Economic Analysis of the Proposed Significant New Use Rule for Per- and Poly-fluoroalkyl Chemical Substances Designated as Inactive on the TSCA Inventory (EPA DOCKET EPA-HQ-OPPT-2020-0876)

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The EPA analyst responsible for this report was Leigh Callahan. Analytical and draft preparation support was provided by Abt Associates Inc. of Rockville, Maryland provided under Contract No. EP-W-16-009 in the preparation of this report.

Executive Summary

Under section 5(a)(2) of the Toxic Substances Control Act (TSCA), the Environmental Protection Agency (EPA) is proposing a significant new use rule (SNUR) for Per- and Polyfluoroalkyl substances (PFAS) by designating as a significant new use manufacturing (including import) or processing for any use of inactive PFAS.

The 2016 amendments to TSCA required EPA to designate chemical substances on the TSCA Chemical Substance Inventory as either "active" or "inactive" in U.S. commerce. To accomplish that, EPA finalized a rule requiring industry reporting of chemicals manufactured (including imported) or processed in the U.S. over a 10-year period ending on June 21, 2016. This reporting was completed in October 2018 and was used to identify chemical substances on the TSCA Inventory as active or inactive in U.S. commerce. Starting August 5, 2019, manufacturers and processors have been required to notify EPA before reintroducing inactive substances into U.S. commerce. The proposed SNUR designates the manufacture (including import) or processing of all inactive PFAS as a "significant new use" under TSCA.

EPA may promulgate a SNUR for a substance when EPA determines that a use of a chemical substance is a significant new use, after consideration of all relevant factors listed at 15 USC § 2604(a)(2). In contrast to PMN requirements, which apply mainly to manufacturers and importers (15 USC §2604(a)(1)(A)(i), 40 CFR §720.22), the SNUR applies to processors as well as to manufacturers and importers (15 USC §2604(a)(1)(A)(ii), 40 CFR §721.5).

The required significant new use notification initiates EPA's evaluation of the conditions of use associated with the chemical substance within the applicable review period. Manufacturing (including import) or processing for the significant new use is prohibited from commencing until EPA has conducted a review of the notice, made an appropriate determination on the notice, and taken such actions as are required in association with that determination.

A firm intending to engage in these activities will be required to submit a significant new use notice (SNUN), incurring an estimated submission cost of approximately $26,737 for large businesses per chemical, and potentially other minor costs. For small businesses, as defined at 13 CFR 121.201, the estimated cost is approximately $11,047 to complete and submit a SNUN. Table ES-1 summarizes costs incurred per firm. Section 3 provides more detail on these cost calculations.

In addition to any firms that may make a SNUN submission, the proposed SNUR may also affect firms that do not make a submission. By avoiding a significant new use, a firm can avoid submission and testing costs but may incur other compliance costs. The firm may also incur "hidden" costs; for example, it could forego profitable opportunities to use the chemical in an application that would be a significant new use. The potential hidden costs to the firms that do not make a submission are not quantified.

Costs in this report are estimated at the firm level. Total costs of the proposed rule are not estimated since the number SNUN submissions is unknown. EPA, however, receives only a handful of SNUNs each year and therefore the anticipated number of SNUN submissions as a result of this rule is low.

Table ES-1: Compliance Options and Associated Costs Incurred by a Firm Due to the SNUR

Option[1]		Costs	Quantified Costs per Chemical (2021$)[2]
1.	Electronic submission of a SNUN, indicating to EPA that the firm would like to import the chemical as part of an article for a significant new use as defined in the SNUR.	Costs of submitting a SNUN, including rule familiarization, CDX registration (for companies that are first-time submitters), form completion, user fee, and any test costs.[3]	$517 rule familiarization cost; $26,737 submission cost (including SNUN recordkeeping under 40 CFR 721.40 and fee $19,020 for large businesses). Export notification costs are estimated at $106 per notification; total cost per company would vary. EPA usually receives well under ten SNUNs per year. First time submitters would incur $244 for CDX registration and associated activities.
2.	Do not manufacture (including import) or process the substances.	Cost of the profit foregone as a result of not engaging in the commercial activity originally planned (opportunity costs).	Opportunity costs are not quantified.

Note(s):

[1] Firms may be subject to both options at once since submission of a SNUN results in profits foregone as a result of not manufacturing (including importing) or processing the chemical.

[2] Quantified costs are attributable to the SNUR only if a firm would not otherwise follow the specified practices. Costs are detailed in Section 3.2.

[3] EPA does not require the development of chemical toxicity test data for submission of a SNUN, although a firm may submit test data already in its possession and/or describe any other available data. Because EPA does not require the development of test data, EPA assumes that no firms will incur testing costs as a result of the proposed SNUR.

1. Introduction

This report presents the estimated costs of the proposed significant new use rule for inactive PFAS. Under section 5(a)(2) of TSCA, is proposing a SNUR for PFAS by designating as a significant new use manufacturing (including importing) or processing of any use of inactive PFAS.

The 2016 amendments to TSCA required EPA to designate chemical substances on the TSCA Chemical Substance Inventory as either "active" or "inactive" in U.S. commerce. To accomplish that, EPA finalized a rule requiring industry reporting of chemicals manufactured (including imported) or processed in the U.S. over a 10-year period ending on June 21, 2016. This reporting was completed in October 2018 and was used to identify chemical substances on the TSCA Inventory as active or inactive in U.S. commerce. The proposed SNUR designates the manufacture (including import) or processing of all inactive PFAS as a "significant new use" under TSCA.

The required significant new use notification initiates EPA's evaluation of the conditions associated with the intended use within the applicable review period. Manufacturing (including import) or processing for the significant new use is prohibited from commencing until EPA has conducted a review of the notice, made an appropriate determination on the notice, and taken such actions as are required in association with that determination.

1.1 Statutory Authority

Section 5(a)(2) of TSCA (15 U.S.C. 2604(a)(2)) authorizes EPA to determine that a use of a chemical substance is a "significant new use." EPA must make this determination by rule after considering all relevant factors, including those listed in TSCA section 5(a)(2). Once EPA determines that a use of a chemical substance is a significant new use, TSCA section 5(a)(1)(B) requires persons to submit a SNUN to EPA at least 90 days before manufacturing (including importing) or processing the chemical substance for that use (15 U.S.C. 2604(a)(1)(B)).

TSCA furthermore prohibits such manufacturing (including importing) or processing from commencing until EPA has conducted a review of the notice, made an appropriate determination on the notice, and taken such actions as are required in association with that determination (15 U.S.C. 2604(a)(1)(B)(ii)). Additionally, section 5(a)(5) of TSCA (15 U.S.C. 2604(a)(5)) authorizes EPA to require notification for the import or processing of a chemical substance as part of an article or category of articles under TSCA section 5(a)(1) (15 U.S.C. 2604(a)(1)(A)(ii)) if EPA makes an affirmative finding in a rule under TSCA section 5(a)(2) (15 U.S.C. 2604(a)(2)) that the reasonable potential for exposure to the chemical substance through the article or category of articles subject to the rule justifies notification.

The general SNUR provisions are found at 40 CFR Part 721, Subpart A.

1.2 Summary of Methodology

This analysis quantifies, to the extent possible, the costs of the proposed rule to society by identifying the costs to industry associated with performing the required reporting and recordkeeping activities, and the costs to EPA of administering the rule. Industry costs consist of rule familiarization; registration with the Central Data Exchange (CDX) electronic reporting tool; collection, compilation, and submission of required information for significant new uses of the subject chemicals; recordkeeping; and a submission fee. Agency costs include reviewing and processing the data

received as a result of the rule. Data sources for this analysis include burden estimates derived from previous information collection requests and economic analyses for related rules, compensation data acquired from government publications, and supplementary market research.

In addition to estimated costs, this report qualitatively discusses the benefits of the rule based on the value of the information it will provide.

1.3 Organization of this Report

The remainder of this report presents EPA's economic analysis in support of the proposed rule. A description of the set of inactive PFAS affected by this SNUR and their uses, are provided in Chapter 2. Chapter 3 contains estimates of the industry costs to comply with the rule, and Chapter 4 presents estimates of the government costs associated with the administration of the rule. Chapter 5 addresses the benefits of the rule. Several additional impact analyses are presented in Chapter 6, including: small entity impact analysis, as mandated by the Regulatory Flexibility Act (RFA); a burden hour analysis that responds to the requirements of the Paperwork Reduction Act (PRA); an analysis of unfunded mandates that pertains to the Unfunded Mandates Reform Act (UMRA); an analysis of environmental justice implications that addresses the requirements of Executive Order 12898; and an analysis of children's health pertinent to Executive Order 13045.

Note that all dollar values in this analysis are reported in 2021 dollars.

2. Chemical Uses and Manufacturers

2.1 Chemicals Subject to the Proposed Rule

PFAS are synthetic organic compounds that do not occur naturally in the environment. The strong carbon-fluorine bonds of PFAS make them resistant to degradation and thus highly persistent in the environment (EPA 2019b; EPA 2017). Some of these chemicals have been used for decades in a wide variety of consumer and industrial products (EPA 2019b). Some PFAS have been detected at high levels in wildlife, including higher trophic organisms, indicating that at least some PFAS have the ability to bioaccumulate (EPA 2017). Some PFAS can accumulate in humans and remain in the human body for long periods of time (e.g., months to years) (EPA 2019b; EPA 2017; EPA 2009c). Because of the widespread use of PFAS in commerce and their tendency to persist in the environment, most people in the United States have been exposed to PFAS (EPA 2019b). As a result, several PFAS have been detected in human blood serum (EPA 2019b; EPA 2017; ASTDR 2021).

EPA believes that the commencement of manufacturing (including import) or processing of currently inactive PFAS would significantly increase the magnitude and duration of exposure to humans and the environment.

2.1.1 Definition of an Inactive PFAS Substance

In this rule, the term inactive PFAS refers to PFAS that the EPA designated as "inactive" in U.S. commerce on the TSCA Chemical Substance Inventory under the 2016 amendments to TSCA. EPA designated chemical substances as "active" or "inactive" based on industry reporting of chemicals manufactured (including imported) or processed in the U.S. over a 10-year period ending on June 21, 2016. Starting August 5, 2019, manufacturers and processors have been required to notify EPA before reintroducing inactive substances into U.S. commerce. As the Agency has not received such notifications for the 300 affected PFAS, the Agency believes that the inactive PFAS included in this proposed SNUR are no longer being manufactured or processed for any uses in the United States.

For the purposes of the proposed rule, the structural definition of PFAS includes chemicals that contain at least one of these three structures:

1) R-(CF2)-CF(R')R'', where both the CF2 and CF moieties are saturated carbons
2) R-CF2OCF2-R', where R and R' can either be F, O, or saturated carbons
3) CF3C(CF3)R'R'', where R' and R" can either be F or saturated carbons.

There are a total of 300 inactive substances that meet this structural definition and are thus subject to the SNUR. The specific chemical identities of 30 of these substances have been claimed as confidential business information (CBI), and their generic names are the nonconfidential substitute for the specific chemical name that is treated as confidential and does not contain "fluor" or "fluorine." Generic names reveal the chemical identity of a substance to the maximum extent practicable while masking those structural elements that are confidential. The lack of "fluor" or "fluorine" in a generic name masks that the chemical substance is a PFAS. Therefore, listing the generic names of these substances on a list of PFAS would disclose structural information for these substances

2.2 Significant New Uses under the SNUR

EPA may promulgate a SNUR for a substance when potential use could result in significant changes in human exposure or environmental release levels and/or that concern exists about the substance's health or environmental effects (40 CFR 721.170). According to TSCA section 5(a)(2), the determination that a chemical use qualifies as a significant new use must consider all relevant factors, including:

- The projected volume of manufacturing, importation, and processing of the chemical substance;
- The extent to which a use changes the type or form of exposure of human beings or the environment to a chemical substance;
- The extent to which a use increases the magnitude and duration of exposure of human beings or the environment to a chemical substance; and
- The reasonably anticipated manner and methods of manufacturing, processing, distribution in commerce, and disposal of a chemical substance.

EPA is proposing to define the significant new use as manufacturing (including import) or processing of any inactive PFAS for any use. A company will be expected to submit a SNUN for any of the chemical substances used that are included in the SNUR prior to initiating a new use.

2.3 Affected Industries and Uses

Over 4,000 PFAS may have been manufactured and used in a variety of industries worldwide since the 1940s (OECD 2018, Guelfo JL 2018.). The EPA's TSCA Chemical Substance Inventory lists over one thousand PFAS, of which approximately half are known to be commercially active within the last decade. PFAS are used in a variety of consumer products and industrial processes, including firefighting foams, chemical processing, building/construction, aerospace, electronics, semiconductor and automotive industries, stain- and water-resistant coatings (e.g., carpets and rain repellent clothing), food packaging, and in waxes and cleaners (EPA 2019b). Due to their desirable chemical properties for consumer goods, PFAS are widely used in commercial products and can be found in almost every U.S. home and business (EPA 2019b).

PFAS subject to this SNUR are currently inactive in commerce; therefore, the set of industries that firms interested in reintroducing currently inactive PFAS belong to is unknown. Table 2-1 lists a potential set of industries—defined via North American Industrial Classification System (NAICS) categories—that could be impacted. Table 2-1 lists the manufacturers (including importers) of reported manufacturing or importing PFAS to the 2016 and 2020 Chemical Data Reporting (CDR). This list is not exhaustive and may not describe the specific entities and corresponding NAICS codes for manufacturers that may be affected.

Table 2-1: NAICS of Parent Companies Reporting on PFAS to CDR

NAICS	NAICS Description
221210	Natural Gas Distribution
236220	Commercial and Institutional Building Construction
324	Petroleum and Coal Product Manufacturing
324191	Petroleum Lubricating Oil and Grease Manufacturing
325	Chemical Manufacturing
325120	Industrial Gas Manufacturing
325180	Other Basic Inorganic Chemical Manufacturing
325199	All Other Basic Organic Chemical Manufacturing
325211	Plastics Material and Resin Manufacturing
325212	Synthetic Rubber Manufacturing
325220	Artificial and Synthetic Fibers and Filaments Manufacturing
325320	Pesticide and Other Agricultural Chemical Manufacturing
325411	Medicinal and Botanical Manufacturing
325412	Pharmaceutical Preparation Manufacturing
325612	Polish and Other Sanitation Good Manufacturing
325613	Surface Active Agent Manufacturing
325998	All Other Miscellaneous Chemical Product and Preparation Manufacturing
326113	Unlaminated Plastics Film and Sheet (except Packaging) Manufacturing
327910	Abrasive Product Manufacturing
333999	All Other Miscellaneous General Purpose Machinery Manufacturing
334511	Search, Detection, Navigation, Guidance, Aeronautical, and Nautical System and Instrument Manufacturing
336111	Automobile Manufacturing
423120	Motor Vehicle Supplies and New Parts Merchant Wholesalers
423420	Office Equipment Merchant Wholesalers
423510	Metal Service Centers and Other Metal Merchant Wholesalers
423740	Refrigeration Equipment and Supplies Merchant Wholesalers
423990	Other Miscellaneous Durable Goods Merchant Wholesalers
424690	Other Chemical and Allied Products Merchant Wholesalers
424720	Petroleum and Petroleum Products Merchant Wholesalers (except Bulk Stations and Terminals)
424950	Paint, Varnish, and Supplies Merchant Wholesalers
441110	New Car Dealers
447190	Other Gasoline Stations
551112	Offices of Other Holding Companies
562	Waste Management and Remediation Services

Source: EPA 2020b; EPA 2022

3. Industry Compliance Costs

The SNUR discussed in this report specifies that manufacture (including import) or processing of inactive PFAS for a designated significant new use would require reporting under section 5(a)(1)(A) of TSCA. Therefore, a firm intending to manufacture (including import), or process inactive PFAS meeting the definition described in Section 2.1.1 must submit a SNUN. Alternatively, a firm can decide not to manufacture (including import) and/or process these chemicals or articles in such a way that it is not considered a significant new use. The firm, therefore, has two options:

- ***Option 1: Submit a SNUN.*** A SNUN indicates to EPA that the firm would like to manufacture (including import), and/or process the chemical or article for a significant new use, which in this case means the manufacturing (including importing) or processing of a PFAS that both meets the structural definition of a PFAS as described in Section 2.1.1 and is listed as "inactive" on the TSCA Chemical Substance Inventory. The required notification initiates EPA's evaluation of the conditions of use associated with the intended new use within the applicable review period. Manufacture and processing for the significant new use is prohibited from commencing until EPA has conducted a review of the notice, made an appropriate determination on the notice, and taken such actions as are required in association with that determination. If EPA allows the manufacture (including import) and/or processing of any of the chemical substances for a significant new use, then the costs associated with this option are the costs of submitting the SNUN (including a user fee) plus, if there is any export of these chemicals, the export notification costs that result from TSCA section 12 (b) requirements that are automatically triggered for chemicals regulated under TSCA section 5 (see Section 3.2.5 for details).
- ***Option 2: Comply with SNUR limits (not manufacture (including import) and/or process a new use of the chemical).*** A firm can avoid engaging in a significant new use and submitting a SNUN by not manufacturing (including importing) and/or processing any of the chemical substances in a manner such that they would be considered new uses. That is, the firm does not manufacture (including importing) or process a PFAS that both meets the structural definition of a PFAS as described in Section 2.1.1 and is listed as "inactive" on the TSCA Chemical Substance Inventory. While this option avoids the costs of submitting a SNUN, it may entail the "hidden" cost of the foregone profit as a result of not engaging in the commercial activity originally planned and may involve substituting one of the subject chemicals for another, more costly substance. If the firm elects to manufacture (including import) or process the chemical for research and development (R&D) purposes only (an exemption for R&D purposes is provided in 40 CFR 721.47), it may have costs associated with R&D recordkeeping. The firm may also pursue this option temporarily by complying with the SNUR restrictions while also pursuing Option 1. Due to the uncertainty related to this option, and EPA's expectation that affected entities would select Option 1, the costs of Option 2 are not fully quantified in this report.

The remainder of this chapter estimates the quantified portion of costs associated with the proposed SNUR. Section 3.1 summarizes the wage rates used in this chapter. Section 3.2 provides the unit industry compliance costs, including the costs of rule familiarization, registration with the CDX electronic reporting tool, completing the SNUN form, and submission fee. Total costs under each option are presented in Section 3.3.

3.1 Wage Rates

The proposed rule involves activities that may require efforts by employees in three labor classifications: managerial, technical, and clerical. Costs for each activity are calculated by estimating the labor hours required in each labor category and multiplying those burden hours by the wage rate for the corresponding labor category. This section presents the estimated wage rate in each labor category.

Loaded wage rates for managerial, technical, and clerical personnel are derived by combining data on wages and fringe benefits with estimates of overhead rates, following the methodology described in *Wage Rates for Economic Analysis of the Toxics Release Inventory Program* (EPA 2002). Wage data for each labor category for December 2021 are provided by the Employer Costs for Employee Compensation (ECEC) Supplemental Tables available on the Bureau of Labor Statistics (BLS) website (BLS 2021). Table 3-1 presents the data used to calculate the loaded wage rates for the three labor categories. Appendix A provides more information on the wage rates and inflation factors used in this analysis.

Table 3-1: Loaded Industry Wage Rates, December 2021

Labor Category	Data Source	Date (mm/yy)	Wage	Fringe Benefit	Total Comp.	Over-head % Total Comp.[1]	Over-head	Loaded Wages[2]
			(a)	(b)	(c)= (a)+(b)	(d)	(e)=(c) * (d)	(f)=(c)+ (e)
Managerial	BLS *ECEC*, Private Manufacturing industries, "Mgt, Business, and Financial"[3]	12/21	$53.49	$24.16	$77.65	20%	$15.53	$93.18
Professional/ Technical	BLS *ECEC*, Private Manufacturing industries, "Professional and related"[3]	12/21	$44.99	$22.84	$67.83	20%	$13.57	$81.40
Clerical	BLS *ECEC*, Private Manufacturing industries, "Office and Administrative Support"[3]	12/21	$21.48	$9.50	$30.98	20%	$6.20	$37.18

Note(s):
[1] Wage data are rounded to the closest penny; however, unrounded values were used in calculations.
[2] An overhead rate of 20% is used based on assumptions in Handbook on Valuing Changes in Time Use Induced by Regulatory Requirements and Other U.S. EPA Actions (U.S. Environmental Protection Agency (EPA) 2020a).
[3] Bureau of Labor Statistics (BLS) 2021

3.2 Unit Industry Compliance Costs

3.2.1 Rule Familiarization

The proposed rule requires manufacturers (including importers), and processors of the chemicals subject to the rule to become familiar with the SNUR and its various requirements. Rule familiarization is estimated to require 0.55 hours of technical labor and 0.27 hours of managerial labor, as described in the Economic Analysis of the Premanufacture Notification Electronic Reporting Final Rule (EPA 2009a), which measures the costs of mandatory electronic reporting of SNUNs and other TSCA Section 5 notices.

The proposed rule also requires firms to become familiar with the structural definition and apply the definition to the set of PFAS they use. Manufacturers are assumed to spend 5.5 hours on familiarization with the structural definition of PFAS.

As shown in Table 3-2, the total labor cost associated with rule familiarization is estimated at $517.

Table 3-2: Rule Familiarization Burden and Cost for SNUN Submitters

Reporting Activity	Clerical Labor (at $37.18/hour)		Technical Labor (at $81.40/hour)		Managerial Labor (at ($93.18/hour)		Total Labor Cost ($2021)	
	Burden	Cost	Burden	Cost	Burden	Cost	Burden	Cost
Rule Familiarization	0	$0.00	0.55	$44.77	0.27	$24.85	0.82	$69.62
Structural Definition Familiarization	0	$0.00	5.5	$447.68	0	$0.00	5.50	$447.68
Total:							**6.32**	**$517.30**

Note(s):
Costs may not equal labor wage rate multiplied by burden hours as shown, due to rounding. Unrounded values were used in calculations.
Source(s):
Wage rates: see Table 3-1; Burden estimates: EPA (2009a).

3.2.2 CDX Registration, CDX Electronic Signature, and Pay.gov Account Setup

The proposed SNUR requires submission of a SNUN for any firm that chooses to manufacture (including import) and/or process a chemical for significant new use. First-time submitters of any TSCA section 5 notice (including Premanufacture Notices (PMNs), SNUNs, Test Market Exemption (TME) applications, Low Volume Exemption (LVE) notices, Low Exposure/Low Release (LoREX) exemption notices, Biotechnology Notices for genetically modified microorganisms, Notices of Commencement (NOC) of Manufacture or Import, and support documents to Section 5 notices) are required to register their company and key users with the CDX reporting tool, deliver a CDX electronic signature to EPA, and establish and use a Pay.gov E-payment account.[1] These activities are only required of first-time submitters of any Section 5 notice. These activities are estimated to require

[1] Although the proposed rule does not require submitters to establish and use a Pay.gov account, the burden estimates in this analysis are conservative insofar as to include the use of Pay.gov as a required activity.

the following burden hours, based on the estimates presented in the Economic Analysis of the Premanufacture Notification Electronic Reporting Final Rule (EPA 2009a):

- ***CDX registration.*** EPA estimates that companies would spend approximately 0.18 hours per employee to register with CDX, and that an average of four technical staff members and one manager would need to register for each company, totaling approximately 0.92 hours of burden per company.
- ***CDX electronic signature.*** EPA estimates that companies would spend 0.25 hours preparing, submitting, and filing an electronic signature agreement (Authentication of Identity) form to EPA per employee. This burden would apply to four technical staff members and one manager per company, totaling 1.25 hours of burden per company. In addition, EPA estimates that a manager would spend an additional 0.50 hours accessing, preparing, and submitting verification forms (Verification of Authorization) for all authorized submitters to EPA. The total burden incurred by companies submitting and then verifying electronic signature agreements is 1.75 hours. Note that this burden does not include any additional time required to contact EPA's CDX help desk to notify a change of submitter status, should one occur. Filing the electronic signature agreement requires an additional mailing cost of $3.40 per company (including five $0.55 stamps2 and five $0.07 business envelopes3).
- ***Payment via Pay.gov account.*** EPA estimates that one manager per company would spend approximately 0.13 hours setting up a Pay.gov ID account, logging into the system, finding the appropriate form, and filling it out. This burden does not include the time required to click 'submit' on the form and wait for payment processing.

As shown in Table 3-3, the labor cost consists of CDX registration, CDX electronic signature, and Pay.gov account setup by a first-time submitter. As noted above, an additional $3.40 in mailing cost per company is attributable to these activities, for a total cost of approximately $244 per company.

[2] Price for a stamp was taken from the U.S. Postal Service website in July 2019 (See U.S. PS 2019). Indexed to $2021 using BLS Series ID: CUUR0000SA0.

[3] Price for an envelope was determined based on the per unit price of a regular business envelope. See "Staples® #10, Self-Sealing Envelopes, 500/Box." Available at: http://www.staples.com/ (Accessed 8/30/2022). Indexed to $2021 using BLS Series ID: CUUR0000SA0.

Table 3-3: CDX Registration, CDX Electronic Signature, and Pay.gov Account Setup Burden and Cost for First-Time Submitters

Reporting Activity	Clerical Labor (at $37.18/hour)		Technical Labor (at $81.40/hour)		Managerial Labor (at ($93.18/hour)		Total Labor Cost ($2021)	
	Burden	Cost	Burden	Cost	Burden	Cost	Burden	Cost
CDX Registration	0.00	$0.00	0.73	$59.69	0.18	$17.08	0.92	$76.77
CDX Electronic Signature	0.00	$0.00	1	$81.40	0.75	$69.89	1.75	$151.28
Mailing Cost								$3.29
E-Payment (Pay.gov ID)	0.00	$0.00	0.00	$0.00	0.13	$12.42	0.13	$12.42
Total	**0.00**	**$0.00**	**1.73**	**$141.08**	**1.07**	**$99.39**	**2.80**	**$243.76**

Note(s):
Costs may not equal labor wage rate multiplied by burden hours as shown, due to rounding. Unrounded values were used in calculations.
Source(s):
Wage rates: see Table 3-1, Burden estimates: EPA (2009a).

3.2.3 Form Completion and Submission Fee

Respondents who choose to submit a SNUN are required to gather and submit information regarding the data elements identified in the applicable SNUN reporting form. The methodology and calculations used in this analysis assume that the employee responsible for collecting, filling out, and submitting the requested information has a reasonable level of familiarity with the company and knowledge of operations at the site. It is assumed that for most entities these tasks are similar to other employee duties that require familiarity with EPA, State, and other Federal agency requests for chemical information and do not require additional familiarization or training beyond the basic rule familiarization described above. In addition, this analysis focuses on the marginal costs of submitting information for the rule and not the total costs for the company to comply with a range of other Federal and State environmental, health, and safety regulations or accounting requirements that rely on this type of information.

Estimates of the costs of completing a SNUN form are based on the costs of completing a PMN submission, since the data requirements are the same and the same form is used for both. The PMN submission costs came from EPA's 1994 *Regulatory Impact Analysis of Amendments to Regulations for TSCA Section 5 Premanufacture Notifications,* which relied on industry estimates of the effort needed to collect and compile all data required for a PMN submission, prepare the form, submit the form and data to EPA, and maintain a file of the submission (EPA 1994, see Table III-2 and pages III-11, -12, and -13). The 1994 estimates were based on a survey conducted by the Chemical Manufacturers Association, which became the American Chemistry Council. These burdens include "the time spent reading and becoming familiar with the form, gathering the required information and preparing the report, producing sanitized responses for items claimed as confidential business information, and maintaining a file of the submission" (EPA 1994, p. III 11-13). The burden associated with SNUN submission and preparation has been adjusted to reflect burden reductions resulting from the 2009 final PMN Electronic Reporting (ePMN) Rule that requires the electronic

submission of all TSCA section 5 notices. Electronic submission of SNUN forms is expected to remove all clerical burden and reduce the recordkeeping burden associated with preparing a SNUN (EPA 2009a).[4] In addition, electronic submission is expected to generate an additional 0.18 hours of technical burden for the completion of the User Fee Payment Identification Number and email address data elements on the electronic SNUN form.

SNUN form completion and electronic submission is estimated to require approximately 74 hours of technical labor and 18 hours of managerial labor (EPA 2009a). Table 3-4 combines the estimated reporting burden and loaded wage rates for all three labor categories to estimate the per-SNUN cost of form completion. The labor cost incurred by a SNUN submission for both large and small business submitters is estimated at $7,717.

Table 3-4: Industry Cost Estimate to Complete the SNUN Form

Reporting Activity	Clerical Labor (at $33.09/hour)		Technical Labor (at $76.21/hour)		Managerial Labor (at ($81.51/hour)		Total Labor Cost ($2021)	
	Burden	Cost	Burden[1]	Cost	Burden	Cost	Burden	Cost
Form Completion	0.00	$0.00	74.2	$6,039.58	18	$1,677.24	92.2	$7,716.82

Note(s):

[1] Costs may not equal labor wage rate multiplied by burden hours as shown, due to rounding.

[2] Loaded wages include fringe benefits and overhead. See Table 3-1 of this report for derivation. Wage rates presented in this table are rounded; however, unrounded values were used in calculations. For this reason, total labor costs may not equal the product of rounded values.

[3] The estimate of zero clerical burden is taken from the Economic Analysis of the Premanufacture Notice Electronic Reporting Final Rule (EPA 2009a, page 7).

[4] Technical and managerial labor burden is from the PMN Amendments RIA (EPA 1994, Table III-2). An additional eleven minutes (0.18 hours) of technical burden is estimated to complete the User Fee Payment Identification Number and Email Address data elements on the Electronic SNUN form (EPA 2009a, page 15).

Source(s):

Burden estimated: EPA (1994) and EPA (2009a); Wage rates: see Table 3-1.

In addition, each business must pay a user fee. The Frank R. Lautenberg Chemical Safety for the 21st Century Act, which updates the Toxic Substances Control Act, authorizes EPA to collect fees pursuant to the amendments made to Title 15 USC CH. 53: Toxic Substances Control Act, Subchapter I, §2625(b)(4). The TSCA amendments include a statute that authorizes EPA to set fees to a level that will defray a portion of the costs associated with carrying out sections 2603, 2604, and 2605. Submitting large business must pay a fee of $19,020 per-SNUN submission and each submitting small business, as defined at 13 CFR 121.201, must pay a fee of $3,330 per-SNUN submission. Table 3-5 adds the labor cost and submission fee to estimate the total cost of a SNUN

[4] The Economic Analysis of the Premanufacture Notification Electronic Reporting Final Rule (EPA 2009a) reported a 0.5 hour clerical and a 0.5 hour technical burden associated with recordkeeping in addition to the burden estimates from the 1994 Regulatory Impact Analysis (EPA 1994, p. III-14). These burden estimates (the 0.5 for clerical burden and 0.5 for technical burden) are based on the recordkeeping burden for polymer exceptions and not the recordkeeping burden associated with PMN submissions.

Therefore, for this analysis, the 0.5 hour for clerical labor and the 0.5 hour for technical labor were removed. It is important to note that for this analysis, clerical burden changes are not applicable because the entire clerical burden is assumed to be eliminated under the electronic reporting requirements. In summary, we do not include the one-hour recordkeeping burden (0.5 hour for clerical, 0.5 for technical) reported in the ePMN Economic Analysis.

submission. The total cost of a SNUN submission is $26,737 for large business submitters and $11,047 for small business submitters.

Table 3-5: Industry Cost Estimate to Complete and Submit the SNUN Form

Reporting Population	Labor Cost	Submission Fee	Total Cost (2021$)
Large Business Submitters	$7,717	$19,020	$26,737
Small Business Submitters	$7,717	$3,330	$11,047

Source(s):
Labor cost: see Table 3-4

3.2.4 Recordkeeping for Companies Choosing to Submit a SNUN

Companies submitting a SNUN must, under 40 CFR 721.40, keep records of the information contained in the SNUN. Some EPA reports have assumed that SNUN recordkeeping hours would be five percent of SNUN submission hours, or about five to six hours. For this report, the SNUN recordkeeping hours were included in the SNUN submission hours (see Section 3.2.3) and the SNUN recordkeeping costs under 40 CFR 721.40 were not separately estimated.

3.2.5 Export Notification

Persons who export or intend to export a chemical substance identified in the proposed SNUR are subject to the export notification provisions of TSCA section 12(b). In accordance with 40 CFR 707.60(b), this proposed SNUR does not trigger notice of export for articles. Under TSCA section 12(b) and the implementing regulations at 40 CFR part 707, subpart D, exporters must notify EPA if they export or intend to export a chemical substance or mixture for which, among other things, a rule has been proposed or promulgated under TSCA section 5. For persons exporting a substance that is the subject of a SNUR, a one-time notice to EPA must be provided for the first export or intended export to a particular country. After receiving a notification from a firm, EPA notifies the importing country and the United States State Department (40 CFR 707.70).

To calculate the burden associated with making a single export notification, EPA first estimated the average annual number of export notifications made by an exporter. EPA then derived the annual and per notification burden associated with preparing and submitting an export notification. EPA estimated the average burden associated with making a single notification, but did not estimate either the total number of exporters of a SNUR chemical or the number of notifications per SNUR chemical. This is because the SNURs apply to a variety of different chemicals with a variety of unrelated uses, manufacturers, and processors, making it impractical within the resources available for this report to assess the potential number of exporters and importing countries per chemical.

Most underlying data in this section come from the (2012 TSCA Section 12(b) ICR), ICR No.: 0795.14 OMB Control Number 2070-0030 [Information Collection Request for] Notification of Chemical Exports - TSCA Section 12(b) Supporting Statement for Request for OMB Review under the Paperwork Reduction Act (EPA 2012).

3.2.5 (A) Estimated Number of Annual Export Notifications per Exporter

EPA's 2012 TSCA Section 12(b) ICR estimated that the average exporter *making notifications* would make 13 notifications per year.[5] This includes notifications resulting from SNURs and notifications resulting from other TSCA activities. Therefore, it is likely that an exporter would make less than 13 notifications per year as a result of this SNUR. A notification is typically no more than one page per chemical/country combination, and one notification mailing often includes multiple chemicals and/or destination countries.[6]

The percent of notifications resulting from SNURs in general is unknown, and it is also unknown how many notifications may result from this rulemaking, as not all manufacturers may choose to export a chemical, or they may make several notifications for a single chemical.

3.2.5 (B) Exporter Costs

The 2012 TSCA Section 12(b) ICR (EPA 2012, page 11, Table 3), estimated the annual export notification cost for an exporter under the one-time export notification requirement. These costs include the cost to the exporter of compiling a list of their products that are subject to TSCA Section 12(b) requirements, writing or revising an export notification letter to EPA, checking the outgoing shipments, and sending the notification letters with the associated shipping costs.

The per-notification cost was calculated based on the average burden per firm. Exporters who make a larger number of notifications per year may benefit from economies of scale and have lower costs per notification; conversely firms making fewer notifications may have a higher cost per notification.

Estimated Submission (Mailing) Costs. Regulated companies would incur mailing costs for export notifications delivered to EPA. Notifications are assumed shipped via the U.S. Postal Service (USPS) as first-class registered mail with a return receipt (USPS 2020). The estimated per-shipment and annual mailing costs incurred by individual submitters are detailed in Table 3-6.

[5] EPA calculated the average number of export notifications per exporter in the 2012 TSCA Section 12(b) ICR (EPA 2012) by dividing the estimated number of submitted notifications (3,090) by the estimated number of exporters (240).

[6] Based on review by an EPA economist of notifications under TSCA sections 4, 5, and 6 over approximately three weeks in early 2010.

Table 3-6: Derivation of Total Mailing Cost for 13 Notices	
Postal Service[1]	**Cost**
Registered mail, *regular, with $0 declared value*	$13.06
Return receipt, *requested at time of mailing*[2]	$2.95
Postage, *regular First Class, up to 1 ounce*	$0.60
Cost per export notice – Subtotal	**$15.86**
	× 13
Total Mailing Cost for 13 Notices	**$215.26**

Notes:
[1] Mailing rates are from the US Postal Service web site as of May 2020 (https://www.usps.com/ship/insurance-extra-services.htm) (U.S. Postal Service (U.S. PS) 2020) and indexed to $2021 (see Appendix A.2). The mailing method comes from the *Economic Analysis of the Proposed Change to TSCA Section 12(b) Export Notification Requirements*, November 2005 (EPA 2005), as clarified in a later SNUR economic analysis (EPA 2007a, Table 8).
[2] Starting with the *Economic Analysis of Expedited New Use Rule for Fifty-seven Chemical Substances EPA Docket EPA-HQ-OPPT-2016-0207* (EPA 2016) the cost for return receipts service is the average of a the cost of receiving a physical return receipt by mail and the cost of receiving an electronic return by email. Prior SNUR economic analysis only used the cost for a physical return receipt.

The 2012 TSCA Section 12(b) ICR (EPA 2012, p. 11, Table 3), estimated the annual export notification cost for an exporter under the one-time export notification requirement. These costs include the cost to the exporter of compiling a list of their products that are subject to TSCA Section 12(b) requirements, writing or revising an export notification letter to EPA, checking the outgoing shipments, and sending the notification letters with the associated shipping costs.

The per-notification cost was calculated based on the average burden per firm making notifications. Exporters making more notifications per year may benefit from economies of scale and have lower costs per notification; those making fewer notifications may have higher costs per notification.

3.2.5 (C) Estimated Submission (Mailing) Costs

Regulated companies will incur mailing costs for export notifications delivered to EPA. Notifications are assumed shipped via the U.S. Postal Service (USPS) as first-class registered mail with a return receipt (USPS) 2020). The estimated per-shipment and annual mailing costs incurred by individual submitters are detailed in Table 3-6.

3.2.5 (D) Compile and Maintain the List of Products

Since TSCA section 12(b) information collection activity has been in place for over twenty years, most respondents will have already developed a list of their products subject to TSCA section 12(b) export notification. Respondents need only check for new regulations promulgated and any new products exported by the company. Updating the list is estimated to take an average of one hour of technical time, which may also include some proportion of legal time (EPA 2012). The total burden can vary from two hours per year up to two hours per month, depending on the number of products exported by the company and the number of their products subject to TSCA section 12(b) (EPA 2012).

The number of submitters per year who report under TSCA section 12(b) has varied over time, rising from around 160 in 1991 to over 460 in 2000, and declining since. In the most recent TSCA section

12(b) ICR, EPA estimated there would be approximately 240 submitters per year in near-future years (EPA 2012). Of these 240 submitters, EPA estimated that 160 companies were near the lower burden estimate of 2 hours per year, and 80 companies were near the upper estimate of 24 hours per year. Compiling the list for all respondents was therefore estimated to take 2,240 hours (2 hours × 160 firms plus 24 hours × 80 firms), or an average of about 9.3 hours of technical time per firm per year for 13 notifications per year (EPA 2012).

3.2.5 (E) Write or Revise Export Notification

Companies that export chemicals subject to TSCA section 12(b) reporting must prepare an export notification to send to EPA when export shipments are made. Time for initial preparation of the export notice may vary depending on whether the company has prior experience with this requirement. This step is estimated to take an average of one hour of technical time (which may also include some proportion of legal time) per firm per year for 13 notifications per year (EPA 2012).

3.2.5 (F) Check Orders and Send Notifications

Companies that export chemicals subject to TSCA section 12(b) reporting must check outgoing shipments against the list of their products described above. A form letter notifying EPA and providing the required data must be printed and mailed within the required time period. This process is estimated to take an average one half hour of clerical time per export notification or 6.5 hours for 13 notifications (EPA 2012).

Compile and Maintain the List of Products. Since TSCA section 12(b) information collection activity has been in place for twenty years, most respondents would have already developed a list of their products subject to TSCA section 12(b) export notification. Respondents need only check for new regulations promulgated and any new products exported by the company. Updating the list is estimated to take an average of one hour of technical time, which may also include some proportion of legal time (EPA 2012). The total burden can vary from two hours per year up to two hours per month, depending on the number of products exported by the company and the number of their products subject to TSCA section 12(b) (EPA 2012).

The number of submitters per year who report under TSCA section 12(b) has varied over time, rising from around 160 in 1991 to over 460 in 2000, and declining since. In the most recent TSCA section 12(b) ICR, EPA estimated that there would be approximately 240 submitters per year in near-future years (EPA 2012). Of these 240 submitters, EPA estimated that 160 companies were near the lower burden estimate of two hours per year, and 80 companies were near the upper estimate of 24 hours per year. Compiling the list for all respondents was therefore estimated to take 2,240 hours (2 hours x 160 firms plus 24 hours x 80 firms), or an average of about 9.3 hours of technical time per firm per year for 13 notifications per year (EPA 2012).

Write or Revise Export Notification. Companies that export chemicals subject to TSCA section 12(b) reporting must prepare an export notification to send to EPA when export shipments are made. Time for initial preparation of the export notice may vary depending on whether the company has prior experience with this requirement. This step is estimated to take an average of one hour of technical time (which may also include some proportion of legal time) per firm per year for 13 notifications per year (EPA 2012).

Check Orders and Send Notifications. Companies that export chemicals subject to TSCA section 12(b) reporting must check outgoing shipments against the list of their products described above. A form letter notifying EPA and providing the required data must be printed and mailed within the required time period. This process is estimated to take an average one half hour of clerical time per

export notification or 6.5 hours for 13 notifications (EPA 2012). The burdens and associated costs for each notification activity are provided in Table 3-7. EPA estimates that the burden associated with making one notification is approximately 1.36 hours and $106.

Table 3-7: TSCA 12(b) Export Notification Cost per Notification (2021$)

Cost Component	Technical Labor			Clerical Labor			Total	
	Wage Rate ($/Hr)	Burden (Hours)	Cost	Wage Rate ($/Hr)	Burden (Hours)	Cost	Hours	2021$
Compile list	$81.40	9.3	$757	--	--	--	9.3	$757
Write letter	$81.40	1	$81	--	--	--	1	$81
Check order and send notice	--	--	--	$37.18	6	$223	6	$223
Mailing cost[1]	--	--	--	--	--	--	--	$216
Total per facility[2]		10.30	$838.38		6.00	$223.06	16.30	$1,277.13
Total per notification		**0.86**	**$69.86**		**0.50**	**$18.59**	**1.36**	**$106.43**

Notes:
[1] Mailing costs reflect May 2020 USPS rates indexed to 2021 (see Appendix A.2).
[2]An average facility *submitting notifications* is assumed to submit 13 export notifications per year.
Sources:
Appendix A of this report derives technical and clerical hourly labor costs. Other costs are from *ICR No.: 0795.14 [Information Collection Request for] Notification of Chemical Exports - TSCA Section 12(b) Supporting Statement for Request for OMB Review under the Paperwork Reduction Act* (EPA 2012, p.10), and are updated to 2021 dollars.

3.3 Summary of per Submission Costs, by Option

The number of firms affected that do not make submissions to EPA (see Option 2 in Table 3-8) is not known; therefore, costs are not aggregated across the affected entities. The following table summarizes the per-company per-chemical costs to comply with the proposed rule, described in more detail in section 3.2 above.

Table 3-8: Compliance Options and Associated Costs Incurred by a Firm Due to the Proposed SNUR

Option[1]		Costs	Quantified Costs per Chemical (2021$)[2]
1.	Electronic submission of a SNUN, indicating to EPA that the firm would like to import the chemical as part of an article for a significant new use as defined in the SNUR.	Costs of submitting a SNUN, including rule familiarization, CDX registration (for companies that are first-time submitters), form completion, user fee, and any test costs.[3]	$517 rule familiarization cost; $26,737 submission cost (including SNUN recordkeeping under 40 CFR 721.40 and fee $19,020 for large businesses). Export notification costs are estimated at $106 per notification; total cost per company would vary. EPA usually receives well under ten SNUNs per year. First time submitters would incur $244 for CDX registration and associated activities.
2.	Do not manufacture (including import) or process the substances.	Cost of the profit foregone as a result of not engaging in the commercial activity originally planned (opportunity costs).	Opportunity costs are not quantified.

Note(s):

[1] Firms may be subject to both options at once since submission of a SNUN results in profits foregone as a result of not manufacturing (including importing) or processing the chemical.

[2] Quantified costs are attributable to the SNUR only if a firm would not otherwise follow the specified practices. Costs are detailed in Section 3.2.

[3] EPA does not require the development of chemical toxicity test data for submission of a SNUN, although a firm may submit test data already in its possession and/or describe any other available data. Because EPA does not require the development of test data, EPA assumes that no firms will incur testing costs as a result of the proposed SNUR.

3.4 Likelihood of SNUN Submission

This analysis assumes that few, if any, entities are expected to submit a SNUN. EPA has, over the years, promulgated SNURs that cover more than 1,000 chemicals. In response, the Agency receives only a handful of SNUNs per year. For example, the number of SNUNs received was 4 in Federal fiscal year (FY) 2005, 8 in FY2006, 6 in FY2007, 8 in FY2008, 7 in FY2009, 2 in FY2010, 10 in FY2011, 10 in FY2012, 11 in FY2013, 19 in FY2014, and 9 in FY2015.[7] In addition, as discussed in Chapter 1, all of the PFAS subject to this proposed rule were designated as "inactive" in U.S. commerce on the TSCA Chemical Substance Inventory under the 2016 amendments to TSCA. EPA designated firms as "active" or "inactive" based on industry reporting of chemicals manufactured (including imported) or processed in the U.S. over a 10-year period ending on June 21, 2016. Therefore, this suggests that it is unlikely a firm would submit a SNUN.

[7] In-person count of SNUNs conducted by Kimberly Wilson of Abt Associates Inc, on April 8, 2010, at EPA's Confidential Information Business Center (CBIC) and updated values for FY2010 and FY2011 provided by Lynne Blake-Hedges of U.S. EPA on September 1, 2011. Updated values for FY2012 through FY2015 provided by Stephanie Suazo of U.S. EPA on May 18, 2016.

3.5 Potential for Subsequent Regulatory Actions

The Agency recognizes that if submission of a SNUN does result from a SNUR, the Agency could take additional regulatory actions under TSCA. These additional regulatory actions following SNUN review might be necessary to further evaluate an intended new use and associated activities, or to prohibit or limit that activity before it occurs to prevent unreasonable risk of injury to human health or the environment, including an unreasonable risk to a potentially exposed or susceptible subpopulation. It is not known what specific subsequent regulatory actions, if any, the Agency may determine are necessary after reviewing a SNUN. Any such actions are highly dependent on the circumstances surrounding the individual SNUN (e.g., available information and scientific understanding about the chemical and its risks at the time the SNUN is being reviewed).

Should the Agency's review of the SNUN result in further regulatory actions, the Agency will initiate and follow the appropriate procedures for taking those actions. Included in those procedures will be an assessment of the costs and benefits of those actions.

4. Agency Costs

This SNUR is expected to generate Agency costs for both SNUN review and processing, and export notification processing. Because it is unknown how many SNUNs and export notifications will be submitted as a result of this rulemaking, all Agency costs are estimated at the per-case level and are not aggregated to estimate the total Agency burden. Section 4.1 describes the burden to the Agency of reviewing and processing a single SNUN submission. Section 4.2 derives the Agency burden of processing and reviewing export notifications.

4.1 SNUN Processing Costs

EPA's cost to review and process SNUN submissions is assumed to be represented by its costs for a larger category of similar TSCA section 5 notices that includes SNUNs. EPA estimated its total annual costs for processing, reviewing, and making determinations under TSCA section 5 between fiscal years 2019 and 2021. EPA estimated its direct and indirect costs for reviewing PMNs, SNUNs, and Microbial Commercial Activity Notices (MCANs) to be $18,934,659 (2016$) per year during this period, and assumed that an average of 462 PMNs, SNUNs, and MCANs will be submitted per year.[8] This yields an average Agency cost of approximately $41,000 apiece for reviewing and processing PMNs, SNUNs and MCANs in $2016.[9] Thus, as shown in Table 4-1, after indexing to $2021, processing and reviewing any SNUNs submitted due to this SNUR is expected to cost EPA approximately $46,000 (2021$).[10]

Table 4-1: Agency Cost per SNUN

Total Annual Agency Cost for PMN/SNUN/MCAN Review (2016$)	Average Number of Annual PMN, SNUN, and MCAN Submissions	Agency Cost per SNUN (2021$)
$18,933,659	462	$46,000

Source(s):
Table 9 - Annual Section 5 PMN/SNUN/MCAN Cost Estimates. EO 12866 Documentation; Draft Submitted to OMB – Technical Background Document (RIN 2070-AK27; Proposed Rule. EPA-HQ-OPPT-2016-0401-0020. https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0401-0020.

Note(s):
Agency costs are comprised of both pay and nonpay (i.e., contract) dollars. Costs are inflated to 2021$ using the U.S. Bureau of Labor Statistics Employment Cost Index – Total Compensation: Professional and Related Private Industry, Not Seasonally Adjusted. (Series ID: CIU2010000120000I (B)) (see Appendix A).

[8] Table 9 - Annual Section 5 PMN/SNUN/MCAN Cost Estimates. *EO 12866 Documentation; Draft Submitted to OMB – Technical Background Document (RIN 2070-AK27; Proposed Rule*. EPA-HQ-OPPT-2016-0401-0020. https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0401-0020.

[9] This $41,000 review cost is lower than the overall average cost of $55,200 for TSCA section 5 activities that EPA calculated for the 2018 proposed fees rule because the $55,200 value includes costs for activities (such as issuing SNURs following a PMN review and reviewing Notices of Commencement) that are not relevant to SNUNs.

[10] Agency costs are comprised of both pay and nonpay (i.e., contract) dollars. Costs are inflated to 2021$ using the U.S. Bureau of Labor Statistics *Employment Cost Index – Total Compensation: Professional and Related Private Industry, Not Seasonally Adjusted. (Series ID: CIU2010000120000I (B))* (see Appendix A).

4.2 Export Notification Cost

Under TSCA section 12(b), exporters must notify EPA if they intend to export chemicals subject to SNURs, as described in Section 3.2.5. The Agency burden and cost due to TSCA section 12(b) export notification result from three tasks. In the first task, EPA receives export notifications from companies that intend to export one of the chemicals subject to TSCA section 12(b) (EPA 2012). In the second task, EPA staff prepares separate notification letters that are subsequently reviewed and delivered to importing countries, their embassies, or representatives, and to the importing country's U.S. embassies (EPA 2012). (See Table 3-7 for the cost of mailing one notification). The third task is comprised of EPA staff responses to public inquiries and other TSCA section 12(b) activities. The work of responding to non-routine requests for information and clarification from industry and importing countries, and of handling other tasks associated with the TSCA section 12(b) program, was estimated to require roughly 400 hours per year (EPA 2012). Since the current rulemaking covers only a very small percent of the chemicals subject to TSCA section 12(b) reporting, a very small percent of such activity would be attributable to the current rulemaking.

Because it is unknown how many, if any, notifications EPA would receive or send as a result of the current rulemaking, the costs to the Agency are presented per activity. The estimated burden for the first two Agency activities is provided in Table 4-2. To estimate the Agency cost, hourly burdens are multiplied by the loaded wage rate of a GS-13, Step 5, which is derived in Appendix A.

Table 4-2: TSCA 12(b) Export Notification Cost: Agency Burden per Activity (2021$)

Agency Activity	Hours per Activity	FTE per Activity[1]	Loaded GS-13, Step 5 FTE Wage Rate	Mailing Cost	Total Agency Cost per Activity
	(a)	(b) = (a)/2,087	(c)	(d)	(e) = ((b)*(c))+(d)
Process notices from companies	0.1	0.00005	$230,361	$0.00	$11.08
Process notices to importing countries	0.5	0.000240385	$230,361	$16.59	$71.97

Notes:
[1] The burden associated with an Agency activity is the burden for the Agency to process one incoming notification, or to prepare and mail an outgoing notification
Sources:
Appendix A of this report derives Agency labor costs. Mailing costs are from Table 3-6 of this report. Other burdens are from ICR No.: 0795.14 [Information Collection Request for] Notification of Chemical Exports - TSCA Section 12(b) Supporting Statement for Request for OMB Review under the Paperwork Reduction Act (EPA 2012), updated for inflation.

5. Benefits

A SNUN submission provides EPA with the opportunity to evaluate the intended use and, if necessary, to prohibit or limit that activity before it occurs. It allows the Agency to take immediate action to mitigate an activity that the Agency deems harmful to the environment or human health. The proposed SNUR allows EPA to designate as significant new uses those uses that impact exposure to the subject chemicals and allows the Agency the opportunity to review potential risks associated with any significant new use.

PFAS are synthetic organic compounds that do not occur naturally in the environment. The strong carbon-fluorine bonds of PFAS make them resistant to degradation and thus highly persistent in the environment (EPA 2019b; EPA 2017). Many PFAS are highly stable, water- and oil-resistant, and exhibit other properties that make them useful in a variety of industrial applications, but also make them persistent in the environment. Some of these chemicals have been used for decades in a wide variety of consumer and industrial products (EPA 2019b). Some PFAS have been detected at high levels in wildlife, including higher trophic organisms, indicating that at least some PFAS have the ability to bioaccumulate (EPA 2017). Some PFAS can accumulate in humans and remain in the human body for long periods of time (e.g. months to years) (EPA 2019b; EPA 2017; EPA 2009c). According to the United States Department of Health and Human Services, Agency for Toxic Substances and Disease Registry (ATSDR), the persistence and mobility of some PFAS, combined with decades of widespread use, have resulted in their presence in surface water, groundwater, drinking water, rainwater, soil, sediment, ice caps, outdoor and indoor air, plants, animal tissue, and human blood serum across the globe. Because of the widespread use of PFAS in commerce and their tendency to persist in the environment, most people in the United States have been exposed to PFAS (EPA 2019b). Exposure to certain PFAS can lead to adverse human health impacts. Research suggests that high levels of certain PFAS may lead to increased cholesterol levels, changes in liver enzymes, small decreases in infant birth weights, decreased vaccine response in children, increased risk of high blood pressure or pre-eclampsia in pregnant women, and increased risk of kidney or testicular cancer (ATSDR 2021).The proposed SNUR initiates EPA's evaluation of the conditions of use associated with the intended new use within the applicable review period. Manufacture and processing for the significant new use is prohibited from commencing until EPA has conducted a review of the notice, made an appropriate determination on the notice, and taken such actions as are required in association with that determination. EPA also expects that the proposed rule may restrict future uses or exposure to the chemicals, as a company may choose to modify planned uses in such a way that does not trigger a SNUN as opposed to submitting a SNUN.

6. Additional Analyses

6.1 Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) (5 U.S.C. 601 et. seq.), as amended by the Small Business Regulatory Enforcement Fairness Act, requires regulators to consider the impact of regulations on small entities, in particular small businesses. The requirement to submit a SNUN applies to any person (including small or large entities) who intends to engage in any activity described in the rule as a significant new use. Where a use is new, by definition no small or large entities presently engage in such activities. Although some small entities may decide to manufacture or process a substance for the new use after the SNUR is promulgated, EPA receives very few SNUNs, and few of those are submitted by small entities. In response to the promulgation of SNURs covering over 1,000 chemical substances, the Agency receives only a handful of SNUNs per year. For example, the number of SNUNs was four in Federal fiscal year 2005, eight in FY2006, six in FY2007, eight in FY2008, seven in FY2009, two in 2010, and ten in 2011 (EPA 2012), for an average of 6 per year from all SNURs. EPA has no reason to believe that this SNUR would alter the pattern of SNUN submissions that EPA has historically seen. In addition, the estimated reporting cost for submission of a SNUN is minimal regardless of the size of the firm, averaging about $26,737 including SNUN recordkeeping and reporting costs. The Agency currently offers some relief to qualifying small businesses, as defined at 13 CFR 121.201, by reducing the SNUN submission fee from $19,020 to $3,300. This lower fee reduces the cost of submitting a SNUN to about $11,047 for smaller firms. During the six-year period from 2005 to 2010, only three submitters self-identified as small in their SNUN submission[11] (EPA 2012). EPA believes the cost of submitting a SNUN is relatively small compared the cost of developing and marketing a chemical new to firm and that the requirement to submit a SNUN generally does not have a significant economic impact.

In response to a SNUR, firms could also decide to request an equivalency determination or a request for SNUR modification or revocation. The submission cost for these requests is about $7,717. EPA believes this cost to be low compared to the cost of developing and marketing a chemical new to the firm. The expected number of requests is also expected to be small. In general, EPA receives from zero to three modification/revocation requests per year due to SNURs; therefore, it is unlikely that a substantial number of small entities would be affected.

6.2 Unfunded Mandates Reform Act (UMRA)

The proposed rule does not impose any enforceable duty, contain any unfunded mandate, or otherwise have any effect on small governments because none of the current producers of the subject chemicals are governments. Additionally, it is not expected that any governments will initiate production of these chemicals.

6.3 Paperwork Reduction Act (PRA)

According to the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 et seq., an Agency may not conduct or sponsor, and a person is not required to respond to a collection of information that requires approval by the Office of Management and Budget (OMB) under the PRA, unless it has been approved by OMB and displays a currently valid OMB Control number. The OMB control numbers for EPA's regulations in title 40 of the CFR, after appearing in the *Federal Register*, are listed in 40

[11] The three “small” submitters were identified by review of actual SNUN submissions from the years 2005-2010.

CFR, part 9, and included on the related collection instrument, or form, if applicable. The information collection requirements related to this action have already been approved by OMB pursuant to the PRA under OMB control numbers 2070-0038 (EPA ICR No. 1188) and 2070-0030 (EPA ICR No. 0795).

If an entity were to submit a SNUN to the Agency, the annual burden is estimated to average 98.2 hours per response: 0.82 hours for rule familiarization (Section 3.2.1), 2.80 hours for CDX registration, CDX electronic signature, and pay.gov account setup (Section 3.2.2), 92.2 hours for form completion, submission and recordkeeping under 40 CFR 721.40 (Sections 3.2.3), and 1 hour for consumer notifications (Section 3.2.6). The burdens for rule familiarization, CDX registration, CDX electronic signature, pay.gov account setup form completion, submission, and recordkeeping consumer notifications are approved under EPA ICR No. 1188 (OMB control number 2070-0038). The burden for export notification is approved under EPA ICR No. 0795 (OMB control number 2070-0030).

6.4 Executive Order 13132, Federalism

Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999), requires EPA to develop an accountable process to ensure "meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications." Policies that have federalism implications are defined in the Executive Order to include regulations that have "substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government" (64 FR 43255, August 10, 1999).

The proposed rule establishes reporting and recordkeeping requirements that apply to manufacturers (including importers) and processors of certain chemicals. EPA has no information to indicate that any state or local government manufactures or processes the chemical substances covered by this action.

6.5 Executive Order 12898, Environmental Justice

Executive Order 12898 (59 FR 7629, February 16, 1994) directs federal agencies, to the greatest extent practicable and permitted by law, to make environmental justice part of their mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of their programs, policies, and activities on minority populations (people of color and/or Indigenous peoples) and low-income populations.

EPA believes that the human health and environmental conditions that exist prior to this action do not result in disproportionate and adverse effects on people of color, low-income populations, and/or Indigenous peoples because the Agency believes that the inactive PFAS included in this action are no longer being manufactured (including imported) or processed for any uses in the United States.

EPA believes that it is not practicable to assess whether this action is likely to result in new disproportionate and adverse effects on people of color, low-income populations and/or Indigenous peoples because the Agency is not able anticipate which chemical substances and uses, if any, will be submitted for a significant new use notice under this action.

6.6 Executive Order 13045, Protection of Children

Executive Order 13045, *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997), requires EPA to identify and assess environmental health and safety risks that may disproportionately affect children. This type of analysis is required for rules that would have an impact of $100 million or more only. The impact of this SNUR will be less than $100 million and therefore no analysis of such impacts on children is required.

6.7 Executive Order 13175, Tribal Governments

Executive Order 13175 is *Consultation and Coordination with Indian Tribal Governments* (59 FR 22951, November 6, 2000). This rule does not have Tribal implications because EPA has no information to indicate that any tribal government manufactures or processes the chemical substances covered by this action.

6.8 Executive Order 13211, Energy Supply, Distribution, or Use

This rule is not subject to Executive Order 13211, entitled *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001), because this action is not expected to affect energy supply, distribution, or use.

6.9 Executive Order 13563, Improving Regulation and Regulatory Review

Executive Order 13563, *Improving Regulation and Regulatory Review* (76 FR 3821, January 21, 2011), requires EPA to base regulations on the best available science, allow for public participation and the open exchange of ideas, promote predictability and reduce uncertainty, identify and use the best, most innovative, and least burdensome tools for achieving regulatory ends, consider both the costs and benefits qualitatively and quantitatively and ensure regulations are accessible, consistent, written in plain language, and easy to understand.

The proposed rule establishes reporting and recordkeeping requirements that apply to manufacturers (including importers) of certain chemicals. Consistent with EO 13563, this document qualitatively and quantitatively describes both the costs and benefits of the proposed rule as well as the underlying data used in the analyses. EPA chose the best available data to analyze the costs and benefits described in this document and the best analytic approaches given the available data and other constraints.

Appendix A: Wage Rate Calculations

This appendix describes the derivation of the fully loaded labor rates and inflation factors used in calculating costs of labor, materials, and other inputs. Costs presented in this report are in 2021 dollars.

A.1 Derivation of Loaded Wage Rates

Unit labor costs are calculated by adding fringe benefits and overhead to the wage or salary to derive a fully loaded labor cost. The basic method is described in *Wage Rates for Economic Analysis of the Toxics Release Inventory Program* (EPA 2002). The resulting loaded labor rates are given in Table A-1. Costs are calculated for several labor categories: Managerial, Professional/Technical, Clerical, and EPA staff.

In March 2004, BLS began using the North American Industry Classification System (NAICS) codes instead of the Standard Industrial Classification (SIC) System, and the Standard Occupational Classification (SOC) system instead of the Occupational Classification System (OCS). The following table shows the crosswalk between old and new occupational titles.

Table A-1: Labor Category Crosswalk

EPAB Reports Labor Category	BLS Old Title (OCS)	BLS New Title (SOC)
Managerial	Executive, administrative, and managerial	Management, business, and financial
Professional/Technical	Professional specialty and technical	Professional and related
Clerical	Administrative support, including clerical	Office and administrative support

Source(s):
Employer Costs for Employee Compensation: Changes to NAICS and SOC, Table 2. ECEC Occupational Comparability between SOC and OCS (BLS 2006; Weinstein & Loewenstein 2004).

A.1.1 Derivation of Labor Rates for Managerial, Professional/Technical, and Clerical Labor

Wages and fringe benefits for managerial, professional/technical, and clerical labor were taken from the Bureau of Labor Statistics (BLS) *Employer Costs for Employee Compensation* (ECEC) data,[12] for December 2021, for manufacturing industries.[13]

[12] This follows the approach introduced in *Economic Analysis of Expedited Significant New Use Rules for 65 Chemical Substances: EPA Docket OPPT-2003-0063* (EPA 2007b).

[13] *Employer Costs for Employee Compensation Supplementary Tables December 2019, US Bureau of Labor Statistics (U.S. Bureau of Labor Statistics (BLS) 2020a*). This follows the approach introduced in EPA (2007b). Earlier PMN SNUR economic analyses, such as EPA, 2003, used ECEC data for "All Goods Producing" sectors (manufacturing, mining, and construction). However, the manufacturing sector data seem more relevant since the SNURs mainly affect the chemicals industry.

The cost of fringe benefits such as paid leave and insurance, specific to each labor category, are taken from the same ECEC series. Fringe benefits as a percent of wages are calculated separately for each labor category.[14]

An overhead rate of 20% is used based on assumptions in Handbook on Valuing Changes in Time Use Induced by Regulatory Requirements and Other U.S. EPA Actions (U.S. Environmental Protection Agency (EPA) 2020a). This overhead loading factor is added to the benefits loading factor, and the total is then applied to the base wage to derive the fully loaded wage.

Fully loaded costs for managerial and clerical labor are calculated in a similar manner, as shown in Table A-2.

A.1.2 Derivation of Labor Rates for EPA Staff

Agency labor costs are calculated based on annual Federal salaries for the Washington-Baltimore area published by the Office of Personnel Management (U.S. Office of Personnel Management 2019). The average salary for one FTE staff member is estimated as the salary for a GS-13 Step 5 employee.[15]

To calculate the loaded agency wages, it was assumed that fringe benefits are 63.9% of wages (as seen in Table B-1: $56.31 x .639 = $35.98) (Falk 2012).

An overhead rate of 20% is used based on assumptions in Handbook on Valuing Changes in Time Use Induced by Regulatory Requirements and Other U.S. EPA Actions (EPA 2020a). This overhead loading factor is added to the benefits loading factor, and the total is then applied to the base wage to derive the fully loaded wage.

[14] This follows terminology introduced in EPA (2007b). Earlier SNUR economic analyses used the term "technical" labor. Here the category is called "professional/technical" labor, to make clear how it relates to BLS categories. In 2004, BLS changed from the Occupational Classification System, OCS, to the Standard Occupational Classification system, SOC. In the process, the "Professional specialty and technical" category became the "Professional and related" category. However, the coverage of the old and new occupational groups is approximately the same. See the BLS article, C*omparing Current and Former Industry and Occupation ECEC Series* (Weinstein & Loewenstein 2004).

[15] The GS-13 Step 5 is consistent with ICR No. 0574.14 (12/18/2007), which covers PMN SNURs. Use of this grade level follows the approach introduced in EPA (2007b). That report represented a change from the earlier PMN SNUR economic analysis (EPA 2003), which used an average of GS-12 Step 1 and GS-12 Step 10 salaries.

Table A-2: Derivation of Loaded Wage Rates ($2021)

EPAB Labor Category	Data Source	Date (mm/yy)	Wage	Fringe Benefit	Total Comp.	Over-head % Total Comp.[1]	Over-head	Loaded Wages[2]
			(a)	(b)	(c)= (a)+(b)	(d)=(c)* (d)	(f)=(c)+(e)	(a)
Managerial	BLS *ECEC*, Private Manufacturing industries, "Mgt, Business, and Financial"[3]	12/21	$53.49	$24.16	$77.65	20%	$15.53	$93.18
Professional/ Technical	BLS *ECEC*, Private Manufacturing industries, "Professional and related"[3]	12/21	$44.99	$22.84	$67.83	20%	$13.57	$81.40
Clerical	BLS *ECEC*, Private Manufacturing industries, "Office and Administrative Support"[3]	12/21	$21.48	$9.50	$30.98	20%	$6.20	$37.18
EPA Staff FTE	Annual Federal staff cost: OPM Washington-Baltimore-Northern Virginia, DC-MD-PA-VA-WV, area, GS-13 Step 5 pay rates[4]	$56.31	$35.98	$92.29	20%	$18.46	$110.75	$56.31

Note(s):

[1]Wage data are rounded to the closest penny; however, unrounded values were used in calculations.

[2] An overhead rate of 20% is used based on assumptions in Handbook on Valuing Changes in Time Use Induced by Regulatory Requirements and Other U.S. EPA Actions (U.S. Environmental Protection Agency (EPA) 2020a).

[3] Bureau of Labor Statistics (BLS) 2021

[4] Agency labor costs are calculated based on annual Federal salaries for the Washington-Baltimore area published by the Office of Personnel Management (U.S. Office of Personnel Management 2019). Fringe as percent of wage is 63.9% in accordance with Falk 2012.

A.2 Derivation of Inflation Factors

Detailed information on the derivation of the inflation factors used is presented in Table A-3. In 2006, the Bureau of Labor Statistics (BLS) made several changes to the Employment Cost Index. The changes are described on a BLS web page, "Change has come to the ECI," (BLS 2006a) and in several April 2006 *Monthly Labor Review* articles posted on the BLS web site: "Changes affecting the Employment Cost Index: an overview" (Caroll 2006); "Employment Cost Index Publication Plans"

(Sleemi 2006); and "Seasonal adjustment in the ECI and the conversion to NAICS and SOC" (Branch & Mason 2006).

Under a mandate from OMB, BLS changed its classification of industries and occupations from the Standard Industrial Classification (SIC) and Occupational Classification System (OCS) to the North American Industry Classification System (NAICS) and Standard Occupational Classification (SOC) system. In 2006, BLS adjusted all ECI series to reflect this change.

In addition to changing the industry and occupational classification systems, in 2006, BLS rebased the ECI from June 1989 = 100 to December 2005 = 100 for *all* current and historical non-seasonally adjusted series, including the NAICS and SIC based series. (Seasonally adjusted indices, including those in Table A-3 of this report, may not exactly equal 100 for December 2005 as a result of the seasonal adjustment. Seasonal adjustments are explained in Branch and Mason (2006).)

According to BLS, the official ECI for the years 1975-2005 is the SIC-OCS based series, and for subsequent years, the official ECI is the NAICS-SOC based series (Sleemi 2006, p.8).[16]

"Starting year" indices in Table A-3 continue to be SIC-OCS based. Current year indices are NAICS-SOC based. We use indices from both the NAICS-SOC and the SIC-OCS based ECI series because neither series spans the entire period over which testing and other costs need to be inflated.

[16] BLS has been publishing the NAICS-SOC based ECI series since March 2001 and it became official in March 2006. The SIC-OCS based series and NAICS-SOC series have different series ID numbers, even when they describe essentially the same population. For example, the series ID for seasonally adjusted total compensation for all private industry workers is ECS10002I for the SIC-OCS series and CIS20100000000000I for the NAICS-SOC series.

Table A-3: Derivation of Inflation Factors

Item	Inflation Index Source[1]	Starting Year	Index for Starting Year (a)	Index for 2021 (b)	Inflation Factor[2] (b)/(a)
Agency costs	BLS ECI, Total comp, Private industry, **Professional and related**, 4th Q (U.S. Bureau of Labor Statistics (BLS) 2020b) [3]	2016	126.7	143.4	1.132
Registered Mail and Return Receipt Costs	BLS ECI, Total comp, Private industry, **Professional and related**, 4th Q (U.S. Bureau of Labor Statistics (BLS) 2020b) [3]	2020	138.4	143.4	1.036
Stamp and Envelope Prices	BLS ECI, Total comp, Private industry, **Professional and related**, 4th Q (U.S. Bureau of Labor Statistics (BLS) 2020b) [3]	2019	135.1	143.4	1.061

Key: BLS = Bureau of Labor Statistics. CPI = Consumer Price Index. ECI = Employment Cost Index. SA = Seasonally Adjusted. Total Comp = Total Compensation (wages/salaries and benefits). 4th Q = Fourth Quarter.

Notes:

[1] In 2006, Bureau of Labor Statistics (BLS) Employment Cost Index (ECI) series "were rebased to December 2005 = 100 from June 1989 = 100." The change is reflected in the indices in this table and explained on the BLS website, *Employment Cost Index News Release Text: Employment Cost Index, March 2006* (BLS 2006b). The Consumer Price Index (CPI) was not rebased. "Starting year" ECI indices are SIC-OCS based: Seasonally Adjusted (SA) ECS10002I for private industry All Workers, and not SA ECU11122I for private industry professional and Related Workers. After 2006, ECI indices are NAICS-SOC based: Seasonally Adjusted (SA) CIS2010000000000I for private industry All Workers, and not SA CIU2010000120000I (B) for private industry Professional, and Related workers (U.S. Bureau of Labor Statistics (BLS) 2020b).

[2] Inflation factors are rounded; however, unrounded values were used in calculations.

[3] Beginning with the report Economic Analysis of Expedited Significant New Use Rules for 25 Chemical Substances: EPA Docket OPPT-2009-0922 (EPA 2011) we began to use the not-seasonally adjusted CIU2010000120000I for private industry Professional, and Related workers, instead of SA CIS2010000W00000I for private industry white collar workers because BLS retired the "white-collar" series.

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