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Request for a Non-Substantive Change to an Existing Approved Information Collection

(EPA ICR No. 0574.14; OMB Control No. 2070-0012)

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I. Introduction

Why is EPA Requesting a Non-Substantive Change?

This non-substantive change request reallocates individual paperwork activities, or information collections (ICs), from a rule-related ICR to an existing approved ICR. This change request also effectuates the burden changes described in the rule-related ICR and summarized herein. The changes described in this request are non-substantive because OMB has already approved them in the rule-related ICR package under OMB Control No. 2070-0173. As explained in both the final rule preamble and the rule-related ICR, the incremental changes to the baseline paperwork activities and their related burden, as well as the analysis of the program change burden, would ultimately be incorporated into an ICR that is approved under OMB Control No. 2070-0012. After doing so, EPA would then discontinue the rule-related ICR.

EPA submitted a single, rule-related ICR to OMB to address the new paperwork activities (i.e., information collections, or ICs) related to implementation of the final rule's electronic reporting requirements. The new ICs apply equally to the existing information collection programs approved under OMB Control Nos. 2070-0012 and 2070-0038. The ICR approved under OMB Control No. 2070-0012 (and the subject of this change request) addresses the paperwork activities associated with Significant New Use Rules (SNURs) issued by EPA's Existing Chemicals Program under section 5 of the Toxic Substances Control Act. The other ICR, approved under OMB Control No. 2070-0038, addresses the paperwork activities associated with EPA's New Chemicals Program under section 5 of TSCA. EPA determined it was more efficient to address the rule's paperwork requirements as they apply to both information collection programs in a single ICR, and to then update the existing approved ICRs after OMB approved the rule-related ICR.

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II. Background

Overview of the Final Rule and Rule-Related ICR

On January 6, 2010, EPA promulgated a final rule entitled, "TSCA Section 5 Premanufacture and Significant New Use Notification Electronic Reporting; Revisions to Notification Regulations" (75 FR 773). The final rule amends the Toxic Substances Control Act (TSCA) section 5 reporting regulations at subpart D of 40 CFR parts 700, 720, 721, 723, and 725. The amendments establish electronic reporting regulations for certain notification requirements under TSCA section 5, including Premanufacture and Significant New Use Notifications (PMNs and SNUNs). The final rule streamlines and reduces the administrative costs and burdens of TSCA section 5 notifications for both industry and EPA by phasing in the requirement that respondents submit certain TSCA section 5 notices and support documents to EPA electronically using the Agency's Central Data Exchange (CDX). The rule also established requirements regarding the use of CDX, including user registration, authorization, and electronic signature. EPA also now requires that respondents include a payment identification number on the PMN form to enable EPA to link user fee payments with specific submissions. The payment identification number may be a check number, a wire transfer number, or a pay gov transaction number. Lastly, EPA no longer requires that designated Agents sign the PMN form. The effective date of the final rule is April 6, 2010.

OMB approved the rule-related ICR on March 29, 2010 under <u>OMB Control No. 2070-0173</u>. The rule-related ICR addresses the paperwork activities associated with the amended reporting and recordkeeping requirements and the incremental program change burdens, specifically:

- Rule familiarization,
- Registering with EPA's electronic reporting portal (the Central Data Exchange, or CDX),
- Obtaining a CDX electronic signature (including authentication of identity and verifying authorization of the CDX registrant to submit on behalf of the company), and,
- Setting up a Pay.gov account (not required by the rule) if respondents wished to make payments for the existing TSCA fees electronically.

In addition, with the approval of the rule-related ICR, OMB approved EPA Form 6300-07 entitled, *TSCA Biotechnology Notice for Online Submissions* (identified as ICR Attachment 9). Biotechnology notices have their own menu option in the e-PMN software. The e-PMN software gives form and format to this information; therefore, EPA sought OMB approval of the form and is including this form as an instrument under OMB Control No. 2070-0012. Instead of selecting "Premanufacture Notice," a submitter will select "Biotech," which will prompt the software to present the submitter a header page with choices of biotech notices, and space to fill in contact information. The e-PMN software will populates this information in form 6300-07, and any additional information will be submitted as an attachment(s).

Did OMB Review the Rule Under Executive Order (EO) 12866?

No. OMB determined that the rule was not a significant regulatory action under the EO. However, EPA did submit the rule-related ICR to OMB for review at both the proposed and final

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rule stages as required under the Paperwork Reduction Act and OMB's implementing regulations at 5 CFR 1320.11. EPA's ICR submission at the proposed rule stage was accompanied by the draft notice of proposed rulemaking; at the final rule stage, the ICR submission was accompanied by the draft final rule.

III. Description of Non-Substantive Changes

What Information Collection Request (ICR) is EPA changing?

ICR Title: Pre-Manufacture Review Reporting and Exemption Requirements for

New Chemical Substances and Significant New Use Reporting

Requirements for Chemical Substances

ICR Numbers: EPA ICR No. 0574.13; OMB Control No. 2070-0012

What is the current status of this ICR?

This ICR is currently approved through Dec. 31, 2011. The ICR currently identifies the information collections (ICs), responses per IC and burden subtotal per IC shown in Table 1. The total annual burden approved for this ICR is 148,084 hours, with an estimated 2,329 responses per year.

Table 1. Currently Approved ICs under EPA ICR No. 0574.13

TITLE	RESPONSES	TIME (HOURS)
Pre-Manufacture Notifications	805	86,135
PMN-Related Significant New Use Notices (SNUNs)	7	749
Microbial Commercial Activity Notices (MCANs)	3	912
Test-Marketing Exemptions (TMEs)	5	500
Low Volume and Low Release/Low Exposure Exemptions (LVE/LoREX)	470	50,290
TSCA Experimental Release Applications (TERAs)	2	1,046
Tier I/Tier II Exemptions	2	232
Bona Fide Intent Notifications (Bona Fides)	133	2,926
Test Data Submissions under Section 5(e) Consent Orders	13	2,470
Non-Testing Activities under Section 5(e) Consent Orders	16	800
Polymer Exemption Post-Manufacture Annual Reports	175	1,050
Instant Photographic Film Articles Exemption	1	1
Research and Development Exemption	200	600
Notice of Commencement	497	373

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What are the changes that EPA is making to this ICR?

EPA is making three distinct changes to the ICR. First, EPA transferring certain information collection activities and related burden recently approved under OMB Control No. 2070-0173 (identified in Table 2 of this request) to this ICR (i.e., OMB Control No. 2070-0012) Second, EPA is adjusting the baseline number of annual responses for five of the ICs identified Table 1 based on a change in the way the number of annual responses were estimated in the "Economic Analysis of the Amendments to TSCA Section 5 Premanufacture and Significant New Use Notification Requirements Final Rule," versus previous practice. Last, EPA is effectuating program change burden reductions related to the clerical level efficiencies of electronic submission. Each of these changes was analyzed and described in the "Economic Analysis of the Amendments to TSCA Section 5 Premanufacture and Significant New Use Notification Requirements Final Rule," as well as the "Impact Analysis of the Final e-PMN Rule on Paperwork Burdens Approved under Existing EPA ICRs" (identified as Appendix 1 of the rule-related ICR), and is summarized here.

Burden Increases/Decreases – Adjustments

Changes to the Baseline Number of Responses

In developing the e-PMN final rule ICR, EPA utilized a somewhat different approach to project the number of new chemicals respondents and responses than was used for the same projection in the ICR approved under 2070-0012. For the rule-related ICR, EPA considered the average number of responses submitted annually over a five year period and the adjusted the annual average by 15 percent to count only valid submissions. Previously, EPA had based its projections on the number of responses submitted in each of the previous three 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. Compared to baseline burden projections for each activity, EPA estimated a net reporting burden decrease of 14,289 hours (see Table 2) and a net recordkeeping burden decrease of about 345 hours (see Table 3). The net reduction of estimated respondents results in a corresponding reduction of 14,634 hours over the present baseline estimate.

Table 2. Baseline Reporting Burden Adjustments by IC

EXISTING	Adjustments - Reporting					
Information Collection	Annual	Burden hours	Burden hours			
Information concetion	responses	per response	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 BURD	EN ADJUSTMEN	TS - SUBTOTAL	-14,289			

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Table 3. Baseline Recordkeeping Burden Adjustments by IC

EXISTING	Adjust	eping	
Information Collection	Annual	Burden hours	Burden hours
	responses	per response	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 BURD	EN ADJUSTMEN	TS - SUBTOTAL	-345

Transfer of New e-PMN Activities and Burden from Rule-Related ICR

Roughly 98 of the 295 new chemicals program respondents (about one-third of respondents) will implement the rule provisions each year during the two-year phase-in, which will result in an increase of 353 annual burden hours for respondents (see Table 4). This increase 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. The activities and the burden increase were considered in the e-PMN final rule ICR and approved as a program change increase under OMB Control No. 2070-0173. The transfer of these activities and the related burden to OMB Control No 2070-0012 does not in itself add any "new" burden – this change is merely an adjustment that reflects the transfer of activities and burden from one ICR to another.

Table 4. New, Rule-Related ICs and Burden (transferred from 2070-0173)

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New ICs Transferred	No. of	Responses	Responses /	Burden /	Annual		
from Rule-related ICR	Respondents	/ Year	Respondent	Response	Burden		
CDX Registration	295	98	0.33	0.9	90		
CDX Electronic Signature	295	98	0.33	1.8	172		
E-Payment (Pay.gov ID)	295	98	0.33	0.1	13		
Rule Familiarization	295	98	0.33	0.8	78		
(Annual average)							
Additional Respondent Burden – Adjustment Increase							

Given these changes to the baseline number of responses and the transfer of paperwork activities and burden from the rule-related ICR, EPA estimates a net burden decrease of 14,281 hours (an adjustment).

Burden Increases/Decreases – Program Changes

As discussed in the final rule preamble and supporting documents, the primary benefit of electronic reporting of TSCA section 5 notices to EPA's New Chemicals Program through CDX is burden reduction. When the Agency prepared the economic analysis and rule-related ICR (EPA No. 2327.02; OMB Control No. 2070-0173), EPA analyzed the impact that adoption of electronic reporting would have on baseline respondent burden. This analysis was presented in Appendix 1 of the rule-related ICR and is summarized in Table 10 of this change request. As described in the economic analysis and Appendix 1 of the rule-related ICR, respondents will not be able to submit

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certain section 5 notices through CDX. Respondents are not permitted to use CDX to complete the paperwork activities related to R&D exemptions, instant photographic film articles exemption notices, non-testing 5(e) submissions, and bona fides. Because rule-related program change reporting and recordkeeping burden reductions are linked with the respondents' use of the e-PMN software to prepare and submit information electronically, and subsequent utilization of electronic storage of records related to the submission, there are no program change reporting or recordkeeping burden changes for those activities.

Reduced Reporting Burden

The e-PMN final rule added two new data fields to the PMN form: (1) a field for entering the User Fee Payment Identification Number, and (2) a field for entering an optional email address of the principals listed on the Submitter Identification section of the PMN form. Based on reporting burden estimates developed for similar data elements on another EPA-required reporting form, the User Fee Payment Identification Number will increase burden on technical staff by 10 minutes per notice and the email address data field will increase technical burden by one minute per notice. This modest increase in reporting burden is offset by the overall burden savings related to electronic reporting. In addition, EPA removed the "Agent Signature Block" from the PMN form. The burden change associated with the removal of this field is negligible because fewer than five percent of submissions have a completed "Agent Signature Block" and, therefore, it was not factored into the rule-related burden analysis.

Implementation of electronic reporting saves respondents between approximately four and 14 hours per response (see Table 5)². There is no reduction of burden at the management and technical levels of respondent activities because the reporting software does not significantly alter their response actions. The burden savings associated with electronic reporting using the e-PMN software are realized at the clerical/administrative level. The deployment and adoption of the e-PMN software results in a reporting burden reduction of about 14,863 hours annually over baseline estimates (see Table 6). This is a program change.

Table 5. Reporting Burden Hour Program Changes (Per Response) by IC

EXISTING	Estimated Res	Program		
Information Collection	Current	New	Change	
Premanufacture Notification	105	92.2	-12.8	
PMN-related Significant New Use Notices	105	92.2	-12.8	
Low Volume and Low Release/Low Exposure (LVE/LoREX) Exemptions	105	92.2	-12.8	
Microbial Commercial Activity Notices (MCANs)	302	288.2	-13.8	
Test Marketing Exemptions	98	86.2	-11.8	
TSCA Experimental Release Applications (TERAs)	521	507.2	-13.8	
Tier I/Tier II Exemptions	114	110.2	-3.8	
Test Data Submissions under Section 5(e) Consent Orders	155	150.7	-4.3	
Notice of Commencement	0.5	0.6	0.1	

¹ Based on engineering estimates for reporting e-mail address for TRI Reporting. Memo entitled, "TRI Reporting Burden Estimates," from Hilary Eustace, David Cooper and Susan Day, Abt Associates, to Paul Borst, US EPA. July, 2004.

² Reporting burden for NOCs will increase slightly because the very small amount of clerical burden that is reduced is offset by the increase of 11 minutes in reporting time due to two new data fields on the e-PMN form (i.e., the User Fee Payment Identification Number and the optional email address of principals listed in the Submitters Identification section). The total increase in reporting burden for NOCs is less than 0.1 hours per response.

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Table 6. Reporting Burden Program Changes by IC

Tuois or reporting auraem 2 regram emanges of 20	Program Changes - Reporting					
EXISTING Information Collection	Annual responses	Burden hours per response	Burden hours per year			
Premanufacture Notification	720	-12.8	-9,216			
PMN-related Significant New Use Notices	8	-12.8	-102			
Microbial Commercial Activity Notices (MCANs)	3	- 13.8	-41			
Test Marketing Exemptions	8	-11.8	-94			
Low Volume and Low Release/Low Exposure (LVE/LoREX) Exemptions	419	-12.8	-5,363			
TSCA Experimental Release Applications (TERAs)	2	-13.8	-28			
Tier I/Tier II Exemptions	3	-3.8	-11			
Test Data Submissions under Section 5(e) Consent Orders	12	-4.3	-52			
Notice of Commencement	443	0.1	44			
REPORTING BURDEN PR	OGRAM CHANG	ES - SUBTOTAL	-14,863			

Reduced Recordkeeping Burden

The recordkeeping burden for respondents submitting TSCA section 5 notices to the New Chemicals Program through CDX is also decreased. Specifically, recordkeeping burden is reduced by half due to the efficiencies in creating and storing electronically section 5 notices and supporting documents (see Table 7). For most section 5 notices, baseline recordkeeping burden is estimated to be two hours. For these notices, one technical and one clerical staff member both 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, one technical and one clerical staff member both 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 both save four minutes on recordkeeping. The deployment and adoption of the e-PMN software results in a recordkeeping burden reduction of about 1,428 hours annually over baseline estimates (see Table 8). This is a program change.

Table 7. Recordkeeping Burden Hour Program Changes (Per Response) by IC

EXISTING Estimated Recordkeeping Burden				
Information Collection	Current	New	Change	
Premanufacture Notification	2.00	1.00	-1.00	
PMN-related Significant New Use Notices	2.00	1.00	-1.00	
Low Volume and Low Release/Low Exposure (LVE/LoREX) Exemptions	2.00	1.00	-1.00	
Microbial Commercial Activity Notices (MCANs)	2.00	1.00	-1.00	
Test Marketing Exemptions	2.00	1.00	-1.00	
TSCA Experimental Release Applications (TERAs)	2.00	1.00	-1.00	
Tier I/Tier II Exemptions	2.00	1.00	-1.00	
Test Data Submissions under Section 5(e) Consent Orders	35.0	17.5	-17.5	
Notice of Commencement	0.25	0.125	-0.125	

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Table 8. Recordkeeping Burden Program Changes by IC

	Program Changes - Recordkeeping					
EXISTING Information Collection	Annual responses	Burden hours per response	Burden hours per year			
Premanufacture Notification	720	-1.00	-720			
PMN-related Significant New Use Notices	8	-1.00	-8			
Microbial Commercial Activity Notices (MCANs)	3	-1.00	-3			
Test Marketing Exemptions	8	-1.00	-8			
Low Volume and Low Release/Low Exposure (LVE/LoREX) Exemptions	419	-1.00	-419			
TSCA Experimental Release Applications (TERAs)	2	-1.00	-2			
Tier I/Tier II Exemptions	3	-1.00	-3			
Test Data Submissions under Section 5(e) Consent Orders	12	-17.5	-210			
Notice of Commencement	443	-0.125	-55			
RECORDKEEPING BURDEN PR	OGRAM CHANGI	ES - SUBTOTAL	-1,428			

Bottom Line Changes in Burden

The adjustments to Agency estimates as well as program changes resulting from implementation of the e-PMN final rule combine for a net burden reduction of 30,572 hours from the 148,084 hours currently approved under OMB Control No. 2070-0012. This represents a total burden reduction of approximately 21 percent over the currently approved ICR (program change reduction of approximately 11 percent and adjustment-related reduction of approximately. 10 percent). Burden changes to the ICs that are already approved under OMB Control No. 2070-0012 are more fully illustrated in Tables 11 through 13. In addition, the transfer of ICs approved under OMB Control No. 2070-0173 would add 353 annual hours. Table 9 shows the bottom line net changes to the annual burden hours currently approved under EPA ICR No. 0574.13 (OMB Control No. 2070-0012). Table 10 shows the updated list of ICs, and the corresponding number of responses and burden hours as requested under this non-substantive change request.

Table 9. Bottom Line Burden Changes

Activity Summary	Burden Hour Change
Reporting – baseline adjustment	-14,289
Recordkeeping – baseline adjustment	-345
Transfer of ICs and Burden from OMB Control Number 2070-0173	353
Reporting – program changes	-14,863
Recordkeeping – program changes	-1,428
Total Burden Change	-30,572

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Table 10. Updated ICs for OMB Control No. 2070-0012

TITLE	RESPONSES	TIME (HOURS)
Pre-Manufacture Notifications	720	67,104
PMN-Related Significant New Use Notices (SNUNs)	8	746
Microbial Commercial Activity Notices (MCANs)	3	868
Test-Marketing Exemptions (TMEs)	8	698
Low Volume and Low Release/Low Exposure Exemptions (LVE/LoREX)	419	39,051
TSCA Experimental Release Applications (TERAs)	2	1,016
Tier I/Tier II Exemptions	3	334
Bona Fide Intent Notifications (Bona Fides)	116	2,552
Test Data Submissions under Section 5(e) Consent Orders	12	2,018
Non-Testing Activities under Section 5(e) Consent Orders	16	800
Polymer Exemption Post-Manufacture Annual Reports	175	1,050
Instant Photographic Film Articles Exemption	1	1
Research and Development Exemption	200	600
Notice of Commencement	443	321
CDX Registration	98	90
CDX Electronic Signature	98	172
Establishment of a Pay.gov account	98	13
e-PMN Rule Familiarization	98	78

Table 11. Summary of Electronic PMN Final Rule Impact on Burden Approved for Existing ICs under EPA ICR No. 0574.13; OMB Control No. 2070-0012

Existing ICs Approved under OMB Control No. 2070-0012	Ве	fore Fina	l e-PMN	Rule	After Final e-PMN Rule				Change			
	Annual Responses	Burden Per	Response	Annual Burden	Annual Responses	Burden Per	Response	Annual Burden (rounded)	Annual Responses	Burden Per	Response	Annual Burden (rounded)
		Rptg	Rkpg	Ar		Rptg	Rpkg	Ā		Rptg	Rkpg	A
Premanufacture Notification	805	105	2	86,135	720	92.2	1	67,104	-85	-12.8	-1	-19,031
PMN-related Significant New Use Notices	7	105	2	749	8	92.2	1	746	1	-12.8	-1	-3
Microbial Commercial Activity Notices (MCANs)	3	302	2	912	3	288.2	1	868	0	-13.8	-1	-44
Test Marketing Exemptions	5	98	2	500	8	86.2	1	698	3	-11.8	-1	198
Low Volume and Low Release/Low Exposure (LVE/LoREX) Exemptions	470	105	2	50,290	419	92.2	1	39,051	-51	-12.8	-1	-11,239
TSCA Experimental Release Applications (TERAs)	2	521	2	1,046	2	507.2	1	1,016	0	-13.8	-1	-30
Tier I/Tier II Exemptions	2	114	2	232	3	110.2	1	334	1	-3.8	-1	102
Bona Fide Intent Notifications (Bona Fides)[1]	133	20	2	2,926	116	20	2	2,552	-17	0	0	-374
Test Data Submissions under Section 5(e) Consent Orders	13	155	35	2,470	12	151	17.5	2,018	-1	-4.3	-17.5	-452
Non-Testing Activities under Section 5(e) Consent Orders[2]	16	25	25	800	16	25	25	800	0	0	0	0
Polymer Exemption Post-Manufacture Annual Reports[3]	175	2	4	1,050	175	2	4	1,050	0	0	0	0
Instant Photographic Film Articles Exemption[4]	1	0.5	0.25	1	1	0.5	0.25	1	0	0	0	0
Research and Development Exemption[5]	200	2.5	0.5	600	200	2.5	0.5	600	0	0	0	0
Notice of Commencement	497	0.5	0.25	373	443	0.6	0.125	321	-54	0.1	-0.125	-52
Totals	2,329			148,084	2,126			117,159	-203			-30,925

Blue-shaded cells reflect Agency adjustments

Orange-shaded cells reflects program changes

Pink-shaded cells reflect both Agency adjustments and program changes

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^[1] Bona fides cannot be submitted to EPA through CDX; therefore, no program change is estimated.

^[2] Paperwork associated with the non-testing activities under Section 5(e) Consent Orders is not submitted to EPA unless specifically requested (e.g., in the course of a compliance audit/inspection) and therefore will not be submitted through CDX.

^[3] Post-manufacture annual reports cannot be submitted to EPA through CDX; therefore, no change is estimated.

^[4] Instant photographic file article exemption notices cannot be submitted to EPA through CDX; therefore, no change is estimated.

^[5] A manufacturer or importer using this exemption must notify all persons in its employ or to whom it distributes the chemical substance and who are involved in any way in the research, of any risk to health associated with the chemical substance. No information is submitted to EPA.

Table 12. Adjustments to Baseline Responses and Burden Approved for Existing ICs under EPA ICR No. 0574.13; OMB Control No. 2070-0012

Existing ICs Approved under OMB Control No. 2070-0012	Current Baseline					Adjusted	Change			
	Annual Responses	Burden Per Response		Annual Burden	Annual Responses	Burden Per Response		Annual Burden (rounded)	Annual Responses	Annual Burden (rounded)
		Rptg	Rkpg	Ā		Rptg	Rpkg	Ar	_	
Premanufacture Notification	805	105	2	86,135	720	105	2	77,040	-85	-9,095
PMN-related Significant New Use Notices	7	105	2	749	8	105	2	856	1	107
Microbial Commercial Activity Notices (MCANs)	3	302	2	912	3	302	2	912	0	0
Test Marketing Exemptions	5	98	2	500	8	98	2	800	3	300
Low Volume and Low Release/Low Exposure (LVE/LoREX) Exemptions	470	105	2	50,290	419	105	2	44,833	-51	-5,457
TSCA Experimental Release Applications (TERAs)	2	521	2	1,046	2	521	2	1,046	0	0
Tier I/Tier II Exemptions	2	114	2	232	3	114	2	348	1	116
Bona Fide Intent Notifications (Bona Fides)[1]	133	20	2	2,926	116	20	2	2,552	-17	-374
Test Data Submissions under Section 5(e) Consent Orders	13	155	35	2,470	12	155	35	2,280	-1	-190
Non-Testing Activities under Section 5(e) Consent Orders[2]	16	25	25	800	16	25	25	800	0	0
Polymer Exemption Post-Manufacture Annual Reports[3]	175	2	4	1,050	175	2	4	1,050	0	0
Instant Photographic Film Articles Exemption[4]	1	0.5	0.25	1	1	0.5	0.25	1	0	0
Research and Development Exemption[5]	200	2.5	0.5	600	200	2.5	0.5	600	0	0
Notice of Commencement	497	0.5	0.25	373	443	0.5	0.25	332	-54	-41
Totals	2,329			148,084	2,126			133,450	-203	-14,634

^[1] Bona fides cannot be submitted to EPA through CDX.

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^[2] Paperwork associated with the non-testing activities under Section 5(e) Consent Orders is not submitted to EPA unless specifically requested (e.g., in the course of a compliance audit/inspection) and therefore will not be submitted through CDX.

^[3] Post-manufacture annual reports cannot be submitted to EPA through CDX.

^[4] Instant photographic file article exemption notices cannot be submitted to EPA through CDX.

^[5] A manufacturer or importer using this exemption must notify all persons in its employ or to whom it distributes the chemical substance and who are involved in any way in the research, of any risk to health associated with the chemical substance. No information is submitted to EPA.

Table 13. Program Changes to Burden for ICs With Adjusted Baselines under EPA ICR No. 0574.13; OMB Control No. 2070-0012

Existing ICs Approved under OMB Control No. 2070-0012	Adjusted Baseline				Burden Estimates with e-Reporting				Program Change
	Annual Responses Burden Per Response		Annual Burden (rounded)	Annual Responses	Burden Per Response		Annual Burden (rounded)	Annual Burden (rounded)	
		Rptg	Rpkg	Ā		Rptg	Rpkg	Ā	Ā
Premanufacture Notification	720	105	2	77,040	720	92.2	1	67,104	-9,936
PMN-related Significant New Use Notices	8	105	2	856	8	92.2	1	746	-110
Microbial Commercial Activity Notices (MCANs)	3	302	2	912	3	288.2	1	868	-44
Test Marketing Exemptions	8	98	2	800	8	86.2	1	698	-102
Low Volume and Low Release/Low Exposure (LVE/LoREX) Exemptions	419	105	2	44,833	419	92.2	1	39,051	-,5782
TSCA Experimental Release Applications (TERAs)	2	521	2	1,046	2	507.2	1	1,016	-30
Tier I/Tier II Exemptions	3	114	2	348	3	110.2	1	334	-14
Bona Fide Intent Notifications (Bona Fides)[1]	116	20	2	2,552	116	20	2	2,552	0
Test Data Submissions under Section 5(e) Consent Orders	12	155	35	2,280	12	151	17.5	2,018	-262
Non-Testing Activities under Section 5(e) Consent Orders[2]	16	25	25	800	16	25	25	800	0
Polymer Exemption Post-Manufacture Annual Reports[3]	175	2	4	1,050	175	2	4	1,050	0
Instant Photographic Film Articles Exemption[4]	1	0.5	0.25	1	1	0.5	0.25	1	0
Research and Development Exemption[5]	200	2.5	0.5	600	200	2.5	0.5	600	0
Notice of Commencement	443	0.5	0.25	332	443	0.6	0.125	321	-11
Totals	2,126			133,450	2,126			117,159	-16,291

^[1] Bona fides cannot be submitted to EPA through CDX, therefore; no program change is estimated.

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^[2] Paperwork associated with the non-testing activities under Section 5(e) Consent Orders is not submitted to EPA unless specifically requested (e.g., in the course of a compliance audit/inspection) and therefore, will not be submitted through CDX.

^[3] Post-manufacture annual reports cannot be submitted to EPA through CDX; therefore, no change is estimated.

^[4] Instant photographic file article exemption notices cannot be submitted to EPA through CDX; therefore, no change is estimated.

^[5] A manufacturer or importer using this exemption must notify all persons in its employ or to whom it distributes the chemical substance and who are involved in any way in the research, of any risk to health associated with the chemical substance. No information is submitted to EPA.