

OMB Control Number 2070-0173; EPA ICR Number 2327.02

New Information Collection Activities for Electronic Submissions under TSCA Section 5

Appendix 1

Impact Analysis of the Final TSCA Section 5 Premanufacture and Significant New Use Notification Electronic Reporting Rule [RIN 2070-AJ41] on Paperwork Burdens Approved under Existing EPA ICRs

TABLE OF CONTENTS

1.0	Introduction.....	1
1.1	Terminology.....	1
1.1.1	Company-level Burden.....	1
1.1.2	Form-level Burden.....	1
1.2	Assumptions.....	2
1.2.1	Respondents.....	2
1.2.2	Number and Types of TSCA Section 5 Notices Submitted Under New Chemicals Program.....	2
1.2.3	Number and Types of Significant New Use Notices Submitted Under Existing Chemicals Program.....	3
2.0	Impacts of e-PMN Final Rule on New Chemicals Program Burdens (OMB Control No. 2070-0012).....	4
2.1	Adjustments to the Baseline Number of Responses.....	4
2.1.1	Impact of Adjusted Baseline Number of Responses on Reporting Burden....	4
2.1.2	Impact of Adjusted Baseline Number of Responses on Recordkeeping Burden	4
2.1.3	Summary Burden Impact of Baseline Response Adjustments.....	5
2.2	Reporting Burden Program Changes.....	6
2.2.1	New Company-Level Reporting Burdens.....	6
2.2.2	Reductions in Form-Level Reporting Burden for New Chemicals Submissions.....	6
2.3	New Chemicals Recordkeeping Burden Program Changes.....	10
2.3.1	Reductions in Form-Level Recordkeeping Burden for New Chemicals Submissions.....	11
2.4	Summary Burden Impact of Rule-Related Program Changes.....	16
2.5	Net Burden Decrease - New Chemicals Program.....	16
3.0	Impacts of e-PMN Final Rule on Existing Chemicals Program Burdens (OMB Control No. 2070-0038).....	16
3.1	Adjustments to the Baseline Reporting and Recordkeeping Estimates for Existing Chemical SNUNs.....	16
3.1.1	Impact of Adjusted Baseline Reporting and Recordkeeping Estimates.....	17
3.2	Reporting Burden Program Changes.....	19
3.2.1	New Company-Level Reporting Burdens.....	19
3.2.2	Reductions in Form-Level Reporting Burden for Existing Chemical SNUN Submissions.....	19
3.3	Existing Chemicals Recordkeeping Burden Program Changes.....	22
3.4	Summary Burden Impact of Rule-Related Program Changes.....	23
3.5	Net Burden Decrease - Existing Chemicals Program.....	23
4.0	Summary of Net Changes to Annual Paperwork Burden Estimates.....	24
4.1	Adjustments.....	24
4.1.1	Fewer New Chemicals Responses.....	24
4.1.2	Harmonized SNUN Reporting and Recordkeeping Burden Estimates.....	24
4.2	Program Changes.....	25
4.2.1	Modest Rule Implementation Burden.....	25
4.2.2	Resulting Burden Reduction.....	25
4.3	Net Changes.....	25

1.0 Introduction

This appendix analyzes the expected impact of the final TSCA Section 5 Premanufacture and Significant New Use Notification Electronic Reporting Rule [RIN 2070-AJ41] on the paperwork burden associated with the following existing approved ICRs:

- Pre-Manufacture Review Reporting and Exemption Requirements for New Chemical Substances and Significant New Use Reporting Requirements for Chemical Substances (OMB Control No. 2070-0012)
- TSCA Section 5(a)(2) Significant New Use Rules for Existing Chemicals (OMB Control No. 2070-0038).

The two ICRs have some similar information collection components; this appendix describes certain baseline adjustments made for consistency between burden estimates. In addition, this appendix also describes the program change-related burden increases and reductions that are the expected outcome of implementing the e-PMN rule.

1.1 Terminology

1.1.1 Company-level Burden

Company-level burden includes those activities that facilitate submission of an e-PMN: CDX registration, CDX electronic signature (i.e., authentication of identity and verification of authorization), setting up a Pay.gov account, and rule familiarization. All activities performed at the company-level occur only once during the first year that an activity is undertaken. Rule familiarization, for example, will be incurred by all companies during the first year following promulgation of the e-PMN rule, regardless of whether the e-PMN is submitted via paper, optical disc, or CDX. In addition, companies that submit section 5 notices for the first time in subsequent years will incur rule familiarization burden the first year they submit a section 5 notice. Those companies that submit e-PMNs again in subsequent years do not incur a subsequent rule familiarization burden. All other company-level activities, while they are incurred only once, will be incurred in the year in which the company adopts electronic reporting via CDX.

1.1.2 Form-level Burden

Form-level burden includes form completion, recordkeeping, and postage. As a result of the e-PMN rule, submitters will experience a reduction in form-level burden due to the efficiencies and reduced time associated with using the new e-PMN software to fill out section 5 notices and using CDX to submit these notices. All form-level burden savings are expected to be realized each time a section 5 notice is submitted. Recordkeeping and postage savings will be realized in years when electronic reporting via CDX is used. However, because all notices must be generated using the new e-PMN software beginning in the first year following rule promulgation, form completion burden saving will be realized by all submitters immediately.

1.2 Assumptions

1.2.1 Respondents

This information collection affects companies that manufacture, process or import chemical substances. These companies are typically found in NAICS major groups 325 (Chemical Manufacture) and 324 (Petroleum and Coal Products). EPA estimates that there are 305 respondent companies that will submit TSCA section 5 notices to EPA. The Agency estimates 295 respondents under the New Chemicals Program and an additional 10 respondents under the Existing Chemicals Program.

Burden and cost calculations are based on the assumption that EPA will receive an annual average of 2,135 TSCA section 5 notices under the New Chemicals program and 10 TSCA significant new use notices (SNUNs) under Existing Chemicals program. The estimated number of notices that will be submitted under the New Chemicals program is derived by averaging the number of notices received in years 2003 through 2007 for each of the submission types listed in the paragraph above, adjusting these averages by 15 percent to reflect only valid submissions and then summing these averages (See Table 1).

Table 1
Universe of Affected Entities and Forms (on an annual basis)

Based on Average Submissions between 2003 and 2007

Number of Companies	305
Number of Companies (PMNs ONLY)	200
Average Number of Notices per Company	5.3
Average Number of PMNs per Company	3.6
Number of PMNs	720
Number of SNUNs - New Chemicals	8
Number of SNUNs - Existing Chemicals	10
Number of MCANs	3
Number of TMEAs	8
Number of LVE/LoREXs	419
Number of TERAs	2
Number of Tier I / IIs	3
Number of 5e Tests	12
Number of NOCs	443
% of Companies that are New in Subsequent Years	25%

1.2.2 Number and Types of TSCA Section 5 Notices Submitted Under New Chemicals Program

The number of notices that EPA expects to be submitted each year is typically estimated by averaging the number of each type of submission received over the past three years according to data provided in the *OPPT New Chemicals Annual Report* (EPA, 2006) and adjusting it by 15 percent to reflect only valid submissions. However, for this ICR, the numbers of notices were

averaged for the past five years (2003 through 2007) to provide a longer term picture of section 5 activity as part of the economic analysis for the e-PMN rule (EPA, 2009.) This change in method of determining the average annual number of responses has resulted in baseline burden adjustments, as described in section 2 of this appendix, for which EPA has accounted prior to analyzing the impact of the final rule on the overall reporting and recordkeeping burden

Prior to the 1995 amendments to the PMN rule, 70 to 80 percent of all TSCA section 5 notices were full PMN submissions. From 1995 through 2003, the increase in exemptions did not significantly change this distribution. However, since 2003, full PMN submissions accounted on average for approximately 60 percent of all TSCA section 5 submissions. EPA expects few persons to submit significant new use notices (SNUNs). The number of SNUNs submitted is a function of the number of chemicals regulated under Significant New Use Rules (SNURs), which are relatively few. Based on the average number of SNUNs received annually during the last five years, the Agency expects to receive approximately eight SNUNs annually.

The amendments also placed stricter control on bona fide notices, which are intended to establish bona fide intent on the part of the submitter to manufacture or import a chemical substance. These controls were established in response to the steadily increasing number of bona fide notices submitted to EPA. The amendments have caused a significant reduction in bona fide submissions. Historical EPA data suggests that EPA should expect 116 bona fide notices to be submitted annually.

On average, EPA expects LVE and LoREX exemptions to account for approximately 419 notices annually. TMEs are expected to average eight applications per year, or less than one percent of all TSCA section 5 notices. NOCs are expected to account for 443 notices annually, while correction requests are expected to account for nine notices annually, or less than one percent of all TSCA section 5 notices (EPA, 2006, and EPA, 2009).

The various exemptions available to submitters since the 1995 PMN amendments have reduced significantly the need for consent order development and post-notice data review. Historical EPA data indicate that such consent orders and post-notice data reviews will account for roughly two percent of the total TSCA section 5 notices. Based on historical data, EPA estimates 28 cases will be subject to TSCA section 5(e) consent order restrictions burden, with 12 cases requiring test data, and 16 non-testing TSCA section 5(e) cases. Testing is usually contracted out to a laboratory, thus the burden associated with testing requirements represents the time that personnel from the submitting firm will spend overseeing the testing, assumed to be 25 percent of the lab burden.

1.2.3 Number and Types of Significant New Use Notices Submitted Under Existing Chemicals Program

As explained in EPA ICR No. 1188.09 (OMB Control No. 2070-0038), EPA estimates that it will receive 10 SNUNs per year under TSCA Section 5(a)(2) during the three-year period covered by this ICR (see Table 2).

Table 2
Anticipated Number of SNURs and SNUNs
Under The Existing Chemicals Program

Year	Anticipated Number of SNURs	Anticipated Number of SNUNs
First Year	5	10
Second Year	5	10
Third Year	5	10
Three Year Totals	15	30

2.0 Impacts of e-PMN Final Rule on New Chemicals Program Burdens (OMB Control No. 2070-0012)

2.1 Adjustments to the Baseline Number of Responses

As mentioned in section 1.2.2 of this appendix, EPA utilized a somewhat different approach to project the number of new chemicals respondents and responses for this burden analysis than was used for the same projection in the ICR currently approved under OMB Control No. 2070-0012. For this analysis, EPA considered the average number of responses submitted annually over a 5-year period and adjusted the annual average by 15 percent to count only valid submissions. Previously, EPA had traditionally based its projections on the number of responses submitted in each of the previous 3 years. This change in calculation led EPA to estimate that 203 fewer net responses would be submitted annually across all types of activities covered under this ICR. The reduction in the number of baseline responses will impact the baseline annual burden estimate of 148,803 hours (143,450 reporting hours + 4,633 recordkeeping hours) currently approved under EPA ICR No. 0574.13.

2.1.1 Impact of Adjusted Baseline Number of Responses on Reporting Burden

With a projected 203 fewer annual responses, EPA estimates a net reporting burden decrease of 14,289 hours (an adjustment) over the current reporting burden baseline projections for each activity in the ICR currently approved under OMB Control No. 2070-0012. A break out of the projected change in number of responses by type of submission, as well as the resulting change in reporting burden, is provided in Table 3.

2.1.2 Impact of Adjusted Baseline Number of Responses on Recordkeeping Burden

Similarly, EPA estimates a net recordkeeping burden decrease of 345 hours (an adjustment) over the current recordkeeping burden baseline projections for each activity in the ICR currently approved under OMB Control No. 2070-0012 as a result of a projected 203 fewer

annual responses. A break out of the projected change in number of responses by type of submission, as well as the resulting change in recordkeeping burden, is provided in Table 4.

**Table 3
New Chemicals Baseline Reporting Burden Adjustments by IC**

EXISTING Information Collection	Adjustments - Reporting		
	Change in Number of Annual Responses	Burden Hours per Response	Burden Hours per Year
Premanufacture Notification	-85	105	-8,925
PMN-related Significant New Use Notices	1	105	105
Microbial Commercial Activity Notices (MCANs)	0	302	0
Test Marketing Exemptions	3	98	294
Low Volume and Low Release/Low Exposure (LVE/LoREX) Exemptions	-51	105	-5,355
TSCA Experimental Release Applications (TERAs)	0	521	0
Tier I/Tier II Exemptions	1	114	114
Bona Fide Intent Notifications (Bona Fides)	-17	20	-340
Test Data Submissions under Section 5(e) Consent Orders	-1	155	-155
Notice of Commencement	-54	0.5	-27
BASELINE REPORTING BURDEN ADJUSTMENTS - SUBTOTAL			-14,289

**Table 4
New Chemicals Baseline Recordkeeping Burden Adjustments by IC**

EXISTING Information Collection	Adjustments - Recordkeeping		
	Change in Number of Annual Responses	Burden hours per response	Burden hours per year
Premanufacture Notification	-85	2	-170
PMN-related Significant New Use Notices	1	2	2
Microbial Commercial Activity Notices (MCANs)	0	2	0
Test Marketing Exemptions	3	2	6
Low Volume and Low Release/Low Exposure (LVE/LoREX) Exemptions	-51	2	-102
TSCA Experimental Release Applications (TERAs)	0	2	0
Tier I/Tier II Exemptions	1	2	2
Bona Fide Intent Notifications (Bona Fides)	-17	2	-34
Test Data Submissions under Section 5(e) Consent Orders	-1	35	-35
Notice of Commencement	-54	0.25	-14
BASELINE RECORDKEEPING BURDEN ADJUSTMENTS - SUBTOTAL			-345

2.1.3 Summary Burden Impact of Baseline Response Adjustments

The overall impact of the adjusted baseline number of responses is a net reduction of 14,634 annual burden hours. With these adjustments, the baseline reporting and recordkeeping burden is reduced to 133,449 hours (129,161 hours and the baseline recordkeeping burden is reduced to 4,288 hours).

Table 5
Total New Chemicals Baseline Burden Adjustments

Baseline Reporting Burden Adjustments – Subtotal	-14,289
Baseline Recordkeeping Burden Adjustments - Subtotal	-345
Total Baseline Burden Adjustments	-14,634

2.2 Reporting Burden Program Changes

Upon implementation of the final rule, the average annual new chemicals reporting burden is estimated to be approximately 114,670 hours. As discussed in section 1 of this appendix, respondents will incur new, company-level reporting burdens while realizing form-level reporting burden savings. Company-level reporting burden includes those activities that facilitate submission of an e-PMN: CDX registration, CDX electronic signature (i.e., authentication of identity and verification of authorization), setting up a Pay.gov account, and rule familiarization. Form-level burden includes completion and submission of TSCA section 5 notices.

2.2.1 New Company-Level Reporting Burdens

EPA estimates that the e-PMN rule will impose an average program change increase of 353 annual burden hours on respondents and is associated with the time required to complete company-level paperwork activities related to the final e-PMN rule requirements, i.e., CDX Registration, CDX electronic signature, E-Payment (Pay.gov ID), and Rule Familiarization. These activities and related burdens are explained in full in the supporting statement for EPA ICR No. 2327.07 (OMB Control No. 2070-0173). They are also included in the burden analysis presented in Tables 7 through 9. As indicated in Table 7, company-level burdens are higher in the first year due to initial rule familiarization burdens which are not incurred in subsequent years.

2.2.2 Reductions in Form-Level Reporting Burden for New Chemicals Submissions

The baseline reporting burden hours for each type of notice were estimated in *Pre-Manufacture Review Reporting and Exemption Requirements for New Chemical Substances and Significant New Use Reporting Requirements for Chemical Substances* (EPA ICR No. 0574.13; OMB Control No. 2070-0012). However, respondent adoption of electronic preparation and submission under the e-PMN rule will affect the existing reporting burden hour estimates for each type of covered notice¹. The adoption of electronic preparation and submission through CDX using the e-PMN software to prepare and submit TSCA section 5 notices will bring about burden savings by creating administrative efficiencies and time savings. The reporting burden savings relative to specific notice types are indicated in Table 6. The net impacts of these changes, coupled with the new rule related burdens described in section 2.2.1 of this appendix, are demonstrated in Tables 7 through 9.

¹ EPA is not accepting the electronic submission of certain types of documents and notices that are customarily part of the new chemicals program. In those cases, there are no program change reductions to form-level reporting or recordkeeping burden.

Table 6
Anticipated New Chemicals Program Reporting Burden Savings Under the e-PMN Rule

Type of New Chemicals Program Notice	Current Estimated Response Burden Hours	Estimated Response Burden Hours after e-PMN rule	Burden Hours Saved Per Response
Full PMN	105	92.2	12.8
New Chemical SNUN	105	92.2	12.8
LVE	105	92.2	12.8
LoREX	105	92.2	12.8
MCAN	302	288.2	13.8
TME	98	86.2	11.8
TERA	521	507.2	13.8
Tier I	114	110.2	3.8
Tier II	114	110.2	3.8
5(e) Test submissions	155	150.7	4.3
NOC	0.5	0.6	(0.1)

Because the final e-PMN rule phases-in the use of CDX over the three-year period, the number of companies and forms using CDX will vary across the phase-in period. Therefore, burden hours are presented separately for each year of the phase-in period. Prior to the e-PMN rule, only form-level burden was estimated for section 5 notices. Due to new activities that will occur at the company-level once electronic reporting via CDX is available, burden is broken out at the company and form level in the rule-related ICR.

Tables 7, 8 and 9 present the respondent reporting burden associated with this information collection during the first 3 years of rule implementation. The form-level during each of these years is estimated to total 114,317 hours. This burden estimate is calculated by multiplying the hours of reporting burden by the number of each type of notice that EPA expects to receive and summing across the notice types. Note that burden is adjusted to reflect the savings associated with the e-PMN rule in each year of the phase-in period, and also reflects adjustments to the baseline number of TSCA section 5 notices expected to be submitted to the new chemicals program. Because all notices must be generated using the new e-PMN software beginning in the first year following rule promulgation, however, form completion burden saving will be realized by all submitters immediately. After accounting for the baseline adjustments described in section 2.1.1 of this appendix, the estimated 114,317 annual hours of form-level reporting burden reflects a 14,844 hour net program change reduction.

Table 7
Revised New Chemicals Program Reporting Burden Under the e-PMN Rule, Year 1

Type of Notice	Avg. Annual Companies/Responses¹	Current Average Reporting Hours per Company/Response	Revised Average Reporting Hours per Company/Response	Revised Total Reporting Hours
COMPANY BURDEN				
CDX Registration	98	0	0.9	90
CDX Electronic Signature	98	0	1.8	172
E-Payment (Pay.gov ID)	98	0	0.1	13
Rule Familiarization	295	0	0.8	236
Total (Company)	589			511
FORM BURDEN				
PMN	720	105	92.2	66,384
SNUN	8	105	92.2	738
MCAN	3	302	288.2	865
<i>Exemptions:</i>				
TME	8	98	86.2	690
LVE/LoREX	419	105	92.2	38,632
TERA	2	521	507.2	1,014
Tier I and II	3	114	110.2	331
Polymer	175	2	2	350
R&D	200	2.5	2.5	500
Instant photographic	1	0.5	0.5	1
Bona Fide	116	20	20	2,320
5(e) Test	12	155	150.7	1,808
Non-Testing 5(e) Burden	16	25	25	400
NOC	443	0.5	0.6	266
Correction Request ²	9	2	2	18
Total (Form)	2,135			114,317
Total (Combined Company and Form)				114,828

¹Average Annual Responses computed as the average of the number of notices filed annually from 2003 through 2007 based on OPPT, 2008, then adjusted by 15% to reflect only valid submissions. For section 5 notices not subject to the e-PMN rule (R&D, Bona Fide, 5(e) Non-Testing, Instant Photographic and Correction Requests), the average annual number of responses is assumed to equal the number presented in *Pre-Manufacture Review Reporting and Exemption Requirements for New Chemical Substances and Significant New Use Reporting Requirements for Chemical Substances* (EPA ICR No. 0574.13; OMB Control No. 2070-0012).

²TSCA Inventory Correction Requests are covered under another ICR entitled, *Correction of Misreported Chemical Substances on the Toxic Substances Control Act Chemical Substances Inventory* (EPA ICR No. 1741.05; OMB Control No. 2070-0145) and are included in this analysis only to provide a full assessment of related program burdens. Such correction requests are typically submitted after EPA has processed an NOC and added the related chemical to the TSCA Inventory.

Table 8
Revised New Chemicals Program Reporting Burden Under the e-PMN Rule, Year 2

Type of Notice	Avg. Annual Companies/Responses¹	Current Average Reporting Hours per Company/Response	Revised Average Reporting Hours per Company/Response	Revised Total Reporting Hours
COMPANY BURDEN				
CDX Registration	98	0	0.9	90
CDX Electronic Signature	98	0	1.8	172
E-Payment (Pay.gov ID)	98	0	0.1	13
Rule Familiarization	0	0	0.8	0
Total (Company)	294			275
FORM BURDEN				
PMN	720	105	92.2	66,384
SNUN	8	105	92.2	738
MCAN	3	302	288.2	865
<i>Exemptions:</i>				
TME	8	98	86.2	690
LVE/LoREX	419	105	92.2	38,632
TERA	2	521	507.2	1,014
Tier I and II	3	114	110.2	331
Polymer	175	2	2	350
R&D	200	2.5	2.5	500
Instant photographic	1	0.5	0.5	1
Bona Fide	116	20	20	2,320
5(e) Test	12	155	150.7	1,808
Non-Testing 5(e) Burden	16	25	25	400
NOC	443	0.5	0.6	266
Correction Request	9	2	2	18
Total (Form)	2,135			114,317
Total (Combined Company and Form)				114,592

¹Average Annual Responses computed as the average of the number of notices filed annually from 2003 through 2007 based on OPPT, 2008, then adjusted by 15% to reflect only valid submissions. For section 5 notices not subject to the e-PMN rule (R&D, Bona Fide, 5(e) Non-Testing, Instant Photographic and Correction Requests), the average annual number of responses is assumed to equal the number presented in *Pre-Manufacture Review Reporting and Exemption Requirements for New Chemical Substances and Significant New Use Reporting Requirements for Chemical Substances* (EPA ICR No. 0574.13; OMB Control No. 2070-0012).

²TSCA Inventory Correction Requests are covered under another ICR entitled, *Correction of Misreported Chemical Substances on the Toxic Substances Control Act Chemical Substances Inventory* (EPA ICR No. 1741.05; OMB Control No. 2070-0145) and are included in this analysis only to provide a full assessment of related program burdens. Such correction requests are typically submitted after EPA has processed an NOC and added the related chemical to the TSCA Inventory.

Table 9
Revised New Chemicals Program Reporting Burden Under the e-PMN Rule, Year 3

Type of Notice	Avg. Annual Companies/Responses¹	Current Average Reporting Hours per Company/Response	Revised Average Reporting Hours per Company/Response	Revised Total Reporting Hours
COMPANY BURDEN				
CDX Registration	98	0	0.9	90
CDX Electronic Signature	98	0	1.8	172
E-Payment (Pay.gov ID)	98	0	0.1	13
Rule Familiarization	0	0	0.8	0
Total (Company)	294			275
FORM BURDEN				
PMN	720	105	92.2	66,384
SNUN	8	105	92.2	738
MCAN	3	302	288.2	865
<i>Exemptions:</i>				
TME	8	98	86.2	690
LVE/LoREX	419	105	92.2	38,632
TERA	2	521	507.2	1,014
Tier I and II	3	114	110.2	331
R&D	200	2.5	2.5	500
Polymer	175	2	2	350
Instant photographic	1	0.5	0.5	1
Bona Fide	116	20	20	2,320
5(e) Test	12	155	150.7	1,808
Non-Testing 5(e) Burden	16	25	25	400
NOC	443	0.5	0.6	266
Correction Request	9	2	2	18
Total (Form)	2,135			114,317
Total (Combined Company and Form)				114,592

¹Average Annual Responses computed as the average of the number of notices filed annually from 2003 through 2007 based on OPPT, 2008, then adjusted by 15% to reflect only valid submissions. For section 5 notices not subject to the e-PMN rule (R&D, Bona Fide, 5(e) Non-Testing, Instant Photographic and Correction Requests), the average annual number of responses is assumed to equal the number presented in *Pre-Manufacture Review Reporting and Exemption Requirements for New Chemical Substances and Significant New Use Reporting Requirements for Chemical Substances* (EPA ICR No. 0574.13; OMB Control No. 2070-0012).

²TSCA Inventory Correction Requests are covered under another ICR entitled, *Correction of Misreported Chemical Substances on the Toxic Substances Control Act Chemical Substances Inventory* (EPA ICR No. 1741.05; OMB Control No. 2070-0145) and are included in this analysis only to provide a full assessment of related program burdens. Such correction requests are typically submitted after EPA has processed an NOC and added the related chemical to the TSCA Inventory.

2.3 New Chemicals Recordkeeping Burden Program Changes

Respondents will not incur any company-level recordkeeping burdens. Rather, they will realize form-level recordkeeping burden savings related to electronically submitted TSCA section 5 notices. However, while respondents will realize immediate reporting burden savings since all respondents will be required to use the e-PMN software to prepare their submissions, not all respondents will realize immediate recordkeeping burden savings. As described in section 1.1.2 of this appendix, recordkeeping and postage savings will be realized in years when

electronic reporting via CDX is used. Reductions in recordkeeping burden are contingent upon adoption of electronic submission via CDX. Once a respondent electronically submits information in an initial TSCA section 5 submission, the burden for maintaining or updating these records is minimal. EPA expects that 33 percent of respondents to submit TSCA section 5 notices electronically via CDX in the first year, 67 percent will do so by the second year, and 100 percent will do so by the third year (when all respondents are required to submit electronically). Thus, the average annual new chemicals recordkeeping burden over the first 3 years of the rule is approximately 3,339 hours (and 2,863 hours annually each year thereafter).

2.3.1 Reductions in Form-Level Recordkeeping Burden for New Chemicals Submissions

The estimated 2 hours for each SNUN recordkeeping reflects is an aggregate annualized recordkeeping burden is an assumption based on the recordkeeping burden associated with essential technical requirements, such as records that demonstrate that the first commercial batch of chemical manufactured for commercial purposes under the exemption met certain eligibility criteria. EPA assumes that recordkeeping burden will be reduced by half due to the efficiencies in electronically creating and storing those TSCA section 5 notices and supporting documents that are covered by the final rule. For most TSCA section 5 notices covered by the rule, baseline recordkeeping burden is estimated to be two hours.

The recordkeeping burden savings relative to specific notice types are indicated in Table 10. For these notices, one technical and one clerical staff member will each save 30 minutes on recordkeeping. For section 5(e) test notices, baseline recordkeeping burden is estimated to be 35 hours because of the need to copy and file relevant records. This includes records related to: manufacturing, importing, or processing volumes; shipment amounts and customer information; labels (documentation of labeling procedures and copies of labels); MSDS; and compliance with any additional restrictions on use, disposal, and discharge limitations. Therefore, for section 5(e) test notices, EPA estimates that one technical and one clerical staff member will each save 8.8 hours on recordkeeping. For Notices of Commencement (NOC), baseline recordkeeping burden is estimated to be 15 minutes. Therefore, for NOCs, one technical and one clerical staff member will each save four minutes on recordkeeping.

As shown in Tables 11, 12, and 13, the total respondent recordkeeping burden associated with this information collection is estimated to equal 3,814 hours in the first year following the effective date of the e-PMN rule, 3,341 hours in the second year, and 2,863 hours in the third year following the effective date of the final rule. This burden estimate is calculated by multiplying the estimated recordkeeping burden associated with each type of submission (as estimated in EPA 1994) by the estimated number of submissions for each notice and then summing across notice types. Note that recordkeeping burden is adjusted by the savings associated with electronic reporting via CDX in each year of the phase-in period, and also reflects adjustments to the baseline number of TSCA section 5 notices expected to be submitted to the new chemicals program

Table 10
Anticipated New & Existing Chemicals Program Recordkeeping Burden Hour Savings Under the e-PMN Rule

Type of TSCA Section 5 Notice (New and Existing Chemicals Programs)	Current Estimated Recordkeeping Burden Per Response	Estimated Recordkeeping per Burden Response after Rule Implementation	Burden Saved Per Response
Full PMN	2.00	1.00	1.00
SNUN ¹	2.00	1.00	1.00
LVE	2.00	1.00	1.00
LoREX	2.00	1.00	1.00
MCAN	2.00	1.00	1.00
TME	2.00	1.00	1.00
TERA	2.00	1.00	1.00
Tier I	2.00	1.00	1.00
Tier II	2.00	1.00	1.00
5(e) Test submissions	35.0	17.5	17.5
NOC	0.25	0.125	0.125

¹The “current” recordkeeping burden for Existing Chemical SNUNs has been adjusted from the estimate of 5.67 hours calculated in *TSCA Section 5(a)(2) Significant New Use Rules for Existing Chemicals* (EPA ICR No 1188.09; OMB Control No. 2070-0038), to 2 hours here, to be consistent with *Pre-Manufacture Review Reporting and Exemption Requirements for New Chemical Substances and Significant New Use Reporting Requirements for Chemical Substances* (EPA ICR No. 0574.13; OMB Control No. 2070-0012) and the Economic Analysis for the final e-PMN rule.

Once a respondent submits information in an initial TSCA section 5 submission, the burden for maintaining or updating these records is minimal. The Agency had assumed an aggregate annualized recordkeeping burden of two hours for each PMN, SNUN, MCAN, or exemption submission, or biotech submission. This was based on the recordkeeping burden associated with essential technical requirements, such as records that demonstrate that the first commercial batch of chemical manufactured for commercial purposes under the exemption met certain eligibility criteria. The recordkeeping burden for 5(e) testing and non-testing 5(e) burden were 35 and 25 hours, respectively (EPA, 1994). The Agency expects that promulgation of the e-PMN rule and the submission of fewer TSCA section 5 notices will reduce the recordkeeping burden from the current total of 4,633 hours to 2,863 hours by the third year.

The average recordkeeping burden of the first 3 years of the rule is 3,339 annual hours. After accounting for the baseline recordkeeping burden adjustments described in section 2.1.2 of this appendix, this figure reflects an average annual 949 hour net program change reduction over the first 3 years of the rule (474 hours in the first year, 947 hours in the second year, and 1,425 in the third year and all subsequent years).

Table 11
Revised New Chemicals Program Respondent Recordkeeping Burden Under the e-PMN Rule, Year 1

Type of Notice	Average Annual Responses via non-CDX ¹	Average Annual Responses via CDX ¹	Current Average Recordkeeping Hours per non-CDX Response	Revised Average Recordkeeping Hours per CDX Response	Total Recordkeeping Hours for non-CDX	Total Recordkeeping Hours for CDX	Total Recordkeeping Hours for all Responses
PMN	480	240	2	1	960	240	1,200
SNUN	5	3	2	1	10	3	13
MCAN	2	1	2	1	4	1	5
<i>Exemptions:</i>							
TME	5	3	2	1	10	3	13
LVE/LoREX	279	140	2	1	558	140	698
TERA	1	1	2	1	2	1	3
Tier I / II	2	1	2	1	4	1	5
R&D	200	0	0.5	0.5	100	0	100
Polymer	175	0	4	4	700	0	700
Instant photographic	1	0	0.25	0.25	1	0	1
Bona Fide	116	0	2	2	232	0	232
5(e) Test	8	4	35	17.5	280	70	350
Non-Testing 5(e) Burden	16	0	25	25	400	0	400
NOC	295	148	0.25	0.125	74	18	92
Correction Request	9	0	0.25	0.25	2	0	2
Total	1,594	541			3,337	477	3,814

¹ Average Annual Responses computed as the average of the number of notices filed annually from 2003 through 2007 based on OPPT, 2008, then adjusted by 15% to reflect only valid submissions. The CDX responses and non-CDX responses are determined by the % of responses that will utilize CDX for a given year: 33% for the first year, 67% for the second year, and 100% for the third year. For section 5 notices not subject to the e-PMN rule (R&D, Bona Fide, Non-Testing 5(e), Instant Photographic and Correction Requests), the average annual number of responses is assumed to equal the number presented in *Pre-Manufacture Review Reporting and Exemption Requirements for New Chemical Substances and Significant New Use Reporting Requirements for Chemical Substances* (EPA ICR No. 0574.13; OMB Control No. 2070-0012).

² TSCA Inventory Correction Requests are covered under another ICR entitled, *Correction of Misreported Chemical Substances on the Toxic Substances Control Act Chemical Substances Inventory* (EPA ICR No. 1741.05; OMB Control No. 2070-0145) and are included in this analysis only to provide a full assessment of related program burdens. Such correction requests are typically submitted after EPA has processed an NOC and added the related chemical to the TSCA Inventory.

Table 12
Revised New Chemicals Program Respondent Recordkeeping Burden Under the e-PMN Rule, Year 2

Type of Notice	Average Annual Responses via non-CDX ¹	Average Annual Responses via CDX ¹	Current Average Recordkeeping Hours per non-CDX Response	Revised Average Recordkeeping Hours per CDX Response	Total Recordkeeping Hours for non-CDX	Total Recordkeeping Hours for CDX	Total Recordkeeping Hours for all Responses
PMN	240	480	2	1	480	480	960
SNUN	3	5	2	1	6	5	11
MCAN	1	2	2	1	2	2	4
<i>Exemptions:</i>							
TME	3	5	2	1	6	5	11
LVE/LoREX	140	279	2	1	280	279	559
TERA	1	1	2	1	2	1	3
Tier I / II	1	2	2	1	2	2	4
R&D	200	0	0.5	0.5	100	0	100
Polymer	175	0	4	4	700	0	700
Instant photographic	1	0	0.25	0.25	1	0	1
Bona Fide	116	0	2	2	232	0	232
5(e) Test	4	8	35	17.5	140	140	280
Non-Testing 5(e) Burden	16	0	25	25	400	0	400
NOC	148	295	0.25	0.125	37	37	74
Correction Request	9	0	0.25	0.25	2	0	2
Total	1,058	1,077			2,390	951	3,341

¹Average Annual Responses computed as the average of the number of notices filed annually from 2003 through 2007 based on OPPT, 2008, then adjusted by 15% to reflect only valid submissions. The CDX responses and non-CDX responses are determined by the % of responses that will utilize CDX for a given year: 33% for the first year, 67% for the second year, and 100% for the third year. For section 5 notices not subject to the e-PMN rule (R&D, Bona Fide, Non-Testing 5(e), Instant Photographic and Correction Requests), the average annual number of responses is assumed to equal the number presented in the *Pre-Manufacture Review Reporting and Exemption Requirements for New Chemical Substances and Significant New Use Reporting Requirements for Chemical Substances* (EPA ICR No. 0574.13; OMB Control No. 2070-0012).

² TSCA Inventory Correction Requests are covered under another ICR entitled, *Correction of Misreported Chemical Substances on the Toxic Substances Control Act Chemical Substances Inventory* (EPA ICR No. 1741.05; OMB Control No. 2070-0145) and are included in this analysis only to provide a full assessment of related program burdens. Such correction requests are typically submitted after EPA has processed an NOC and added the related chemical to the TSCA Inventory.

Table 13

Revised New Chemicals Program Respondent Recordkeeping Burden Under the e-PMN Rule, Year 3

Type of Notice	Average Annual Responses via non-CDX ¹	Average Annual Responses via CDX ¹	Current Average Recordkeeping Hours per non-CDX Response	Revised Average Recordkeeping Hours per CDX Response	Total Recordkeeping Hours for non-CDX	Total Recordkeeping Hours for CDX	Total Recordkeeping Hours for all Responses
PMN	0	720	2	1	0	720	720
SNUN	0	8	2	1	0	8	8
MCAN	0	3	2	1	0	3	3
<i>Exemptions:</i>							
TME	0	8	2	1	0	8	8
LVE/LoREX	0	419	2	1	0	419	419
TERA	0	2	2	1	0	2	2
Tier I / II	0	3	2	1	0	3	3
R&D	200	0	0.5	0.5	100	0	100
Polymer	175	0	4	4	700	0	700
Instant photographic	1	0	0.25	0.25	1	0	1
Bona Fide	116	0	2	2	232	0	232
5(e) Test	0	12	35	17.5	0	210	210
Non-Testing 5(e) Burden	16	0	25	25	400	0	400
NOC	0	443	0.25	0.125	0	55	55
Correction Request	9	0	0.25	0.25	2	0	2
Total	517	1,618			1,435	1,428	2,863

¹Average Annual Responses computed as the average of the number of notices filed annually from 2003 through 2007 based on OPPT, 2008, then adjusted by 15% to reflect only valid submissions. The CDX responses and non-CDX responses are determined by the % of responses that will utilize CDX for a given year: 33% for the first year, 67% for the second year, and 100% for the third year. For section 5 notices not subject to the e-PMN rule (R&D, Bona Fide, Non-Testing 5(e), Instant Photographic and Correction Requests), the average annual number of responses is assumed to equal the number presented in *Pre-Manufacture Review Reporting and Exemption Requirements for New Chemical Substances and Significant New Use Reporting Requirements for Chemical Substances* (EPA ICR No. 0574.13; OMB Control No. 2070-0012).

² TSCA Inventory Correction Requests are covered under another ICR entitled, *Correction of Misreported Chemical Substances on the Toxic Substances Control Act Chemical Substances Inventory* (EPA ICR No. 1741.05; OMB Control No. 2070-0145) and are included in this analysis only to provide a full assessment of related program burdens. Such correction requests are typically submitted after EPA has processed an NOC and added the related chemical to the TSCA Inventory.

2.4 Summary Burden Impact of Rule-Related Program Changes

The overall impact of the rule-related program changes is a net reduction of annual burden hours.

Table 14
Total New Chemicals Burden Program Changes (Years 1 through 3)

Company-level Reporting Burden Program Changes – Subtotal	353
Form-level Reporting Burden Program Changes – Subtotal	-14,844
Recordkeeping Burden Program Changes – Subtotal	-947
Total Burden Program Changes	-15,438

2.5 Net Burden Decrease - New Chemicals Program

EPA expects an average net burden decrease of 30,410 hours annually (14,634 hour net adjustment decrease and 15,438 hour net program change reduction) over the 148,803 total annual hours presently approved under EPA ICR No 0574.13 (OMB Control No. 2070-0012), based on the changes described in sections 2.1 through 2.3 of this appendix.

Table 15
New Chemicals Program Average Annual Burden Changes (Adjustments and Program Changes)

Form-level Reporting Burden Adjustments	-14,289 hours
Form-level Reporting Burden Program Changes	-14,844 hours
Company-level Reporting Burden Program Changes	+353 hours
Recordkeeping Burden Adjustments	-345 hours
Recordkeeping Burden Program Changes	-947 hours
Total Burden Changes	-30,410 hours

3.0 Impacts of e-PMN Final Rule on Existing Chemicals Program Burdens (OMB Control No. 2070-0038)

3.1 Adjustments to the Baseline Reporting and Recordkeeping Estimates for Existing Chemical SNUNs

The baseline reporting and recordkeeping burden for the currently approved ICR entitled *TSCA Section 5(a)(2) Significant New Use Rules for Existing Chemicals* (EPA ICR No. 1188.09; OMB Control No. 2070-0038) is 1,423 annual hours. Of the 1,423 annual burden hours approved under that ICR, EPA estimated that the annual reporting and recordkeeping burden related to the submission of existing chemical SNUNs is 1,189 hours (about 1,132 reporting hours and 57 recordkeeping hours).

In calculating the SNUN-related burden subtotal for that ICR, EPA estimated that the SNUN-related reporting burden ranges between 94.25 and 113.25 hours per response, as shown in Table 16. In keeping with the conservative assumptions already employed, EPA used the high end of the range of reporting burden hours (i.e., 113.25 hours) in subsequent cost and overall annual burden hour calculations. EPA then assumed that SNUN-related recordkeeping requires about 5 percent of the time spent on reporting, or 5.67 hours per SNUN.

Respondents submitting a SNUN, whether for a new or an existing chemical, use the same form to submit the information to EPA. As estimated in the currently approved ICR entitled *Pre-Manufacture Review Reporting and Exemption Requirements for New Chemical Substances and Significant New Use Reporting Requirements for Chemical Substances* (EPA ICR No. 0574.13; OMB Control No. 2070-0012), and as analyzed throughout section 2 of this appendix and in the economic analysis for the final rule, the reporting burden for a new chemical SNUN is 105 hours and the recordkeeping burden for a new chemical SNUN is 2 hours. The estimated 105 hours for a new chemical SNUN submission is the approximate mid-point estimate of the range presented in Table 16. The estimated 2 hours for each SNUN recordkeeping reflects an aggregate annualized recordkeeping burden is an assumption based on the recordkeeping burden associated with essential technical requirements, such as records that demonstrate that the first commercial batch of chemical manufactured for commercial purposes under the exemption met certain eligibility criteria.

EPA is adjusting the estimated reporting and recordkeeping burden for an existing chemical SNUN from 113.25 hours to 105 hours and 5.67 hours to 2 hours, respectively, to ensure consistency with SNUN-related estimates presented in EPA ICR No. 0574.13 and in the economic analysis for the final rule.

3.1.1 Impact of Adjusted Baseline Reporting and Recordkeeping Estimates

As explained in section 3.1 of this appendix, to make this analysis consistent with that presented in EPA ICR No. 0574.13 for SNUN submission and recordkeeping, the baseline reporting burden for submitting an existing chemical SNUN is adjusted to the estimated mid-point of 105 hours, rather than the upper-bound estimate of 113.25 hours of reporting burden presented in EPA ICR No. 1188.09. This reporting burden adjustment results in a decrease of 82 annual hours. The recordkeeping burden for SNUN submission activities is also adjusted, from 5.67 hours per response to 2 hours per response. This recordkeeping adjustment results in a decrease of 37 annual hours. Thus, these baseline adjustments result in a burden decrease of 119 annual hours, from 1,189 annual hours to 1,070 annual hours (1,050 reporting hours and 20 recordkeeping hours).

Table 16
Current Unit Reporting Burden Estimates Associated
With Filing an Existing Chemical SNUN, By Labor Category

Activity	Secretarial Hours	Technical Hours	Managerial Hours	Total Hours
General information/ instructions	2 - 2.5	1.5 - 2	3 - 4	6.5 - 8.5
Chemical identity	1.5 - 2	3 - 6	1	5.5 - 9
Trade name ID		.25		.25
Byproducts/impurities identification		1		1
Production & marketing data	1.5		2 - 3	3.5 - 4.5
Production volume		1		1
Category of use		3		3
Hazard information		3 - 4		3 - 4
Human exposure and environmental release	2.5 - 3.5		6 - 7	8.5-10.5
Site information		14 - 16		14 - 16
Occupational exposure		13 - 14		13 - 14
Environmental release/ disposal		9 - 10		9 - 10
Sites controlled by others	2	10 - 12	2 - 2.5	14 - 16.5
List of attachments	2	6 - 8	1 - 1.5	9 - 11.5
Certification			.5	.5
Data submissions	.5	1.5 - 2	.5	2.5 - 3
Totals	12 - 14	66.25 - 79.25	16 - 20	94.25 - 113.25

Source: EPA, 1994.

Table 17
Existing Chemicals Baseline Reporting and Recordkeeping Burden Adjustments

Existing Chemical SNUN Response Activity	Number of SNUNs/Year	Current Baseline	Adjusted Baseline	Change per SNUN	Total Change
		Hours/SNUN	Hours/SNUN	Hours/SNUN	Hours/Year
Reporting	10	113.25	105	-8.25	-82
Recordkeeping	10	5.67	2	-3.67	-37
Total	10	118.92	107	-11.92	-119

3.2 Reporting Burden Program Changes

Upon implementation of the final rule, the average annual existing chemicals reporting burden is estimated to be approximately 934 hours. As discussed in section 1 of this appendix, respondents will incur new, company-level reporting burdens while realizing form-level reporting burden savings. Company-level reporting burden includes those activities that facilitate submission of an e-PMN: CDX registration, CDX electronic signature (i.e., authentication of identity and verification of authorization), setting up a Pay.gov account, and rule familiarization. Form-level reporting burden includes completion and submission of Existing Chemical SNUNs.

EPA projects that one-third of first year submissions and two-thirds of all second year submissions will be made via CDX. All submissions must be made via CDX by the third year and beyond. The actual rates of adoption of CDX in years one and two of the rule could be higher or lower than EPA’s projections. However, lacking any data on which to base other projections, EPA assumes an even rate of adoption over the two-year phase-in period.

3.2.1 New Company-Level Reporting Burdens

EPA estimates that the e-PMN rule will impose an average program change increase of 12 annual burden hours on respondents and is associated with the time required to complete company-level paperwork activities related to the final e-PMN rule requirements, i.e., CDX Registration, CDX electronic signature, E-Payment (Pay.gov ID)², and Rule Familiarization. These activities and related burdens are explained in full in the supporting statement for EPA ICR No. 2327.07 (OMB Control No. 2070-0173). The activities are also included in the burden analysis presented in Tables 18 through 20. As indicated in Table 18 company-level burdens are higher in the first year due to initial rule familiarization burdens that not incurred in subsequent years.

3.2.2 Reductions in Form-Level Reporting Burden for Existing Chemical SNUN Submissions

In addition to the baseline adjustments described in section 3.1 of this appendix, respondent adoption of electronic preparation and submission under the e-PMN rule will further affect the reporting burden estimates for existing chemical SNUNs. The adoption of electronic

² Use of Pay.gov to remit the SNUN submission fee is not be mandatory under the final e-PMN rule, but EPA assumes conservatively in the Economic Analysis for the final e-PMN rule that SNUN submitters will send the fee via a Pay.gov account.

preparation and submission through CDX using the e-PMN software to prepare and submit existing chemical SNUNs will bring about burden savings by creating administrative efficiencies and time savings. Specifically, EPA estimates that the reporting burden will be reduced from 105 hours per submission to 92.2 hours per submission, saving 12.8 hours per response. The net impacts of these changes, coupled with the new rule related burdens described in section 3.2.1 of this appendix, are demonstrated in Tables 18 through 20.

Because the final e-PMN rule phases-in the use of CDX over the three-year period, the number of companies and forms using CDX will vary across the phase-in period. Therefore, burden hours are presented separately for each year of the phase-in period. Prior to the e-PMN rule, only form-level burden was estimated for existing chemical SNUNs. Due to new activities that will occur at the company-level once electronic reporting via CDX is available, burden is broken out at the company and form level in the rule-related ICR. EPA is assuming an even rate of adoption over the two-year phase-in period. For existing chemical SNUNs, this means that EPA is assuming that companies will incur the burden associated with CDX registration, completing the Electronic Signature Agreements, and setting up a Pay.gov account to submit the TSCA fee, at the rate of 3.3 (10/3) additional companies in each of year of the ICR's approval. At that point, all SNUN submissions will be made via CDX.

Tables 18, 19 and 20 present the respondent reporting burden associated with this information collection during the first 3 years of rule implementation. The form-level during each of these years is estimated to total 922 hours. This burden estimate is calculated by multiplying the hours of reporting burden by the number of existing chemical SNUNs that EPA expects to receive. Note that burden is adjusted to reflect the savings associated with the e-PMN rule in each year of the phase-in period, and also reflects adjustments to the existing chemical SNUN baseline reporting burden for consistency purposes. Because all existing chemical SNUNs must be generated using the new e-PMN software beginning in the first year following rule promulgation, however, form completion burden saving will be realized by all submitters immediately. After accounting for the baseline adjustments described in section 3.1.1 of this appendix, the estimated 922 annual hours of form-level reporting burden reflects a 128 hour program change reduction.

Table 18
Revised Existing Chemical SNUN Reporting Burden Under the e-PMN Rule, Year 1

Type of Notice	Avg. Annual Additional Companies/Responses¹	Current Average Reporting Hours per Company/Response	Revised Average Reporting Hours per Company/Response	Revised Total Reporting Hours
COMPANY BURDEN				
CDX Registration	3.3	0	0.9	2.97
CDX Electronic Signature	3.3	0	1.8	5.94
E-Payment (Pay.gov ID)	3.3	0	0.1	0.33
Rule Familiarization	10	0	0.8	8
Total (Company)				17.2
FORM BURDEN				
SNUN	10	105	92.2	922
Total (Combined Company and Form)				939

¹The CDX responses and non-CDX responses are determined by the number of additional companies/responses that will utilize CDX for a given year: About one-third of the companies each year- (10/3) ~ 3.3 companies.

Table 19
Revised Existing Chemical SNUN Reporting Burden Under the e-PMN Rule, Year 2

Type of Notice	Avg. Annual Additional Companies/Responses¹	Current Average Reporting Hours per Company/Response	Revised Average Reporting Hours per Company/Response	Revised Total Reporting Hours
COMPANY BURDEN				
CDX Registration	3.3	0	0.9	2.97
CDX Electronic Signature	3.3	0	1.8	5.94
E-Payment (Pay.gov ID)	3.3	0	0.1	0.33
Rule Familiarization	0	0	0.8	0.0
Total (Company)				9.2
FORM BURDEN				
SNUN	10	105	92.2	922
Total (Combined Company and Form)				931.2

¹The CDX responses and non-CDX responses are determined by the number of additional companies/responses that will utilize CDX for a given year: About one-third of the companies each year- (10/3) ~ 3.3 companies.

Table 20
Revised Existing Chemical SNUN Reporting Burden Under the e-PMN Rule, Year 3

Type of Notice	Avg. Annual Additional Companies/Responses¹	Current Average Reporting Hours per Company/Response	Revised Average Reporting Hours per Company/Response	Revised Total Reporting Hours
COMPANY BURDEN				
CDX Registration	3.3	0	0.9	2.97
CDX Electronic Signature	3.3	0	1.8	5.94
E-Payment (Pay.gov ID)	3.3	0	0.1	0.33
Rule Familiarization	0	0	0.8	0.0
Total (Company)				9.2
FORM BURDEN				
SNUN	10	105	92.2	922
Total (Combined Company and Form)				931.2

¹The CDX responses and non-CDX responses are determined by the number of additional companies/responses that will utilize CDX for a given year: About one-third of the companies each year- (10/3) ~ 3.3 companies.

3.3 Existing Chemicals Recordkeeping Burden Program Changes

Respondents will not incur any company-level recordkeeping burdens. Rather, they will realize form-level recordkeeping burden savings related to electronically submitted existing chemical SNUNs. Upon the rule's effective date, all respondents will be required to use the e-PMN software to prepare their submissions and therefore will realize immediate reporting burden savings. However, not all respondents will realize immediate recordkeeping burden savings. As described in section 1.1.2 of this appendix, recordkeeping and postage savings will be realized in years when electronic reporting via CDX is used. Reductions in recordkeeping burden are contingent upon adoption of electronic submission via CDX. Once a respondent electronically submits an existing chemical SNUN, the burden for maintaining or updating related records is minimal. EPA expects that 33 percent of respondents to submit existing chemical SNUNs electronically via CDX in the first year, 67 percent will do so by the second year, and 100 percent will do so by the third year (when all respondents are required to submit electronically).

As discussed in section 3.1.1 of this appendix, the existing chemicals SNUN-related recordkeeping burden was adjusted from 5.67 hours per SNUN to 2 hours per SNUN ensure consistency with burden estimates for new chemical SNUNs. EPA expects that respondents submitting existing chemical SNUNs will experience the same reporting and recordkeeping burden savings as respondents submitting new chemical SNUNs (i.e., one technical and one clerical staff member are estimated to each save 30 minutes on recordkeeping, for a total recordkeeping burden of one hour, as CDX is adopted). EPA therefore assumes that recordkeeping burden will be reduced by half (from 2 hours to 1 hour) due to the efficiencies in creating and storing SNUNs and supporting documents electronically.

Table 21 shows that in the first year of the ICR approval period, when EPA assumes three companies will submit SNUNs via CDX, the total recordkeeping burden is estimated to be 17 hours. By year three, when all 10 existing chemical SNUNs expected each year will be submitted via CDX, the total record keeping drops to 10 hours. The total three-year recordkeeping burden is estimated to be 40 hours, or an annual average of slightly more than 13 hours.

Table 21
Revised Respondent Recordkeeping Burden For Existing Chemical SNUNs Under the e-PMN Rule, Years 1 through 3

Year	Average Annual Responses via non-CDX	Average Annual Responses via CDX	Current Average Recordkeeping Hours per non-CDX Response	Revised Average Recordkeeping Hours per CDX Response	Total Recordkeeping Hours for non-CDX	Total Recordkeeping Hours for CDX	Total Recordkeeping Hours for all Responses
Year 1	6.7	3.3	2	1	13.3	3.3	16.7
Year 2	3.3	6.7	2	1	6.7	6.7	13.3
Year 3	0	10	2	1	0	10	10
TOTAL							40.0

Thus, the average annual SNUN-related recordkeeping burden over the first 3 years of the rule is approximately 13 hours (and 10 hours annually each year thereafter).

3.4 Summary Burden Impact of Rule-Related Program Changes

The overall impact of the rule-related program changes is a net reduction of annual burden hours.

Table 22
Average Annual Existing Chemicals Burden Program Changes (Years 1 through 3)

Company-level Reporting Burden Program Changes – Subtotal	12
Form-level Reporting Burden Program Changes – Subtotal	-128
Recordkeeping Burden Program Changes – Subtotal	-13
Total Burden Program Changes	-129

3.5 Net Burden Decrease - Existing Chemicals Program

EPA expects an average net burden decrease of 248 hours annually (119 hour adjustment decrease and 129 hour net program change reduction) over the 1,423 total annual hours presently approved under EPA ICR No 1188.09 (OMB Control No. 2070-0038), based on the changes described in sections 3.2 through 3.3.

Table 23
Existing Chemicals Program Average Annual Burden Changes (Adjustments and Program Changes)

Form-level Reporting Burden Adjustments	-82 hours
Form-level Reporting Burden Program Changes	-128 hours
Company-level Reporting Burden Program Changes	+12 hours
Recordkeeping Burden Adjustments	-37 hours
Recordkeeping Burden Program Changes	-13 hours
Total Burden Changes	-248 hours

4.0 Summary of Net Changes to Annual Paperwork Burden Estimates

4.1 Adjustments

Adjustments to baseline estimates for both of the ICRs addressed in this appendix are responsible for notable changes in EPA's overall annual burden estimates. The baseline adjustments to EPA ICR Nos. 0574.13 and 1188.09 are responsible for a combined reduction of 14,753 burden hours. This section of this appendix summarizes those adjustments.

4.1.1 Fewer New Chemicals Responses

EPA estimated the annual number of new chemicals-related submissions over a 5-year average and the adjusted that annual average by 15 percent to count only valid submissions. In previous ICR renewals, EPA would have based its projection, in part, on the average number of annual responses submitted in the previous 3 years. This change led EPA to estimate that 203 fewer net responses would be submitted annually across all types of activities covered under this ICR. The result of this change is an estimated net decrease of 14,634 reporting and recordkeeping hours. This adjustment is addressed in section 2.1 of this appendix.

4.1.2 Harmonized SNUN Reporting and Recordkeeping Burden Estimates

Respondents submitting a SNUN, whether for a new or an existing chemical, use the same form to submit the information to EPA. However, EPA had utilized different points in the same estimated burden range when developing separate reporting burden associated with SNUNs for ICR Nos. 0574.13 and 1188.09. The reporting burden estimate presented in ICR No. 0574.13 reflected the approximate mid-point of the estimated burden range (105 hours), while the reporting burden estimate presented in ICR No. 1188.09 reflected the high-end of the same estimated burden range (about 113 hours). To ensure consistent analysis, EPA harmonized the SNUN reporting burden estimates for both new and existing chemical SNUNs by utilizing the mid-point of the range (105 hours). The application of this harmonized estimate to EPA ICR No. 1188.09 results in an adjustment decrease of about 82 annual reporting burden hours.

Similarly, EPA had utilized different SNUN-related recordkeeping estimates when developing the annual burden estimates for ICR Nos. 0574.13 and 1188.09 (2 hours and 5.67 hours, respectively, per SNUN). Again, to ensure consistent analysis, EPA harmonized the SNUN-related recordkeeping burden estimates for both new and existing chemical SNUNs by adopting the SNUN-related recordkeeping estimate of 2 hours per SNUN as presented in ICR No. 0574.13. As explained in sections 2.3.1 and 3.1 of this appendix, the estimated 2 hours for each SNUN recordkeeping reflects an aggregate annualized recordkeeping burden and is an assumption based on the recordkeeping burden associated with essential technical requirements, such as records that demonstrate that the first commercial batch of chemical manufactured for commercial purposes under the exemption met certain eligibility criteria. The application of this harmonized estimate to EPA ICR No. 1188.09 results in an additional adjustment decrease of about 37 annual recordkeeping burden hours.

4.2. Program Changes

The net impact of the e-PMN rule is an estimated 15,567 hour administrative-level program change burden reduction on TSCA section 5 respondents. This section of this appendix summarizes those program changes.

4.2.1 Modest Rule Implementation Burden

EPA estimates that the e-PMN rule will impose an average program change increase of 365 annual burden hours on both new and existing chemical respondents submitting TSCA section 5 notices (353 hours + 12 hours, respectively). This estimate reflects modest start-up burden associated with CDX registration, obtaining a CDX electronic signature, optional E-Payment (establishing a Pay.gov ID), and Rule Familiarization. Each of these activities will facilitate electronic preparation and submission of TSCA section 5 notices to EPA, which in turn will bring about burden reduction for respondents. Company-level rule-implementation burdens are higher in the first year due to initial rule familiarization burdens which are not incurred in subsequent years.

4.2.2 Resulting Burden Reduction

The 365 annual burden hours of new, company-level burden is offset by a program change reduction of 14,972 annual form-level reporting burden hours on both new and existing chemical respondents submitting TSCA section 5 notices (14,844 hours + 128 hours, respectively). These form-level burden reductions will be realized immediately because the reductions are attributed primarily to the electronic preparation of TSCA section 5 notices. In addition, new and existing chemical respondents will realize a program change reduction of an average 960 annual burden hours (947 hours + 13 hours, respectively) over the first 3 years.

4.3 Net Changes

EPA projects that the combined burden adjustments and program changes result in a net burden reduction of 30,320 annual hours. Adjustments combine for a net decrease of 14,753 annual burden hours for both new and existing chemical respondents. Program changes combine for a net decrease of 15,567 annual burden for both and existing chemical respondents.