the first TSCA fees rule. It also suggests a need for a larger, more formal process to assess and evaluate EPA's current reporting systems, the expansion of users and data submitted, and for EPA money to update and ensure CDX capacity.

**Closing Recommendations**

The scope of this proposed rule is unprecedented and will likely have far reaching, cross-cutting economic impacts on commerce and jobs; it has the potential to disrupt complex supply chains that are 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. All this effort will be required at the very time the Administration is focusing on a stronger, more robust vision for U.S. competitiveness and the economy. Before moving forward with a final rule, it is critical that EPA provide an accurate and realistic estimate of the true burden that this rulemaking will impose. While we appreciate that EPA has revised its economic analyses, they fail to present the sheer magnitude of reports that will be submitted. EPA's assumption that an average of 5 reports per entity will be required is an unrealistically low estimate.

The EPA's Initial Regulatory Flexibility Analysis and Updated Economic Analysis fails to explain how EPA has ensured that it does not require unnecessary or duplicative reporting, has minimized the cost of compliance, and applied reporting obligations to only those entities likely to have relevant information, as required by TSCA Section 8(a)(5). In fact, we are concerned that the proposed rule does not meet those statutory criteria: 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.[32] 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 four recommendations:

1. Complete an accurate economic analysis to support EPA's Information Collection Request.
2. Remove articles from reporting requirements.
3. Limit the scope of the rule, as outlined above.
4. 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 them, and we reiterate our goal to work with EPA to find a feasible and appropriate pathway to address articles under TSCA.

Sincerely,

Catherine Palin
Alliance for Automotive Innovation

[32] Comments from Alliance for Automotive Innovation (Sept. 27, 2021), Docket ID No. EPA-HQ-OPPT-2020-0549-0068.