Economic Analysis for the Final Inventory Update Reporting (IUR) Modifications Rule

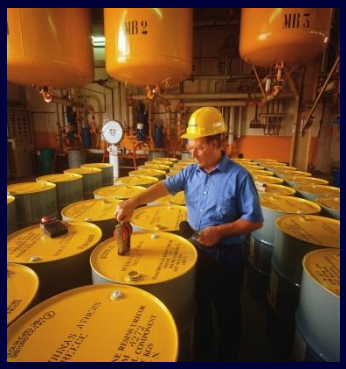

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Table of Contents

Contributors ..... **i**
Table of Contents ..... **ii**
List of Tables ..... **vii**
Executive Summary ..... **xiv**
1. Introduction **1-1**
1.1 Statutory Authority 1-1
1.2 Regulatory History 1-1
2. IUR Requirements and Affected Entities **2-1**
2.1 Overview of IUR Requirements 2-1
2.2 Overview of the Regulated Community 2-2
3. Changes in Reporting Requirements under the Final IUR Modifications Rule **3-1**
3.1 Technical Modifications to the Regulatory Text 3-1
3.1.1 Move the IUR Regulatory Text from 710 Subpart C to 711 and Eliminate Subpart Divisions 3-1
3.1.2 Consolidation of Definitions 3-1
3.1.3 Remove "Non-isolated Intermediate" Definition from §710.3 3-2
3.1.4 Remove Subpart B Text 3-2
3.1.5 Remove Superfluous Text Associated With Reporting Production Volumes 3-2
3.1.6 Correct Text Associated With Reporting Number of Sites and Number of Workers 3-2
3.2 Modifications to Selected Definitions 3-2
3.2.1 Manufacture and Manufacturer 3-2
3.2.2 Site 3-3
3.2.3 Electronic Reporting-Related Definitions 3-3
3.2.4 Processing and Use-Related Definitions 3-3
3.2.5 Principal Reporting Year and Submission Period 3-4
3.3 Modifications to Reporting Thresholds 3-4
3.3.1 Method for Determining Whether a Manufacturer is subject to IUR Reporting Requirements 3-4
3.3.2 Replacing the 300,000 lb Threshold for Processing and Use Information 3-5
3.3.3 Reducing the 25,000 lb Threshold for Specific Regulated Chemical Substances 3-5
3.4 Changes to Chemical Substances Subject to the IUR Rule 3-6
3.4.1 Make Chemical Substances Subject to Enforceable Consent Agreements (ECAs) Ineligible for Exemptions 3-6
3.4.2 Full Exemption for Manufactured Water 3-7
3.4.3 Remove Fully Exempt Polymers from the Partially Exempt List 3-7
3.5 Modifications to Reportable Data Elements 3-7
3.5.1 Parent Company and Site Identity 3-7
3.5.2 Technical Contact 3-7
3.5.3 Chemical Identity 3-8
3.5.4 Report Production Volume for Each of the Years since the Last Principal Reporting Year 3-9
3.5.5 Volume of Chemical Substance Used On-Site 3-9
3.5.6 Indicate Whether Imported Chemical Substances Are Physically at Reporting Site 3-9
3.5.7 Report Production Volume Exported 3-9
3.5.8 Identify Whether a Chemical Substance is to be Recycled, Remanufactured, Reprocessed, or Reused 3-10

3.6 Concentration Ranges 3-10
3.7 Industrial Processing and Use Information Reporting 3-10
3.7.1 Revise Industrial Function Categories 3-10
3.7.2 Industrial Sectors 3-11
3.8 Consumer and Commercial Use Reporting 3-11
3.8.1 Revise Consumer and Commercial Product Categories 3-11
3.8.2 Designation of Consumer or Commercial Use 3-12
3.8.3 Number of Commercial Workers Reasonably Likely To Be Exposed 3-12
3.9 Changes to Standard for the Reporting of Processing and Use Information 3-12
3.10 Modifications to Confidential Business Information (CBI) Claims 3-12
3.10.1 Chemical Identity CBI Claims 3-13
3.10.2 Upfront Substantiation for Processing and Use Information CBI Claims 3-13
3.10.3 Prohibition of Confidentiality Claims for Data Elements Identified as "Not Known or Reasonably Ascertainable" 3-14
3.11 Method of Submission 3-14
3.11.1 Updated e-IUR Reporting Tool 3-14
3.11.2 Require Electronic Submissions over the Internet 3-15
3.11.3 Electronic Signature Process 3-15
3.12 Modifications Specifically Affecting Importers 3-15
3.13 Modify Reporting Frequency 3-16
4. Industry Burden and Cost Estimates 4-1
4.1 Methodology for Compliance Cost and Burden Analysis 4-1
4.2 Industry Unit Burden and Cost Estimates 4-2
4.2.1 Estimates of Wage Rates 4-2
4.2.2 Estimates of Baseline Labor Hours (Burden) 4-3
4.2.3 Estimates of Baseline Submission (Mailing) Costs 4-7
4.2.4 Estimates of Baseline Cost per Report 4-8
4.2.5 Estimates of the Number of Sites and Reports 4-11
4.2.6 Estimates of Future Reporting Cycles' Labor Hours (Burden) 4-11
4.3 Total Baseline IUR Industry Compliance Burden and Costs 4-17
4.4 Changes in Industry Burden and Costs Due to the Final IUR Modifications Rule 4-18
4.4.1 Technical Modifications to the Regulatory Text 4-18
4.4.2 Modifications to Selected Definitions 4-18
4.4.3 Method for Determining Whether a Manufacturer is Subject to IUR Reporting Requirements 4-18
4.4.4 Replace the 300,000 lb Threshold for Processing and Use Reporting 4-20
4.4.5 Reducing the 25,000 lb Threshold for Specific Regulated Chemical Substances 4-22
4.4.6 Make Chemical Substances Subject to Enforceable Consent Agreements (ECAs) Ineligible for Exemptions 4-24
4.4.7 Full Exemption for Manufactured Water 4-26
4.4.8 Remove Fully-Exempt Polymers from the Partially-Exempt List 4-27
4.4.9 Parent Company and Site Identity 4-28
4.4.10 Technical Contact 4-28
4.4.11 Chemical Identity 4-28
4.4.12 Report Production Volume for Each of the Years since Last Principal Reporting Year 4-29
4.4.13 Volume of Chemical Substance Used On-Site 4-31
4.4.14 Indicate Whether Chemical Substance Is Physically at Reporting Site 4-32
4.4.15 Report Production Volume Exported 4-34

4.4.16 Identify Whether a Chemical Substance is to be Recycled, Remanufactured, Reprocessed, or Reused 4-35
4.4.17 Concentration Ranges 4-36
4.4.18 Revise Industrial Function Categories 4-36
4.4.19 Replace NAICS Codes with Industrial Sectors 4-38
4.4.20 Revise Consumer and Commercial Product Categories 4-38
4.4.21 Designation of Consumer or Commercial Use 4-40
4.4.22 Number of Commercial Workers Reasonably Likely To Be Exposed 4-40
4.4.23 Changes to the Standard for the Reporting of Processing and Use Information 4-41
4.4.24 Chemical Identity CBI Claims 4-41
4.4.25 Upfront Substantiation for Processing and Use Information CBI Claims 4-41
4.4.26 Limitation on the Confidentiality Claims for Data Elements Identified as "Not Known or Reasonably Ascertainable" 4-43
4.4.27 Require Electronic Submissions over the Internet 4-43
4.4.28 Updated e-IUR Reporting Software 4-45
4.4.29 Electronic Signature Process 4-45
4.4.30 Modifications Specifically Affecting Importers 4-46
4.4.31 Modify Reporting Frequency 4-47
4.5 Total Industry Compliance Burden and Cost of all Amendments 4-49
4.5.1 Modifications that Affect the Number of Reports Submitted 4-49
4.5.2 Modifications That Affect the Reporting Burden 4-52
4.5.3 Amendment that Affects the Reporting Frequency 4-58
4.5.4 Average Cost and Burden per Site 4-58
4.6 Annualized Industry Cost Estimates for all Modifications 4-60
5. Agency Burden and Cost Estimates 5-1
5.1 Methodology for Agency Burden and Cost 5-1
5.2 Data for Agency Cost Estimates 5-1
5.2.1 Agency Wage Rates 5-1
5.2.2 Extramural (Contractor) Costs 5-2
5.3 Current Total Agency Burden and Cost 5-2
5.4 Changes to Agency Burden and Cost as a Result of the Modifications 5-4
5.4.1 Technical Modifications to the Regulatory Text 5-4
5.4.2 Modifications to Selected Definitions 5-4
5.4.3 Method for Determining Whether a Manufacturer is subject to IUR Reporting Requirements 5-5
5.4.4 Replace the 300,000 lb Threshold for Processing and Use Reporting 5-6
5.4.5 Reduce the 25,000 lb Threshold for Specific Regulated Chemical Substances 5-7
5.4.6 Make Chemical Substances Subject to Enforceable Consent Agreements (ECAs) Ineligible for Exemptions 5-9
5.4.7 Full Exemption for Manufactured Water 5-9
5.4.8 Remove Fully-Exempt Polymers from the Partially-Exempt List 5-10
5.4.9 Parent Company and Site Identity 5-10
5.4.10 Technical Contact 5-10
5.4.11 Chemical Identity 5-11
5.4.12 Report Production Volume for Each of the Years since Last Principal Reporting Year 5-12
5.4.13 Volume of Chemical Substance Used On-Site 5-13
5.4.14 Indicate Whether an Imported Chemical Substance Is Physically at the Reporting Site 5-14
5.4.15 Report Production Volume Exported 5-15

5.4.16 Identify Whether Chemical Substance is to be Recycled, Remanufactured, Reprocessed, or Reused 5-15
5.4.17 Concentration Ranges 5-16
5.4.18 Revise Industrial Function Categories 5-16
5.4.19 Replace NAICS Codes with Industrial Sectors 5-17
5.4.20 Revise Consumer and Commercial Product Categories 5-17
5.4.21 Designation of Consumer or Commercial Use 5-19
5.4.22 Number of Commercial Workers Reasonably Likely To Be Exposed 5-19
5.4.23 Changes to the Standard for the Reporting of Processing and Use Information 5-20
5.4.24 Chemical Identity CBI Claims 5-20
5.4.25 Upfront Substantiation for Processing and Use Information CBI Claims 5-20
5.4.26 Limitation on Confidentiality Claims for Data Elements Identified as "Not Known or Reasonably Ascertainable" 5-21
5.4.27 Require Electronic Submissions over the Internet 5-21
5.4.28 Updated e-IURweb Reporting Software 5-22
5.4.29 Electronic Signature Process 5-22
5.4.30 Modifications Specifically Affecting Importers 5-23
5.4.31 Modify Reporting Frequency 5-23
5.5 Total Agency Cost of All Modifications 5-25
5.6 Annualized Agency Cost Estimates for All Modifications 5-1
6. Social Cost Summary 6-1
7. Impact of the Final IUR Rule Modifications Rule on the Benefits of the IUR 7-1
7.1 Benefits of Information-Based Policies 7-2
7.2 Benefits of Individual Amendments 7-3
7.2.1 Tailor Information Collected to More Closely Match the Agency's Information Needs 7-3
7.2.2 Increase EPA's Ability to Effectively Provide Public Access to the Information 7-7
7.2.3 Obtain New and Updated Exposure Information 7-8
7.2.4 Improve Utility of Information Reported 7-12
7.3 Potential Users of Information Generated by the IUR Modifications Rule 7-14
7.3.1 EPA Risk-Screening and Management Programs 7-15
7.3.2 Other Federal Risk Management Programs 7-18
7.3.3 State and Local Programs 7-18
7.3.4 Nongovernmental Organization (NGO) Initiatives and Private-Sector Stewardship 7-19
8. Small Entity Analysis 8-1
8.1 Select a Relevant Small Entity Definition 8-1
8.2 Identify Number of Small Companies Reporting in 2006 8-2
8.3 Estimate Number of Parent Companies 8-3
8.4 Estimate Number of Small Companies 8-3
8.5 Estimate Cost-to-Sales Ratios for Small Companies 8-4
8.6 Summary 8-6
9. Additional Analyses 9-1
9.1 Executive Order 12866 9-1
9.2 Unfunded Mandates Reform Act (UMRA) 9-1
9.3 Paperwork Reduction Act (PRA) 9-1
9.4 Executive Order 13132 - Federalism 9-2
9.5 Executive Order 12898 – Environmental Justice 9-2
9.6 Executive Order 13045 – Children's Health 9-3
9.7 Executive Order 13175 – Consultation and Coordination with Indian Tribal Governments 9-3

9.8 Executive Order 13211 – Energy Supply, Distribution, or Use 9-3
9.9 National Technology Transfer Advancement Act 9-3
10. References 10-1
Appendix A. – Current and Revised Industrial Function Categories A-1
Appendix B. Current and Revised Consumer and Commercial Product Categories B-1
Appendix C. Industrial Sectors C-1
Appendix D. Sensitivity Analyses D-1
D.1 Method for Determining Whether the Threshold Is Met D-1
D.2 Reporting Production Volume Used On-Site D-4
D.3 Revising Industrial Function Categories D-5
D.4 "Other" as a Consumer and/or Commercial Product Category D-8
D.5 Upfront CBI Substantiation D-10
Appendix E. Alternative Regulatory Options E-1
E.1 Require Submitters to Submit Full Data Annually E-1
E.1.1 Annual Reporting Cost and Burden when the Option is Considered by Itself E-1
E.1.2 Annual Reporting Cost and Burden when the All the Proposed Amendments are Considered E-3
E.1.3 Small Entity Analysis E-5
E.2 Modify Reporting Frequency to a Three-Year Cycle E-6
E.2.1 Three-Year Reporting Cycle Cost and Burden when the Option is Considered by Itself E-6
E.2.2 Three-Year Cycle Cost and Burden when the All the Proposed Amendments are Considered E-9
E.2.3 Small Entity Analysis E-11
E.3 Change the Threshold for Reporting to 10,000 lb E-12
E.3.1 10,000 lb Reporting Threshold Cost and Burden when the Option is Considered by Itself E-13
E.3.2 Change the Threshold for Reporting to 10,000 lb when All Proposed Amendments are Considered E-15
E.3.3 Small Entity Analysis E-24
Appendix F. Additional Exposure-Related Data Elements F-1
F.1 Estimated Number of Affected Entities F-6
F.2 Industry Burden Estimate F-7
F.3 Industry Cost Estimate F-11
F.4 Agency Burden Estimate F-15
F.5 Agency Cost Estimate F-19
F.6 Small Entity Analysis F-23
Appendix G. Estimated Burden and Cost of a Section 8(a) Rule for Exposure-Related Data Elements G-1
G.1 Estimated Number of Affected Entities G-1
G.2 Industry Burden Estimate G-2
G.3 Industry Cost Estimate G-4
G.4 Agency Burden Estimate G-5
G.5 Agency Cost Estimate G-7
G.6 Small Entity Analysis G-8

List of Tables

Table ES- 1 Summary of the Costs and Benefits Associated with the IUR Rule xvii
Table 4-1: Derivation of Loaded Wage Rates for the Private Manufacturing Sector (2008$) 4-3
Table 4-2: Baseline First-Cycle Labor Burden per Form U, in Hours 4-5
Table 4-3: Burden Percentages Attributed to Site-Limited Activity and Production Volume Questions 4-7
Table 4-4: Mailing Submission Costs (December, 2009) 4-8
Table 4-5: Baseline First-Cycle Total Cost per Form U (2008$) 4-9
Table 4-6: Baseline Number of Reports and Sites 4-11
Table 4-7: Weighting Factors for Burden Estimates for Sites That Have Previously Submitted a Form U 4-12
Table 4-8: Baseline Future-Cycle Labor Burden per Report, in Hours 4-13
Table 4-9: Baseline Future-Cycle Total Cost per Report (2008$) 4-15
Table 4-10: Total Baseline Cost and Burden to Industry (2012 Reporting Cycle) 4-17
Table 4-11: Total Baseline Cost and Burden to Industry (Future Reporting Cycles) 4-17
Table 4-12: Change in Industry Burden as a Result of Modifying the Method for Determining Whether a Manufacturer is Subject to IUR Reporting Requirements 4-19
Table 4-13: Change in Industry Cost as a Result of Modifying the Method for Determining Whether a Manufacturer is Subject to IUR Reporting Requirements 4-20
Table 4-14: Change in Industry Burden as a Result of Replacing the 300,000 lb Threshold for Downstream Processing and Use Information Reporting 4-21
Table 4-15: Change in Industry Cost as a Result of Reducing the 300,000 lb Threshold for Downstream Processing and Use Information Reporting 4-22
Table 4-16: Change in Industry Burden as a Result of Reducing the 25,000 lb Threshold for Specific Regulated Chemical Substances 4-23
Table 4-17: Change in Industry Cost as a Result of Reducing the 25,000 lb Threshold for Specific Regulated Chemical Substances 4-24
Table 4-18: Change in Industry Burden as Result of Making Chemical Substances Subject to ECAs Ineligible for Exemptions 4-25
Table 4-19: Change in Industry Cost as a Result of Making Chemical Substances Subject to ECAs Ineligible for Exemptions 4-26
Table 4-20: Change in Industry Burden as a Result of Exempting Manufactured Water from Reporting 4-27
Table 4-21: Change in Industry Cost as a Result of Exempting Manufactured Water from Reporting 4-27
Table 4-22: Change in Industry Burden as a Result of Accession Number Requests 4-29
Table 4-23: Change in Industry Cost as a Result of Accession Number Requests 4-29
Table 4-24: Change in Industry Burden as a Result of Requiring the Reporting of Production Volume in all Non-Principal Reporting Years 4-30
Table 4-25: Change in Industry Cost as a Result of Requiring the Reporting of Production Volume in all Non-Principal Reporting Years 4-30
Table 4-26: Change in Industry Burden as a Result of Requiring the Reporting of Production Volume Used On-Site 4-32
Table 4-27: Change in Industry Cost as a Result of Requiring the Reporting of Production Volume Used On-Site 4-32
Table 4-28: Change in Industry Burden as a Result of Indicating Whether a Chemical Substance is Physically at the Reporting Site 4-33
Table 4-29: Change in Industry Cost as a Result of Indicating Whether a Chemical Substance is Physically at the Reporting Site 4-33
Table 4-30: Change in Industry Burden as a Result of Requiring Reporting of Volume Exported 4-34
Table 4-31: Change in Industry Cost as a Result of Requiring Reporting of Volume Exported 4-34

Table 4-32: Change in Industry Burden as a Result of Indicating Whether Chemical Substance is to be Recycled, Remanufactured, Reprocessed, or Reused 4-35
Table 4-33: Change in Industry Cost as a Result of Indicating Whether Chemical Substance is to be Recycled, Remanufactured, Reprocessed, or Reused 4-36
Table 4-34: Change in Industry Burden as a Result of Revising the Industrial Function Categories 4-37
Table 4-35: Change in Industry Cost as a Result of Revising the Industrial Function Categories 4-37
Table 4-36: Change in Industry Burden as a Result of Revising the Consumer and Commercial Product Categories 4-39
Table 4-37: Change in Industry Cost as a Result of Revising the Consumer and Commercial Product Categories 4-39
Table 4-38: Change in Industry Burden as a Result of Requiring the Number of Commercial Workers Reasonably Likely To Be Exposed 4-40
Table 4-39: Change in Industry Cost as a Result of Requiring the Number of Commercial Workers Reasonably Likely To Be Exposed 4-41
Table 4-40: Change in Industry Burden as a Result of Requiring Upfront Substantiation for Claiming Processing and Use Information as CBI 4-42
Table 4-41: Change in Industry Cost as a Result of Requiring Upfront Substantiation for Claiming Processing and Use Information as CBI 4-43
Table 4-42: Change in Industry Burden as a Result of Requiring Electronic Submission 4-44
Table 4-43: Change in Industry Cost as a Result of Requiring Electronic Submission 4-45
Table 4-44: Change in Industry Burden as a Result of Requiring CDX Registration for Secondary Submitters 4-46
Table 4-45: Change in Industry Cost as a Result of Requiring CDX Registration for Secondary Submitters 4-46
Table 4-46: Change in Industry Burden as a Result of Modifying the Reporting Frequency, over a 26-Year Period 4-48
Table 4-47: Change in Industry Cost as a Result of Modifying the Reporting Frequency, over a 26-Year Period 4-49
Table 4-48: Change in the Number of Sites and Reports Submitted for All Amendments Combined (First Reporting Cycle) 4-51
Table 4-49: Change in the Number of Sites and Reports Submitted for All Amendments Combined (Future Cycles) 4-52
Table 4-50: Change in the First Year Reporting Cycle Burden for All Amendments Combined, by Labor Category 4-55
Table 4-51: Change in the Future Reporting Cycle Burden for All Amendments Combined, by Labor Category 4-55
Table 4-52: Total Industry Burden for All Amendments Combined 4-57
Table 4-53: Total Industry Cost When All Amendments Are Combined 4-58
Table 4-54: Average Number of Full and Partial Reports per Site 4-59
Table 4-55: Average Total Burden per Site 4-59
Table 4-56: Average Total Cost per Site 4-60
Table 4-57: Industry Burden over a Period of 26 Years if All Amendments Are Implemented 4-61
Table 4-58: Industry Cost over a Period of 26 Years if All Amendments Are Implemented 4-62
Table 5-1: Derivation of Loaded Agency Wage Rates (2008$) 5-2
Table 5-2: Derivation of Extramural Task Costs, per Reporting Cycle 5-2
Table 5-3: Total Agency Cost under the Current IUR Requirements 5-3
Table 5-4: Baseline Agency Burden per Report 5-4
Table 5-5: Change in Agency Burden as a Result of Modifying the Method for Determining Whether a Manufacturer is Subject to IUR Reporting Requirements 5-5
Table 5-6: Change in Agency Cost as a Result of Modifying the Method for Determining Whether a Manufacturer is Subject to IUR Reporting Requirements 5-6

Table 5-7: Change in Agency Burden as a Result of Replacing the 300,000 lb Threshold for Processing and Use Reporting....5-7
Table 5-8: Change in Agency Cost as a Result of Replacing the 300,000 lb Threshold for Processing and Use Reporting....5-7
Table 5-9: Change in Agency Burden as a Result of Reducing the 25,000 lb Threshold for Specific Regulated Chemical Substances (Future Cycles Only)....5-8
Table 5-10: Change in Agency Cost as a Result of Reducing the 25,000 lb Threshold for Specific Regulated Chemical Substances (Future Cycles Only)....5-8
Table 5-11: Change in Agency Burden as a Result of Making Chemical Substances Subject to ECAs Ineligible for Exemptions....5-9
Table 5-12: Change in Agency Cost as a Result of Making Chemical Substances Subject to ECAs Ineligible for Exemptions....5-9
Table 5-13: Change in Agency Burden as a Result of a Full Exemption for Manufactured Water....5-10
Table 5-14: Change in Agency Cost as a Result of a Full Exemption for Manufactured Water....5-10
Table 5-15: Change in Agency Burden as a Result of Accession Nnumber Requests....5-11
Table 5-16: Change in Agency Cost as a Result of Accession Number Requests....5-12
Table 5-17: Change in Agency Burden as a Result of Reporting of Production Volume for Each of the Years since Last Principal Reporting Year....5-12
Table 5-18: Change in Agency Cost as a Result of Reporting of Production Volume for Each of the Years since Last Principal Reporting Year....5-13
Table 5-19: Change in Agency Burden as a Result of Reporting of Production Volume Used On-Site....5-13
Table 5-20: Change in Agency Cost as a Result of Reporting of Production Volume Used On-Site....5-14
Table 5-21: Change in Agency Burden as a Result of Indicating Whether an Imported Chemical Substance is Physically at the Reporting Site....5-14
Table 5-22: Change in Agency Cost as a Result of Indicating Whether an Imported Chemical Substance is Physically at the Reporting Site....5-14
Table 5-23: Change in Agency Burden as a Result of Requiring the Reporting of Export Volume....5-15
Table 5-24: Change in Agency Cost as a Result of Requiring the Reporting of Export Volume....5-15
Table 5-25: Change in Agency Burden as a Result of Indicating Whether Chemical Substance is to be Recycled, Remanufacture, Reprocessed, or Reused....5-16
Table 5-26: Change in Agency Cost as a Result of Indicating Whether Chemical Substance is to be Recycled, Remanufactured, Reprocessed, or Reused....5-16
Table 5-27: Change in Agency Burden as a Result of Revising the Industrial Function Categories....5-17
Table 5-28: Change in Agency Cost as a Result of Revising the Industrial Function Categories....5-17
Table 5-29: Change in Agency Burden as a Result of Revising the Consumer and Commercial Product Categories....5-18
Table 5-30: Change in Agency Cost as a Result of Revising the Consumer and Commercial Product Categories....5-18
Table 5-31: Change in Agency Burden as a Result of Designation of Consumer or Commercial Use....5-19
Table 5-32: Change in Agency Cost as a Result of Designation of Consumer or Commercial Use....5-19
Table 5-33: Change in Agency Burden as a Result of Requiring the Number of Commercial Workers Reasonably Likely To Be Exposed....5-19
Table 5-34: Change in Agency Cost as a Result of Requiring the Number of Commercial Workers Reasonably Likely To Be Exposed....5-20
Table 5-35: Change in Agency Burden as a Result of Requiring Upfront Substantiation for CBI Claims....5-20
Table 5-36: Change in Agency Cost as a Result of Requiring Upfront Substantiation for CBI Claims....5-21
Table 5-37: Change in Agency Burden as a Result of Requiring Electronic Submission....5-22
Table 5-38: Change in Agency Cost as a Result of Requiring Electronic Submission....5-22
Table 5-39: Change in Agency Burden as a Result of Modifying the Reporting Frequency....5-24
Table 5-40: Change in Agency Cost as a Result of Modifying the Reporting Frequency....5-24

Table 5-41: Change in Agency Burden as a Result of All the IUR Modifications (First Reporting Cycle) 5-26
Table 5-42: Change in Agency Burden as a Result of All the IUR Modifications (Future Reporting Cycles) 5-26
Table 5-43: Total Agency Burden for All Amendments Combined 5-27
Table 5-44: Total Agency Cost of All Amendments Combined 5-28
Table 5-45: Agency Burden per Report when All Amendments are Combined (First Cycle) 5-30
Table 5-46: Agency Burden per Report when All Amendments are Combined (Future Cycles) 5-30
Table 5-47: Agency Cost per Report When All Amendments are Combined (First Reporting Cycle) ... 5-32
Table 5-48: Agency Cost per Report When All Amendments are Combined (Future Reporting Cycles) .. 5-32
Table 5-49: Agency Cost per Report when All Amendments are Combined 5-0
Table 5-50: Agency Burden over a Period of 26 Years if All Amendments are Implemented 5-1
Table 5-51: Annual and Discounted Total Cost to the Agency of All Modifications 5-2
Table 6-1: Change in Total Burden to Society If All Modifications are Implemented 6-1
Table 6-2: Change in Total Costs to Society if All Modifications are Implemented 6-2
Table 8-1: Results of Dun & Bradstreet Analysis 8-3
Table 8-2: Estimated Number of Small Companies under the IUR Rule Amendments 8-4
Table 8-3: Derivation of Cost-to-Sales Ratios for Small Companies under the IUR Rule Amendments .8-5
Table A-1: List of Current and Revised Industrial Function Categories A-1
Table B-1: List of Current and Revised Consumer and Commercial Product Categories B-1
Table D-1: Sensitivity Analysis of Industry Burden Estimates for Modifying the Method for Determining Whether the Threshold Is Met (Future Reporting Cycles Only) D-2
Table D-2: Sensitivity Analysis of Industry Cost Estimates for Modifying the Method for Determining Whether the Threshold Is Met (Future Reporting Cycles Only) D-2
Table D-3: Sensitivity Analysis of Agency Burden Estimates for Modifying the Method for Determining Whether the Threshold Is Met (Future Reporting Cycles Only) D-3
Table D-4: Sensitivity Analysis of Agency Cost Estimates for Modifying the Method for Determining Whether the Threshold Is Met (Future Reporting Cycles Only) D-3
Table D-5: Sensitivity Analysis of Industry Burden Estimates for Reporting Production Volume Used On-Site D-4
Table D-6: Sensitivity Analysis of Industry Cost Estimates for Reporting Production Volume Used On-Site D-4
Table D-7: Sensitivity Analysis of Agency Burden Estimates for Reporting Production Volume Used On-Site D-5
Table D-8: Sensitivity Analysis of Agency Cost Estimates for Reporting Production Volume Used On-Site D-5
Table D-9: Sensitivity Analysis of Industry Burden Estimates for Requiring Write-in Text for “Other” as an Industrial Function Category D-6
Table D-10: Sensitivity Analysis of Industry Cost Estimates for Requiring Write-in Text for “Other” as an Industrial Function Category D-7
Table D-11: Sensitivity Analysis of Agency Burden Estimates for Requiring Write-in Text for “Other” as an Industrial Function Category D-7
Table D-12: Sensitivity Analysis of Agency Cost Estimates for Requiring Write-in Text for “Other” as an Industrial Function Category D-8
Table D-13: Sensitivity Analysis of Industry Burden Estimates for Requiring Write-in Text for “Other” as a Consumer and/or Commercial Product Category D-9
Table D-14: Sensitivity Analysis of Industry Cost Estimates for Requiring Write-in Text for “Other” as a Consumer and/or Commercial Product Category D-9
Table D-15: Sensitivity Analysis of Agency Burden Estimates for Requiring Write-in Text for “Other” as a Consumer and/or Commercial Product Category D-10

Table D-16: Sensitivity Analysis of Agency Cost Estimates for Requiring Write-in Text for "Other" as a Consumer and/or Commercial Product Category D-10
Table D-17: Sensitivity Analysis of Industry Burden Estimates for Requiring Upfront CBI Substantiation D-11
Table D-18: Sensitivity Analysis of Industry Cost Estimates for Requiring Upfront CBI Substantiation . D-11
Table D-19: Sensitivity Analysis of Agency Burden Estimates for Requiring Upfront CBI Substantiation D-12
Table D-20: Sensitivity Analysis of Agency Cost Estimates for Requiring Upfront CBI Substantiation .. 12
Table E-1: Industry Burden under the Alternative Option to Require Submitters to Submit Full Data Annually E-1
Table E-2: Industry Cost under the Alternative Option to Require Submitters to Submit Full Data Annually E-2
Table E-3: Agency Burden under the Alternative Option to Require Submitters to Submit Full Data Annually E-2
Table E-4: Agency Cost under the Alternative Option to Require Submitters to Submit Full Data Annually E-3
Table E-5: Industry Burden under the Alternative Option to Require Submitters to Submit Full Data Annually when all the Proposed Amendments are Considered E-3
Table E-6: Industry Cost under the Alternative Option to Require Submitters to Submit Full Data Annually when all the Proposed Amendments are Considered E-4
Table E-7: Agency Burden under the Alternative Option to Require Submitters to Submit Full Data Annually when all the Proposed Amendments are Considered E-4
Table E-8: Agency Cost under the Alternative Option to Require Submitters to Submit Full Data Annually when all the Proposed Amendments are Considered E-5
Table E-9: Derivation of Cost-to-Sales Ratios for Small Manufacturers for Collection of Annual Reporting E-6
Table E-10: Annual Industry Burden under the Alternative Option of a Three-Year Reporting Cycle ... E-7
Table E-11: Industry Cost under the Alternative Option of a Three-Year Reporting Cycle E-7
Table E-12: Burden to the Agency under the Alternative Option of a Three-Year Reporting Cycle E-8
Table E-13: Agency Cost under the Alternative Option of a Three-Year Reporting Cycle E-8
Table E-14: Annual Industry Burden under the Alternative Option of a Three-Year Reporting Cycle when the All the Proposed Amendments are Considered E-9
Table E-15: Industry Cost under the Alternative Option of a Three-Year Reporting Cycle when the All the Proposed Amendments are Considered E-10
Table E-16: Agency Burden under the Alternative Option of a Three-Year Reporting Cycle when the All the Proposed Amendments are Considered E-10
Table E-17: Agency Cost under the Alternative Option of a Three-Year Reporting Cycle when the All the Proposed Amendments are Considered E-11
Table E-18: Derivation of Cost-to-Sales Ratios for Small Manufacturers for a Three-Year Reporting Cycle E-12
Table E-19: Number of Reports and Sites in 2002 ..... E-13
Table E-20: Industry Burden as a Result of Changing the Threshold for Reporting to 10,000 lb E-14
Table E-21: Industry Cost as a Result of Changing the Threshold for Reporting to 10,000 lb E-14
Table E-22: Change in Burden to the Agency as a Result of Changing the Threshold for Reporting to 10,000 lb E-15
Table E-23: Change in Agency Cost as a Result of Changing the Threshold for Reporting to 10,000 lb .. E-15
Table E-24: Change in the Number of Sites and Reports Submitted of All Amendments Combined with the 10,000 lb Reporting Threshold (First Reporting Cycle) E-17

Table E-25: Change in the Number of Sites and Reports Submitted of All Amendments Combined with the 10,000 lb Reporting Threshold (Future Reporting Cycles) E-18
Table E-26: Industry Burden as a Result of Changing the Threshold for Reporting to 10,000 lb when All Proposed Amendments are Considered E-19
Table E-27: Industry Cost as a Result of Changing the Threshold for Reporting to 10,000 lb when All Proposed Amendments are Considered E-20
Table E-28: Industry Burden under the Alternative Option of a Lowered Reporting Threshold and All Other Amendments when All Proposed Amendments are Considered E-20
Table E-29: Change in Industry Cost as a Result of Changing the Threshold for Reporting to 10,000 lb and All Other Amendments when All Proposed Amendments are Considered E-21
Table E-30: Agency Burden as a Result of Lowered Threshold Reporting and All Other Amendments when All Proposed Amendments are Considered E-22
Table E-31: Agency Cost as a Result of Lowered Threshold Reporting and All Other Amendments when All Proposed Amendments are Considered E-23
Table E-32: Agency Burden under the Alternative Option of a Lowered Reporting Threshold and All Other Amendments when All Proposed Amendments are Considered E-23
Table E-33: Change in Agency Cost as a Result of Changing the Threshold for Reporting to 10,000 lb and All Other Amendments when All Proposed Amendments are Considered E-24
Table E-34: Derivation of Cost-to-Sales Ratios for Small Manufacturers for a 10,000 lb Reporting Threshold E-25
Table F-1: Description of Additional Data Elements F-1
Table F-2: Change in Industry Burden to Manufacturers as a Result of Additional Exposure-Related Data Elements F-8
Table F-3: Schedule of Annual Industry Burden to Manufacturers if All Proposed Amendments Are Implemented F-9
Table F-4: Change in Industry Burden to Processors as a Result of Additional Exposure-Related Data Elements F-9
Table F-5: Schedule of Annual Industry Burden to Processors F-10
Table F-6: Change in Industry Burden to Manufacturers and Processors as a Result of Additional Exposure-Related Data Elements F-10
Table F-7: Schedule of Annual Industry Burden to Manufacturers and Processors if All Proposed Amendments Are Implemented F-11
Table F-8: Per-Report Cost for Additional Data Elements, based on PMN Burden F-11
Table F-9: Change in Industry Cost to Manufacturers as a Result of Additional Exposure-Related Data Elements F-12
Table F-10: Annual Increase in Industry Cost to Manufacturers if All Proposed Amendments Are Implemented (2008$) F-13
Table F-11: Change in Industry Cost to Processors as a Result of Additional Exposure-Related Data Elements F-13
Table F-12: Annual Increase in Industry Cost to Processors if All Proposed Amendments Are Implemented (2008$) F-14
Table F-13: Change in Industry Cost to Manufacturers and Processors as a Result of Additional Exposure-Related Data Elements F-14
Table F-14: Annualized Increase in Industry Cost to Manufacturers and Processors if All Amendments Are Implemented (2008$) F-15
Table F-15: Change in Agency Burden to Process Manufacturer Data as a Result of Additional Exposure-Related Data Elements F-16
Table F-16: Annual Increase in Agency Burden to Process Manufacturer Data if All Proposed Amendments Are Implemented F-17
Table F-17: Change in Agency Burden to Process Processor Data as a Result of Additional Exposure-Related Data Elements F-17

Table F-18: Annual Increase in Agency Burden to Process Processor Data if All Proposed Amendments Are Implemented F-18
Table F-19: Change in Agency Burden to Process Manufacturer and Processor Data as a Result of Additional Exposure-Related Data Elements..... F-18
Table F-20: Annual Increase in Agency Burden to Process Data if All Proposed Amendments Are Implemented F-19
Table F-21: Change in Agency Cost of Processing Manufacturer Data as a Result of Additional Exposure-Related Data Elements..... F-20
Table F-22: Annual Increase in Agency Cost to Process Manufacturer Data if All Proposed Amendments Are Implemented (2008$)..... F-20
Table F-23: Change in Agency Cost to Process Processor Data as a Result of Additional Exposure-Related Data Elements..... F-21
Table F-24: Annual Increase in Agency Cost to Process Processor Data if All Proposed Amendments Are Implemented (2008$)..... F-21
Table F-25: Change in Agency Cost of Processing Manufacture and Processor Data as a Result of Additional Exposure-Related Data Elements..... F-22
Table F-26: Annual Increase in Agency Cost to Process Manufacturer and Processor Data if All Proposed Amendments Are Implemented (2008$)..... F-22
Table F-27. Derivation of Cost-to-Sales Ratios for Small Manufacturers for Collection of Additional Data Elements..... F-24
Table F-28: Derivation of Cost-to-Sales Ratios for Small Processors for Collection of Additional Data Elements..... F-25
Table G-1: Annual Industry Burden as a Result of a TSCA Section 8(a) Data Collection G-3
Table G-2: Schedule of Annual Industry Burden G-4
Table G-3: Per-Report Cost for Additional Data Elements, based on PMN Burden.....G-4
Table G-4: Annual Industry Cost as a Result of a TSCA Section 8(a) Data Collection.....G-4
Table G-5: Annual Increase in Industry Cost if All Amendments Are Implemented (2008$).....G-5
Table G-6: Per-Report Burden for Data Elements Similar to Those Included in a TSCA Section 8(a) Data Collection.....G-5
Table G-7:Agency Burden to Process Data as a Result of a TSCA Section 8(a) Data Collection G-6
Table G-8: Schedule of Annual Agency Burden G-6
Table G-9: Per-Report Cost for Data Elements Similar to Those Included in a TSCA Section 8(a) Data Collection.....G-7
Table G-10:Agency Cost to Process Data as a Result of the TSCA Section 8(a) Data Collection G-7
Table G-11: Annual Increase in Agency Cost (2008$).....G-7
Table G-12: Derivation of Cost-to-Sales Ratios for Small Manufacturers for Collection of Exposure-Related Data Elements.....G-9
Table G-13: Derivation of Cost-to-Sales Ratios for Small Processors for Collection of Exposure-Related Data Elements G-10

Executive Summary

As part of the Inventory Update Reporting (IUR) Modifications final rule, EPA is changing the identification of the regulation from IUR to Chemical Data Reporting (CDR). However, EPA is retaining the use of the IUR acronym throughout this document. The reader should recognize that where IUR is used to refer to the 40 CFR 711 regulations or to future IUR submission periods, IUR and CDR are synonymous.

The U.S. Environmental Protection Agency (EPA) requires manufacturers (including importers) of certain chemical substances to periodically report information to the Agency under reporting requirements known as the TSCA Inventory Update Reporting (IUR) rule. This information is collected based on EPA's authority under section 8(a) of the Toxic Substances Control Act (TSCA), which requires EPA to compile and keep current a listing of chemical substances in commerce in the United States and is known as the TSCA Inventory. The data reported under the IUR rule are used to support many EPA and other federal agency health, safety, and environmental protection activities. Established in 1986, the IUR rule was amended extensively in 2003, and amended again in 2005. EPA is now finalizing further amendments to the IUR rule ("2011 amendments").

Prior to the 2011 amendments, the IUR rule required companies to report information every five years on certain chemical substances listed on the TSCA Inventory. For reportable substances that a company manufactures (including imports) in volumes of 25,000 lb or more at a plant site during the principal reporting year, a submitter is required to provide plant site, production volume, and manufacturing information. Sites must also provide processing and use information for chemical substances manufactured (including imported) in volumes that meet or exceed an annual 100,000 lb threshold. Submitters do not need to provide this processing and use information for chemical substances that are "partially exempt," such as specifically listed petroleum process streams, and listed chemical substances for which the IUR information is of low current interest. These chemical substances are all referred to as "partially exempt" from reporting because companies must provide manufacturing information for them but not processing and use information. Prior to the 2011 amendments, submitters did not need to provide the processing and use information for any chemicals manufactured (including imported) below a 300,000 lb threshold.

Since the publishing of the proposed rule in August of 2010, EPA has issued a suspension of the 2011 data collection. Under the final rule, EPA has issued new IUR collection dates of February 1, 2012 to June 30, 2012, and a new principal reporting year; 2011. In addition, EPA has made several other modifications to the final rule. Under the proposed rule, EPA required submitters to report chemical substance production volumes for each of the five years since the last principal reporting year beginning with the 2012 reporting cycle. Under the final rule the Agency is requiring the reporting of 2010 and 2011 production volumes with the 2012 reporting cycle, and the reporting of all past year production beginning with the 2016 reporting cycle. In addition, EPA proposed the elimination of the 25,000 lb reporting threshold for specific regulated chemical substances and would have required manufacturers (including importers) of these chemical substances to report under the IUR rule, regardless of production volume. Under the final rule, EPA is reducing the reporting threshold for specific regulated chemical substances from 25,000 lb to 2,500 lb. Finally, EPA proposed the elimination of the 300,000 lb reporting

threshold for processing and use information. Under the final rule, EPA has replaced this threshold. The complete list of IUR modifications under the final rule is found below:

- Technically modify the regulatory text to move various provisions to other sections, to increase clarity;
- Consolidate the definitions currently found at §710.3 and §710.43 into the amended §711.3, except where an appropriate definition is already in place in section 3 of TSCA or at §704.3, and delete the definition for "non-isolated intermediate" from §710.3;
- Modify the definitions of "importer," "manufacture," "site," "commercial use," "consumer use," "reporting year," and "submission period" to increase clarity of these definitions and make them consistent with the amendments to IUR requirements and with other regulations;
- Add definitions for "manufacturer," "Central Data Exchange (CDX)," "*e-IURweb"*, and "industrial function";
- For the reporting cycles subsequent to the 2012 reporting cycle, add a requirement to report whether, for any calendar year since the previous IUR principal reporting year, the subject chemical substance was manufactured in production volumes of 25,000 lb or greater per year;
- Replace the 300,000 lb reporting threshold for processing and use information by phasing in a lower reporting threshold. For the 2012 IUR manufacturers (including importers) of non-excluded substances with production volumes greater than 100,000 lb are required to report processing and use information. Subsequent to the 2012 reporting cycle, the reporting threshold for processing and use information will be 25,000 lb;
- Reduce the 25,000 lb threshold for reporting to 2,500 lb for certain regulated chemical substances and require manufacturers (including importers) of such chemical substances to report under the IUR rule, if production volume is greater than 2,500 lb beginning with the 2016 reporting cycle;
- Make chemical substances subject to Enforceable Consent Agreements (ECAs) ineligible for exemptions;
- Exempt manufactured water from reporting requirements;
- Remove fully exempt polymers from the partially exempt list;
- Amend reportable data elements such as the company identification number, technical contact, and chemical identity;
- Require, for the 2012 reporting cycle, submitters to report chemical substance production volumes for both 2010 and 2011. For the reporting cycles subsequent to the 2012 reporting cycle, submitters are required to report the chemical substance's production volume for each year since the last principal reporting year;
- Require submitters to report separately production volume used on-site;
- Require submitters of imported chemical substances to indicate whether the chemical substance is physically at the reporting site;
- Require submitters to report production volume exported;
- Require submitters to indicate whether the chemical substance is to be recycled, remanufactured, reprocessed, or reused;
- Revise the set of industrial function categories and provide industrial sectors instead of NAICS codes, for downstream processing and use information, and revise the set of consumer and commercial product categories;
- Require submitters to identify whether a use is a consumer use, a commercial use, or both;

- Require submitters to report the total number of commercial workers, including those at sites not under the submitter's control, that are reasonably likely to be exposed while using the reportable chemical substance, with respect to each commercial use;
- Change the reporting standard for processing and use information from "readily obtainable" to "known to or reasonably ascertainable by";
- Require upfront substantiation for claims that processing and use data are confidential business information (CBI);
- Restrict submitters from being able to claim not "known to or reasonably ascertainable by" data as CBI;
- Require submitters to submit forms electronically using the e-IURweb tool and EPA's CDX; and
- Change the frequency of reporting from every five years to every four years.

These amendments overall will increase IUR rule reporting costs. Over the first 26 years of the rule, EPA estimates the net present value of the rule modifications will be $494.7 million in social cost. Annualized costs are expected to be $17.15 million (at a three percent discount rate) and $14.70 million (at a seven percent discount rate).[1] EPA estimates all of the amendments combined will increase the burden to industry by approximately 0.50 million hours to 2.34 million hours, and increase the cost to industry by approximately $36.8 million to $143.7 million in total for the 2012 reporting cycle. EPA estimates in future reporting cycles, the industry burden will increase by 1.14 million hours to a total of 2.57 million hours, and industry cost will increase by $75.12 million to $157.94 million. EPA further estimates over a 26-year period, industry burden will increase by 7.62 million hours and Agency burden will decrease by 5,200 hours. EPA estimates the net burden to society will increase by 7.61 million hours over a 26-year period. The information gathered will enable the Agency to continue to target educational, regulatory, or enforcement activities to industries or chemical substances posing the greatest potential risks and to target programs for population groups at the highest potential risk.

With this more targeted information designed to better meet Agency needs, EPA will improve its ability to screen chemical substances to identify whether additional risk assessment and management steps are needed. More complete reporting of the processing and use data, more careful consideration of confidentiality claims, and adjustments to specific data elements will help provide the needed data. By enhancing the data supplied to Agency risk-screening programs, EPA expects to more effectively and expeditiously reduce the risks posed by chemical substances. The more EPA can base its decisions on actual data rather than on assumptions, the better EPA is able to tailor its risk management decisions to the level of actual risk, whether higher or lower than it would be if based only on assumptions. Ultimately, an enhanced risk screening process will have positive consequences for human and ecosystem health, and will use EPA's and society's resources more efficiently. Additional benefits will accrue from changes in reporting requirements that will improve consistency and compatibility with other EPA databases. EPA will have an increased ability to anticipate industry trends, particularly for chemical substances for which EPA has concerns.

The costs and benefits of the rule are summarized in Table ES- 1 below.

[1] All values are in year 2008 dollars.

Table ES- 1 Summary of the Costs and Benefits Associated with the IUR Rule

	Burden (Millions of Hours)			Cost (Millions of 2010$)			Benefits (Not Quantified)
	First Reporting Cycle	Future Reporting Cycles	Total (over 26 years)	First Reporting Cycle	Future Reporting Cycle	Total (over 26 years)	
Industry	2.34	2.57	15.20	$143.73	$157.94	$933.42	Electronic reporting and other changes, such as modifying and clarifying definitions, will increase the efficiency of industry reporting.
Agency	0.003	0.002	0.016	$0.399	$0.292	$1.856	The IUR rule modifications will allow the Agency to collect better information to meet the Agency's overall needs, to increase its ability to effectively provide public access to the information, to obtain new and updated information relating to potential exposures to a subset of chemical substances listed on the TSCA Inventory, and to improve the usefulness of the information reported. It will also allow the Agency to save time and resources in screening chemical substances and in developing risk management priorities and reduce EPA's costs of processing the IUR data and result in a better quality database.
TOTAL (Industry & Agency)	**2.34**	**2.57**	**15.21**	**$144.13**	**$158.23**	**$935.28**	--
Other Government Entities	--	--	--	--	--	--	IUR data will help state and local authorities with rulemaking, information collection, and voluntary program activities. Because state and local governments must address chemical substances, use patterns, and exposure scenarios that may be unique or isolated, state and local agency access to the enhanced data will assist in identifying situations posing potentially high exposures for individual states or locations within those states.

	Burden (Millions of Hours)			Cost (Millions of 2010$)			Benefits (Not Quantified)
	First Reporting Cycle	Future Reporting Cycles	Total (over 26 years)	First Reporting Cycle	Future Reporting Cycle	Total (over 26 years)	
NGOs and Other Private Entities	--	--	--	--	--	--	Private-sector organizations with a strong interest in reducing risks and providing leadership in preventing pollution can better meet these objectives by developing a better understanding of how chemical substances are used in general. This will allow them to manage exposures more effectively and participate in setting chemical substance priorities at community, regional, and national levels.
General Public	--	--	--	--	--	--	The IUR rule modifications will reduce the cost of risk-based decision making in the public sector, and will free up resources for other public or private uses. The rule will also increase public access to the information and improve the usefulness of the information reported.

1. Introduction

As part of the Inventory Update Reporting (IUR) Modifications final rule, EPA is changing the identification of the regulation from IUR to Chemical Data Reporting (CDR). However, EPA is retaining the use of the IUR acronym throughout this document. The reader should recognize that where IUR is used to refer to the 40 CFR 711 regulations or to future IUR submission periods, IUR and CDR are synonymous.

This report assesses the costs and benefits EPA expects to result from the revisions to the TSCA Inventory Update Reporting (IUR) rule. The amendments will provide information to better address Agency and public information needs, improve the usability and reliability of the reported data, and ensure that data are available in a timely manner. This chapter provides background information on EPA's statutory authority for collecting information through the IUR rule and a discussion of the regulatory history of the IUR rule.

1.1 Statutory Authority

EPA is required under TSCA section 8(b), 15 U.S.C. 2607(b), to compile and keep current an inventory of chemical substances manufactured or processed in the United States. This inventory is known as the TSCA Chemical Substance Inventory (the TSCA Inventory). TSCA section 8(a)(1) authorizes the EPA Administrator to promulgate regulations under which manufacturers and processors of chemical substances and mixtures must maintain such records and submit such information as the Administrator may reasonably require. TSCA section 8(a) generally excludes small manufacturers and processors of chemical substances from the reporting requirements established in TSCA section 8(a). However, EPA is authorized by TSCA section 8(a)(3) to require TSCA section 8(a) reporting from small manufacturers and processors with respect to any chemical substance that is the subject of a regulation proposed or promulgated under TSCA sections 4, 5(b)(4), or 6; that is the subject of an order under TSCA section 5(e); or that is the subject of relief that has been granted pursuant to a civil action under TSCA section 5 or 7. The standard for determining whether an entity qualifies as a small manufacturer for purposes of 40 CFR part 710 is found at 40 CFR 704.3. Processors currently are not subject to the regulations at 40 CFR part 710.

1.2 Regulatory History

When Congress passed TSCA, it granted EPA broad authority to collect information on chemical substances to help EPA and others assess the magnitude and extent of human and environmental exposure to chemical substances used in commerce. Specifically, under §8 of TSCA (15 U.S.C. 2607), EPA is authorized to promulgate regulations requiring manufacturers and processors of chemical substances to report manufacturing (including importing), processing and use information on various types and classes of chemical substances. In 1977, EPA used its authority under TSCA §8 to create the TSCA Chemical Substances Inventory, also known as the TSCA Inventory (42 FR 64572), which currently is codified at 40 CFR part 710 Subpart A. The TSCA Inventory lists all TSCA chemical substances in commerce in the United States, thereby providing a listing of chemical substances manufactured or processed in the United States. All chemical substances are included, with the exception of pesticides, tobacco, nuclear material, firearms and ammunition, food and food additives, drugs, and cosmetics, which are not under the

jurisdiction of TSCA. Chemical Substances are added to the TSCA Inventory after a company completes EPA's New Chemical Substances review process and files a Notice of Commencement.[2]

In 1986, EPA used its authority under TSCA §8(a) to promulgate regulations requiring chemical substance manufacturers, including importers, to report data periodically to EPA on certain chemical substances listed in the TSCA Inventory (51 FR 21447). The IUR regulations applicable to the 1986 through 2002 reporting cycles currently are codified at 40 CFR Part 710 Subpart B. These regulations are commonly called the TSCA Inventory Update Reporting rule, or IUR rule. Under this rule, EPA collected data every four years for organic chemical substances produced in volumes of 10,000 lb or more per site. (Inorganic chemical substances, polymers, microorganisms, and naturally occurring chemical substances were generally excluded from reporting.) From 1986 to 1998, an average of 9,200 individual chemical substances was reported per reporting cycle. The IUR data provided a more up-to-date picture of a subset of the TSCA chemical substances in commerce, generating data used to support TSCA risk management activities, as well as to provide support to other EPA and non-EPA program activities.

In January 2003, EPA promulgated amendments to the IUR rule, referred to in this report as the "2003 Amendments" (68 FR 848). The amended IUR rule, applicable to the 2006 reporting cycle and beyond, was codified at 40 CFR Part 710 Subpart C. The 2003 Amendments required reporting for inorganic chemical substances; added new site and manufacturing data elements; required companies to provide basic additional manufacturing, processing, and use information related to potential chemical substance exposures; changed the period of coverage from corporate fiscal year to calendar year; and extended the recordkeeping period from four years to five years. The 2003 Amendments partially mitigated the industry burden increase by raising the reporting threshold to 25,000 lb; creating a partial exemption from reporting processing and use information for inorganic chemical substances for the 2006 IUR collection only, and for specifically-listed petroleum process streams and other specifically listed chemical substances for 2006 and future reporting cycles; and by exempting from reporting certain natural gas substances. As part of the interagency review of the 2003 Amendments under Executive Order 12866, EPA agreed to propose a subsequent rulemaking to change the reporting frequency in an effort to further reduce industry reporting burden. In 2005, EPA promulgated further modifications to the IUR rule (70 FR 75059) (referred to in this report as the "2005 Amendments"), which extended the reporting cycle to five years, and made further changes to the rule that reduced industry burden and clarified rule requirements.

[2]Currently, more than 83,000 chemicals are listed on the TSCA Inventory (EPA, 2008a).

2. IUR Requirements and Affected Entities

2.1 Overview of IUR Requirements

The IUR rule requires U.S. manufacturers (including importers) of chemical substances listed on the TSCA Inventory to report to EPA every five years the identity of chemical substances manufactured (including imported) during the principal reporting year in quantities of 25,000 lb or greater at any single site they own or control (see 40 CFR part 710, subpart C). The principal reporting year is defined as the calendar year in which full manufacturing, processing, and use activities associated with the data reported to EPA during an IUR submission period occur. IUR data was collected last in 2006. EPA uses the TSCA Inventory and data reported under the IUR rule to support many TSCA-related activities and to provide overall support for a number of EPA and other federal health, safety, and environmental protection activities. To the extent possible due to restrictions related to confidential business information (CBI), the Agency also makes the data available to the public.

Persons manufacturing (including importing) chemical substances are required to report information related to company, site, and chemical identity and, for each reportable chemical substance, manufacturing exposure-related information (40 CFR §710.52). The 2006 submission year was the first time information on inorganic chemical substances was required to be reported. The IUR rule generally exempts several groups of chemical substances from its reporting requirements, i.e., polymers, microorganisms, naturally occurring chemical substances, and certain natural gas substances (40 CFR §710.46).

Manufacturers (including importers) of chemical substances in larger volumes (i.e., 300,000 lb or greater manufactured or imported during the principal reporting year at any single site) additionally are required to report exposure-related processing and use information (40 CFR §710.52(c)(4)). The IUR rule generally grants a partial exemption to specifically-listed petroleum process streams and other specifically-listed chemical substances, and manufacturers (including importers) of such substances were not required to report processing and use information for those substances. For the 2006 IUR only, inorganic chemical substances were partially exempted.

Form U, the tool used to collect the IUR information, is divided into three parts: Site Identification Information (Part I), Manufacturing Information (Part II), and Processing and Use Information (Part III). An overview of the information collected under the IUR rule in 2006 is as follows:

- **Company Reporting Number.** An 8-digit alphanumeric number assigned by the submitter to each specific IUR submission (for electronic submissions only).
- **Certification statement.** A form that must be signed by a company-authorized official, to certify the information provided is complete and accurate.
- **Company information.** Includes the company name and Dun & Bradstreet number.
- **Plant site information.** Includes the name, address, and Dun & Bradstreet number for the plant site reporting.
- **Technical contact information.** Includes the name, address, telephone number, and email address for a technical contact.

- **Chemical identification.** Includes both the specific chemical name and the Chemical Abstracts Service Registry Number (CASRN), or other identifying number, of the chemical substance.
- **Manufacturing information.** Includes an indication of whether the chemical substance is manufactured or imported; whether it is site-limited (whether it is produced and used at the same site, and does not undergo packaging and shipping); and its manufactured (including imported) production volumes. Also contains the number of workers involved in manufacturing that are reasonably likely to be exposed to the chemical substance, the physical form(s) as the chemical substance leaves the site (including the percent of the production volume in each form), and the maximum concentration of the chemical substance as it leaves the site. Codes representing ranges are used to report these data. These data are reported to the extent they are "known to or reasonably ascertainable" by the submitter.
- **Industrial processing and use data.** Includes the types of process or use for the chemical substance, the related North American Industrial Classification System (NAICS) codes, and the industrial function categories. For each unique combination of process or use/NAICS/function, includes the percentage of production volume, the number of sites, and the number of workers attributable to each processing or use activity reported. These data are reported for up to ten uses with the largest production volume (by weight) for the chemical substance. The industrial function categories used in the 2006 reporting are listed in Appendix A. of this report. These data are reported to the extent they are "readily obtainable by" the submitter.
- **Consumer and commercial end-use data.** Includes the relevant consumer and commercial product category, the percentage of the production volume in each product category, the maximum concentration of the chemical substance in each final product, and an indication of whether the chemical substance is used in a product intended for use by children. The consumer and commercial product categories used in the 2006 reporting are listed in Appendix B. of this report. These data are reported to the extent they are "readily obtainable by" the submitter.
- **Confidential Business Information.** CBI can be claimed for each data element reported. Submitters who claim the chemical identity or plant site identity as CBI must provide upfront substantiation of the need for such confidentiality.

Non-confidential data, including both searchable and separately downloadable databases and a 2006 IUR data summary report, are available for public use on the IUR website (http://www.epa.gov/iur).

2.2 Overview of the Regulated Community

The regulated community for the IUR rule (i.e., those who potentially will be affected by the amendments to the IUR rule) consists of companies manufacturing or importing chemical substances in amounts of 25,000 lb or more annually listed on the TSCA Inventory and regulated under TSCA §8. Manufacturers (including importers) of non-TSCA chemical substances (such as pesticides, tobacco, nuclear material, firearms and ammunition, food and food additives, drugs, and cosmetics) are not required to report information on those chemical substances under the IUR rule. Some chemical substances might have both TSCA and non-TSCA uses. In that case, the production associated with the TSCA use must be reported. Companies engaged in chemical substance manufacturing (NAICS code 325) or petroleum refining (NAICS code

324110) are the most likely to report under the IUR rule. Chemical substance users and processors who may manufacture a byproduct chemical substance, e.g., utilities, paper manufacturers, primary metal manufacturers, and semiconductor and other electronic component manufacturers (NAICS codes 22, 322, 331, and 3344) also are likely to be subject to the rule. However, companies in any industry are subject to reporting if they manufacture or import listed chemical substances at or above the reporting threshold. Companies must review the rule to determine whether they are required to report.

3. Changes in Reporting Requirements under the Final IUR Modifications Rule

The 2011 final amendments encompass several specific changes to the IUR. Each of these amendments is described below.

3.1 Technical Modifications to the Regulatory Text

Prior to the 2011 amendments, 40 CFR part 710 contained three subparts. Subpart A contained regulatory text associated with the original compilation of the TSCA Inventory; Subpart B contained regulatory text associated with the IUR rule covering the update reporting in 2002; and Subpart C contained the regulatory text associated with the IUR rule for 2006 and beyond. The chemical substances covered by the IUR rule are on the Master Inventory File, which includes chemical substances from the original TSCA Inventory compilation and those added subsequently through the notice requirements of section 5 of TSCA. Because the IUR rule applies to a list of chemical substances included in the original TSCA Inventory plus additional chemical substances added subsequently, and because the Agency from time to time has modified the IUR rule, the Agency believes the regulatory text associated with the IUR rule should be in its own section in the Code of Federal Regulations (CFR), distinct from both the original TSCA Inventory rules and from the TSCA section 5 requirements.

3.1.1 Move the IUR Regulatory Text from 710 Subpart C to 711 and Eliminate Subpart Divisions

Subpart C of 40 CFR part 710, §§710.43 to 710.59, contained the IUR regulatory text. Under the 2011 amendments, EPA is moving all of the Subpart C text from 40 CFR part 710 to a new 40 CFR part 711 and is adding a new Scope and Compliance section (40 CFR 711.1). Specific sections are being moved as follows: §710.43 becomes §711.3; §710.45 becomes §711.5; §710.46 becomes §711.6; §710.48 becomes §711.8; §710.49 becomes §711.9; §710.50 becomes §711.10; §710.52 becomes §711.15; §710.53 becomes §711.20; §710.55 becomes §711.22; §710.57 becomes §711.25; §710.58 becomes §711.30; and §710.59 becomes §711.35. Because all of the text of Subpart C is being moved to 40 CFR part 711, 40 CFR part 710 no longer have a Subpart C. Neither part 710 nor part 711 will have any subparts.

3.1.2 Consolidation of Definitions

As part of moving the regulatory text from 40 CFR part 710, subpart C to 40 CFR part 711, EPA is consolidating definitions copied from §710.3 and those currently found at §710.43 into the new §711.3, except where an appropriate definition is already in place in section 3 of TSCA or at §704.3, and an additional definition of the term in §711.3 would therefore be unnecessarily duplicative. The definitions at §704.3 are included in §711.3, except insofar as§711.3 provides a modified definition of a term also defined at §704.3.

The term *mixture* is defined in both §710.3 and section 3 of TSCA. For purposes of the IUR rule, EPA is including the definition of *mixture* from section 3 of TSCA with the definitions at 40 CFR 711.3. The TSCA mixture definition differs from the definition in §710.3 and §720.3, the regulations used to determine the chemical substances listed on the TSCA Inventory, in that it does not specifically address hydrates. A hydrate is a mixture of water and an anhydrous chemical substance. Because they are mixtures, hydrates are not listed as such on the TSCA Inventory. For this reason, EPA believes it is superfluous to include hydrates separately in the definition of mixture. The Agency will continue to include such a discussion in the Instructions for Reporting.

3.1.3 Remove "Non-isolated Intermediate" Definition from §710.3

EPA added a definition to 40 CFR 710.43 for the term "non-isolated intermediate" as part of the 2003 Amendments (68 FR 848, January 7, 2003). Subsequently, as part of the IUR Revisions Rule (70 FR 75059, December 19, 2005), EPA erroneously moved the definition to §710.3 from §710.43. EPA is removing the definition from §710.3 as this definition was not associated with the original TSCA Inventory, and therefore does not belong in §710.3. A definition of this term, codified elsewhere at §704.3, is included with the IUR definitions at amended §711.3.

3.1.4 Remove Subpart B Text

EPA is removing the regulatory text contained in 40 CFR part 710, §§710.23 to 710.39 (subpart B). This text refers to IUR submission periods of 2002 and earlier, and is obsolete. As noted in §710.1, the Agency expressed its intent to remove subpart B once the 2002 update was complete.

3.1.5 Remove Superfluous Text Associated With Reporting Production Volumes

EPA is removing the phrase "provided that the reported figures are within ±10% of the actual volume" from the production volume reporting requirements currently found in §710.52(c)(3)(iv) which appears in the new §711.15(b)(3)(iv). The revised wording is, "This amount must be reported to two significant figures of accuracy." The phrase that was removed is superfluous because any number reported accurately to two significant figures is within 10% of the correct value.

3.1.6 Correct Text Associated With Reporting Number of Sites and Number of Workers

EPA is replacing the phrase "less than" with the phrase "fewer than" in the ranges used to report the number of workers found in the table in §710.52(c)(3)(v) which appears in the new §711.15(b)(3)(vii) and the number of sites found in the table in §710.52(c)(4)(i)(E) which appears in the new §711.15(b)(4)(i)(E). This change makes the phrases describing the ranges grammatically correct.

3.2 Modifications to Selected Definitions

As part of developing the definition section for part 711, EPA is modifying six definitions associated with the IUR rule and adding four new definitions. In §704.3 and §710.3, EPA is also modifying the citation in the definition of *importer* by removing the citation to 19 CFR 11.1 to 19 CFR 101.1..

3.2.1 Manufacture and Manufacturer

To improve the information submitted through the IUR rule, EPA is modifying the definition of *manufacture* by including elements from the §720.3 definition for *manufacturer*. The Agency is also adding a simple definition for the term *manufacturer* to §711.3. In addition to the change to the definition of *manufacture*, EPA is adding a paragraph (c) to the regulation at §711.22 to clarify the reporting relationship between the contracting company and the toll manufacturer. Both the company and manufacturer are liable if no report is made. Note the contracting company and the toll manufacturer should confer with each other to avoid duplicate reporting.

This final rule defines the term *manufacture* under the IUR to mean "to manufacture, produce, or import, for commercial purposes. Manufacture includes the extraction, for commercial purposes, of a component chemical substance from a previously existing chemical substance or a complex combination of substances. When a chemical substance, manufactured other than by import, is:(1) Produced exclusively for another person who contracts for such production, and (2) that other person specifies the identity of the chemical substance and controls the total amount produced and the basic technology for the

plant process, that chemical substance is comanufactured by the producing manufacturer and the person contracting for such production." Also under this rule, the term *manufacturer* is defined under the IUR rule to mean "a person who manufactures a chemical substance."

3.2.2 Site

EPA is amending the definition of *site* to (1) clarify that the importer's site must be a U.S. address, (2) accommodate manufacturing under contract, and (3) accommodate portable manufacturing units.

EPA identified the need to accommodate portable manufacturing units during the 2006 IUR submission period. Two examples of portable manufacturing units are tanks used to manufacture calcium hydroxide slurry for use in building construction and road and highway projects, and tanks used to mix anhydrous ammonia and water to manufacture ammonium hydroxide prior to application to agricultural lands. EPA is interested in including chemical substance manufacturing that is, for instance, performed by road crews or is occurring at construction sites at which chemical substances are mixed on site in such a manner to create a different chemical substance, e.g., asphalt emulsifiers. The site of physical manufacturing could change on a frequent basis. Manufacturers will report the aggregated production volume for all of the portable manufacturing units sent out to different locations from a single distribution center. The address of the distribution center will be reported as the site location.

Under the final rule, the term *site* means "a contiguous property unit". Property divided only by a public right-of-way shall be considered one site. More than one plant may be located on a single site. For substances manufactured under contract, i.e., by a toll manufacturer, the site is the location where the chemical substance is physically manufactured. The site for an importer who imports a chemical substance described in §711.5 is the U.S. site of the operating unit within the person's organization directly responsible for importing the substance. The import site, in some cases, may be the organization's headquarters in the United States. If there is no such operating unit or headquarters in the United States, the site address for the importer is the U.S. address of an agent acting on behalf of the importer who is authorized to accept service of process for the importer. For portable manufacturing units sent out to different locations from a single distribution center, the distribution center shall be considered the site."

3.2.3 Electronic Reporting-Related Definitions

EPA is adding two new terms, *Central Data Exchange (CDX)* and *e-IURweb* to provide clarity to the requirement for electronic reporting of IUR data. The term *CDX* means "EPA's centralized electronic document receiving system, or its successors, including associated instructions for registering to submit electronic documents." The new definition makes the term consistent with the new Premanufacture Notice (PMN) definition. The term *e-IURweb* means the "electronic, web-based IUR tool provided by the EPA for the completion and submission of the IUR data."

3.2.4 Processing and Use-Related Definitions

EPA is amending the definitions of the terms *commercial use* and *consumer use* to make them more consistent with the definitions developed collaboratively by the United States and Canada. The new definitions for these two terms differ in wording from the Canadian versions to ensure the use of terminology defined in IUR and related regulations. EPA believes the basic application of these two terms will not differ from the basic application of the Canadian definitions. The term *commercial use* means "the use of a chemical substance or a mixture containing a chemical substance (including as part of an article) in a commercial enterprise providing saleable goods or services." Examples included in the §710.43 definition have been eliminated. The slightly modified definition of *consumer use* is "the use of a chemical substance or a mixture containing a chemical substance (including as part of an article) when

sold to or made available to consumers for their use." The restrictions associated with where a consumer would use the product have been removed.

EPA is adding a definition for the term *industrial function.* For the 2006 IUR, EPA defined *industrial use* and did not define *industrial function*. The inclusion of both definitions provides clarity for the industrial processing and use reporting requirements and makes the Agency's requirements consistent with those collaboratively developed with Canada. With this final rule, *industrial function* means "the intended physical or chemical substance characteristic for which a chemical substance or mixture is consumed as a reactant; incorporated into a formulation, mixture, reaction product, or article; repackaged; or used."

3.2.5 Principal Reporting Year and Submission Period

As described in Section 3.13, EPA is changing the reporting cycle from every five years to every four years and requiring the reporting of production volumes for each calendar year since the last principal reporting year. EPA is modifying the terms *reporting year* and *submission period* to reflect these changes.

The term *reporting year* is modified to add the term "principal" and the word "information" is replaced with "manufacturing, processing and use data." These changes are to indicate the principal reporting year is the year in which most of the reported data are based. Under the final rule, the principal reporting year is the latest complete calendar year proceeding the submission period. Additionally, EPA is removing the reference to "the calendar year at 5-year intervals thereafter" and removing the reference to "calendar year 2005." With these changes, the term *principal reporting year* is defined as "the latest complete calendar year proceeding the submission period." Production volume for manufacturing activities in other years of the reporting cycle may also be reportable during the submission period, but full manufacturing, processing, and use data are reported only for activities during the principal reporting year.

The term *submission period* is modified by deleting the phrase "generated during the reporting year." With this change, the definition of *submission period* reflects that data for years in addition to the principal reporting year would be reported. The new definition of *submission period* means "the period in which manufacturing, processing and use data are submitted to EPA."

3.3 Modifications to Reporting Thresholds

Reporting thresholds are used to determine when IUR reporting is required for a subject chemical substance at a manufacturing (including importing) site. Every person manufacturing (including importing) a non-excluded substance at or above the 25,000 lb threshold is required to report information in Parts I and II of the IUR Form U. Beginning with the 2006 IUR submission period, every person manufacturing (including importing) a non-excluded substance at or above the 300,000 lb threshold was required to report information in Part III of Form U, unless the substance was partially exempt. EPA is making three changes related to the reporting thresholds: (1) determination of whether you meet the 25,000 lb threshold, (2) replacing the 300,000 lb threshold for reporting information in Part III, and (3) reducing the 25,000 lb threshold requirement for specific regulated chemical substances to 2,500 lb.

3.3.1 Method for Determining Whether a Manufacturer is subject to IUR Reporting Requirements

Currently, a one-year "snapshot" of manufacturing (including importing) is used to determine the need to report for the IUR rule. The method used to make the reporting determination involves determining that an entity manufactured (including imported) a chemical substance

listed on the TSCA Inventory during the principal reporting year (e.g., 2005 for the 2006 IUR reporting cycle); the chemical substance was not otherwise exempt; and the associated production volume (domestically manufactured plus imported volumes) met or exceeded the 25,000 lb threshold for the principal reporting year (e.g., 2005 for the 2006 IUR reporting cycle). EPA is not changing the method for determining whether a manufacturer (including importer) is subject to IUR reporting requirements for the 2012 submission period.

EPA is modifying the method used to determine whether a person is subject to IUR reporting for submission periods subsequent to the 2012 submission period. The method for submission periods subsequent to 2012 is based on whether, for any calendar year since the last principal reporting year, a chemical substance was manufactured (including imported) at a site in production volumes of 25,000 lb or greater. For example, for the 2016 submission period, it will be necessary to examine the annual production volumes for the calendar years 2012 to 2015 for the site. If the production volume for a reportable chemical substance were 25,000 lb or greater for any calendar year during that four year period, then it will be necessary to report the chemical substance, unless it is otherwise exempt. For instance, a subject chemical substance with production volumes of 5,000 lb in 2015 and 35,000 lb in 2012 will be reported for the 2016 IUR. Regardless of the 2015 production volume, in this example scenario the 2016 IUR submission will contain detailed information based on manufacturing during the 2015 calendar year and only production volume information for the years 2012 through 2014.

3.3.2 Replacing the 300,000 lb Threshold for Processing and Use Information

EPA is replacing the 300,000 lb threshold for processing and use information by phasing in a lower reporting threshold. For the 2012 IUR, all submitters of non-excluded chemical substances are required to report processing and use information if they manufactured (including imported) 100,000 lb or more of a chemical substance in 2011. Subsequent to the 2012 reporting cycle, the reporting threshold will be 25,000 lb. EPA is replacing in the 300,000 lb reporting threshold by phasing in the lower volume threshold in order to collect information necessary to complete screening-level exposure characterizations for IUR-reportable chemical substances. The exposure information is an essential part of developing risk evaluations and, based on its experience in using this information, the Agency believes collecting this exposure information is critical to its mission of characterizing exposure, identifying potential risks, and noting uncertainties for these lower production volume chemical substances. In addition, this change will provide the public with information on a greater number of chemical substances. In the 2003 Amendments to the final rule (68 FR 848, January 7, 2003), EPA acknowledged the value of information for chemical substances manufactured in lower volumes and stated that if the Agency were to find it necessary in the future, it would collect information on chemical substances at reporting thresholds below the thresholds that were introduced in that action (i.e., 25,000 lb and 300,000 lb).

3.3.3 Reducing the 25,000 lb Threshold for Specific Regulated Chemical Substances

Beginning with the 2016 reporting cycle, the reporting threshold will be reduced to 2,500 lb for those chemical substances that are the subject of a rule proposed or promulgated under TSCA section 5(a)(2), 5(b)(4), or 6; the subject of an order issued under TSCA section 5(e) or 5(f); or the subject of relief that has been granted under a civil action under TSCA section 5 (See Appendix B of the Instructions for the 2012 TSCA Inventory Update Reporting (EPA, 2011)). For the 2016 submission period and submission periods thereafter, a manufacturer (including importer) of such chemical substances is required to report manufacturing information on the chemical substances if they are manufactured (including imported) in

volumes of 2,500 lb or more during any of the years since the last principal reporting year (e.g., 2011). Information on the processing and use of the chemical substances must be reported if they were manufactured (including imported) in volumes of 25,000 lb or more during any of the years since the last principal reporting year. In addition to the manufacturing, processing and use information for the principal reporting year (e.g., 2015), the production volumes for each year since the last principal reporting year must also be reported. For the 2015 reporting cycle, for example, a manufacturer (including importer) must consider the manufactured or imported volume during the years 2012 through 2015 to determine the need to report; must report the production volumes for each year from 2012 to 2015; and must report the full manufacturing, processing, and use information for 2015.

Chemical substances that are the subject of these particular TSCA actions are of demonstrated high interest to the Agency. EPA is promulgating this change to help reduce the reporting burden for submitters and to ensure the availability of current information when the Agency has expressed a concern in the form of regulatory action on those chemical substances manufactured below 25,000 lb. EPA will use the IUR data associated with these specific regulated chemical substances to monitor chemical substance production and compliance with the rules. In the future, EPA may find it necessary to collect information on chemical substances at a reporting threshold below the 2,500 lb threshold introduced in this action. Although the 2,500 lb threshold is slightly higher than the proposed threshold of zero, the enhanced information that will be gathered during the 2016 reporting cycle will enable the Agency and others to more efficiently identify those chemical substances warranting further, more in depth review, as well as chemical substances of lesser concern.

3.4 Changes to Chemical Substances Subject to the IUR Rule

3.4.1 Make Chemical Substances Subject to Enforceable Consent Agreements (ECAs) Ineligible for Exemptions

EPA may enter into an enforceable consent agreement (ECA), pursuant to procedures at 40 CFR part 790, with a manufacturer of a chemical substance, to obtain testing where a consensus exists among EPA, affected manufacturers and/or processors, and interested members of the public concerning the need for and scope of testing. Chemical substances covered by an ECA are of demonstrated high interest to EPA. The Agency has an interest in identifying the manufacturing, processing, and use of substances under such agreements, and therefore is requiring such substances be reported for IUR purposes, regardless of whether the substance otherwise meets the requirements listed in 40 CFR §710.46 (amended 40 CFR §711.6) as an exempt or partially exempt chemical substance. This provision will ensure the availability of current information if EPA has expressed a concern in the form of an ECA on any substance otherwise excluded from the IUR rule. For example, EPA could use the IUR data associated with these regulated chemical substances to monitor chemical substance production and compliance with the agreements. EPA is therefore making chemical substances that are the subject of an ECA ineligible for IUR exemptions.

Under this final rule, chemical substances that are the subject of an ECA will be included in the list of chemical substances ineligible for an IUR exemption, in the introductory paragraph of 40 CFR 710.46 (amended 40 CFR 711.6) listing the other chemical substances likewise not eligible for an IUR exemption. The paragraph will state a chemical substance "is not exempted from any of the reporting requirements of this part if that substance is the subject of a rule proposed or promulgated under section 4, 5(a)(2), 5(b)(4), or 6 of the Act, or is the subject of a consent agreement developed under the procedures of 40 CFR Part 790, or is the subject of an order issued under section 5(e) or 5(f) of the Act, or is the subject of relief that has been granted under a civil action under section 5 or 7 of the Act."

3.4.2 Full Exemption for Manufactured Water

Naturally occurring water is exempted from reporting under the IUR rule, but manufactured water, which is not naturally occurring, is a reportable substance. EPA is granting a full exemption to all (both naturally occurring and manufactured) water (CASRN 7732-18-5) and is removing water from the petroleum streams partial exemption (40 CFR §710.46(b)(1)).

3.4.3 Remove Fully Exempt Polymers from the Partially Exempt List

Polymers are a class of chemical substances for which IUR reporting is not required (40 CFR §710.46(a)(1)). However, three polymers are listed in the partially exempt list of chemical substances at §710.46(b)(2)(iv): Starch (CASRN 9005-25-8), Dextrin (CASRN 9004-53-9), and Maltodextrin (CASRN 9050-36-6). Improperly including substances meeting the IUR definition of a polymer in the partially exempt list of chemical substances may be confusing to submitters and may lead to unnecessary reporting for these substances. EPA is amending the partially exempt list of chemical substances at §710.46(b)(2)(iv) to remove these three chemical substances which, as polymers, are fully exempt from reporting.

3.5 Modifications to Reportable Data Elements

3.5.1 Parent Company and Site Identity

Manufacturers (including importers) are required to report the company name and Dun & Bradstreet (D&B) D-U-N-S® number to identify the company associated with the plant site, and also to report the site name, address, and D-U-N-S® number. If the company associated with the plant site does not have a D&B number, the manufacturer must obtain a D-U-N-S® number for the company. Likewise, if the plant site does not have a D-U-N-S® number, the manufacturer must obtain a D-U-N-S® number for the site. EPA is now clarifying what is meant by company name, by requiring the company name provided be the ultimate domestic parent company name. "U.S. parent company" is defined to mean "the highest level company, located in the United States that directly owns at least 50 percent of the voting stock of the manufacturer." EPA believes this change will reduce confusion by making this reporting requirement consistent with the Toxic Release Inventory (TRI) requirements for parent company name. The requirement that the ultimate domestic parent company name be reported under the IUR rule does not affect the determination of small business status, which is not limited to domestic companies. Persons subject to the IUR rule should continue to base small business determinations on the ultimate parent company, regardless of whether that company is domestic or foreign.

The 2006 IUR submissions from different reporting sites contained varying D-U-N-S® numbers for parent companies that appeared to be the same company. In order to better identify when reporting sites are under the same parent company, EPA is requiring the address as well as the D-U-N-S® number of the parent company.

3.5.2 Technical Contact

Manufacturers (including importers) are required to provide a technical contact for their IUR submission. The technical contact must be a person who can answer questions EPA may have about the reported chemical substance and but does not have to be located at the manufacturing site. Based on EPA's experience with contacting the reported technical contact with follow-up

questions concerning 2006 IUR submissions, submitters often provide the names of individuals who are not directly connected to the reporting site, and therefore, are not knowledgeable about either the chemical substance or the submission. EPA has also seen situations where the technical contact is a contracted employee who is able to address subsequent concerns only if he or she remains under contract. EPA is also allowing multiple technical contacts on a chemical substance-by-chemical substance basis, as provided by the new e-IURweb tool.

3.5.3 Chemical Identity

Chemical Name. EPA is requiring reporting of the Chemical Abstracts (CA) Index Name currently used to list the substance on the TSCA Inventory as the chemical name reported for IUR. Currently, submitters are required to report a specific chemical name, with no further elaboration in the regulatory text. For the 2012 submission period, the reporting software will be directly linked to the non-confidential portion of the TSCA Inventory through the Agency's Substance Registry System (SRS) database. Therefore, submitters will be required to select the correct CA Index Name for their reportable chemical substance(s) from SRS. EPA believes the requirement to use SRS to select the chemical name as currently listed on the TSCA Inventory will greatly reduce the number of poorly identified chemical substances and allow the data to be released more quickly to the public.

Manufacturers (including importers) will be allowed to supply an alternate chemical name, and in the case of importers, a trade name, in those instances where a supplier will not disclose to the submitter the specific chemical name of the imported Inventory substance or a reactant used to manufacture TSCA Inventory substance. In these cases, the manufacturer (including importer) and the supplier report the information required in this part in a joint submission (see Section 3.12).

In order to clarify this requirement, EPA is amending 40 CFR 711.15(b)(3)(i), to state that the importer must have the supplier of the confidential chemical substance directly provide EPA with the correct chemical identity, in a joint submission with the manufacturer. Furthermore, in the event the manufacturer submitting a report cannot provide the whole chemical identity because the reportable chemical substance is manufactured using a reactant having a specific chemical identity claimed as confidential by its supplier, the manufacturer must submit a report directly to EPA containing all other information known to or reasonably ascertainable by the manufacturer about the chemical identity of the reported chemical substance and must properly ask that the supplier directly provides to EPA the correct chemical identity of the confidential reactant in a joint submission. Nothing in §711.15(b)(3)(i) relieves a manufacturer (including an importer) of its obligation to report information that it actually knows or can reasonably ascertain.

*Chemical Identifying Number***.** As part of the chemical identity, submitters provide a chemical identifying number associated with the correct CA Index Name. EPA is requiring submitters to report only the CASRN as a chemical identifying number or, in the case of confidential chemical substances, the TSCA accession number assigned when the Notice of Commencement (NOC) was submitted to the Agency. Because the reporting tool will be directly linked to the non-confidential portion of the TSCA Inventory through SRS, submitters no longer will be allowed to claim the CASRN as confidential. For this reason, EPA is requiring submitters to report the TSCA accession number if they choose to assert a CBI claim on the chemical identity. Submitters will be able to look up the accession number in SRS using the PMN number for their chemical substance. Only those submitters who know only the CAS number and not the PMN number for the confidential chemical substance should submit a written request to EPA to obtain the TSCA accession number.

EPA also is removing the PMN number as an allowed chemical identifying number because each Inventory substance has either (or both) a CASRN (for the public Inventory) or a TSCA accession number (for the confidential Inventory), which are likely to be known already to the submitter.

3.5.4 Report Production Volume for Each of the Years since the Last Principal Reporting Year

For the 2012 submission period, manufactures (including importers) will be required to report the calendar year 2010 production volume of a chemical substance. For submission periods subsequent to the 2012 submission period, manufacturers (including importers) will be required to report the production volume for each year since the last IUR principal reporting year. For example, for the 2016 IUR, manufacturers (including importers) of a chemical substance at or above the 25,000 lb threshold during the principal reporting year will report the production volume of that chemical substance for each of the following calendar years: 2015, 2014, 2013, and 2012. Collecting the production volume for multiple years will provide EPA with more accurate and up-to-date information than what is provided under the current, once-every-five-years snapshot.

3.5.5 Volume of Chemical Substance Used On-Site

EPA is requiring submitters to report the volumes of a manufactured (including imported) chemical substance used at the reporting site. The requirement to report the volume used on-site is replacing the requirement to indicate the chemical substance is site-limited. Under this final rule, either domestically manufactured or imported chemical substances could be reported as used at the reporting site, whereas, under the current reporting requirements, only domestically manufactured chemical substances, consumed entirely at the manufacture site, were reported as site-limited.

3.5.6 Indicate Whether Imported Chemical Substances Are Physically at Reporting Site

EPA is adding a requirement to indicate whether an imported chemical substance is physically at the reporting site. Often, the site reporting an imported chemical substance never physically receives the chemical substance, but instead ships it directly to another location such as a warehouse, a processing or use site, or a customer's site. Identifying whether the chemical substance is physically at the reporting site provides more accurate information for screening-level analyses and other uses of the IUR data.

3.5.7 Report Production Volume Exported

EPA is adding a requirement to report the production volume directly exported and not domestically processed or used. This will allow EPA to better identify the proportion of the production volume included in the use reporting, given that downstream reporting is not required for exported substances.

3.5.8 Identify Whether a Chemical Substance is to be Recycled, Remanufactured, Reprocessed, or Reused

EPA is adding a requirement to indicate whether a manufactured chemical substance, such as a byproduct, is to be recycled, remanufactured, reprocessed, or reused. Submitters should indicate whether their manufactured chemical substance, which otherwise would be disposed of as a waste, is being removed from the waste stream and has a commercial purpose (i.e., it is being recycled, remanufactured, reprocessed, or reused). EPA believes such information will help the Agency identify where these activities are already occurring, and can be used to encourage such activities. Collecting information on whether a chemical substance is being recycled, remanufactured, reprocessed or reused and is not entering the waste stream provides valuable information to EPA and others regarding trends in chemical substance manufacturing. This information also can be used to help determine the effectiveness of various programs, such as EPA's Resource Conservation Challenge (RCC) Program. EPA launched the RCC in 2002, implementing Congress' instruction to prevent pollution and conserve natural resources and energy by managing materials more efficiently. The RCC Program's goals include promoting reuse and recycling and reducing chemical substances of national concern in products and waste. Indicating a manufactured chemical substance, such as a byproduct, is to be recycled, remanufactured, reprocessed, or reused does not affect the reporting requirements associated with any substance manufactured from the byproduct.

3.6 Concentration Ranges

EPA is eliminating gaps in the ranges used to report concentration in §710.52(c)(3) and (4). The new ranges are: (1) less than one percent by weight, (2) at least one percent but less than 30 percent by weight, (3) at least 30 percent but less than 60 percent by weight, (4) at least 60 percent but less than 90 percent by weight, and (5) at least 90 percent by weight.

3.7 Industrial Processing and Use Information Reporting

In 2003, EPA added industrial processing and use data to the information collected through the IUR rule for chemical substances manufactured in quantities of 300,000 lb or greater during the principal reporting year. The industrial processing and use information included industrial function categories and North American Industrial Classification System (NAICS) codes. EPA found that knowing these two data elements for a chemical substance was useful in selecting a scenario characterizing the frequency, route, and duration of exposure to a chemical substance during manufacture, processing, and use of the substance. These data are also useful when EPA characterizes the quantity of the chemical substance in wastes and emissions entering the environment and for anticipating the environmental media into which wastes will be released. The Agency now is revising the list of industrial function categories and replacing the NAICS codes with industrial sectors.

3.7.1 Revise Industrial Function Categories

EPA is revising the list of industrial function categories by combining categories leading to common exposure scenarios and adding categories where the Agency believes the existing categories do not adequately describe potential uses. EPA worked with Environment Canada and Health Canada to develop the revised set of categories, which will be used by both the United States and Canada for Inventory reporting. Harmonization of the categories for reporting the industrial functions of chemical substances will facilitate the exchange of information between

EPA and Canadian agencies and could serve as a model to be used by Mexico in developing an inventory of chemical substances. In addition, the harmonized categories will facilitate consistent reporting of chemical substance use information by industry in the United States and Canada.

EPA is adding eight new industrial function categories and removing six existing categories from the current list; the total number of industrial function categories will increase to 35. Also, EPA is renaming several of the industrial function categories to provide a more informative description of the function of the chemical substances that should be reported in that category. Lastly, EPA is requiring that if a submitter selects the category "Other," the submitter must provide its own description of the industrial function of the chemical substance. Appendix A. lists both the existing and amended sets of industrial function categories.

3.7.2 Industrial Sectors

EPA is replacing the five-digit North American Industrial Classification System (NAICS) codes with 48 Industrial Sectors (IS). The sectors were adapted from the European Union's (EU's) "Guidance on Information Requirements and Chemical Safety Assessment." The Industrial Sectors chosen divide the entire range of NAICS codes into sectors so a sector corresponds to every NAICS code. The Agency believes this change will provide several benefits. First, the sectors will reduce reporting burden because submitters will not have to look up the NAICS code. Second, it will encourage more complete reporting by using terms already familiar to industry. Third, the sectors reduce the likelihood of errors that result from the selection of miscellaneous or inappropriate NAICS codes. Fourth, it will reduce the number of codes that could apply to one substance. Appendix A. of this report provides a list of the revised industrial sectors.

When the category chosen for the Industrial Sector code is "Other," a written description of the use of the chemical substance, which may include the NAICS code, also must be provided.

3.8 Consumer and Commercial Use Reporting

In the 2003 Amendments, EPA added a reporting requirement for submitters to include information about the consumer and commercial uses of chemical substances they reported under the IUR rule. For the 2006 IUR, manufacturers (including importers) of subject chemicals manufactured in quantities of 300,000 lb or more during calendar year 2005 were required to select up to ten consumer and commercial product categories from a list of 20 categories corresponding to the actual use of the chemical substance they were reporting.

3.8.1 Revise Consumer and Commercial Product Categories

EPA is revising the list of consumer and commercial product categories by combining categories leading to common exposure scenarios and adding categories not adequately described in the initial set of categories. EPA worked with Environment Canada and Health Canada to develop the revised categories. The revised list includes 33 product categories, including "Other." Examples of new categories that have been added include explosive materials, building/construction products not covered elsewhere, and air care products. The glass and ceramic products category had relatively few IUR submissions in 2006 and overlaps with new categories, and so has been eliminated. Also, several of the consumer and commercial product categories have been renamed to better describe the products that should be reported in those categories. See Appendix B. of this report for a list of the revised categories.

3.8.2 Designation of Consumer or Commercial Use

EPA is requiring submitters to designate whether the use is a consumer use or a commercial use, or both. The Agency's experience using the 2006 IUR data identified a need to distinguish between potentially exposed consumer and commercial populations. The designation of consumer or commercial use, or both, will allow EPA to complete a better characterization of the potentially exposed populations.

3.8.3 Number of Commercial Workers Reasonably Likely To Be Exposed

EPA is requiring submitters to report the total number of commercial workers, including those at sites not under the submitter's control, that are reasonably likely to be exposed while using the reportable chemical substance, with respect to each commercial use. The approximate number of workers should be reported using the same definitions and ranges used for manufacturing and industrial processing and use workers, required by 40 CFR 710.52. The revised ranges are: (1) fewer than 10 workers, (2) at least 10 but fewer than 25 workers, (3) at least 25 but fewer than 50 workers, (4) at least 50 but fewer than 100 workers, (5) at least 100 but fewer than 500 workers, (6) at least 500 but fewer than 1,000 workers, (7) at least 1,000 but fewer than 10,000 workers, and (8) at least 10,000 workers.

3.9 Changes to Standard for the Reporting of Processing and Use Information

In order to collect more complete information regarding the industrial processing and industrial, commercial, and consumer use of chemical substances, EPA is replacing the "readily obtainable" reporting standard used for reporting under 40 CFR 710.52(c)(4) in 2006 with the "known to or reasonably ascertainable by" reporting standard set forth under TSCA for this type of TSCA reporting. TSCA section 8(a)(2) authorizes EPA to require persons to report information "known to or reasonably ascertainable by" the submitter. This is the same standard that currently applies to the reporting of information described in the regulations at §§710.52(c)(1), (c)(2), and (c)(3), and this standard will continue to apply to the reporting of such information under amended §§711.15(c)(1), (c)(2), and (c)(3). It covers all information in a person's possession or control, plus all information a reasonable person similarly situated might be expected to possess, control, or know. The "known to or reasonably ascertainable by" reporting standard was the only standard used for IUR reporting purposes prior to the 2006 IUR submission period.

EPA is clarifying that, in general, submitters are not required to conduct customer surveys. However, to the extent that customer surveys are already in the submitter's possession or control, and to the extent that reasonable efforts to analyze or synthesize already-available customer surveys may develop new processing and use information, the information is generally "reasonable ascertainable." For certain data fields on Form U where the information is not known and cannot be reasonably ascertained, EPA is permitting submitters to enter "NKRA" (not known to or reasonably ascertainable by).

3.10 Modifications to Confidential Business Information (CBI) Claims

Submitters currently may claim certain information reported under the IUR as confidential business information (CBI) in accordance with 40 CFR part 2 and IUR rules at §710.38

(amended §711.30). Submitters must assert claims of confidentiality at the time information is submitted to EPA. EPA's procedures for handling information claimed as confidential are set forth at 40 CFR part 2, subpart B.

To claim information as confidential, a submitter must assert its claim by checking the appropriate box and signing the certification statement on the reporting form. A submitter must assert its claims at the time the information is submitted. If a submitter fails to follow these procedures, EPA may release the information to the public without further notice to the submitter. By signing the certification statement, the submitter attests to the secrecy and value of the information for which confidentiality claims have been asserted. EPA expects the changes to the method for claiming information as CBI will reduce the number of unjustifiable CBI claims. Reducing the number of CBI claims will increase the amount of information available to the public and improve the timeliness of its public availability. As a result, the Agency will be able to publicly discuss and explain its risk management actions and decisions more clearly.

3.10.1 Chemical Identity CBI Claims

A submitter may assert a claim of confidentiality for the identity of the reported chemical substance only when the chemical substance is listed on the confidential portion of the TSCA Inventory. Submitters who assert a confidentiality claim for chemical name must also provide substantiation for the claim at time of filing. At times, submitters have asserted a claim of confidentiality for the chemical identity of a substance listed on the public portion of the Master Inventory File. Where the identity of a chemical substance is already provided on the public portion of the TSCA Chemical Substances Inventory, which is publicly available from the National Technical Information Service, EPA's website and other sources, EPA believes the identity itself, even assuming it might otherwise be CBI, as well as any information that might be derived from it about processes or portions, has already been disclosed. Under the final rule, when this occurs, the Agency may make the information available to the public without further notice to the submitter.

In this final rule, 40 CFR 711.15(a)(3)(i) has been revised to provide that submitters who wish to report chemical substances listed on the confidential portion of the TSCA Inventory will need to report the substance using a TSCA accession number. Requiring the use of accession numbers will allow EPA to adequately protect confidential CASRNs and CA Index Names (by omitting them from the pre-populated selection list in the SRS) while still obtaining the improvements in reporting accuracy it sought in the proposed rule.

3.10.2 Upfront Substantiation for Processing and Use Information CBI Claims

Under the IUR rule, a submitter may assert a claim of confidentiality for data associated with the processing and use of its chemical substance if the submitter has reason to believe release of the information will reveal trade secrets or confidential commercial or financial information, as provided by section 14 of TSCA and 40 CFR part 2.

Under the final rule, submitters will be required to both check the appropriate box on the reporting form and substantiate the CBI claim in writing, within the reporting software, by answering certain questions provided in§711.30(d) of the final rule. Where a submitter fails to substantiate the processing and use CBI claim in accordance with the applicable rules (i.e., the submitter does not provide an answer to the required questions), EPA will consider the

information not subject to a confidentiality claim and may make the information available to the public without further notice to the submitter.

3.10.3 Prohibition of Confidentiality Claims for Data Elements Identified as "Not Known or Reasonably Ascertainable"

Under the final rule, EPA is prohibiting claims of confidentiality pertaining to the designation that information is not "known to or reasonably ascertainable by" (NKRA) the submitter. For the 2012 and future IUR collections, submitters will be required to report processing and use information to the extent that it is known to or reasonably ascertainable by them.

For the 2006 IUR collection, EPA observed that, on occasion, processing and use information was claimed as confidential when a submitter determined that the information was not readily obtainable. Section 14 of TSCA limits the disclosure of information entitled to confidential treatment under Exemption 4 of the Freedom of Information Act (FOIA). EPA has considered the NKRA designation and its relationship to a potential CBI or trade secret claim. Given that a NKRA assertion is an assertion that no information is available, the Agency does not believe that the designation conveys trade secret or confidential commercial or financial information.

3.11 Method of Submission

EPA accepted 2006 IUR submissions in several ways. Submissions could be completed and delivered electronically via the Internet and CDX, or submissions could be completed on paper or electronic media (i.e., as a file on a CD-ROM) and delivered by mail or a delivery service. Approximately one-third of the submissions were made electronically, and EPA was able to immediately process and quickly begin to use the information from those electronic submissions. Submissions sent as a file on a CD were printed and, along with paper submissions, scanned by EPA into an electronic system. Due mostly to the time and resources needed to review and correct submitter- and scanning-related errors associated with non-electronic submissions, EPA required more than two years to validate and process the data from the 2006 IUR.

EPA now is requiring the mandatory use of Agency-provided reporting tool (e-IURweb) to complete the IUR Form U and CDX to submit the completed Form U to the Agency. CDX users are required to register with CDX and to submit an authorized electronic signature agreement. Each IUR submission must have an authorized official associated with the submission, who is the person signing the certification statement and submitting the IUR report via CDX. The authorized official must complete both an ESA and the CDX registration process. The reporting software, instruction manual, and other guidance materials are available on EPA's website at www.epa.gov/iur.

3.11.1 Updated e-IUR Reporting Tool

EPA, based on its experience collecting and managing the 2006 IUR reports, has concluded that mandatory electronic reporting is a critical next step for collection of the 2012 data. Optional electronic reporting for the 2006 IUR provided the Agency with experience relating to both industry and Agency needs, and the Agency has applied this experience in the course of developing of the 2012 electronic reporting tool (e-IURweb). For example, the use of a web-based tool for the 2012 IUR will eliminate many of the software compatibility and firewall setting issues that were encountered during the 2006 submission period. In addition, e-IURweb utilizes other Agency systems, such as SRS, enabling the submitter to readily select the chemical identity in the correct format, thereby eliminating problems relating to the previous need to type or write in the chemical name. With these enhancements, EPA believes the use of e-IURweb will substantially reduce error rates and burden.

3.11.2 Require Electronic Submissions over the Internet

EPA is requiring manufacturers (including importers) to submit their IUR reports to the Agency through CDX via the Internet. EPA will require all submissions to be generated using e-IURweb reporting software. Electronic submissions will ensure that IUR data will have completed a basic validation check, could be incorporated quickly into a database and be ready for immediate Agency use, and will not be subject to subsequent data entry errors. Furthermore, EPA believes the required use of e-IURweb and CDX will reduce the reporting burden on industry by reducing both the cost and the time required to review, edit and transmit data to the Agency. After the final rule's effective date, EPA will no longer accept paper submissions or electronic media (i.e., as a file on a CD-ROM) for any IUR submission.

3.11.3 Electronic Signature Process

In order to submit electronically to EPA via CDX, individuals acting on behalf of the submitter must first register with CDX. CDX registration is a requirement for all electronic submissions using CDX and is not being introduced with this final rule. During the 2006 IUR, submitters were required to complete an electronic signature agreement (ESA) and to submit the agreement in hard copy with a wet ink signature to EPA in order to complete the CDX registration. There was confusion among some submitters regarding the correct identity of the individual eligible to register for CDX and the individual required to sign the ESA.

EPA is making changes to the registration process in order to address problems identified during the 2006 IUR electronic reporting. For 2012 IUR reports, EPA is modifying the 2006 ESA to identify more clearly the individual(s) required to sign the agreement. The Agency is developing an ESA process similar to that planned for New Chemicals Program electronic submissions. Each IUR submission must have an authorized official associated with the submission, who is the person signing the certification statement and submitting the IUR report via CDX. The authorized official will need to complete both an ESA and the CDX registration process.

3.12 Modifications Specifically Affecting Importers

Submitters report IUR data on chemical substances they manufacture domestically and import into the United States. Current IUR regulations require the site responsible for reporting for imported chemical substances to be the site of the operating unit directly responsible for importing the substance and controlling the import transaction. In some cases, the import site may be the organization's headquarters in the United States. The regulations defining the site for importer reporting are found in both the definition for *site* in §710.3 and in paragraph §710.48(b). EPA is eliminating unnecessary duplication in the IUR regulation by moving the additional information regarding the importer site from §710.48(b) into a revised definition for *site*, and eliminating paragraph §710.48(b).

In addition, EPA has observed submitters occasionally use a foreign address as the site address for the importer. In the final rule, EPA is now is requiring submitters to report a U.S. site address, by modifying the definition for *site* to state specifically that the site must be a U.S. site. The U.S. address of an agent acting on behalf of the importer, and authorized to accept service of process for the importer, may be reported as the importer's site address if the operating unit directly responsible for importing the substance and controlling the import transaction has no U.S. address. The Agency expects all importers will have a U.S. site, as defined in the amended §711.3 definition for site. Under U.S. Customs regulations at §141.18, a non-resident corporation is not permitted to enter merchandise for consumption

unless it has a resident agent in the State where the port of entry is located, who is authorized to accept service of process against the corporation.

For purposes of IUR, submitters currently are allowed to report the IUR information jointly with the foreign manufacturer of the chemical substance. Importers may not know the specific chemical identity of a substance because the foreign supplier chooses to keep it confidential. In such a situation, the importer must use e-IURweb to ask the foreign supplier to submit its chemical identity information to EPA and may do so through by submitting a joint report. To submit a joint report, the importer completes the majority of the required information, and supplies a trade name or other designation to identify the chemical substance, and provides contact information for the foreign supplier. The importer then uses e-IURweb to contact the foreign supplier and to request that the foreign supplier notify it of the need to report the specific chemical identity information directly to EPA. The importer must submit a copy of such request to EPA, along with the rest of its IUR submission for the chemical substance. As a general matter, EPA expects that importers will supply the information described at §711.15(b)(3)(i)(A), rather than a "NKRA" designation, when importers do not know the confidential chemical identity of a chemical substance they import. EPA believes that a NKRA designation would generally be appropriate only in the unlikely event that an importer did not know, and could not reasonably ascertain, the information needed to link its submission with a secondary report from the supplier.

Under the final rule, the process will be the same, except submitters will be required to use CDX and e-IURweb for preparation and submission of joint submissions. Previously, joint submissions could not be made electronically. In order to submit electronically to EPA via CDX, individuals must first register with CDX. Therefore, the authorized officials of the jointly submitting companies will need to register in order to submit their reports to EPA. The secondary submitter (e.g., a foreign supplier or manufacturer) will have to register as someone authorized by the primary submitter's (e.g., the importer's) authorized official to send joint submissions to EPA.

For joint submissions to be submitted electronically, the primary submitter will use e-IURweb to identify the need to submit a joint report and will identify itself as a primary submitter. The primary submitter will then complete his or her portion of the report and provide the secondary submitter's company information, along with select information on the chemical substance(s) manufactured using a chemical substance made by the secondary submitter. The primary submitter reports only the volume that it used. A secondary submitter will also need to use e-IURweb to identify the need to submit a joint report and will identify itself as a secondary submitter. In an acceptable joint submission, the secondary submitter supplies the chemical identity, as well as its technical contact and company information, and provides the primary submitter's site information. EPA will not accept joint submissions that are not submitted electronically using e-IURweb and CDX. All information will be saved by the reporting software and both submissions will be matched based upon company and chemical substance information. Once the forms are linked, EPA will process the joint submission as one report for the reported chemical substance.

For the 2006 IUR reporting cycle, EPA set aside joint submissions until both were received and matched. EPA often had no way to determine whether a submission was a "joint" submission, which increased the time required for manual processing of the data. EPA anticipates the use of the reporting tool will help to make joint IUR reporting easier for industry and streamline EPA processing of the IUR information submitted in the 2012 reporting cycle.

3.13 Modify Reporting Frequency

Prior to the 2003 Amendments, the IUR collection occurred every four years. EPA reduced the reporting frequency from every four years to every five years starting with the 2006 IUR to

lessen the burden associated with the amended IUR. The Agency now has determined that reporting every five years is too infrequent, and is returning to reporting every four years.

While the less frequent reporting does reduce burden, EPA now believes reporting every five years does not provide data sufficiently current to meet Agency and public needs. The Agency has been criticized for using outdated information. EPA, therefore, considered increasing the frequency of reporting to every three years, or possibly to annual reporting. The Agency believes efficiencies are gained with more frequent reporting, both for the submitter and for EPA. With more frequent reporting, companies will be able to establish standard systems and practices to collect the required information.

4. Industry Burden and Cost Estimates

4.1 Methodology for Compliance Cost and Burden Analysis

This chapter analyzes the changes in industry compliance burden and cost associated with the amendments to the IUR rule. EPA calculates the incremental burden and cost, or savings, of the amendments by comparing the burden and cost of complying with the amendments to the burden and cost industry would incur to comply with current IUR requirements in the 2012 reporting cycle absent the amendments (the baseline). The methodology for estimating the change in industry burden and cost can be summarized as follows:

- **Step 1**: Identify the tasks sites perform to comply with reporting requirements for both the current IUR requirements and the IUR amendments.
- **Step 2**: Determine the unit burden and cost for all activities identified in Step 1, based on labor requirements for managerial, technical, and clerical staff; current wage rates; and other current costs.
- **Step 3**: Determine the expected number of sites and reports filed under both the current IUR requirements and the IUR amendments.
- **Step 4**: Multiply the burden and cost per form by the number of forms to determine the estimated total burden and cost of compliance for the current IUR and the IUR amendments.
- **Step 5**: Subtract the compliance burden and cost after the IUR amendments from the burden and cost under the current IUR requirements to calculate the incremental additional burden and cost or savings attributable to the amendments.

A chemical company may own many sites, each of which may manufacture (including import) multiple chemical substances. Each site must submit a Form U if it exceeds the 25,000 lb threshold for at least one chemical substance not exempt from reporting. A site will submit one Form U Part I, and either a full or partial report for each chemical substance that meets or exceeds the reporting threshold. Each report is submitted for a unique chemical substance/site combination. The activities under these tasks are as follows:

- **Compliance Determination**: To determine whether it must submit a Form U, a site must determine whether (1) it manufactures (including imports) any chemical substances not falling into one of the categories exempt from reporting; (2) the annual production or import volume of the chemical substance is at or above the reporting threshold; and (3) the company meets the small business criteria set forth in the TSCA §8(a) Small Manufacturer Exemption Rule (40 CFR §704.3). For simplicity, the cost for compliance determination is considered to be incurred once per site, and not to vary with the number of chemical substances at the site. A portion of the compliance determination cost depends on the number of chemical substances, but for most chemical substances this component of the burden will be extremely small. The majority of the time required for this task involves identifying the requirements and reviewing information to determine whether the site must submit a Form U.
- **Rule Familiarization**: Once a site has determined it must submit a Form U, staff must familiarize themselves with the requirements of the rule. Sites reporting previously must become familiar with new requirements, and sites new to reporting must become familiar with all requirements. This entails reading the rule, understanding the various reporting and administrative requirements, and determining the manner in which the reporting requirements will be met.

- **Preparation and Submission of Reports**: Once a site has determined it must submit a Form U for a chemical substance and has become familiar with the rule, the required information must be collected and a Form U covering all of the reportable chemical substances at that site must be completed, reviewed, and submitted to EPA. This task involves any research necessary to identify the correct information to report, the act of completing Form U (technical and clerical burden), managerial review, and any mailing or other submission costs.
- **Recordkeeping**: Submitters must keep records supporting their submissions for five years.

More information on estimating compliance costs under the current IUR rule can be found in the economic analyses for the 2003 Amendments, *Economic Analysis for the Amended Inventory Update Rule* (EPA, 2002a) and for the 2005 Amendments (EPA, 2005).

4.2 Industry Unit Burden and Cost Estimates

The industry reporting burden and cost are calculated based on estimates of wage rates, labor hours, and the numbers of sites and reports. This section describes the specific data used to develop these estimates.

4.2.1 Estimates of Wage Rates

Standard wage rates for managerial, technical, and clerical levels were developed from information published by the Bureau of Labor Statistics (BLS) and a method outlined in the document *Wage Rates for Economic Analyses of the Toxics Release Inventory Program* (EPA, 2002b). Average wage data for the three major occupational groups are published quarterly by the BLS in the Employer Costs for Employer Compensation (ECEC) reports. Managerial, technical, and clerical wage rates are taken from the "Management, Business, and Financial", "Professional and Related", and "Office and Administrative Support" occupational groups, respectively. Wage data for the three occupational categories was gathered for manufacturing industries from *Employer Costs for Employee Compensation Supplementary Tables: Historical Data December 2006 – December 2008* (BLS, 2009).

Fringe benefits costs, such as health insurance and vacation, for each labor category are taken from the same ECEC series. Following the methodology outlined in EPA, 2002b, fringe benefits are calculated as a percentage of total wages for each category. An additional 17 percent is added to the wages in each category to account for overhead, based on information provided by the chemical industry and chemical industry trade associations in the *Revised Economic Analysis for the Amended Inventory Update Rule: Final Report* (EPA, 2002a). The wages for each of the three categories are then multiplied by benefits and overhead factors to estimate loaded, annual salaries in 2008 dollars. Table 4-1 contains the loaded wage rates for the managerial, technical and clerical occupation categories.

Table 4-1: Derivation of Loaded Wage Rates for the Private Manufacturing Sector (2008$)

	Wage[1] (a)	Fringe Benefits[1] (b)	Fringes as % of Wage (c) = (b)/(a)	Overhead % of Wage[2] (d)	Fringe + Overhead Factor (e)=(1)+(c)+(d)	Loaded Wages (f) = (a)*(e)
Managerial	$43.22	$19.46	48.37%	17%	1.62	$70.03
Technical	$35.29	$17.55	47.58%	17%	1.67	$58.84
Clerical	$17.22	$8.33	45.03%	17%	1.65	$28.48

Notes:
[1]*Employer Costs for Employee Compensation Supplementary Tables: Historical Data December 2006 – December 2008*, US Bureau of Labor Statistics, March 12, 2009 (BLS, 2009).
[2] An overhead rate of 17% was estimated based on industry data gathered for the *Revised Economic Analysis for the Amended Inventory Update Rule: Final Report* (EPA, 2002a).

4.2.2 Estimates of Baseline Labor Hours (Burden)

As mentioned earlier, the reporting tool for the IUR rule is Form U. Each site must determine whether it must comply with the IUR rule. Sites that are required to report then must become familiar with the rule's reporting requirements. The costs associated with these tasks are calculated per site, and do not vary with the number of chemical substances reported by the site. Each reporting site is required to file only one Part I of Form U, regardless of the number of reportable chemical substances it manufactures (including imports). The information required in Part I, such as site and company identification, are common to all chemical substances produced at a single site; therefore, this information need only be reported once. For each reportable chemical substance, a site must prepare and submit Part II and, if applicable, Part III of Form U. For the purpose of this analysis, a "report" can be either a partial report (Parts I and II of Form U) or a full report (Parts I, II, and III of Form U), submitted for one chemical substance. Submission costs, in the baseline, consist of mailing costs, and are calculated per-site. Recordkeeping costs are calculated as per-report costs (so total reporting and recordkeeping costs vary with the number of chemical substances reported).

In summary, compliance costs are determined as follows:

- Compliance Determination: per-site basis;
- Rule Familiarization: per-site basis;
- Preparation of Part I: per-site basis;
- Preparation of Parts II and III: per-report basis;
- Submission: per-site basis; and
- Recordkeeping: per-report basis.

The baseline estimates of the labor hours required for the various tasks are taken from the Economic Analyses from the 2002 and 2005 IUR rule Amendments (EPA, 2002a and EPA, 2005). An industry survey conducted for the 2002 Economic Analysis provides estimates of the burden to complete each section and subsection of Form U. Compliance determination, rule familiarization, and recordkeeping burdens are also taken from the 2002 Economic Analysis. The Economic Analysis for the 2005 Amendments assumed a 15 percent reduction in burden for the

completion of Part III because submitters no longer were required to report use and downstream processing information for exports.[3] Therefore, this 15 percent reduction was applied to all of the 2002 burden estimates in Part III of the form, to estimate the current baseline.

The 2002 Economic Analysis presents low and high estimates for each burden element; for simplicity, this report uses the midpoints of these ranges. Table 4-2 contains the burden estimates, per site, to complete and submit a Form U (one report for one chemical substance).

[3]In the 2005 Economic Analysis, EPA estimated that 15 percent of the production volume at an average site is exported. Because processing and use information was no longer required for this percentage of production volume, the effort to collect and report this information would decrease accordingly.

Table 4-2: Baseline First-Cycle Labor Burden per Form U, in Hours

Form U Section and Activity		Clerical Burden (a)	Technical Burden (b)	Managerial Burden (c)	Total Burden (d) = (a)+(b)+(c)
	Compliance Determination (Total Burden for Form U Compliance Determination)	***0.00***	***2.50***	***0.00***	***2.50***
	Rule Familiarization (Total Burden for Form U Submission)	***0.00***	***19.00***	***9.00***	***28.00***
	Recordkeeping (Total Burden for Form U Recordkeeping)	***1.50***	***3.00***	***1.50***	***6.00***
	Submission (Total Burden for Form U Submission)	***0.00***	***0.00***	***0.00***	***0.00***
	Mailing Burden	0.00	0.00	0.00	0.00
Part I.	Site Identification Information (Total Burden for Part I)	***0.76***	***0.95***	***1.05***	***2.76***
1	Certification	0.68	0.85	1.01	2.54
2	Company Information				
	Company Name, Technical Contact, Address, D&B Number, Mailing Address	0.04	0.04	0.02	0.10
3	Plant Site Identification				
	Plant Name, D&B Number, Address, Mailing Address	0.05	0.06	0.02	0.13
Part II.	Manufacturing Information (Total Burden for Part II)	***1.55***	***8.78***	***3.49***	***13.82***
1	Chemical Identification				
2	(Other) Manufacturing Information				
	Site-Limited, Activity, Production Volume (lb)	0.52	2.28	0.56	3.36
	Chemical Identification Upfront CBI Substantiation	0.26	1.45	0.67	2.38
	Plant Site Upfront Substantiation	0.12	0.83	0.51	1.46
	Total Number of Workers	0.21	1.43	0.59	2.23

Form U Section and Activity		Clerical Burden (a)	Technical Burden (b)	Managerial Burden (c)	Total Burden (d) = (a)+(b)+(c)
	Maximum Concentration, Physical Form, Percent Volume of Production	0.44	2.79	1.07	4.30
Part III	Processing and Use Information (Total Burden for Part III)	***7.94***	***45.31***	***16.66***	***69.92***
1	Industrial Processing and Use Exposure-Related Data				
	Determination of Applicability	0.13	1.01	0.28	1.42
	Industrial Function Category	2.11	4.41	2.07	8.59
	Function Code	0.19	0.94	0.40	1.52
	Percent of Production Volume	1.23	10.00	5.27	16.51
	Total Number of Processing and Use Sites	1.57	9.14	3.52	14.24
	Total Number of Potentially Exposed Workers	2.10	15.43	3.83	21.36
2	Consumer and Commercial Use Exposure-Related Data				
	Determination of Applicability	0.14	0.94	0.25	1.33
	Identification of Production Category/Use by Children	0.14	0.84	0.25	1.23
	Percent of Production Volume	0.20	1.26	0.45	1.91
	Maximum Concentration by Category	0.11	1.36	0.34	1.81
Total Burden for Report Preparation and Submission					
Partial Report (Parts I, II, Recordkeeping and Submission Burden)		**3.81**	**34.23**	**15.04**	**53.08**
Full Report (Parts I, II, III, Recordkeeping and Submission Burden)		**11.74**	**79.54**	**31.70**	**122.99**

Note: Totals may not sum due to rounding.
Source: *Revised Economic Analysis for the Amended Inventory Update Rule: Final Report* (EPA, 2002a).

The survey conducted for the economic analysis for the Final TSCA IUR rule 2003 Amendments (EPA, 2002a) estimated a single burden for reporting site-limited activity and production volume. This burden is estimated to be 3.36 hours per site (see Table 4-3) and covers four separate activities:

- Answering a yes/no question to indicate whether the volume is site-limited volume;
- Indicating whether the chemical substance is manufactured or imported;
- Providing the manufactured production volume; and
- Providing the imported production volume.

Several of the amendments are expected to create burdens similar to one of the above activities, but none are expected to generate a burden equivalent to all four questions combined. To estimate more accurately the burden of several amendments, EPA used its best professional judgment and estimated the percent burden each activity contributed to the total burden of 3.36 hours. These burden estimates are found in Table 4-3.

Table 4-3: Burden Percentages Attributed to Site-Limited Activity and Production Volume Questions

Activity	Percent of Total Burden	Burden (hours)
Answering a yes/no question to indicate whether the volume is site-limited volume	5%	0.17
Indicating whether the chemical substance is manufactured or imported	5%	0.17
Providing the manufactured production volume	45%	1.51
Providing the imported production volume	45%	1.51
Total	**100%**	**3.36**

Source: *Revised Economic Analysis for the Amended Inventory Update Rule: Final Report* (EPA, 2002a).

4.2.3 Estimates of Baseline Submission (Mailing) Costs

As noted above, the baseline scenario in this analysis is the total cost a site would incur to comply with the current IUR rule, absent any of the amendments. Therefore, the Agency estimated the cost of a mail-in submission of Form U, using data from the United States Postal Service website. Following the mailing requirements outlined in the *Economic Analysis of Expedited Significant New Use Rules for 56 Chemical Substances* (EPA, 2008b), a mail-in submission is assumed to consist of mailing a document via first class registered mail with a return receipt. The cost is estimated to be $13.78 per report and is itemized in Table 4-4.

Table 4-4: Mailing Submission Costs (December, 2009)

USPS Service	Cost (2009$)
Registered mail, *regular, with $0 declared value*[1]	$10.60
Return receipt, *requested at time of mailing (receive by mail)*[1]	$2.30
Postage, *First Class Mail for larger envelopes, up to 1 ounce*[2]	$0.88
Total	**$13.78**

Source: USPS, 2009

Notes: While all other costs are presented in 2008$, the most recent mailing costs as of the preparation of this analysis were used, following the methodology outlined in other reports such as the *Economic Analysis of Expedited Significant New Use Rules for 56 Chemical Substances* (EPA, 2008b). EPA does not expect mailing costs to significantly differ between 2008 and 2009.

4.2.4 Estimates of Baseline Cost per Report

EPA estimated the baseline cost to industry of completing and submitting Form U, using the loaded wages rates in Section 4.2.1, the estimated labor hours in Section 4.2.2, and the mail-in submission costs derived in Section 4.2.3.The burden hours for each occupation category are multiplied by the corresponding wage rate to calculate the baseline cost per site of completing each section of Form U. EPA estimates the total cost per site of submitting and completing a partial report (Parts I, II, recordkeeping and submission costs)for the first time is $3,188. EPA estimates the cost to a site of submitting and completing a full report (Parts I, II, III, recordkeeping and submission costs) for the first time is $7,247, for one chemical substance. Table 4-5 contains the submission costs by section for first-time submitters, including the costs for compliance determination, rule familiarization, report preparation, report submission, and recordkeeping costs.

Table 4-5: Baseline First-Cycle Total Cost per Form U (2008$)

Form U Section and Activity		Clerical Cost (a)	Technical Cost (b)	Managerial Cost (c)	Total Cost (d)=(a)+(b)+(c)
	Compliance Determination (Total Burden for Form U Compliance Determination)	***$0.00***	***$147***	***$0.00***	***$147***
	Rule Familiarization (Total Burden for Form U Submission)	***$0.00***	***$1,118***	***$630***	***$1,748***
	Recordkeeping (Total Cost for Form U Recordkeeping)	***$42.72***	***$177***	***$104***	***$324***
	Submission (Total Cost for Form U Submission)				***$13.78***
	Mailing Cost				$13.78
Part I.	Site Identification Information (Total Cost for Part I)	***$21.50***	***$54.08***	***$73.53***	***$149.10***
1	Certification	$19.22	$50.01	$70.73	$139.96
2	Company Information				
	Company Name, Contact, Address , D&B Number, Mailing Address	$1.00	$2.35	$1.40	$4.75
3	Plant Site Identification				
	Plant Name, D&B Number, Address, Mailing Address	$1.28	$1.71	$1.40	$4.39
Part II.	Manufacturing Information (Total Burden for Part II)	***$44.14***	***$516.61***	***$244.40***	***$805.14***
1	Chemical Identification				
2	(Other) Manufacturing Information				
	Site-Limited, Activity, Production Volume (lb)	$14.81	$134.15	$39.22	$188.18
	Chemical Identification Upfront CBI Substantiation	$7.40	$85.32	$53.57	$146.29
	Plant Site Upfront Substantiation	$3.42	$48.84	$35.57	$87.97
	Total Number of Workers	$5.98	$84.14	$40.97	$131.09
	Maximum Concentration, Physical Form, Percent Volume of	$12.53	$164.16	$74.93	$251.62

Form U Section and Activity		Clerical Cost (a)	Technical Cost (b)	Managerial Cost (c)	Total Cost (d)=(a)+(b)+(c)
	Production				
Part III	Processing and Use Information (Total Cost for Part III)	***$226.08***	***$2,666***	***$1,167***	***$4,059***
1	Industrial Processing and Use Exposure-Related Data				
	Determination of Applicability	$3.63	$59.27	$19.94	$82.84
	Industrial Function Category	$60.15	$259.57	$144.64	$464.36
	Function Code	$5.33	$55.01	$27.68	$88.02
	Percent of Production Volume	$35.10	$588.41	$369.34	$992.85
	Total Number of Processing and Use Sites	$44.78	$537.89	$246.72	$829.40
	Total Number of Potentially Exposed Workers	$59.91	$907.74	$268.15	$1,236
2	Consumer and Commercial Use Exposure-Related Data				
	Determination of Applicability	$4.11	$55.01	$17.56	$76.69
	Identification of Production Category/Use by Children	$4.11	$49.26	$17.56	$70.64
	Percent of Production Volume	$5.81	$74.02	$31.55	$111.38
	Maximum Concentration by Category	$3.15	$80.02	$24.11	$107.28
Total Cost for Report Preparation and Submission					
Partial Report (Parts I, II, Recordkeeping and Submission Costs)		**$108**	**$2,012**	**$1,053**	**$3,188**
Full Report (Parts I, II, III, Recordkeeping and Submission Costs)		**$334**	**$4,678**	**$2,220**	**$7,247**

Note: Totals may not sum due to rounding.
Source: *Revised Economic Analysis for the Amended Inventory Update Rule: Final Report* (EPA, 2002a).

4.2.5 Estimates of the Number of Sites and Reports

The baseline number of reports EPA is expecting, and the number of sites submitting those reports, were calculated based on 2006 IUR submissions to EPA. Because there is a cost difference between the two types of reports, the total number of reports is broken down into sites that filed full reports and sites that filed partial reports. The number of reports EPA is expecting was estimated using data compiled from EPA's 2006 IUR Database (EPA, 2008c). The database contains information collected under the IUR rule for previous reporting cycles and was used to generate estimated numbers of expected reports. The Agency assumes because of the low company turnover rate within the chemical manufacturing industry, the baseline number of sites submitting Form U in 2012 will be equivalent to the number of sites submitting Form U in 2006. In addition, for the purposes of this analysis, EPA assumes the baseline number of reports submitted will not change from the 2006 submissions. In 2006, a total of 4,085 sites completed 25,896 reports as shown in Table 4-6.

Table 4-6: Baseline Number of Reports and Sites

	Number of Partial Reports	Number of Full Reports	Total
Number of Sites	568	3,517	**4,085**
Number of Reports	8,821	17,075	**25,896**

Source: U.S. EPA, Office of Pollution Prevention and Toxics, Information Management Division *2006 IUR Database Statistics for IUR Modifications Rule*. Washington, DC. December 17, 2008 (EPA, 2008c).

Limitations of Analysis. Due to inconsistencies and limitations in the data collected in 2002 and 2006, including the amendment requiring reports for inorganic chemical substances for the first time in 2006 and the change in the reporting threshold from 10,000 lb to 25,000 lb, it was not possible for EPA to compare records to determine whether the number of sites and reports submitted for a consistent set of chemical substances had changed significantly between the two reporting cycles. Such an analysis potentially could provide support for EPA's assumption the number of sites and reports will remain relatively unchanged in the next reporting cycle. Therefore, to the extent changes in the chemical industry unrelated to the IUR rule amendments could affect the number of site and reports submitted, this analysis may under- or overestimate costs and burden.

4.2.6 Estimates of Future Reporting Cycles' Labor Hours (Burden)

EPA assumes that sites that previously have submitted a Form U will incur a reduced burden for processing and submitting Form U in future reporting cycles. All sites will incur a higher reporting cost in the first reporting cycle under the final rule due to the need to become familiar with the revised requirements. However, the Agency assumes unit costs for report preparation and submission in future reporting cycles will be lower than the unit costs attributed to reporting in the first reporting cycle because of efficiencies achieved through the establishment of compliance processes (EPA, 2002a). Furthermore, after a site's first reporting cycle, the availability of data from previous reporting cycles and familiarity with reporting requirements will expedite the process for submitters who have previously submitted a Form U. The burden estimates for these sites are weighted to reflect this decreased burden (EPA, 2002a).

Table 4-7 contains the weighting factors for each section of the form. Table 4-8 contains the baseline, future reporting cycle, per-report burden estimates, which are calculated using the weights in Table 4-7 and the first reporting cycle burden estimates in Table 4-2. Table 4-9 contains the baseline future reporting cycle costs per report, which are calculated using the wage rates in Table 4-1 and the hourly burden estimates from Table 4-8.

Table 4-7: Weighting Factors for Burden Estimates for Sites That Have Previously Submitted a Form U

Section of Form U		Percent of Initial Burden Incurred [1]
Part I. Site Identification		
	Certification	100%
Section A	Company Information	20%
Section B	Plant Site Identification	20%
Section C	Technical Contact	20%
Part II. Manufacturing Information		
Section A	Chemical Identification	20%
Section B	(Other) Manufacturing Information	80%
Part III. Processing and Use Information		
Section A	Industrial Processing and Use Exposure Related Data	80%
Section B	Industrial Processing and Use Exposure Related Data	80%

[1] Weighting factors are from the *Revised Economic Analysis for the Amended Inventory Update Rule: Final Report* (EPA, 2002a), pp. 3-17.

Table 4-8: Baseline Future-Cycle Labor Burden per Report, in Hours

Form U Section and Activity		Clerical Burden (a)	Technical Burden (b)	Managerial Burden (c)	Total Burden (d) = (a)+(b)+(c)
	Compliance Determination (Total Burden for Form U Compliance Determination)	***0.00***	***2.50***	***0.00***	***2.50***
	Rule Familiarization (Total Burden for Form U Submission)	***0.00***	***2.00***	***2.00***	***4.00***
	Recordkeeping (Total Burden for Form U Recordkeeping)	***1.50***	***3.00***	***1.50***	***6.00***
	Submission (Total Burden for Form U Submission)	***0.00***	***0.00***	***0.00***	***0.00***
	Mailing Burden	0.00	0.00	0.00	0.00
Part I.	Site Identification Information (Total Burden for Part I)	***0.69***	***0.87***	***1.02***	***2.58***
1	Certification	0.68	0.85	1.01	2.54
2	Company Information				
	Company Name, Technical Contact, Address, D&B Number, Mailing Address	0.01	0.01	0.00	0.02
3	Plant Site Identification				
	Plant Name, D&B Number, Address, Mailing Address	0.01	0.01	0.00	0.03
Part II.	Manufacturing Information (Total Burden for Part II)	***1.24***	***7.02***	***2.79***	***11.06***
1	Chemical Identification				
2	(Other) Manufacturing Information				
	Site Limited, Activity, Production Volume (lb)	0.42	1.82	0.45	2.69
	Chemical Identification Upfront CBI Substantiation	0.21	1.16	0.61	1.98
	Plant Site Upfront Substantiation	0.10	0.66	0.41	1.17
	Total Number of Workers	0.17	1.14	0.47	1.78
	Maximum Concentration, Physical Form, Percent Volume of Production	0.35	2.23	0.86	3.44

Form U Section and Activity		Clerical Burden (a)	Technical Burden (b)	Managerial Burden (c)	Total Burden (d) = (a)+(b)+(c)
Part III	Processing and Use Information (Total Burden for Part III)	***6.35***	***36.25***	***13.33***	***55.93***
1	Industrial Processing and Use Exposure-Related Data				
	Determination of Applicability	0.10	0.81	0.23	1.14
	Industrial Function Category	1.69	3.53	1.65	6.87
	Function Code	0.15	0.75	0.32	1.21
	Percent of Production Volume	0.99	8.00	4.22	13.21
	Total Number of Processing and Use Sites	1.26	7.31	2.82	11.39
	Total Number of Potentially Exposed Workers	1.68	12.34	3.06	17.09
2	Consumer and Commercial Use Exposure-Related Data				
	Determination of Applicability	0.12	0.75	0.20	1.06
	Identification of Production Category/Use by Children	0.12	0.67	0.20	0.98
	Percent of Production Volume	0.16	1.01	0.36	1.53
	Maximum Concentration by Category	0.09	1.09	0.28	1.45
Total Burden for Report Preparation and Submission					
Partial Form (Parts I, II, Recordkeeping and Submission Burden)		**3.43**	**15.39**	**7.31**	**26.14**
Full Form (Parts I, II, III, Recordkeeping and Submission Burden)		**9.78**	**51.64**	**20.64**	**82.07**

Note: Totals may not sum due to rounding.

Table 4-9: Baseline Future-Cycle Total Cost per Report (2008$)

	Form U Section and Activity	Clerical Cost (a)	Technical Cost (b)	Managerial Cost (c)	Total Cost (d)=(a)+(b)+(c)
	Compliance Determination (Total Cost for Form U Compliance Determination)	***$0.00***	***$147***	***$0.00***	***$147***
	Rule Familiarization (Total Cost for Form U Submission)	***$0.00***	***$118***	***$140***	***$258***
	Recordkeeping and Submission Costs (Total Cost for Form U Recordkeeping)	***$42.72***	***$176.52***	***$105.04***	***$324.28***
	Submission (Total Cost for Form U Submission)				***$13.78***
	Mailing Cost				$13.78
Part I.	Site Identification Information (Total Cost for Part I)	***$19.68***	***$51.19***	***$71.29***	***$142.16***
1	Certification	$19.22	$50.01	$70.73	$139.96
2	Company Information				
	Company Name, Technical Contact, Address, D&B Number, Mailing Address	$0.20	$0.47	$0.28	$0.95
3	Plant Site Identification				
	Plant Name, D&B Number, Address, Mailing Address	$0.26	$0.71	$0.28	$1.24
Part II.	Manufacturing Information (Total Cost for Part II)	***$35.31***	***$413.29***	***$195.52***	***$644.12***
1	Chemical Identification				
2	(Other) Manufacturing Information				
	Site Limited, Activity, Production Volume (lb)	$11.85	$107.32	$31.37	$150.54
	Chemical Identification Upfront CBI Substantiation	$5.92	$68.25	$42.86	$117.03
	Plant Site Upfront Substantiation	$2.73	$39.07	$28.57	$70.37
	Total Number of Workers	$4.78	$67.31	$32.77	$104.87
	Maximum Concentration, Physical Form, Percent Volume of Production	$10.02	$131.33	$59.94	$201.30

Form U Section and Activity			Clerical Cost (a)	Technical Cost (b)	Managerial Cost (c)	Total Cost (d)=(a)+(b)+(c)
Part III	Processing and Use Information (Total Burden for Part III)		***$180.87***	***$2,132.97***	***$933.56***	***$3,247.40***
1	Industrial Processing and Use Exposure-Related Data					
		Determination of Applicability	$2.90	$47.41	$15.95	$66.27
		Industrial Function Category	$48.12	$207.66	$115.71	$371.49
		Function Code	$4.26	$44.01	$22.14	$70.41
		Percent of Production Volume	$28.08	$470.73	$295.47	$794.28
		Total Number of Processing and Use Sites	$35.82	$430.32	$197.38	$663.52
		Total Number of Potentially Exposed Workers	$47.93	$726.19	$214.52	$988.64
2	Consumer and Commercial Use Exposure-Related Data					
		Determination of Applicability	$3.29	$44.01	$14.05	$61.35
		Identification of Production Code/Use by Children	$3.29	$39.41	$13.81	$56.51
		Percent of Production Volume	$4.65	$59.22	$25.24	$89.10
		Maximum Concentration by Category	$2.52	$64.02	$19.29	$85.82
Total Cost for Report Preparation and Submission						
Partial Form (Parts I, II, Recordkeeping and Submission Costs)			**$97.71**	**$906**	**$512**	**$1,529**
Full Form (Parts I, II, III, Recordkeeping and Submission Costs)			**$279**	**$3,039**	**$1,446**	**$4,777**

Note: Totals may not sum due to rounding.

4.3 Total Baseline IUR Industry Compliance Burden and Costs

The estimated wage rates, burden hours, and number of sites were combined to estimate the total baseline costs to comply with the current IUR rule in the 2012 reporting cycle. Costs were aggregated either per site or per report, depending on how the costs are incurred. Compliance determination and rule familiarization were estimated on a per-site basis; the costs for completing Part I of Form U were estimated on a per-site basis. The cost of completing Parts II and III of Form U were calculated on a per-report basis, and submission and recordkeeping were estimated on a per-report basis.

Table 4-10 shows the total burden and cost to industry under the current baseline. The current IUR rule would cost industry approximately 1.84 million hours and $106.97 million during the 2012 reporting cycle.

Table 4-10: Total Baseline Cost and Burden to Industry (2012 Reporting Cycle)

	Burden and Cost for All Part Is, Rule Familiarization, Compliance Determination and Submission	Burden and Cost for All Part IIs and Recordkeeping	Burden and Cost for All Part IIIs	Total Burden and Cost Under the Current IUR Requirements
Burden in Hours	135,847	513,259	1,193,829	**1,842,934**
Cost (2008$)	$8,407,651	$29,247,454	$69,311,707	**$106,966,812**

Table 4-11 contains the total annual baseline costs to industry for future reporting cycles; that is, the burden and cost to industry for reporting cycles after the 2012 cycle, in the absence of the amendments. The baseline for future reporting cycles is different than the baseline for the first reporting cycle due to efficiency gains. EPA assumes costs for report preparation and submission in future reporting cycles will be lower than costs in the first reporting cycle because of efficiencies achieved through the establishment of compliance processes, the availability of data from previous reporting cycles, and familiarity with reporting requirements (EPA, 2002a). The weighting factors found in Table 4-7 were applied to the baseline burden estimates found in Table 4-2 and Table 4-5. In all future reporting cycles, EPA estimated the baseline burden to industry to be approximately 1.43 million hours and the cost, $82.82 million.

Table 4-11: Total Baseline Cost and Burden to Industry (Future Reporting Cycles)

	Burden and Cost for all Part Is, Rule Familiarization, Compliance Determination and Submission	Burden and Cost for all Part IIs and Recordkeeping	Burden and Cost for all Part IIIs	Total Burden and Cost Under the Current IUR Requirements
Burden in Hours	37,088	441,682	955,063	**1,433,833**
Cost (2008$)	$2,290,736	$25,077,449	$55,449,366	**$82,817,550**

Limitations of Analysis. As described in Section 4.2.5, due to inconsistencies and limitations in the IUR data collected in 2002 and 2006, it was not possible for EPA to compare records to determine whether there was a significant change in the number of sites and reports submitted for a consistent set of chemical substances between the two reporting cycles. Such an analysis potentially could provide support for EPA's assumption the number of sites and reports will remain relatively unchanged in the next reporting cycle. Therefore, to the extent changes in the chemical industry unrelated to the IUR rule amendments could affect the number of site and reports submitted, the baseline burden and cost may be under- or overestimated.

4.4 Changes in Industry Burden and Costs Due to the Final IUR Modifications Rule

The expected cost and burden impacts of each of the amendments to the IUR rule are outlined below. See Section 3 for more detailed information about each of these amendments.

In each of the following sections, the burden estimates for each amendment are calculated *independently of the other amendments*. See Section 4.5 for an estimate of the aggregated impact of all amendments.

4.4.1 Technical Modifications to the Regulatory Text

EPA is reorganizing certain existing rule text and deleting obsolete text. These amendments do not substantively affect the rule text, so EPA assumes these modifications will not affect industry burden or cost.

4.4.2 Modifications to Selected Definitions

EPA is modifying the definitions of "importer," "manufacture," "site," "commercial use," "consumer use," "reporting year," and "submission period," and adding definitions for "manufacturer," "Central Data Exchange (CDX)," "e-IURweb," and "industrial function," as described in Section 3. These changes are clarifications only; EPA is clarifying in rule text what has been previously explained through outreach with the regulated community. Therefore, EPA does not expect changes to definitions to impact industry burden or cost.

4.4.3 Method for Determining Whether a Manufacturer is Subject to IUR Reporting Requirements

Under the current IUR rule requirements, a submitter completes a report only if its chemical substance production has met or exceeded the 25,000 lb reporting threshold during the principal reporting year. EPA is modifying the timeframe for reporting, so chemical manufacturers (including importers) will be subject to the IUR rule if a chemical substance's production volume has exceeded the threshold in any calendar year since the last principal reporting year. This modification will not take effect until after the first post-amendment reporting cycle (2012); for the first reporting cycle, submitters will still consider production volume for only the principal reporting year.

EPA believes this amendment will cause an increase in the numbers of submitters and reports in future reporting cycles. Because data on the production volume of chemical substances reportable under the IUR rule during non-principal reporting years currently is not available, the actual percentage increase in these numbers is unknown. The Agency, using its best professional

judgment, estimates for the purpose of this analysis, the amendment will increase the number of submitters and reports in future reporting cycles by approximately five percent.

Using an estimated five percent increase over the baseline number of sites and reports (baseline presented in Table 4-6), EPA estimates 204 additional sites will submit reports in future reporting cycles. EPA further estimates those sites will submit an additional 854 full reports and 441 partial reports, for a total of 1,295 additional reports for each future reporting cycle.

As described in Section 4.1, sites need to complete Part I of Form U only once, and complete Part II and Part III (as applicable) for each chemical substance manufactured or imported. Taking this allocation of activities into consideration, and using the baseline unit burden estimates as shown in Table 4-2 and Table 4-8, Table 4-12 shows the industry burden estimate as a result of this amendment. The Agency estimates the amendment will not cause a change in industry burden during the 2012 reporting cycle, but will generate an increase of approximately 71,700 hours during all future reporting cycles.

Table 4-12: Change in Industry Burden as a Result of Modifying the Method for Determining Whether a Manufacturer is Subject to IUR Reporting Requirements

	Burden for Compliance Determination, Rule Familiarization, Submission and to Prepare Part I (hours per site) (a)	Number of Sites (b)	Burden for Recordkeeping and to Prepare Part II (hours per report) (c)	Number of Reports (d)	Burden to Prepare Part III (hours per report) (e)	Number of Reports with Part III (f)	Industry Burden (hours) (g) = (a*b)+(c*d)+(e*f)
First Cycle, Baseline	33.26	4,085	19.82	25,896	69.92	17,075	1,842,934
First Cycle, Post-Amendment	33.26	4,085	19.82	25,896	69.92	17,075	1,842,934
Change from the Baseline, First Cycle	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0**
Future Cycle, Baseline	9.08	4,085	17.06	25,896	55.93	17,075	1,433,833
Future Cycle, Post-Amendment	9.08	4,289	17.06	27,191	55.93	17,929	1,505,524
Change from the Baseline, Future Cycles	**0.00**	**204**	**0.00**	**1,295**	**0.00**	**854**	**71,692**

Note: Values in *Change from the Baseline* rows are calculated by subtracting the corresponding baseline value from the post-amendment value.

The cost of the amendment was calculated using the unit costs shown in Table 4-5 and Table 4-9. Table 4-13 shows the industry cost estimate as a result of this amendment. EPA estimates

the amendment will not cause a change in industry cost in the first reporting cycle, but will increase costs by $4.14 million in all future reporting cycles.

Table 4-13: Change in Industry Cost as a Result of Modifying the Method for Determining Whether a Manufacturer is Subject to IUR Reporting Requirements

	Cost for Compliance Determination, Rule Familiarization, Submission and to Prepare Part I (2008$ per site) (a)	Number of Sites (b)	Cost for Recordkeeping and to Prepare Part II (2008$ per report) (c)	Number of Reports (d)	Cost to Prepare Part III (2008$ per report) (e)	Number of Reports with Part III (f)	Industry Cost (millions 2008$) (g) = (a*b)+(c*d)+(e*f)
First Cycle, Baseline	$2,058	4,085	$1,129	25,896	$4,059	17,075	$106.97
First Cycle, Post-Amendment	$2,058	4,085	$1,129	25,896	$4,059	17,075	$106.97
Change from the Baseline, First Cycle	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$0.00**
Future Cycle, Baseline	$561	4,085	$968	25,896	$3,247	17,075	$82.82
Future Cycle, Post-Amendment	$561	4,289	$968	27,191	$3,247	17,929	$86.96
Change from the Baseline, Future Cycles	**$0**	**204**	**$0**	**1,295**	**$0**	**854**	**$4.14**

Note: Values in *Change from the Baseline* rows are calculated by subtracting the corresponding baseline value from the post-amendment value.

Limitations of Analysis. To the extent the change in method for determining whether a manufacturer is subject to the IUR reporting requirements causes an increase in numbers of sites and reports submitted that is higher or lower than five percent, this analysis may under- or overestimate the total burden and cost increase. A sensitivity analysis is performed in Appendix D.1.

In the proposal, EPA also requested comment on returning to the previous, lower reporting threshold of 10,000 lb. Appendix E. contains an analysis of the cost and burden of this lower threshold, which EPA has decided not to adopt in the final rule.

4.4.4 Replace the 300,000 lb Threshold for Processing and Use Reporting

EPA is replacing the 300,000 lb threshold for processing and use information and phasing in a lower reporting threshold. For the 2012 IUR, all submitters of non-excluded chemical substances are required to report processing and use information if they manufactured (including imported) 100,000 lb or more of a chemical substance in 2011. Subsequent to the 2012 reporting cycle, the reporting threshold will be 25,000 lb, therefore requiring all manufacturers of non-excluded substances to report information in all

parts of the IUR Form U. Replacing this threshold will increase industry burden by requiring more sites to complete Part III of Form U (Part III contains the downstream processing and use information).

This amendment affects only the burden and costs associated with completing Part III; it will not cause an increase in the number of sites submitting reports. In the 2006 IUR reporting cycle, a total of 3,627 reports were submitted with production volumes between 100,000 lb and 300,000 lb (EPA, 2008c). Therefore, EPA assumes that, due to the amended rule, there will be an increase of 3,627 reports with Part III in the first reporting cycle.

In future reporting cycles (after the 2012 cycle) Part III will need to be completed for all non-excluded substances. In the 2006 reporting cycle, the total number of partial reports submitted (that is, forms with only Part I and Part II completed) was 8,821 (see Table 4-6); 618 of these reports were submitted for partially exempt (i.e., excluded) chemical substances (EPA, 2009a). (Under the amendment, submitters of partially exempt chemical substances still will not be required to submit a Part III.) For the purposes of this analysis, EPA assumes that partially exempt chemical substances all have production volumes less than 100,000 lb and therefore these reports are not considered in estimations for the first reporting cycle. Therefore, EPA assumes that, due to the amended rule, there will be an increase of 8,203 (i.e, 8,821 minus 618) in future reporting cycles.

Using the baseline unit burden estimate as shown in Table 4-2 and Table 4-8, Table 4-14 shows the industry burden estimate as a result of this amendment. The Agency estimates the amendment will cause an increase in industry burden of approximately 253,600 hours during the first reporting cycle, and 458,800 hours during all future reporting cycles.

Table 4-14: Change in Industry Burden as a Result of Replacing the 300,000 lb Threshold for Downstream Processing and Use Information Reporting

	Burden per Report (Part III) (hours)	Total Number of Reports with Part III	Total Industry Burden (hours)
First Cycle, Baseline	69.92	17,075	1,193,829
First Cycle, Post-Amendment	69.92	20,702	1,447,417
Change from the Baseline, First Cycle	**0**	**3,627**	**253,588**
Future Cycle, Baseline	55.93	17,075	955,063
Future Cycle, Post-Amendment	55.93	25,278	1,413,884
Change from the Baseline, Future Cycles	**0**	**8,203**	**458,822**

Notes: Values in *Change from the Baseline* rows are calculated by subtracting the corresponding baseline value from the post-amendment value. Totals may not sum due to rounding.

The cost of the amendment was calculated using the unit costs shown in Table 4-5 and Table 4-9. Table 4-15 shows the industry cost estimate as a result of this amendment. EPA estimates the industry cost will increase by $14.72 million in the 2012 reporting cycle and by $26.64 million in all future reporting cycles.

Table 4-15: Change in Industry Cost as a Result of Reducing the 300,000 lb Threshold for Downstream Processing and Use Information Reporting

	Cost per Report (Part III) (2008$)	Number of Reports with Part III	Total Industry Cost (millions 2008$)
First Cycle, Baseline	$4,059.25	17,075	$69.31
First Cycle, Post-Amendment	$4,059.25	20,702	$84.03
Change from the Baseline, First-Year	**$0.00**	**3,627**	**$14.72**
Future Cycle, Baseline	$3,247.40	17,075	$55.45
Future Cycle, Post-Amendment	$3,247.40	25,278	$82.09
Change from the Baseline, Future Cycles	**$0.00**	**8,203**	**$26.64**

Note: Values in *Change from the Baseline* rows are calculated by subtracting the corresponding baseline value from the post-amendment value.Totals may not sum due to rounding.

Limitations of Analysis. The estimate of 3,627 additional reports for the 2012 reporting cycle may be an overestimate as some of these reports may be for partially exempt chemicals that are not required to submit Part IIs. In subsequent reporting cycles EPA is assuming each partially exempt chemical substance is produced at four different sites. To the extent this is not the case, this analysis may over- or underestimate the number of additional Part IIIs.

4.4.5 Reducing the 25,000 lb Threshold for Specific Regulated Chemical Substances

Beginning with the 2016 submission period and for submission periods thereafter, EPA is reducing the 25,000 lb threshold to 2,500 lb for chemical substances that are: (1) the subject of a regulation promulgated under section 5(a)(2), 5(b)(4), or 6 of the Act; (2) the subject of an order issued under section 5(e) or 5(f) of the Act, or (3) the subject of relief that has been granted under a civil action under section 5 or 7 of the Act. As of the 2016 submission period, a manufacturer (including importer) of such chemical substances will be required to report manufacturing information on the chemical substances if they are manufactured (including imported) in volumes of 2,500 lb or more during any of the years since the last principal reporting year (e.g., 2011). Information on the processing and use of the chemical substances must be reported if they were manufactured (including imported) in volumes of 25,000 lb or more during any of the years since the last principal reporting year. To determine how many specific chemical substances this amendment will affect, EPA referred to Appendix C of the *Instructions for Reporting for the 2006 Partial Updating of the TSCA Chemical Inventory Database* (EPA, 2006a), which lists chemical substances that are the subject of certain TSCA orders, proposed or final TSCA rules, or relief granted under civil actions. A count of all the chemical substances, listed by CASRN, that are subject to a regulation proposed or promulgated under sections 5(a)(2), 5(b)(4), or 6 of the Act, subject of an order issued under section 5(e) or 5(f)[4] of the Act, or the subject of relief that has been granted under a civil action under section 5

[4] There are two chemicals subject of an order issued under section 5(f) of TSCA that would be subject to the reduced threshold that have not been included in the development of estimates in this section of the Economic Analysis, however, the overall estimates of costs and burdens for this requirement are not expected to be significantly affected.

or 7 of the Act, identified 1,129 chemical substances. CASRNs were provided for 739 of these chemical substances, and an additional 390 chemical substances were listed by accession numbers (EPA, 2006a). Of the 739 chemical substances with CASRNs, no reports were filed for 651 chemical substances, or 88 percent (EPA, 2009e). EPA also assumes no reports were filed for 88 percent of the 390 chemical substances with accession numbers, or 344 chemical substances. In addition, Form Us were submitted voluntarily for eight chemical substances with production volume levels below the 25,000 lb threshold during the 2006 reporting cycle (EPA, 2009a). EPA estimates that a total of approximately 1,003 chemical substances are subject to one of the TSCA sections above and are not currently reported under IUR (651+344+8 = 1,003). However, no production volume data are available for these chemical substances. Therefore, EPA assumes that approximately 90 percent of these chemical substances (902 chemical substances) have production volumes between 2,500 and 25,000 lb.

Based on the data provided in the 2006 IUR reporting cycle (EPA, 2008c), on average, each chemical substance is produced at approximately four sites; therefore, EPA expects 3,609 additional reports (Part IIs) to be submitted for these chemical substances. The Agency also assumes the reports generated by this amendment will be for production volumes lower than 25,000 lb (therefore, lower than 300,000 lb), so, as a result of this amendment alone, submitters will not be required to complete Part III (see Section 4.5 for an estimate of the aggregated impact of all amendments). In addition, the Agency is assuming that manufacturers (including importers) of these chemical substances already will be submitting reports for other non-exempt chemical substances; so, therefore, the number of sites will not increase from the baseline as a result of this amendment.

Using the baseline unit burden estimate for completion of Part II as shown in Table 4-2 and Table 4-8, Table 4-16 presents the estimated increase in industry burden as a result of this amendment. The Agency estimates the amendment will cause an increase in industry burden of approximately 0 hours during the first reporting cycle and 61,600 hours during all future reporting cycles.

Table 4-16: Change in Industry Burden as a Result of Reducing the 25,000 lb Threshold for Specific Regulated Chemical Substances

	Burden for Recordkeeping and to Prepare Part II (hours per report)	Number of Reports	Industry Burden (hours)
First Cycle, Baseline	0	0	0
First Cycle, Post-Amendment	0	0	0
Change from the Baseline, First Cycle	**0.00**	**0**	**0**
Future Cycle, Baseline	17.06	25,896	441,682
Future Cycle, Post-Amendment	17.06	29,505	503,241
Change from the Baseline, Future Cycles	**0.00**	**3,609**	**61,559**

Note: Values in *Change from the Baseline* rows are calculated by subtracting the corresponding baseline value from the post-amendment value.

The cost of the amendment was calculated using the unit costs shown in Table 4-5 and Table 4-9. Table 4-17 shows the industry cost estimate as a result of this amendment. The cost to industry is expected to increase by $3.50 million during all future reporting cycles, and will not increase during the 2011 reporting cycle.

Table 4-17: Change in Industry Cost as a Result of Reducing the 25,000 lb Threshold for Specific Regulated Chemical Substances

	Cost for Recordkeeping and to Prepare Part II (2008$ per report)	Number of Reports	Industry Cost (millions 2008$)
First Cycle, Baseline	$0	0	$0
First Cycle, Post-Amendment	$0	0	$0
Change from the Baseline, First Cycle	**$0**	**0**	**$0**
Future Cycle, Baseline	$968	25,896	$25.08
Future Cycle, Post-Amendment	$968	29,505	$28.57
Change from the Baseline, Future Cycles	**$0**	**3,609**	**$3.50**

Note: Values in *Change from the Baseline* rows are calculated by subtracting the corresponding baseline value from the post-amendment value.

Limitations of Analysis. The number of additional reports EPA receives as a result of this amendment may be an overestimate to the extent manufacturers (including importers) already are submitting reports for these chemical substances. That is, to the extent some portion of these chemical substances already are subject to IUR reporting because they are produced in volumes of 25,000 lb or greater, the Agency is overestimating the number of additional reports it will receive as a result of the amendment. Furthermore, to the extent manufacturers (including importers) of these chemical substances do not already submit reports for other chemical substances, EPA is underestimating the number of sites will increase from the baseline as a result of this amendment. In addition, the number of chemical substances with production volumes between 2,500 and 25,000 lb may be an over- or underestimate.

4.4.6 Make Chemical Substances Subject to Enforceable Consent Agreements (ECAs) Ineligible for Exemptions

Chemical substances subject to enforceable consent agreements (ECAs) are of demonstrated interest to the Agency. For instance, EPA will use the IUR data associated with these regulated chemical substances to monitor chemical substance production and compliance with the agreements. Therefore, EPA is making these chemical substances ineligible for reporting exemptions. Manufacturers (including importers) of these chemical substances no longer will be partially exempt, and so must complete Part III of Form U.

EPA publishes and updates on its website a list of TSCA Section 4 Federal Register Enforceable Consent Agreements (http://www.epa.gov/oppt/chemtest/pubs/4eca.html) (EPA, 2009f). Since 1985, the Agency has entered into ECAs for 67 chemical substances. Six of the 67 chemical substances were composite substances developed for the sole purpose of conducting testing under ECAs, and were never listed on the TSCA Inventory. Eliminating those six substances leaves a total of 61 chemical substances subject to ECAs.

EPA also maintains a table showing the sunset date and status for chemical substances subject to section 4 actions, including ECAs (http://www.epa.gov/oppt/chemtest/pubs/sunset.html) (EPA, 2009g).Only two of the 61 chemical substances were identified as currently being subject to an ongoing

ECA. Therefore, only two chemical substances will lose the partial exemption under the amendment, and so will need to complete Part III of Form U. In addition, EPA is assuming an additional two chemical substances could be under ECAs in future reporting cycles. Therefore, EPA is estimating the amendment would cause submitters of a total of four chemical substances to complete Part III of Form U. Based on data from the 2006 IUR reporting cycle, the Agency estimates approximately four sites produce each chemical substance (EPA, 2008c); therefore, a total of 16 Part IIIs would be submitted for the first time for chemical substances subject to an ECA.

Using the baseline unit burden estimate for completion of Part III as shown in Table 4-2and Table 4-8, Table 4-18 shows the industry burden estimate as a result of this amendment. The Agency estimates the amendment will cause an increase in industry burden of approximately 1,100 hours during the first reporting cycle, and 900 hours during all future reporting cycles.

Table 4-18: Change in Industry Burden as Result of Making Chemical Substances Subject to ECAs Ineligible for Exemptions

	Burden per Report (Part III) (hours)	Total Number of Reports with Part III	Total Industry Burden (hours)
First Cycle, Baseline	69.92	17,075	1,193,829
First Cycle, Post-Amendment	69.92	17,091	1,194,947
Change from the Baseline, First Cycle	**0**	**16**	**1,119**
Future Cycle, Baseline	55.93	17,075	955,063
Future Cycle, Post-Amendment	55.93	17,091	955,958
Change from the Baseline, Future Cycles	**0**	**16**	**895**

Note: Values in *Change from the Baseline* rows are calculated by subtracting the corresponding baseline value from the post-amendment value.

The cost of the amendment was calculated using the unit costs shown in Table 4-5 and Table 4-9. Table 4-19 shows the industry cost estimate as a result of this amendment. EPA estimates the industry cost will increase by $64,900 during the 2011 reporting cycle and by approximately $52,000 during all future reporting cycles.

Table 4-19: Change in Industry Cost as a Result of Making Chemical Substances Subject to ECAs Ineligible for Exemptions

	Cost per Report (Part III) (2008$)	Number of Reports with Part III	Total Industry Cost (2008$)
First Cycle, Baseline	$4,059	17,075	$69,311,707
First Cycle, Post-Amendment	$4,059	17,091	$69,376,655
Change from the Baseline, First Cycle	**$0**	**16**	**$64,948**
Future Cycle, Baseline	$3,247	17,075	$55,449,366
Future Cycle, Post-Amendment	$3,247	17,091	$55,501,324
Change from the Baseline, Future Cycles	**$0**	**16**	**$51,958**

Note: Values in *Change from the Baseline* rows are calculated by subtracting the corresponding baseline value from the post-amendment value.

Limitations of Analysis. EPA is assuming each of these chemical substances is produced at four different sites. To the extent this is not the case, this analysis may over- or underestimate the number of additional Part IIIs. In addition, some of these chemical substances may be produced in volumes of 300,000 lb or greater, and therefore already will be required to submit a full report. To the extent this is the case, this analysis overestimates the total number of additional Part IIIs. Finally, to the extent additional chemical substances become subject to ECAs in the future, this analysis may underestimate the total number of additional Part IIIs.

4.4.7 Full Exemption for Manufactured Water

Under the current IUR regulations, manufactured water is partially exempt from reporting; therefore, facilities producing manufactured water only need to complete Parts I and II of Form U. The Agency is granting a full exemption for manufactured water. In 2006, a total of 43 partial reports were submitted for manufactured water (EPA, 2008c). EPA assumes manufactured water is a byproduct of chemical substance production. Therefore, sites submitting a report for manufactured water will continue to submit reports for other chemical substances. Thus, the burden reduction for this amendment will be the result of 43 fewer Part IIs being submitted.

Using the baseline unit burden estimate as shown in Table 4-2 and Table 4-8, Table 4-20 shows the reduction in industry burden estimate as a result of this amendment. The Agency estimates the amendment will cause a decrease in industry burden of approximately 850 hours during the first reporting cycle, and 700 hours during all future reporting cycles.

Table 4-20: Change in Industry Burden as a Result of Exempting Manufactured Water from Reporting

	Burden for Recordkeeping and to Prepare Part II (hours per report)	Number of Reports	Total Industry Burden (hours)
First Cycle, Baseline	19.82	25,896	513,259
First Cycle, Post-Amendment	19.82	25,853	512,406
Change from the Baseline, First Cycle	**0**	**-43**	**-852**
Future Cycle, Baseline	17.06	25,896	441,682
Future Cycle, Post-Amendment	17.06	25,853	440,949
Change from the Baseline, Future Cycles	**0**	**-43**	**-733**

Note: Values in *Change from the Baseline* rows are calculated by subtracting the corresponding baseline value from the post-amendment value.

The cost savings due to the amendment were determined using the unit costs shown in Table 4-5and Table 4-9. Table 4-21 shows the industry cost estimate as a result of this amendment. EPA estimates the industry cost will decrease by approximately $48,600 in the first reporting cycle and $41,600 in all future reporting cycles.

Table 4-21: Change in Industry Cost as a Result of Exempting Manufactured Water from Reporting

	Cost for Recordkeeping and to Prepare Part II (2008$ per report)	Number of Reports	Total Industry Cost (2008$)
First Cycle, Baseline	$1,129	25,896	$29,247,454
First Cycle, Post-Amendment	$1,129	25,853	$29,198,889
Change from the Baseline, First Cycle	**$0**	**-43**	**-$48,565**
Future Cycle, Baseline	$968	25,896	$25,077,449
Future Cycle, Post-Amendment	$968	25,853	$25,035,808
Change from the Baseline, Future Cycles	**$0**	**-43**	**-$41,641**

Note: Values in *Change from the Baseline* rows are calculated by subtracting the corresponding baseline value from the post-amendment value.

Limitations of Analysis. EPA is assuming the sites producing manufactured water are also producing other chemical substances above the reporting threshold, and will continue to submit a Form U, which may not be the case for all sites. In that case, the above estimate underestimates the savings to the industry.

4.4.8 Remove Fully-Exempt Polymers from the Partially-Exempt List

EPA is amending the partially-exempt list of chemical substances to remove three chemical substances: Starch (CASRN 9005-25-8), Dextrin (CASRN 9004-53-9), and Maltodextrin (CASRN 9049-76-7).These chemical substances, as polymers, are already fully exempt from reporting. EPA expects this amendment will not impact industry burden or costs, because these substances currently are fully exempt from reporting and therefore no submitters currently are required to submit reports for them. That is, this amendment is a clarification only and EPA assumes it will not change the behavior of the regulated community.

4.4.9 Parent Company and Site Identity

Under the final rule, submitters will be required to provide the name, address, and D&B number of their ultimate domestic parent company, as well as for the site. This information was required as part of Form U prior to the 2006 amendments, so the 2002 Economic Analysis, on which these burden estimates are based, already included the cost of providing the information for the ultimate domestic parent company. The rule is now consistent with the 2002 analysis, and EPA assumes the burden estimate will not change from the baseline. Furthermore, companies that do not yet have a D&B number incur no cost to obtain one.

4.4.10 Technical Contact

Manufacturers (including importers) are required to provide a technical contact for their IUR submission. EPA is amending the IUR rule to require the technical contact be a person who is knowledgeable about the chemical substance but does not need to be located at the plant site. Because submitters already are required to identify a technical contact, EPA assumes this amendment will not cause an increase in burden.

4.4.11 Chemical Identity

EPA is requiring submitters to report only the CASRN as a chemical identifying number or, in the case of confidential chemical substances, the TSCA accession number assigned when the Notice of Commencement (NOC) was submitted to the Agency. EPA is removing the PMN number as an allowed chemical identifying number. Because the reporting tool will be directly linked to the non-confidential portion of the TSCA Inventory through SRS, submitters no longer will be allowed to claim the CASRN as confidential. For this reason, EPA is requiring submitters to report the TSCA accession number if they choose to assert a CBI claim on the chemical identity. Submitters will be able to look up the accession number in SRS using the PMN number for their chemical substance.

EPA expects that manufacturers (including importers) will have either the PMN number or a TSCA accession number for their confidential Inventory substance, or will be able to obtain the accession number. Those submitters who, in the past, have reported using the CASRN of a confidential substance or do not have the PMN number or accession number, or who are not able to obtain the accession number using SRS, may contact EPA by letter if necessary to obtain the accession number. Those submitters who know only the CASRN and not the PMN or Accession number for a confidential chemical substance are the only manufacturers that EPA expects to contact the Agency to obtain an accession number. Those submitters who are not claiming the chemical identity as CBI will be able to continue using the CASRN.

EPA assumes that the time it will take submitters who do not already know their accession number to look it up using the PMN number in SRS will be minimal, and therefore, is not estimating that burden here. However, some submitters may not know either the PMN or accession number, and will therefore need to request it in writing from EPA. As an upper bound estimate, the number of 2006 IUR reports with CASRNs claimed as CBI was used as a proxy for the number letters submitted to EPA. (All other 2006 IUR reports with CBI claims for chemical identity were made using accession numbers or PMN number, and therefore, EPA assumes that those sites will not need to send a written request to EPA.) A total of 343 reports claimed CASRNs as CBI in 2006 (EPA, 2010b).

EPA assumes that the burden to submit a written accession number request is half of the burden of providing the specific chemical identification in a *bona fide* submission. *Bona fides* are written requests a company sends to EPA when the company intends to manufacture (including import) a chemical substance, but is unsure of the TSCA Inventory status of the chemical substance. The specific chemical identification information required by a *bona fide* includes the CAS name and number as well as the chemical substance's molecular formula, a chemical substance structure diagram, and the name of the

chemical substance's precursors and reactants. EPA estimates that submitters of *bona fides* incur a burden of approximately 2.0 hours of technical time per notice to prepare the notice (EPA, 1994). EPA estimates that the burden associated with written accession number requests is approximately half of the burden (one hour) associated with providing specific chemical identification information for a *bona fide*. The accession number requests will not require information on the chemical substance's molecular formula, structure, or the name of the chemical substance's precursors and reactants. The total industry burden is approximately 343 hours (See Table 4-22). While some sites may need to submit an accession number request in future cycles, EPA expects that most sites that need accession numbers will request them in the first reporting cycle. Therefore, the burden to industry in future cycles is expected to be minimal and was not estimated for this analysis.

Table 4-22: Change in Industry Burden as a Result of Accession Number Requests

	Burden for Accession Number Request (hours per request)	Number of Requests	Total Industry Burden (hours)
First Cycle, Baseline	0	0	0
First Cycle, Post-Amendment	1.0	343	343
Change from the Baseline, First Cycle	**1.0**	**343**	**343**

Note: Values in *Change from the Baseline* rows are calculated by subtracting the corresponding baseline value from the post-amendment value.
Source: Burden hours are taken the Regulatory Impact Analysis of Amendments to Regulations for TSCA Section 5 Premanufacture Notices (EPA, 1994, Table III-8) and adjusted based on EPA's best professional judgment

Table 4-23 presents the change in industry cost as a result of accession number requests. EPA estimates a $20,200 increase in industry cost in the first reporting cycle.

Table 4-23: Change in Industry Cost as a Result of Accession Number Requests

	Cost for Accession Number Requests (2008$ per request)	Number of Requests	Total Industry Cost Million (2008$)
First Cycle, Baseline	$0	0	$0
First Cycle, Post-Amendment	$58.84	343	$20,182
Change from the Baseline, First Cycle	**$58.84**	**343**	**$20,182**

Note: Values in *Change from the Baseline* rows are calculated by subtracting the corresponding baseline value from the post-amendment value.

4.4.12 Report Production Volume for Each of the Years since Last Principal Reporting Year

EPA is requiring submitters to report production volume for both year 2010 and year 2011 in the 2012 reporting cycle. In subsequent reporting cycles, production volume must be reported for each of the four years since the last IUR principal reporting year. Thus, for the 2012 IUR submission, manufacturers (including importers) of subject chemical substances will report the production volume for the calendar years 2010 and 2011, and will report production volumes for 2012, 2013, 2014, and 2015 in the 2016 reporting cycle. While sites will still submit data to EPA only in the submission year, EPA assumes there will be an increase in burden as the result of gathering data and reporting production volumes for an additional year in the first reporting cycle and an additional four years in subsequent reporting cycles.

According to the baseline burden estimate, a site spends approximately 3.36 hours to gather production volume and site-limited activity (see Table 4-3). EPA estimates approximately 45

percent of these 3.36 hours (i.e., 1.51 hours) is attributed to gathering production volume information. (See Table 4-3 for an explanation of this percentage breakdown.) Therefore, the Agency estimates a site will spend an additional 1.51 hours to gather the production volume information for the extra year's worth of data required in the first reporting cycle. In future reporting cycles, approximately an additional 3.63 hours (approximately) (i.e., 1.21 x 3) is expected to report production volumes for the three additional, non-principal reporting years.

Table 4-24 shows the increase in industry burden as a result of this amendment. The Agency estimates the amendment will cause a total increase in industry burden of approximately 39,200 hours in the first reporting cycle and approximately 94,000 hours in all future reporting cycles.

Table 4-24: Change in Industry Burden as a Result of Requiring the Reporting of Production Volume in all Non-Principal Reporting Years

	Burden to Report Production Volume (hours per report)	Number of Reports	Industry Burden (hours)
First Cycle, Baseline	1.51	25,896	39,155
First Cycle, Post-Amendment	3.02	25,896	78,310
Change from the Baseline, First Cycle	**1.51**	**0**	**39,155**
Future Cycle, Baseline	1.21	25,896	31,324
Future Cycle, Post-Amendment	4.838	25,896	125,295
Change from the Baseline, Future Cycles	**3.63**	**0**	**93,971**

Note: Values in *Change from the Baseline* rows are calculated by subtracting the corresponding baseline value from the post-amendment value.

The cost of the amendment was calculated using the unit costs shown in Table 4-5 and Table 4-9. Table 4-25 shows the industry cost estimate as a result of this amendment. EPA estimates the industry cost will increase by $2.19 million in the 2012 reporting cycle and $5.26 million in all future reporting cycles.

Table 4-25: Change in Industry Cost as a Result of Requiring the Reporting of Production Volume in all Non-Principal Reporting Years

	Cost to Report Production Volume (2008$ per report)	Number of Reports	Industry Cost (millions 2008$)
First Cycle, Baseline	$84.68	25,896	$2.19
First Cycle, Post-Amendment	$169.36	25,896	$4.39
Change from the Baseline, First Cycle	**$84.68**	**0**	**$2.19**
Future Cycle, Baseline	$67.74	25,896	$1.75
Future Cycle, Post-Amendment	$270.98	25,896	$7.02
Change from the Baseline, Future Cycles	**$203.23**	**0**	**$5.26**

Note: Values in *Change from the Baseline* rows are calculated by subtracting the corresponding baseline value from the post-amendment value.

Limitations of Analysis. This analysis is based on an assumption about the percentage breakdown of burden estimated to gather production volume and site-limited activity. To the

extent the actual burden is higher or lower than estimated, this analysis under- or overestimates the burden and cost of this amendment.

4.4.13 Volume of Chemical Substance Used On-Site

Previous Form Us have required submitters to indicate whether a chemical substance was site-limited, referring to a chemical substance manufactured and/or processed only within a site and not distributed for commercial purposes as a substance or as part of a mixture or article outside the site. A chemical used off-site is one that does not meet this definition; for example, a chemical produced as an end product. EPA is removing the site-limited data element and requiring submitters to report the production volume used on-site.

The Agency expects the burden to the submitter of reporting the production volume used on-site to be similar to the burden to report the total production volume, given that the activities to identify the necessary information are similar. EPA estimates it will take a submitter 1.51 hours to provide the production volume (see Table 4-3).

EPA expects an increase in the number of submitters who will report volume used on-site, due to the way this information will be reported under the amendment. In the data submitted to EPA for the 2006 reporting year, about 14.8 percent of reports include a site-limited volume (EPA 2008c); therefore, EPA assumes this is the minimum number of reports that will be affected.

Site-limited chemical substances are those not distributed (either as the chemical substance itself or in a mixture) outside the plant site for commercial purposes. Therefore, EPA assumes all chemical substances used on-site must be chemical substance intermediates. According to data from the 2006 IUR database (EPA, 2008c), approximately 24 percent of all reports containing downstream processing and use information included chemical substances used as intermediates. Therefore, EPA assumes 24 percent of all reports is the maximum percentage of reports that will be affected. Not all chemical substances produced as intermediates are used on-site; they may be shipped for use at another site. EPA used 19.4 percent, which is the midpoint of 14.8 and 24, to estimate the increase in the number of reports with chemical substances used on-site, i.e., 5,024 reports.

Table 4-26 shows the industry burden estimate as a result of this amendment. The Agency estimates the amendment will cause a total increase in industry burden of approximately 7,600 hours during the first reporting cycle and 6,100 hours during all future reporting cycles.

Table 4-26: Change in Industry Burden as a Result of Requiring the Reporting of Production Volume Used On-Site

	Burden to Report Production Volume Used On-Site (hours)	Number of Reports with Production Volume Used On-Site Information	Total Industry Burden (hours)
First Cycle, Baseline	0.00	0	0
First Cycle, Post-Amendment	1.51	5,024	7,596
Change from the Baseline, First Cycle	**1.51**	**5,024**	**7,596**
Future Cycle, Baseline	0.00	0	0
Future Cycle, Post-Amendment	1.21	5,024	6,077
Change from the Baseline, Future Cycles	**1.21**	**5,024**	**6,077**

Note: Values in *Change from the Baseline* rows are calculated by subtracting the corresponding baseline value from the post-amendment value.

The cost of the amendment was calculated using the unit costs shown in Table 4-5 and Table 4-9. Table 4-27 shows the industry cost estimate as a result of this amendment. EPA estimates the total industry cost will increase by $425,400 during the first reporting cycle and $340,300 during all future reporting cycles.

Table 4-27: Change in Industry Cost as a Result of Requiring the Reporting of Production Volume Used On-Site

	Cost to Report Production Volume Used On-Site (2008$)	Number of Reports with Production Volume Used On-Site Information	Total Industry Cost (2008$)
First Cycle, Baseline	$0.00	0	$0.00
First Cycle, Post-Amendment	$84.68	5,024	$425,416
Change from the Baseline, First Cycle	**$84.68**	**5,024**	**$425,416**
Future Cycle, Baseline	$0.00	0	$0.00
Future Cycle, Post-Amendment	$67.74	5,024	$340,333
Change from the Baseline, Future Cycles	**$67.74**	**5,024**	**$340,333**

Note: Values in *Change from the Baseline* rows are calculated by subtracting the corresponding baseline value from the post-amendment value.

Limitations of Analysis. To the extent the burden of reporting the production volume used on-site is different from the burden to report the total production volume, this analysis may over- or underestimate the burden and cost of this amendment. Furthermore, to obtain the maximum number of reports that may be affected, EPA assumes the percentage of reports containing downstream processing and use information that included chemical substances used as intermediates will be the same as the percentage of all reports that include chemical substances used as intermediates (that is, that the percentage of chemical substances used as intermediates is consistent whether a submitter completed Part III or not.) To the extent this is not the case, the analysis may over- or underestimate the number of reports affected.

4.4.14 Indicate Whether Chemical Substance Is Physically at Reporting Site

EPA is requiring submitters to indicate whether an imported chemical substance is physically at the reporting site. Under the current IUR requirements, a submitter must state whether the site's chemical substance is manufactured or imported. The Agency estimates providing this

information requires 0.17 hours per report (see Table 4-3). EPA assumes the burden to indicate whether a chemical substance is physically on-site will be similar to the burden incurred to indicate whether a chemical substance is manufactured or imported, given the similarity of these activities to identify the necessary information. Table 4-28 shows the industry burden estimates as a result of this amendment. The Agency estimates the amendment will cause a total increase in industry burden of approximately 4,400 hours for the 2011 reporting cycle, and 3,500 for all future reporting cycles.

Table 4-28: Change in Industry Burden as a Result of Indicating Whether a Chemical Substance is Physically at the Reporting Site

	Burden to Indicate Whether Chemical Substance is at the Reporting Site (hours)	Number of Reports	Industry Burden (hours)
First Cycle, Baseline	0.00	25,896	0
First Cycle, Post-Amendment	0.17	25,896	4,351
Change from the Baseline, First Cycle	**0.17**	**0**	**4,351**
Future Cycle, Baseline	0.00	25,896	0
Future Cycle, Post-Amendment	0.13	25,896	3,480
Change from the Baseline, Future Cycles	**0.13**	**0**	**3,480**

Note: Values in *Change from the Baseline* rows are calculated by subtracting the corresponding baseline value from the post-amendment value.

The cost of the amendment was calculated using the unit costs shown in Table 4-5 and Table 4-9. Table 4-29 shows the industry cost estimate as a result of this amendment. EPA estimates the total industry cost will increase by approximately $243,700 in the first reporting cycle and $194,900 in all future reporting cycles.

Table 4-29: Change in Industry Cost as a Result of Indicating Whether a Chemical Substance is Physically at the Reporting Site

	Cost to Indicate Whether Chemical Substance is Physically at Reporting Site (2008$)	Number of Reports	Industry Cost (2008$)
First Cycle, Baseline	$0.00	25,896	$0
First Cycle, Post-Amendment	$9.41	25,896	$243,652
Change from the Baseline, First Cycle	**$9.41**	**0**	**$243,652**
Future Cycle, Baseline	$0.00	25,896	$0
Future Cycle, Post-Amendment	$7.53	25,896	$194,921
Change from the Baseline, Future Cycles	**$7.53**	**0**	**$194,921**

Note: Values in *Change from the Baseline* rows are calculated by subtracting the corresponding baseline value from the post-amendment value.

Limitations of Analysis. To the extent the burden of indicating whether a chemical substance is physically at the reporting site is different from the burden to report whether a chemical substance is manufactured or imported, this analysis may over- or underestimate the burden and cost of this amendment. Furthermore, this requirement may apply only to importers; the number of reports affected, therefore, is likely to be an overestimation.

4.4.15 Report Production Volume Exported

EPA is adding a requirement for submitters to report the production volume directly exported and not domestically processed or used. The Agency assumes the burden to the submitter to report the volume exported will be similar to the burden to report the production volume, given the similarity of the activities. EPA estimates it will take a submitter 1.51 hours to provide the volume exported (see Table 4-3).

Using the baseline unit burden estimate as shown in Table 4-2 and Table 4-8, Table 4-30 shows the industry burden estimate as a result of this amendment. The Agency estimates the amendment will increase industry burden by approximately 39,200 hours for the 2012 reporting cycle, and 31,300 hours for all future reporting cycles.

Table 4-30: Change in Industry Burden as a Result of Requiring Reporting of Volume Exported

	Burden to Report Export Volume (hours)	Number of Reports	Industry Burden (hours)
First Cycle, Baseline	0.00	25,896	0
First Cycle, Post-Amendment	1.51	25,896	39,155
Change from the Baseline, First Cycle	**1.51**	**0**	**39,155**
Future Cycle, Baseline	0.00	25,896	0
Future Cycle, Post-Amendment	1.21	25,896	31,324
Change from the Baseline, Future Cycles	**1.21**	**0**	**31,324**

Note: Values in *Change from the Baseline* rows are calculated by subtracting the corresponding baseline value from the post-amendment value.

The cost of the amendment was calculated using the unit costs shown in Table 4-5 and Table 4-9. Table 4-31 shows the industry cost estimate as a result of this amendment. EPA estimates the industry cost will increase by $2.19 million during the first reporting cycle and $1.75 million during all future reporting cycles.

Table 4-31: Change in Industry Cost as a Result of Requiring Reporting of Volume Exported

	Cost to Report Export Volume (2008$)	Number of Reports	Industry Cost (millions 2008$)
First Cycle, Baseline	$0.00	25,896	$0.00
First Cycle, Post-Amendment	$84.68	25,896	$2.19
Change from the Baseline, First Cycle	**$84.68**	**0**	**$2.19**
Future Cycle, Baseline	0	25,896	$0.00
Future Cycle, Post-Amendment	$67.74	25,896	$1.75
Change from the Baseline, Future Cycles	**$67.74**	**$0.00**	**$1.75**

Note: Values in *Change from the Baseline* rows are calculated by subtracting the corresponding baseline value from the post-amendment value.

Limitations of Analysis. To the extent the burden of reporting the volume exported is different from the burden to report the total production volume, this analysis may over- or underestimate the burden and cost of this amendment.

4.4.16 Identify Whether a Chemical Substance is to be Recycled, Remanufactured, Reprocessed, or Reused

EPA is adding a requirement to indicate whether a manufactured chemical substance, such as a byproduct, is being recycled, remanufactured, reprocessed, or reused. Given the similarity in activities to research records and identify the appropriate information, the Agency estimates this activity will generate the same burden as indicating whether a chemical substance is used on-site. As shown in Table 4-3, EPA estimated this burden to be approximately 0.17 hours.

Using the baseline unit burden estimate as shown in Table 4-2 and Table 4-8, Table 4-32 shows the industry burden estimates as a result of this amendment. The Agency estimates the amendment will cause a total increase in industry burden of approximately 4,400 hours in the first reporting cycle and approximately 3,500 hours during all future reporting cycles.

Table 4-32: Change in Industry Burden as a Result of Indicating Whether Chemical Substance is to be Recycled, Remanufactured, Reprocessed, or Reused

	Burden for Completing a Checkbox to Indicate Whether a Chemical Substance is Recycled, Remanufactured, Reprocessed, or Reused, (hours)	Number of Reports	Industry Burden (hours)
First Cycle, Baseline	0.00	25,896	0
First Cycle, Post-Amendment	0.17	25,896	4,351
Change from the Baseline, First Cycle	**0.17**	**0**	**4,351**
Future Cycle, Baseline	0.00	25,896	0
Future Cycle, Post-Amendment	0.13	25,896	3,480
Change from the Baseline, Future Cycles	**0.13**	**0**	**3,480**

Note: Values in *Change from the Baseline* rows are calculated by subtracting the corresponding baseline value from the post-amendment value.

The cost of the amendment was calculated using the unit costs shown in Table 4-5 and Table 4-9. Table 4-33 shows the industry cost estimate as a result of this amendment. EPA estimates the cost to industry will increase by $243,700 for the 2012 reporting cycle and $194,900 for all future reporting cycles.

Table 4-33: Change in Industry Cost as a Result of Indicating Whether Chemical Substance is to be Recycled, Remanufactured, Reprocessed, or Reused

	Cost for Completing a Checkbox to Indicate Whether a Chemical Substance is Recycled, Remanufactured, Reprocessed or Reused (2008$)	Number of Reports	Industry Cost (millions 2008$)
First Cycle, Baseline	$0.00	25,896	$0
First Cycle, Post-Amendment	$9.41	25,896	$243,652
Change from the Baseline, First Cycle	**$9.41**	**0**	**$243,652**
Future Cycle, Baseline	$0.00	25,896	$0
Future Cycle, Post-Amendment	$7.53	25,896	$194,921
Change from the Baseline, Future Cycles	**$7.53**	**0**	**$194,921**

Note: Values in *Change from the Baseline* rows are calculated by subtracting the corresponding baseline value from the post-amendment value.

Limitations of Analysis. To the extent the burden of indicating whether a chemical substance is recycled, remanufactured, reprocessed, or reused is different from the burden to report whether a chemical substance is site-limited, this analysis may over- or underestimate the burden and cost of this amendment.

4.4.17 Concentration Ranges

EPA is amending the ranges used to report concentration in §710.52(C)(3) and (4) by changing the ranges to: (1) less than one percent by weight, (2) at least one percent but less than 30 percent by weight, (3) at least 30 percent but less than 60 percent by weight, (4) at least 60 percent but less than 90 percent by weight, and (5) at least 90 percent by weight.

This is a technical correction to eliminate gaps in the ranges as previously listed in the IUR rule. Therefore, EPA assumes it will have no impact on industry burden or cost.

4.4.18 Revise Industrial Function Categories

EPA is revising the current industrial function categories (found in Part III, Section A of Form U), by deleting six current categories and adding eight new categories. In addition, EPA is requiring submitters to write in a free-text descriptor when they select "Other".

EPA anticipates a small additional burden for submitters to familiarize themselves with the eight new categories; based on best professional judgment, EPA estimates 15 minutes of technical labor. EPA also estimates it will take three minutes of clerical labor and six minutes of technical labor to write in the text description if the submitter selects "Other". According to 2006 IUR data (EPA, 2008a), the response "Other" was selected in 1,206 reports. Using its best professional judgment, EPA expects the new categories in the IUR modifications rule will reduce by half the number of submitters selecting "Other" as an industrial function category. Therefore, EPA estimates this amendment will affect 603 reports.

Using the baseline unit burden estimates as shown in Table 4-2 and Table 4-8, Table 4-34 shows the industry burden estimate as a result of this amendment. The Agency estimates the amendment will cause a total increase in industry burden in the first reporting cycle of

approximately 4,400 hours. In future reporting cycles, submitters will no longer need to familiarize themselves with the new industrial function categories, and EPA estimates the industry burden to be approximately 70 hours.

Table 4-34: Change in Industry Burden as a Result of Revising the Industrial Function Categories

	Burden for Rule Familiarization of Additional Categories (hours)	Number of Reports with Function Categories	Burden to Write in Text for "Other" (hours)	Number of Reports with "Other" as a Function Category	Total Industry Burden (hours)
First Cycle, Baseline	1.52	17,075	0.00	0	25,907
First Cycle, Post-Amendment	1.77	17,075	0.15	603	30,266
Change from the Baseline, First Cycle	**0.25**	**0**	**0.15**	**603**	**4,359**
Future Cycle, Baseline	1.21	17,075	0.00	0	20,726
Future Cycle, Post-Amendment	1.21	17,075	0.12	603	20,798
Change from the Baseline, Future Cycles	**0.00**	**0**	**0.12**	**603**	**72**

Note: Values in *Change from the Baseline* rows are calculated by subtracting the corresponding baseline value from the post-amendment value.

The cost of the amendment was calculated using the unit costs shown in Table 4-5 and Table 4-9. Table 4-35 shows the industry cost estimate as a result of this amendment. EPA estimates the industry cost will increase by approximately $255,600 in the first reporting cycle and $3,500 in the following reporting cycles.

Table 4-35: Change in Industry Cost as a Result of Revising the Industrial Function Categories

	Cost for Rule Familiarization of Additional Categories (2008$)	Number of Reports with Industrial Function Categories	Cost to Write in Text for "Other" (2008$)	Number of Reports with Text for "Other"	Total Industry Cost (2008$)
First Cycle, Baseline	$88.02	17,075	$0.00	0	$1,502,913
First Cycle, Post-Amendment	$102.73	17,075	$7.31	603	$1,758,490
Change from the Baseline, First Cycle	**$14.71**	**0**	**$7.31**	**603**	**$255,577**
Future Cycle, Baseline	$70.41	17,075	$0.00	0	$1,202,331
Future Cycle, Post-Amendment	$70.41	17,075	$5.85	603	$1,205,856
Change from the Baseline, Future Cycles	**$0.00**	**0**	**$5.85**	**603**	**$3,525**

Note: Values in *Change from the Baseline* rows are calculated by subtracting the corresponding baseline value from the post-amendment value.

Limitations of Analysis. EPA estimates submitters will use 15 minutes of technical labor burden to become familiar with the new categories; this may be an over- or underestimate. EPA is assuming the number of submitters selecting “Other” as an industrial function category will be

reduced by half; this may be an over- or underestimate. In addition, EPA assumes there is no burden for rule familiarization with the new industrial function categories during future reporting cycles. This may not be the case if sites have different employees complete Form U from reporting year to reporting year, or for sites submitting a Form U for the first time.

4.4.19 Replace NAICS Codes with Industrial Sectors

EPA is replacing the five-digit North American Industrial Classification System (NAICS) codes with 48 Industrial Sectors (IS). The industrial sectors are based on those used in the European Union's REACH program. The Agency believes this change may reduce the reporting burden slightly because submitters will not need to look up NAICS codes, and the new industrial sectors will be more intuitive. However, because the submitter still will be required to look up some type of code, EPA assumes the burden reduction will be negligible and does not estimate it here.

4.4.20 Revise Consumer and Commercial Product Categories

EPA is revising the list of consumer and commercial use categories by combining categories leading to common exposure scenarios and adding categories not adequately described in the current set of codes. The resultant revised list includes 33 product categories, including "Other." Several of the existing consumer and commercial use categories have been renamed to better describe the products that should be reported under that category. EPA anticipates the effort submitters will make to familiarize themselves with the new categories will increase the burden for completing the consumer and commercial product categories by 0.84 hours. This is the burden for the technical employee to identify the consumer and commercial uses of a product (see Table 4-2). This burden will occur only during the first reporting cycle.

EPA is also requiring that if the product category "Other" is reported, a descriptor for the consumer and commercial use of the chemical substance also be reported. Using its best professional judgment, EPA estimates it will take three minutes of clerical burden and six minutes of technical burden to write in the text description.

According to 2006 IUR data (EPA, 2008c), "Other" was listed as a consumer or commercial product category in 1,207 reports. Based on best professional judgment, EPA expects the new categories in this rule will reduce by half the number of submitters selecting "Other" as a consumer and commercial product category. Therefore, EPA assumes this amendment will affect 604 reports.

Using the baseline unit burden estimate as shown in Table 4-2 and Table 4-8, Table 4-36 shows the industry burden estimate as a result of this amendment. The Agency estimates the amendment will cause a total increase in industry burden of approximately 14,400 hours during the first reporting cycle. In future reporting cycles, submitters no longer will need to familiarize themselves with the new industrial function categories, so the industry burden is estimated at approximately 70 hours to write in text for "Other" responses.

Table 4-36: Change in Industry Burden as a Result of Revising the Consumer and Commercial Product Categories

	Burden for Rule Familiarization for Additional Categories (hours)	Number of Reports with Industrial Function Categories	Burden to Write in Text for "Other" (hours)	Number of Reports with "Other" as a Function Category	Total Industry Burden (hours)
First Cycle, Baseline	1.23	17,075	0.00	0	20,972
First Cycle, Post-Amendment	2.07	17,075	0.15	604	35,359
Change from the Baseline, First Cycle	**0.84**	**0**	**0.15**	**604**	**14,387**
Future Cycle, Baseline	0.98	17,075	0.00	0	16,778
Future Cycle, Post-Amendment	0.98	17,075	0.12	604	16,850
Change from the Baseline, Future Cycles	**0.00**	**0**	**0.12**	**604**	**72**

Note: Values in *Change from the Baseline* rows are calculated by subtracting the corresponding baseline value from the post-amendment value

The cost of the amendment was calculated using the unit costs shown in Table 4-5 and Table 4-9. Table 4-37 shows the industry cost estimate as a result of this amendment. EPA estimates the industry cost will increase by approximately $845,600 in the first reporting cycle, and $3,500 during all future reporting cycles.

Table 4-37: Change in Industry Cost as a Result of Revising the Consumer and Commercial Product Categories

	Cost for Rule Familiarization for Additional Categories (2008$)	Number of Reports with Function Categories	Cost to Write in Text for "Other" (2008$)	Number of Reports with "Other" as a Function Category	Total Industry Cost(2008$)
First Cycle, Baseline	$70.64	17,075	$0.00	0	$1,206,177
First Cycle, Post-Amendment	$119.90	17,075	$7.31	604	$2,051,756
Change from the Baseline, First Cycle	**$49.26**	**0**	**$7.31**	**604**	**$845,579**
Future Cycle, Baseline	$56.51	17,075	$0.00	0	$964,942
Future Cycle, Post-Amendment	$56.51	17,075	$5.85	604	$968,470
Change from the Baseline, Future Cycles	**$0.00**	**0**	**$5.85**	**604**	**$3,528**

Note: Values in *Change from the Baseline* rows are calculated by subtracting the corresponding baseline value from the post-amendment value.

Limitations of Analysis. EPA estimates submitters will need 0.84 hours of technical labor to become familiar with the new codes; this may be an over- or underestimate. EPA is assuming the number of submitters selecting “Other” as a consumer and commercial use code will be reduced by half; this may be an over- or underestimate. In addition, EPA assumes there is no burden for rule familiarization with the new product categories during the future reporting cycles. This may not be the case if sites have different employees complete Form U from reporting year to reporting year, or for sites submitting a Form U for the first time.

4.4.21 Designation of Consumer or Commercial Use

EPA is requiring submitters to indicate whether the downstream use of their chemical substance is a consumer or a commercial use, or both. The Agency's experience using the 2006 IUR data identified a need to distinguish between potentially exposed consumers versus commercial populations. The indication of consumer or commercial use will allow EPA to complete a better characterization of the potentially exposed populations.

EPA anticipates the submitter will indicate whether a use is a consumer or commercial use as part of the activity involved in selecting the correct consumer and commercial use categories, as described above. The burden to fill in a checkbox for the correct use will be negligible. Therefore, EPA assumes this amendment does not cause any additional burden beyond that estimated in Section 4.4.20.

4.4.22 Number of Commercial Workers Reasonably Likely To Be Exposed

EPA is requiring submitters to report the total number of commercial workers, including those at sites not under the submitter's control, reasonably likely to be exposed while using the reportable chemical substance, with respect to each commercial use. EPA will provide a set of ranges of numbers of workers for the submitter to choose from. The Agency expects this reporting burden to be similar to the burden for providing the number of workers potentially exposed when using the chemical substance with respect to its industrial use, which is already required, because of the similarity of the required data. This burden is approximately 21.36 hours (see Table 4-2) or $1,236 (see Table 4-5) per report. EPA assumes the number of submitters will not change from the baseline under this amendment.

Using the baseline unit burden estimate as shown in Table 4-2 and Table 4-8, Table 4-38 shows the industry burden estimate as a result of this amendment. The Agency estimates the amendment will cause a total increase in industry burden of approximately 364,700 hours in the first reporting cycle and 291,800 during all future reporting cycles.

Table 4-38: Change in Industry Burden as a Result of Requiring the Number of Commercial Workers Reasonably Likely To Be Exposed

	Burden to Provide the Number of Commercial Workers (hours)	Number of Reports	Burden (hours)
First Cycle, Baseline	0	17,075	0
First Cycle, Post-Amendment	21.36	17,075	364,731
Change from the Baseline, First Cycle	**21.36**	**0**	**364,731**
Future Cycle, Baseline	0	17,075	0
Future Cycle, Post-Amendment	17.09	17,075	291,784
Change from the Baseline, Future Cycles	**17.09**	**0**	**291,784**

Note: Values in *Change from the Baseline* rows are calculated by subtracting the corresponding baseline value from the post-amendment value.

The cost of the amendment was calculated using the unit costs shown in Table 4-5 and Table 4-9. Table 4-39 shows the industry cost estimate as a result of this amendment. EPA estimates the industry cost will increase by $21.10 million for the 2012 reporting cycle and $16.88 million during all future reporting cycles.

Table 4-39: Change in Industry Cost as a Result of Requiring the Number of Commercial Workers Reasonably Likely To Be Exposed

	Cost to Provide the Number of Commercial Workers (2008$)	Number of Reports	Cost (millions 2008$)
First Cycle, Baseline	$0	17,075	$0
First Cycle, Post-Amendment	$1,236	17,075	$21.10
Change from the Baseline, First Cycle	**$1,236**	**0**	**$21.10**
Future Cycle, Baseline	$0	17,075	$0
Future Cycle, Post-Amendment	$989	17,075	$16.88
Change from the Baseline, Future Cycles	**$989**	**0**	**$16.88**

Note: Values in *Change from the Baseline* rows are calculated by subtracting the corresponding baseline value from the post-amendment value.

Limitations of Analysis. EPA is assuming the burden to report the number of commercial workers reasonably likely to be exposed is equivalent to reporting the number of industrial workers likely to be exposed. However, this is likely an underestimate of the burden for several reasons. There may be more commercial uses for a product, and more workers exposed than the submitter is aware of. The commercial uses may be difficult for manufacturers (including importers) to identify (see "NRO" discussion responses in Section 3.9); therefore, the number of workers exposed may be even more difficult to identify.

4.4.23 Changes to the Standard for the Reporting of Processing and Use Information

EPA is eliminating the "not readably obtainable" (NRO) standard and replacing it with the more stringent "known to or reasonably ascertainable by" standard. EPA assumes this amendment will increase the reporting burden. However, all burden estimates in this economic analysis are based on an industry survey conducted for the 2002 IUR EA (EPA, 2002a). At the time of the survey, EPA required the higher reporting standard of "reasonably ascertainable" information. The rule will now be consistent with the higher standard of information used by the survey, therefore, the burden estimates will not change.

4.4.24 Chemical Identity CBI Claims

EPA is proposing that when a submitter asserts a claim of confidentiality for the chemical identity of a substance listed on the public portion of the Master Inventory File, the Agency may make the information available to the public without further notice to the submitter. This will not reveal any data to the public that is actually confidential and will not incur any cost or burden on the manufacturer.

4.4.25 Upfront Substantiation for Processing and Use Information CBI Claims

EPA is requiring an upfront substantiation when a submitter claims processing and use information as Confidential Business Information (CBI).Upfront substantiation involves providing a written response to a set of questions provided in the rule, for each individual item to be claimed as CBI.

In 2002, when EPA first required upfront substantiation for claiming the plant site ID as CBI, the Agency saw a 64 percent reduction in the number of CBI claims. The Agency expects the

number of processing and use CBI claims to decrease by the same amount as a result of this amendment. According to 2006 IUR data (EPA, 2008c), a total of 8,133 reports had claimed processing and use information was CBI, with an average of three processing and use information CBI claims per report. EPA estimates the number of reports with processing and use CBI claims will be reduced to 2,928 as a result of the amendment.

For the purposes of this analysis, EPA assumes the per-item burden to complete this substantiation will be similar to the burden estimated to complete the substantiation questions when a submitter makes a plant site identity CBI claim and must answer the two questions in §710.58(c)(1). As shown in Table 4-2 and Table 4-4, this is a burden of 1.46 hours and cost of $87.34 per CBI claim. Assuming an average of three processing and use CBI claims per report, EPA estimates submitters will incur 4.38 additional hours of burden per report as a result of the amendment.

Table 4-40 shows the industry burden estimate as a result of this amendment. The Agency estimates the amendment will cause a total increase in industry burden of approximately 12,800 hours in the first reporting cycle and 10,300 hours in all future reporting cycles.

Table 4-40: Change in Industry Burden as a Result of Requiring Upfront Substantiation for Claiming Processing and Use Information as CBI

	Burden for Upfront CBI Substantiation for CBI Claims in Part III (hours)	Number of Reports with Upfront Substantiation for CBI Claims in Part III	Industry Burden (hours)
First Cycle, Baseline	0	0	0
First Cycle, Post-Amendment	4.38	2,928	12,824
Change from the Baseline, First Cycle	**4.38**	**2,928**	**12,824**
Future Cycle, Baseline	0	0	0
Future Cycle, Post-Amendment	3.50	2,928	10,259
Change from the Baseline, Future Cycles	**3.50**	**2,928**	**10,259**

Note: Values in *Change from the Baseline* rows are calculated by subtracting the corresponding baseline value from the post-amendment value.

The cost of the amendment was calculated using the unit costs shown in Table 4-5 and Table 4-9. Table 4-41 shows the industry cost estimate as a result of this amendment. EPA estimates the industry cost will increase by approximately $772,700 in the first reporting cycle and $618,100 in future reporting cycles.

Table 4-41: Change in Industry Cost as a Result of Requiring Upfront Substantiation for Claiming Processing and Use Information as CBI

	Cost for Upfront CBI Substantiation for CBI Claims in Part III	Number of Reports with Upfront Substantiation for CBI Claims in Part III	Industry Cost (2008$)
First Cycle, Baseline	$0	0	$0
First Cycle, Post-Amendment	$263.90	2,928	$772,678
Change from the Baseline, First Cycle	**$263.90**	**2,928**	**$772,678**
Future Cycle, Baseline	$0	0	$0
Future Cycle, Post-Amendment	$211.12	2,928	$618,143
Change from the Baseline, Future Cycles	**$211.12**	**2,928**	**$618,143**

Note: Values in *Change from the Baseline* rows are calculated by subtracting the corresponding baseline value from the post-amendment value.

Limitations of Analysis. EPA assumes the percent reduction in CBI claims for processing and use information will be the same as the percent reduction when upfront substantiation was required for plant site identification. However, to the extent the actual burden differs, this analysis may over- or underestimate the burden and cost of this amendment.

4.4.26 Limitation on the Confidentiality Claims for Data Elements Identified as "Not Known or Reasonably Ascertainable"

Under the final rule, IUR submitters will be unable to enter a claim of confidentiality if "not known or reasonably ascertainable" is selected for the industrial processing and use or consumer and commercial use information. EPA assumes this amendment will not impact industry burden because submitters are not being required to do anything additional (e.g., gather information or provide a written response); they are simply prohibited from claiming "not known or reasonably ascertainable" data items as CBI.

4.4.27 Require Electronic Submissions over the Internet

EPA is requiring electronic submissions of all Form Us over the Internet using e-IURweb and EPA's Central Data Exchange (CDX). The Agency's cost estimates were calculated following the methodology outlined in the economic analysis for the e-PMN rule (EPA, 2009b), where EPA is requiring TSCA section 5 pre-manufacturing notices be submitted electronically. The costs and savings of this IUR amendment will be realized on a per-site basis, as well as per report.

Following the methodology outlined in the economic analysis for the e-PMN rule (EPA, 2009b) the clerical burden used in the preparation of Parts I, II and III of Form U will be eliminated with this amendment. Specifically, the Agency assumes the burden savings associated with electronic reporting and submission via CDX are due to the reduction or elimination of clerical/administrative time. The baseline time estimate for clerical burden (approximately six percent of the burden) was assumed to approximate the amount of clerical/administrative time involved in filling out and submitting the paper IUR Form U. This estimate of potential form completion and submission savings is in line with the estimated savings in switching from paper to electronic submissions as estimated in the *Cross-Media Electronic Reporting Rule (CROMERR) Cost Benefit Analysis* of 10 percent (EPA, 2004).

The technical burden to gather and organize data, and managerial burden for review and approval, will not change from the baseline. Overall, this amendment will decrease the burden to prepare Parts I, II, and III.

In addition, estimates developed in the CROMERR report were used to develop estimates of burdens to register with EPA's CDX, and to complete electronic signature agreements. These burdens are incurred on a per-site basis. EPA estimated these costs in the economic analysis for the e-PMN rule, which used CROMERR to develop estimates of burden from CDX registration and electronic signature agreements, to be a total of 0.93 hours of managerial burden and 1.73 hours of technical time per site (EPA, 2009b; EPA, 2004).Based on the e-PMN EA, recordkeeping costs will be halved because of the efficiencies in creating and storing documents electronically (EPA, 2009b), reducing overall burden per report by three hours.

Table 4-42 shows the industry burden estimate as a result of this amendment. The Agency estimates the amendment will cause a total decrease in industry burden of approximately 245,600 hours in the first reporting cycle and 210,200 hours in all future reporting cycles.

Table 4-42: Change in Industry Burden as a Result of Requiring Electronic Submission

	Burden for Report, Compliance Determination, Rule Familiarization, Submission and Part I (per site) (hours) (a)	Number of Sites (b)	Burden for Recordkeeping and Part II (hours per report) (c)	Number of Reports (d)	Burden per Part III(hours) (e)	Number of Reports with Part III (f)	Industry Burden (hours) (g) = (a*b) + (c*d) + (e*f)
First Cycle, Baseline	33.26	4,085	19.82	25,896	69.92	17,075	1,842,934
First Cycle, Post-Amendment	35.17	4,085	15.27	25,896	61.98	17,075	1,597,358
Change from the Baseline, First Cycle	**1.91**	**0**	**-4.55**	**0**	**-7.94**	**0**	**-245,576**
Future Cycle, Baseline	**9.08**	4,085	17.06	25,896	55.93	17,075	1,433,833
Future Cycle, Post-Amendment	**11.05**	4,085	12.82	25,896	49.58	17,075	1,223,658
Change from the Baseline, Future Cycles	**1.98**	**0**	**-4.24**	**0**	**-6.35**	**0**	**-210,175**

Note: Values in *Change from the Baseline* rows are calculated by subtracting the corresponding baseline value from the post-amendment value.

EPA calculated the cost savings of the amendment using the unit costs shown in Table 4-5 and Table 4-9. Table 4-43 shows the industry cost estimate as a result of this amendment. EPA estimates the industry cost will decrease by $9.02 million during the first reporting cycle and by $8.01 million during all future reporting cycles.

Table 4-43: Change in Industry Cost as a Result of Requiring Electronic Submission

	Cost for Report, Compliance Determination, Rule Familiarization, Submission and Part I (per site) (2008$) (a)	Number of Sites (b)	Cost for Recordkeeping and Part II (2008$ per report) (c)	Number of Reports (d)	Cost per Part III (2008$) (e)	Number of Reports with Part III (f)	Industry Cost (millions 2008$) (g) = (a*b)+(c*d)+(e*f)
First Cycle, Baseline	$2,058	4,085	$1,143	25,896	$4,059	17,075	$107.32
First Cycle, Post-Amendment	$2,190	4,085	$923	25,896	$3,833	17,075	$98.30
Change from the Baseline, First Cycle	**$132**	**0**	**-$220**	**0**	**-$226**	**0**	**-$9.02**
Future Cycle, Baseline	$561	4,085	$982	25,896	$3,247	17,075	$83.17
Future Cycle, Post-Amendment	$695	4,085	$771	25,896	$3,067	17,075	$75.16
Change from the Baseline, Future Cycles	**$134**	**0**	**-$211**	**0**	**-$181**	**0**	**-$8.01**

Note: Values in *Change from the Baseline* rows are calculated by subtracting the corresponding baseline value from the post-amendment value.

Limitations of Analysis. EPA assumes the clerical burden will decrease by percentages similar to the decrease estimated for the e-PMN rule. To the extent any differences exist (given the differences in the two rules), this analysis may over- or underestimate the burden and cost of this amendment.

4.4.28 Updated e-IUR Reporting Software

EPA developed the e-IUR reporting software for use in preparing and submitting reports electronically during the 2006 IUR reporting cycle. For the 2012 submission period, EPA will provide a free, web-based application in place of the 2006 downloadable software. The updated e-IURweb reporting tool will feature several improved capabilities over the previous e-IUR reporting tool. This amendment is not expected to change industry burden, other than as described in Section 4.4.27.

4.4.29 Electronic Signature Process

In order to submit Form U electronically via EPA's Central Data Exchange (CDX), individuals acting on behalf of the submitter must first register with CDX. This process involves completing an Electronic Signature Agreement form along with a signature and date, having the form notarized, and mailing it back to EPA. The burden of the electronic signature agreement, one hour per submission, was included in the burden reduction estimate used in the economic analysis for the e-PMN rule (EPA, 2009b). The burden and cost reduction estimates for electronic submission, as shown in Section 4.4.27, include the cost of the electronic signature process because they are based on the estimates used in the economic analysis for the e-PMN rule.

4.4.30 Modifications Specifically Affecting Importers

For purposes of IUR, importers currently are allowed to report the IUR information jointly with the foreign manufacturer of the chemical substance. Importers, or primary submitters, may not know the specific chemical identity of a substance because the foreign supplier, or secondary submitter, chooses to keep it confidential. In such a situation, the importer is still responsible for ensuring the IUR information is submitted to EPA and may do so by submitting a joint report. Overall, the amount of information submitted via Form U for primary and secondary submitters will not change as a result of this amendment, although EPA plans to revise the Form U for joint submitters. Under the amendment, the foreign manufacturer must now register with CDX and submit its report electronically. Previously, joint submissions could not be made electronically.

As described in Section 4.4.27, submission costs to register with EPA's CDX, and complete the Electronic Signature Agreement forms are incurred on a per-site basis. EPA estimated these costs in the economic analysis for the e-PMN rule to be a total of 0.93 hours of managerial burden and 1.73 hours of technical time per site (EPA, 2009b). Based on previous IUR submissions, EPA estimates between 10 and 20 sites were importers, and therefore, the same approximate number were secondary submitters (EPA, 2009h). For this analysis, EPA uses the conservative upper-bound of 20 secondary submitter sites.

Table 4-44 shows the industry burden estimate as a result of this amendment. The Agency estimates the amendment will cause an increase in industry burden of approximately 53.3 hours in the first reporting cycle. Future reporting cycles are assumed to the similar to the first reporting cycle.

Table 4-44: Change in Industry Burden as a Result of Requiring CDX Registration for Secondary Submitters

	Burden for CDX Registration (per site) (hours)	Number of Sites	Industry Burden (hours)
First Cycle, Baseline	0.00	0	0.00
First Cycle, Post-Amendment	2.67	20	53.3
Change from the Baseline, First Cycle	**2.67**	**20**	**53.3**

Note: Values in *Change from the Baseline* rows are calculated by subtracting the corresponding baseline value from the post-amendment value.

Table 4-45 shows the industry cost estimate as a result of this amendment. EPA estimates the industry cost will increase by approximately $3,300 during the first and future reporting cycles.

Table 4-45: Change in Industry Cost as a Result of Requiring CDX Registration for Secondary Submitters

	Cost for CDX Registration (per site) (2008$)	Number of Sites	Industry Cost (2008$)
First Cycle, Baseline	$0	0	$0
First Cycle, Post-Amendment	$167	20	$3.347
Change from the Baseline, First Cycle	**$167**	**20**	**$3.347**

Note: Values in *Change from the Baseline* rows are calculated by subtracting the corresponding baseline value from the post-amendment value.

4.4.31 Modify Reporting Frequency

The Agency is modifying the IUR reporting cycle from a five-year reporting frequency to a four-year reporting frequency. While the industry burden for the principal reporting year will not change, the longer-term industry burden will increase because reporting will become more frequent; therefore, EPA estimated the annual reporting burden to industry over a 26-year period. A 26-year period allows EPA to analyze a set of complete reporting cycles under both the baseline and post-amendment scenarios. Under the baseline, a five-year reporting cycle is used, and the cost of five complete cycles is presented. Under the post-amendment scenario, reporting occurs every four years, and the cost of six complete cycles is presented. (Note the 2012 reporting cycle covers a six-year period, under either scenario). For more information on the distribution of burden over a reporting cycle, see the discussion in Section 4.6.

The baseline industry burden in the 2012 reporting cycle was calculated in Table 4-10 as 1.84 million hours. As shown in Table 4-11, the industry reporting burden in future reporting cycles is reduced to 1.43 million hours because EPA assumes sites have submitted Form U previously incur a lower burden for processing and submitting the Form, as these firms have become more familiar with reporting and may be more efficient at the compliance process. Table 4-11 contains the total annual baseline costs to industry for future reporting cycles – that is, the burden and cost to industry for reporting cycles after the 2012 cycle, in the absence of the amendments. EPA assumes costs for report preparation and submission in future reporting cycles will be lower than costs in the first reporting cycle because of efficiencies achieved through the establishment of compliance processes, the availability of data from previous reporting cycles, and familiarity with reporting requirements (EPA, 2002a). The weighting factors found in Table 4-7 were applied to the baseline burden estimates found in Table 4-2 and Table 4-5, to estimate in all future reporting cycles, the baseline burden to industry is approximately 1.43 million hours.

As shown in Table 4-46, EPA estimates the industry burden will increase by 1.43 million hours over a 26-year period as a result of this amendment.

Table 4-46: Change in Industry Burden as a Result of Modifying the Reporting Frequency, over a 26-Year Period

Reporting Cycle	Year(s)	Baseline Burden (millions of hours)	Post-Amendment Burden (millions of hours)	Change in Burden (millions of hours)
1	**2007 to 2012**	1.84	1.84	0.00
2	**2013 to 2017**	1.43	--	0.00
	2013 to 2016	--	*1.43*	
3	**2018 to 2022**	1.43	--	0.00
	2017 to 2020	--	*1.43*	
4	**2023 to 2027**	1.43	--	0.00
	2021 to 2024	--	*1.43*	
5	**2028 to 2032**	1.43	--	0.00
	2025 to 2028	--	*1.43*	
6	***2029 to 2032***	--	*1.43*	1.43
Total		**7.58**	***9.01***	**1.43**
Annual Average		**0.29**	**0.34**	**0.05**

Note: The non-italicized reporting cycles are baseline, five-year cycles, and the italicized reporting cycles are four-year cycles.

As shown in Table 4-10, the total industry cost in the baseline first reporting cycle is approximately $106.97 million, and as shown in Table 4-11, the baseline cost is $82.82 million in all future reporting cycles. Table 4-47 shows the annual industry cost estimate as a result of this amendment. In total, EPA estimates the amendment will increase the cost to industry by $82.82 million over a 26-year period.

In the proposal, EPA requested comment on increasing the frequency of reporting to annual reporting of all data; biennial reporting; and reporting once every three years, with processing and use data (Part III) reported only in the principal reporting year. EPA conducted a preliminary analysis of the cost and burden of increasing the frequency of reporting to annually, and every three years. The results of the analysis are presented in Appendix E.

Table 4-47: Change in Industry Cost as a Result of Modifying the Reporting Frequency, over a 26-Year Period

Reporting Cycle	Year(s)	Baseline Cost (millions of 2008$)	Post-Amendment Cost (millions of 2008$)	Change in Cost (millions of 2008$)
1	**2007 to 2012**	$106.97	$106.97	$0.00
2	**2013 to 2017**	$82.82	--	$0.00
	2013 to 2016	--	*$82.82*	
3	**2018 to 2022**	$82.82	--	$0.00
	2017 to 2020	--	*$82.82*	
4	**2023 to 2027**	$82.82	--	$0.00
	2021 to 2024	--	*$82.82*	
5	**2028 to 2032**	$82.82	--	$0.00
	2025 to 2028	--	*$82.82*	
6	***2029 to 2032***	--	*$82.82*	$82.82
Total		**$438.24**	***$521.05***	**$82.82**
Annual Average		**$16.87**	**$20.06**	**$3.19**

Note: The non-italicized reporting cycles are baseline, five-year cycles, and the italicized reporting cycles are four-year cycles.

Limitations of Analysis. EPA assumes future reporting cycle costs will decrease due to efficiency gains and a reduction in the time required for submitters to become familiar with the rule and its amendments. To the extent these reductions in burden do not occur, this analysis may underestimate the burden and cost of the rule amendment.

4.5 Total Industry Compliance Burden and Cost of all Amendments

The burdens and costs presented in Section 4.4 are the stand-alone industry compliance burden and cost for each amendment, and do not take into account the interaction of amendments (i.e., how the impact of one amendment will affect the burden of another amendment). For this reason, when calculating the total industry cost of all amendments described in EPA's rule, the Agency cannot simply add the individual changes in burden for each amendment, but must consider the effect of one amendment on another. As described below, amendments fall into three categories: those affecting the number of reports submitted during a reporting cycle, those affecting the reporting burden, and those affecting the reporting frequency. The impact each amendment has on the others depends on its category.

4.5.1 Modifications that Affect the Number of Reports Submitted

Several of the IUR rule amendments change the number of full and/or partial reports EPA expects to be submitted, based on the specific chemical substances they affect. The amendment changing the method for determining whether a manufacturer is subject to the IUR reporting requirements is expected to increase the overall number of reports and submitters by five percent; therefore, the combined impact will also increase each of the impacts of the other amendments in this category by five percent. Furthermore, the amendment to replace the 300,000 lb threshold for downstream processing and use reporting in future reporting cycles will make Part IIIs necessary for all the additional Part IIs required by other amendments. The following

steps describe how the combined effect of the amendments affecting the number of reports was calculated.

Step 1: Sum the affected amendments. Table 4-48 and Table 4-49 present the number of full and partial reports EPA expects to be submitted as a result of the IUR amendments, in the 2012 reporting cycle and future reporting cycles, respectively. The amendments changing the number of full and/or partial reports expected to be submitted are as follows:

- **Reducing the 300,000 lb threshold for downstream processing and use reporting:** When taken alone, EPA expects this amendment to increase the number of Part IIIs submitted by 3,627 reports in the first reporting cycle and 8,203 reports in future reporting cycles (see Section 4.4.4).
- **Reducing the 25,000 lb threshold for specific regulated chemical substances:** This amendment affects future reporting cycles only. The amendment, by itself, will increase in the number of Part IIs submitted by 3,609 in future reporting cycles (see Section 4.4.5).
- **Make chemical substances subject to ECAs ineligible for exemptions:** EPA estimated this amendment will increase the number of Part IIIs submitted by 16 reports (see Section 4.4.6).
- **Full exemption for manufactured water:** EPA expects this amendment, by itself, will decrease the number of Part IIIs submitted by 43 reports (see Section 4.4.7).

Step 2: Consider the effects of the change in method for determining rule applicability (future cycles only). In future reporting cycles, the Agency expects the change in the method for determining whether a manufacturer is subject to the IUR reporting requirements to increase the number of reports and submitters by five percent. Therefore, for future reporting cycles, EPA multiplied the Step 1 results by 1.05, to account for this amendment. Then the Agency added in the number of additional sites and reports estimated for this amendment individually. (In Table 4-48, for the first cycle calculations, this step is merely a placeholder and does not cause any change.)

- **Method for determining whether a manufacturer is subject to the IUR reporting requirements.** When taken by itself, this amendment will generate 204 additional submitters in future reporting cycles (five percent of the baseline number of 4,085), 1,295 additional Part IIs (five percent of the baseline number of 25,896), and 854 additional Part IIIs (five percent of the baseline number of 17,075) (see Section 4.4.3).

Step 3: Consider the effect of replacing the 300,000 lb. threshold for processing and use reporting (and avoid double-counting) (future cycles only). In future cycles, under this amendment, all submitters of non-exempt chemical substances will be required to submit a Part III. Therefore, the number of Part IIIs must be increased by the increased number of Part IIs, to account for the effect of replacing the 300,000 lb threshold for processing and use reporting. For example, under the future reporting cycle calculations, EPA started with the Step 2 total for Part III reports (9,484), and added the Step 2 total for Part II reports (5,039), minus the number of new Part III reports as a result of making ECAs ineligible for exemptions (16) and the number of new Part II reports as a result of changing the method of determining whether a manufacturer is subject to reporting requirements (1,295). As shown in Table 4-49, the number of reports with Part III will increase by 13,212 in future reporting cycles.

This step is not needed for the 2012 reporting cycle, because during this first reporting cycle the threshold for processing and use information is not being eliminated, but being lowered to 100,000 lb; additional Part IIs generated by the new modifications will be for chemical

substances with production volumes less than 100,000 lb. In addition, no new Part IIs will be generated by the changing of the method of determining whether a manufacturer is subject to reporting requirements, because this modification will not go into effect until future reporting cycles.

Step 4: Calculate the number of reports when all amendments are considered together. The total number of additional reports from Step 3 is added to the number of reports in the baseline to calculate the total number of reports when all the final amendments are considered together. In future reporting cycles, there will be a total of 4,289 Part Is, 30,935 Part IIs and 30,287 Part IIIs. The difference between the total number of Part IIs and Part IIIs, 648 reports, is equal to the number of partially exempt reports with the five percent increase taken into account (618 x 1.05 = 648).

Table 4-48: Change in the Number of Sites and Reports Submitted for All Amendments Combined (First Reporting Cycle)

Modification	Number of Sites	Number of Reports	Number of Reports with Part III
Baseline	**4,085**	**25,896**	**17,075**
Step 1: Sum affected amendments			
Replace the 300,000 lb. Threshold for Downstream Processing and Use Reporting to 100,00lbs (see Section 4.4.6)	--	--	3,627
Make Chemical Substances Subject to ECAs Ineligible for Exemptions (see Section 4.4.6)	--	--	16
Full Exemption for Manufactured Water (see Section 4.4.7).	--	(43)	--
STEP 1 TOTAL	**--**	**-43**	**3,643**
Step 2: Account for change in the method for determining whether you are subject to the IUR reporting requirements			
N/A	--	--	--
Step 3: Consider the effect of eliminating the 300,000 lb threshold for processing and use reporting (and avoid double-counting) (Future Cycles Only)			
N/A	--	--	--
Step 4:Calculate the total number of reports by adding the Step 1 Total to the Baseline			
STEP 4 TOTAL (Baseline + Step 1 Total)	**4,085**	**25,853**	**20,718**

Table 4-49: Change in the Number of Sites and Reports Submitted for All Amendments Combined (Future Cycles)

Modification	Number of Sites	Number of Reports	Number of Reports with Part III
Baseline	**4,085**	**25,896**	**17,075**
Step 1:Sum affected amendments			
Replace 300,000 lb Threshold for Downstream Processing and Use Reporting (see Section 4.4.6)	--	--	8,203
Reduce the 25,000 lb Threshold for Specific Regulated Chemical Substances to 2,500 lb (see Section 4.4.5)	--	3,609	--
Make Chemical Substances Subject to ECAs Ineligible for Exemptions (see Section 4.4.6)	--	--	16
Full Exemption for Manufactured Water (see Section 4.4.7).	--	(43)	--
STEP 1 TOTAL	**--**	**3,566**	**8,219**
Step 2:Account for change in the method for determining whether you are subject to the IUR reporting requirements			
Step 1 Total Multiplied by 1.05		3,745	8,630
Method for Determining Whether you are Subject to the IUR Reporting Requirements (see Section 4.4.3)	204	1,295	854
STEP 2 TOTAL	**204**	**5,039**	**9,484**
Step 3: Consider the effect of replacing the 300,000 lb threshold for processing and use reporting (and avoid double-counting) (Future Cycles Only)			
Step 2 total for Part II reports minus number of new Part III reports as a result of making ECAs ineligible for exemptions and the number of new Part II reports as a result of changing the method of determining whether subject to reporting requirements	--	--	3,736
STEP 3 TOTAL (Step 3 + Step 2 Total)	**204**	**5,039**	**13,212**
Step 4:Calculate the total number of reports by adding the Step 3 Total to the Baseline			
STEP 4 TOTAL (Baseline + Step 3 Total)	**4,289**	**30,935**	**30,287**

4.5.2 Modifications That Affect the Reporting Burden

Several amendments affect the burden to complete a report. As discussed in Section 4.4.27, EPA assumes the amendment to require electronic submission over the Internet will eliminate clerical burden used in the preparation of Parts I, II and III of Form U, and the burden for recordkeeping across all wage rate categories will be reduced by half. Table 4-50 contains the total burden by labor category for the 2011 reporting cycle when all the amendments are considered together. Table 4-51 contains the future reporting cycle burden, by labor category. The steps below describe how the combined effect of the amendments affecting the reporting burden was calculated.

Step 1: Sum the affected amendments. The amendments affecting the reporting burden are as follows:

- **Report Chemical Identity:** This amendment is estimated to require an additional hour of technical time in the first reporting cycle for approximately 343 reports (or 1 percent of all reports). Therefore, this amendment will add approximately 0.013 hours per report in the first reporting cycle only (see Section 4.4.11).
- **Report production volume for each of the years since last report:** This amendment is estimated to require 1.51 hours of additional burden in the first reporting cycle (see Section 4.4.12). In future reporting cycles, an additional 3.63 hours is needed to supply three years of additional production volumes per reporting cycle (1.51 x 3).
- **Report production volume used on-site:** This amendment is estimated to require 1.51 additional hours of burden to complete Part II (see Section 4.4.13). Table 4-50 presents the per-report total burden of 0.293 hours to reflect only 24 percent of reports are expected to report volume used on site.
- **Indicate whether the chemical substance is physically at reporting site:** This amendment is estimated to require 0.17 additional hours of burden to complete Part II (see Section 4.4.14).
- **Report volume exported:** This amendment is estimated to require 1.51 additional hours of burden to complete Part II (see Section 4.4.15).
- **Identify whether a chemical substance is to be recycled, remanufactured, reprocessed, reused, or reworked:** This amendment is estimated to require 0.17 additional hours of burden to complete Part II (see Section 4.4.16).
- **Revise industrial function categories:** This amendment is estimated to require 0.25 additional hours to complete Part III (for submitters to familiarize themselves with the new categories), and an additional 0.15 hours (for submitters selecting "Other") (see Section 4.4.18). Table 4-50 presents the per-report total burden of 0.26 hours to reflect that only 3.5 percent of reports are expected to select "Other" and thus incur this additional cost.
- **Revise consumer and commercial product categories:** This amendment is estimated to require 0.84 additional hours of burden to complete Part III (for submitters to familiarize themselves with the new categories), and an additional 0.15 hours (for submitters selecting "Other") (see Section 4.4.20). Table 4-50 presents the per-report total burden of 0.84 hours, which reflects only 3.5 percent of reports are expected to select "Other" and thus incur this additional burden.
- **Number of commercial workers reasonably likely to be exposed:** This amendment is estimated to require 21.36 additional hours to complete Part III (see Section 4.4.22).
- **Upfront substantiation for processing and use information Confidential Business Information claims:** This amendment is estimated to require 4.38 additional hours of burden to complete Part III for all submitters claiming processing and use information as CBI (see Section 4.4.25). Table 4-50 presents the per-report total burden of 0.75 hours, which reflects that only 17 percent of reports are expected to incur additional costs because of the amendment.
- **Modifications specifically affecting importers:** This amendment requires that those foreign manufacturers who are filing joint submissions with an importer now register with CDX and submit its report electronically. EPA expects this will add an additional 2.63 hours to complete Part I of Form U for approximately 20 sites (0.5 percent of all sites). Therefore, this amendment will add an additional burden of approximately 0.013 hours per site in the first reporting cycle only (see Section 4.4.30).

Step 2: Consider the effect of the amendment to require electronic submission over the Internet. This amendment will eliminate the need for clerical tasks such as typing information into Form U, photocopying, and mailing. In Step 2, EPA subtracts the clerical burden for all amendments, eliminating a burden of 0.76 hours per Part I, 2.82 hours per Part II, and 10.11 hours per Part III. The burden reductions in recordkeeping will be reduced by 50 percent for all wage categories and will not change from what is presented in Section 4.4.27.

Step 3: Calculate the total burden when all amendments are combined. To calculate the total industry burden estimates, EPA added the total from Step 2 to the baseline. In total, the clerical burden will be 0.75 hours per full report with one chemical substance, the technical burden will be 102.83 hours per full report with one chemical substance, and the managerial burden will be 37.74 hours per full report with one chemical substance.

Table 4-50: Change in the First Year Reporting Cycle Burden for All Amendments Combined, by Labor Category

Modification	Compliance Determination, Rule Familiarization, and Submission Burden			Burden to Complete Part I			Recordkeeping Burden			Burden to Complete Part II			Burden to Complete Part III		
	C	T	M	C	T	M	C	T	M	C	T	M	C	T	M
Baseline	--	21.50	9.00	0.76	0.95	1.05	1.50	3.00	1.50	1.55	8.78	3.49	7.94	45.31	16.66
Step 1: Sum the Affected Amendments															
Report chemical identity as CAS number or EPA Ascension Number	--	--	--	--	--	--	--	--	--	--	0.013	--	--	--	--
Report production volume for each of the years since last report	--	--	--	--	--	--	--	--	--	0.234	1.026	0.252	--	--	--
Report production volume used on-site	--	--	--	--	--	--	--	--	--	0.045	0.199	0.049	--	--	--
Indicate whether chemical substance is physically at reporting site	--	--	--	--	--	--	--	--	--	0.026	0.114	0.028	--	--	--
Report the volume exported	--	--	--	--	--	--	--	--	--	0.234	1.026	0.252	--	--	--
Identify whether a chemical substance is to be recycled, remanufactured, reprocessed, reused, or reworked	--	--	--	--	--	--	--	--	--	0.026	0.114	0.028	--	--	--
Revise industrial function categories	--	--	--	--	--	--	--	--	--	--	--	--	0.002	0.254	0.000
Revise commercial and consumer product categories	--	--	--	--	--	--	--	--	--	--	--	--	0.002	0.841	0.000
Number of commercial workers reasonably likely to be exposed	--	--	--	--	--	--	--	--	--	--	--	--	2.104	15.428	3.829
Upfront substantiation for processing and use information CBI claims	--	--	--	--	--	--	--	--	--	--	--	--	0.062	0.427	0.262
CDX registration for joint submissions with foreign manufactures	--	--	--	--	0.005	0.008	--	--	--	--	--	--	--	--	--
Step 1 Total	**--**	**--**	**--**	**--**	**0.005**	**0.008**	**--**	**--**	**--**	**0.565**	**2.492**	**0.609**	**2.169**	**16.949**	**4.092**
Step 2:Add the Effect of the Electronic Reporting Amendments															
Electronic submission	--	1.73	0.93	-0.76	--	--	-0.75	-1.50	-0.75	-2.12	--	--	-10.11	--	--
Step 2 Total (Electronic Submission + Step 1 Total)	**--**	**1.73**	**0.93**	**-0.76**	**0.005**	**0.008**	**-0.75**	**-1.50**	**-0.75**	**-1.55**	**2.49**	**0.61**	**-7.94**	**16.95**	**4.09**
Step 3 Total Burden															
Step 2 Total + Baseline	**--**	**23.23**	**9.93**	**--**	**0.95**	**1.06**	**0.75**	**1.50**	**0.75**	**--**	**11.27**	**4.10**	**--**	**62.26**	**20.76**
Note: C = Clerical; T = Technical; and M = Managerial wage categories															

Table 4-51: Change in the Future Reporting Cycle Burden for All Amendments Combined, by Labor Category

Modification	Compliance Determination, Rule Familiarization, and Submission Burden			Burden to Complete Part I			Recordkeeping Burden			Burden to Complete Part II			Burden to Complete Part III		
	C	T	M	C	T	M	C	T	M	C	T	M	C	T	M
Baseline	--	4.500	2.000	0.691	0.870	1.018	1.500	3.000	1.500	1.240	7.024	2.792	6.351	36.251	13.33
Step 1: Sum the Affected Amendments															
Report production volume for each of the years since last report	--	--	--	--	--	--	--	--	--	0.562	2.462	0.605	--	--	--
Report production volume used on-site	--	--	--	--	--	--	--	--	--	0.036	0.159	0.039	--	--	--
Indicate whether chemical substance is physically at reporting site	--	--	--	--	--	--	--	--	--	0.021	0.091	0.022	--	--	--
Report the volume exported	--	--	--	--	--	--	--	--	--	0.187	0.821	0.202	--	--	--
Identify whether a chemical substance is to be recycled, remanufactured, reprocessed, reused, or reworked	--	--	--	--	--	--	--	--	--	0.021	0.091	0.022	--	--	--
Revise industrial function categories	--	--	--	--	--	--	--	--	--	--	--	--	0.001	0.003	0.000
Revise commercial and consumer product categories	--	--	--	--	--	--	--	--	--	--	--	--	0.001	0.003	0.000
Number of commercial workers reasonably likely to be exposed	--	--	--	--	--	--	--	--	--	--	--	--	1.683	12.342	3.063
Upfront substantiation for processing and use information CBI claims	--	--	--	--	--	--	--	--	--	--	--	--	0.049	0.427	0.210
Step 1 Total	--	--	--	--	--	--	--	--	--	**0.827**	**3.625**	**0.890**	**1.735**	**12.775**	**3.273**
Step 2:Add the Effect of the Electronic Reporting Amendments															
Electronic Submission	--	**1.73**	**0.93**	**-0.69**	--	--	-0.75	-1.50	-0.75	**-2.07**	--	--	**-8.09**	--	--
Step 2 Total (Electronic Submission + Step 1 Total)	--	**1.73**	**0.93**	**-0.69**	--	--	**-0.75**	**-1.50**	**-0.75**	**-1.24**	**3.62**	**0.89**	**-6.35**	**12.77**	**3.27**
Step 3 Total Burden															
Step 2 Total + Baseline	--	**6.23**	**2.93**	--	**0.87**	**1.02**	**0.75**	**1.50**	**0.75**	--	**10.65**	**3.68**	--	**49.03**	**16.60**

Note: C = Clerical; T = Technical; and M = Managerial wage categories

Table 4-52 contains the estimated change in the burden and the total burden per reporting cycle as a result of the all the IUR amendments during the first reporting cycle. It also presents the burden in future reporting cycles. EPA estimates the total industry burden will increase by approximately 0.50 million hours to 2.34 million hours in total for the 2012 reporting cycle. In future reporting cycles, EPA estimates industry burden will increase by 1.14 million hours to 2.57 million hours.

Table 4-52: Total Industry Burden for All Amendments Combined

	Burden for Compliance Determination, Rule Familiarization, Submission and to Prepare Part I (hours per site)	Number of Sites	Burden for Record Keeping and to Prepare Part II (hours per report)	Number of Reports (with Part II)	Burden to Prepare Part III (hours per report)	Number of Reports (with Part III)	Industry Burden (millions of hours)
	(a)	(b)	(c)	(d)	(e)	(f)	(g) = (a*b)+(c*d)+(e*f)
First Cycle, Baseline	33.26	4,085	19.82	25,896	69.92	17,075	1.84
First Cycle, Post-Amendment	35.18	4,085	18.37	25,853	83.02	20,718	2.34
Change from the Baseline, First Cycle	**1.92**	**0**	**-1.45**	**-43**	**13.10**	**3,643**	**0.50**
Future-Cycle, Baseline	9.08	4,085	17.06	25,896	55.93	17,075	1.43
Future Cycle, Post-Amendment	11.05	4,289	17.33	30,935	65.63	30,287	2.57
Change from the Baseline, Future Cycles	**1.98**	**204**	**0.28**	**5,039**	**9.70**	**13,212**	**1.14**

Note: Values in *Change from the Baseline* rows are calculated by subtracting the corresponding baseline value from the post-amendment value.

Table 4-53 shows the total industry cost. To calculate the total industry cost, the burden estimates located in Table 4-50 and Table 4-51were multiplied by the wage rates found in Table 4-1. The costs were then multiplied by the number of submissions located in Table 4-49. EPA estimates the total industry cost will increase by approximately $36.76 million to $143.73million in total for the 2012 reporting cycle. In future reporting cycles, EPA estimates the industry cost will increase by $75.12 million to $157.94 million.

Table 4-53: Total Industry Cost When All Amendments Are Combined

	Cost for Compliance Determination, Rule Familiarization, Submission and to Prepare Part I (2008$ per site)	Number of Sites	Cost for Record Keeping and to Prepare Part II (2008$ per report)	Number of Partial Reports (with Part II)	Cost to prepare Part III (2008$ per report)	Number of Full Reports (with Part III)	Industry Cost (millions 2008$)
	(a)	(b)	(c)	(d)	(e)	(f)	(g) = (a*b)+(c*d)+(e*f)
First Cycle, Baseline	$2,058	4,085	$1,129	25,896	$4,059	17,075	$106.97
First Cycle, Post-Amendment	$2,193	4,085	$1,112	25,853	$5,117	20,718	$143.73
Change from the Baseline, First Cycle	**$135**	**0**	**-$16.99**	**-43**	**$1,058**	**3,643**	**$36.76**
Future-Cycle, Baseline	$561	4,085	$968.39	25,896	$3,247	17,075	$82.82
Future Cycle, Post-Amendment	$695	4,289	$1,047	30,935	$4,047	30,287	$157.94
Change from the Baseline, Future Cycles	**$134**	**204**	**$78.18**	**5,039**	**$800**	**13,212**	**$75.12**

Note: Values in *Change from the Baseline* rows are calculated by subtracting the corresponding baseline value from the post-amendment value.

4.5.3 Amendment that Affects the Reporting Frequency

This amendment to modify the reporting frequency from every five years to every four years will not change the number of submissions or the submission burden, but will increase the cost to submitters over multiple reporting cycles because submissions are made more frequently. The effect of this amendment, in combination with the other amendments, is shown in Section 4.5.4.

4.5.4 Average Cost and Burden per Site

Under the baseline, 4,085 sites submit a total of 25,896 reports; 17,075 of these are full reports and the remainder is partial reports (See Table 4-6). Thus, an average site submits IUR data for 6.34 chemical substances (25,896 reports divided by 4,085 sites), and submits full reports for 4.18 of those chemical substances (17,075 reports divided by 4,085 sites) (See Table 4-54). Table 4-52 contains the total number of reports submitted and sites when all the amendments are considered together. Under the first and future reporting cycles, an estimated 4,085 and 4,289 sites, respectively, submit a total of 25,853 and 30,935 reports; 20,718 and 30,287 of which will be full reports. Therefore, in the post-amendment scenario, an average site will submit 6.33 reports comprised of 5.07 full reports and 1.26 partial reports in the first reporting cycle and 7.21 reports comprised of 7.06 full reports and 0.15 partial reports in future reporting cycles (see Table 4-54). This is a decrease of 0.90 partial reports per site in the first reporting cycle and 2.01 partial reports per site in future reporting cycles. The number of full reports per site will increase by 0.89 reports in the first reporting cycle and 2.88 in future reporting cycles when compared to the baseline.

Table 4-54: Average Number of Full and Partial Reports per Site

	Total Number of Sites	Total Number of Reports	Average Number of Reports per Site	Total Number of Full Reports	Average Number Full Reports per Site	Average Number of Partial Reports per Site
	(a)	(b)	(c) = (b)/(a)	(d)	(e) = (d)/(a)	(f) = (c)-(e)
First Cycle, Baseline	4,085	25,896	6.34	17,075	4.18	2.16
Post-Amendment	4,085	25,853	6.33	20,718	5.07	1.26
Change from the Baseline	**0**	**-43**	**-0.01**	**3,643**	**0.89**	**-0.90**
Future Cycle, Baseline	4,085	25,896	6.34	17,075	4.18	2.16
Future Cycle, Post-Amendment	4,289	30,935	7.21	30,287	7.06	0.15
Change from the Baseline, Future Cycles	**204**	**5,039**	**0.87**	**13,212**	**2.88**	**-2.01**

Source: U.S. EPA, Office of Pollution Prevention and Toxics, Information Management Division *2006 IUR Database Statistics for IUR Modifications Rule*. Washington, DC. December 17, 2008 (EPA, 2008c).
Note: Values in *Change from the Baseline* rows are calculated by subtracting the corresponding baseline value from the post-amendment value.

Table 4-55 contains the average total burden per site. Each site will submit only one Part I under both the baseline and post-amendment scenarios. The average numbers of Part IIs and Part IIIs submitted per site are taken from Table 4-54. EPA calculated the baseline from the per-report burden presented in Table 4-2. In the first cycle baseline, the average site's burden is 451 hours during the first reporting cycle and 351 hours in future reporting cycles. The post-amendment burden per report is found in Table 4-52. The average burden per site is expected to be 572 hours in the first reporting cycle and 600 hours in future reporting cycles. This is an increase of 121 hours per site during the first reporting cycle and 249 hours per site in future reporting cycles compared to the baseline.

Table 4-55: Average Total Burden per Site

	Burden for Compliance Determination, Rule Familiarization, Submission and to Prepare Part I (hours per site)	Average Number of Part Is per Site	Burden for Record Keeping and to Prepare Part II (hours per report)	Average Number of Part IIs per Site	Burden for Part III (hours per report)	Average Number of Part IIIs per Site	Total Average Burden per Site (hours)
	(a)	(b)	(c)	(d)	(e)	(f)	(g) = (a*b) +(c*d)+(e*f)
First Cycle, Baseline	33.26	1	19.82	6.34	69.92	4.18	451
Post-Amendment	35.18	1	18.37	6.33	83.02	5.07	572
Change from the Baseline	**1.92**	**0**	**-1.45**	**-0.01**	**13.10**	**0.89**	**121**
Future Cycle, Baseline	9.08	1	17.06	6.34	55.93	4.18	351
Future Cycle, Post-Amendment	11.05	1	17.33	7.21	65.63	7.06	600
Change from the Baseline, Future Cycles	1.98	**0**	0.28	0.87	9.70	2.88	**249**

Note: Values in *Change from the Baseline* rows are calculated by subtracting the corresponding baseline value from the post-amendment value.

The average baseline and post-amendment scenario costs per site are found in Table 4-56. Baseline cost per report costs is taken from Table 4-5 and Table 4-8 and used in calculating the average baseline cost per site. In the first reporting cycle, the average baseline cost per site is estimated to be $26,185. Future cycle average baseline cost is estimated to be $20,274 per site. Post-amendment cost per report is derived in Table 4-52 and Table 4-53. The average post-amendment cost per site is calculated to be approximately $35,200 in first reporting cycle, and $36,800 for all future reporting cycles. This is an increase of approximately $9,000 per site during the first reporting cycle and $16,600 during future reporting cycles compared to the baseline.

Table 4-56: Average Total Cost per Site

	Cost for Submission Compliance Determination, Rule Familiarization, and to Prepare Part I (2008$ per site)	Average Number of Part Is per Site	Cost for Record Keeping and to Prepare Part II (2008$ per report)	Average Number of Part IIs per Site	Cost to Prepare Part III (2008$ per report)	Average Number of Part IIIs per Site	Total Average Cost per Site(2008$)
	(a)	(b)	(c)	(d)	(e)	(f)	(g) = (a*b) + (c*d)+(e*f)
First Cycle, Baseline	$2,058	1	$1,129	6.34	$4,059	4.18	$26,185
Post-Amendment	$2,193	1	$1,112	6.33	$5,117	5.07	$35,185
Change from the Baseline	**$135**	**0**	**-$16.99**	**-0.01**	**$1,058**	0.89	**$9,000**
Future Cycle Baseline	$561	1	$968	6.34	$3,247	4.18	$20,274
Future Cycle, Post-Amendment	$695	1	$1,047	7.21	$4,047	7.06	$36,824
Change from the Baseline, Future Cycles	**$134**	**0**	**$78.18**	**0.87**	**$800**	2.88	**$16,551**

Note: Values in *Change from the Baseline* rows are calculated by subtracting the corresponding baseline value from the post-amendment value.

4.6 Annualized Industry Cost Estimates for all Modifications

EPA estimated the total burden to industry of all of the amendments over a 26-year period. EPA used a 20-year annualization period in the previous economic analyses of the IUR rule (EPA, 2002a and EPA, 2005), but for this report, a 26-year period allows EPA to analyze a set of complete reporting cycles under both the baseline and post-amendment scenarios.

While the IUR data submission activity itself occurs in one reporting year (e.g., 2012), EPA believes rule compliance and data collection activities, and thus, costs and burdens, are incurred over the course of the reporting cycle. Consequently, costs and burdens are presented for a reporting cycle, rather than per year, because EPA cannot precisely predict the annual breakdown of how the costs are actually incurred by each site over a four- or five-year reporting cycle. Industry has indicated to EPA efforts related to rule compliance and data collection are spread out over multiple years. For example, EPA began receiving calls about reporting requirements for 2012 reporting in early 2009, and the Agency has already held conference calls with companies and EPA IT staff to discuss electronic reporting issues. Companies have stated they prefer to set up a system to collect the IUR information during the time the chemical

substances are being manufactured. Thus, for the 2012 reporting cycle, EPA has evidence some companies set up their data systems in 2009 to early 2010, are collecting the information in 2010 and 2011, and will compile and report that information in 2012. Furthermore, as described in section 4.2.2, IUR burden estimates are taken from the 2002 EPA *Economic Analysis for the Amended Inventory Update Final Rule* and were based on an industry survey conducted by EPA and designed to measure industry effort associated with collecting chemical substance exposure data under TSCA Section 8. Nowhere in the survey or its cover letter are these burden estimates discussed as being annual burdens. They are interpreted in the 2002 EA, and in previous IUR ICRs, as being the total burden incurred over the entire reporting cycle.

The total industry burden calculated in Table 4-52 included the burden during the first reporting cycle. EPA expects during future reporting cycles, the industry burden will decrease as submitters become more efficient with the data and more familiar with the reporting requirements. Section 4.2.6 discusses the burden reductions associated with this rule familiarization and efficiency gains. Table 4-52 also shows the total burden to industry in future reporting cycles. Table 4-57 shows the burdens associated with each reporting cycle over a period of 26 years, including the years covered by the next (2012) reporting cycle. Under the baseline, a five-year reporting cycle is used, and the cost of four complete cycles is analyzed. Under the post-amendment scenario, reporting occurs every four years, and the cost of five complete cycles is presented. (Note the 2012 reporting year covers a six-year period under either scenario).

Over a 26-year period, EPA estimates the amendments will increase industry burden by approximately 7.62 million hours.

Table 4-57: Industry Burden over a Period of 26 Years if All Amendments Are Implemented

Reporting Cycle[1]	Year(s)	Baseline Burden (millions of hours)	Post-Amendment Burden (millions of hours)	Change in Burden (millions of hours)
1	**2007 to 2012**	1.84	2.34	0.50
2	**2013 to 2017**	1.43	--	1.14
	2013 to 2016	--	2.57	
3	**2087 to 2022**	1.43	--	1.14
	2017 to 2020	--	2.57	
4	**2023 to 2027**	1.43	--	1.14
	2021 to 2024	--	2.57	
5	**2028 to 2032**	1.43	--	1.14
	2025 to 2028	--	2.57	
6	***2029 to 2032***	--	2.57	2.57
Total		**7.58**	**15.20**	**7.62**
Annual Average		**0.29**	**0.58**	**0.29**

[1] The non-italicized reporting cycles are baseline, five-year cycles, and the italicized reporting cycles are four-year cycles.

Table 4-58 presents the annual and annualized costs estimates of all the amendments. Over a 26-year period, EPA estimates the amendments to the IUR rule will increase the annualized industry cost by $17.16 million, with a three percent discount rate, and $14.71 million with a seven percent discount rate.

Table 4-58: Industry Cost over a Period of 26 Years if All Amendments Are Implemented

Reporting Cycle[1]	Year(s)	Baseline Cost	Post-Amendment Cost	Change in Cost
		(millions of 2008$)	(millions of 2008$)	(millions of 2008$)
1	**2007 to 2012**	$106.97	$143.73	$36.76
2	**2013 to 2017**	$82.82	--	$75.12
	2013 to 2016	--	$157.94	
3	**2087 to 2022**	$82.82	--	$75.12
	2017 to 2020	--	$157.94	
4	**2023 to 2027**	$82.82	--	$75.12
	2021 to 2024	--	$157.94	
5	**2028 to 2032**	$82.82	--	$75.12
	2025 to 2028	--	$157.94	
6	***2029 to 2032***	--	$157.94	$157.94
Total		**$438.24**	**$933.42**	**$495.19**
Annualized @ 3%		**$15.88**	**$33.05**	**$17.16**
Annualized @ 7%		**$14.62**	**$29.33**	**$14.71**

[1] The non-italicized reporting cycles are baseline, five-year cycles, and the italicized reporting cycles are, four-year cycles.

5. Agency Burden and Cost Estimates

5.1 Methodology for Agency Burden and Cost

This chapter analyzes the changes in burden and cost to EPA as a result of the amendments to the IUR rule. This chapter calculates the incremental cost and burden changes of the amendments by comparing the Agency costs under the current baseline to Agency costs after the rule amendments. The methodology for estimating the change in Agency cost is similar to estimating the change in burden to industry:

- **Step 1**: Identify the tasks performed by the Agency under both the current IUR requirements and the IUR rule amendments.
- **Step 2**: Determine the unit cost and burden for all activities identified in Step 1.
- **Step 3**: Determine the estimated total cost and burden by multiplying the unit cost and burden by the frequency of the activity.
- **Step 4**: Subtract the total Agency cost or burden after the IUR amendments from the cost or burden under the current IUR rule to calculate the incremental Agency cost or savings

Based on the supporting statement for the 2008 *Information Collection Request for the Partial Update of the TSCA Production and Site Reports* (EPA 2008d), tasks associated with the costs and burden to the Agency under the IUR rule include:

- Document receipt and tracking;
- Data entry and quality control of data entry;
- Backup systems operation;
- Data processing;
- Systems development;
- Contract oversight and management;
- Publication and printing of forms and materials; and
- Operation of the TSCA Hotline to handle IUR-related calls.

Costs related to using the data are not included. The one-time costs associated with the requirements of previous IUR amendments are also not considered here.

5.2 Data for Agency Cost Estimates

5.2.1 Agency Wage Rates

Of the tasks listed above, Agency personnel are responsible for (1) quality control of data entry; and (2) data processing, systems development, and contract oversight and management. Under the current IUR rule, the Agency is expected to require one FTE at the GS-12 level, per-reporting cycle, to perform quality control of data entry (EPA, 2008d). An additional FTE at the GS-13 level is needed to complete data processing, systems development, and contract oversight and management per-reporting cycle (EPA, 2008d). The total baseline burden to the Agency is

therefore 4,160 hours under the baseline. EPA assumes the Agency burden will remain the same for all reporting cycles.

EPA labor costs are based on annual Federal wage rates published by the Office of Personnel Management for the Washington-Baltimore-Northern Virginia, DC-MD-PA-VA-WV locality pay area for 2008 (OPM, 2008). Wages are presented in terms of GS-level and step. Based on previous IUR economics analyses, a Step3 is assumed for all FTEs (EPA, 2002a and EPA, 2005). Following the methodology outlined in *Economic Analysis for the Amended Inventory Update Rule: Final Report* (EPA, 2002a), an additional 58 percent is added to the wage rate to account for fringe benefits and overhead costs. Table 5-1 shows the loaded wage rates for Agency staff at the GS-12 Step 3, and GS-13 Step 3 levels.

Table 5-1: Derivation of Loaded Agency Wage Rates (2008$)

Pay Grade	Annual Salary	Overhead and Fringe Benefits % of Wages	Overhead and Fringe Benefit Cost	Total
GS 12 Step 3	$77,416	58%	$44,901	$122,317
GS 13 Step 3	$88,493	58%	$51,326	$139,819

Source: The unloaded Federal salary for calendar 2008 is from the Office of Personnel Management salary table for Washington-Baltimore-Northern Virginia (OPM, 2008).

5.2.2 Extramural (Contractor) Costs

In addition to costs incurred by EPA staff, burden is associated with extramural tasks performed by contractors. These tasks include data receipt, tracking and data entry; backup systems operations and maintenance; printing and publishing forms and materials; and managing the TSCA hotline. The 2008 Information Collection Request (ICR) supporting statement (EPA, 2008d) estimates these costs. EPA inflated these costs to 2008 dollars from 2007 dollars using an inflation factor developed from data from the BLS Employee Cost Index (ECI) "Professional, scientific, and technical services" group (BLS, 2009). Table 5-2 shows the derivation of the extramural task cost in 2008 dollars. In total, EPA estimates it will spend approximately $204,000 on these tasks per reporting cycle.

Table 5-2: Derivation of Extramural Task Costs, per Reporting Cycle

Tasks Performed by Contractor Staff	Annual Cost (2007$)[1]	Inflation Factor	Annual Cost (2008$)
Document Receipt, Tracking and Data Entry	$90,737	1.04	$94,632
Maintaining and Operating Back Up Systems	$56,711	1.04	$59,145
Printing and Publishing Forms and Materials	$5,298	1.04	$5,525
Managing the TSCA Hotline	$42,855	1.04	$44,694
Total	**$195,601**	**n/a**	**$203,997**

[1]Source: ICR No. 1884.04. *[Information Collection Request for]* Partial Update of the TSCA Section 8(b) Inventory Data Base, Production and Site Report *Supporting Statement for a Request for OMB Review under the Paperwork Reduction Act*, September 5, 2008 (EPA, 2008d).

5.3 Current Total Agency Burden and Cost

As shown in Table 5-3, EPA calculated the total baseline Agency costs by combining the costs of EPA staff and the extramural tasks performed by contractors.

Table 5-3: Total Agency Cost under the Current IUR Requirements

Task	Staff	Cost per Reporting Cycle(2008$)
VARIABLE COSTS (DEPENDENT ON THE NUMBER OF REPORTS SUBMITTED)		
Quality Control of Data Entry	EPA Employee (GS 12 Step 3)	$122,317
Document Receipt, Tracking and Data Entry	Contractor	$94,632
	TOTAL VARIABLE COST	***$216,949***
FIXED COSTS		
Data Processing, Systems Development, and Contract Oversight and Management	EPA Employee (GS 13 Step 3)	$139,819
Maintaining and Operating Back Up Systems	Contractor	$59,145
Printing and Publishing Forms and Materials	Contractor	$5,525
Managing the TSCA Hotline	Contractor	$44,694
	TOTAL FIXED COST	***$249,183***
	TOTAL AGENCY COST	**$466,133**

Note: Totals may not sum due to rounding.

Previous estimates of Agency costs, on which the estimates included in this analysis are based, provide only cost estimates, not burden estimates. Therefore, EPA's per report burden was estimated as described in this section. The EPA GS 13 staff's responsibilities for data processing, systems development, and contract oversight and management task are not strongly tied to the number of reports received, nor are the contractor tasks of maintaining and operating a back-up system and managing the TSCA hotline. However, quality control of data entry, and the document receipt, tracking, and data entry burdens, are dependent upon the number of reports received. The combined cost of these activities is $216,949 (see Table 5-3). EPA assumes an Agency burden of 2,080 hours, accounting for a year of the GS 12's burden (contractor hours are included as costs to the Agency, not burden.) EPA assumes it incurs the same cost to perform the data entry and processing for each data element in Form U.

To calculate the Agency burden per data element, EPA followed a methodology outlined in the *Economic Analysis of the Final Rule to Add Certain Industry Groups to EPCRA Section 313* (EPA, 2007). EPA first calculated the total number of data elements in Form U (126 elements) and the percentage of data elements in each section of the form, and derived a weighted percentage of elements in each section of the form. For example, there are 19 data elements in Part I, and 4,085 sites submit Part I of Form U. These 77,615 data elements (19 x 4,085 = 77,615) account for approximately 3.4 percent of all data elements. Similarly, 52.5 percent of all data elements are in Part II of the form, and 44.1 percent are in Part III. The Agency then multiplied the total burden of IUR processing, 2,080 hours, by the percentage of data elements in a section and divided by the total number reports submitted for each section. An example of this calculation can be seen in Equation 1 for Part I.

Equation 1: Burden to Process Part I per Report = (2,080 hours x 0.034) / 4,085 = 0.017 hours

The burden per section was then divided by the total number of data items in that section to calculate the burden per item, 0.0009 hours (approximately 0.054 minutes) (see Equation 2).

Equation 2: Burden per Data Element = 0.017 hours / 19 = 0.0009 hours

To calculate the cost to EPA, the process described above was repeated; however, instead of using 2,080 hours, EPA used the combined cost for the quality control of data entry, and document receipt, tracking, and data entry, which was $216,949. Thus, EPA calculated it costs the Agency approximately $0.09 to process a single data element of Form U. The total Agency burden per report is approximately 0.113 hours and $11.79. Table 5-4contains the Agency burden and cost per report by section of Form U. This baseline burden will remain the same for all reporting cycles.

Table 5-4: Baseline Agency Burden per Report

	Number of Data Elements	Burden per Data Element		Total	
		Burden (hours)	Cost (2008$)	Burden (hours)	Cost (2008$)
Part I	19	0.0009	$0.09	0.017	$1.78
Part II	47	0.0009	$0.09	0.042	$4.40
Part III	60	0.0009	$0.09	0.054	$5.61
Total (Full Report)	**126**	**-**	**-**	**0.113**	**$11.79**

5.4 Changes to Agency Burden and Cost as a Result of the Modifications

The estimated cost and burden impacts on the Agency for each of the amendments to the IUR are outlined below. See Section 3. for more information about each of the amendments.

In each of the following sections, the burden estimates for each amendment are calculated *independently of the other amendments*. See Section 5.5 for an estimate of the aggregated impact of all the amendments.

5.4.1 Technical Modifications to the Regulatory Text

EPA is reorganizing certain existing regulatory text and to delete obsolete regulatory text. These amendments do not substantively affect the regulatory text, so EPA assumes this amendment will not impact Agency burden or cost.

5.4.2 Modifications to Selected Definitions

EPA is modifying the definitions of “importer,” “manufacture,” “site,” “commercial use,” “consumer use,” “reporting year,” and “submission period,” and to add definitions for “manufacturer,” “Central Data Exchange (CDX),” “e-IURweb,” and “industrial function,” as described in Section 3. These changes are clarifications only; EPA is clarifying in regulatory text what has been previously explained through outreach with the regulated community. Therefore, EPA assumes these definition changes will not impact Agency burden or cost.

5.4.3 Method for Determining Whether a Manufacturer is subject to IUR Reporting Requirements

EPA is requiring reporting if, for any calendar year since the previous IUR principal reporting year, the subject chemical substance was manufactured or imported in volumes of 25,000 lb or greater. The Agency estimates this will increase the total number of sites and reports by five percent from the baseline. This modification would not take effect until after the first post-amendment reporting cycle (2012); for the first reporting cycle, submitters will still consider production volume only for the principal reporting year. This creates a difference in the number of sites and reports expected in the first cycle versus future cycles. (See Section 4.4.3 for more information.) Therefore, the tables below show estimated changes in cost and burden for both the first and future reporting cycles.

Table 5-5 shows the estimated Agency burden of the amendment, using the baseline burden estimates found in Table 5-4. The Agency estimates no change in burden for the first reporting cycle and a burden increase of 104 hours in future reporting cycles as a result of modifying the method for determining whether the 25,000 lb reporting threshold is met.

Table 5-5: Change in Agency Burden as a Result of Modifying the Method for Determining Whether a Manufacturer is Subject to IUR Reporting Requirements

	Burden to Process Part I Submission (hours) (a)	Number of Sites (b)	Burden to Process Part II (hours per report) (c)	Number of Reports (with Part II) (d)	Burden to Process Part III (hours per report) (e)	Number of Reports with Part III (f)	Agency Burden (hours) (g) = (a*b)+(c*d) +(e*f)
First Cycle, Baseline	0.017	4,085	0.042	25,896	0.054	17,075	2,080
First Cycle, Post-Amendment	0.017	4,085	0.042	25,896	0.054	17,075	2,080
Change from the Baseline, First Cycle	**0.000**	**0**	**0.000**	**0**	**0.000**	**0**	**0**
Future Cycle Baseline	0.017	4,085	0.042	25,896	0.054	17,075	2,080
Future Cycle, Post-Amendment	0.017	4,289	0.042	27,191	0.054	17,929	2,184
Change from the Baseline, Future Cycles	**0.000**	**204**	**0.000**	**1,295**	**0.000**	**854**	**104**

Note: Values in *Change from the Baseline* rows are calculated by subtracting the corresponding baseline value from the post-amendment value.

Table 5-6 shows the estimated change in cost to EPA as a result of the amendment. The Agency estimates no change in cost for the first reporting cycle and a cost increase of approximately $10,800 in future reporting cycles.

Table 5-6: Change in Agency Cost as a Result of Modifying the Method for Determining Whether a Manufacturer is Subject to IUR Reporting Requirements

	Cost to Process Part I Submission (2008$) (a)	Number of Sites (b)	Cost to Process Part II (2008$ per report) (c)	Number of Reports (with Part II) (d)	Cost to Process Part III (2008$ per report) (e)	Number of Reports with Part III (f)	Agency Burden (2008$) (g) =(a*b)+(c*d) +(e*f)
First Cycle, Baseline	$1.78	4,085	$4.40	25,896	$5.61	17,075	$216,949
First Cycle, Post-Amendment	$1.78	4,085	$4.40	25,896	$5.61	17,075	$216,949
Change from the Baseline, First Cycle	**0.000**	**0**	**0.000**	**0**	**0.000**	**0**	**0**
Future Cycle Baseline	$1.78	4,085	$4.40	25,896	$5.61	17,075	$216,949
Future Cycle, Post-Amendment	$1.78	4,289	$4.40	27,191	$5.61	17,929	$227,796
Change from the Baseline, Future Cycles	**$0.00**	**204**	**$0.00**	**1,295**	**$0.00**	**854**	**$10,847**

Note: Values in *Change from the Baseline* rows are calculated by subtracting the corresponding baseline value from the post-amendment value.

5.4.4 Replace the 300,000 lb Threshold for Processing and Use Reporting

For the 2012 IUR submission, all submitters of non-excluded chemical substances are required to report processing and use information if they manufactured (including imported) 100,000 lb or more of a chemical substance in 2011. Subsequent to the 2012 reporting cycle, the reporting threshold will be 25,000 lb. Replacing this threshold will increase industry burden by requiring more sites to complete Part III of Form U (Part III contains the downstream processing and use information). EPA estimates the number of Part IIIs submitted will increase by 3,627 reports in the first reporting cycle and by 8,203 reports in future reporting cycles (see Section 4.4.4 for more information).

Table 5-7 shows the estimated Agency burden of the amendment, using the baseline burden estimates found in Table 5-4. The Agency expects a burden increase of 195 hours in the first reporting cycle and 441 hours in subsequent reporting cycles as a result of this amendment.

Table 5-7: Change in Agency Burden as a Result of Replacing the 300,000 lb Threshold for Processing and Use Reporting

	Burden to Process Part III (hours per report) (a)	Number of Reports with Part III (b)	Agency Burden (hours) (c) = (a)*(b)
First Cycle, Baseline	0.05	17,075	919
First Cycle, Post-Amendment	0.05	20,702	1,114
Change from the Baseline, First Cycle	**0**	**3,627**	**195**
Future Cycle, Baseline	0.05	17,075	919
Future Cycle, Post-Amendment	0.05	25,278	1,360
Change from the Baseline, Future Cycles	**0**	**8,203**	**441**

Note: Values in *Change from the Baseline* rows are calculated by subtracting the corresponding baseline value from the post-amendment value.

Table 5-8 shows the estimated change in cost to EPA as a result of the amendment. The Agency estimates a cost increase of approximately $20,400 in the first reporting cycle and by $46,000 in future reporting cycles.

Table 5-8: Change in Agency Cost as a Result of Replacing the 300,000 lb Threshold for Processing and Use Reporting

	Cost to Process Part III (2008$ per report) (a)	Number of Reports (b)	Agency Cost (2008$) (c) = (a)*(b)
First Cycle, Baseline	$5.61	17,075	$95,835
First Cycle, Post-Amendment	$5.61	20,702	$116,192
Change from the Baseline, First Cycle	**0.00**	**3,627**	**$20,357**
Future Cycle, Baseline	$5.61	17,075	$95,835
Future Cycle, Post-Amendment	$5.61	25,278	$141,876
Change from the Baseline, Future Cycles	**$0.00**	**8,203**	**$46,040**

Note: Values in *Change from the Baseline* rows are calculated by subtracting the corresponding baseline value from the post-amendment value.

5.4.5 Reduce the 25,000 lb Threshold for Specific Regulated Chemical Substances

Beginning with the 2016 reporting cycle, EPA is reducing the 25,000 lb reporting threshold to 2,500 lb for chemical substances that are: (1) the subject of a regulation promulgated under sections 5(a)(2), 5(b)(4), or 6 of the Act; (2) the subject of an order issued under section 5(e) or 5(f) of the Act, or (3) the subject of relief that has been granted under a civil action under section 5 or 7 of the Act. The manufacturers (including importers) of these chemical substances would be required to report under the IUR rule, regardless of the production volume.

Approximately 902 chemical substances fall into these categories and are expected to have a production volume above 2,500 lb (EPA, 2006a)[5]. Because the amendment would affect only chemical substances subject to a promulgated rule, this figure is an overestimate. EPA estimated these chemical substances will generate a total of 3,609 additional reports (see Section 4.4.5 for more details).

Table 5-9 shows the estimated Agency burden of the amendment, using the baseline burden estimates found in Table 5-4. The Agency expects a burden increase of 152 hours as a result of the lowering of the 25,000 lb threshold for certain regulated chemical substances to 2,500 lb beginning with the 2016 reporting cycle.

Table 5-9: Change in Agency Burden as a Result of Reducing the 25,000 lb Threshold for Specific Regulated Chemical Substances (Future Cycles Only)

	Burden to Process Part II (hours per report) (a)	Number of Reports (b)	Agency Burden (hours) (c) = (a)*(b)
Baseline	0.04	25,896	1,092
Future Cycle, Post-Amendment	0.04	29,505	1,244
Change from the Baseline, Future Cycles	**0**	**3,609**	**152**

Note: Values in *Change from the Baseline* rows are calculated by subtracting the corresponding baseline value from the post-amendment value.

Table 5-10 shows the estimated change in cost to EPA as a result of the amendment. The Agency estimates a cost increase of approximately $15,900 beginning with the 2016 reporting cycle.

Table 5-10: Change in Agency Cost as a Result of Reducing the 25,000 lb Threshold for Specific Regulated Chemical Substances (Future Cycles Only)

	Cost to Process Part II (2008$ per report) (a)	Number of Reports (b)	Agency Cost (2008$) (c) = (a)*(b)
Baseline	$4.40	25,896	$113,853
Future Cycle, Post-Amendment	$4.40	29,505	$129,721
Change from the Baseline, Future Cycles	**$0.00**	**3,609**	**$15,868**

Note: Values in *Change from the Baseline* rows are calculated by subtracting the corresponding baseline value from the post-amendment value.

[5] There are two chemicals subject of an order issued under section 5(f) of TSCA that would be subject to the reduced threshold that have not been included in the development of estimates in this section of the Economic Analysis, however, the overall estimates of costs and burdens for this requirement are not expected to be significantly affected.

5.4.6 Make Chemical Substances Subject to Enforceable Consent Agreements (ECAs) Ineligible for Exemptions

The Agency is making all chemical substances subject to enforceable consent agreements ineligible for exemptions. A total of four chemical substances and 16 sites are affected by this amendment (see Section 4.4.6 for more information). These sites would submit Part III of Form U for these chemical substances for the first time in the next submission period.

Table 5-11 shows the estimated Agency burden of the amendment, using the baseline burden estimates found in Table 5-4. The Agency expects a burden increase of one hour as a result of this amendment.

Table 5-11: Change in Agency Burden as a Result of Making Chemical Substances Subject to ECAs Ineligible for Exemptions

	Burden to Process Part III (hours per report) (a)	Number of Reports (b)	Agency Burden (hours) (c) = (a)*(b)
Baseline	0.05	17,075	919
Post-Amendment	0.05	17,091	920
Change from the Baseline	**0**	**16**	**1**

Note: Values in *Change from the Baseline* rows are calculated by subtracting the corresponding baseline value from the post-amendment value.

Table 5-12 shows the estimated change in cost to EPA as a result of the amendment. The Agency estimates a cost increase of approximately $90.

Table 5-12: Change in Agency Cost as a Result of Making Chemical Substances Subject to ECAs Ineligible for Exemptions

	Cost to Process Part III (2008$ per report) (a)	Number of Reports (b)	Agency Cost (2008$) (c) = (a)*(b)
Baseline	$5.61	17,075	$95,835
Post-Amendment	$5.61	17,091	$97,925
Change from the Baseline	**$0.00**	**16**	**$90**

Note: Values in *Change from the Baseline* rows are calculated by subtracting the corresponding baseline value from the post-amendment value.

5.4.7 Full Exemption for Manufactured Water

Under the current IUR regulations, manufactured water is partially exempt from reporting; therefore, facilities that produce manufactured water need to complete only Parts I and II of Form U. The Agency now is granting a full exemption for manufactured water. Thus, the burden reduction for this amendment would be the result of 43 fewer Part IIs being submitted (see Section 4.4.7 for more information.)

Table 5-13 shows the estimated Agency burden of the amendment, using the baseline burden estimates found in Table 5-4. The Agency estimates a burden reduction of two hours as a result of this amendment.

Table 5-13: Change in Agency Burden as a Result of a Full Exemption for Manufactured Water

	Burden to Process Part II (hours per report) (a)	Number of Reports (b)	Agency Burden (hours) (c) = (a)*(b)
Baseline	0.04	25,896	1,092
Post-Amendment	0.04	25,853	1,090
Change from the Baseline	**0**	**-43**	**-2**

Note: Values in *Change from the Baseline* rows are calculated by subtracting the corresponding baseline value from the post-amendment value.

Table 5-14 shows the estimated change in cost to EPA as a result of the amendment. The Agency estimates a cost savings of approximately $190.

Table 5-14: Change in Agency Cost as a Result of a Full Exemption for Manufactured Water

	Cost to Process Part II (2008$ per report) (a)	Number of Reports (b)	Agency Cost (2008$) (c) = (a)*(b)
Baseline	$4.40	25,896	$113,853
Post-Amendment	$4.40	25,853	$113,664
Change from the Baseline	**$0.00**	**-43**	**-$189**

Note: Values in *Change from the Baseline* rows are calculated by subtracting the corresponding baseline value from the post-amendment value.

5.4.8 Remove Fully-Exempt Polymers from the Partially-Exempt List

EPA is amending the list of partially exempt chemical substances to remove three chemical substances (Starch (CASRN 9005-25-8), Dextrin (CASRN 9004-53-9), and Maltodextrin (CASRN 9049-76-7)) which, as polymers, are fully exempt from reporting. This will not change the Agency burden because these substances currently are fully exempt from reporting, and therefore no additional reports will be submitted to EPA.

5.4.9 Parent Company and Site Identity

Manufacturers (including importers) currently are required to report the name and other information to identify the company associated with their plant site on Part I of Form U. EPA is requiring the company name to be the ultimate domestic parent name. EPA assumes no additional Agency burden for processing the ultimate domestic parent name, compared to the current IUR reporting requirement of the parent company name.

5.4.10 Technical Contact

Manufacturers (including importers) are required to provide a technical contact for their IUR submission. EPA is amending the IUR rule to require the technical contact to be a person who works at the site and is knowledgeable about the chemical substance. EPA assumes no additional Agency burden to process the technical contact regardless of the location of the contact.

5.4.11 Chemical Identity

EPA is requiring reporting of the Chemical Abstracts (CA) Index Name currently used to list the substance on the TSCA Inventory as the chemical name reported for IUR. Currently, submitters are required to report a specific chemical name, with no further elaboration in the regulatory text. For the 2011 submission period, the reporting software will be directly linked to the non-confidential portion of the TSCA Inventory through the Agency's Substance Registry System (SRS) database. Therefore, submitters will be required to select the correct CA Index Name for their reportable chemical substance(s) from SRS.

Manufacturers (including importers) will be allowed to supply an alternate chemical name, and in the case of importers, a trade name, in those instances where a supplier will not disclose to the submitter the specific chemical name of the imported TSCA Inventory substance or a reactant used to manufacture the Inventory substance. In these cases, the manufacturer (including importer) and the supplier report the information required in this part in a joint submission.

For the chemical identifying number, EPA is requiring reporting of only the CASRN (for the public Inventory), or in the case of confidential chemical substances, the TSCA accession number. In addition, EPA is removing the PMN number as an allowed chemical identifying number because each Inventory substance has either a CASRN or a TSCA accession number or both, which are likely to be known already to the submitter.

EPA assumes no additional Agency burden to process either a CA Index Name compared to an alternative chemical name, or a request for an accession number compared to a CASRN for a chemical identifying number, and so is not adding any burden to the baseline Agency burden and cost estimates for chemical identity. However, there may be an increase in accession number requests because some submitters may not know their accession number or PMN number. The number of 2006 reports with CAS numbers claimed as CBI was used as a proxy for the number letters submitted to EPA; a total of 343 reports was estimated (EPA, 2010b). The Agency burden to process an accession number request is 0.5 hours per request, based on EPA's best professional judgment of the time needed to process a request and mail the accession number back to the company. Table 5-15 shows the change in Agency burden as a result of processing accession number requests. EPA estimates a burden increase of 170 hours in the first reporting cycle. No change in burden is expected in future reporting cycles (see Section 4.4.11).

Table 5-15: Change in Agency Burden as a Result of Accession Number Requests

	Burden per Request (hours)	Number of Requests	Agency Burden (hours)
	(a)	(b)	(c) = (a)*(b)
Baseline	0	0	0.0
Post-Amendment	0.5	343	171.5
Change from the Baseline	**0.5**	**343**	**171.5**

Note: Values in *Change from the Baseline* rows are calculated by subtracting the corresponding baseline value from the post-amendment value.

Table 5-16 shows the change in Agency cost as a result of accession number requests. EPA estimates a cost increase of $11,528 in the first reporting cycle.

Table 5-16: Change in Agency Cost as a Result of Accession Number Requests

	Cost per Request ($) (a)	Number of Requests (b)	Agency Cost ($) (c) = (a)*(b)
Baseline	$0	0	$0.00
Post-Amendment	$33.61	343	$11,528
Change from the Baseline	**$33.61**	**343**	**$11,528**

Note: Values in *Change from the Baseline* rows are calculated by subtracting the corresponding baseline value from the post-amendment value.

5.4.12 Report Production Volume for Each of the Years since Last Principal Reporting Year

EPA is requiring reporting of a chemical substance's production volume manufactured in 2010 and 2011 for the first reporting cycle and each of the four years since the last IUR principal reporting year for subsequent reporting cycles, beginning with the 2016 reporting cycle. This amendment will result in one additional data item for EPA to process in Part II of Form U in the first reporting cycle, adding approximately 0.06 minutes (0.001 hours) of processing burden per form. In future reporting cycles, the Agency burden is expected to increase by 0.003 hours or 0.16 minutes (see Table 5-4).

Table 5-17 shows the estimated Agency burden of the amendment, using the baseline burden estimates found in Table 5-4. The Agency estimates a burden increase of 23 hours in the first reporting cycle and 70 hours in future reporting cycles as a result of this amendment.

Table 5-17: Change in Agency Burden as a Result of Reporting of Production Volume for Each of the Years since Last Principal Reporting Year

	Burden for Processing Production Volume (hours per report) (a)	Number of Reports (b)	Agency Burden (hours) (c) = (a)*(b)
First Cycle, Baseline	0.001	25,896	23
First Cycle, Post-Amendment	0.002	25,896	46
Change from the Baseline, First Cycle	**0.001**	**0**	**23**
Future Cycle, Baseline	0.001	25,896	23
Future Cycle, Post-Amendment	0.004	25,896	93
Change from the Baseline, Future Cycles	**0.003**	**0**	**70**

Note: Values in *Change from the Baseline* rows are calculated by subtracting the corresponding baseline value from the post-amendment value.

Table 5-18 shows the estimated change in cost to EPA as a result of the amendment. The Agency estimates a cost increase of approximately $2,400 in the first reporting cycle, and $7,200 in future reporting cycles.

Table 5-18: Change in Agency Cost as a Result of Reporting of Production Volume for Each of the Years since Last Principal Reporting Year

	Cost for Processing Production Volume (2008$ per report) (a)	Number of Reports (b)	Agency Cost (2008$) (c) = (a)*(b)
First Cycle, Baseline	$0.09	25,896	$2,422
First Cycle, Post-Amendment	$0.19	25,896	$4,845
Change from the Baseline, First Cycle	**$0.09**	**0**	**$2,422**
Future Cycle, Baseline	$0.09	25,896	$2,422
Future Cycle, Post-Amendment	$0.37	25,896	$9,690
Change from the Baseline, Future Cycles	**$0.28**	**0**	**$7,267**

Note: Values in *Change from the Baseline* rows are calculated by subtracting the corresponding baseline value from the post-amendment value.

5.4.13 Volume of Chemical Substance Used On-Site

Under the current IUR requirements, submitters who manufacture a chemical substance exclusively for on-site use are required to indicate this on Form U. The Agency is requiring submitters to report both production volumes used on- and off-site. EPA expects there will be a slight increase in the number of submitters who will report product volume used on-site; about 19.4 percent of all submitters will report the volume used on-site (see Section 5.4.13 for more information).

Table 5-19 shows the estimated Agency burden of the amendment, using the baseline burden estimates found in Table 5-4. The Agency estimates a burden increase of five hours as a result of this amendment.

Table 5-19: Change in Agency Burden as a Result of Reporting of Production Volume Used On-Site

	Burden to Process Information (hours per report)	Number of Reports	Number of Reports with Production Volume Used On-Site	Agency Burden (hours)
Baseline	0.042	25,896	0	1,092
Post-Amendment	0.043	25,896	5,024	1,096
Change from the Baseline	**0.001**	**0**	**5,024**	**5**

Note: Values in *Change from the Baseline* rows are calculated by subtracting the corresponding baseline value from the post-amendment value.

Table 5-20 shows the estimated change in cost to EPA as a result of the amendment. The Agency estimates a cost increase of approximately $470.

Table 5-20: Change in Agency Cost as a Result of Reporting of Production Volume Used On-Site

	Cost to Process Information(2008$ per report)	Number of Reports	Number of Reports with Production Volume Used On-Site	Agency Cost (2008$)
Baseline	$4.40	25,896	0	$113,853
Post-Amendment	$4.49	25,896	5,024	$114,323
Change from the Baseline	**$0.09**	**0**	**5,024**	**$470**

Note: Values in *Change from the Baseline* rows are calculated by subtracting the corresponding baseline value from the post-amendment value.

5.4.14 Indicate Whether an Imported Chemical Substance Is Physically at the Reporting Site

EPA is requiring submitters to indicate whether an imported chemical substance is physically at the reporting site. This will add one data element for EPA to process.

Table 5-21 shows the estimated Agency burden of the amendment, using the baseline burden estimates found in Table 5-4. The Agency estimates a burden increase of 23 hours as a result of this amendment.

Table 5-21: Change in Agency Burden as a Result of Indicating Whether an Imported Chemical Substance is Physically at the Reporting Site

	Burden to Process Information (hours per report) (a)	Number of Reports (b)	Agency Burden (hours) (c) = (a)*(b)
Baseline	0.042	25,896	1,092
Post-Amendment	0.043	25,896	1,115
Change from the Baseline	**0.001**	**0**	**23**

Note: Values in *Change from the Baseline* rows are calculated by subtracting the corresponding baseline value from the post-amendment value.

Table 5-22 shows the estimated change in cost to EPA as a result of the amendment. The Agency estimates a cost increase of approximately $2,400.

Table 5-22: Change in Agency Cost as a Result of Indicating Whether an Imported Chemical Substance is Physically at the Reporting Site

	Cost to Process Information (2008$ per report) (a)	Number of Reports (b)	Agency Cost (2008$) (c) = (a)*(b)
Baseline	$4.40	25,896	$113,853
Post-Amendment	$4.49	25,896	$116,275
Change from the Baseline	**$0.09**	**0**	**$2,422**

Note: Values in *Change from the Baseline* rows are calculated by subtracting the corresponding baseline value from the post-amendment value.

5.4.15 Report Production Volume Exported

EPA is requiring all submitters to provide the exported chemical substance volume in Section II of the report. This will add one data element to Part II of Form U for EPA to process.

Table 5-23 shows the estimated Agency burden of the amendment, using the baseline burden estimates found in Table 5-4. The Agency estimates a burden increase of 23 hours as a result of this amendment.

Table 5-23: Change in Agency Burden as a Result of Requiring the Reporting of Export Volume

	Burden to Process Information (hours per report) (a)	Number of Reports (b)	Agency Burden (hours) (c) = (a)*(b)
Baseline	0.042	25,896	1,092
Post-Amendment	0.043	25,896	1,115
Change from the Baseline	**0.001**	**0**	**23**

Note: Values in *Change from the Baseline* rows are calculated by subtracting the corresponding baseline value from the post-amendment value.

Table 5-24 shows the estimated change in cost to EPA as a result of the amendment. The Agency estimates a cost increase of approximately $2,400.

Table 5-24: Change in Agency Cost as a Result of Requiring the Reporting of Export Volume

	Cost to Process Information (2008$ per report) (a)	Number of Reports (b)	Agency Cost (2008$) (c) = (a)*(b)
Baseline	$4.40	25,896	$113,853
Post-Amendment	$4.49	25,896	$116,275
Change from the Baseline	**$0.09**	**0**	**$2,422**

Note: Values in *Change from the Baseline* rows are calculated by subtracting the corresponding baseline value from the post-amendment value.

5.4.16 Identify Whether Chemical Substance is to be Recycled, Remanufactured, Reprocessed, or Reused

EPA is revising Form U for submitters to indicate whether a chemical substance is to be recycled, remanufactured, reprocessed, or reused. This will add one data element to Part II of Form U for EPA to process.

Table 5-25 shows the estimated Agency burden of the amendment, using the baseline burden estimates found in Table 5-4. The Agency estimates a burden increase of 23 hours as a result of this amendment.

Table 5-25: Change in Agency Burden as a Result of Indicating Whether Chemical Substance is to be Recycled, Remanufacture, Reprocessed, or Reused

	Burden to Process a Checkbox to Indicate Whether a Product is Recycled, Remanufactured, Reprocessed, or Reused (hours per report) (a)	Number of Reports (b)	Agency Burden (hours) (c) = (a)*(b)
Baseline	0.042	25,896	1,092
Post-Amendment	0.043	25,896	1,115
Change from the Baseline	**0.001**	**0**	**23**

Note: Values in *Change from the Baseline* rows are calculated by subtracting the corresponding baseline value from the post-amendment value.

Table 5-26 shows the estimated change in cost to EPA as a result of the amendment. The Agency estimates a cost increase of approximately $2,400.

Table 5-26: Change in Agency Cost as a Result of Indicating Whether Chemical Substance is to be Recycled, Remanufactured, Reprocessed, or Reused

	Cost to Process a Checkbox to Indicate Whether a Product is Recycled, Remanufactured, Reprocessed, or Reused (2008$ per report) (a)	Number of Reports (b)	Agency Cost (2008$) (c) = (a)*(b)
Baseline	$4.40	25,896	$113,853
Post-Amendment	$4.49	25,896	$116,275
Change from the Baseline	**$0.09**	**0**	**$2,422**

Note: Values in *Change from the Baseline* rows are calculated by subtracting the corresponding baseline value from the post-amendment value.

5.4.17 Concentration Ranges

EPA is amending the ranges used to report chemical substance concentration in §710.52(C)(3) and (4) by changing the ranges to: (1) less than one percent by weight, (2) at least one percent but less than 30 percent by weight, (3) at least 30 percent but less than 60 percent by weight, (4) at least 60 percent but less than 90 percent by weight, and (5) at least 90 percent by weight.

This is a technical correction to eliminate gaps in the ranges as previously listed in the rule. EPA assumes it will have no impact on Agency burden or cost.

5.4.18 Revise Industrial Function Categories

The Agency is revising the industrial function categories by adding eight new categories, eliminating six existing categories and requiring submitters to write in text when they claim "Other" as the category. This would add one data element to Part III of Form U for EPA to process. EPA expects the number of submitters who select "Other" to decrease, for a total of 603 submitters expected to write-in this text descriptor (see Section 4.4.18 for more information).

Table 5-27 shows the estimated Agency burden of the amendment, using the baseline burden estimates found in Table 5-4. The Agency estimates a burden increase of 0.54 hours as a result of this amendment.

Table 5-27: Change in Agency Burden as a Result of Revising the Industrial Function Categories

	Burden to Process Function Categories(hours per report) (a)	Number of Reports with Function Categories (b)	Burden to Process Write-in Text for "Other" (hours) (c)	Number of Reports with Text Descriptor for "Other" (d)	Burden (hours) (e) = (a*b)+ (c*d)
Baseline	0.05	17,075	0.000	0	918.82
Post-Amendment	0.05	17,075	0.001	603	919.36
Change from the Baseline	**0.00**	**0**	**0.001**	**603**	**0.54**

Note: Values in *Change from the Baseline* rows are calculated by subtracting the corresponding baseline value from the post-amendment value.

Table 5-28 shows the estimated change in cost to EPA as a result of the amendment. The Agency estimates a cost increase of approximately $56.

Table 5-28: Change in Agency Cost as a Result of Revising the Industrial Function Categories

	Cost to Process Industrial Function Categories (2008$ per report) (a)	Number of Reports with Industrial Function Categories (b)	Cost to Process Write-in Text for "Other" (2008$) (c)	Number of Reports with Text Descriptor for "Other" (d)	Cost (2008$) (e) = (a*b)+ (c*d)
Baseline	$5.61	17,075	$0.00	0	$95,835
Post-Amendment	$5.61	17,075	$0.09	603	$95,892
Change from the Baseline	**$0.00**	**0**	**$0.09**	**603**	**$56**

Note: Values in *Change from the Baseline* rows are calculated by subtracting the corresponding baseline value from the post-amendment value.

5.4.19 Replace NAICS Codes with Industrial Sectors

EPA is replacing the five-digit North American Industrial Classification System (NAICS) codes with 48 Industrial Sectors. This amendment will not change the Agency's data processing burden. EPA expects the Agency's burden to process the industrial sectors will remain the same regardless of the code system used.

5.4.20 Revise Consumer and Commercial Product Categories

The Agency is revising the consumer and commercial product categories by adding 12 new categories and requiring submitters to write in text when they select "Other" as a consumer or

commercial product category. EPA expects 604 submitters to write in this text descriptor for "Other" (see Section 4.4.20 for more information), adding one data element to Part III of Form U for EPA to process.

Table 5-29 shows the estimated Agency burden of the amendment, using the baseline burden estimates found in Table 5-4. The Agency estimates a 0.54 hour burden increase as a result of this amendment.

Table 5-29: Change in Agency Burden as a Result of Revising the Consumer and Commercial Product Categories

	Burden to Process Consumer or Commercial Product Categories (hours per report) (a)	Number of Reports with Consumer or Commercial Product Categories (b)	Burden to Process Write-in Text for "Other" (hours) (c)	Number of Reports with Write-in Text for "Other" (d)	Burden (hours) (e) = (a)*(b)+ (c)*(d)
Baseline	0.05	17,075	0.000	0	918.82
Post-Amendment	0.05	17,075	0.001	604	919.36
Change from the Baseline	**0.00**	**0**	**0.001**	**604**	**0.54**

Note: Values in *Change from the Baseline* rows are calculated by subtracting the corresponding baseline value from the post-amendment value.

Table 5-30 shows the estimated change in cost to EPA as a result of the amendment. The Agency estimates a cost increase of approximately $56.

Table 5-30: Change in Agency Cost as a Result of Revising the Consumer and Commercial Product Categories

	Cost to Process Consumer or Commercial Product Categories (hours per report) (a)	Number of Reports with Consumer or Commercial Product Categories (b)	Cost to Write-in Text for "Other" (2008$) (c)	Number of Reports with Write-in Text for "Other" (d)	Cost (2008$) (e) = (a)*(b)+ (c)*(d)
Baseline	$5.61	17,075	$0.00	0	$95,835
Post-Amendment	$5.61	17,075	$0.09	604	$95,892
Change from the Baseline	**$0.00**	**0**	**$0.09**	**604**	**$56**

Note: Values in *Change from the Baseline* rows are calculated by subtracting the corresponding baseline value from the post-amendment value.

5.4.21 Designation of Consumer or Commercial Use

EPA is requiring the identification of whether the downstream use is a consumer or a commercial use, or both, adding one data element to Part III of Form U for EPA to process.

Table 5-31 shows the estimated Agency burden of the amendment, using the baseline burden estimates found in Table 5-4. The Agency expects a burden increase of 15 hours as a result of this amendment.

Table 5-31: Change in Agency Burden as a Result of Designation of Consumer or Commercial Use

	Burden per Report (hours)	Number of Reports with Part III	Burden (hours)
Baseline	0.054	17,075	919
Post-Amendment	0.055	17,075	934
Change from the Baseline	**0.001**	**0**	**15**

Note: Values in *Change from the Baseline* rows are calculated by subtracting the corresponding baseline value from the post-amendment value.

Table 5-32 shows the estimated change in cost to EPA as a result of the amendment. The Agency estimates a cost increase of approximately $1,600.

Table 5-32: Change in Agency Cost as a Result of Designation of Consumer or Commercial Use

	Cost per Report (2008$)	Number of Reports with Part III	Cost (2008$)
Baseline	$5.61	17,075	$95,835
Post-Amendment	$5.71	17,075	$97,433
Change from the Baseline	**$0.09**	**0**	**$1,597**

Note: Values in *Change from the Baseline* rows are calculated by subtracting the corresponding baseline value from the post-amendment value.

5.4.22 Number of Commercial Workers Reasonably Likely To Be Exposed

EPA is requiring submitters of reports with processing and use information to provide the number of commercial workers who are reasonably likely to be exposed to a chemical substance, in ranges. This amendment adds one data element to Part III of Form U for EPA to process.

Table 5-33 shows the estimated Agency burden of the amendment, using the baseline burden estimates found in Table 5-4. The Agency expects a burden increase of 15 hours as a result of this amendment.

Table 5-33: Change in Agency Burden as a Result of Requiring the Number of Commercial Workers Reasonably Likely To Be Exposed

	Burden per Report (hours)	Number of Reports with Part III	Burden (hours)
Baseline	0.054	17,075	919
Post-Amendment	0.055	17,075	934
Change from the Baseline	**0.001**	**0**	**15**

Note: Values in *Change from the Baseline* rows are calculated by subtracting the corresponding baseline value from the post-amendment value.

Table 5-34 shows the estimated change in cost to EPA as a result of the amendment. The Agency estimates a cost increase of approximately $1,600.

Table 5-34: Change in Agency Cost as a Result of Requiring the Number of Commercial Workers Reasonably Likely To Be Exposed

	Cost per Report (2008$)	Number of Reports with Part III	Cost (2008$)
Baseline	$5.61	17,075	$95,835
Post-Amendment	$5.71	17,075	$97,433
Change from the Baseline	**$0.09**	**0**	**$1,597**

Note: Values in *Change from the Baseline* rows are calculated by subtracting the corresponding baseline value from the post-amendment value.

5.4.23 Changes to the Standard for the Reporting of Processing and Use Information

EPA is eliminating the "not readily obtainable (NRO)" standard and replacing it with the more stringent "known to or reasonably ascertainable by" standard for reporting of processing and use information. This amendment does not affect the number of submitters or the number of data elements in Form U, and therefore, EPA assumes it will not increase the Agency burden or cost.

5.4.24 Chemical Identity CBI Claims

EPA is proposing, when a submitter asserts a claim of confidentiality for the chemical identity of a substance listed on the public portion of the Master Inventory File, the Agency may make the information available to the public without further notice to the submitter. See the regulatory text at 40 CFR 711.30(e). Any such action on EPA's part would be as part of regular and routine use of the data and will not create any additional burden.

5.4.25 Upfront Substantiation for Processing and Use Information CBI Claims

EPA is requiring upfront substantiation for all CBI claims in the processing and use section of Form U. This amendment adds two data elements per item claimed as CBI, to Part III of Form U for EPA to process. EPA expects 2,928 reports will claim processing and use information as CBI, and on average they will make three CBI claims per report (see section 4.4.25 for more information).

Table 5-35 shows the estimated Agency burden of the amendment, using the baseline burden estimates found in Table 5-4. The Agency expects a burden increase of eight hours as a result of this amendment.

Table 5-35: Change in Agency Burden as a Result of Requiring Upfront Substantiation for CBI Claims

	Burden per Report (hours)	Number of Reports with Part III	Burden for Upfront CBI Substantiation	Number of Reports with Substantiated	Burden (hours)

			for CBI Claims in Part III	CBI Claims in Part III	
Baseline	0.05	17,075	0.000	0	919
Post-Amendment	0.05	17,075	0.003	2,928	927
Change from the Baseline	**0.00**	**0**	**0.003**	**2,928**	**8**

Note: Values in *Change from the Baseline* rows are calculated by subtracting the corresponding baseline value from the post-amendment value.

Table 5-36shows the estimated change in cost to EPA as a result of the amendment. The Agency estimates a cost increase of approximately $822.

Table 5-36: Change in Agency Cost as a Result of Requiring Upfront Substantiation for CBI Claims

	Cost per Report (2008$)	Number of Reports with Part III	Cost for Upfront CBI Substantiation for CBI Claims in Part III	Number of Reports with Substantiated CBI Claims in Part III	Cost (2008$)
Baseline	$5.61	17,075	$0.00	0	$95,835
Post-Amendment	$5.61	17,075	$0.28	2,928	$96,657
Change from the Baseline	**$0.00**	**0**	**$0.28**	**2,928**	**$822**

Note: Values in *Change from the Baseline* rows are calculated by subtracting the corresponding baseline value from the post-amendment value.

5.4.26 Limitation on Confidentiality Claims for Data Elements Identified as "Not Known or Reasonably Ascertainable"

EPA is no longer allowing CBI claims for data elements identified as "not known or reasonably ascertainable." EPA expects there will be no change in Agency burden as a result of this amendment because the number of submitters and data elements will not change.

5.4.27 Require Electronic Submissions over the Internet

EPA is requiring all Form Us to be submitted to the Agency electronically, via e-IURweb and EPA's Central Data Exchange (CDX) over the Internet. EPA expects mandatory electronic submission will reduce significantly the Agency's data processing time. Based on a study conducted by EPA, "A Business Case Analysis of EPA's Central Data Exchange" (EPA, 2007) on of the costs and benefits of the CDX system, EPA's processing burden is expected to decrease by 88.6 percent, not including the operating and maintenance and troubleshooting costs included in the general CDX operating budget.

Table 5-37 shows the estimated Agency burden of the amendment, using the baseline burden estimates found in Table 5-4. The Agency estimates a burden decrease of approximately 1,800 hours as a result of this amendment.

Table 5-37: Change in Agency Burden as a Result of Requiring Electronic Submission

	Burden per Report to Process Part I (hours per site)	Number of Sites	Burden per Report to Process Part II(hours per report)	Number of Reports	Burden per Report to Process Part III (hours per site)	Number of Sites with Part III	Burden (hours)
Baseline	0.017	4,085	0.0422	25,896	0.054	17,075	2,080
Post-Amendment	0.002	4,085	0.005	25,896	0.006	17,075	238
Change from the Baseline	**-0.015**	**0**	**-0.0373**	**0**	**-0.048**	**0**	**-1,842**

Note: Values in *Change from the Baseline* rows are calculated by subtracting the corresponding baseline value from the post-amendment value.

Table 5-38 shows the estimated change in cost to EPA as a result of the amendment. The Agency estimates a cost savings of approximately $192,200.

Table 5-38: Change in Agency Cost as a Result of Requiring Electronic Submission

	Cost per Report to Process Part I (2008$)	Number of Sites	Cost per Report to Process Part II(2008$ per report)	Number of Reports	Cost per Report to Process Part III (2008$ per site)	Number of Sites with Part III	Cost (2008$)
Baseline	$1.78	4,085	$4.40	25,896	$5.61	17,075	$216,949
Post-Amendment	$0.20	4,085	$0.50	25,896	$0.64	17,075	$24,794
Change from the Baseline	**-$1.57**	**0**	**-$3.89**	**0**	**-$4.97**	**0**	**-$192,155**

Note: Values in *Change from the Baseline* rows are calculated by subtracting the corresponding baseline value from the post-amendment value.

5.4.28 Updated e-IURweb Reporting Software

EPA developed the e-IUR reporting software for use by manufacturers (including importers) in preparing and submitting reports electronically during the 2006 IUR reporting cycle. For the 2012 submission period, EPA will provide a free, web-based application in place of the 2006 downloadable software. The updated e-IURweb reporting tool for the 2012 IUR collection will feature several improved capabilities over the current e-IUR reporting tool. Although not quantified here, EPA expects updated e-IURweb tool will reduce Agency burden to process and correct errors in the form.

5.4.29 Electronic Signature Process

In order to submit IUR data electronically to EPA via the Central Data Exchange (CDX), individuals acting on behalf of the submitter must first register with CDX. To register in CDX, the CDX registrant (also referred to as "Electronic Signature Holder") downloads two forms: the Electronic Signature Agreement and the Verification by Company Authorizing Official Form. Registration enables CDX to perform two important functions: authenticate identity, and verify authorization. For authentication of identity, the submitter completes the Electronic Signature

Agreement form, signs and dates it, has the form notarized, and mails it back to EPA. The Verification of Authorization form requires the signatures of the authorized company official and anyone he/she authorizes to submit support documents for the company.

The storage and processing of these forms is expected to generate a small burden for EPA. To estimate the Agency burden of processing, reviewing, approving, and filing the wet ink copies of these forms, EPA used the burden estimates found in the *Cross-Media Electronic Reporting Rule (CROMERR) Cost Benefit Analysis: Final Rule* (EPA, 2004). EPA estimates the burden to receive, process, review, approve, and file wet-ink signature agreements for new submitters or submissions as a result of employee turnover is 0.17 hours per form (EPA, 2004). All 4,085 sites will be required to submit new electronic signature agreements in the 2012 submission year. In future reporting cycles, only sites which have not previously registered with CDX or sites with a new authorized company official must submit the electronic signature agreements. EPA expects this number to be negligible. Therefore EPA expects the Agency burden of this amendment to be approximately 645 hours (4,085 sites x 0.17 hours per site).

The processing, reviewing, approving, and filing of the electronic signature agreements is expected to be completed by the GS-13 Step-3 employee currently responsible for data processing, systems development, and contract oversight and management. EPA multiplied the burden estimate of 645 hours with an hourly wage rate of $67.22. This wage rate was calculated by dividing the annual total loaded wage of the GS-13 Step 3 employee ($139,819) found in Table 5-1 by one FTE of 2,080 hours. Therefore, the total cost to the Agency of processing, reviewing, approving, and filing of the electronic signature agreement form is approximately $46,700 during the 2012 reporting cycle.

5.4.30 Modifications Specifically Affecting Importers

For purposes of IUR, importers currently are allowed to report the IUR information jointly with the foreign manufacturer of the chemical substance. Under the amendment, the foreign manufacturer must now register with CDX and submit its report electronically. Previously, joint submissions could not be made electronically.

For the 2006 IUR reporting cycle, EPA set aside joint submissions until both were received and matched. Oftentimes, EPA had no way to determine whether a submission was a "joint" submission, which increased the time required for manual processing of the data. EPA anticipates the use of the reporting tool will help to make joint IUR reporting easier for industry. Although not quantified, EPA also anticipates the electronic reporting tool will streamline EPA's processing of the IUR information submitted in the 2012 reporting cycle, thus reducing Agency burden.

5.4.31 Modify Reporting Frequency

EPA is modifying the IUR reporting cycle from five years to four years. This will increase the Agency burden because the Agency will receive and process IUR data more frequently. The annual baseline Agency burden is two FTEs, or 4,160 hours. Table 5-39 contains the change in burden over a 26-year period. In total, EPA estimates the Agency will spend 4,160 more hours over a 26-year period as a result of modifying the IUR reporting frequency.

Table 5-39: Change in Agency Burden as a Result of Modifying the Reporting Frequency

Reporting Cycle[1]	Year(s)	Baseline Burden	Post-Amendment Burden	Change in Burden
		(Hours)	(Hours)	(Hours)
1	**2006 to 2012**	4,160	4,160	0
2	**2013 to 2017**	4,160	--	0
	2013 to 2016	--	*4,160*	
3	**2018 to 2022**	4,160	--	0
	2017 to 2020	--	*4,160*	
4	**2023 to 2027**	4,160	--	0
	2021 to 2024	--	*4,160*	
5	**2028 to 2032**	4,160	--	0
	2025 to 2028	--	*4,160*	
6	***2029 to 2032***	--	*4,160*	4160
Total		**20,800**	***24,960***	**4,160**
Annual Average		**800**	**960**	**160**

Note: [1] The non-italicized reporting cycles are baseline, five-year cycles, and the italicized reporting cycles are four-year cycles

Table 5-40 contains the 26-year cost estimate as a result of modifying the reporting frequency. The baseline cost estimate is for data entry only and is discussed in Section 5.2. This table includes extramural costs which are incurred by the Agency. In total, EPA estimates it will cost the Agency approximately $466,100 to increase the frequency of reporting from a five-year reporting cycle to a four- year reporting cycle over a 26-year period. EPA estimates the annualized changes in cost would be $16,463 and $14,285 with a three percent and seven percent discount rate, respectively.

Table 5-40: Change in Agency Cost as a Result of Modifying the Reporting Frequency

Reporting Cycle	Year(s)	Baseline Cost	Post-Amendment Cost	Change in Cost
		(2008$)	(2008$)	(2008$)
1	**2006 to 2012**	$466,132.9	$466,132.9	$0.0
2	**2013 to 2017**	$466,132.9	--	$0.0
	2013 to 2016	--	*$466,132.9*	
3	**2018 to 2022**	$466,132.9	--	$0.0
	2017 to 2020	--	*$466,132.9*	
4	**2023 to 2027**	$466,132.9	--	$0.0
	2021 to 2024	--	*$466,132.9*	
5	**2028 to 2032**	$466,132.9	--	$0.0
	2025 to 2028	--	*$466,132.9*	
6	***2029 to 2032***	--	*$466,132.9*	$466,132.9
Total		**$2,330,664**	***$2,796,797***	**$466,133**
Annualized @ 3%		$83,030	$99,493	$16,463
Annualized @ 7%		$74,650	$88,935	$14,285

Note: The non-italicized reporting cycles are baseline, five-year cycles, and the italicized reporting cycles are four-year cycles

5.5 Total Agency Cost of All Modifications

As EPA did with the industry cost calculations, EPA calculated the cost for each individual amendment as a stand-alone cost, and did not take into account the effect of individual amendments on the others. For this reason, when calculating the total Agency cost, EPA could not simply add the changes in burden for each amendment, but had to consider the interactions among the amendments. For a more detailed discussion of the interactions among the amendments, see Section 4.5. In the 2012 reporting cycle the Agency will also experience additional burden of accession number requests (see Section 5.4.11). The Agency will have to process electronic signature agreements (see Section 5.4.29) in both the 2012 and subsequent reporting cycles. However, in reporting cycles following the 2012 reporting cycle, EPA will only need to process electronic signature agreements from new sites, or approximately 5 percent of all sites. As shown in Table 5-37, EPA expects the electronic submission amendment will decrease Agency burden of processing a Form U by approximately 88.6 percent.

Table 5-41: Change in Agency Burden as a Result of All the IUR Modifications (First Reporting Cycle)

Option	Burden per Part I of Report (hours)	Burden per Part II of Report (hours)	Burden per Part III of Report (hours)
Baseline	**0.0170**	**0.0422**	**0.0538**
Production Volume Used On-Site	--	0.0002	--
Industrial Function Categories	--	--	0.00003
Recycled, Remanufactured, Reprocessed, or Reused,	--	0.0009	--
Whether Chemical Substance is Physically at Site	--	0.0009	--
Exported Volume Reporting	--	0.0009	--
Consumer/Commercial Product Categories	--	--	0.00003
Number of Workers Exposed	--	--	0.0009
CBI	--	--	0.0005
Production Volume in Off-Years	--	0.0009	--
Electronic Submission	-0.0151	-0.0407	-0.0489
Ascension Number Requests (First Reporting Cycle)	-	0.0058	
Electronic Signature Agreements	0.1700	-	
Total Change from the Baseline with All Amendments	***0.1549***	***-0.0311***	***-0.0475***
Total, All Amendments	**0.1719**	**0.0111**	**0.0063**

Table 5-42: Change in Agency Burden as a Result of All the IUR Modifications (Future Reporting Cycles)

Option	Burden per Part I of Report (hours)	Burden per Part II of Report (hours)	Burden per Part III of Report (hours)
Baseline	**0.0170**	**0.0422**	**0.0538**
Production Volume Used On-Site	--	0.0002	--
Industrial Function Categories	--	--	0.00003
Recycled, Remanufactured, Reprocessed, or Reused,	--	0.0009	--
Whether Chemical substance is Physically at Site	--	0.0009	--
Exported Volume Reporting	--	0.0009	--
Consumer/Commercial Product Categories	--	--	0.00003
Number of Workers Exposed	--	--	0.0009
CBI	--	--	0.0005
Production Volume in Off-Years	--	0.0027	--
Electronic Submission	-0.0151	-0.0423	-0.0489
Electronic Signature Agreements	0.0081	--	--
Total Change from the Baseline with All Amendment	***-0.0070***	***-0.0367***	***-0.0475***
Total, All Amendments	**0.0100**	**0.0054**	**0.0063**

To calculate the combined effect on Agency costs when all amendments are enacted, EPA used the baseline number of reports and sites taken from the 2006 IUR database (EPA, 2008c) and the baseline per report cost and burden estimates as found in Table 5-4. The change in the

number of reports due to the effect of the amendments combined is calculated in Table 4-48 and Table 4-49 for the first and future reporting cycles, respectively. EPA added the cost of one additional FTE (2,080 hours) to the baseline hours to account for the additional activities conducted by the GS-13 employee (see Table 5-3) and all extramural costs not related to data entry (see Table 5-2).

Table 5-43 presents the total Agency burden for all the amendments combined. In total, EPA estimates the Agency will save 940 hours during the first reporting cycle and 1,678 hours in each future reporting cycle. Table 5-44 presents the total Agency cost estimates; the Agency will save approximately $68,000 in the first reporting cycle and $175,000 in future reporting cycles as a result of the IUR amendments. The baseline and post-amendment costs both contain the cost of all extramural activities, found in Table 5-2.

Table 5-43: Total Agency Burden for All Amendments Combined

	Burden per Report (Part I) (hours) (a)	Number of Sites (b)	Burden to Process Part II (hours) (c)	Number of Reports (with Part II) (d)	Burden to Process Part III (hours) (e)	Number of Reports (with Part III) (f)	Agency Burden (hours) (g) = (a*b)+(c*d)+(e*f)[1,2]
First-year Baseline	0.017	4,085	0.042	25,896	0.05381	17,075	4,160
First year, Post Amendment	0.1719	4,085	0.012	25,853	0.00631	20,718	3,220
Change from the Baseline, First year[3]	**0.15**	**0**	**-0.030**	**-43**	**-0.05**	**3,643**	**-940**
Future-cycle Baseline	0.017	4,085	0.042	25,896	0.054	17,075	4,160
Future-cycle, Post Amendment	0.01	4,289	0.005	30,935	0.01	30,287	2,482
Change from the Baseline, Future cycles[3]	**-0.01**	**204**	**-0.04**	**5,039**	**-0.05**	**13,212**	**-1,678**

Notes:
[1] Totals include an additional 2,080 hours to account for additional Agency activities conducted one GS-13 employee.
[2] Total may not sum due to rounding.
[3] Values in *Change from the Baseline* rows are calculated by subtracting the corresponding baseline value from the post-amendment value.

Table 5-44: Total Agency Cost of All Amendments Combined

	Cost per Report (Part I) (2008$) (a)	Number of Sites (b)	Cost to Process Part II (2008$) (c)	Number of Reports (with Part II) (d)	Cost to Process Part III (2008$) (e)	Number of Reports (with Part III) (f)	Agency Cost (2008$) (g) = (a*b)+ (c*d)+(e*f)
First-year Baseline	$1.78	4,085	$4.40	25,896	$5.61	17,075	$466,133
First year, Post Amendment	$11.63	4,085	$3.38	25,853	$0.70	20,718	$398,571
Change from the Baseline, First year[3]	**$9.85**	**0**	**-$1.02**	**-43**	**-$4.91**	**3,643**	**-$67,562**
Future-cycle Baseline	$1.78	4,085	$4.40	25,896	$5.61	17,075	$466,133
Future-cycle, Post Amendment	$0.75	4,289	$0.58	30,935	$0.70	30,287	$291,515
Change from the Baseline, Future cycles[3]	**-$1.03**	**204**	**-$3.82**	**5,039**	**-$4.91**	**13,212**	**-$174,618**

Notes:
[1] Totals include an additional $149,387 to account for additional Agency activities conducted one GS-13 employee and contactor staff.
[2] Total may not sum due to rounding.
[3] Values in *Change from the Baseline* rows are calculated by subtracting the corresponding baseline value from the post-amendment value.

To calculate the Agency burden per report, EPA first followed the same methodology used to calculate the baseline burden per data element (see Section 5.3). EPA calculated the total number of data elements in the revised Form U (166 elements in the first reporting cycle) and the percentage of data elements in each section of the form, and derived a weighted percentage of elements in each section of the form. For example, the revised Part I contains 24 data elements, and 4,085 sites are expected to submit Part I when all the amendments are considered. These 114,380 data elements (28 x 4,085 = 114,380) account for approximately 2.9 percent of all data elements. Similarly, 49.1percent of all data elements are in Part II of the form, and 47.9 percent are in Part III. The Agency then multiplied the total variable burden of Form U processing, 274 hours, by the percentage of data elements in a section and divided by the total number reports submitted for each section. The total burden per data element does not account for the burden associated with processing electronic signature forms or accession number requests, because these are not data elements on the Form U. To calculate the total variable burden to the Agency, EPA took the total burden estimate of 3,220 hours (Table 5-43) and subtracted the fixed burden of 2,080 hours, the burden associated with processing electronic signature agreements, 695.5

hours (Section 5.4.29) and the burden associated with accession number request 171.5 hours (Table 5-15). An example of this calculation can be seen in Equation 3 for Part I.

Equation 3: Burden to Process Part I per Report = (274 hours x 0.03239) / 4,085 = 0.002 hours

The burden per section was then divided by the total number of data items in that section to calculate the burden per item, 0.00008 hours (approximately 0.0049 minutes) (See Equation 2).

Equation 4: Burden per Data Element = 0.002 hours / 24 = 0.00008 hours

EPA then added the burden for processing electronic signature forms and ascension number requests, which were not included in the per data element burden. EPA added the burden per report for both activities from Table 5-43 to calculate the total burden per-report. Therefore for section one, the per report burden of processing electronic signatures (0.17 hours) was added to the total burden of processing all data elements in the section (0.002 hours) to calculate the total burden per report.

Equation 5: Burden per Report Section = (0.00008 hours x 24 data elements) + 0.17 hours = 0.1720 hours

Table 5-45 contains the total post-amendment burden to the Agency at the per-report and per-data element level. Because of the electronic submission, the Agency burden increase by 0.77 hours per full report in both the first reporting cycles and decreases by 0.091 hours in future reporting cycles despite 43 data elements being added to Form U in the second cycle.

Table 5-45: Agency Burden per Report when All Amendments are Combined (First Cycle)

Form U Section	Number of Data Elements			Burden per Data Element (hours)			Burden for Processing Other Submissions Related to IUR Reporting (hours)			Total Burden per Report (hours)		
	Baseline	Post-Amendment	Change from Baseline	Baseline	Post-Amendment	Change from Baseline	Baseline	Post-Amendment	Change from Baseline	Baseline	Post-Amendment	Change from Baseline
Part I	19	24	**5**	0.0009	0.00008	**-0.0008**	0.0000	0.1700	**0.1700**	0.017	0.1720	**0.155**
Part II	47	64	**17**	0.0009	0.00008	**-0.0008**	0.0000	0.0066	**0.0066**	0.042	0.0118	**-0.030**
Part III	60	78	**18**	0.0009	0.00008	**-0.0008**	0.0000	0.0000	**0.0000**	0.054	0.0063	**-0.047**
Total (Full Report)	**126**	**166**	**40**	-	-	-	-	-	-	**0.113**	**0.190**	**0.077**

Note: Totals may not exactly match totals presented in Table 5-43 due to rounding

Table 5-46: Agency Burden per Report when All Amendments are Combined (Future Cycles)

Form U Section	Number of Data Elements			Burden per Data Element (hours)			Burden for Processing Other Submissions Related to IUR Reporting (hours)			Total Burden per Report (hours)		
	Baseline	Post-Amendment	Change from Baseline	Baseline	Post-Amendment	Change from Baseline	Baseline	Post-Amendment	Change from Baseline	Baseline	Post-Amendment	Change from Baseline
Part I	19	24	5	0.0009	0.00008	**-0.0008**	0.0000	0.0081	**0.0081**	0.017	0.0100	**-0.007**
Part II	47	67	20	0.0009	0.00008	**-0.0008**	0.0000	0.0000	**0.0000**	0.042	0.0054	**-0.037**
Part III	60	78	18	0.0009	0.00008	**-0.0008**	0.0000	0.0000	**0.0000**	0.054	0.0063	**-0.047**
Total (Full Report)	**126**	**169**	**43**	-	-	-	-	-	-	**0.113**	**0.022**	**-0.091**

Note: Totals may not exactly match totals presented in Table 5-43 due to rounding

To calculate the cost to EPA, the process described above was repeated; however, instead of using the hourly burden, EPA used the combined cost for the quality control of data entry, document receipt, tracking, data entry processing electronic signature forms and ascension number requests which was $31,691. This cost was calculated by subtracting the fixed Agency costs, $249,184 (see Table 5-3), processing electronic signature forms $46,681 (Section 5.4.29) and the cost associated with ascension number requests $11,528 (Table 5-16) from the total post-amendment cost of $ 398,571. Thus, EPA calculated it costs the Agency approximately $0.01 to process a single data element of Form U. The total Agency cost per report is approximately $15.72 in the first reporting cycle and $2.03 in all future cycles. Table 5-47 and Table 5-48 contain the Agency cost per report by section of Form U for the first and future reporting cycles.

Table 5-47: Agency Cost per Report When All Amendments are Combined (First Reporting Cycle)

Form U Section	Number of Data Elements			Cost per Data Element (2008$)			Cost for Processing Other Submissions Related to IUR Reporting (2008$)			Total Cost per Report (2008$)		
	Baseline	Post-Amendment	Change from Baseline	Baseline	Post-Amendment	Change from Baseline	Baseline	Post-Amendment	Change from Baseline	Baseline	Post-Amendment	Change from Baseline
Part I	19	24	5	$0.09	$0.01	-$0.08	$0.00	$11.43	$11.43	$1.71	$11.64	**$9.93**
Part II	47	64	17	$0.09	$0.01	-$0.08	$0.00	$2.82	$2.82	$4.23	$3.39	**-$0.84**
Part III	60	78	18	$0.09	$0.01	-$0.08	$0.00	$0.00	$0.00	$5.40	$0.69	**-$4.71**
Total (Full Report)	**126**	**166**	**40**	**-**	**-**					**$11.34**	**$15.72**	**$4.38**

Note: Totals may not exactly match totals presented in Table 5-44 due to rounding

Table 5-48: Agency Cost per Report When All Amendments are Combined (Future Reporting Cycles)

Form U Section	Number of Data Elements			Cost per Data Element (2008$)			Cost for Processing Other Submissions Related to IUR Reporting (2008$)			Total Cost per Report (2008$)		
	Baseline	Post-Amendment	Change from Baseline	Baseline	Post-Amendment	Change from Baseline	Baseline	Post-Amendment	Change from Baseline	Baseline	Post-Amendment	Change from Baseline
Part I	19	24	5	$0.09	$0.01	-$0.08	$0.00	$0.54	**$0.54**	$1.71	$0.76	**-$0.95**
Part II	47	67	20	$0.09	$0.01	-$0.08	$0.00	$0.00	**$0.00**	$4.23	$0.59	**-$3.64**
Part III	60	78	18	$0.09	$0.01	-$0.08	$0.00	$0.00	**$0.00**	$5.40	$0.69	**-$4.71**
Total (Full Report)	**126**	**169**	**43**	**-**	**-**					**$11.34**	**$2.03**	**-$9.31**

Note: Totals may not exactly match totals presented in Table 5-44 due to rounding

Table 5-49 contains Agency costs per-data element and per-report separated by EPA and contractor staff. Using the values in Table 5-3, EPA estimates in the baseline, approximately 56.4 percent of the variable Agency costs are attributed to EPA staff ($122,317/$216,949). The remaining 43.6 percent of data processing costs are incurred by contractor staff ($94,632/$216,949). EPA does not expect the distribution of per-data element costs between Agency and contractor staff to change as a result of the rule. Thus, to calculate the post-amendment cost attributed to contractor staff, EPA multiplied the per-data element cost by 43.6 percent. All processing of electronic signature forms, and the processing of accession number requests is expected to be conducted by Agency staff. Therefore, the per-report costs of processing submissions related to IUR reporting was added to the Agency staff total. The cost to contract staff is approximately $0.64 in the first reporting cycle and $0.65 in future reporting cycles per report. The EPA staff cost is approximately $15.08 in the first reporting cycle and $1.38 in future reporting cycles.

Table 5-49: Agency Cost per Report when All Amendments are Combined

Form U Section	Cost per Data Element (2008$)			Total Cost per Report (2008$)[1]		
	Agency Staff Cost	Contractor Cost	Total Post-Amendment Cost	Agency Staff Cost	Contractor Cost	Total Post-Amendment Cost
Part I	$0.005	$0.004	**$0.009**	$11.55	$0.09	**$11.64**
Part II	$0.005	$0.004	**$0.009**	$3.14	$0.25	**$3.39**
Part III	$0.005	$0.004	**$0.009**	$0.39	$0.30	**$0.69**
Total (Full Report)	-	-	-	**$15.08**	**$0.64**	**$15.72**
Part I (Future Cycles)	$0.005	$0.004	**$0.009**	$0.66	$0.09	**$0.76**
Part II (Future Cycles)	$0.005	$0.004	**$0.009**	$0.33	$0.26	**$0.59**
Part III (Future Cycles)	$0.005	$0.004	**$0.009**	$0.39	$0.30	**$0.69**
Total (Future Cycles) (Full Report)	-	-	-	**$1.38**	**$0.65**	**$2.03**

[1] Note: Totals may not sum due to rounding.

5.6 Annualized Agency Cost Estimates for All Modifications

Table 5-50 presents the annual Agency burden estimates for data entry and extramural costs over a 26-year period. The annual baseline Agency burden is equivalent to two FTEs, or 4,160 hours. The post-amendment Agency burden is calculated in Table 5-43, and an FTE is added to account for all the GS-13 level tasks (see Table 5-3), which are not affected by any of the amendments. In total, EPA estimates the Agency burden for the IUR rule will be reduced by 5,202 hours over a 26-year period under the IUR amendments.

Table 5-50: Agency Burden over a Period of 26 Years if All Amendments are Implemented

Reporting Cycle[1]	Year(s)	Baseline Burden (Hours)	Post-Amendment Burden (Hours)	Change in Burden (Hours)
1	**2006 to 2012**	4,160	3,220	-940
2	**2013 to 2017**	4,160	--	-1,678
	2013 to 2016	--	*2,482*	
3	**2018 to 2022**	4,160	--	-1,678
	2017 to 2020	--	*2,482*	
4	**2023 to 2027**	4,160	--	-1,678
	2021 to 2024	--	*2,482*	
5	**2028 to 2032**	4,160	--	-1,678
	2025 to 2028	--	*2,482*	
6	***2029 to 2032***	--	*2,482*	2,448
Total		**20,800**	**15,632**	**-5,202**
Annual Average		**800**	**601**	**-199**

[1] The non-italicized reporting cycles are baseline, five-year cycles, and the italicized reporting cycles are , four-year cycles

To estimate the per-reporting cycle cost of all the amendments over a 26-year period, EPA used the total baseline cost estimate in Table 5-3. These costs include the data entry performed by both EPA and contractor staff, and all extramural activities conducted by contractor staff. Under the baseline, EPA estimates the total Agency cost will be $466,100 during each reporting cycle. The annualized post-amendment cost also includes all extramural costs from Table 5-2 in addition to the data entry and quality control costs.

Table 5-51 contains the annualized cost estimation. In total, annual post-amendment cost will be $398,571 during the first reporting cycle and $291,515 thereafter. Over a 26-year period, EPA estimates the Agency will save approximately $474,500. Annualized savings are approximately $15,300 and $12,100, discounted at three percent and seven percent, respectively.

Table 5-51: Annual and Discounted Total Cost to the Agency of All Modifications

Reporting Cycle[1]	Year(s)	Baseline Cost	Post-Amendment Cost	Change in Cost
		(2008$)	(2008$)	(2008$)
1	**2006 to 2012**	$466,133	$398,571	-$67,562
2	**2013 to 2017**	$466,133	--	-$174,618
	2013 to 2016	--	*$291,515*	
3	**2018 to 2022**	$466,133	--	-$174,618
	2017 to 2020	--	*$291,515*	
4	**2023 to 2027**	$466,133	--	-$174,618
	2021 to 2024	--	*$291,515*	
5	**2028 to 2032**	$466,133	--	-$174,618
	2025 to 2028	--	*$291,515*	
6	***2029 to 2032***	--	*$291,515*	$291,515
Total		**$2,330,664**	**$1,856,146**	**-$474,519**
Annualized @ 3%		**$80,612**	**$65,279**	**-$15,333**
Annualized @ 7%		**$69,767**	**$57,618**	**-$12,149**

[1] The non-italicized reporting cycles are baseline, five-year cycles, and the italicized reporting cycles are , four-year cycles

6. Social Cost Summary

To calculate the total burden to society of the IUR amendments, EPA added the total industry burden to the Agency burden savings. Table 6-1 contains the annual burden estimates for the years 2006 through 2032.

The baseline burden for the first reporting cycle is calculated by adding the baseline burden to industry, 1.84 million hours (see Table 4-10), and the baseline burden to EPA, 4,160 hours (see Table 5-3), for a total of 1.85 million hours. EPA estimates the IUR rule amendments would increase the industry burden in the first reporting cycle by 0.50 million hours (see Table 4-52) and decrease Agency burden by 940 hours (see Table 5-43). The net burden increase is 0.49 million hours.

The burden in future reporting cycles will be less than for the first reporting cycle. The shift from a five-year cycle to a four-year cycle increases both industry and Agency burden. All of these changes are shown in Table 6-1. EPA estimates all of the amendments combined would increase the burden to society by 7.61 million hours over a 26-year period. This includes a burden increase of 7.62 million hours to the affected industry over the 26 years (see Table 4-57), and a burden decrease of 5,200 hours to the Agency (see Table 5-50) over the same period.

As shown in Table 6-1, EPA estimates the total increase in burden as a result of the IUR rule amendments over a 26-year period will be 7.61 million hours.

Table 6-1: Change in Total Burden to Society If All Modifications are Implemented

Reporting Cycle	Year(s)	Baseline Burden (millions of hours)	Post-Amendment Burden (millions of hours)	Change in Burden (millions of hours)
1	**2006 to 2012**	1.85	2.34	0.49
2	**2013 to 2017**	1.44	0.00	1.14
	2013 to 2016	0.00	2.57	
3	**2018 to 2022**	1.44	0.00	1.14
	2017 to 2020	0.00	2.57	
4	**2023 to 2027**	1.44	0.00	1.14
	2021 to 2024	0.00	2.57	
5	**2028 to 2032**	1.44	0.00	1.14
	2025 to 2028	0.00	2.57	
6	***2029 to 2032***	0.00	2.57	2.57
Total		**7.60**	**15.21**	**7.61**
Annual Average		**0.29**	**0.59**	**0.29**

Note: The non-italicized reporting cycles are baseline, five-year cycles, and the italicized reporting cycles are four-year cycle.s

Table 6-2 contains the total cost and change in cost to society as a result of the IUR rule amendments. The cost to society is expected to increase by $494.71 million over the 26-year period as a result of the IUR amendments. The cost to industry is expected to increase by $495.2 million over this period (see Table 4-58), and the Agency cost is expected to decrease by $

474,500 (see Table 5-51). The annualized cost to society over a 26-year period is $17.15 million and $14.70 million at three percent and seven percent discount rates, respectively.

Table 6-2: Change in Total Costs to Society if All Modifications are Implemented

Reporting Cycle[1]	Year(s)	Baseline Cost (millions of 2008$)	Post-Amendment Cost (millions of 2008$)	Change in Cost (millions of 2008$)
1	**2007 to 2011**	$107.43	$144.13	$36.70
2	**2012 to 2016**	$83.28	--	$74.95
	2012 to 2015	--	$158.23	
3	**2017 to 2021**	$83.28	--	$74.95
	2016 to 2019	--	$158.23	
4	**2022 to 2026**	$83.28	--	$74.95
	2020 to 2023	--	$158.23	
5	**2027 to 2031**	$83.28	--	$74.95
	2024 to 2027	--	$158.23	
6	***2028 to 2031***	--	$158.23	$158.23
Total		**$440.57**	**$935.28**	**$494.71**
Annualized @ 3%		**$15.97**	**$33.11**	**$17.15**
Annualized @ 7%		**$14.70**	**$29.39**	**$14.70**

Note[1] The non-italicized reporting cycles are baseline, five-year cycles, and the italicized reporting cycles are four-year cycles

7. Impact of the Final IUR Rule Modifications Rule on the Benefits of the IUR

The IUR rule is one of EPA's most valuable tools for meeting the Agency's mandate under TSCA to manage the risks resulting from chemical substance production and use in the United States. It is EPA's most comprehensive source of data on the chemical industry, and IUR data are used in almost all of OPPT's risk screening and management programs. However, the IUR data in their current form have numerous limitations, which in turn limit EPA's effectiveness in meeting its mandate under TSCA.

In an effort to improve the quality and usefulness of the data the Agency collects under the IUR rule, EPA is promulgating a set of IUR amendments. The amendments would improve the completeness and accuracy of the IUR data by requiring electronic reporting using the e-IURweb reporting software, expanding the range of chemical substances for which full information would be reported, adjusting the specific reported information, increasing the frequency of collecting the information, and modifying CBI requirements. EPA expects the amendments will reduce many of the current data constraints and, as a result, improve the effectiveness of EPA's chemical substance risk management programs. Most importantly, the IUR rule amendments will require submitters to provide processing and use exposure-related information for more chemical substances. This additional information will allow EPA to more accurately assess human and environmental exposures to specific chemical substances, including the concentrations, frequency, and durations of these exposures.

With this additional information, EPA will improve its ability to screen chemical substances to identify whether additional risk assessment and management steps are needed. More complete reporting of the processing and use data, more careful consideration of confidentiality claims, and adjustments to specific data elements will help provide the needed data. By enhancing the data supplied to Agency risk-screening programs, EPA expects to more effectively and expeditiously reduce the risks posed by chemical substances. The more EPA can base its decisions on actual data, rather than on assumptions, the better EPA is able to tailor its risk management decisions to the level of actual risk, whether higher or lower than it would be if based only on assumptions. Ultimately, an enhanced risk screening process will have positive consequences for human and ecosystem health, and will use EPA's and society's resources more efficiently. Additional benefits will accrue from changes in reporting requirements that will improve consistency and compatibility with other EPA databases. EPA will be better able to anticipate industry trends, particularly for chemical substances for which EPA has concerns, and to measure the effectiveness of Agency programs.

The benefits resulting from the IUR rule amendments are discussed qualitatively in this section. Quantification of the benefits of the rule would require more specific information about each user's use patterns and preferences, and the changes in the use patterns and preferences which will result from the additional information made available under the rule. These data are not readily available, and collecting such data would be cost-prohibitive. For example, one approach would be to conduct a national willingness-to-pay (WTP) survey of the general public to determine the value the public places on the availability of the information resulting from the rule. However, such a survey, or a survey to collect similar information, has not been conducted.

7.1 Benefits of Information-Based Policies

Improvements in the IUR data will allow EPA and others to use the data more effectively as part of the Agency's risk screening and prioritization programs. Screening chemical substances for potential risks is an essential first step in developing and prioritizing risk management activities. Effective risk-screening by EPA depends on the ability to characterize chemical substance uses accurately and to predict potential exposures. Current screening activities are greatly hampered by the incomplete data supplied through the 2006 IUR. In addition, EPA's current screening activities for medium production volume chemical substances are hampered further by the fact EPA has only estimates of production volume for many chemical substances and must rely on relatively limited public sources of information. This final rule will benefit society by filling these information gaps and contributing to better assessments of potential risks and risk management decisions.

The amendments to the IUR rule will increase the amount of publicly available data about a chemical substance's potential risks, and consequently are likely to result in (a) a reduction in the costs of risk-based decisions about the chemical substance, and (b) an improvement in the expected outcome of the decisions.

- **Reduced cost of risk-based decision making.** By making new information about toxic substances available to the public (including EPA and other government agencies), this rule can replace other information-gathering, management, and dissemination activities related to the regulated chemical substances. Once the data are publicly available, information users and decision makers will avoid the time and resource costs required to individually perform these activities. In effect, the rule increases the efficiency and strength of the decision-making process.
- **Improved outcome of decisions.** Information-based policies contribute to better decisions by redirecting resources toward their most highly valued uses. With incomplete information regarding toxic chemical substances, public and private decision makers are unable to make adequate assessments of the benefits and costs of actions involving these substances. For example, EPA decisions regarding whether, when, and how to target chemical substances for further risk assessment can be misdirected if basic risk-screening information is unavailable or inadequate. With more information, EPA can better direct its limited resources toward high-priority risks. Improved information can therefore help lead to more socially optimal reductions in risks to humans and the environment.

The rule amendments will generate both types of benefits. First, it will reduce EPA's and other decision makers' reliance on other databases and information sources that are inadequate for accurately and efficiently characterizing the risks associated with the thousands of chemical substances in commerce that need to be evaluated. As discussed in Chapter 5. EPA will incur additional costs for collecting and managing the new IUR data; however, by providing more reliable and complete data on chemical substance uses and exposures, the rule will also allow EPA to save time and resources in screening chemical substances and in developing risk management priorities. Furthermore, by requiring data to be submitted electronically, the rule will reduce EPA's costs of processing the IUR data and result in a better quality database.

Second, it will allow EPA to better prioritize its risk management activities and to move more quickly in addressing chemical substances posing relatively high risks (and/or relatively low risk-management costs).

A more detailed discussion about the value of information-based policies can be found in the Economic Analysis for the 2003 Amendments (EPA, 2002a). Specific benefits accruing from the use of the information generated by this final rule are discussed in the following sections.

7.2 Benefits of Individual Amendments

The IUR amendments expand the range of chemical substances for which full information is to be reported, adjust the specific reported information, increase the frequency of collecting the information, and modify CBI requirements. These amendments also will provide information to better address Agency and public information needs, improve the usability and reliability of the reported data, and ensure data are available in a timely manner. EPA is finalizing these amendments to the IUR rule to meet four primary goals:(1) to tailor the information collected to better meet the Agency's overall information needs, (2) to increase its ability to effectively provide public access to the information, (3) to obtain new and updated information relating to potential exposures to a subset of chemical substances listed on the TSCA Inventory, and (4) to improve the usefulness of the information reported. The following sections describe how each of the amendments meets these goals and generates benefits to data users.

7.2.1 Tailor Information Collected to More Closely Match the Agency's Information Needs

EPA's efforts to use the 2006 IUR data have identified areas where further improvements are needed. Several of the amendments described in this rule will change some of the reporting requirements in an effort by EPA to increase the usability of the collected information and to focus IUR reporting on the information needed most by the Agency. These changes will enable EPA and other Federal agencies to improve their risk screening programs, enabling them to better assess and manage risk and improve public awareness of basic information about a large number of chemical substances. These amendments and their specific benefits are described below.

Parent Company Name and Site Identity

Manufacturers (including importers) are required to report the company name and Dun & Bradstreet (D&B) D-U-N-S® number to identify the company associated with the plant site, and also to report the site name, address, and D-U-N-S® number EPA received a variety of questions concerning the correct company name to report during the 2006 IUR reporting cycle. EPA is now clarifying what is meant by company name, by requiring the company name provided to be the ultimate domestic parent company name. EPA believes this change will reduce confusion by making this reporting requirement consistent with the Toxic Release Inventory (TRI) requirements for parent company name. Reduced confusion leads to more accurate information, which in turn leads to more accurate risk characterizations.

Furthermore, the 2006 IUR submissions from different reporting sites contained varying D-U-N-S® numbers for parent companies appearing to be the same company. In order to better identify when reporting sites are under the same parent company, EPA is including the address as well as the D-U-N-S® number of the parent company. Similar to the change in parent company name, this change also will lead to more accurate information, which will lead to more accurate risk characterizations and small business analyses.

Technical Contact

Manufacturers (including importers) are required to provide a technical contact for their IUR submission. The technical contact must be a person who can answer questions EPA may have about the reported chemical substance and should be a person located at the manufacturing site. Based on EPA's experience with contacting the reported technical contact with follow-up questions concerning 2006 IUR submissions, submitters often provide the names of individuals who are not connected directly to the reporting site, and therefore, are not knowledgeable about either the chemical substance or the submission. EPA has also seen situations where the technical contact is a contracted employee who is able to address subsequent concerns only as long as he or she remains under contract to the company. EPA may raise follow-up questions about an IUR submission possibly for years after the submission date. EPA is now allowing multiple technical contacts on a chemical substance-by-chemical substance basis, and is no longer requiring that the technical contact be located at the manufacturing site. The benefit of this amendment will be increased clarity, which leads to improved accuracy in the information collected, which in turn leads to more accurate risk characterizations.

Chemical Identity

EPA is requiring the reporting of the Chemical Abstracts (CA) Index Name currently used to list the substance in the TSCA Inventory as the chemical name reported for IUR. Currently, submitters are required to report a specific chemical name, with no further elaboration in the regulatory text. EPA has found, however, that submitters sometimes supply a name that is somewhat generic or excludes parts of the specific chemical identity distinguishing one substance from another. EPA's experience in the 2006 IUR was that up to five percent of the reports submitted contained chemical identity problems serious enough that the Agency was unable to precisely identify the substance. These problems resulted in the temporary exclusion of the information associated with the poorly or erroneously identified chemical substance from the IUR database until the Agency was able to obtain correct and specific chemical identity information from the submitter. EPA believes the requirement to use the substance name as currently listed on the TSCA Inventory will greatly reduce the number of poorly identified substances. Improved chemical identification ultimately leads to more accurate risk characterizations.

EPA is removing the PMN number as an allowed chemical identifying number because each Inventory substance has either (or both) a CASRN (for the public Inventory) or a TSCA accession number (for the confidential Inventory), which are likely to be known already to the submitter.

This amendment will save the Agency considerable time and effort to access and review reported information that has been identified only by a PMN case number.

Report Production Volume for Each of the Years since the Last Principal Reporting Year

EPA is requiring reporting of production volume for each of the years since the last IUR principal reporting year in all future reporting cycles, and the reporting of 2011 and 2010 production volumes for the 2012 reporting cycle. Thus, starting with the 2016 IUR reporting cycle, manufacturers (including importers) of a chemical substance at or above the 25,000 lb threshold in any calendar year in the cycle will be required to report the production volumes for all years in the cycle (e.g., 2012, 2013, 2014 and 2015). Collecting the production volume for multiple years will provide greater detail than the current "once-every-five-years" snapshot.

EPA has mounting evidence that many chemical substances, including larger volume chemical substances, are manufactured in volumes that may fluctuate widely from year to year. This can result in the production volume of a chemical substance exceeding the threshold for several years, then falling below the threshold during the IUR principal reporting year. Therefore, EPA believes a single snapshot of annual production volume (i.e., taken just once each reporting cycle) does not provide an accurate picture of the chemical substances in commerce, and may provide an erroneous view of the exposure scenarios associated with a particular chemical substance.

EPA uses production volume data in several important ways. The data help the Agency to establish trends in chemical manufacturing; to determine the effectiveness of various Agency programs; to estimate the magnitude of consumer, worker, and environmental exposures; and to determine the costs (and financial impacts) of potential control strategies in economic analyses. Voluntary EPA programs such as Design for the Environment (DfE) and other pollution prevention programs will use the annual production volume data to identify trends and program performance. Relying on a single snapshot of annual production volume in each reporting cycle hampers EPA's ability to identify the programs and techniques that are most effective, using measurable, readily identifiable production trend data. Therefore, this amendment will provide information EPA and others need for the assessment of programs and will provide greater accuracy of the volumes of chemical substances in commerce than the current once-every-five year snapshot.

Volume of Chemical Substance Used On-Site

EPA is requiring submitters to report the volumes of a manufactured or imported chemical substance used at the reporting site. The requirement to report the volume used on-site is replacing the requirement to indicate whether the chemical substance is site-limited. Under this final rule, either domestically manufactured or imported chemical substances could be reported as used at the reporting site, whereas under the current reporting requirements, only domestically manufactured chemical substances, consumed entirely at the site of manufacture, should be reported as site-limited.

EPA is changing this requirement to simplify reporting and to collect information that better addresses the Agency's needs. In the past, submitters sometimes erroneously reported their production volume separately to identify the portion of their chemical substance consumed at the manufacturing site. For the 2006 IUR, many submitters continued this practice and erroneously filed separate reports to indicate a portion of their production volume was site-limited. Filing separate reports resulted in the need to report separately processing and use information when the combined production volume was 300,000 lb or greater. Including all production volumes on one report simplifies reporting for such submitters and results in a less complicated database, thereby making the data easier to use. The amendment to require reporting the volume used on-site will provide valuable information related to potential exposures associated with the on-site volumes, therefore providing the Agency with better information for exposure assessments and other data analyses.

Indicate Whether Imported Chemical Substances Are Physically at the Reporting Site

EPA is adding a requirement to indicate whether an imported chemical substance is physically at the reporting site. Often, the site reporting an imported chemical substance never physically receives the chemical substance, but instead ships it directly to another location such as a warehouse, a processing or use site, or a customer's site. Identifying whether the chemical substance is physically at the reporting site provides more accurate information for screening-level analyses and other uses of the IUR data.

Report Volume Exported

EPA is adding a requirement to report the production volume directly exported and not domestically processed or used. This amendment will allow EPA to better identify the proportion of the production volume accounted for by the use reporting, given that downstream reporting is not required for exported substances.

Identify Whether Chemical Substance Is To Be Recycled, Remanufactured, Reprocessed, or Reused

EPA is adding a requirement to indicate whether a manufactured chemical substance, such as a byproduct, is being recycled, remanufactured, reprocessed, or reused. Submitters will identify that their manufactured chemical substance, which otherwise would be disposed of as a waste, is being removed from the waste stream and is being used for a commercial purpose (i.e., recycled, remanufactured, reprocessed, or reused). Such information will benefit the Agency by identifying where these activities are already occurring, and can be used to encourage such activities. Collecting information on whether a chemical substance is being recycled, remanufactured, reprocessed, or reused and is not entering the waste stream provides valuable information to EPA and others regarding trends in chemical manufacturing and can be used to help determine the effectiveness of various programs, such as EPA's Resource Conservation Challenge (RCC) Program.

Designation of Consumer or Commercial Use

EPA is requiring submitters to designate whether the use is a consumer or a commercial use, or both. The Agency's experience using the 2006 IUR data identified a need to distinguish between potentially exposed consumer and commercial populations. Designation of consumer or commercial use, or both, will allow EPA to complete a better characterization for the potentially exposed populations.

Number of Commercial Workers Reasonably Likely To Be Exposed

EPA is requiring submitters to report the total number of commercial workers, including those at sites not under the submitter's control, that are reasonably likely to be exposed while using the reportable chemical substance, with respect to each commercial use. The approximate number of workers will be reported using the same definitions and ranges used for manufacturing and industrial processing and use workers. Information on the number of commercial workers reasonably likely to be exposed to the reportable chemical substance will be used to characterize the commercial population reasonably likely to be exposed to the subject

chemical substance. Therefore, this amendment will improve the population characterization, which is important to the development of the overall exposure characterization.

7.2.2 Increase EPA's Ability to Effectively Provide Public Access to the Information

EPA anticipates the amendments will result in the Agency receiving more publicly available, non-CBI information. It is therefore important for the Agency to be able to provide public access to the information in a timely manner; requiring all submissions in an electronic format will better enable the Agency to accomplish this.

Require Electronic Submissions over the Internet

EPA is requiring the mandatory use of EPA's Central Data Exchange (CDX) through the Internet for manufacturers (including importers) to report IUR information. EPA will require all submissions to be generated using the e-IURweb reporting software. EPA will no longer accept paper submissions or electronic media for any IUR submission after the effective date of the final rule.

The amendment to eliminate paper-based submissions in favor of mandatory e-IURweb reporting will provide several benefits to EPA and industry. EPA expects the required use of e-IURweb and CDX will reduce the reporting burden on industry by reducing both the cost and the time required to review, edit and transmit data to the Agency. Data systems into which data were once manually entered will now be populated electronically, thus reducing the potential for error when data are entered by hand or when data are entered through a scanning process. All information sent by submitters via CDX will be transmitted securely to protect CBI.EPA will be able to communicate electronically with submitters, e.g., to confirm receipt of a submission or to identify a problem with the submission. Electronic submissions enable data to be available for Agency and public use more quickly and it eliminates inefficiencies and errors introduced in the process to scan paper submissions.

EPA developed e-IUR reporting software for use in preparing and submitting reports electronically during the 2006 IUR submission period (see www.epa.gov/iur). For the 2012 submission period, EPA will provide a free web-based application in place of the 2006 downloadable software. The 2012 e-IURweb will feature several enhancements over the 2006 e-IUR. These improvements include a sophisticated validation system, which will alert users when a required field on the form is either missing information or contains certain kinds of potentially incorrect information. Other updates are expected to include automated chemical identity checks, automated company and site identity checks, and the facilitation of joint submissions and amendments. The reporting software also will include user-friendly features such as drop-down selections, searchable chemical substance lists, imbedded help files, and an error-checking process to help identify common reporting errors before the report is submitted. All of these applications will increase the accuracy of the data and reduce Agency time spent in manually performing these checks.

Coupled with EPA's e-IURweb reporting software, electronic reporting has become the most efficient method of reporting for industry as well as for EPA. During the comment period for the Information Collection Request (ICR) renewal (73 FR 51805, September 5, 2008), EPA received positive comments regarding the use of CDX, the encrypted Internet submission process, and the ability to use a secure electronic signature method to submit IUR reports.

7.2.3 Obtain New and Updated Exposure Information

The EPA Administrator has announced her intention to increase efforts to assess, prioritize, and take action on existing chemical substances, with particular emphasis on protecting children. The Agency is developing a broader, more vigorous approach on existing chemical substances, which will utilize the full range of TSCA regulatory tools to reduce or eliminate risks from chemical substances of concern. The IUR rule is one of the tools available for this effort. Through the IUR rule, the Agency collects the information it needs to conduct an initial characterization and screening of potential exposures associated with chemical substances. EPA needs more in-depth exposure-related information to fine-tune the screening process, and to better assess, prioritize, and take action on existing chemical substances. The various programs and tools EPA uses to evaluate and manage chemical substance risks are described in Section 7.3. The amendments will increase the amount of exposure information collected are described in the following sections.

Method for Determining Whether a Manufacturer is Subject to IUR Reporting Requirements

For the 2012 reporting cycle, reporting for subject chemical substances will be required if the production volume in the 2011 principal reporting year only meets or exceeds the 25,000 lb reporting threshold, which is the current requirement. For the 2016 reporting cycle and future reporting cycles, a site will examine its annual production volumes for each of the four calendar years since the last principal reporting year. If the production volume for a reportable chemical substance is 25,000 lb or greater for any calendar year during that four-year period, then the site will need to report the chemical substance, unless it is otherwise exempt.

EPA is changing the determination method because of the mounting evidence many chemical substances, even larger volume chemical substances, often experience wide fluctuations in manufacturing volume from year to year. This can result in the production volume of chemical substance exceeding the threshold for several years, then falling below the threshold during the IUR principal reporting year. Consequently, historical IUR reporting has resulted in a change of approximately 30 percent in the composition of the chemical substances being reported from one reporting cycle to the next. Therefore, the one-year snapshot of production volume does not provide an accurate picture of the chemical substances in commerce, and may provide an erroneous view of the exposure scenarios associated with a particular chemical substance.

Further evidence that capturing production volume for only the IUR principal reporting year is causing EPA to miss a significant amount of chemical substance production was revealed in the comments the Agency received from the proposed “reset” of the TSCA Inventory. The *Federal Register* notice of November 21, 2008 (73 FR 70460) requested industry provide comment on whether a three-year reporting cycle was sufficient for deciding whether a chemical substance they manufactured or imported should remain listed on the TSCA Inventory. Commenters overwhelmingly expressed concern the proposed three-year reporting cycle would drastically misrepresent the chemical substances presently in commerce.(See Docket No:EPA-HQ-OPPT-2008-0785.)

In submitted comments, companies agreed unanimously that if they were to report for one year only, the reset would inappropriately remove chemical substances from the TSCA Inventory. While all commenters felt the three-year reporting cycle was inadequate, a majority of

the industry comments suggested reporting should cover a 10-year period. The comments strongly indicated there were chemical substances manufactured or imported only occasionally, and these chemical substances would not be captured if the reporting covered too short a period. Therefore, requiring chemical substance manufacturers (importers) to evaluate production volume for any calendar year since the previous IUR principal reporting year would benefit users of IUR data by yielding a much more accurate picture of the chemical substances currently in commerce and properly the subject of EPA's risk screening, assessment, and management activities.

Replacing the 300,000 lb Threshold for Processing and Use Information Reporting

EPA is replacing the 300,000 lb threshold for reporting processing and use information to 100,000 lb for the 2012 reporting cycle, and replacing the threshold for all subsequent reporting cycles. EPA is therefore requiring all submitters of non-excluded substances to report information in all parts of the IUR Form U in future reporting cycles. EPA is lowering this reporting threshold in order to collect information necessary to complete screening-level exposure characterizations and subsequent risk-based prioritizations for medium production volume (MPV) chemical substances. In the 2003 Amendments final rule (68 FR 848, January 7, 2003), EPA acknowledged the value of information for chemical substances manufactured in lower volumes and stated if the Agency were to find it necessary in the future, it would collect information on chemical substances at reporting thresholds below the thresholds introduced in that action. The IUR processing and use information is needed now to complete the characterizations and prioritizations for those chemical substances manufactured (including imported) in volumes of 100,000 to 300,000 lb in the first reporting cycle and 25,000 to 300,000 lb in all future reporting cycles.

The Agency currently is unable to develop screening level risk evaluations for medium and lower production volume chemical substances because most of these chemical substances are produced below the volume for which exposure and use information is required under the current IUR rule (i.e. 300,000 lb per year).The exposure information is an essential part of developing screening-level risk evaluations and, based on its experience in using this information, the Agency has concluded collecting this information is critical to its mission of characterizing exposure, identifying potential risks, and noting uncertainties for these lower production volume chemical substances.

Both hazard and exposure information is needed to develop screening level evaluations. Once the IUR processing and use information is available for these medium and lower volume chemical substances, EPA will be able to develop the exposure characterizations needed to develop the evaluations. As with the high-production volume (HPV) chemical substances, EPA will then be able to identify potential risks, note scientific issues and uncertainties, and indicate the initial priority assigned by the Agency for potential future appropriate action. Therefore, the rule will provide this necessary processing and use information for chemical substances manufactured or imported in volumes of 25,000 lb to 300,000 lb

Reduce the 25,000 lb Threshold for Specific Regulated Chemical Substances

In reporting cycles subsequent to the 2012 reporting cycle, EPA is reducing the 25,000 lb reporting threshold to 2,500 lb for specific regulated chemical substances that are the subject of particular TSCA rules and/or orders and to require manufacturers (including importers) of such chemical substances to report under the IUR, regardless of the production volume. This provision will ensure the availability of current information when EPA has expressed a concern in the form of regulatory action on those chemical substances, regardless of the production volume. EPA is reducing the 25,000 lb threshold for those chemical substances that are: (1) the subject of a rule promulgated under sections 5(a)(2), 5(b)(4), or 6 of TSCA; (2) the subject of an order issued under section or 5(e) or 5(f) of TSCA; or, (3) the subject of relief that has been granted under a civil action under section 5 or 7 of TSCA.

Beginning with reporting cycles subsequent to 2012, manufacturers (including importers) of these specific regulated chemical substances will be required to report production volumes each year from 2012 to 2015, and the full manufacturing, processing, and use information for 2015, if they have production volumes above the 2,500 lb threshold.

Chemical substances regulated under TSCA are of demonstrated interest to the Agency. EPA has made a determination that such substances either "may present," "will present," or "do present" an unreasonable risk to human health and/or the environment or that the substances have "substantial production/significant or substantial exposure." Therefore, this amendment will enable EPA to use the IUR data associated with these regulated chemical substances to monitor chemical substance production and compliance with the rules.

Making Chemical Substances Subject to Enforceable Consent Agreements Ineligible for Exemptions

EPA may enter into an enforceable consent agreement (ECA) with a manufacturer of a chemical substance to obtain testing where a consensus exists among EPA, affected manufacturers and/or processors, and interested members of the public concerning the need for and scope of testing. Chemical substances covered by ECAs are of demonstrated interest to EPA. The Agency has an interest in identifying the manufacturing, processing, and use of substances under such agreements, and therefore is requiring such substances to be reported for IUR purposes, regardless of whether the substance otherwise meets the requirements listed in 40 CFR §710.46 (amended §711.6) as an exempt or partially exempt chemical substance. This amendment will ensure the availability of current information if EPA has expressed a concern in the form of an ECA on any substance otherwise excluded from the IUR rule. For example, EPA could use the IUR data associated with these regulated chemical substances to monitor chemical substance production and compliance with the agreements.

Changes to Standard for the Reporting of Processing and Use Information

In order to collect more complete information regarding the industrial processing and use and commercial and consumer use of chemical substances, EPA is replacing the "readily obtainable" reporting standard in the 2006 IUR with the "known to or reasonably ascertainable by" reporting standard for the reporting of processing and use information. TSCA section 8(a)(2) authorizes

EPA to require persons to report information "known to or reasonably ascertainable by" the submitter. This is the same standard currently applying to the reporting of information described in the regulations at 710.52(c)(1), (c)(2), and (c)(3).It covers all information in a person's possession or control, plus all information a reasonable person similarly situated might be expected to possess, control, or know. The "known to or reasonably ascertainable by" reporting standard was the only standard used for IUR reporting purposes prior to the 2006 IUR reporting cycle.

EPA is changing the reporting standard because reporting under the "readily obtainable" standard did not generate sufficiently precise processing and use information for screening-level reviews. The Agency believes reporting under the "known to or reasonably ascertainable by" standard will generate processing and use information sufficiently precise for screening-level reviews.

The 2006 IUR response rate for the processing and use data captured only a portion of the volume the Agency suspects actually was used for industrial processing and use or commercial and consumer use. Considering only those chemical substances meeting the criteria to require reporting of processing and use information, only 72 percent of the total volume was accounted for in the industrial processing and use data and 22 percent in the commercial and consumer use data. At a minimum, EPA is lacking industrial processing and use data on 28 percent of the expected volume reported, and is lacking consumer and commercial processing and use data on 78 percent of the expected volume reported.[6] Because of this low level of reporting, EPA now believes the reporting standard of "not readily obtainable" was too lenient and resulted in an underreporting of the actual processing and use situation.

The Agency's experience using the 2006 IUR data to develop exposure characterizations has alerted EPA to the fact the IUR processing and use data are incomplete and inconsistent. Effective risk screening by EPA depends on the ability to accurately characterize chemical substance uses and to predict potential exposures. If the information provided does not include these data, EPA must make assumptions about the use of the unreported production volume. Incorrect assumptions may lead EPA to designate an inappropriately high priority level to the chemical substance, resulting in unnecessary effort and resource expenditures for both regulated parties and EPA in cases where adequate data would have led the Agency to act differently.

Therefore, using the reporting standard "known to or reasonably ascertainable by" will result in companies reporting more consistent and complete processing and use information in their IUR reports, and more efficient use of EPA resources.

Change to Reporting Frequency

Prior to the 2003 Amendments, the IUR collection occurred every four years. EPA reduced the reporting frequency from every four years to every five years starting with the 2006 IUR rule

[6]The Agency believes the percentage of missing processing and use information actually is larger than indicated by this analysis. As described in the 2003 Amendments final rule (68 FR 861), EPA anticipated that, on an individual report basis, the total percentages of production volumes associated with the industrial processing or use information may add up to more than 100 percent of the reported production volume. This could happen because the submitter reported on the distribution of a chemical to sites in its control as well as downstream sites, some of which were not immediate purchasers from the original manufacturing site.

modifications, to reduce the burden associated with the amended IUR requirements. While the less frequent reporting does reduce burden, the Agency now has determined reporting every five years does not provide data sufficiently current to meet Agency and public needs, and is returning to reporting every four years.

As described above, the Agency has been criticized for using outdated information. Also, a review of the previous reporting under IUR has revealed a change of approximately 30 percent in the chemical substances reported from one reporting cycle to the next. Receiving IUR information more frequently will provide EPA with a more accurate, up-to-date overview of the chemical manufacturing industry, addressing a criticism the Agency has received for relying on outdated information. More timely information will help EPA to better prioritize chemical substances for screening, and will lead to more efficient use of EPA resources.

7.2.4 Improve Utility of Information Reported

Some of the amendments in the final rule will change reporting requirements, in an effort by EPA to increase the usability of the collected information. By increasing data transparency, increasing international compatibility, or changing the method by which the data are submitted, these final changes will ultimately enable EPA and other Federal agencies to improve their risk screening programs, enabling them to better assess and manage risk, and improve public awareness of basic information about a large number of chemical substances.

Industrial Function Categories

EPA is revising the list of industrial function categories by combining categories leading to common exposure scenarios and adding categories where the Agency believes the existing categories do not adequately describe potential uses. EPA worked with Environment Canada and Health Canada to develop the set of categories, which will be used by both the United States and Canada for Inventory reporting. Harmonization of the categories for reporting the industrial functions of chemical substances will benefit both EPA and Canadian agencies by facilitating the exchange of information, and will serve as a model to be used by Mexico in developing an Inventory of chemical substances .In addition, the harmonized categories will facilitate consistent reporting of chemical substance use information by industry in the United States and Canada.

Another benefit of revising the list of industrial function categories will be to reduce the number of uses reported as “Other.” EPA is requiring that if a submitter chooses the category “Other,” the submitter include a text description for the industrial function category associated with the use of chemical substance.

Industrial Sectors

EPA is replacing the five-digit North American Industrial Classification System (NAICS) codes with 48 Industrial Sectors (IS).The industrial sectors were adopted from the European Union’s guidance on information requirements and chemical substance safety assessment. The chosen Industrial Sectors divide the entire range of NAICS codes into sectors so any NAICS code has a corresponding Industrial Sector. The Agency believes this change will provide several benefits .First, it will encourage more complete reporting by using terms already familiar to industry .Second, the industrial sectors will reduce the likelihood of errors resulting from the

selection of miscellaneous or inappropriate NAICS codes. Third, it will reduce the number of codes that could apply to one substance.

One of the primary purposes of the IUR data collection is to group together similar data for priority setting exercises and activities. Respondents to the 2006 IUR submitted 342 unique five-digit NAICS codes, which made it difficult for EPA to group chemical substances based on industrial processing and use scenarios. The 2006 IUR database has 2,330 unique combinations of processing or use categories, NAICS, and industrial function categories, in all. This large number of unique combinations increases the difficulty and time required by EPA to sort and classify chemical substances because EPA either would need to develop exposure scenarios for each unique combination, or determine which three-code combinations have similar exposure scenarios and can be grouped. Therefore, another benefit of using the industrial sectors will be to reduce the number of unique combinations, thereby increasing the usability of the data.

Consumer and Commercial Product Categories

EPA is revising the list of consumer and commercial use categories by combining categories leading to common exposure scenarios and adding categories not adequately described in the initial set of categories. EPA worked with Environment Canada and Health Canada to develop the categories, which will be adopted by the United States and Canada for reporting of Inventory information. Harmonized categories for reporting the consumer and commercial uses of chemical substances will benefit both EPA and Canadian agency by facilitating the exchange of information and will serve as a model to be used by Mexico in developing an Inventory of chemical substances. In addition, the harmonized categories will facilitate consistent reporting of chemical substance use information by industry in the United States and Canada.

Additional benefits of expanding the list of consumer and commercial use categories will be to provide persons submitting IUR information with a greater opportunity to characterize the products in which chemical substances they manufacture are used, and to reduce the number of uses reported as "Other."

EPA is requiring that if a submitter chooses the category "Other," the submitter include a text description for the consumer and commercial product containing the chemical substance. The 2006 IUR reports showed the category "Other" was reported with the greatest frequency. A total of 1,206 reports, or 26 percent, out of 4,666 reports containing commercial and consumer use information, included "Other." Although one of EPA's objectives of revising the consumer and commercial product categories is to reduce the reporting frequency of "Other," EPA believes in many cases where "Other" was reported, submitters may not have selected the correct categories for their situation .In addition to revising the overall product categories, narrower definitions and expanded lists of examples of products in which the chemical substance will be used were added to each category descriptor. By requiring the submitters to supply a written description for "Other," this amendment will enable the Agency to evaluate and improve the inclusiveness of future consumer and commercial category lists or descriptions.

Upfront Substantiation for Processing and Use Information CBI Claims

Under the rule, in order to submit a claim of confidentiality for processing and use information data elements, the submitter will be required to both check the appropriate box on

the reporting form and substantiate the claim in writing by answering certain questions provided in the rule. Where a submitter fails to substantiate the processing and use CBI claim in accordance with the applicable rules, EPA may make the information available to the public without further notice to the submitter.

EPA has observed, on occasion, processing and use information has been claimed as confidential even though it was revealed in submissions sent to the Agency in response to the HPV Challenge program and published on the EPA website. In addition, EPA has observed some of the processing and use information claimed as confidential appears to be available on submitter's websites or in published Material Safety Data Sheets (MSDS). The high number of confidentiality claims asserted for the reported 2006 IUR reports on industrial processing and use information meant EPA was unable to make available to the public important data or to completely describe the analysis or provide the support information used to reach Agency conclusions. This included the number of processing sites, the number of potentially exposed industrial workers, and the percent production volume for each industrial processing or use scenario. This amendment decrease in the number of inappropriate CBI claims under the new substantiation requirement, which will improve EPA's ability to make current plant site information available to other Federal agencies and the public because more information submitted under IUR could be released publicly. This will increase the transparency and public accessibility of the chemical substance risk information, may increase public confidence in EPA's chemical management program, and is consistent with the President's policy goals for government reliance on and public availability of scientific information.[7]

7.3 Potential Users of Information Generated by the IUR Modifications Rule

EPA will be the primary user of the information generated by the rule amendments, although other public and private organizations, in particular those with interests in managing chemical substance risks, will also use the data. The information is expected to be applied and disseminated by these users in a number of ways; however, it will serve primarily to reduce the costs of screening and managing chemical substance risks and to improve risk management decisions. The American public will be the ultimate beneficiary of the amended IUR. By lowering the cost of decision making in the public sector, the rule will free up resources for other public or private uses. Similar gains will also result from cost savings in private-sector decision making. By improving risk management decisions, the rule will also help to better target risk management activities to the areas where the net benefits (i.e., risk reductions net of control costs) are expected to be the largest.

IUR data users and the benefits they derive from IUR data are discussed in more detail in the following sections.

[7] On March 9, 2009, President Obama, writing about Scientific Integrity in a Presidential Memorandum for the Heads of Executive Departments and Agencies, wrote: "The public must be able to trust the science and scientific process informing public policy decisions. Political officials should not suppress or alter scientific or technological findings and conclusions. If scientific and technological information is developed and used by the Federal Government, it should ordinarily be made available to the public. To the extent permitted by law, there should be transparency in the preparation, identification, and use of scientific and technological information in policymaking."

7.3.1 EPA Risk-Screening and Management Programs

EPA's Office of Pollution Prevention and Toxics (OPPT) has a multifaceted approach to identifying and managing chemical substance risks. OPPT can initiate the review of a chemical substance in a number of ways, including under an Agency program, through a request by the Interagency Testing Committee or because of a request by the public. The Agency has a number of more detailed screening tools, such as the Use Cluster Scoring System (UCSS). Depending on the outcome of these screening processes, the next step may include entering one of EPA's risk management programs. These types of programs and the benefits derived from the processing and use information provided on the IUR Form U are examined in detail in the economic analysis for the 2003 Amendments (EPA, 2002). EPA's current programs and tools to evaluate and manage chemical substance risks include:

- **Risk Screening**. OPPT screens chemical substances on the TSCA Inventory to identify potential risks and determine whether more detailed assessments should be undertaken. With the data currently available, EPA does not have the information needed to effectively and systematically screen some of the chemical substances on the TSCA Inventory. The amended IUR will supply exposure-related information the Agency does not currently have, recognizing industry has a greater knowledge than EPA about its own operations and the uses of chemical substances it manufactures and sells. Without this information, EPA will likely: (1) not screen these chemical substances, (2) screen them using outdated or anecdotal exposure information, or (3) screen them but rely on exposure estimates (which are typically conservative) using modeling data. Therefore, data collected as a result of the rule will improve the Agency's ability to screen chemical substances in commerce, allowing the Agency to focus its chemical substance screening programs and to identify potentially risky situations earlier than otherwise possible.

  The 2006 IUR data did not provide sufficient information on medium production volume (MPV) chemical substances for risk screening activities under the Agency's Existing Chemicals Program, in particular. Screening chemical substance risks generally requires a combination of both hazard and exposure information. Because most MPV chemical substances were produced below the 300,000 lb reporting threshold for processing and use information, EPA did not have exposure information available from the 2006 IUR for these chemical substances. EPA therefore developed hazard based prioritizations which were supported by a screening level hazard characterization and consideration of very limited exposure and use data. When the screening level hazard characterization for an MPV chemical substance indicated that the hazard was low, the magnitude of exposure was generally less significant for the prioritization. However, when the screening level hazard characterization identified either a medium or high hazard, information on the magnitude and type of exposure would be essential for a realistic prioritization determination. Basic hazard data are easier to find in existing databases; however, specific exposure data are needed to make a priority determination risk-based. EPA believes that the lower threshold will provide more exposure-related information on a greater number of MPV chemical substances.

- **High Production Volume Chemical Substance Testing.** EPA's major efforts to prioritize existing chemical substances began with data collected under the High-Production Volume (HPV) Challenge Program, which makes available to the public screening-level environmental and health effects information on HPV chemical substances produced or imported in the United States in quantities of one million lb or more per year. At the

conclusion of the voluntary HPV Challenge Program, EPA developed the first in a series of test rules to require the testing of high production volume chemical substances for which no voluntary agreement was made. EPA finalized its first HPV test rule, covering 37 chemical substances, in 2006. A second HPV rule was promulgated in 2011 for 19 chemical substances; a third rule was proposed in 2010, and additional HPV test rules are being planned.

When attempting to use the 2006 IUR data for its screening level exposure assessments, EPA found that numerous chemical substances previously identified as HPVs were reported in amounts classifying them as MPV chemical substances below the 300,000 lb cut-off, and thus processing and use information was not provided for chemical substances for which EPA had a relatively complete hazard data set from the HPV challenge. This led EPA to believe that the threshold was too high to provide sufficient exposure-related information on these chemical substances. Additionally, some previously MPV chemical substances were reported in amounts which classified them as HPV chemical substances in 2006.

- **Existing and New Chemicals Program**. The Existing Chemicals Program conducts detailed analyses of potentially high-risk chemical substances and develops strategies to reduce or eliminate the exposure risks. Chemical substances are screened first to identify those (1) requiring additional testing, (2) presenting potentially significant risk management concerns, or (3) currently not requiring further review. While the amendments to the IUR data will increase EPA's ability to screen existing chemical substances based on exposure and, ultimately, risk, more in-depth data similar to the New Chemicals Program data will lead to improved screening and a quicker identification of chemical substances with a high priority for follow-up action. This will result in a more appropriate entry into EPA's chemical substance management programs. The range of benefits EPA anticipates from being able to obtain more accurate and broader use information could be expanded with a greater amount of in-depth exposure and use information. The improved IUR data will be particularly helpful for screening medium and lower volume chemical substances not covered by the HPV program.

  More recently, the Existing Chemicals Program used the IUR database when developing the Chemical Action Plans. For some Action Plan chemical substances, the 2006 IUR was not a useful source of information. An example is the Action Plan for Dyes Derived from Benzidine and Its Congeners, where the substances of concern are known or reasonably anticipated human carcinogens; however, those listed were produced in amounts below the 300,000 lb threshold and so little exposure data was reported. Based on IUR data from prior reporting periods, some of the other dyes had been reported in the 10,000 to 25,000 lb range, but no 2006 IUR data were available to determine whether these chemical substances were still being used in amounts beyond the small amounts used as analytical reagents. The Action Plans are available on EPA's web site at http://www.epa.gov/opptintr/existingchemicals/pubs/ecactionpln.html

  IUR data are also used under the New Chemicals Program as a source of information on chemical substances that are analogous to new chemical substance submissions to supplement data submitted with the new chemical substance. EPA is able to increase the rigor of its review of a new chemical substance submission by comparing its characteristics

with analogous chemical substances that previously have undergone a review under the New Chemicals Program.

- **Use Cluster Scoring System (UCSS).** The UCSS tool identifies potential risks of chemical substances used in similar applications, or "use clusters." This system enables the Agency to view the potential risks of a given chemical substance in the context of the potential risks presented by related products on the market and allows the Agency to establish regulatory review priorities for those use clusters. However, some of the UCSS data sources are outdated and the estimating methodologies are approximate. More in-depth exposure-related data could be used to create a database providing additional information that will allow the Agency to provide more accurate screening-level estimates for use clusters and to target Agency programs to areas currently needing attention. The additional exposure-related data will also enable EPA to more easily conduct broader chemical substance screening analyses across several industries.
- **Master Testing List.** IUR data also help EPA determine which chemical substances are on the Master Testing List (MTL).The MTL is a list of chemical substances identified by the Agency as having inadequate data for health and/or environmental risk assessments. OPPT uses the MTL to establish priorities for chemical substance testing, keep the public informed, solicit input from industry on specific chemical substance exposure and risk assessment needs, and to encourage industry to perform testing. More in-depth exposure-related manufacturing, processing, and use data will enable EPA to better target testing needs to situations in which potential exposures are known to occur, thereby increasing the efficiency of efforts in these programs and facilitating earlier completion of critical testing needs.
- **Screening Information Data Set (SIDS) program.** The Organisation for Economic Co-operation and Development's (OECD) voluntary SIDS program allows OECD member countries to share the burden of testing internationally traded, large production volume chemical substances. The United States is responsible for testing 25 percent of the chemical substances identified for the program. The information needed is collected by industry sponsors; however, the data elements included may not be consistent across sponsors, and some companies may not participate in developing all of the data elements. Currently collected data and data collected through more in-depth exposure and use data requirements will enable the EPA to meet many key needs for exposure data and will provide a consistent database of information from manufacturers (including importers). This information will increase the program's efficiency by helping to identify chemical substances requiring additional testing or assessment while excluding those with low domestic exposure. An improved exposure database will also improve evaluation of potential risk in the assessment reports prepared at the end of the SIDS process.
- **Design for the Environment (DfE) program.** EPA's DfE program incorporates principles and strategies from both the Existing Chemicals Program and the UCSS, by focusing on specific chemical substance uses and establishing partnerships with industry to develop voluntary, long-range plans for risk management. Currently collected IUR data, which will be enhanced by data collected through more in-depth exposure and use data requirements, helps to identify use cluster candidates for this program. The more in-depth exposure-related data will also better enable the initial assessment of exposures and help identify potential

substitutes. The data could be used to assist in ranking activities, identifying high-risk areas, and developing realistic approaches for reducing risk.

7.3.2 Other Federal Risk Management Programs

Under TSCA section 4, EPA has the authority to require firms to conduct tests of specific chemical substances to determine the potential risk posed by these substances. However, other governmental agencies, such as the Occupational Safety and Health Administration (OSHA),the National Institute for Occupational Safety and Health (NIOSH), and the Consumer Product Safety Commission (CPSC), share regulatory authority over chemical substances or products containing them. In the case of NIOSH, the agency compiles summaries of available information and recommends exposure limits. Therefore, EPA serves as a conduit for chemical substance hazard information between the chemical substance producers and these other agencies.

OSHA currently manages occupational exposure to chemical substances by setting a variety of chemical substance and personal protection standards, by requiring preparation of emergency response and process safety management plans and by requiring provision of health and safety data to workers for chemical substances used in the workplace. OSHA will be able to use the IUR data to identify chemical substances with large numbers of potentially exposed workers or with uses suggesting greater exposure potential. The information provided by the rule could increase OSHA's ability to manage chemical substance hazards, exposures, and risks in occupational settings.

NIOSH will also benefit from the additional exposure-related information collected under the rule amendments. The exposure information NIOSH uses to determine occupational safety and health in businesses nationwide may be based on outdated information collected under the National Occupational Exposure Survey (NOES). Completed in 1983, NOES collected information such as plant site location, plant site Standard Industrial Classification (SIC), information on the plant site's occupational safety and health programs, occupational titles of workers potentially exposed, the number of employees per occupational title, information on process steps, and trade names of products. NIOSH could use IUR data in place of the NOES data to identify chemical substances with large numbers of potentially exposed workers or with uses suggesting greater exposure potential.

CPSC also could use the new data directly in conducting its exposure and risk assessment activities (e.g. screening consumer products for chemical substance hazards). CPSC obtains risk information to screen chemical substance hazards from a network of hospital emergency rooms. This information is limited to injuries and illnesses resulting from acute exposures only.

Additional data required by the final IUR amendments will provide a better source of reliable information on the chemical substances used in consumer products. CPSC will improve its ability to identify the chemical substances used in consumer products and, with consideration of hazard data, to identify chemical substance consumer use scenarios presenting greater potential risk. The information could improve CPSC's ability to meet its program objective of protecting the public from chemical substance hazards in consumer products.

7.3.3 State and Local Programs

IUR data also help state and local authorities with rulemaking, information collection, and voluntary program activities. Because state and local governments must address chemical substances, use patterns, and exposure scenarios that may be unique or isolated, state and local

agency access to the enhanced data will assist in identifying situations posing potentially high risks for individual states or locations within those states. The information added to the IUR includes county data, which will enable states to identify which counties are likely to have specific issues or which counties may have multiple chemical substance risk situations. The additional data also could be used to assist with setting goals, targeting actions, and developing or expanding pollution prevention activities.

7.3.4 Nongovernmental Organization (NGO) Initiatives and Private-Sector Stewardship

Many private-sector organizations have a strong interest in reducing risks and providing leadership in preventing pollution while still maintaining productive economic enterprises. These organizations can better meet these objectives by developing a better understanding of how chemical substances are used in general. This will allow them to manage risks more effectively and participate in setting chemical substance priorities at community, regional, and national levels.

The publicly available (non-CBI) information provided by the IUR supports activities typically undertaken by NGOs, such as tracking industry trends, organizing grassroots involvement in risk-based decision making, and conducting outreach and educational programs. These organizations could use the new data to identify and establish priorities for risks; to evaluate chemical substances and chemical substance use patterns to determine areas of concern; to identify and promote pollution prevention opportunities; and to focus pollution prevention, public outreach, and education initiatives and activities.

Industry can use the amended IUR information to improve corporate product stewardship programs through access to use information reported by multiple companies. The American Chemistry Council's Responsible Care® Program is one example of one such program that could use this information. The Responsible Care® Program requires companies to take responsibility for their products from cradle to grave, which requires an understanding of how their product is being used not only by their customers, but further down the chain. Despite this private effort, some companies have told EPA they do not know how their chemical substances are used. Non-CBI use information provided by multiple companies could give an individual company a better understanding of the downstream uses of its products, therefore enabling more effective implementation of the Responsible Care® concepts.

8. Small Entity Analysis

This chapter estimates the impact the amendments to the IUR rule may have on small entities by examining the relationship between the compliance costs and company sales for small companies.

The Regulatory Flexibility Act (RFA) of 1980, as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA) of 1996, requires regulators to assess the effects of regulations on small entities, including businesses, nonprofit organizations, and governments. In some instances, agencies also are required to examine regulatory alternatives that may reduce adverse economic effects on significantly impacted small entities. The RFA requires agencies to prepare an initial and final regulatory flexibility analysis for each rule unless the Agency certifies the rule will not have a significant economic impact on a substantial number of small entities. The RFA, however, does not specifically define "a significant economic impact on a substantial number" of small entities. Sections 603 and 604 of the RFA require regulatory flexibility analyses to identify the types, and estimate the numbers, of small entities to which the rule will apply, and describe the rule requirements to which small entities will be subject and any regulatory alternatives, including exemptions and deferral, that will lessen the rule's burden on small entities.

The existing IUR rule, at §710.29, generally exempts from reporting small businesses, defined at §704.3 as entities with annual sales of less than $40 million and less than 100,000 lb production of any given chemical substance at a site; or annual sales of less than $4 million. This exemption is maintained in the amendments. In addition, a small business currently is required to report if it produces any chemical substance that is the subject of a regulation proposed or promulgated under TSCA sections 4, 5(b)(4), or 6; that is the subject of an order under TSCA section 5(e); or that is the subject of relief that has been granted pursuant to a civil action under TSCA section 5 or 7. A small business may also report voluntarily.

The major steps followed in the analysis are described in the following sections.

8.1 Select a Relevant Small Entity Definition

The RFA relies on the definition of "small business" found in the Small Business Act, which authorizes the Small Business Administration (SBA) to develop definitions for "small business" for industries in each North American Industry Classification System (NAICS) code. The SBA definitions typically are based upon either a sales or an employment level, depending on the nature of the industry. Companies engaged in chemical manufacturing (NAICS Code 325) or petroleum refining (NAICS Code 324110) are the most likely to report under the IUR rule. Specifically, entities potentially affected by the rule include companies manufacturing or importing chemicals in amounts of 25,000 lb or more annually and are listed on the TSCA Inventory and regulated under TSCA §8. Under 13 CFR part 121, SBA defines small business for the six-digit NAICS industry based on employment thresholds (SBA, 2004). These employee size standards range from 500 employees to 1,500 employees for NAICS Codes 325 and 324110. For example, SBA defines a company in NAICS 325320 (Pesticide and Other Agricultural Chemical Manufacturing) as small if it has fewer than 500 employees. In comparison, a company in NAICS 324110 (Petroleum Refineries) is considered small if it has fewer than 1,500 employees. To obtain an average estimate of the number of small companies affected by the rule,

EPA chose an employment threshold of 1,000 employees to determine small business status. Throughout the remainder of this report, this definition is referred to as the "employment-based definition."

For comparative purposes, EPA also considered an alternative definition based upon sales. Under this definition, a manufacturer or importer is defined as small under 40 CFR 704.3 if it meets either of the following criteria:

- Total annual sales of the company, combined with those of any parent company, are below $40 million and annual production volume or importation volume at the facility is less than or equal to 100,000 lb; or,
- Total annual sales of the company, combined with those of any parent company, are below $4 million.

Consistent with the methodology used in the 2002 Economic Analysis for the Amended Inventory Update Final Rule (EPA, 2002), EPA assumed any company with sales less than or equal to $40 million is small, regardless of production volume.[8] This assumption may tend to overestimate the number of small businesses affected because it includes entities that may not meet all small business requirements under TSCA §8(a). Throughout the remainder of this report, this definition is referred to as the "sales-based definition."

8.2 Identify Number of Small Companies Reporting in 2006

To identify the percentage of small companies reporting under the IUR rule, EPA obtained a list of all companies that submitted a Form U during the 2006 reporting cycle (EPA, 2009c). Using the Dun & Bradstreet D-U-N-S® number reported by the company, EPA identified the ultimate parent company and obtained sales and employment data for companies for which data are available from Dun & Bradstreet Corporate Leads Portal (Dun & Bradstreet, 2009).[9]

During the 2006 reporting cycle, 4,188[10] sites submitted reports. Parent company data was available for 3,392 of these sites,[11] with 872 associated parent companies. Information for the remaining companies was unavailable for several reasons. First, these companies may be too small to be listed in Dun & Bradstreet. Second, the IUR data used may be out of date because it is based on IUR reporting for 2006 (e.g., some companies may have gone out of business or changed hands since the information was reported). Finally, certain companies may have

[8] It is important to note that the $40 million level is for parent company sales, not individual site sales.

[9]Dun & Bradstreet is a New York-based company that provides business information through a global commercial database. It assigns D-U-N-S® numbers to identify businesses around the world. These numbers are required for many U.S. federal government transactions and therefore are widely used and assigned. D-U-N-S® numbers are also used frequently in corporate research. Database entries provide legal and trade names, physical and mailing addresses, geographical descriptions, product and industry descriptors, sales and number of employees for three years and associated growth rates, as well as up to 40 vital statistics about each organization. While the reporting year varied by company, company sales and employment data were retrieved from the database in April 2009.

[10]Note that this value (4,188) does not equal the number of sites assumed for the baseline in Table 4-6 (4,085).The data used to prepare Table 4-6 counted only sites submitting reports for chemicals with production volumes equal to or greater than 25,000 lb. (that is, those sites subject to the rule). The 4,188 sites in this dataset may include submitters who voluntarily submitted reports for chemicals with production volumes lower than 25,000 lb.

[11] This does not include parent companies listed in D&B as having either 0 employees or $0 sales.

requested to be removed from, or may have declined to provide information to, Dun & Bradstreet.

Using the sales data collected for the companies for which data was available, EPA estimated the average sales for the parent companies considered small under both definitions.

Table 8-1 shows the percentage of parent companies from the 2006 IUR reporting which qualified for "small business" status, under both the employment-based and the sales-based definitions specified above. These results are fairly consistent with the 2002 EA's estimates between 21 and 35 percent of the regulated community could be considered small businesses (EPA, 2002a).

Table 8-1: Results of Dun & Bradstreet Analysis

Existing Sites (2006 Reporting Cycle)	Employment-based Definition	Sales-based Definition
Number of Global Parent Companies with Data	872	872
Number of Global Parent Companies Considered Small	360	218
Percentage of Global Parent Companies Considered Small	41.3%	25.0%
Average Annual Sales of Global Parent Companies Considered Small (2008$)	**$412,713,310**	**$11,638,441**

Source: Analysis of data from Dun & Bradstreet's *Corporate Leads Portal*, April 2009.

8.3 Estimate Number of Parent Companies

Incomplete information on global parent companies from Dun & Bradstreet for all of the companies that submitted IUR reports in 2006 required EPA estimate the total number of parent companies in the baseline. One global parent company may submit reports for more than one site. Based on the sample of companies for which the parent company information is available, EPA estimates 3.89 sites per global parent company. Given that 4,188 sites submitted reports, EPA estimates the number of parent companies for the 2006 IUR reporting baseline is 1,076.

As described in Section 4.5, the amendments are expected to increase the number of sites reporting by 204. Therefore, EPA estimates the total number of global parent companies reporting under the revised IUR rule to increase by 52 from the baseline (that is, 52 "new" companies (204÷3.89 = 52)).

8.4 Estimate Number of Small Companies

EPA estimated the number of small companies potentially impacted by the IUR amendments by applying the percentage of small companies derived in Table 8-1to the total number of parent companies EPA expects to be subject to the rule under the amendments.

Table 8-2 shows the number of expected small companies, under both definitions.

Table 8-2: Estimated Number of Small Companies under the IUR Rule Amendments

	Employment-based Definition		Sales-based Definition	
	Baseline Companies	New Companies	Baseline Companies	New Companies
Total Number of Parent Companies	1,076	52	1,076	52
Percent of Parent Companies Considered Small	41.3%		24.8%	
Number of Parent Companies Considered Small	444	22	267	13
Total Number of Parent Companies Considered Small	**466**		**280**	

Limitations of the Analysis: The amendments cause an increase in the number of sites reporting because of changes to the reporting volume thresholds and the timeframe in which the thresholds are applied. These amendments may have a disproportionate effect on smaller companies because they may be the ones manufacturing (including importing) chemical substances at or around the 25,000 lb threshold. Therefore, this method may underestimate the number of small businesses. Furthermore, to the extent the set of companies for which EPA was not able to find data are not statistically similar to the set of companies for which data was available, this analysis may under- or over-estimate the percentage of small companies.

8.5 Estimate Cost-to-Sales Ratios for Small Companies

Table 4-53 shows the total increase in industry costs associated with the amendments, if all amendments are implemented. As described in Section 4, industry costs involve compliance determination, rule familiarization, preparation and submission of reports, and recordkeeping. Because these costs will be incurred once every four years under a four-year reporting cycle, these costs were annualized over four years at both a three percent and seven percent discount rate.[12] By dividing the annualized costs for the entire industry in the first reporting cycle by the number of expected sites (4,085), EPA obtained the per-site incremental cost. EPA assumes that the per-site cost is the same for each site, regardless of whether a site is small.

EPA divided the total number of parent companies considered small (under either definition) by the number of sites associated with these parent companies to estimate the average number of sites per small parent company. This resulted in an average of approximately 1.76 sites per small company under the employee-based definition of small business and approximately 1.92 sites per small company under the sales-based definition.

The RFA does not define the terms "significant" or "substantial" analytically with regard to the extent of the economic impact and number of small entities affected. However, EPA has often defined the lower threshold as compliance costs of one percent of sales and the higher threshold as compliance costs of three percent of sales to establish whether the level of economic impacts faced by the small entities can be presumed as not significant. Therefore, to determine the magnitude of any potential adverse impact, EPA

[12] A seven percent discount rate, reflecting the opportunity cost of capital, is consistent with OMB Circular A-4 (OMB, 2003). A three percent discount rate was also used as a sensitivity analysis to examine the robustness of the results to a change in the annualization assumptions.

compared the average, annualized incremental costs on a per-company basis to the average annual sales for small businesses to develop cost-to-sales ratios. The derivation of these ratios is shown in Table 8-3.

Table 8-3: Derivation of Cost-to-Sales Ratios for Small Companies under the IUR Rule Amendments

	Employment-based Definition		Sales-based Definition	
	3% Discount Rate	7% Discount Rate	3% Discount Rate	7% Discount Rate
Total Annualized Costs	$17,161,997.89	$14,709,281.77	$17,161,997.89	$14,709,281.77
Annualized Costs per Site	$4,201	$3,601	$4,201	$3,601
Number of Sites per Small Parent Company	**1.76**		**1.92**	
Annualized Costs per Small Parent Company	$7,394	$6,337	$8,066	$6,914
Annual Sales per Small Parent Company	$412,713,310	$412,713,310	$11,821,104	$11,821,104
Cost-to-Sales Ratio	0.0018%	0.0015%	0.0682%	0.0585%
Number of Companies Potentially Affected	**466**		**280**	

As shown in Table 8-3, under the employment-based definition, a small parent company affected by the rule on average has sales of more than $412.7 million. The annualized costs of the IUR rule amendments per small parent company, however, are $7,394 at a three percent discount rate, and even lower under a seven percent discount rate. The cost-to-sales ratio for an average small company under the employment-based definition will be 0.0018 percent or less. Under the more conservative sales-based definition, small parent company sales are on average more than $11.8 million, with annualized costs associated with the amendments of $8,066 or lower. The cost-to-sales ratio for an average small company under the sales-based definition will be 0.068 percent or less.

Using the highest annual cost shown in Table 8-3, $8,066, a small company will have to have annual sales of less than $0.81 million in order to have a cost-to-sales ratio larger than one percent. As mentioned in Section 8. , firms with sales of $4 million or less are generally exempt from IUR reporting because they fall within the applicable definition of “small manufacturer,” regardless of production volume (40 CFR §704.3).Therefore, companies small enough to have a cost-to-sales ratio greater than one percent generally will be exempt from reporting under the IUR rule, and thus will not be significantly affected by the amendments.

8.6 Summary

EPA analyzed potential small business impacts from this rule using the SBA employment-based definition and the TSCA sales-based definition. EPA estimates 466 small firms potentially will be affected by this rule under the employment-based definition of the term, and 280 small firms potentially will be affected under the sales-based definition of the term. Based on costs annualized over a four-year period and average sales data, EPA estimated the cost-to-sales ratio of the rule will be 0.018 percent or less under the employment-based definition for an average small company subject to the rule, and 0.068 percent or less under the sales-based definition. As noted above, EPA often defines the lower threshold as compliance costs of one percent of sales and the higher threshold as compliance costs of three percent of sales to establish whether the level of economic impacts faced by the small entities can be presumed as not significant. For a company to have a cost-to-sales ratio larger than one percent, company sales will have to be less than $0.81 million. Because the small businesses affected by the rule actually have average sales of more than $11 million, and because any potentially affected companies with sales of $0.81 million or less will generally be exempt from reporting obligations under the IUR, small entities will not be significantly affected by the amendments to the IUR rule.

9. Additional Analyses

9.1 Executive Order 12866

Under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993), this action is a "significant regulatory action" under section 3(f) of the Executive Order because it may raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order. Accordingly, EPA submitted this action to the Office of Management and Budget (OMB) for review under Executive Order 12866 and any changes made in response to OMB recommendations have been documented in the docket for this action.

9.2 Unfunded Mandates Reform Act (UMRA)

Pursuant to Title II of the Unfunded Mandates Reform Act of 1995 (Public Law 104-4), EPA has determined this regulatory action does not contain a Federal mandate that may result in expenditures of $100 million or more for State, local, and tribal governments, in the aggregate, or for the private sector, in any one year. The analysis of the costs associated with this action is described in Unit VII.A. Thus, this rule is not subject to the requirements of sections 202 or 205 of UMRA.

In addition, EPA has determined this rule does not significantly or uniquely affect small governments. This is because only manufacturers (including importers) of chemical substances are affected by the rule. No action is required by small governments that are not chemical substance manufacturers (including importers). Accordingly, this rule is not subject to the requirements of sections 203 of UMRA.

9.3 Paperwork Reduction Act (PRA)

According to the Paperwork Reduction Act (PRA), 44 USC 3501 *et seq.*, an agency may not conduct or sponsor, and a person is not required to respond, to a collection of information that requires Office of Management and Budget (OMB) approval under the PRA, unless it has been approved by OMB and displays a valid OMB control number. The information collection requirements related to the submission of Form Us are already approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq*. That Information Collection Request (ICR) document has been assigned EPA ICR number 1884.04 and OMB control number 2070-0162.Because this rule involves new or revised information collection activities requiring additional OMB approval, EPA has prepared an addendum to the currently approved ICR (EPA, 2010a).

The Paperwork Reduction Act mandates federal agencies estimate the recordkeeping and reporting burden of a final rule. In this context, the term "burden" is interpreted as the total time, effort, or financial resources expended by people to generate, maintain, retain, disclose, or provide information to or for a federal agency. This includes the time needed by regulated entities to review instructions and to develop, acquire, install, and use technology and systems to collect, validate, verify, and disclose information. Time taken to adjust existing ways to comply with any previously applicable instructions and requirements and to train personnel to respond to the information collection task is also included. In this section, burden hours for both industry respondents and the government are estimated.

In this report, total industry burden hours represent the sum of time spent on reporting and on other administrative activities. Industry respondents will spend time on the following activities associated with the IUR rule: compliance determination, rule familiarization, preparation and submission of reports, and recordkeeping.

As derived in Section 4.5 of this report, EPA estimates the rule will impose a total estimated incremental industry burden of 0.50 million hours, in the first reporting cycle, if all amendments are implemented. The burden for the average site will increase by approximately 121 hours per site to 572 hours.

9.4 Executive Order 13132 - Federalism

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

EPA has determined this rule does not have federalism implications because it will not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government, as specified in the Order. This rule simply amends the TSCA Inventory Update Reporting rule in several ways to provide information to better address Agency and public information needs, improve the usability and reliability of the reported data, and ensure data are available in a timely manner. Because EPA has no information indicating any state or local government manufactures or processes the chemical substances covered by this action, the rule does not apply directly to states and localities and will not affect state and local governments. Thus, Executive Order 13132 does not apply to the rule.

9.5 Executive Order 12898 – Environmental Justice

Executive Order (EO) 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629 (Feb. 16, 1994)),establishes federal executive policy on environmental justice. Its main provision directs federal agencies, to the greatest extent practicable and permitted by law, to make environmental justice part of their mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of their programs, policies, and activities on minority populations and low-income populations in the United States.

The rule does not have an adverse impact on the environmental and health conditions in low-income and minority communities requiring special consideration by the Agency under EO 12898.The Agency believes the information collected under this rule, if finalized, will assist EPA and others in determining the potential hazards and risks associated with the chemical substances covered by the rule. Because the IUR rule is an information collection requirement, the information that will become available through the rule will enable the Agency to target educational, regulatory, or enforcement activities towards industries or chemical substances

posing the greatest risks and/or to target programs for geographic areas that are at the highest risk. Thus, the information to be gathered under the rule will help EPA make decisions that will benefit potentially at-risk communities, some of which may be disadvantaged.

The rule is directed at manufacturers or importers of chemical substances. All consumers of these chemical substance products and all workers who come into contact with these chemical substances could benefit if data regarding the chemical substances' health and environmental effects were developed. Therefore, it does not appear that the costs and the benefits of the rule will be disproportionately distributed across different geographic regions or among different categories of individuals.

9.6 Executive Order 13045 – Children's Health

Executive Order 13045, "Protection of Children from Environmental Health Risks and Safety Risks" (62 FR 19885, April 23, 1997), requires that federal agencies examine the impacts of each regulatory action on children for any economically significant regulation (as defined by Executive Order 12866) that the agency has reason to believe may disproportionately affect children. The rule is not subject to EO 13045, because it does not establish an environmental standard intended to mitigate health or safety risks, nor does it otherwise have a disproportionate effect on children. Furthermore, the rule is not economically significant. Nevertheless, the information obtained by the reporting required by this rule will be used to inform the Agency's decision-making process regarding chemical substances to which children may be disproportionately exposed. This information will also assist the Agency and others in determining whether the chemical substances in this rule present potential risks, allowing the Agency and others to take appropriate action to investigate and mitigate those risks.

9.7 Executive Order 13175 – Consultation and Coordination with Indian Tribal Governments

As required by Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 9, 2000), EPA has determined that this rule does not have tribal implications because it will not have any effect on tribal governments, on the relationship between the Federal government and the Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes, as specified in the Order. Thus, Executive Order 13175 does not apply to this rule.

9.8 Executive Order 13211 – Energy Supply, Distribution, or Use

This action is not a "significant energy action" as defined in Executive Order 13211, entitled *Actions Concerning Regulations that Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355 (May 22, 2001)) because it is not likely to have a significant adverse effect on the supply, distribution, or use of energy.

9.9 National Technology Transfer Advancement Act

Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law No. 104-113, 12(d) (15 U.S.C. 272 note) directs EPA to use voluntary

consensus standards in its regulatory activities unless to do so would be inconsistent with applicable law or impractical. Voluntary consensus standards are technical standards (e.g., materials specifications, test methods, sampling procedures, and business practices) that are developed or adopted by voluntary consensus standards bodies. NTTAA directs EPA to provide Congress, through OMB, explanations when the Agency decides not to use available and applicable voluntary consensus standards.

This action does not involve technical standards. Therefore, EPA did not consider the use of any voluntary consensus standards.

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Appendix A. – Current and Revised Industrial Function Categories

Table A-1: List of Current and Revised Industrial Function Categories

Current IUR Industrial Function Categories	Revised IUR Industrial Function Categories
1. Adsorbents and absorbents	1. Abrasives[+]
2. Adhesives, binders, and sealants	2. Adsorbents and absorbents
3. Aerosol Propellants[*]	3. Adhesives and sealant chemicals
4. Agricultural chemicals (non-pesticidal)	4. Agricultural chemicals (non-pesticidal)
5. Anti-adhesive agents	5. Anti-adhesive agents
6. Bleaching agents	6. Bleaching agents
7. Coloring agents, dyes[1]	7. Corrosion inhibitors and anti-scaling agents
8. Coloring agents, pigments[1]	8. Dyes[1]
9. Corrosion inhibitors and anti-scaling agents	9. Fillers
10. Fillers	10. Finishing agents[+]
11. Fixing agents[*]	11. Flame retardants
12. Flame retardants	12. Fuels and fuel additives
13. Flotation agents[*]	13. Functional fluids (closed systems)[3]
14. Fuels	14. Functional fluids (open systems)[3]
15. Functional fluids[3]	15. Intermediates
16. Intermediates	16. Ion exchange agents[+]
17. Lubricants[1]	17. Lubricants and lubricant additives[1]
18. Odor agents[2]	18. Odor agents
19. Oxidizing agents	19. Oxidizing/reducing agents[2]
20. pH-regulating agents[*]	20. Photosensitive chemicals
21. Photosensitive chemicals	21. Pigments[1]
22. Plating agents and surface treating agents	22. Plasticizers[+]
23. Processing aids, not otherwise listed	23. Plating agents and surface treating agents
24. Process regulators, used in vulcanization or polymerization processes[2]	24. Process regulators[2]
25. Process regulators, other than polymerization or vulcanization processes[2]	25. Processing aids, specific to petroleum production[+]
26. Reducing agents[2]	26. Processing aids, not otherwise listed
27. Solvents (for cleaning and degreasing)	27. Propellants and blowing agents[+]
28. Solvents (which become part of product formulation or mixture)	28. Solids separation agents[+]
29. Solvents (for chemical manufacture and processing and are not part of product at greater than 1% by weight)[*]	29. Solvents (for cleaning and degreasing)
30. Stabilizers[*]	30. Solvents (which become part of product formulation or mixture)
31. Surface active agents	31. Surface active agents
32. Viscosity adjustors	32. Viscosity adjustors
33. Other[1]	33. Laboratory chemicals
	34. Paint additives and coating additives not described by other categories
	35. Other (specify) [1]

Notes:
[1] A current industrial function category has been renamed under the amendment, but the definition of the category has not changed.
[2] Two current industrial function categories have been combined into one category under the final rule.
[3] A single industrial function category has been divided into two categories under the final rule.
[*] Indicates that a current industrial function category is being eliminated under the final rule.
[+] Indicates that a current function category is added under the final rule.

Appendix B. Current and Revised Consumer and Commercial Product Categories

EPA is revising the list of consumer and commercial product categories by combining categories that lead to common exposure scenarios and adding categories that were not adequately described in the current set of categories.

Table B-1: List of Current and Revised Consumer and Commercial Product Categories

Current IUR Consumer and Commercial Product Categories	Revised IUR Consumer and Commercial Product Categories
1.Adhesives and sealants 2.Agricultural products (non-pesticidal) 3.Artists' supplies 4.Automotive care products 5.Electrical and electronic products 6.Fabrics, textiles and apparel 7.Glass and ceramic products 8.Lawn and garden products (non-pesticidal) 9.Leather products 10. Lubricants, greases and fuel additives 11. Metal products 12. Paints and coatings 13. Paper products 14. Photographic supplies 15. Polishes and sanitation goods 16. Rubber and plastic products 17. Soaps and detergents 18. Transportation products 19. Wood and wood furniture 20. Other 21. Not readily obtainable	**Chemical Substances in Furnishing, Cleaning, Treatment/Care Products** 1.Floor Coverings 2.Foam Seating and Bedding Products 3.Furniture and Furnishings not covered elsewhere 4.Fabric, Textile, and Leather Products not covered elsewhere 5.Cleaning and Furnishing Care Products 6.Laundry and Dishwashing Products 7.Water Treatment Products 8.Personal Care Products 9.Air Care Products 10.Apparel and Footwear Care Products **Chemical Substances in Construction, Paint, Electrical, and Metal Products** 11.Adhesives and Sealants 12.Paints and Coatings 13.Building/Construction Materials - Wood and Engineered Wood Products 14.Building/Construction Materials not covered elsewhere 15.Electrical and Electronic Products 16.Metal Products not covered elsewhere 17.Batteries **Chemical Substances in Packaging, Paper, Plastic, Toys, Hobby Products** 18.Food Packaging 19.Paper Products 20.Plastic and Rubber Products not covered elsewhere 21.Toys, Playground, and Sporting Equipment 22.Arts, Crafts, and Hobby Materials 23.Ink, Toner, and Colorant Products 24.Photographic Supplies, Film, and Photochemicals **Chemical Substances in Automotive, Fuel, Agriculture, Outdoor Use Products** 25.Automotive Care Products 26.Lubricants and Greases 27.Anti-Freeze and De-icing Products 28.Fuels and Related Products 29.Explosive Materials 30.Agricultural Products (non-pesticidal) 31.Lawn and Garden Care Products **Chemical Substances in Products not Described by**

Current IUR Consumer and Commercial Product Categories	Revised IUR Consumer and Commercial Product Categories
	Other Categories 32.Non-TSCA Use 33.Other (specify)

Appendix C. Industrial Sectors

EPA is replacing the NAICS codes used in the industrial processing and use information section with a new set of Industrial Sectors, developed from the European Union's REACH program.

Code	Sector Description
IS1	Agriculture, Forestry, Fishing and Hunting
IS2	Oil and Gas Drilling, Extraction, and support activities
IS3	Mining (except Oil and Gas) and support activities
IS4	Utilities
IS5	Construction
IS6	Food, beverage, and tobacco product manufacturing
IS7	Textiles, apparel, and leather manufacturing
IS8	Wood Product Manufacturing
IS9	Paper Manufacturing
IS10	Printing and Related Support Activities
IS11	Petroleum Refineries
IS12	Asphalt Paving, Roofing, and Coating Materials Manufacturing
IS13	Petroleum Lubricating Oil and Grease Manufacturing
IS14	All other Petroleum and Coal Products Manufacturing
IS15	Petrochemical Manufacturing
IS16	Industrial Gas Manufacturing
IS17	Synthetic Dye and Pigment Manufacturing
IS18	Carbon Black Manufacturing
IS19	All Other Basic Inorganic Chemical Manufacturing
IS20	Cyclic Crude and Intermediate Manufacturing
IS21	All Other Basic Organic Chemical Manufacturing
IS22	Plastics Material and Resin Manufacturing
IS23	Synthetic Rubber Manufacturing
IS24	Organic Fiber Manufacturing
IS25	Pesticide, Fertilizer, and Other Agricultural Chemical Manufacturing
IS26	Pharmaceutical and Medicine Manufacturing
IS27	Paint and Coating Manufacturing
IS28	Adhesive Manufacturing
IS29	Soap, Cleaning Compound, and Toilet Preparation Manufacturing
IS30	Printing Ink Manufacturing
IS31	Explosives Manufacturing
IS32	Custom Compounding of Purchased Resins
IS33	Photographic Film, Paper, Plate, and Chemical Manufacturing
IS34	All Other Chemical Product and Preparation Manufacturing
IS35	Plastics Product Manufacturing
IS36	Rubber Product Manufacturing
IS37	Nonmetallic Mineral Product Manufacturing (includes clay, glass, cement, concrete, lime, gypsum, and other nonmetallic mineral product manufacturing)
IS38	Primary Metal Manufacturing
IS39	Fabricated Metal Product Manufacturing
IS40	Machinery Manufacturing
IS41	Computer and Electronic Product Manufacturing
IS42	Electrical Equipment, Appliance, and Component Manufacturing
IS43	Transportation Equipment Manufacturing
IS44	Furniture and Related Product Manufacturing
IS45	Miscellaneous Manufacturing
IS46	Wholesale and Retail Trade
IS47	Services
IS48	Other (requires additional information)

Appendix D. Sensitivity Analyses

Some of EPA's amendments to the IUR rule are expected to change the number of submitters, reports, or the number of responses to a specific question on Form U. For several options, data available from the 2006 IUR was used to directly estimate the number of chemical substances or submitters affected by the amendment. For example, the number of submitters who produce manufactured water above the threshold is known. However, a lack of available data for other amendments meant EPA only was able to estimate the impact broadly, such as a percentage increase or decrease in the number of submitters caused by the amendment, using the Agency's best professional judgment. These amendments include (1) the method for determining whether the threshold is met, (2) reporting production volume used on-site, (3) requiring write-in text if submitter selects "Other" as a product function category, (4) requiring write-in text if selecting "Other" as a consumer or commercial use, and, (5) upfront substantiation for all CBI claims for processing and use information. In estimating the cost of these amendments, EPA used a midpoint estimate for the percentage increase or decrease in the number of submitters, reports filed, or number of submitters answering a specific question. To show the possible range of costs as a result of the amendments more accurately, EPA presents a range of costs in this section, using the lower and upper bounds for the item estimated.

D.1 Method for Determining Whether the Threshold Is Met

Currently, the IUR rule requires a report be filed for a chemical substance only if the chemical substance's production volume exceeds the 25,000 lb threshold in the principal IUR reporting year. EPA is modifying the timeframe for reporting in future reporting cycles subsequent to 2012 so chemical substance manufacturers (including importers) will be subject to the IUR rule if a chemical substance's production volume has met or exceeded the threshold in any calendar year since the last principal reporting year. The Agency expects this will increase the number of sites and reports submitted by between zero and ten percent of the baseline (see Table 4-6). In Section 5.4, the Agency estimated the increase in cost and burden to industry using a midpoint estimate of five percent. Using a five percent increase in the number of sites and reports, EPA expects the burden to industry will increase by approximately 72,000 hours in future reporting cycles (see Table 4-12). Table D-1: contains the results of the sensitivity analysis using a lower bound estimate of a zero percent increase in the number of submitters and an upper bound estimate of a ten percent increase. All baseline burden estimates were taken from Table 4-2. The increase in burden to industry is expected to range from zero hours to approximately 143,000 hours as a result of modifying the method for determining whether the 25,000 lb threshold is met in future reporting cycles.

Table D-1: Sensitivity Analysis of Industry Burden Estimates for Modifying the Method for Determining Whether the Threshold Is Met (Future Reporting Cycles Only)

	Burden to Prepare Part I, Rule Familiarization, Compliance Determination, and Submission (hours per site)	Number of Sites		Burden to Prepare Part II and Record Keeping (hours per report)	Number of Reports (with Part II)		Burden to Prepare Part III (hours per report)	Number of Reports (with Part III)		Industry Burden (hours)	
		Lower Bound (0% increase)	Upper Bound (10% increase)		Lower Bound (0% increase)	Upper Bound (10% increase)		Lower Bound (0% increase)	Upper Bound (0% increase)	Lower Bound (10% increase)	Upper Bound (10% increase)
	(a)	(b)	(b)	(c)	(d)	(d)	(e)	(f)	(f)	(g) = (a*b)+(c*d)+(e*f)	
Baseline	9.08	4,085	4,085	17.06	25,896	25,896	55.93	17,075	17,075	1,433,833	1,433,833
Post-Amendment	9.08	4,085	4,494	17.06	25,896	28,486	55.93	17,075	18,783	1,433,833	1,577,216
Change from the Baseline	**0.00**	**0**	**409**	**0.00**	**0**	**2,590**	**0.00**	**0**	**1,708**	**0**	**143,383**

Note: Values in *Change from the Baseline* rows are calculated by subtracting the corresponding baseline value from the post-amendment value.

Table D-2 shows the range of cost estimates using a zero percent lower bound and ten percent upper bound increase in the number of reports and submitters as a result of the amendment. All baseline cost estimates are taken from Table 4-5. EPA estimates a cost to industry between $0 and $8.28 million. The midpoint cost estimate of $4.14 million is used in Table 4-13.

Table D-2: Sensitivity Analysis of Industry Cost Estimates for Modifying the Method for Determining Whether the Threshold Is Met (Future Reporting Cycles Only)

	Cost to Prepare Part I, Rule Familiarization, Compliance Determination and Submission (2008$ per site)	Number of Sites		Cost to Prepare Part II and Record Keeping (2008$ per report)	Number of Reports (with Part II)		Cost to Prepare Part III (2008$ per report)	Number of Reports (with Part III)		Industry Cost (millions 2008$)	
		Lower Bound (0% increase)	Upper Bound (10% increase)		Lower Bound (0% increase)	Upper Bound (10% increase)		Lower Bound (0% increase)	Upper Bound (10% increase)	Lower Bound (0% increase)	Upper Bound (10% increase)
	(a)	(b)	(b)	(c)	(d)	(d)	(e)	(f)	(f)	(g) = (a*b)+(c*d)+(e*f)	
Baseline	$560.77	4,085	4,085	$968.39	25,896	25,896	$3,247.40	17,075	17,075	$82.82	$82.82
Post-Amendment	$560.77	4,085	4,494	$968.39	25,896	28,486	$3,247.40	17,075	18,783	$82.82	$91.10
Change from the Baseline	**$0.00**	**0**	**409**	**$0.00**	**0**	**2,590**	**$0.00**	**0**	**1,708**	**$0.00**	**$8.28**

Note: Values in *Change from the Baseline* rows are calculated by subtracting the corresponding baseline value from the post-amendment value.

The cost and burden to the Agency of this amendment were calculated in Section 5.4. With a five- percent increase in the number of reports, the Agency's burden is expected to increase by 104 hours (see Table 5-5). The range in the burden increase to EPA, using a lower bound zero percent increase in the number reports and an upper bound increase of ten percent, is presented in Table D-3. Baseline Agency burden is taken from Table 5-4. The amendment is expected to increase the Agency burden by between zero and 208 hours.

Table D-3: Sensitivity Analysis of Agency Burden Estimates for Modifying the Method for Determining Whether the Threshold Is Met (Future Reporting Cycles Only)

	Burden to Process Part I (hours) (a)	Number of Sites		Burden to Process Part II (hours) (c)	Number of Reports (with Part II)		Burden to Process Part III (hours) (e)	Number of Reports (with Part III)		Industry Burden (hours)	
		Lower Bound (0% increase) (b)	Upper Bound (10% increase) (b)		Lower Bound (0% increase) (d)	Upper Bound (10% increase) (d)		Lower Bound (0% increase) (f)	Upper Bound (10% increase) (f)	Lower Bound (0% increase) (g) = (a*b)+(c*d)+(e*f)	Upper Bound (10% increase) (g) = (a*b)+(c*d)+(e*f)
Baseline	0.017	4,085	4,085	0.042	25,896	25,896	0.054	17,075	17,075	2,080	2,080
Post-Amendment	0.017	4,085	4,494	0.042	25,896	28,486	0.054	17,075	18,783	2,080	2,288
Change from the Baseline	**0.000**	**0**	**409**	**0.000**	**0**	**2,590**	**0.000**	**0**	**1,708**	**0**	**208**

Note: Values in *Change from the Baseline* rows are calculated by subtracting the corresponding baseline value from the post-amendment value.

Table D-4 shows the range in Agency costs as a result of modifying the method for determining whether the threshold is met. Baseline Agency costs are taken from Table 5-4. The amendment is expected to increase the Agency cost between approximately $0 and $21,700 during the first reporting cycle.

Table D-4: Sensitivity Analysis of Agency Cost Estimates for Modifying the Method for Determining Whether the Threshold Is Met (Future Reporting Cycles Only)

	Cost to Process Part I (2008$) (a)	Number of Sites		Cost to Process Part II (2008$) (c)	Number of Reports (with Part II)		Cost to Process Part III (2008$) (e)	Number of Reports (with Part III)		Industry Cost (2008$)	
		Lower Bound (0% increase) (b)	Upper Bound (10% increase) (b)		Lower Bound (0% increase) (d)	Upper Bound (10% increase) (d)		Lower Bound (0% increase) (f)	Upper Bound (10% increase) (f)	Lower Bound (0% increase) (g) = (a*b)+(c*d)+(e*f)	Upper Bound (10% increase) (g) = (a*b)+(c*d)+(e*f)
Baseline	$1.78	4,085	4,085	$4.40	25,896	25,896	$5.61	17,075	17,075	$216,949	$216,949
Post-Amendment	$1.78	4,085	4,494	$4.40	25,896	28,486	$5.61	17,075	18,783	$216,949	$238,644
Change from the Baseline	**$0.00**	**0**	**409**	**$0.00**	**0**	**2,590**	**$0.00**	**0**	**1,708**	**$0**	**$21,695**

Note: Values in *Change from the Baseline* rows are calculated by subtracting the corresponding baseline value from the post-amendment value.

D.2 Reporting Production Volume Used On-Site

The cost to industry of requiring the reporting of production volume used on-site is estimated in Section 4.4.13. EPA estimated between 14.8 percent of all reports (the percentage of reports which included a site-limited volume in 2006 reporting (EPA 2008c)) and 24 percent of all reports (the percentage of 2006 reports which claim the chemical substances is an intermediate in the downstream use and processing section (EPA, 2008c)) will report production volume used on-site. Therefore, the total number of reports with volume used on-site ranges from 3,833 to 6,215 reports. Using a midpoint of 19.4 percent, industry burden is expected to increase by 7,596 hours (see Table 4-26). Table D-5shows the burden estimates using the lower and upper bounds for the number of reports that will contain information on production volume used on-site. The baseline cost per report is taken from Table 4-6. EPA expects the total industry burden to range from 5,800 to 9,400 hours.

Table D-5: Sensitivity Analysis of Industry Burden Estimates for Reporting Production Volume Used On-Site

	Burden per Report to Report Production Volume Used On-Site (hours)	Number of Reports with Production Volume Used On-Site		Total Industry Burden (hours)	
		Lower Limit (14.8% of all Reports)	Upper Limit (24% of all Reports)	Lower Limit (14.8% of all Reports)	Upper Limit (24% of all Reports)
Baseline	0.00	0	0	0	0
Post-Amendment	1.51	3,833	6,215	5,795	9,397
Change from the Baseline	**1.51**	**3,833**	**6,215**	**5,795**	**9,397**

Note: Values in *Change from the Baseline* rows are calculated by subtracting the corresponding baseline value from the post-amendment value.

Table D-6 contains the range of cost estimates using a 14.8 percent lower bound and 24 percent upper bound increase in the number of reports under the amendment .All baseline cost estimates are taken from Table 4-5. EPA estimates a cost to industry between $324,500 and $526,300, with a midpoint estimate of $0.43 million (see Table 4-27).

Table D-6: Sensitivity Analysis of Industry Cost Estimates for Reporting Production Volume Used On-Site

	Cost per Report to Report Production Volume Used On-Site (2008$)	Number of Reports with Production Volume Used On-Site		Total Industry Cost (2008$)	
		Lower Limit (14.8% of all Reports)	Upper Limit (24% of all Reports)	Lower Limit (14.8% of all Reports)	Upper Limit (24% of all Reports)
Baseline	$0.00	0	0	$0	$0
Post-Amendment	$84.68	3,833	6,215	$324,544	$526,288
Change from the Baseline	**$84.68**	**3,833**	**6,215**	**$324,544**	**$526,288**

Note: Values in *Change from the Baseline* rows are calculated by subtracting the corresponding baseline value from the post-amendment value.

In Section 5.4.13, EPA calculated the burden to the Agency of requiring the reporting of production volume used on-site, using 19.4 percent as the estimated amount of reports listing

production volume used on-site is calculated in Section 5.4.13. The resulting burden was 4.51 hours. In Table D-7, EPA calculates the range of burden estimates to the Agency, using a range of 14.8 to 24 percent as the amount of reports listing production volume used on-site. The resulting burden is 3.44 to 5.57 hours per reporting cycle. The baseline burden per report is taken from Table 5-4.

Table D-7: Sensitivity Analysis of Agency Burden Estimates for Reporting Production Volume Used On-Site

	Burden per Report to Report Production Volume Used On-Site (hours)	Number of Reports with Production Volume Used On-Site		Burden per Report to Report Production Volume Used On-Site (hours)	
		Lower Limit (14.8% of all Reports)	Upper Limit (24% of all Reports)	Lower Limit (14.8% of all Reports)	Upper Limit (24% of all Reports)
Baseline	0.000	0	0	0.00	0.00
Post-Amendment	0.001	3,833	6,215	3.44	5.57
Change from the Baseline	**0.001**	**3,833**	**6,215**	**3.44**	**5.57**

Note: Values in *Change from the Baseline* rows are calculated by subtracting the corresponding baseline value from the post-amendment value.

Table D-8 contains the range in costs to EPA as a result of modifying the method for determining whether the threshold is met. Baseline costs to EPA are taken from Table 5-4. The amendment is expected to increase the Agency cost between approximately $359 and $581 during the first reporting cycle.

Table D-8: Sensitivity Analysis of Agency Cost Estimates for Reporting Production Volume Used On-Site

	Cost per Report to Report Production Volume Used On-Site (2008$)	Number of Reports with Production Volume Used On-Site		Cost per Report to Report Production Volume Used On-Site (2008$)	
		Lower Limit (14.8% of all Reports)	Upper Limit (24% of all Reports)	Lower Limit (14.8% of all Reports)	Upper Limit (24% of all Reports)
Baseline	$0.00	0	0	$0.00	$0.00
Post-Amendment	$0.09	3,833	6,215	$359	$581
Change from the Baseline	**$0.09**	**3,833**	**6,215**	**$359**	**$581**

Note: Values in *Change from the Baseline* rows are calculated by subtracting the corresponding baseline value from the post-amendment value.

D.3 Revising Industrial Function Categories

EPA is revising the current industrial function categories (found in Part III, Section A of Form U), by eliminating seven existing categories and adding seven new categories, and requiring submitters to write in a free-text descriptor when they select "Other". EPA anticipates these actions will reduce the number of submitters selecting "Other" by approximately 50 percent, from 1,206 reports to 603 (EPA, 2008a). The burden increase of 4,400 hours and cost increase of $260,000 are calculated in Section 4.4.18.

The Agency conducted a sensitivity analysis for these estimates, with the decrease in reports selecting "Other" ranging from a 25 percent reduction of the total (905 reports in total) to a 75

percent reduction in total (302 reports in total). The results of this analysis for industry burden are found in Table D-9. A 75 percent reduction in the number of submitters claiming "Other" means 25 percent of submitters are now claiming "Other," and a 25 percent reduction means 75 percent of submitters are now claiming "Other." The columns in this table and the remaining tables in this Appendix are labeled to reflect the resulting numbers; e.g., they show the lower resulting number in the "Lower Bound" column and the higher resulting number in the "Upper Bound" column.

Baseline burden estimates are taken from Table 4-2 and the baseline number of reports is found in Table 4-6. EPA estimates the burden to industry will increase by between 4,300 and 4,400 hours.

Table D-9: Sensitivity Analysis of Industry Burden Estimates for Requiring Write-in Text for "Other" as an Industrial Function Category

	Burden for Rule Familiarization of Additional Categories (hours)	Number of Reports with Industrial Function Categories	Burden for Write-in Text for "Other" (hours)	Number of Reports with "Other" Write-in Text		Total Industry Burden (hours)	
				Lower Bound (25% of Submitters Claim "Other")	Upper Bound (75% of Submitters Claim" Other")	Lower Bound (25% of Submitters Claim "Other")	Upper Bound (75% of Submitters Claim "Other")
Baseline	8.59	17,075	0.00	0	0	146,661	146,661
Post-Amendment	8.84	17,075	0.15	302	905	150,975	151,066
Change from the Baseline	**0.25**	**0**	**0.15**	**302**	**905**	**4,314**	**4,404**

Note: Values in *Change from the Baseline* rows are calculated by subtracting the corresponding baseline value from the post-amendment value.

Table D-10 contains the range of cost estimates to industry with a lower bound estimate of a 75 percent decrease in the number of reports with "Other" as industrial function categories and an upper bound of a 25 percent decrease in the number of reports with "Other" as industrial function categories. All baseline cost estimates are taken from Table 4-5. EPA estimates a cost to industry between $253,400 and $257,800, with a midpoint estimate of $256,000 (see Table 4-35).

Table D-10: Sensitivity Analysis of Industry Cost Estimates for Requiring Write-in Text for "Other" as an Industrial Function Category

	Cost for Rule Familiarization of Additional Categories (2008$)	Number of Reports with Industrial Function Categories	Cost for Write-in Text for "Other" (2008$)	Number of Reports with "Other" Write-in Text		Total Industry Cost (2008$)	
				Lower Bound (25% of Submitters Claim "Other")	Upper Bound (75% of Submitters Claim "Other")	Lower Bound (25% of Submitters Claim "Other")	Upper Bound (75%of Submitters Claim "Other")
Baseline	$88.02	17,075	$0.00	0	0	$1,502,913	$1,502,913
Post-Amendment	$102.73	17,075	$7.31	302	905	$1,756,287	$1,760,693
Change from the Baseline	**$14.71**	**0**	**$7.31**	**302**	**905**	**$253,374**	**$257,780**

Note: Values in *Change from the Baseline* rows are calculated by subtracting the corresponding baseline value from the post-amendment value.

Using a 50 percent decrease in the number of reports with "Other" selected, the burden to the Agency during a reporting cycle is 0.54 hours and is calculated in Section 5.4.18. Table D-11 contains the range of burden estimates to the Agency, 0.27 hour to 0.81 hours per reporting cycle. The baseline Agency burden estimates per report are taken from Table 5-4.

Table D-11: Sensitivity Analysis of Agency Burden Estimates for Requiring Write-in Text for "Other" as an Industrial Function Category

	Burden to Process Write-in Text for "Other" (hours)	Number of Reports with "Other" Write-in Text		Total Agency Burden (hours)	
		Lower Bound (25% of Submitters Claim "Other")	Upper Bound (75%of Submitters Claim "Other")	Lower Bound (25% of Submitters Claim "Other")	Upper Bound (75%of Submitters Claim "Other")
Baseline	0.000	0	0	0.00	0.00
Post-Amendment	0.001	302	905	0.27	0.81
Change from the Baseline	**0.001**	**302**	**905**	**0.27**	**0.81**

Note: Values in *Change from the Baseline* rows are calculated by subtracting the corresponding baseline value from the post-amendment value.

Table D-12 contains the range in costs to EPA as a result of modifying the industrial function categories. Baseline costs to EPA are taken from Table 5-4. The amendment is expected to increase the Agency cost between approximately $28 and $85 during the first reporting cycle.

Table D-12: Sensitivity Analysis of Agency Cost Estimates for Requiring Write-in Text for "Other" as an Industrial Function Category

	Cost to Process Write-in Text for "Other" (2008$)	Number of Reports with "Other" Write-in Text		Total Agency Cost (2008$)	
		Lower Bound (25%of Submitters Claim "Other")	Upper Bound (75%of Submitters Claim "Other")	Lower Bound (25%of Submitters Claim "Other")	Upper Bound (75%of Submitters Claim "Other")
Baseline	$0.00	0	0	$0	$0
Post-Amendment	$0.09	302	905	$28	$85
Change from the Baseline	**$0.09**	**302**	**905**	**$28**	**$85**

Note: Values in *Change from the Baseline* rows are calculated by subtracting the corresponding baseline value from the post-amendment value

D.4 "Other" as a Consumer and/or Commercial Product Category

EPA is revising the list of consumer and commercial product categories by combining categories leading to common exposure scenarios and adding categories not adequately described in the current set of categories. The resultant list includes 33 product categories, including "Other." Several consumer and commercial product categories have been renamed to better describe the products that should be reported in that category. EPA is also requiring that if the product category "Other" is selected; a descriptor for the consumer and/or commercial product containing the chemical substance also to be reported. According to 2006 IUR data (EPA, 2008c), 1,207 reports listed "Other" as a consumer and/or commercial product category .Based on EPA's best professional judgment, EPA expects the new categories in the amendment will reduce by half the number of submitters selecting "Other" as a consumer and/or commercial product category. Therefore, this amendment will affect 604 reports. The cost and burden to industry with a 50 percent reduction in the number of submitters is found in Section 4.4.20.

The Agency conducted a sensitivity analysis for the decrease in reports selecting "Other" ranging from a 25 percent reduction of the total (905 reports in total) to a 75 percent reduction of the total (302 reports in total). The results of this analysis for industry are found in Table D-13. Baseline burden estimates are taken from Table 4-2 and the baseline number of reports is found in Table 4-6. EPA estimates the burden to industry will increase between 16,000 and 16,100 hours.

Table D-13: Sensitivity Analysis of Industry Burden Estimates for Requiring Write-in Text for "Other" as a Consumer and/or Commercial Product Category

	Burden for Rule Familiarization of Additional Categories (hours)	Number of Reports with Consumer/ Commercial Product Categories	Burden for Write-in Text for "Other" (hours)	Number of Reports with "Other" Write-in Text		Total Industry Burden (hours)	
				Lower Bound (25%of Submitters Claim "Other")	Upper Bound (75%of Submitters Claim "Other")	Lower Bound (25%of Submitters Claim "Other")	Upper Bound (75%of Submitters Claim "Other")
Baseline	8.59	17,075	0.00	0	0	146,661	146,661
Post-Amendment	9.52	17,075	0.15	302	905	162,672	162,762
Change from the Baseline	**0.94**	**0**	**0.15**	**302**	**905**	**16,010**	**16,101**

Note: Values in *Change from the Baseline* rows are calculated by subtracting the corresponding baseline value from the post-amendment value.

Table D-14shows the range of cost estimates to industry with a lower bound estimate of a 75 percent decrease in the number of "Other" as a consumer and/or commercial product category and an upper bound of a 25 percent decrease in the number of "Other" as a consumer and/or commercial product categories. All baseline cost estimates are taken from Table 4-5. EPA estimates a cost to industry of between $843,000 and $848,000, with a midpoint estimate of $846,000 (see Table 4-37).

Table D-14: Sensitivity Analysis of Industry Cost Estimates for Requiring Write-in Text for "Other" as a Consumer and/or Commercial Product Category

	Cost for Rule Familiarization of Additional Categories (2008$)	Number of Reports with Consumer/ Commercial Product Categories	Cost for Write-in Text for "Other" (2008$)	Number of Reports with "Other" Write-in Text		Total Industry Cost (2008$)	
				Lower Bound (25%of Submitters Claim "Other")	Upper Bound (75%of Submitters Claim "Other")	Lower Bound (25%of Submitters Claim "Other")	Upper Bound (75%of Submitters Claim "Other")
Baseline	$70.64	17,075	$0.00	0	0	$1,206,177	$1,206,177
Post-Amendment	$119.90	17,075	$7.31	302	905	$2,049,551	$2,053,962
Change from the Baseline	**$49.26**	**0**	**$7.31**	**302**	**905**	**$843,374**	**$847,785**

Note: Values in *Change from the Baseline* rows are calculated by subtracting the corresponding baseline value from the post-amendment value.

Using a 50 percent decrease in the number of reports with "Other" selected, the burden to the Agency during each reporting cycle is 0.54 hours and is calculated in Section 5.4.20. Table D-15

shows the range of burden estimates to the Agency; 0.27 hour to 0.81 hours per reporting cycle. The baseline Agency burden estimates per report are taken from Table 5-4.

Table D-15: Sensitivity Analysis of Agency Burden Estimates for Requiring Write-in Text for "Other" as a Consumer and/or Commercial Product Category

	Burden to Process Write-in Text for "Other" (hours)	Number of Reports with "Other" Write-in Text		Total Agency Burden (hours)	
		Lower Bound (25%of Submitters Claim "Other")	Upper Bound (75%of Submitters Claim "Other")	Lower Bound (25%of Submitters Claim "Other")	Upper Bound (75%of Submitters Claim "Other")
Baseline	0.000	0	0	0.00	0.00
Post-Amendment	0.001	302	905	0.27	0.81
Change from the Baseline	**0.001**	**302**	**905**	**0.27**	**0.81**

Note: Values in *Change from the Baseline* rows are calculated by subtracting the corresponding baseline value from the post-amendment value.

Table D-16 shows the range in costs to EPA as a result of modifying the consumer and commercial product categories. Baseline costs to EPA are taken from Table 5-4.The amendment is expected to increase the Agency cost between $28 and approximately $85 during the first reporting cycle.

Table D-16: Sensitivity Analysis of Agency Cost Estimates for Requiring Write-in Text for "Other" as a Consumer and/or Commercial Product Category

	Number of Reports with "Other" Write-in Text		Total Agency Cost (2008$)	
	Lower Bound (25%of Submitters Claim "Other")	Upper Bound (75%of Submitters Claim "Other")	Lower Bound (25%of Submitters Claim "Other")	Upper Bound (75%of Submitters Claim "Other")
Baseline	0	0	$0	$0
Post-Amendment	302	905	$28	$85
Change from the Baseline	**302**	**905**	**$28**	**$85**

Note: Values in *Change from the Baseline* rows are calculated by subtracting the corresponding baseline value from the post-amendment value.

D.5 Upfront CBI Substantiation

EPA is requiring an upfront substantiation when a submitter claims processing and use information as confidential business information (CBI). In 2002, when EPA first required upfront substantiation for claiming plant site IDs as CBI, the Agency saw a 64 percent reduction in the number of CBI claims. The Agency expects the number of DPU CBI claims to decrease by the same amount as a result of this amendment. According to 2006 IUR data (EPA, 2008c), a total of 8,133 reports had claimed processing and use information was CBI, with an average of three CBI claims for processing and use information per report. The estimates for industry cost of $773,000 and burden of 12,800 hours, associated with the 8,133 CBI claims are found in Section 4.4.25.

The Agency conducted a sensitivity analysis, assuming the reduction in CBI claims has a lower bound of 84 percent, meaning 16 percent of submitters make a CBI claim in Part III, and an upper bound of 44 percent, meaning 56 percent of submitters make a CBI claim in Part III. Table D-17 contains range in burden increase to industry as a result of the amendment. The burden is expected to increase by between 5,700 and 19,900 hours.

Table D-17: Sensitivity Analysis of Industry Burden Estimates for Requiring Upfront CBI Substantiation

	Burden for Upfront CBI Substantiation for CBI Claims in Part III (hours)	Number of Reports with CBI Claims in Part III		Industry Burden (hours)	
		Lower Limit (16%of Submitters Claim CBI)	Upper Limit (56%of Submitters Claim CBI)	Lower Limit (16%of Submitters Claim CBI)	Upper Limit (56%of Submitters Claim CBI)
Baseline	0.00	8,133	8,133	0	0
Post-Amendment	4.38	1,301	4,554	5,700	19,949
Change from the Baseline	**4.38**	**-6,832**	**-3,579**	**5,700**	**19,949**

Note: Values in *Change from the Baseline* rows are calculated by subtracting the corresponding baseline value from the post-amendment value.

Table D-18shows the range of cost estimates to industry, with a lower bound estimate of an 84 percent decrease in the number of DPU CBI claims and an upper bound of a 44 percent decrease in the number of DPU CBI claims. All baseline cost estimates are taken from Table 4-5. EPA estimates industry cost of between $343,400 and $1.2 million, with a midpoint estimate of $773,000 (see Table 4-35).

Table D-18: Sensitivity Analysis of Industry Cost Estimates for Requiring Upfront CBI Substantiation

	Cost for Upfront CBI Substantiation for CBI Claims in Part III (2008$)	Number of Reports with CBI Claims in Part III		Industry Cost (2008$)	
		Lower Limit (16%of Submitters Claim CBI)	Upper Limit (56%of Submitters Claim CBI)	Lower Limit (16%of Submitters Claim CBI)	Upper Limit (56%of Submitters Claim CBI)
Baseline	$0.00	8,133	8,133	$0	$0
Post-Amendment	$263.90	1,301	4,554	$343,413	$1,201,944
Change from the Baseline	**$263.90**	**-6,832**	**-3,579**	**$343,413**	**$1,201,944**

Note: Values in *Change from the Baseline* rows are calculated by subtracting the corresponding baseline value from the post-amendment value.

Using a 64 percent decrease in the number CBI claims, the Agency burden increase during each reporting cycle is calculated as eight hours in Section 5.4.25. Table D-19 contains the range of burden estimates to the Agency, which is 3.50 hours to 12.25 hours per reporting cycle. The baseline Agency burden estimates per report are taken from Table 5-4.

Table D-19: Sensitivity Analysis of Agency Burden Estimates for Requiring Upfront CBI Substantiation

	Burden for Upfront CBI Substantiation for CBI Claims in Part III (hours)	Number of Reports with CBI Claims in Part III		Agency Burden (hours)	
		Lower Limit (16%of Submitters Claim CBI)	Upper Limit (56%of Submitters Claim CBI)	Lower Limit (16%of Submitters Claim CBI)	Upper Limit (56%of Submitters Claim CBI)
Baseline	0.00	8,133	8,133	0	0
Post-Amendment	0.28	1,301	4,554	3.50	12.25
Change from the Baseline	**0.28**	**-6,832**	**-3,579**	**3.50**	**12.25**

Note: Values in *Change from the Baseline* rows are calculated by subtracting the corresponding baseline value from the post-amendment value.

Table D-20 contains the range in costs to EPA as a result of modifying the industrial function categories. Baseline costs to EPA are taken from Table 5-4.The amendment is expected to increase the Agency cost between $365 and $1,278 during the first reporting cycle.

Table D-20: Sensitivity Analysis of Agency Cost Estimates for Requiring Upfront CBI Substantiation

	Cost for Upfront CBI Substantiation for CBI Claims in Part III	Number of Reports with CBI Claims in Part III		Agency Cost (2008$)	
		Lower Limit (16%of Submitters Claim CBI)	Upper Limit (56%of Submitters Claim CBI)	Lower Limit (16%of Submitters Claim CBI)	Upper Limit (56%of Submitters Claim CBI)
Baseline	$0.00	8,133	8,133	$0	$0
Post-Amendment	$0.28	1,301	4,554	$365	$1,278
Change from the Baseline	**$0.28**	**-6,832**	**-3,579**	**$365**	**$1,278**

Note: Values in *Change from the Baseline* rows are calculated by subtracting the corresponding baseline value from the post-amendment value.

Appendix E. Alternative Regulatory Options

In developing the amendments to the IUR rule, EPA considered other regulatory options as alternatives to some of the proposed amendments. These options were considered both as alternatives to all the proposed amendments, and in addition to the proposed amendments outlined in Chapter 3. The burden and cost for these alternate regulatory options are described in the following sections. Because these options were considered only during the proposed rule, the total costs, submission dates, and annualization periods associated with them may not match what is presented in the main text for the final rule.

E.1 Require Submitters to Submit Full Data Annually

As an alternative to the amendment described in Section 3.5.4, which will require submitters to report production volume for each of the years since the last IUR report, EPA considered an option in which submitters would be required to submit *all* Form U data for each year they meet or exceed the reporting threshold. EPA calculated the cost and burden of this option under two different scenarios. The first calculates the cost and burden to the industry and the Agency without considering the other proposed amendments. The second scenario estimates the cost and burden to all affected entities if all the proposed amendments outlined in Section 3. are enacted.

E.1.1 Annual Reporting Cost and Burden when the Option is Considered by Itself

Under this alternative option, EPA estimated the cost to the industry and the Agency of annual reporting when the option is considered by itself, with none of the other proposed amendments considered. The annual reporting cost and burden would be the same as in the baseline burden shown in Table 4-10. The number of submitters is not expected to change from year to year, after the first reporting cycle. While the Agency is aware that a site's production volume may vary yearly, causing the site to meet or exceed the threshold in some years but not in others, EPA believes on average, the total number of sites and reports would remain unchanged from year to year.

EPA analyzed the burden and costs over a 25-year period. EPA assumes submitters will become more efficient at reporting data over time, and therefore incur a smaller burden in future reporting cycles. Future-cycle reporting burden is taken from Table 4-11.

The annual industry burden under the baseline and the alternative option is shown in Table E-1. In total, EPA estimates the industry burden would increase by approximately 22.94 million hours over 25 years (five reporting cycles). Over one future five-year reporting cycle, the industry burden is expected to increase by 5.74 million hours (1.43 million hours x 4 years) compared to the baseline.

Table E-1: Industry Burden under the Alternative Option to Require Submitters to Submit Full Data Annually

Reporting Cycle	Years	Baseline Burden	Post-Alternative Option Burden	Change from Baseline
		(millions of hours)	(millions of hours)	(millions of hours)
1	**2007 to 2011**	1.84	1.84	0.00
2	**2012 to 2016**	1.43	7.17	5.74

3	**2017 to 2021**	1.43	7.17	5.74
4	**2022 to 2026**	1.43	7.17	5.74
5	**2027 to 2031**	1.43	7.17	5.74
Total		**7.58**	**30.52**	**22.94**
Annual Average		**0.30**	**1.22**	**0.92**

The industry cost under the baseline and this alternative option is shown in Table E-2. EPA estimates the industry cost would increase by $1.33 billion over a 25-year period. The annualized cost increase ranges from $44.34 million with a seven percent discount rate to $49.54 million with a three percent discount rate. Over one five-year reporting cycle, this option would increase industry cost by approximately $331 million ($82.8 million x 4 years) compared to the baseline.

Table E-2: Industry Cost under the Alternative Option to Require Submitters to Submit Full Data Annually

Reporting Cycle	Years	Baseline Cost	Post-Alternative Option Cost	Change from Baseline
		(2008$ millions)	(2008$ millions)	(2008$ millions)
1	**2007 to 2011**	$106.97	$106.97	$0.00
2	**2012 to 2016**	$82.82	$414.09	$331.27
3	**2017 to 2021**	$82.82	$414.09	$331.27
4	**2022 to 2026**	$82.82	$414.09	$331.27
5	**2027 to 2031**	$82.82	$414.09	$331.27
Total		**$438.24**	**$1,763.32**	**$1,325.08**
Annual Average		**$17.53**	**$70.53**	**$53.00**
Annualized at 3%		**$16.80**	**$66.34**	**$49.54**
Annualized at 7%		**$15.88**	**$60.22**	**$44.34**

The baseline burden to EPA during each reporting cycle is two FTEs, or 4,160 hours (see Section 5-2). While the burden for each reporting cycle would not change as a result of this amendment, more frequent reporting would increase costs to the Agency. Table E-3 contains the total Agency burden of the annual reporting option, over a 25-year period. EPA estimates Agency burden would increase by a total of 66,600 hours over a 25-year period (five reporting cycles). Over one five-year reporting cycle, the Agency burden would increase by 16,600 hours (4,160 hours x 4 years) compared to the baseline.

Table E-3: Agency Burden under the Alternative Option to Require Submitters to Submit Full Data Annually

Reporting Cycle	Years	Baseline Burden	Post-Alternative Option	Change from Baseline
		(hours)	(hours)	(hours)
1	**2007 to 2011**	4,160	4,160	0
2	**2012 to 2016**	4,160	20,800	16,640
3	**2017 to 2021**	4,160	20,800	16,640
4	**2022 to 2026**	4,160	20,800	16,640
5	**2027 to 2031**	4,160	20,800	16,640
Total		**20,800**	**87,360**	**66,560**

Annual Average	**832**	**3,494**	**2,662**

The annual Agency cost under the baseline and the alternative option is shown in Table E-4, and is taken from Table 5-3.In total, EPA estimates this option would increase the Agency cost by approximately $1.86 million over one five-year reporting cycle. Over a 25-year period, the annualized Agency cost is expected to increase between $359,900 with a seven percent discount rate, and $367,300 with a three percent discount rate compared to the baseline.

Table E-4: Agency Cost under the Alternative Option to Require Submitters to Submit Full Data Annually

Reporting Cycle	Years	Baseline Cost	Post-Alternative Option Cost	Change from Baseline
		(2008$)	(2008$)	(2008$)
1	**2007 to 2011**	$466,133	$466,132	$0.00
2	**2012 to 2016**	$466,133	$2,330,664	$1,864,532
3	**2017 to 2021**	$466,133	$2,330,664	$1,864,532
4	**2022 to 2026**	$466,133	$2,330,664	$1,864,532
5	**2027 to 2031**	$466,133	$2,330,664	$1,864,532
Total		**$2,330,664**	**$9,788,790**	**$7,458,126**
Annual Average		**$93,227**	**$391,552**	**$298,325**
Annualized at 3%		**$87,798**	**$366,630**	**$291,617**
Annualized at 7%		**$81,056**	**$466,133**	**$359,885**

E.1.2 Annual Reporting Cost and Burden when the All the Proposed Amendments are Considered

EPA estimated the cost and burden of annual reporting in addition to the proposed amendments outlined in Chapter 3. Under this alternative, the annual reporting cost and burden would be the same as the burden when all the amendments are considered, as shown in Table 4-52. After the first reporting cycle, the number of submitters is not expected to change from year to year.

The industry burden of annual reporting is shown in Table E-5. The annual reporting option is expected to increase the industry burden by approximately 39.58 million hours over a 25-year period, for a total industry burden of 56.01 million hours. EPA estimates over one four-year reporting cycle (note under the final amendments, a reporting cycle will be changed to four years) the industry burden would increase by approximately 7.92 million hours (2.64 million hours x 3 years) compared to the baseline.

Table E-5: Industry Burden under the Alternative Option to Require Submitters to Submit Full Data Annually when all the Proposed Amendments are Considered

Reporting Cycle	Years	Baseline Burden	Post-Alternative Option Burden	Change from Baseline
		(millions of hours)	(millions of hours)	(millions of hours)
1	**2007 to 2011**	3.24	3.24	0.00
2	**2012 to 2015**	2.64	10.56	7.92
3	**2016 to 2019**	2.64	10.56	7.92
4	**2020 to 2023**	2.64	10.56	7.92

5	**2024 to 2027**	2.64	10.56	7.92
6	**2028 to 2031**	2.64	10.56	7.92
Total		**16.43**	**56.01**	**39.58**
Annual Average		**0.66**	**2.24**	**1.58**

The industry baseline cost is taken from Table 4-53. EPA estimates annual reporting would increase industry cost by approximately $2.43 billion over a 25-year period. The change in annualized cost ranges from $81.39 million with a seven percent discount rate to $90.90 million with a three percent discount rate as shown in Table E-6. Over one four-year reporting cycle, this option would increase industry cost by approximately $486 million ($162.08 x 3 years) compared to the baseline.

Table E-6: Industry Cost under the Alternative Option to Require Submitters to Submit Full Data Annually when all the Proposed Amendments are Considered

Reporting Cycle	Years	Baseline Cost	Post-Alternative Option Cost	Change from Baseline
		(2008$ millions)	(2008$ millions)	(2008$ millions)
1	**2007 to 2011**	$198.84	$198.84	$0.00
2	**2012 to 2015**	$162.08	$648.33	$486.25
3	**2016 to 2019**	$162.08	$648.33	$486.25
4	**2020 to 2023**	$162.08	$648.33	$486.25
5	**2024 to 2027**	$162.08	$648.33	$486.25
6	**2028 to 2031**	$162.08	$648.33	$486.25
Total		**$1,009.25**	**$3,440.49**	**$2,431.24**
Annual Average		**$40.37**	**$137.62**	**$97.25**
Annualized at 3%		**$38.40**	**$129.30**	**$90.90**
Annualized at 7%		**$35.83**	**$117.22**	**$81.39**

The Agency baseline burden when all the proposed amendments are considered is taken from Table 5-43. The annual reporting option is expected to increase Agency burden by approximately 36,800 hours when all amendments are considered (see Table E-7). Over a four-year reporting cycle, EPA estimates Agency burden would increase by approximately 7,400 hours (2,456 hours x 3 years) compared to the baseline.

Table E-7: Agency Burden under the Alternative Option to Require Submitters to Submit Full Data Annually when all the Proposed Amendments are Considered

Reporting Cycle	Years	Baseline Burden	Post-Alternative Option Burden	Change from Baseline
		(millions of hours)	(millions of hours)	(millions of hours)
1	**2007 to 2011**	2,439	2,439	0
2	**2012 to 2015**	2,456	9,826	7,369
3	**2016 to 2019**	2,456	9,826	7,369
4	**2020 to 2023**	2,456	9,826	7,369
5	**2024 to 2027**	2,456	9,826	7,369
6	**2028 to 2031**	2,456	9,826	7,369

Total	**14,721**	**51,568**	**36,847**
Annual Average	**589**	**2,063**	**1,474**

The baseline Agency cost when all the proposed amendments are enacted is taken from Table 5-44. The total Agency cost under the annual reporting option when all proposed amendments are considered is shown in Table E-8. Over a 25-year period, Agency cost would increase by approximately $4.33 million, with annualized costs increases ranging from approximately $205,000 with a seven percent discount rate to $227,000 with a three percent discount rate. Over one four-year reporting cycle, the Agency cost is expected to increase by $865,000 ($288,450 x 3 years) compared to the baseline.

Table E-8: Agency Cost under the Alternative Option to Require Submitters to Submit Full Data Annually when all the Proposed Amendments are Considered

Reporting Cycle	Years	Baseline Cost (2008$)	Post-Alternative Option Cost (2008$ millions)	Change from Baseline (2008$ millions)
1	**2007 to 2011**	$286,580	$286,580	$0
2	**2012 to 2015**	$288,450	$1,153,800	$865,350
3	**2016 to 2019**	$288,450	$1,153,800	$865,350
4	**2020 to 2023**	$288,450	$1,153,800	$865,350
5	**2024 to 2027**	$288,450	$1,153,800	$865,350
6	**2028 to 2031**	$288,450	$1,153,800	$865,350
Total		**$1,728,830**	**$6,055,580**	**$4,326,750**
Annual Average		**$69,153**	**$242,223**	**$173,070**
Annualized at 3%		**$65,011**	**$226,783**	**$161,773**
Annualized at 7%		**$59,642**	**$204,495**	**$144,853**

E.1.3 Small Entity Analysis

The following section provides a preliminary assessment of the impact annual Form U submissions may have on small entities by examining the relationship between the compliance costs and company sales for small companies. This analysis is based on the methodology described in Chapter 8 of this report. All costs and burdens are estimated under the assumption all the proposed amendments are enacted.

EPA estimated in Chapter 8 of this report there are 3.89 manufacturing sites per global parent company; 41.3 percent of global parent companies (466 companies) are considered small under the SBA employment-based definition,[13] and 24.8 percent (280 companies) are considered small under the TSCA sales-based definition.[14] EPA also estimated an average of approximately 1.76 sites per small company under the employment-based definition of small business, and approximately 1.92 sites per small company under the sales-based definition. EPA estimated average annual sales revenue of global parent companies considered small under either definition using data from Dun & Bradstreet, as also described in Chapter 8.

[13] Threshold of 1,000 employees.

[14] Total annual sales of the company, combined with those of any parent company, are below $40 million and annual production volume or importation volume at the facility is less than or equal to 100,000 lb.; or total annual sales of the company, combined with those of any parent company, are below $4 million.

Table 4-53 shows the annual incremental cost of the rule to industry. Because this cost would be incurred once every year under an annual reporting cycle, it was not discounted. As shown in Table E-9 below, these costs were divided by the total number of sites expected to submit data, for the annualized costs per site. This was multiplied by the number of sites per small parent company to arrive at the annualized costs per small parent company. This value was divided by the annual sales per small parent company to derive the cost-to-sales ratio.

As shown in Table E-9, under the employment-based definition, a small parent company affected by the rule on average has sales of more than $412.7 million. The annual costs of the proposed IUR rule amendments per small parent company, however, are $39,582. The cost-to-sales ratio for an average small company under the employment-based SBA definition would be 0.01 percent or less. Under the more conservative sales-based TSCA definition, small parent company sales are on average more than $11.8 million, with annualized costs associated with the proposed amendments of $43,181. The cost-to-sales ratio for an average small company under the sales-based definition would be 0.364 percent or less.

Using the highest annual cost shown in Table E-9of $43,181, a small company would have to have annual sales of less than $4.32 million in order to have a cost-to-sales ratio larger than one percent.

Table E-9: Derivation of Cost-to-Sales Ratios for Small Manufacturers for Collection of Annual Reporting

	Employment-based Definition	Sales-based Definition
Total Incremental Annual Costs	**$91,871,064**	
Total Number of Sites	4,085	
Annual costs per site	$21,490	
Number of sites per small parent company	1.76	1.92
Annualized costs per small parent company	$39,582	$43,181
Annual sales per small parent company	$412,713,310	$11,821,104
Cost-to-sales ratio	0.010%	0.365%
Number of companies potentially affected	466	280

E.2 Modify Reporting Frequency to a Three-Year Cycle

As an alternative to the amendment described in Section 3.13, which will modify the reporting frequency to a four-year cycle, the Agency considered increasing the reporting frequency to once every three years, if the manufacturer exceeds the production volume threshold in any calendar year of the cycle. EPA estimates the burden of this option on all affected entities, both when the option is considered by itself and when all the proposed amendments are considered.

E.2.1 Three-Year Reporting Cycle Cost and Burden when the Option is Considered by Itself

EPA's analysis of industry burden and cost for this option is similar to that described in Section 4.4.31; the burden in any one reporting cycle would not change, but the longer-term burden to industry would increase because reporting will become more frequent. However, the Agency assumes no additional reports would be submitted as a result of reducing the length of

the reporting cycle.(While the mix of chemical substances might change, EPA assumes the total number of reports would remain relatively static.) To be comparable with the four-year reporting cycle amendment, costs to industry are calculated over a 20-year period.

The annual industry burdens under the baseline and under this alternative option are shown in Table E-10. The industry burden is taken from Table 4-10 for the first reporting cycle and from Table 4-11 for all future reporting cycles. In total, EPA estimates under this option, industry would incur an additional burden of 2.87 million hours over a 20-year period.

Table E-10: Annual Industry Burden under the Alternative Option of a Three-Year Reporting Cycle

Reporting Cycle[1]	Years	Baseline Burden	Post-Amendment Burden	Change in Burden
		(millions of hours)	(millions of hours)	(millions of hours)
1	**2007 to 2011**	1.84	*1.84*	0.00
2	**2012 to 2016**	1.43	--	
	2012 to 2014	--	*1.43*	0.00
3	**2017 to 2021**	1.43	--	
	2015 to 2017	--	*1.43*	0.00
4	**2022 to 2026**	1.43	--	
	2018 to 2020	--	*1.43*	0.00
5	***2021 to 2023***	--	*1.43*	1.43
6	***2024 to 2026***	--	*1.43*	1.43
Total		**6.14**	**9.01**	**2.87**
Annual Average		**0.31**	**0.45**	**0.14**

[1] The non-italicized reporting cycles are baseline, five-year cycles, and the italicized reporting cycles are alternative, three-year cycles.

The annual industry cost under the baseline and this alternative option are shown in Table E-11. In total, EPA estimates this option would increase costs to industry by $165.64 million over a 20-year period, with annualized costs increases ranging from $6.96 million with a seven percent discount rate to $7.75 million with a three percent discount rate.

Table E-11: Industry Cost under the Alternative Option of a Three-Year Reporting Cycle

Reporting Cycle[1]	Years	Baseline Cost	Post-Alternative Option Cost	Change from Baseline
		(2008$ millions)	(2008$ millions)	(2008$ millions)
1	**2007 to 2011**	$106.97	106.97	0.00
2	**2012 to 2016**	$82.82	--	
	2012 to 2014	--	$82.82	0.00
3	**2017 to 2021**	$82.82	--	
	2015 to 2017	--	$82.82	0.00
4	**2022 to 2026**	$82.82	--	
	2018 to 2020	--	$82.82	0.00
5	***2021 to 2023***	--	$82.82	$82.82
6	***2024 to 2026***	--	$82.82	$82.82
Total		**$355.42**	**$521.05**	**$165.64**
Annual Average		**$17.77**	**$26.05**	**$8.28**
Annualized at 3%		**$17.00**	**$24.75**	**$7.75**

Annualized at 7%	**$16.03**	**$22.99**	**$6.96**

[1] The non-italicized reporting cycles are baseline, five-year cycles, and the italicized reporting cycles are alternative, three-year cycles.

The baseline burden to EPA during reporting years would be two FTEs or 4,160 hours (see Section 5-2). While the burden per reporting year would not change as a result of this alternative option, more frequent reporting would increase costs to the Agency. Table E-12 contains the total burden to the Agency of the option, over a 20-year period. During this period, EPA estimates Agency burden would increase by a total of approximately 8,300 hours.

Table E-12: Burden to the Agency under the Alternative Option of a Three-Year Reporting Cycle

Reporting Cycle[1]	Years	Baseline Burden (millions of hours)	Post-Amendment Burden (millions of hours)	Change in Burden (millions of hours)
1	**2007 to 2011**	4,160	4,160	0
2	**2012 to 2016**	4,160	--	0
	2012 to 2014	--	4,160	
3	**2017 to 2021**	4,160	--	0
	2015 to 2017	--	4,160	
4	**2022 to 2026**	4,160	--	0
	2018 to 2020	--	4,160	
5	***2021 to 2023***	--	4,160	4,160
6	***2024 to 2026***	--	4,160	4,160
Total		**16,640**	**24,960**	**8,320**
Annual Average		**832**	**1,248**	**416**

[1] The non-italicized reporting cycles are baseline, five-year cycles, and the italicized reporting cycles are alternative, three-year cycles.

The annual Agency costs under the baseline and the alternative option are shown in Table E-13, and are taken from Table 5-3. In total, EPA estimates this option would increase Agency costs by$932,300 over a 20-year period with an annual average of $46,600.

Table E-13: Agency Cost under the Alternative Option of a Three-Year Reporting Cycle

Reporting Cycle[1]	Years	Baseline Cost (2008$)	Post-Alternative Option Cost (2008$)	Change from Baseline (2008$)
1	**2007 to 2011**	$466,133	$466,133	$0
2	**2012 to 2016**	$466,133	--	$0
	2012 to 2014	--	$466,133	
3	**2017 to 2021**	$466,133	--	$0
	2015 to 2017	--	$466,133	
4	**2022 to 2026**	$466,133	--	$0
	2018 to 2020	--	$466,133	
5	***2021 to 2023***	--	$466,133	$466,133
6	***2024 to 2026***	--	$466,133	$466,133
Total		**$1,864,532**	**$2,796,797**	**$932,266**
Annual Average		**$93,227**	**$139,840**	**$46,613**

Annualized at 3%	**$87,798**	**$131,412**	**$43,614**
Annualized at 7%	**$81,056**	**$120,247**	**$39,190**

[1] The non-italicized reporting cycles are baseline, five-year cycles, and the italicized reporting cycles are alternative, three-year cycles.

E.2.2 Three-Year Cycle Cost and Burden when the All the Proposed Amendments are Considered

EPA estimated the cost and burden of a three-year reporting cycle in addition to the proposed amendments outlined in Chapter3. Under this alternative option, the reporting burden for industry would be the same as the combined post amendment burden shown in Table 4-52; however the reporting cycle would be shortened from four years to three years. For both industry and the Agency, the post-amendment burden would increase from the baseline because of the increased reporting frequency.

The total increase in industry burden over 17 years as a result of increasing the reporting frequency to three years from four years is 2.64 million hours (see Table E-14). This equates to an annual increase in the reporting burden of approximately 0.13 million hours.

Table E-14: Annual Industry Burden under the Alternative Option of a Three-Year Reporting Cycle when the All the Proposed Amendments are Considered

Reporting Cycle[1]	Years	Baseline Burden	Post-Amendment Burden	Change in Burden
		(millions of hours)	(millions of hours)	(millions of hours)
1	**2007 to 2011**	3.24	3.24	0.00
2	**2012 to 2015**	2.64	--	
	2012 to 2014	--	2.64	0.00
3	**2016 to 2019**	2.64	--	
	2015 to 2017	--	2.64	0.00
4	**2020 to 2023**	2.64	--	
	2018 to 2020	--	2.64	0.00
5	***2021 to 2023***	--	2.64	2.64
Total		**11.15**	**13.79**	**2.64**
Annual Average		**0.56**	**0.69**	**0.13**

[1] The non-italicized reporting cycles are baseline, four-year cycles, and the italicized reporting cycles are alternative, three-year cycles.

The industry cost for a three-year reporting cycle is shown in Table E-15. Baseline costs are taken from Table 4-50. Over a 17-year period, total costs would increase by $162.08 million, with an annualized increase of $8.93 million at a three percent discount rate and $8.07 million at a seven percent discount rate.

Table E-15: Industry Cost under the Alternative Option of a Three-Year Reporting Cycle when the All the Proposed Amendments are Considered

Reporting Cycle[1]	Years	Baseline Cost (2008$ millions)	Post-Alternative Option Cost (2008$ millions)	Change from Baseline (2008$ millions)
1	**2007 to 2011**	$19.88	*$19.88*	$0.00
2	**2012 to 2015**	$162.08	--	
	2012 to 2014	--	*$162.08*	$0.00
3	**2016 to 2019**	$162.08	--	
	2015 to 2017	--	*$162.08*	$0.00
4	**2020 to 2023**	$162.08	--	
	2018 to 2020	--	*$162.08*	$0.00
5	***2021 to 2023***	--	*$162.08*	$162.08
Total		**$506.13**	***$668.21***	**$162.08**
Annual Average		**$29.77**	***$39.31***	**$9.53**
Annualized at 3%		**$38.29**	***$47.23***	**$8.93**
Annualized at 7%		**$35.70**	***$43.76***	**$8.07**

[1] The non-italicized reporting cycles are baseline, four-year cycles, and the italicized reporting cycles are alternative, three-year cycles.

The Agency baseline burdens of 2,439 hours (first reporting cycle) and 2,456 (future reporting cycles) when all the proposed amendments are considered together is taken from Table 5-43. The annual reporting option is expected to increase Agency burden by approximately 2,500 hours over 17 years when all amendments are considered (see Table E-16).

Table E-16: Agency Burden under the Alternative Option of a Three-Year Reporting Cycle when the All the Proposed Amendments are Considered

Reporting Cycle[1]	Years	Baseline Burden (hours)	Post-Amendment Burden (hours)	Change in Burden (hours)
1	**2007 to 2011**	2,439	2,439	0
2	**2012 to 2015**	2,456	--	0
	2012 to 2014	--	*2,456*	
3	**2016 to 2019**	2,456	--	0
	2015 to 2017	--	*2,456*	
4	**2020 to 2023**	2,456	--	0
	2018 to 2020	--	*2,456*	
5	***2021 to 2023***	--	*2,456*	2,456
Total		**9,807**	***12,264***	**2,456**
Annual Average		**577**	**721**	**145**

[1] The non-italicized reporting cycles are baseline, four-year cycles, and the italicized reporting cycles are alternative, three-year cycles.

Table E-17 contains the total Agency cost under a three-year reporting cycle. EPA estimates the Agency cost would increase by approximately $288,500 over a 17-year period. The annualized cost is expected to increase by $15,600 with a three percent discount rate and $14,400 with a seven percent discount rate.

Table E-17: Agency Cost under the Alternative Option of a Three-Year Reporting Cycle when the All the Proposed Amendments are Considered

Reporting Cycle[1]	Years	Baseline Cost	Post-Alternative Option Cost	Change from Baseline
		(2008$)	(2008$)	(2008$)
1	**2007 to 2011**	$286,580	*$286,580*	$0
2	**2012 to 2015**	$288,450	--	$0
	2012 to 2014	--	*$288,450*	
3	**2016 to 2019**	$288,450	--	$0
	2015 to 2017	--	*$288,450*	
4	**2020 to 2023**	$288,450	--	$0
	2018 to 2020	--	*$288,450*	
5	***2021 to 2023***	--	*$288,450*	$288,450
Total		**$1,151,930**	***$1,440,380***	**$288,450**
Annual Average		**$67,761**	***$84,728***	**$16,968**
Annualized at 3%		**$63,741**	**$79,637**	**$15,896**
Annualized at 7%		**$58,612**	**$72,971**	**$14,359**

[1] The non-italicized reporting cycles are baseline, four-year cycles, and the italicized reporting cycles are alternative, three-year cycles.

E.2.3 Small Entity Analysis

The following section provides a preliminary assessment of the impact a three-year reporting cycle may have on small entities by examining the relationship between the compliance costs and company sales for small companies. This analysis is based on the methodology found in Chapter 8 of this report and all costs and burdens are estimated under the assumption all the proposed amendments are enacted. EPA estimated 3.89 manufacturing sites per global parent company in Chapter 8 of this report; 41.3 percent of global parent companies (466 companies) are considered small under the SBA employment-based definition,[15] and 24.8 percent (280 companies) are considered small under the TSCA sales-based definition.[16] EPA also estimated an average of approximately 1.76 sites per small company under the employment-based definition of small business, and approximately 1.92 sites per small company under the sales-based definition. Average annual sales revenue of global parent companies considered small under either definition were estimated using data from Dun & Bradstreet, as also described in the EA.

Table 4-53 shows the incremental cost to the industry. Because these costs would be incurred once every three years under a three-year reporting cycle, these costs were summed and annualized over three years at both a three percent and seven percent discount rate.[17] As shown in Table E-18, these costs were divided by the total number of sites expected to submit data, for

[15] Threshold of 1,000 employees.

[16] Total annual sales of the company, combined with those of any parent company, are below $40 million and annual production volume or importation volume at the facility is less than or equal to 100,000 lb.; or total annual sales of the company, combined with those of any parent company, are below $4 million.

[17] A seven percent discount rate, reflecting the opportunity cost of capital, is consistent with OMB Circular A-4 (OMB, 2003). A three percent discount rate was also used as a sensitivity analysis to examine the robustness of the results to a change in the annualization assumptions.

the annualized costs per site. This was multiplied by the number of sites per small parent company to arrive at the annualized costs per small parent company. This value was divided by the annual sales per small parent company to derive the cost-to-sales ratio.

As shown in Table E-18, under the employment-based definition, a small parent company affected by the rule on average has sales of more than $412.7 million. The annualized costs of the proposed IUR rule amendments per small parent company, however, are $14,096 at a seven percent discount rate, and even lower under a three percent discount rate. The cost-to-sales ratio for an average small company under the employment-based SBA definition would be 0.0034 percent or less. Under the more conservative sales-based TSCA definition, small parent company sales are on average more than $11.8 million, with annualized costs associated with the proposed amendments of $32.7 million or lower. The cost-to-sales ratio for an average small company under the sales-based definition would be 0.13 percent or less.

Using the highest annual cost shown in Table E-18 of $15,378, a small company would have to have annual sales of less than $1.58million in order to have a cost-to-sales ratio larger than one percent.

Table E-18: Derivation of Cost-to-Sales Ratios for Small Manufacturers for a Three-Year Reporting Cycle

	Employment-based Definition		Sales-based Definition	
	3% Discount Rate	7% Discount Rate	3% Discount Rate	7% Discount Rate
Incremental Costs of Proposed Other Amendments	$91,871,064			
Total Annualized Costs	$31,533,214	$32,717,404	$31,533,214	$32,717,404
Total Number of Sites	4,085			
Annualized Costs per Site	$7,719	$8,009	$7,719	$8,009
Number of Sites per Small Parent Company	**1.76**		**1.92**	
Annualized Costs per Small Parent Company	$13,586	$14,096	$14,821	$15,378
Annual Sales per Small Parent Company	$412,713,310	$412,713,310	$11,821,104	$11,821,104
Cost-to-Sales Ratio	0.0033%	0.0034%	0.1254%	0.1301%
Number of Companies Potentially Affected	**466**		**280**	

E.3 Change the Threshold for Reporting to 10,000 lb

The Agency also considered an option that would lower the reporting threshold from 25,000 lb to 10,000 lb. Prior to the amendments to the 2006 IUR rule, EPA required sites to submit a Form U for chemical substances produced at 10,000 lb or greater. The 2006 amendments increased the threshold for reporting to 25,000 lb. This alternative regulatory option would return to the previous threshold for reporting.

E.3.1 10,000 lb Reporting Threshold Cost and Burden when the Option is Considered by Itself

EPA used data from the 2002 reporting cycle (EPA, 2009d) to estimate the additional number of reports that would be submitted under the alternative threshold option. The total number of reports and sites reporting at three different production levels (10,000 lb ≤ P V < 25,000 lb, 25,000 lb ≤ P V <300,000 lb, and PV ≥ 300,000 lb) were analyzed to obtain the total range of reports submitted in 2002.Table E-19contains the total number of reports and sites at all three production levels. In total, 882 sites, or 19 percent, of all the sites submitting reports data in 2002 produced chemical substances in amounts between 10,000 lb and 25,000 lb. Thirteen percent of all reports, or 3,595 reports, were submitted in 2002 for chemical substances produced between 10,000 lb and 25,000 lb

Table E-19: Number of Reports and Sites in 2002

Production Volume	Number of Sites	Percent of Total	Number of Reports	Percent of Total
10,000 lb ≤ P V < 25,000 lb	882	19%	3,595	13%
25,000 lb ≤ P V < 300,000 lb	1,392	30%	8,548	32%
PV ≤ 300,000 lb	2,304	50%	14,818	55%
Total	**4,578**	**100%**	**26,961**	**100%**

Source:
U.S. EPA, Office of Pollution Prevention and Toxics, Information Management Division *2002 IUR Database Statistics for IUR Modifications Rule*. Washington, DC. April 30, 2009 (EPA, 2009d).

To estimate the total number of additional sites submitting reports as a result of the option, EPA applied the percentage of total sites with production volumes between 10,000 lb and 25,000 lb in 2002 (19 percent), to the total number of sites in 2006; 4,085 (baseline 2006 numbers are presented in Table 4-6). Therefore, the Agency estimates 787 additional sites would submit reports as a result of the option. The same methodology was applied to calculating the additional number of reports; EPA estimates a 13 percent increase in the number of 2006 reports, for a total of 3,453 new reports. Because all reports submitted as a result of the proposed amendments would be for production volumes less than 300,000 lb, EPA assumes only additional partial reports (Part IIs) would be submitted.

As described in Section 4.2.2, sites need to complete Part I of Form U only once, and complete Part II and Part III (as applicable) for each chemical substance manufactured (or imported). Taking this allocation of activities into consideration, and using the baseline unit burden estimates as shown in Table 4-2, Table E-20 shows the industry burden estimate as a result of this option. The Agency estimates the option would cause an increase in industry burden of approximately 94,600 hours.

Table E-20: Industry Burden as a Result of Changing the Threshold for Reporting to 10,000 lb

	Number of Sites (a)	Burden per Part I of Report, Compliance Determination, Rule Familiarization, and Submission (b)	Number of Partial Reports (c)	Burden per Part II of Report and Recordkeeping (d)	Number of Full Reports (e)	Burden per Part III of Report (f)	Industry Burden (hours) (g) = (a*b) + (c*d) + (e*f)
Baseline	4,085	33.26	25,896	19.82	17,075	69.92	1,842,934
Post-Amendment	4,872	33.26	29,349	19.82	17,075	69.92	1,937,544
Change from the Baseline	**787**	**0**	**3,453**	**0**	**0**	**0**	**94,611**

[1] Baseline unit burden derivations shown in Table 4.4

Note: Values in Change from the Baseline rows are calculated by subtracting the corresponding baseline value from the post-amendment value.

The cost of the option was calculated using the unit costs shown in Table 4-5. Table E-21 shows the industry cost estimate as a result of this option. The cost to industry is expected to increase by $5.52 million.

Table E-21: Industry Cost as a Result of Changing the Threshold for Reporting to 10,000 lb

	Number of Sites	Cost per Part I of Report, Compliance Determination, Rule Familiarization, and Submission (2008$)	Number of Partial Reports	Cost per Part II of Report and Recordkeeping (2008$)	Number of Full Reports	Cost per Part III of Report (2008$)	Industry Cost (millions 2008$)
Baseline	4,085	$2,058.18	25,896	$1,129.42	17,075	$4,059.25	$106.97
Post-Amendment	4,872	$2,058.18	29,349	$1,129.42	17,075	$4,059.25	$112.49
Change from the Baseline	**787**	**$0.00**	**3,453**	**$0.00**	**0**	**$0.00**	**$5.52**

Note: Values in Change from the Baseline rows are calculated by subtracting the corresponding baseline value from the post-amendment value.

The baseline burden to EPA of data processing and entry would not change from the baseline of 2,080 hours (see Section 5-2). However, the increased number of reports and submitters would increase the burden to the Agency. While the burden per reporting cycle would not change as a result of this option, more frequent reporting would increase costs to the Agency. Table E-22 contains the total Agency of the option. EPA's burden is expected to increase by a total of 159 hours.

Table E-22: Change in Burden to the Agency as a Result of Changing the Threshold for Reporting to 10,000 lb

	Burden to Process Part I Submission (hours) (a)	Number of Sites (b)	Burden to Process Part II (hours per report) (c)	Number of Reports (with Part II) (d)	Burden to Process Part III (hours per report) (e)	Number of Reports (with Part III) (f)	Agency Burden (hours) (g) =(a*b)+(c*d)+(e*(f)
Baseline	0.017	4,085	0.042	25,896	0.054	17,075	2,080
Post-Amendment	0.017	4,872	0.042	29,349	0.054	17,075	2,239
Change from the Baseline	**0.000**	**787**	**0.000**	**3,453**	**0.000**	**0**	**159**

Note: Values in Change from the Baseline rows are calculated by subtracting the corresponding baseline value from the post-amendment value.

Table E-23 shows the estimated change in cost to EPA as a result of the option. The Agency estimates a cost increase of approximately $16,600.

Table E-23: Change in Agency Cost as a Result of Changing the Threshold for Reporting to 10,000 lb

	Cost to Process Part I Submission (2008$) (a)	Number of Sites (b)	Cost to Process Part II (2008$ per report) (c)	Number of Reports (with Part II) (d)	Cost to Process Part III (2008$ per report) (e)	Number of Reports (with Part III) (f)	Agency Cost (2008$) (g) =(a*b)+(c*d)+(e*f)
Baseline	$1.78	4,085	$4.40	25,896	$5.61	17,075	$216,949
Post-Amendment	$1.78	4,872	$4.40	29,349	$5.61	17,075	$233,529
Change from the Baseline	**$0.00**	787	**$0.00**	3,453	**$0.00**	**0**	**$16,580**

Note:Values in Change from the Baseline rows are calculated by subtracting the corresponding baseline value from the post-amendment value.

E.3.2 Change the Threshold for Reporting to 10,000 lb when All Proposed Amendments are Considered

EPA estimated the cost and burden of lowering the reporting threshold to 10,000 lb when all of the proposed amendments outlined in Chapter 3. have been considered. A 10,000 lb reporting threshold is expected to increase the number of partial reports submitted by approximately 13 percent and the number sites submitting data by 19 percent (See Table E-19). In addition, EPA assumes this option would affect the proposed amendment to lower the threshold for reporting

downstream processing and use information from 300,000 lb to 25,000 lb (See Section 3.3.2). Under this option, the threshold for reporting this information would be 10,000 lb. The total number of sites and reports, when all the proposed amendments and the 10,000 lb. threshold reporting option are considered, is found in Table E-25. To calculate the number of additional submitters and reports, EPA followed the method outlined in Section 4.5.1. While Steps 1 and 2 remain unchanged from what is described in Section4.5.1, the other steps have been modified and an additional step has been added. The calculations for Steps 3, 4, and 5 are outlined below.

Step 3:C**onsider the effect of decreasing the reporting threshold to 10,000 lb** This option is expected to increase the number of sites submitting Form U by approximately 19 percent and the number of partial reports by approximately 13 percent (See Table E-19). To estimate this effect on the proposed amendments, EPA multiplied the total number of sites calculated in Step 2 (0 in the first reporting cycle and 204 in future reporting cycles) by 1.19 and the number of partial reports calculated in step 2 (3,975 in the first reporting cycle and 5,469 in future reporting cycles) by 1.13. EPA then added the additional number of reports and sites calculated in Section E.3.1, which accounts for the increase from the baseline as a result of this option. The number of Part IIIs submitted is not affected by this step.

Step 4: Consider the effect of eliminating the 300,000 lb threshold for processing and use reporting (and avoid double-counting). Under this amendment, all submitters of non-exempt chemical substances would be required to submit a Part III. Therefore, the number of Part IIIs must be increased by the increased number of Part IIs, to account for the effect of eliminating the 300,000 lb threshold for processing and use reporting. EPA started with the Step 3 total for Part III reports (8,219 in the first reporting cycle and 9,484 in future reporting cycles), and added the Step 3 total for Part II reports (7,985 in the first reporting cycle and 9,632 in future reporting cycles), minus the number of new Part III reports as a result of making ECAs ineligible for exemptions (16), the number of new Part II reports as a result of changing the method of determining whether a manufacturer is subject to reporting requirements (0 in the first reporting cycle and1,295 in future reporting cycles) and the number of new Part II reports that will be for ECA chemical substances as a result of the 10,000 lb threshold (80 in in the first reporting cycle and 86in future reporting cycles). The number of ECA chemical substances as a result of the 10,000 lb threshold in the first reporting cycle is calculated by multiplying the number of ECA chemical substances by 1.13. In future reporting cycles, the number of ECA chemical substances as a result of the 10,000 lb threshold is calculated by multiplying the number of ECA chemical substances after the five percent has been taken into account, 649, by 1.13 to calculate the total number of ECA chemical substances take into account the five percent. This number, 649, is then multiplied by 1.13. The number of reports with Part III would increase by 16,801 in the first reporting cycle and 17,737 in future reporting cycles.

Step 5: Calculate the number of reports when all amendments are considered together. The total number of additional reports from Step 4 is added to the number of reports in the baseline to calculate the total number of reports when all the proposed amendments are considered together. There would now be a total of 4,872 Part Is, 33,854 Part IIs and 33,156 Part IIIs in the first reporting cycle. In future reporting cycles there would be a total of 5,115 Part Is, 35,528 Part IIs and 34,812 Part IIIs. The difference between the total number of Part IIs and Part IIIs, 698 reports, is equal to the number of ECA chemical substances times 1.13 (618 x 1.13=698).In future cycles, the difference of 735 reports is equal to the number of partially

exempt reports with the five and 13 percent increase taken into account ((618x1.05)x1.13)) = 735).

Table E-24: Change in the Number of Sites and Reports Submitted of All Amendments Combined with the 10,000 lb Reporting Threshold (First Reporting Cycle)

Modification	Number of Sites	Number of Reports	Number of Reports with Part III
Baseline	**4,085**	**25,896**	**17,075**
Step 1: Sum affected amendments			
Eliminate 300,000 lb Threshold for Downstream Processing and Use Reporting (see Section 4.4.6)	--	--	8,203
Eliminate the 25,000 lb Threshold for Specific regulated Chemical substances (see Section 4.4.5)	--	4,018	--
Make Chemical substances Subject to ECAs Ineligible for Exemptions (see Section 4.4.6)	--	--	16
Full Exemption for Manufactured Water (see Section 4.4.7).	--	(43)	--
STEP 1 TOTAL	**--**	**3,975**	**8,219**
Step 2: Account for change in the method for determining whether you are subject to the IUR reporting requirements			
Step 1 Total Multiplied by 1	**--**	**3,975**	**8,219**
Method for Determining Whether you are Subject to the IUR Reporting Requirements (see Section 4.4.3)	0	0	0
STEP 2 TOTAL	**0**	**3,975**	**8,219**
Step 3:Account for 10,000 lb reporting threshold			
Step 2 Total Multiplied by 1.19 for sites and 1.13 for reports	**0**	4,505	--
10,000 lb threshold reporting threshold (See Section E.3.1)	787	3,453	--
STEP 3 TOTAL(Step 3 + Step 2 Total)	**787**	**7,985**	**8,219**
Step 4: Consider the effect of eliminating the 300,000 lb threshold for processing and use reporting (and avoid double-counting).			
Step 3 total for Part II reports minus number of new Part III reports as a result of making ECAs ineligible for exemptions and the number of new Part II reports as a result of changing the method of determining whether subject to reporting requirements	--	--	7,826
STEP4 TOTAL (Step 4 + Step 3 Total)	**787**	**7,985**	**16,801**
Step 5:Calculate the total number of reports by adding the Step 3 Total to the Baseline			
STEP 5 TOTAL (Baseline + Step 3 Total)	**4,872**	**33,854**	**33,156**

Table E-25: Change in the Number of Sites and Reports Submitted of All Amendments Combined with the 10,000 lb Reporting Threshold (Future Reporting Cycles)

Modification	Number of Sites	Number of Reports	Number of Reports with Part III
Baseline	**4,085**	**25,896**	**17,075**
Step 1: Sum affected amendments			
Eliminate 300,000 Threshold for Downstream Processing and Use Reporting (see Section 4.4.6)	--	--	8,203
Eliminate the 25,000 lb Threshold for Specific regulated Chemical substances (see Section 4.4.5)	--	4,018	--
Make Chemical substances Subject to ECAs Ineligible for Exemptions (see Section 4.4.6)	--	--	16
Full Exemption for Manufactured Water (see Section 4.4.7).	--	(43)	--
STEP 1 TOTAL	**--**	**3,975**	**8,219**
Step 2: Account for change in the method for determining whether you are subject to the IUR reporting requirements			
Step 1 Total Multiplied by 1.05	--	4,174	8,630
Method for Determining Whether you are Subject to the IUR Reporting Requirements (see Section 4.4.3)	204	1,295	854
STEP 2 TOTAL	**204**	**5,469**	**9,484**
Step 3:Account for 10,000 lb reporting threshold			
Step 2 Total Multiplied by 1.19 for sites and 1.13 for reports	243	6,179	--
10,000 lb threshold reporting threshold (See Section E.3.1)	787	3,453	--
STEP 3 TOTAL(Step 3 + Step 2 Total)	**1,030**	**9,632**	**9,484**
Step 4: Consider the effect of eliminating the 300,000 lb threshold for processing and use reporting (and avoid double-counting).			
Step 3 total for Part II reports minus number of new Part III reports as a result of making ECAs ineligible for exemptions and the number of new Part II reports as a result of changing the method of determining whether subject to reporting requirements	--	--	8,253
STEP4 TOTAL (Step 4 + Step 3 Total)	**1,030**	**9,632**	**17,737**
Step 5:Calculate the total number of reports by adding the Step 3 Total to the Baseline			
STEP 5 TOTAL (Baseline + Step 3 Total)	**5,115**	**35,528**	**34,812**

EPA estimated the cost to the industry of the 10,000 lb threshold when all the proposed amendments are considered in Table E-26. The baseline values are taken from Table 4-52. Lowering the reporting threshold to 10,000 lb would not increase the industry per-form burden; however it would increase the number of Form Us submitted. EPA estimates this option would increase the industry burden by 0.44 million hours in the first reporting cycle and by 0.35 million hours in all future reporting cycles.

Table E-26: Industry Burden as a Result of Changing the Threshold for Reporting to 10,000 lb when All Proposed Amendments are Considered

	Burden per Part I of Report and Submission (hours per site) (a)	Number of Sites (b)	Burden for Part II and Record Keeping(hours per report) (c)	Number of Reports (with Part II) (d)	Burden for Part III (hours per report) (e)	Number of Reports (with Part III) (f)	Total Burden (millions of hours) (g) =(a*b)+(c*d)+(e*(f)
First-year Baseline	35.17	4,085	22.19	29,871	83.02	29,253	**3.24**
First year, Post Amendment	35.17	4,872	22.19	33,854	83.02	33,156	**3.68**
Change from the Baseline, First year	**0.00**	**787**	**0.00**	**3,983**	**0.00**	**3,903**	**0.44**
Future-Cycle Baseline	11.05	4,289	18.35	31,365	65.63	30,716	**2.64**
Future Cycle, Post Amendment	11.05	5,115	18.35	35,547	65.63	34,812	**2.99**
Change from the Baseline, Future Cycles	**0.00**	**826**	**0.00**	**4,182**	**0.00**	**4,096**	**0.35**

Note: Values in Change from the Baseline rows are calculated by subtracting the corresponding baseline value from the post-amendment value.

Baseline costs are taken from Table 4-53. The 10,000 lb reporting threshold is expected to increase industry cost by $27.06 million during the first reporting cycle and by $21.79 million during all future reporting cycles (See Table E-27).

Table E-27: Industry Cost as a Result of Changing the Threshold for Reporting to 10,000 lb when All Proposed Amendments are Considered

	Cost per Part I of Report and Submission (2008$) (a)	Number of Sites (b)	Cost for Part II and Record Keeping(2008$) (c)	Number of Reports (with Part II) (d)	Cost for Part III and (2008$) (e)	Number of Reports (with Part III) (f)	Total Burden (millions of 2008$) (g) =(a*b)+(c*d)+(e*(f)
First-year Baseline	$2,192	4,085	$1,346	29,871	$5,117	29,253	$198.84
First year, Post Amendment	$2,192	4,872	$1,346	33,854	$5,117	33,156	$225.89
Change from the Baseline, First year	**$0**	**787**	**$0**	**3,983**	**$0**	**3,903**	**$27.06**
Future-Cycle Baseline	$695	4,289	$1,109	31,365	$4,047	30,716	$162.08
Future Cycle, Post-Amendment	$695	5,115	$1,109	35,547	$4,047	34,812	$183.87
Change from the Baseline, Future Cycles	**$0**	**826**	**$0**	**4,182**	**$0**	**4,096**	**$21.79**

Note: Values in Change from the Baseline rows are calculated by subtracting the corresponding baseline value from the post-amendment value.

The annual industry burden over a 25-year period is shown in Table E-28. Over a 25-year period, the total industry burden would increase by 2.12 million hours when all the proposed amendments are considered.

Table E-28: Industry Burden under the Alternative Option of a Lowered Reporting Threshold and All Other Amendments when All Proposed Amendments are Considered

Reporting Cycle	Years	Baseline Cost	Post-Alternative Option Cost	Change from Baseline
		(millions of hours)	(millions of hours)	(millions of hours)
1	**2007 to 2011**	3.24	3.68	0.44
2	**2012 to 2015**	2.64	2.99	0.35
3	**2016 to 2019**	2.64	2.99	0.35
4	**2020 to 2023**	2.64	2.99	0.35
5	**2023 to 2027**	2.64	2.99	0.35
6	**2026 to 2031**	2.64	2.99	0.35
Total		**16.43**	**18.64**	**2.21**
Annual Average		**0.66**	**0.75**	**0.09**

Table E-29 shows the annual industry cost over a 25-year period as a result of lowering the reporting threshold. EPA estimates a 10,000 lb reporting threshold would increase costs by

approximately $136.00 million. Annualized costs range from $5.18 million with a three percent discount rate to $4.84 million with a seven percent discount rate.

Table E-29: Change in Industry Cost as a Result of Changing the Threshold for Reporting to 10,000 lb and All Other Amendments when All Proposed Amendments are Considered

Reporting Cycle	Years	Baseline Cost	Post-Alternative Option Cost	Change from Baseline
		(2008$ millions)	(2008$ millions)	(2008$ millions)
1	**2007 to 2011**	$198.84	$225.89	$27.06
2	**2012 to 2015**	$162.08	$183.87	$21.79
3	**2016 to 2019**	$162.08	$183.87	$21.79
4	**2020 to 2023**	$162.08	$183.87	$21.79
5	**2023 to 2027**	$162.08	$183.87	$21.79
6	**2026 to 2031**	$162.08	$183.87	$21.79
Total		**$1,009.25**	**$1,145.25**	**$136.00**
Annual Average		**$40.37**	**$45.81**	**$5.44**
Annualized at 3%		**$38.40**	**$43.58**	**$5.18**
Annualized at 7%		**$35.83**	**$40.66**	**$4.84**

As previously explained in Section E.3.1, the Agency burden per-report would not change as a result of lowering the reporting threshold. However, the number of reports and the number of sites submitting reports would increase. Table E-30 contains the Agency burden as a result of lowering the threshold for reporting when all the other amendments are considered. EPA estimates the Agency burden would increase by 48 hours in the first reporting cycle and 51hours during each future reporting cycle.

Table E-30: Agency Burden as a Result of Lowered Threshold Reporting and All Other Amendments when All Proposed Amendments are Considered

	Burden to Process Part I Submission (hours) (a)	Number of Sites (b)	Burden to Process Part II (hours per report) (c)	Number of Reports (with Part II) (d)	Burden to Process Part III (hours per report) (e)	Number of Reports (with Part III) (f)	Agency Burden (hours) (g) =(a*b)+(c*d)+(e*(f)
Baseline	0.002	4,085	0.0056	29,871	0.0063	29,253	2,439
Post-Amendment	0.002	4,872	0.0056	33,854	0.0063	33,156	2,487
Change from the Baseline	**0**	**787**	**0**	**3,983**	**0**	**3,903**	**48.29**
Future-cycle Baseline	0.002	4,289	0.006	31,365	0.006	30,716	2,456
Future cycle, Post Amendment	0.002	5,115	0.006	35,547	0.006	34,812	2,507
Change from the Baseline, Future cycles	**0**	**826**	**0**	**4,182**	**0**	**4,096**	**50.69**

Note: Values in Change from the Baseline rows are calculated by subtracting the corresponding baseline value from the post-amendment value.

Table E-31 contains the Agency cost as a result of lowering the reporting threshold. Baseline values are taken from Table 5-43. Lowering the 10,000 lb threshold is expected to increase the Agency cost by approximately $5,000 during the first reporting cycle and $5,300 in future reporting cycles.

Table E-31: Agency Cost as a Result of Lowered Threshold Reporting and All Other Amendments when All Proposed Amendments are Considered

	Cost to Process Part I Submission (2008$) (a)	Number of Sites (b)	Cost to Process Part II (2008$ per report) (c)	Number of Reports (with Part II) (d)	Cost to Process Part III (2008$ per report) (e)	Number of Reports (with Part III) (f)	Agency Burden (2008$) (g) =(a*b)+(c*d)+(e*(f)
Baseline	$0.203	4,085	$0.58	29,871	$0.66	29,253	$37,396
Post-Amendment	$0.203	4,872	$0.58	33,854	$0.66	33,156	$42,433
Change from the Baseline	**0**	**826**	**$0.00**	**4,163**	**$0.00**	**4,096**	**$5,037**
Future-cycle Baseline	$0.203	4,289	$0.58	31,365	$0.66	30,716	$39,266
Future cycle, Post Amendment	$0.203	5,115	$0.58	35,547	$0.66	34,812	$44,554
Change from the Baseline, Future cycles	**$0.00**	**826**	**$0.00**	**4,182**	**$0.00**	**4,096**	**$5,287**

Note: Values in Change from the Baseline rows are calculated by subtracting the corresponding baseline value from the post-amendment value.

The annual Agency burden over a 25-year period is shown in Table E-32. Over a 25-year period, the total Agency burden would increase by 302 hours when all the proposed amendments are considered.

Table E-32: Agency Burden under the Alternative Option of a Lowered Reporting Threshold and All Other Amendments when All Proposed Amendments are Considered

Reporting Cycle	Years	Baseline Burden	Post-Alternative Option Burden	Change from Baseline
		hours	hours	Hours
1	**2007 to 2011**	2,439	2,487	48.29
2	**2012 to 2015**	2,456	2,507	50.69
3	**2016 to 2019**	2,456	2,507	50.69
4	**2020 to 2023**	2,456	2,507	50.69
5	**2023 to 2027**	2,456	2,507	50.69
6	**2026 to 2031**	2,456	2,507	50.69
Total		**14,720.86**	**15,022.62**	**301.76**
Annual Average		**588.83**	**600.90**	**12.07**

Table E-33 contains the annual Agency cost over a 25-year period as a result of lowering the reporting threshold. EPA estimates a 10,000 lb reporting threshold would increase the Agency cost by approximately $31,500 over 25 years. Annualized increases in costs range from $1,100 with a seven percent discount rate to $1,200 with a three percent discount rate.

Table E-33: Change in Agency Cost as a Result of Changing the Threshold for Reporting to 10,000 lb and All Other Amendments when All Proposed Amendments are Considered

Reporting Cycle	Years	Baseline Cost	Post-Alternative Option Cost	Change from Baseline
		(2008$)	(2008$)	(2008$)
1	2007 to 2011	$37,396	$42,433	$5,037
2	2012 to 2015	$39,266	$44,554	$5,287
3	2016 to 2019	$39,266	$44,554	$5,287
4	2020 to 2023	$39,266	$44,554	$5,287
5	2023 to 2027	$39,266	$44,554	$5,287
6	2026 to 2031	$39,266	$44,554	$5,287
Total		**$233,727**	**$265,201**	**$31,474**
Annual Average		**$9,349**	**$10,608**	**$1,259**
Annualized at 3%		**$8,770**	**$9,951**	**$1,181**
Annualized at 7%		**$8,020**	**$9,100**	**$1,080**

E.3.3 Small Entity Analysis

The following section provides a preliminary assessment of the impact a 10,000 lb reporting threshold may have on small entities by examining the relationship between the compliance costs and company sales for small companies. This analysis is based on the methodology found in Chapter 8 of this report. All costs and burdens are estimated under the assumption all the proposed final amendments have been enacted. EPA estimated 3.89 manufacturing sites per global parent company in Chapter 8 of this report; 41.3 percent of global parent companies (466 companies) are considered small under the SBA employment-based definition[18], and 24.8 percent (280 companies) are considered small under the TSCA sales-based definition[19]. EPA also estimated an average of approximately 1.76 sites per small company under the employment-based definition of small business, and approximately 1.92 sites per small company under the sales-based definition. Average annual sales revenue of global parent companies considered small under either definition were estimated using data from Dun &Bradstreet, as also described in Chapter 8.

Table E-29 shows the cost to the industry as a result of annual reporting. Because these costs would be incurred once every four years under a four-year reporting cycle, these costs were summed and annualized over four years at both a three percent and seven percent discount rate[20]. As shown in Table E-34, these costs were divided by the total number of sites expected to submit data, for the annualized cost per site. This was multiplied by the number of sites per small parent company to arrive at the annualized costs per small parent company. This value was divided by the annual sales per small parent company to derive the cost-to-sales ratio.

[18] Threshold of 1,000 employees.

[19] Total annual sales of the company, combined with those of any parent company, are below $40 million and annual production volume or importation volume at the facility is less than or equal to 100,000 lb.; or total annual sales of the company, combined with those of any parent company, are below $4 million.

[20] A seven percent discount rate, reflecting the opportunity cost of capital, is consistent with OMB Circular A-4 (OMB, 2003). A three percent discount rate was also used as a sensitivity analysis to examine the robustness of the results to a change in the annualization assumptions.

As shown in Table E-34 under the employment-based definition, a small parent company affected by the rule on average has sales of more than $412.7 million. The annualized costs of the proposed IUR rule amendments per small parent company, however, are $11,854 at a seven percent discount rate, and even lower under a three percent discount rate. The cost-to-sales ratio for an average small company under the employment-based SBA definition would be 0.003 percent or less. Under the more conservative sales-based TSCA definition, small parent company sales are on average more than $11.8 million, with annualized costs associated with the proposed amendments of $12,931 or lower. The cost-to-sales ratio for an average small company under the sales-based definition would be 0.11 percent or less.

Using the highest annual cost shown in Table E-34 of $12,931 a small company would have to have annual sales of less than $1.29 million in order to have a cost-to-sales ratio larger than one percent.

Table E-34: Derivation of Cost-to-Sales Ratios for Small Manufacturers for a 10,000 lb Reporting Threshold

	Employment-based Definition		Sales-based Definition	
	3% Discount Rate	7% Discount Rate	3% Discount Rate	7% Discount Rate
Incremental Costs of 10,000 lb threshold	$27,055,019			
Incremental Costs of Proposed Other Amendments	$91,871,064			
Total Annualized Costs	$31,062,459	$32,813,387	$31,062,459	$32,813,387
Total Number of Sites	4,872			
Annualized Costs per Site	$6,376	$6,735	$6,376	$6,735
Number of Sites per Small Parent Company	1.76		1.92	
Annualized Costs per Small Parent Company	$11,221	$11,854	$12,241	$12,931
Annual Sales per Small Parent Company	$412,713,310		$11,821,104	
Cost-to-Sales Ratio	0.0027%	0.0029%	0.1036%	0.1094%
Number of Companies Potentially Affected	466		280	

Appendix F. Additional Exposure-Related Data Elements

In developing the proposed rule EPA considered the collection of additional exposure-related data, similar to the data collected under the TSCA section 5 New Chemicals Program, to further enhance the Agency's capabilities in conducting screening-level risk assessments of chemical substances reported to the TSCA Inventory Update, and would substantially improve EPA's ability to quantify chemical substance risks. The ability to quantify chemical substance risks would further improve the Agency's ability to identify and manage those risks. The burden and cost for these additional exposure-related data elements is described in the following Appendix. Because this data collection was only considered during the proposed rule, the total costs, submission dates, and annualization periods associated with them may not match what is presented in the main text for the final rule. The additional exposure-related data elements and brief descriptions are as provided in Table F-1: EPA solicited comment in the preamble for the proposed IUR rule amendments on the suitability of these data elements for enabling the Agency to develop more comprehensive and complete screening assessments of the risks that may be encountered in manufacture, processing, and use of chemical substances. Additionally, the Agency was interested in whether any additional data should be collected, and in any other considerations relating to the collection of additional data. EPA also solicited comment on the best method to collect these data, and whether processors, in addition to manufacturers, should be required to report processing and use data. The Agency considered three approaches to collecting the data. They are:1) integrating these data elements into the IUR, 2)promulgating a new reporting mechanism under TSCA section 8(a), and, 3) using TSCA section 11(c) subpoena authority to collect these data from known manufacturers (including importers). These additional data elements were not included as part of the proposed rule; therefore, they were not addressed in the main part of this economic analysis.

This Appendix provides a preliminary estimate of the burden and cost of collecting data for these additional data elements under the first approach of integrating the data elements into the IUR rule requirements.

Table F-1: Description of Additional Data Elements

Data Element		Description
Manufacturing Process Information		
1	Description of manufacturing process	Provide a process flow diagram which describes the manufacturing operations involving the chemical substance. "Unit operation" means a functional step in which substances undergo chemical changes and/or changes in location, temperature, pressure, physical state, or similar characteristics. Include steps in which the substance is formulated into gels, mixtures, suspensions, solutions, etc. and in which the substance is transferred into interim storage or shipping containers. Indicate in the diagram the entry and exit points of the chemical substance. Number all points from which the chemical substance will be released to the environment or to control equipment, including small or intermittent releases (e.g. some cleaning releases, drum residues, etc.) and trace amounts of the substance.
2	Continuous or batch process	Indicate whether the chemical substance is manufactured in discrete batches or is produced by continuously adding reactants and removing the reaction product.
3	Amount of substance produced per day or per batch	If the chemical substance is produced in discrete batches, indicate the amount of the substance in pounds produced in each batch; if the substance is produced in a continuous process, indicate the amount of substance in pounds manufactured each day.
4	Batch or daily run time	If the chemical substance is produced in discrete batches, indicate the batch time (hours/batch); if the substance is produced in a continuous process, indicate the daily run time (hours/day).

Data Element		Description
5	Days of operation per year or number of batches per year	If the chemical substance is produced in discrete batches, indicate the number of batches necessary to produce the reported production volume; if the chemical substance is produced in a continuous process, indicate the number of days of operation per year needed to produce the reported production volume.
6	Unit operations	List the unit operations needed to produce the chemical substance. Unit operation means a functional step in manufacturing, processing, or use operation where substances undergo chemical changes, or changes in temperature, pressure, physical state, concentration, purity, or similar characteristics. Examples of unit operations include blending, distillation, filtration, and drying.
7	Storage and shipping containers	List the types of containers used to transport or store the chemical substance and their capacity. Examples of containers include 1-liter bottles, 5-gallon pails, 55-gallon drums, 200-pound totes, 5000-gallon tank trucks, and 20,000-gallon railcars.
Manufacturing Worker Exposure Information		
8	Worker activities	Describe each specific activity in the operation during which workers may be exposed to the chemical substance. Such activities may include charging reactor vessels, sampling for quality control, transferring substances from one container to another, changing filters, filling drums, loading and loading tank cars or trucks, etc. Activities must be described even if workers wear protective equipment.
9	Duration and frequency of worker exposure	For each worker activity, enter the maximum duration in hours and number of days per year that any one worker will engage in the activity during a normal work day based on the reported production volume.
10	Physical form	For each worker activity, indicate the physical form of the substance at the time of exposure.
11	Maximum concentration	For each worker activity, indicate the maximum concentration of the substance in the product at the time of exposure.
12	Personal protective equipment and engineering controls used by workers	For each worker activity, identify the specific types of protective equipment and engineering controls that will be employed to protect the worker from potential exposure to the chemical substance, i.e. gloves, goggles, protective garment, local ventilation, respirator, etc.
13	Worker monitoring data available	Indicate whether monitoring data on occupational exposure of workers is available.
14	Summary of occupational exposure monitoring included	Indicate whether a summary of occupational exposure monitoring data are included. Summary should include information on the number of workers involved, number of samples taken, types of samples (area or personal), average and standard deviations of exposure.
Manufacturing Releases to the Environment		
15	Release source (or release point)	For each point of release containing the chemical substance, identify and describe the point in the process description at which the release occurs (e.g. releases due to spillage, residues, separation losses, and other sources from each batch or each day).
16	Media and type of release	For each release, indicate the type (gas or vapor, aqueous or liquid solution, or solid) and media (stack air, fugitive air, surface water, on-site or off-site land or incineration, POTW, or other (specify)) which describes the release stream containing the chemical.

Data Element		Description
17	Quantity of substance released a) directly to the environment or b) into control technology to the environment	For each release, provide the quantity (in pounds) of chemical substance released: a) directly to the environment; or
18		b) into control technology to the environment in pounds per day for continuous operation or pounds per batch for batch operations.
19	Control technology	For each release, describe the type of technology used to control the release of the substance to the environment. Examples of control technologies include carbon filter, scrubber and biological treatment (primary, secondary, etc.).
20	Efficiency of control technology	Indicate the established efficiency of the control technology in removing or destroying the chemical substance.
21	Destination of release	For aqueous releases containing the chemical substance, indicate whether release enters a navigable waterway, a publicly-owned treatment works (POTW), or other. Identify the name of the POTW and/or National Pollutant Discharge Elimination System (NPDES) number as appropriate. For other releases, indicate whether the release goes to a municipal or hazardous waste landfill, a commercial incinerator, enters the atmosphere, or is otherwise disposed (specify).
22	Additional release related information attached	Indicate whether a description of the releases, calculations or monitoring data on the quantities of releases, or additional information on control technologies and/or treatment is attached.
Industrial Processing or Use Activities		
23	Description of Processing or Use	Provide a process flow diagram which describes the processing or use operation involving the chemical substance. "Unit operation" means a functional step in which substances undergo chemical changes and/or changes in location, temperature, pressure, physical state, or similar characteristics. Include steps in which the substance is formulated into gels, mixtures, suspensions, solutions, etc. and in which the substance is transferred into interim storage or shipping containers. Indicate in your diagram the entry and exit points of the chemical substance. Number all points from which the chemical substance will be released to the environment or to control equipment, including small or intermittent releases (e.g. some cleaning releases, drum residues, etc.) and trace amounts of the substance.
24	Processing or use at sites controlled by manufacturer	Indicate whether the sites at which the chemical is processed or used are owned by the manufacturer or others.
25	Continuous or batch process	Indicate whether the industrial process in which the chemical is processed or used is a batch or continuous process.
26	Amount of substance processed per day or per batch	Provide the amount of the substance in pounds processed or used per batch for batch operation or processed or used per day for continuous operation, respectively.
27	Batch or daily run time	If the chemical substance is processed in discrete batches, indicate the batch time (hours/batch); if the substance is processed in a continuous process, indicate the daily run time (hours/day).
28	Days of operation per year or number of batches per year	If the chemical substance is processed in discrete batches, indicate the number of batches necessary to process the reported production volume; if the chemical substance is produced in a continuous process, indicate the number of days of operation per year needed to process the reported production volume.
29	Unit operations	List the unit operations needed to process the chemical substance. Unit operation means a functional step in manufacturing, processing, or use operation where substances undergo chemical changes, or changes in temperature, pressure, physical state, concentration, purity, or similar characteristics. Examples of unit operations include blending, distillation, filtration, and drying.

Data Element		Description
30	Storage and shipping containers used	List the types of containers used to transport or store the chemical substance and their capacity. Examples of containers include 1-liter bottles, 5-gallon pails, 55-gallon drums, 5,000-gallon tank trucks, and 20,000-gallon railcars.
Industrial Processing or Use Occupational Exposures Information		
31	Worker activities	Describe each specific activity in the operation during which workers may be exposed to the chemical substance. Such activities may include charging reactor vessels, sampling for quality control, transferring substances from one container to another, changing filters, filling drums, loading and loading tank cars or trucks, etc. Activities must be described even if workers wear protective equipment.
32	Duration and frequency of worker exposure	For each worker activity, provide the number of hours per day and the number of days per year during which the worker is engaged in processing or using the chemical substance.
33	Physical form	For each worker activity, indicate the physical form of the substance at the time of exposure.
34	Maximum concentration	For each worker activity, indicate the maximum concentration of the substance in the product at the time of exposure.
35	Personal protective equipment and engineering controls used by workers	For each worker activity, identify the specific types of protective equipment and engineering controls that will be employed to protect the worker from potential exposure to the chemical.
36	Worker monitoring data available	Indicate whether monitoring data on occupational exposure of workers is available.
37	Summary of occupational exposure monitoring included	Indicate whether a summary of occupational exposure monitoring data are included. Summary should include information on the # of workers involved, # of samples taken, types of samples (area or personal), average and standard deviations of exposure.
Industrial Processing or Use Releases to the Environment Information		
38	Release source (or point)	For each point of release containing the chemical substance, identify and describe the point in the process description at which the release occurs (e.g. releases due to spillage, residues, separation losses, and other sources from each batch or each day).
39	Media and type of release	For each release, indicate the type (gas or vapor, aqueous or liquid solution, or solid) and media (stack air, fugitive air, surface water, on-site or off-site land or incineration, POTW, or other (specify)) which describes the release stream containing the chemical.
40	Quantity of substance released a) directly to the environment or b) into control technology to the environment	For each release, provide the quantity (in pounds) of chemical substance released: a) directly to the environment; or
41		b) into control technology to the environment in pounds per day for continuous operation or pounds per batch for batch operations.
42	Control technology	For each release, describe the type of technology used to control the release of the substance to the environment. Examples of control technologies include carbon filter, scrubber and biological treatment (primary, secondary, etc.).
43	Efficiency of control technology	Indicate the established efficiency of the control technology in removing or destroying the chemical substance.
44	Destination of release	For aqueous releases containing the chemical substance, indicate whether release enters a navigable waterway, a publicly-owned treatment works (POTW), or other. Identify the name of the POTW and/or NPDES # as appropriate. For other releases, indicate whether the release goes to a municipal or hazardous waste landfill, a commercial incinerator, enters the atmosphere, or is otherwise disposed (specify).
45	Additional release related information attached	Indicate whether a description of the releases, calculations or monitoring data on the quantities of releases, or additional information on control technologies and/or treatment is attached.

Data Element		Description
Commercial Use Occupational Exposure Information		
46	Description of commercial use	Describe the commercial use(s) of products containing the chemical substance.
47	Function of chemical in commercial product	Describe the function of the chemical in the commercial product, e.g., dispersive dye, solvent, stabilizer, hardener, plasticizer, filler, etc.
48	Number of potentially exposed commercial workers	Indicate the number of workers in commercial establishments who are reasonably likely to be exposed to the chemical substance.
49	Physical form of commercial product	Indicate the physical form of the product containing the chemical substance.
50	Method of commercial product application	Describe the application method (e.g. sprayed applied via pump sprayer or aerosols, poured or applied manually) of the product containing the chemical substance and whether the commercial use is destructive, contained, dispersive, etc.
51	Duration and frequency of commercial product use	Indicate the duration of use, e.g. 5 minutes or less, 30 minutes or less, 1 hour or less, etc. and frequency of commercial use, e.g. used more than once a day, used once a day, used several times a week, etc.
Consumer Use and Exposure Information		
52	Description of consumer use	Describe the consumer use(s) of products containing the chemical substance.
53	Function of chemical in consumer product	Describe the function of the chemical in the consumer product, e.g., dispersive dye, solvent, stabilizer, hardener, plasticizer, filler, etc.
54	Number of potentially exposed consumers	Indicate the number of consumers reasonably likely to be exposed to the chemical substance.
55	Physical form of consumer product(s) containing the chemical substance	Indicate the physical form, e.g., gel, foam, powder, etc. of the consumer product containing the chemical substance.
56	Method of consumer product application	Describe the application of the consumer product containing the chemical substance, for example, chemicals in products that will be sprayed via pump sprayer or aerosols; products that are poured, mixed, applied by hand/mechanical device; chemicals that can be released via diffusion, evaporation, abrasion, etc., from articles; or chemicals that are incorporated into articles with no potential for release, etc.
57	Duration and frequency of consumer product use	Indicate the duration of consumer use, e.g., used for 5 minutes or less, 30 minutes or less, less than 1 hour, etc. and frequency of consumer use, e.g. used more than once a day, used once a day, used several times a week, etc.

F.1 Estimated Number of Affected Entities

In order to estimate the burden and cost of collecting the additional data, EPA assumes the impacts on manufacturers and processors would be different. Manufacturers would be required to complete an integrated Form U, which would be a Form U revised to incorporate the new data elements. For the purpose of this analysis, EPA assumes all of the amendments currently being proposed also would be included. EPA assumes processors, on the other hand, would be required to complete a tailored Form U focusing only on the additional processing and use information.

Manufacturers

For manufacturers, EPA assumes the numbers of sites and reports that would be affected by the requirement to provide additional exposure-related data would be the same as the numbers of manufacturing sites and reports as estimated in Section 4.5 of this report. As shown in Table 4-48, a total of 4,085 manufacturers are expected to submit 29,871 reports in the first reporting cycle, including both full and partial reports, when all the proposed amendments are considered. As shown in Table 4-49, in future reporting cycles a total of 4,289 manufacturers are expected to submit a total of 31,365 reports. To the extent any specific chemical substances would be exempt from the requirement to provide these additional data elements, the number of manufacturers and reports may be an overestimate.

Processors

The number of processors that may be affected by a requirement to submit the additional data elements was estimated using data from EPA's Toxic Release Inventory (TRI) reporting program. Under the TRI program, EPA collects information annually on toxic chemical substance releases and waste management activities from manufacturers, processors, and users of a set of 581 toxic chemical substances and 30 toxic chemical substance categories. The chemical substances regulated under the TRI program are a smaller set than those regulated under the IUR rule, but the TRI data collection activity currently is the most comprehensive information collection EPA administers for chemical substance processors. Therefore, EPA assumes information on processors who report under TRI is a suitable proxy for processors who may report under an amended IUR rule.

EPA used TRI Form R submission data from the 2007 TRI Public Data Release for 2002 through 2005 (to be consistent with the time period of the most recent IUR reporting cycle). EPA filtered the data to include only IUR chemical substances (i.e., the chemical substances listed in the public 2006 IUR database).[21] Processors submitted TRI data on an average of 220 of the IUR chemical substances during each of the four years of interest. For this analysis, EPA counted as a "processor" each TRI submitter indicating it processes a toxic chemical substance as a reactant, as a formulation component, as an article component, for repackaging, or as an impurity; or, that it otherwise uses the chemical substance as a chemical substance processing aid.[22]Because EPA assumes any company that both manufactures and processes a chemical substance would be considered a manufacturer for the purposes of IUR reporting of the additional data elements, TRI submitters who indicated they also manufactured or otherwise used a chemical substance were filtered out of the dataset.

The TRI data revealed an average of 137 processors reported information per TRI chemical substance. However, the average value is greatly skewed by certain high-volume chemical substances

[21] The TRI program may collect data on certain chemicals for which IUR reporting is not required. A list of CASRNs for the non-confidential IUR chemicals was found at "Non-confidential 2006 IUR Records by Chemical, including Manufacturing, Processing and Use Information" http://cfpub.epa.gov/iursearch/index.cfm?s=chem Accessed August 30, 2009.

[22]TRI submitters indicate their activities and uses of the toxic chemical at the facility in Part II Section 3 of Form R.

processed by a large number of processors.[23] Therefore, EPA chose to use the median number of 15 processors per chemical substance, assuming it to be more representative of the universe of chemical substance processors who would report under the IUR rule.

Information was reported for a total of 6,140 chemical substances under the IUR rule in 2006. By applying the average number of processors per chemical substance derived from TRI data, EPA estimates a total of 92,100 reports would be submitted by processors as a result of this option (15 x 6,140 = 92,100).

This approach is limited to the extent the universe of processors is different under the TRI regulation and IUR rule. Because the sets of chemical substances covered under the TRI and IUR rules are different, the median number of processors per chemical substance may be an over- or underestimate. (EPA attempted to minimize this by filtering the TRI data to only include known IUR chemical substances, but not all IUR chemical substances would be subject to TRI reporting requirements.)Additionally, the TRI rule applies to facilities included within a specific set of NAICS codes; the IUR rule presently does not limit its applicability to a defined set of NAICS codes. This may cause the number of processors estimated here to be an underestimate. Furthermore, "processor" may be defined differently by the two rules; any specific criteria EPA may use to define a "processor" for the purpose of the IUR rule may cause the median number of processors per chemical substance estimated here to be an overestimate. Finally, the data used in this analysis was for submissions of TRI Form R only. This was done because Form A, the other, simpler, TRI reporting form, does not request information that would identify the submitter as a processor or manufacturer. Form R is used for high-volume chemical substances (i.e., those manufactured, processed, or otherwise used in amounts greater than one million pounds) or for chemical substances meeting other specific criteria; as a result, processors of small volumes may not be included, causing the median number to be an underestimate.

F.2 Industry Burden Estimate

Manufacturers

Given the similarity between the additional exposure-related data elements and the exposure data collected under EPA's New Chemical Program, EPA assumes the incremental cost for the additional data elements would be similar to the estimated burden to complete a premanufacture notice (PMN).[24]Therefore, EPA calculated the burden to complete an "integrated Form U" (that is, a Form U modified to include the additional data elements) by adding the base burden for a full form (estimated in Section 4.5 of this report) to the burden to complete a PMN. EPA assumes every site would be required to complete the additional exposure information.

The burden of completing a paper PMN form was estimated in the supporting statement for *Premanufacture Review Reporting and Exemption Requirements for New Chemical Substances and Significant New Use Reporting Requirements for Chemical Substances*, EPA ICR No: 574.12 (EPA,. 2003). According to this source, the total burden to complete a PMN form in the first reporting cycle is 107 hours. To be consistent with the proposed amendment to require electronic submission (discussed in Section 4.4.27 of this economic analysis), EPA reduced the estimated burden to 93 hours. Because paper filing would not be permitted under the amendment, all clerical burden is eliminated. Consistent with the method described in Section 4.2.6 of this report, the future cycle burden was calculated by applying a weighting factor of 80 percent to the first cycle burden, resulting in an estimated burden of 74.4 hours.

[23] For example, an average of 3,240 processors per year reported for lead alone.

[24]Anyone who plans to manufacture or import a new chemical substance for a non-exempt commercial purpose is required by section 5 of TSCA to provide EPA with notice before initiating the activity. This premanufacture notice, or PMN, must be submitted at least 90 days prior to the manufacture or import of the chemical.

Using the numbers of manufacturing sites and reports as estimated in Section 4.5 of this report, EPA estimates the total burden to manufacturers to submit additional exposure-related data as part of their IUR reporting is 2.78 million hours in the first reporting cycle and 2.33 million hours in all future reporting cycles (See Table F-2:).

This approach is limited to the extent the data elements requested in any modification to the IUR match the PMN form and the burden it imposes. Furthermore, the PMN form includes some site and chemical identification data which may overlap with the data provided on IUR Part I; however, this overlap was considered to be minimal.

Table F-2: Change in Industry Burden to Manufacturers as a Result of Additional Exposure-Related Data Elements

	Burden for Rule Familiarization, Compliance Determination, Submission and to Prepare Part I (hours per site) (a)	Number of Sites (b)	Burden for Record Keeping and to Prepare Part II (hours per report) (c)	Number of Reports (with Part II) (d)	Burden to Prepare Part III (hours per report) (e)	Number of Reports (with Part III) (f)	Burden to Complete New Data Elements (hours per report) (g)	Number of Reports (with New Data elements) (h)	Industry Burden (millions of hours) (g) = (a* b)+(c*d)+(e*f)+(g*h)
Manufacturer Burden (First Cycle) Considering all Proposed Amendments (As Estimated in Table 4-47)	35.17	4,085	22.19	29,871	83.02	29,253	0.00	0	3.24
Total Manufacturer Burden (First Cycle) Including Additional Data Elements	35.17	4,085	22.19	29,871	83.02	29,253	93	29,871	6.01
Incremental Increase due to Additional Data Elements (First Cycle)	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**93.00**	**29,871**	**2.78**
Manufacturer Burden (Future Cycles) Considering all Proposed Amendments (As Estimated in Table 4-47)	11.05	4,289	18.35	31,365	65.63	30,716	0	0	2.64
Total Manufacturer Burden (Future Cycles) Including Additional Data Elements	11.05	4,289	18.35	31,365	65.63	30,716	74.4	31,365	4.97
Incremental Increase due to Additional Data Elements (Future Cycles)	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**74.40**	**31,365**	**2.33**

Note: Values in *Incremental Increase* rows are calculated by subtracting the corresponding baseline value from the post-amendment value.

Table F-3 contains the annual burden to manufacturers of the additional enhanced data elements over a 25-year period. The baseline burden estimates for completing Form U after all the proposed amendments are considered is taken from Table 4-57. EPA estimates over a 25-year period, the total burden to manufacturers for completing Form U, including the additional data elements, would be 30.88 million hours. The data elements add 14.45 million hours to the industry burden over this period.

Table F-3: Schedule of Annual Industry Burden to Manufacturers if All Proposed Amendments Are Implemented

Reporting Cycle	Years	Baseline Form U Burden (When all Amendments are Considered) (millions of hours)	Burden for Enhanced Data Elements (millions of hours)	Total Industry Burden (millions of hours)
1	**2007 to 2011**	3.24	2.78	6.01
2	**2012 to 2015**	2.64	2.33	4.97
3	**2016 to 2019**	2.64	2.33	4.97
4	**2020 to 2023**	2.64	2.33	4.97
5	**2023 to 2027**	2.64	2.33	4.97
6	**2026 to 2031**	2.64	2.33	4.97
Total		**16.43**	**14.45**	**30.88**
Annual Average		**0.66**	**0.58**	**1.24**

Manufacturers and Processors Combined

Because processors would not need to complete manufacturing information on Form U, Section II and other elements of Form U may not be applicable. For the purpose of this estimation, EPA assumes the burden on processors to complete an IUR form tailored to processing and use information would be similar to that of a PMN form alone.

Using the number of processors and number of reports as estimated in Section H.1, the total burden to processors to submit exposure-related data elements is estimated to be 8.57 million hours in the first reporting cycle and 6.85 million hours in future reporting cycles, and is shown in Table F-4.

This approach is also limited to the extent the data elements requested from processors in any modification to the IUR match the PMN form and the burden it imposes.

Table F-4: Change in Industry Burden to Processors as a Result of Additional Exposure-Related Data Elements

	Burden to Complete Enhanced Data Elements (hours per report)	Number of Reports (with Enhanced Data Elements)	Industry Burden (millions of hours)
Processor Burden (First Cycle) Considering all Proposed Amendments	0	0	0.00
Total Processor Burden (First Cycle) Including Additional Data Elements	93	92,100	8.57
Incremental Increase due to Additional Data Elements (First Cycle)	**93**	**92,100**	**8.57**
Processor Burden (Future Cycles) Considering all Proposed Amendments	0	0	0.00
Total Processor Burden (Future Cycles) Including Additional Data Elements	74	92,100	6.85
Incremental Increase due to Additional Data Elements (Future Cycles)	**74**	**92,100**	**6.85**

Note: Values in *Incremental Increase* rows are calculated by subtracting the corresponding baseline value from the post-amendment value.

Table F-5 contains the annual burden to processors of the additional enhanced data elements over a 25-year period. EPA estimates over a 25-year period, the total burden to processors for completing Form U, including the additional data elements, would be 42.83 million hours. This burden consists of labor to complete only the additional data elements because processors currently are not required to submit Form U.

Table F-5: Schedule of Annual Industry Burden to Processors

Reporting Cycle	Years	Baseline Form U Burden (When all Amendments are Considered) (millions of hours)	Burden for Enhanced Data Elements (millions of hours)	Total Industry Burden (millions of hours)
1	**2007 to 2011**	0.00	8.57	8.57
2	**2012 to 2015**	0.00	6.85	6.85
3	**2016 to 2019**	0.00	6.85	6.85
4	**2020 to 2023**	0.00	6.85	6.85
5	**2023 to 2027**	0.00	6.85	6.85
6	**2026 to 2031**	0.00	6.85	6.85
Total		**0.00**	**42.83**	**42.83**
Annual Average		**0.00**	**1.71**	**1.71**

The total industry burden to both manufacturers and processors if EPA were to require them to provide the additional exposure data are calculated by summing the total additional burdens for manufacturers and processors. The result is an estimated 11.34 million hours in the first reporting cycle and 9.19 million hours all future reporting cycles. The derivation of these numbers is found in Table F-6.

Table F-6: Change in Industry Burden to Manufacturers and Processors as a Result of Additional Exposure-Related Data Elements

	Total Burden to Manufacturers (millions of hours)	Total Burden to Processors (millions of hours)	Total Industry Burden (millions of hours)
Burden (First Cycle) Considering all Proposed Amendments	3.24	0.00	3.24
Total Burden (First Cycle) Including Additional Data Elements	6.32	8.57	14.88
Incremental Increase due to Additional Data Elements (First Cycle)	**2.78**	**8.57**	**11.34**
Burden (Future Cycles) Considering all Proposed Amendments	2.64	0.00	2.64
Total Burden (Future Cycles) Including Additional Data Elements	4.97	6.85	11.83
Incremental Increase due to Additional Data Elements (Future Cycles)	**2.33**	**6.85**	**9.19**

Note: Values in *Incremental Increase* rows are calculated by subtracting the corresponding baseline value from the post-amendment value.

Table F-7contains the annual burden to industry of the additional enhanced data elements over a 25-year period. The baseline burden estimates for completing Form U after all the proposed amendments are considered is taken from Table 4-52. EPA estimates over a 25-year period, the total burden to industry for completing Form U, including the additional data

elements, would be 73.70 million hours. The additional data elements add 57.27 million hours to the industry burden over this period.

Table F-7: Schedule of Annual Industry Burden to Manufacturers and Processors if All Proposed Amendments Are Implemented

Reporting Cycle	Years	Baseline Form U Burden (When all Amendments are Considered) (millions of hours)	Form U Burden with Enhanced Data Elements (millions of hours)	Total Industry Burden (millions of hours)
1	**2007 to 2011**	3.24	11.34	14.58
2	**2012 to 2015**	2.64	9.19	11.82
3	**2016 to 2019**	2.64	9.19	11.82
4	**2020 to 2023**	2.64	9.19	11.82
5	**2023 to 2027**	2.64	9.19	11.82
6	**2026 to 2031**	2.64	9.19	11.82
Total		**16.43**	**57.27**	**73.70**
Annual Average		**0.66**	**2.29**	**2.95**

F.3 Industry Cost Estimate

EPA calculated the per-report cost to industry of the additional data elements by multiplying the managerial and technical burdens found in *Premanufacture Review Reporting and Exemption Requirements for New Chemical Substances and Significant New Use Reporting Requirements for Chemical Substances*, EPA ICR No: 574.12 (EPA, 2003) by the wage rates for technical and managerial staff described in Section4.2.1. No clerical cost was calculated because EPA assumes electronic submission requirement will eliminate all clerical burden for processing and submitting Form U. As shown in Table F-8, EPA estimates the additional per report cost to be $5,673 in the first reporting cycle and $4,539 in all future reporting cycles, as a result of the requirement to report the additional data.

Table F-8: Per-Report Cost for Additional Data Elements, based on PMN Burden

	Technical			Managerial			Total	
	Burden (hours)	**Wage Rate (2008$)**	**Cost (2008$)**	**Burden (hours)**	**Wage Rate (2008$)**	**Cost (2008$)**	**Burden (hours)**	**Cost (2008$)**
PMN Burden/Cost per Report (First Cycle)	75	$58.84	$4,413	18	$70.03	$1,260	93	$5,673
PMN Burden/Cost per Report (Future Cycles)	60	$58.84	$3,530	14.4	$70.03	$1,008	74.4	$4,539

Manufacturers

The cost to manufacturers of the additional data elements was derived as shown in Table F-9. EPA estimates the option would cost manufacturers an additional $169 million during the first reporting cycle and an additional $142 million during all future reporting cycles.

Table F-9: Change in Industry Cost to Manufacturers as a Result of Additional Exposure-Related Data Elements

	Cost for Submission, Compliance Determination, Rule Familiarization, and to Prepare Part I (2008$) (a)	Number of Sites (b)	Cost for Record Keeping and to Prepare Part II (2008$) (c)	Number of Reports (with Part II) (d)	Cost to Prepare Part III (2008 $) (e)	Number of Reports (with Part III) (f)	Cost to Complete New Data Elements (2008$) (g)	Number of Reports (with New Data Elements) (h)	Industry Cost (millions of 2008$) (g) = (a* b) +(c*d)+(e*f)+(g*h)
Manufacturer Cost (First Cycle) Considering all Proposed Amendments (As Estimated in Table 4-48)	$2,192	4,085	$1,346	29,871	$5,117	29,253	0	0	$198.84
Total Manufacturer Cost (First Cycle) Including Additional Data Elements	$2,192	4,085	$1,346	29,871	$5,117	29,253	$5,673	29,871	$368.31
Incremental Increase due to Additional Data Elements (First Cycle)	**$0.00**	**0**	**$0.00**	**0**	**$0.00**	**$0.00**	**$5,673.44**	**29,871**	**$169.47**
Manufacturer Cost (Future Cycles) Considering all Proposed Amendments (As Estimated in Table 4-48)	$695	4,289	$1,109	31,365	$4,047	$30,716	0	0	$162.08
Total Manufacturer Cost (Future Cycles) Including Additional Data Elements	$695	4,289	$1,109	31,365	$4,047	30,716	$4,538.75	31,365	$304.44
Incremental Increase due to Additional Data Elements (Future Cycles)	**$0.00**	**0**	**$0.00**	**0**	**$0.00**	**0**	**$4,539**	**31,365**	**$142.36**

Note: Values in *Incremental Increase* rows are calculated by subtracting the corresponding baseline value from the post-amendment value.

Table F-10presents the annual and annualized costs estimates to manufacturers of competing Form U with the additional exposure-related data elements. The baseline cost estimates for completion of Form U come from Table 4-58. Over a 25-year period, EPA estimates the annualized cost to manufacturers would be $72 million at a three percent discount rate, and $67 million at a seven percent discount rate.

Table F-10: Annual Increase in Industry Cost to Manufacturers if All Proposed Amendments Are Implemented (2008$)

Reporting Cycle	Years	Baseline Form U Cost (When all Amendments are Considered) (millions 2008$)	Form U Cost for Enhanced Data Elements (millions 2008$)	Total Cost To Industry (millions 2008$)
1	**2007 to 2011**	$198.84	$169.47	$368.31
2	**2012 to 2015**	$162.08	$142.36	$304.44
3	**2016 to 2019**	$162.08	$142.36	$304.44
4	**2020 to 2023**	$162.08	$142.36	$304.44
5	**2023 to 2027**	$162.08	$142.36	$304.44
6	**2026 to 2031**	$162.08	$142.36	$304.44
Total		**$1,009.25**	**$881.26**	**$1,890.51**
Annual Average		**$40.37**	**$35.25**	**$75.62**
Annualized at 3%		**$38.40**	**$33.47**	**$71.88**
Annualized at 7%		**$35.83**	**$31.15**	**$66.98**

Manufacturers and Processors Combined

To calculate the cost to processors, EPA multiplied the per report cost ($5,673 in the first reporting cycle and $4,539 during all future reporting cycles) by the total number of reports EPA expects to be submitted by processors, 141,220. As shown in Table F-11, EPA estimates the cost to processors to be $523 million in the first reporting cycle and $418 million in all future reporting cycles.

Table F-11: Change in Industry Cost to Processors as a Result of Additional Exposure-Related Data Elements

	Cost to Prepare New Data Elements (2008$)	Number of Reports (with New Data Elements)	Industry Cost (millions 2008$)
Processor Cost (First Cycle) Considering all Proposed Amendments	0	0	$0
Total Processor Cost (First Cycle) Including Additional Data Elements	$5,673	92,100	$523
Incremental Increase due to Additional Data Elements (First Cycle)	**$5,673**	**92,100**	**$523**
Processor Cost (Future Cycles) Considering all Proposed Amendments	0	0	$0
Total Processor Cost (Future Cycles) Including Additional Data Elements	$4,539	92,100	$418
Incremental Increase due to Additional Data Elements (Future Cycles)	**$4,539**	**92,100**	**$418**

Note: Values in *Incremental Increase* rows are calculated by subtracting the corresponding baseline value from the post-amendment value.

Table F-12 presents the annual and annualized costs estimates to processors of competing Form U with the additional exposure-related data elements. Over a 25-year period, EPA

estimates the annualized cost to processors would be $116 million at a three percent discount rate, and $125 million at a seven percent discount rate.

Table F-12: Annual Increase in Industry Cost to Processors if All Proposed Amendments Are Implemented (2008$)

Reporting Cycle	Years	Baseline Form U Cost (When all Amendments are Considered) (millions 2008$)	Form U Cost for Enhanced Data Elements (millions 2008$)	Total Cost To Industry (millions 2008$)
1	**2007 to 2011**	$0.00	$523.00	$523.00
2	**2012 to 2015**	$0.00	$418.00	$418.00
3	**2016 to 2019**	$0.00	$418.00	$418.00
4	**2020 to 2023**	$0.00	$418.00	$418.00
5	**2023 to 2027**	$0.00	$418.00	$418.00
6	**2026 to 2031**	$0.00	$418.00	$418.00
Total		**$0.00**	**$2,613.00**	**$2,613.00**
Annual Average		**$0.00**	**$104.52**	**$104.52**
Annualized at 3%		**$0.00**	**$116.03**	**$116.03**
Annualized at 7%		**$0.00**	**$125.45**	**$125.45**

Total estimated industry cost is presented in Table F-13 and is calculated by summing the costs to both manufactures and processors. EPA estimates the cost to the industry of the additional exposure elements, if both manufacturers and processor are required to provide the data, would be $692 million in the first reporting cycle and $560 million in all future reporting cycles.

Table F-13: Change in Industry Cost to Manufacturers and Processors as a Result of Additional Exposure-Related Data Elements

	Total Cost to Manufacturers (millions 2008$)	Total Cost to Processors (millions 2008$)	Total Industry Cost (millions 2008$)
Cost (First Cycle) Considering all Proposed Amendments	$199	$0	$199
Total Cost (First Cycle) Including Additional Data Elements	$368	$523	$891
Incremental Increase due to Additional Data Elements (First Cycle)	**$169**	**$523**	**$692**
Cost (Future Cycles) Considering all Proposed Amendments	$162	$0	$162
Total Cost (Future Cycles) Including Additional Data Elements	$304	$418	$722
Incremental Increase due to Additional Data Elements (Future Cycles)	**$142**	**$418**	**$560**

Note: Values in *Incremental Increase* rows are calculated by subtracting the corresponding baseline value from the post-amendment value.

Table F-14presents the annual and annualized costs estimates to industry of competing Form U with the additional exposure-related data elements. The baseline cost estimates for completion of Form U come from Table 4-53. Over a 25-year period, EPA estimates the annualized cost to the industry would be $166 million at a three percent discount rate, and $150 million at a seven percent discount rate.

Table F-14: Annualized Increase in Industry Cost to Manufacturers and Processors if All Amendments Are Implemented (2008$)

Reporting Cycle	Years	Baseline Form U Cost (When all Amendments Are Considered) (millions 2008$)	Form U Burden with Enhanced Data Elements (millions 2008$)	Total Cost To Industry (millions 2008$)
1	**2007 to 2011**	$198.84	$692.47	$891.31
2	**2012 to 2015**	$162.08	$560.36	$722.44
3	**2016 to 2019**	$162.08	$560.36	$722.44
4	**2020 to 2023**	$162.08	$560.36	$722.44
5	**2023 to 2027**	$162.08	$560.36	$722.44
6	**2026 to 2031**	$162.08	$560.36	$722.44
Total		**$1,009.25**	**$3,494.26**	**$4,503.51**
Annual Average		**$40.37**	**$139.77**	**$180.14**
Annualized at 3%		**$37.28**	**$129.14**	**$166.43**
Annualized at 7%		**$33.48**	**$116.05**	**$149.53**

F.4 Agency Burden Estimate

Agency burden for both contractor and EPA staff related to document receipt, tracking and data entry quality control of data entry would increase with the promulgation of additional exposure-related data elements. To calculate the additional Agency burden associated with the additional data elements, EPA used the per-data element burden to the EPA after all the proposed amendments are considered, 0.00008 hours, as derived in Section 5.5). This burden was multiplied by the number of new data elements, 57 (as listed in Table F-1) to calculate the total per-report burden of processing the new data elements for manufacturers, 0.0048 hours. EPA assumes there would be no change in the fixed Agency costs associated with this modification to the IUR rule, as described in Table 5-3.

Manufacturers

All manufactures are expected to submit the additional data, increasing the Agency burden by 150 hours for all report years, as estimated in Table F-15. EPA does not expect the future reporting cycle burden to differ from first reporting cycle burden.

Table F-15: Change in Agency Burden to Process Manufacturer Data as a Result of Additional Exposure-Related Data Elements

	Burden to Process Part I (hours)	Number of Sites	Burden to Process Part II (hours)	Number of Reports (with Part II)	Burden to Process Part III (hours)	Number of Reports (with Part III)	Burden to Process New Data Elements (hours)	Number of Reports (With New Data Elements)	Agency Burden (hours)
First Year, Baseline Burden (All Proposed Amendments)	0.0019	4,085	0.0056	29,871	0.0063	29,253	0	0	2,439
First year, With Enhanced Data Elements	0.0019	4,085	0.0056	29,871	0.0063	29,253	0.0048	29,871	2,582
Change, first year	**0**	**0**	**0**	**0**	**0**	**0**	**0.0048**	**29,871**	**143**
Future-cycle Baseline	0.0019	4,289	0.0056	31,365	0.0063	30,716	0	0	2,456
Future cycle, Post Amendment	0.0019	4,289	0.0056	31,365	0.0063	30,716	0.0048	31,365	2,607
Change from the Baseline, Future cycles	**0**	**0**	**0**	**0**	**0**	**0**	**0.0048**	**31,365**	**150**

Table F-16 presents the estimated annual burden to the Agency of processing Form U with the additional exposure-related data elements. Over a 25-year period, EPA estimates the total Agency burden to process manufacturer data would be 15,600 hours.

Table F-16: Annual Increase in Agency Burden to Process Manufacturer Data if All Proposed Amendments Are Implemented

Reporting Cycle	Years	Baseline Form U Burden (When all Amendments are Considered) (hours)	Form U Burden with Enhanced Data Elements (hours)	Total Industry Burden (hours)
1	**2007 to 2011**	2,439	143	2,582
2	**2012 to 2015**	2,456	150	2,607
3	**2016 to 2019**	2,456	150	2,607
4	**2020 to 2023**	2,456	150	2,607
5	**2023 to 2027**	2,456	150	2,607
6	**2026 to 2031**	2,456	150	2,607
Total		**14,721**	**896**	**15,617**
Annual Average		**589**	**36**	**625**

Manufacturers and Processors Combined

Table F-17 shows the estimated burden to the Agency of processing the additional data submitted by processors. As described above, EPA expects to receive a total of 92,100 processor reports. The Agency burden, per-report, to process the additional data elements is 0.0048 hours, and is the same for both processors and manufactures. Therefore, as shown in Table H-10, the Agency burden to process the processor data are approximately 442 hours for all reporting cycles.

Table F-17: Change in Agency Burden to Process Processor Data as a Result of Additional Exposure-Related Data Elements

	Per-Report Burden to Process New Data Elements (hours)	Number of Reports (with New Data Elements)	Agency Burden (hours)
Agency Burden to Process Processor Data Considering all Proposed Amendments	0.0000	0	0
Total Agency Burden Including Processing Additional Data Elements for Processors	0.0048	92,100	442
Incremental Increase due to Additional Data Elements	**0.0048**	**92,100**	**442**

Note: Values in *Incremental Increase* rows are calculated by subtracting the corresponding baseline value from the post-amendment value.

Table F-18 presents the estimated annual burden to the Agency of processing Form U with the additional exposure-related data elements. Over a 25-year period, EPA estimates the total Agency burden to process processor data would be 2,651 hours.

Table F-18: Annual Increase in Agency Burden to Process Processor Data if All Proposed Amendments Are Implemented

Reporting Cycle	Years	Baseline Form U Burden (When all Amendments are Considered) (hours)	Form U Burden with Enhanced Data Elements (hours)	Total Industry Burden (hours)
1	**2007 to 2011**	0.00	442	442
2	**2012 to 2015**	0.00	442	442
3	**2016 to 2019**	0.00	442	442
4	**2020 to 2023**	0.00	442	442
5	**2023 to 2027**	0.00	442	442
6	**2026 to 2031**	0.00	442	442
Total		**0.00**	**2,651**	**2,651**
Annual Average		**0.00**	**106**	**106**

Table F-19 presents the burden to EPA of processing the additional data elements from both the processors and the manufacturers. This option is expected to increase the Agency burden by 592 hours for all reporting cycles.

Table F-19: Change in Agency Burden to Process Manufacturer and Processor Data as a Result of Additional Exposure-Related Data Elements

	Total Burden of Processing Manufacturer Data (hours)	Total Burden of Processing Processor Data (hours)	Total Agency Burden (hours)
Burden (First Cycle) Considering all Proposed Amendments	2,439	0	2,439
Total Burden (First Cycle) Including Additional Data Elements	2,582	442	3,024
Incremental Increase due to Additional Data Elements (First Cycle)	**143**	**442**	**585**
Burden (Future Years) Considering all Proposed Amendments	2,456	0	2,456
Total Burden (Future Years) Including Additional Data Elements	2,607	442	3,049
Incremental Increase due to Additional Data Elements (Future Years)	**150**	**442**	**592**

Table F-20 presents the estimated annual burden to the Agency of processing Form U with the additional exposure-related data elements from both manufacturers and processors. Over a 25-year period, EPA estimates the total Agency burden to process manufacturer and processor data would be 18,269 hours.

Table F-20: Annual Increase in Agency Burden to Process Data if All Proposed Amendments Are Implemented

Reporting Cycle	Years	Baseline Burden (When all Amendments are Considered)	Form U Burden with Enhanced Data Elements (hours)	Total Agency Burden (hours)
1	**2007 to 2011**	2,439	585	3,024
2	**2012 to 2015**	2,456	592	3,049
3	**2016 to 2019**	2,456	592	3,049
4	**2020 to 2023**	2,456	592	3,049
5	**2023 to 2027**	2,456	592	3,049
6	**2026 to 2031**	2,456	592	3,049
Total		**14,721**	**3,548**	**18,269**
Annual Average		**589**	**142**	**731**

F.5 Agency Cost Estimate

The additional exposure data elements are expected to increase the cost to both EPA and contractor staff. To calculate the additional Agency cost associated with the additional data elements, EPA used the per-data element cost to the EPA after all the proposed amendments are considered, $0.009, as derived in Section 5.5).This unit cost was multiplied by the number of new data elements, 57 (as listed in Table F-1) to calculate the total per-report cost of processing the new data elements for manufacturers, $0.51.

Manufacturers

The total cost to EPA of processing these new data elements for manufacturers is approximately $15,100 in the first reporting cycle and $15,800 in future reporting cycles, as shown in Table F-21. This table reflects both the variable cost to the Agency, which is dependent on the number of reports, and a fixed cost to the Agency of $249,200 (see Section 5.3) which would not change as a result of including the additional data option in the IUR.

Table F-21: Change in Agency Cost of Processing Manufacturer Data as a Result of Additional Exposure-Related Data Elements

	Cost to Process Part I (2008$)	Number of Sites	Cost to Process Part II (2008$)	Number of Reports (with Part II)	Cost to Process Part III (2008$)	Number of Reports (with Part III)	Cost to Process New Data Elements (2008$)	Number of Reports (with new data elements)	Agency Burden (millions of 2008$)
First Year, Baseline Cost (All Proposed Amendments)	$0.20	4,085	$0.58	29,871	$0.66	29,253	$0.00	0	$241,393
First year, with Enhanced Data Elements	$0.20	4,085	$0.58	29,871	$0.66	29,253	$0.51	29,871	$256,481
Change, first year	**$0.00**	**0**	**$0.00**	**0**	**$0.00**	**0**	**$0.51**	**29,871**	**$15,089**
Future-Cycle Baseline	$0.20	4,289	$0.58	31,365	$0.66	30,716	0.00	0	$243,263
Future-Cycle, Post Amendment	$0.20	4,289	$0.58	31,365	$0.66	30,716	0.51	31,365	$259,106
Change from the Baseline, Future Cycles	**$0.00**	**0**	**$0.00**	**0**	**$0.00**	**0**	**0.51**	**31,365**	**$15,843**

Table F-22 presents the annual and annualized costs estimates to the Agency of processing manufacturer Form U with the additional exposure-related data elements. Over a 25-year period, EPA estimates the annualized cost to the Agency would be $58,350 at a three percent discount rate, and $53,517 at a seven percent discount rate.

Table F-22: Annual Increase in Agency Cost to Process Manufacturer Data if All Proposed Amendments Are Implemented (2008$)

Reporting Cycle	Years	Baseline Cost (2008$)	Post-Alternative Option Cost (2008$)	Change from Baseline (2008$)
1	**2007 to 2011**	$241,393	$15,089	$256,481
2	**2012 to 2015**	$243,263	$15,843	$259,106
3	**2016 to 2019**	$243,263	$15,843	$259,106
4	**2020 to 2023**	$243,263	$15,843	$259,106
5	**2023 to 2027**	$243,263	$15,843	$259,106
6	**2026 to 2031**	$243,263	$15,843	$259,106
Total		**$1,457,707**	***$94,306***	**$1,552,013**
Annual Average		**$58,308**	**$3,772**	**$62,081**
Annualized at 3%		**$54,812**	**$3,538**	**$58,350**
Annualized at 7%		**$50,281**	**$3,236**	**$53,517**

Manufacturers and Processors Combined

Table F-23 shows the Agency cost of processing the processor data. To estimate this cost, EPA multiplied the number of processors derived in Section H.1 (141,220) by the per report cost of processing the additional data, $0.51. EPA estimates the total Agency cost to process the processor data are $46,500.

Table F-23: Change in Agency Cost to Process Processor Data as a Result of Additional Exposure-Related Data Elements

	Per-Report Cost to Process New Data Elements (2008$)	Number of Reports (with New Data Elements)	Agency Cost (2008$)
Agency Cost to Process Processor Data Considering all Proposed Amendments	$0.00	0	$0
Total Agency Cost Including Processing Additional Data Elements for Processors	$0.51	92,100	$46,522
Incremental Increase due to Additional Data Elements	**$0.51**	**92,100**	**$46,522**

Note: Values in *Incremental Increase* rows are calculated by subtracting the corresponding baseline value from the post-amendment value.

Table F-24 presents the annual and annualized costs estimates to the Agency of processing a processor Form U with the additional exposure-related data elements. Over a 25-year period, EPA estimates annualized cost to the Agency would be $10,500 at a three percent discount rate, and $9,600 at a seven percent discount rate.

Table F-24: Annual Increase in Agency Cost to Process Processor Data if All Proposed Amendments Are Implemented (2008$)

Reporting Cycle	Years	Baseline Cost(2008$)	Post-Alternative Option Cost(2008$)	Change from Baseline(2008$)
1	**2007 to 2011**	$0	$46,522	$46,522
2	**2012 to 2015**	$0	$46,522	$46,522
3	**2016 to 2019**	$0	$46,522	$46,522
4	**2020 to 2023**	$0	$46,522	$46,522
5	**2023 to 2027**	$0	$46,522	$46,522
6	**2026 to 2031**	$0	$46,522	$46,522
Total		**$0**	**$279,132**	**$279,132**
Annual Average		**$0**	**$11,165**	**$11,165**
Annualized at 3%		**$0**	**$10,500**	**$10,500**
Annualized at 7%		**$0**	**$9,638**	**$9,638**

Table F-25shows the cost to EPA of processing the additional data elements from both the processors and the manufactures. This option is expected to increase the Agency cost by $61,600 in the first reporting cycle and $62,400 in all future reporting cycles.

Table F-25: Change in Agency Cost of Processing Manufacture and Processor Data as a Result of Additional Exposure-Related Data Elements

	Total Burden of Processing Manufacturer data (2008$)	Total Burden of Processing Processor data (2008$)	Total Agency Burden (2008$)
Cost (First Cycle) Considering all Proposed Amendments	$241,393	$0	**$241,393**
Total Cost (First Cycle) Including Additional Data Elements	$256,481	$46,522	**$303,004**
Incremental Increase due to Additional Data Elements (First Cycle)	**$15,089**	**$46,522**	**$61,611**
Cost (Future Years) Considering all Proposed Amendments	$243,263	$0	**$241,393**
Total Cost (Future Years) Including Additional Data Elements	$259,106	$46,522	**$305,629**
Incremental Increase due to Additional Data Elements (Future Years)	**$15,843**	**$46,522**	**$62,366**

Table F-26 presents the annual and annualized costs estimates to the Agency of processing manufacturer and processor Form Us with the additional exposure-related data elements. Over a 25-year period, EPA estimates annualized cost to the Agency would be $68,900 at a three percent discount rate, and $63,200 at a seven percent discount rate.

Table F-26: Annual Increase in Agency Cost to Process Manufacturer and Processor Data if All Proposed Amendments Are Implemented (2008$)

Reporting Cycle	Years	Baseline Burden (When all Amendments are Considered) (2008$)	Form U Burden with Enhanced data Elements (2008$)	Total Agency Burden (2008$)
1	**2007 to 2011**	$241,393	$61,611	$303,004
2	**2012 to 2015**	$243,263	$62,366	$305,629
3	**2016 to 2019**	$243,263	$62,366	$305,629
4	**2020 to 2023**	$243,263	$62,366	$305,629
5	**2023 to 2027**	$243,263	$62,366	$305,629
6	**2026 to 2031**	$243,263	$62,366	$305,629
Total		**$1,457,707**	**$373,440**	**$1,831,147**
Annual Average		**$58,308**	**$14,938**	**$73,246**
Annualized at 3%		**$54,812**	**$14,039**	**$68,850**
Annualized at 7%		**$50,281**	**$12,874**	**$63,155**

F.6 Small Entity Analysis

As described in Chapter 8 of this economic analysis, EPA assessed the impact the proposed amendments to the IUR rule may have on small entities by examining the relationship between the compliance costs and company sales for small companies. EPA performed a similar analysis to determine the impact of the collection of additional exposure-related data elements on small entities.

Manufacturers

For manufacturers, EPA estimated (in Chapter 8) 3.89 manufacturing sites per global parent company; 41.3 percent of global parent companies (466 companies) are considered small under the SBA employment-based definition,[25] and 24.8 percent (280 companies) are considered small under the TSCA sales-based definition.[26]EPA also estimated an average of approximately 1.76 sites per small company under the employment-based definition of small business and approximately 1.92 sites per small company under the sales-based definition. Average annual sales revenue of global parent companies considered small under either definition were estimated using data from Dun & Bradstreet, as also described in Chapter 8.

Table F-13 shows the incremental cost to manufacturers as a result of adding the additional exposure related data elements to Form U. Table 4-48 (in the main text of the report) shows the incremental cost to manufacturers related to the other proposed amendments. Because these costs would be incurred once every four years under a proposed four-year reporting cycle, these costs were summed and annualized over four years at both a three percent and seven percent discount rate.[27] As shown in Table F-27, these costs were divided by the total number of sites expected to submit data, for the annualized costs per site. This was multiplied by the number of sites per small parent company to arrive at the annualized costs per small parent company. This value was divided by the annual sales per small parent company to derive the cost-to-sales ratio.

As shown in Table F-27, under the employment-based definition, a small parent company affected by the rule on average has sales of more than $412.7 million. The annualized costs of the proposed IUR rule amendments per small parent company, however, are $31,067 at a seven percent discount rate, and even lower under a three percent discount rate. The cost-to-sales ratio for an average small company under the employment-based SBA definition would be 0.008 percent or less. Under the more conservative TSCA sales-based definition, small parent company sales are on average more than $11.8 million, with annualized parent company costs associated with the proposed amendments of $33,892 or lower. The cost-to-sales ratio for an average small company under the sales-based definition would be 0.29 percent or less.

[25]Threshold of 1,000 employees.

[26] Total annual sales of the company, combined with those of any parent company, are below $40 million and annual production volume or importation volume at the facility is less than or equal to 100,000 lb.; or total annual sales of the company, combined with those of any parent company, are below $4 million.

[27] A seven percent discount rate, reflecting the opportunity cost of capital, is consistent with OMB Circular A-4 (OMB, 2003). A three percent discount rate was also used as a sensitivity analysis to examine the robustness of the results to a change in the annualization assumptions.

Using the highest annual cost shown in Table F-27of $33,892 a small company would have to have annual sales of less than $3.39 million in order to have a cost-to-sales ratio larger than one percent.

Table F-27. Derivation of Cost-to-Sales Ratios for Small Manufacturers for Collection of Additional Data Elements

	Employment-based Definition		Sales-based Definition	
	3% Discount Rate	7% Discount Rate	3% Discount Rate	7% Discount Rate
Incremental Costs of Enhanced Data Elements	**$169,471,347.15**			
Incremental Costs of Proposed Other Amendments	**$91,871,064.30**			
Total Annualized Costs	$68,260,366	$72,108,063	$68,260,366	$72,108,063
Total Number of Sites	4,085			
Annualized Costs per Site	$16,710	$17,652	$16,710	$17,652
Number of Sites per Small Parent Company	1.76		1.92	
Annualized Costs per Small Parent Company	$29,410	$31,067	$32,083	$33,892
Annual Sales per Small Parent Company	$412,713,310		$11,821,104	
Cost-to-Sales Ratio	0.007%	0.008%	0.271%	0.287%
Number of Companies Potentially Affected	466		280	

Processors

EPA is limited in its efforts to estimate the impact of the collection of additional exposure-related data elements on processors by the availability of data. As described above, EPA used TRI submission data to estimate the number of processors that may be affected by the requirement. However, data provided under the TRI program does not include information about a submitter's parent company or annual revenues. For this screening-level analysis, EPA assumes the chemical substance processor industry shares many characteristics with the chemical substance manufacturing industry. To the extent this is not the case, this analysis may over- or underestimate the impact of additional data elements on processors.

Specifically, EPA assumes 3.89 manufacturing sites per global parent company. EPA also assumes 41.3 percent of global parent companies are considered small under an employment-based definition, and 24.8 percent are considered small under a sales-based definition. EPA further assumes 1.76 sites per small parent company under the employment-based definition , and 1.92 sites per small parent company under the sales-based definition, consistent with manufacturer information. Given the large number of companies identified as processors according to TRI submissions, EPA was unable to examine Dun & Bradstreet data to estimate annual parent company revenue for this analysis. EPA used manufacturer revenue as a proxy, so this analysis provides only a preliminary estimate of impacts.

EPA divided the number of expected processor reports (92,100) by the average number of chemical substances for which a processor submitted TRI data (2.45) to obtain the estimated number of processors (37,592) who would report under an amended IUR rule. EPA divided this number by 3.89 (the number of sites per global parent company) for an estimated 9,664 global parent companies. This number was then multiplied by 41.3 percent and 24.8 percent to estimate the number of small global parent companies (the number of companies potentially affected), under the employment-based and sales-based definitions,

respectively. To calculate cost-to-sales ratios, EPA followed the same methodology for processors as described above for manufacturers. Results are presented in Table F-28.

Table F-28: Derivation of Cost-to-Sales Ratios for Small Processors for Collection of Additional Data Elements

	Employment-based Definition		Sales-based Definition	
	3% Discount Rate	7% Discount Rate	3% Discount Rate	7% Discount Rate
Incremental Costs of Enhanced Data Elements	$522,523,888			
Incremental Costs of Proposed Other Amendments	$0.00			
Total Annualized Costs	$136,478,697	$144,171,723	$136,478,697	$144,171,723
Total Number of Sites	37,592			
Annualized Costs per Site	$3,631	$3,835	$3,631	$3,835
Number of Sites per Small Parent Company	1.76		1.92	
Annualized Costs per Small Parent Company	$6,390	$6,750	$6,971	$7,364
Annual Sales per Small Parent Company	$412,7613,310		$11,821,104	
Cost-to-Sales Ratio	0.002%	0.002%	0.059%	0.062%
Number of Companies Potentially Affected	3,990		2,397	

As shown in Table F-28, under the employment-based definition, a small parent company affected by the rule on average has sales of more than $412.7 million. The annualized costs of the IUR rule amendments per small parent company, however, are $6,750 at a seven percent discount rate, and even lower under a three percent discount rate. The cost-to-sales ratio for an average small company under the employment-based definition would be 0.002 percent or less. Under the more conservative sales-based definition, small parent company sales on average are more than $11.8million, with annualized costs associated with the proposed amendments of $7,364 or lower. The cost-to-sales ratio for an average small company under the sales-based definition would be 0.062 percent or less.

As described in Chapter 8, the Regulatory Flexibility Act does not define the terms "significant" or "substantial" analytically with regard to extent of economic impact and number of small entities affected. However, EPA typically defines a threshold as compliance costs of one percent of sales to establish whether the level of economic impacts faced by the small entities can be presumed as not significant (EPA, 2006). Using the highest annual cost shown in Table F-28, $7,346, a small company would have to have annual sales of less than $734,600 in order to have a cost-to-sales ratio larger than one percent.

Appendix G. Estimated Burden and Cost of a Section 8(a) Rule for Exposure-Related Data Elements

In developing the proposed rule, EPA considered the annual collection of exposure-related data elements for approximately 100 chemical substances under a TSCA section 8(a) rulemaking. TSCA section 8(a) gives EPA the authority to require, by rulemaking, manufacturers (including importers) and processors of chemical substances to maintain records and/or report such data as EPA may reasonably require to carry out the TSCA mandates. Section 8(a) regulations can be tailored to meet unique information needs (e.g., via chemical-specific rules) or information can be obtained via use of "model" or standardized reporting rules. The Agency requested comment on a "model" reporting rule that would enable the Agency to undertake periodic data collection of information similar to that collected under the TSCA section 5 New Chemicals Program. The information would enhance the Agency's capabilities to conduct screening-level risk assessments of selected chemical substances. Each data collection would be specific to a unique set of IUR chemical substances for which the information is needed; EPA would request the information through one or more notices or letter writing actions per year, for an approximate total of 100 chemical substances per year. Because this data collection was only considered during the proposed rule, the total costs, submission dates, and annualization periods associated with them may not match what is presented in the main text for the final rule.

The additional data elements are the same as those proposed under the option outlined in Appendix H. A brief description of the exposure-related data elements that may be included in such a section 8(a) rule are provided in Table F-1.

G.1 Estimated Number of Affected Entities

For the purpose of this analysis, EPA assumes a section 8(a) rule would apply to both manufacturers and processors of the subject chemical substances.

Manufacturers

Because the applicability of a section 8(a) rule would be similar to that of the IUR rule (i.e., it would apply to manufacturers or importers of a subject chemical substance when produced in volumes greater than 25,000 lb), EPA estimated the number of manufacturers who would report and the number of reports it expects to be submitted using data from Section4.2.5 of this report. On average, 0.66 sites submit data under the IUR rule per regulated chemical substance, and an average of 4.21 full reports are submitted for each chemical substance. Therefore, EPA estimates a total of 66 sites would submit 421 reports for the estimated 100 chemical substances. To the extent the specific chemicals subject to a section 8(a) rule do not have an average number of manufacturers, this may be an over- or underestimate.

Processors

The number of processors that may be affected by a section 8(a) rule was estimated using data from EPA's Toxic Release Inventory (TRI) reporting program. Under the TRI program, EPA collects information annually on toxic chemical substance releases and waste management activities from manufacturers, processors, and users of a set of 581 toxic chemical substances and 30 toxic chemical substance categories. The chemical substances regulated under the TRI program are a smaller set than those regulated under the IUR rule, but the TRI data collection activity currently is the most comprehensive collection of information EPA administers for chemical substance processors. Therefore, EPA assumes information on processors who report under TRI is a suitable proxy for processors who may report under a section 8(a) rule.

EPA used TRI Form R submission data from the 2007 TRI Public Data Release in this analysis. To be consistent with the Economic Analysis for the Proposed IUR Modifications Rule (from which other

data for this analysis is derived), EPA used TRI data for the years 2002 through 2005 (the time period of the most recent IUR reporting cycle), filtered to include only IUR chemical substances (i.e., the chemical substances listed in the public 2006 IUR database).[28] Processors submitted TRI data on an average of 220 of the IUR chemical substances during each of the four years of interest. For this analysis, EPA counted as a "processor" each TRI submitter who indicated it processes a toxic chemical substance as a reactant, as a formulation component, as an article component, for repackaging, or as an impurity; or, that it otherwise uses the toxic chemical substance as a chemical substance processing aid.[29]Because EPA assumes any company that both manufactures and processes a chemical substance would be considered a manufacturer for the purposes of a section 8(a) rule, TRI submitters who indicated they also manufactured or otherwise used a chemical substance were filtered out of the dataset.

The TRI data revealed an average of 137 processors reported information per TRI chemical substance. However, the average value is greatly skewed by certain high-volume chemical substances processed by a large number of processors.[30] Therefore, EPA chose to use the median number of 15 processors per chemical substance, assuming it to be more representative of the universe of TSCA chemical substance processors. Using the median of 15 processors per chemical substance, EPA expects a total of 1,500 reports would be submitted for an estimated 100 chemical substances. According to the TRI data, each processor processes approximately 2.45 chemical substances; therefore, EPA expects a section 8(a) rule to affect 612 sites.

This approach is limited to the extent the universe of TRI processors is different from that of a section 8(a) rule. Because the set of chemical substances covered under the rules is different, the median number of processors per chemical substance may be an over- or underestimate. Additionally, the TRI rule is applicable to facilities included within a specific set of NAICS codes; a section 8(a) rule may not limit its applicability to a defined set of NAICS codes, which could cause the number of processors estimated here to be an underestimate. Furthermore, "processor" may be defined differently by the two rules; any specific criteria EPA may use to define a "processor" for the purpose of a section 8(a) rule may cause the median number of processors per chemical substance estimated here to be an overestimate. Finally, the data used in this analysis was for submissions of TRI Form R only. This was done because Form A, the other, simpler, TRI reporting form, does not request information that would identify the submitter as a processor or manufacturer. Form R is used for high-volume chemical substances (i.e., those manufactured, processed, or otherwise used in amounts greater than one million pounds) or for chemical substances meeting other specific criteria; as a result, processors of small volumes may not be included, causing the median number to be an underestimate.

G.2 Industry Burden Estimate

The section 8(a) rule would require submitters (both manufacturers and processors) to provide data similar to the exposure-related data elements that are collected under EPA's New Chemicals Program through a premanufacture notice (PMN) and under the IUR rule. Therefore, the burden associated with a section 8(a) rule is calculated by estimating the burden to complete a PMN.

The burden to complete a paper PMN form was estimated in the supporting statement for *Premanufacture Review Reporting and Exemption Requirements for New Chemical Substances and*

[28] The TRI program may collect data on certain chemicals for which IUR reporting is not required. A list of CASRNs for the non-confidential IUR chemicals was found at "Non-confidential 2006 IUR Records by Chemical, including Manufacturing, Processing and Use Information" http://cfpub.epa.gov/iursearch/index.cfm?s=chem Accessed August 30, 2009.

[29] TRI submitters indicate their activities and uses of the toxic chemical at the facility in Part II Section 3 of Form R.

[30] For example, an average of 3,240 processors reported under TRI per year for lead alone.

Significant New Use Reporting Requirements for Chemical Substances, EPA ICR No: 574.12 (EPA, 2003). According to this source, the total burden to complete a PMN form is 107 hours. EPA assumes a section 8(a) rule would require electronic submission, so EPA reduced the estimated burden to 93 hours. This reduction is consistent with the assumption in section 4.4.27; all clerical burden will be eliminated because paper filing will not be permitted with electronic submission.

Using the number of manufacturer reports as estimated in Section I-1 of this appendix, the total burden to manufacturers to submit additional exposure-related data elements as part of their IUR reporting is estimated to be 39,200 hours. Using the number of processor reports as estimated in Section I-1 above, the total burden to processors to submit exposure-related data elements is estimated to be 139,500 hours (See Table G-1). Because each individual collection under the rule would be for a different set of chemical substances, EPA assumes different sites would be submitting reports every year, so the burden would be the same in future individual collections.

This approach is limited to the extent the data elements requested in a section 8(a) rule match the IUR Form U and the PMN form, and the burden they incur.

Table G-1: Annual Industry Burden as a Result of a TSCA Section 8(a) Data Collection

Entity Subject to the Data Collection	Burden to Complete Exposure-Related Data Elements (hours per report)	Number of Reports	Total Burden (hours)
Manufacturers	93	421	39,166
Processors	93	1,500	139,500
Total for Manufacturers and Processors	**93**	**1,921**	**178,666**

Annual Industry Burden Estimates

EPA estimated the total annual burden and cost to industry of a section 8(a) rule over a 25-year period. A 25-year period was used so the burden and cost to the industry are directly comparable to the annual burden presented in Table 4-52 and the annual cost estimates for the proposed amendments to the IUR rule, found in Table 4-53. Table G-2 contains the annual burden to industry over 20 years as a result of a section 8(a) rule and of completing Form U. Over a 25-year period, EPA estimates the total burden to industry of both the IUR data collection and a section 8(a) collection will be 20.04 million hours. The section 8(a) rule adds 3.57 million hours to the industry burden during this time period.

Table G-2: Schedule of Annual Industry Burden

Reporting Cycle	Years	Baseline Cost (When all Amendments are Considered)	Manufacturer Section 8(a) Cost	Processor Section 8(a) Cost	Manufacturer and Processor Section 8(a) Cost	Total Cost to Industry (Manufacturer and Processor + Baseline)
		(millions of hours)	(millions of hours)	(millions of hours)	(millions of hours)	(millions of hours)
1	**2007 to 2011**	3.24	0.04	0.14	0.18	3.41
2	**2012 to 2015**	2.61	0.16	0.56	0.71	3.32
3	**2016 to 2019**	2.61	0.16	0.56	0.71	3.32
4	**2020 to 2023**	2.61	0.16	0.56	0.71	3.32
5	**2023 to 2027**	2.61	0.16	0.56	0.71	3.32
6	**2026 to 2031**	2.61	0.16	0.56	0.71	3.32
Total		**16.29**	**0.82**	**2.93**	**3.75**	**20.04**
Annual Average		**0.65**	**0.03**	**0.12**	**0.15**	**0.80**

G.3 Industry Cost Estimate

EPA calculated the per-report cost to industry of the additional data elements by multiplying the managerial and technical burdens found in *Premanufacture Review Reporting and Exemption Requirements for New Chemical Substances and Significant New Use Reporting Requirements for Chemical Substances*, EPA ICR No: 574.12 (EPA, 2003), by the wage rates for technical and managerial staff described in Section 4.2.1. No clerical cost was calculated because of the proposed electronic submission requirement (see Section 4.4.27) which EPA assumes all clerical burden for preparing and submitting Form Us eliminated. As shown in Table G-3, EPA estimates the additional per report cost to be $5,673.

Table G-3: Per-Report Cost for Additional Data Elements, based on PMN Burden

	Technical			Managerial			Total	
	Burden (hours)	Wage Rate (2008$)	Cost (2008$)	Burden (hours)	Wage Rate (2008$)	Cost (2008$)	Burden (hours)	Cost (2008$)
PMN Burden/Cost per Report	75	$58.84	$4,413	18	$70.03	$1,260	93	$5,673

The cost to manufacturers and processors to submit the exposure-related data elements was derived as shown in Table G-4. EPA estimates the section 8(a) rule would cost manufacturers $2.39 million and processors $8.51 million each year.

Table G-4: Annual Industry Cost as a Result of a TSCA Section 8(a) Data Collection

Entity Subject to the Data Collection	Cost to Prepare Exposure-related Data Elements (2008$)	Number of Reports	Industry Cost (millions of 2008$)
Manufacturers	$5,673	421	$2.39
Processors	$5,673	1,500	$8.51
Total for Manufacturers and Processors	**$5,673**	**1,921**	**$10.90**

Annual Industry Cost Estimates

Table G-5presents the annual and annualized cost estimates to industry of completing Form U and a section 8(a) collection. The cost estimates for completion of Form U come from Table 4-53. Over a 25-year period, EPA estimates total annualized cost to the industry would be $46.98 million, with a three percent discount rate, and $43.56 million with a seven percent discount rate.

Table G-5: Annual Increase in Industry Cost if All Amendments Are Implemented (2008$)

Reporting Cycle	Years	Baseline Cost (When all Amendments are Considered)	Manufacturer Section 8(a) Cost	Processor Section 8(a) Cost	Manufacturer and Processor Section 8(a) Cost	Total Cost to Industry (Manufacturer and Processor + Baseline)
		(2008$ millions)	(2008$ millions)	(2008$ millions)	(2008$ millions)	(2008$ millions)
1	2007 to 2011	$198.84	$2.39	$8.51	$10.90	$209.74
2	2012 to 2015	$162.08	$9.56	$34.04	$43.60	$205.68
3	2016 to 2019	$162.08	$9.56	$34.04	$43.60	$205.68
4	2020 to 2023	$162.08	$9.56	$34.04	$43.60	$205.68
5	2023 to 2027	$162.08	$9.56	$34.04	$43.60	$205.68
6	2026 to 2031	$162.08	$9.56	$34.04	$43.60	$205.68
Total		**$1,009.25**	**$50.19**	**$178.71**	**$228.90**	**$1,238.15**
Annual Average		**$40.37**	**$2.01**	**$7.15**	**$9.16**	**$49.53**
Annualized at 3%		**$38.40**	**$1.88**	**$6.69**	**$8.57**	**$46.98**
Annualized at 7%		**$35.83**	**$1.70**	**$6.04**	**$7.73**	**$43.56**

G.4 Agency Burden Estimate

For the purposes of this analysis, EPA assumed the Agency burden was similar to that associated with the IUR rule, and would include contractor and EPA staff burden related to document receipt, tracking and quality control of data entry. To calculate the Agency burden associated with the exposure-related data elements, EPA used the per-data element burden to EPA after all the proposed amendments are considered, 0.00008 hours, as calculated in Section 5.5. The number of exposure-related data elements is 57, as shown in Table F-1. The section 8(a) burden per-report is estimated as shown in Table G-6.

Table G-6: Per-Report Burden for Data Elements Similar to Those Included in a TSCA Section 8(a) Data Collection

Data Elements	Number of Data Elements	Per-Data Element Burden (hours)	Per-report Burden (hours)
Exposure-related Data Elements	57	0.00008	0.0048

Table G-7shows the estimated burden to the Agency of processing the data submitted by chemical substance manufacturers and processors. As described above, EPA expects a total of 421 manufacturer reports and 1,500 processor reports. The Agency burden to process the exposure-related data elements, per-form, 0.0048 hours, is the same for both processors and manufacturers. Therefore, the Agency burden to process the manufacturer data are 2.02 hours, and for processor data, is approximately 7.20 hours.

Table G-7:Agency Burden to Process Data as a Result of a TSCA Section 8(a) Data Collection

	Per-Report Burden to Process Exposure-Related Data Elements (hours)	Number of Reports	Agency Burden (hours)
Agency Burden to Process Manufacturer Data	0.0048	421	2.02
Agency Burden to Process Processor Data	0.0048	1,500	7.20
Total Agency Burden	**0.0048**	**1,921**	**9.22**

Annual Agency Burden Estimates

Table G-8presents the annual Agency burden estimates for data entry and extramural costs during all principal reporting and non-principal reporting years over a 25-year period. The Agency burden for processing Form U is taken from Table 5-42. In total, EPA estimates the Agency burden for the IUR rule and a section 8(a) rule would be 15,000 hours over a 25-year period. The total burden as a result of a section 8(a) rule would be 240 hours over a 25-year period.

Table G-8: Schedule of Annual Agency Burden

Reporting Cycle	Years	Baseline Cost (When all Amendments are Considered) (hours)	Manufacturer Section 8(a) Cost (hours)	Processor Section 8(a) Cost (hours)	Manufacturer and Processor Section 8(a) Cost (hours)	Total Cost to Industry (Manufacturer and Processor + Baseline) (hours)
1	**2007 to 2011**	2,439	2.02	7.20	9.22	2,448
2	**2012 to 2015**	2,456	10.10	35.98	46.08	2,503
3	**2016 to 2019**	2,456	10.10	35.98	46.08	2,503
4	**2020 to 2023**	2,456	10.10	35.98	46.08	2,503
5	**2023 to 2027**	2,456	10.10	35.98	46.08	2,503
6	**2026 to 2031**	2,456	10.10	35.98	46.08	2,503
Total		**14,721**	**52.52**	**187.12**	**239.64**	**14,960**
Annual Average		**589**	**2.10**	**7.48**	**9.59**	**598**

G.5 Agency Cost Estimate

To calculate the Agency cost associated with processing the data received from a section 8(a) rule, EPA used the cost per-data element to the EPA estimated in the IUR EA, $0.0089 (Section 5.5).This unit cost was multiplied by the number of data elements to calculate the total per-report cost of processing the data elements, as shown in Table G-9.

Table G-9: Per-Report Cost for Data Elements Similar to Those Included in a TSCA Section 8(a) Data Collection

Data Elements	Number of Data Elements	Per-Data Element Cost (2008$)	Per-Report Cost (2008$)
Exposure-related Data Elements	57	$0.0089	$0.51

Table G-10 shows the Agency cost of processing the processor data. EPA estimates the total Agency cost to process the manufacturer data are $213, and the total cost to the Agency of processing the processor data are $758. The total Agency data processing cost would be $970.

Table G-10:Agency Cost to Process Data as a Result of the TSCA Section 8(a) Data Collection

	Per-Report Cost to Process Exposure-Related Data Elements (2008$)	Number of Reports	Agency Cost (2008$)
Agency Cost to Process Manufacturer Data	$0.51	421	$213
Agency Cost to Process Processor Data	$0.51	1,500	$758
Total Agency Cost	**$0.51**	**1,921**	**$970**

Annual Agency Cost Estimates

Table G-11presents the estimated annual and annualized costs to the Agency of processing Form U and a section 8(a) data collection. The cost estimates for completion of Form U come from Table 4-53. Over a 25-year period, EPA estimates total cost to the Agency would be $65,800, with a three percent discount rate, and $60,300 with a seven percent discount rate.

Table G-11: Annual Increase in Agency Cost (2008$)

Reporting Cycle	Years	Baseline Cost (When all Amendments are Considered)	Manufacturer Section 8(a) Cost	Processor Section 8(a) Cost	Manufacturer and Processor Section 8(a) Cost	Total Cost to Industry (Manufacturer and Processor + Baseline)
		(2008$)	(2008$)	(2008$)	(2008$)	(2008$)
1	**2007 to 2011**	$286,580	$213	$758	$970	$287,550
2	**2012 to 2015**	$288,450	$1,065	$3,790	$4,855	$293,305
3	**2016 to 2019**	$288,450	$1,065	$3,790	$4,855	$293,305
4	**2020 to 2023**	$288,450	$1,065	$3,790	$4,855	$293,305
5	**2023 to 2027**	$288,450	$1,065	$3,790	$4,855	$293,305
6	**2026 to 2031**	$288,450	$1,065	$3,790	$4,855	$293,305
Total		**$1,728,831**	**$5,538**	**$19,708**	**$25,245**	**$1,754,076**

Annual Average	**$69,153**	**$222**	**$788**	**$1,010**	**$70,163**
Annualized at 3%	**$65,011**	**$168**	**$596**	**$763**	**$65,774**
Annualized at 7%	**$59,643**	**$151**	**$538**	**$688**	**$60,331**

G.6 Small Entity Analysis

The following section provides a preliminary assessment of the impact a section 8(a) rule may have on small entities by examining the relationship between the compliance costs and company sales for small companies. This analysis is based on the methodology found in Chapter 8 of this report.

Manufacturers

For manufacturers, EPA estimated 3.89 manufacturing sites per global parent company in Chapter 8; 41.3 percent of global parent companies (466 companies) are considered small under the SBA employment-based definition,[31] and 24.8 percent (280 companies) are considered small under the TSCA sales-based definition,[32] EPA also estimated an average of approximately 1.76 sites per small company under the employment-based definition of small business, and approximately 1.92 sites per small company under the sales-based definition. Average annual sales revenue of global parent companies considered small under either definition were estimated using data from Dun & Bradstreet, as also described in Chapter 8.

Table G-4 shows the cost to manufacturers as a result of a section 8(a) rule. These costs were summed and annualized over four years (the likely timeframe for the rule) at both a three percent and seven percent discount rate.[33] As shown in Table I-12, these costs were divided by the total number of sites elected to submit data, for the annualized costs per site. This was multiplied by the number of sites per small parent company to arrive at the annualized costs per small parent company. This value was divided by the annual sales per small parent company to derive the cost-to-sales ratio.

As shown in Table G-12, under the employment-based definition, a small parent company affected by the rule on average has sales of more than $412.7 million. The annualized costs of the proposed IUR rule amendments per small parent company, however, are $19,443 at a seven percent discount rate, and even lower under a three percent discount rate. The cost-to-sales ratio for an average small company under the employment-based SBA definition would be 0.005 percent or less. Under the more conservative sales-based TSCA definition, small parent company sales are on average more than $11.8 million, with annualized costs associated with the proposed amendments of $19,047 or lower. The cost-to-sales ratio for an average small company under the sales-based definition would be 0.16% or less.

[31] Threshold of 1,000 employees.

[32] Total annual sales of the company, combined with those of any parent company, are below $40 million and annual production volume or importation volume at the facility is less than or equal to 100,000 lb.; or total annual sales of the company, combined with those of any parent company, are below $4 million.

[33] A seven percent discount rate, reflecting the opportunity cost of capital, is consistent with OMB Circular A-4 (OMB, 2003). A three percent discount rate was also used as a sensitivity analysis to examine the robustness of the results to a change in the annualization assumptions.

Using the highest annual cost shown in Table G-12 of $19,443, a small company would have to have annual sales of less than $1.94 million in order to have a cost-to-sales ratio larger than one percent.

This approach is limited to the extent the universe of manufacturers identified under the economic analysis for the IUR rule would be similar to the manufacturers subject to a section 8(a) rule.

Table G-12: Derivation of Cost-to-Sales Ratios for Small Manufacturers for Collection of Exposure-Related Data Elements

	Employment-based Definition		Sales-based Definition	
	3% Discount Rate	7% Discount Rate	3% Discount Rate	7% Discount Rate
Cost of Section 8(a) Rule	$2,388,518.53			
Total Annualized Costs	$623,860	$659,026	$623,860	$659,026
Total Number of Sites	66			
Annualized Costs per site	$9,391	$9,920	$9,391	$9,920
Number of Sites per Small Parent Company	1.76		1.92	
Annualized Costs per Small Parent Company	$16,528	$19,443	$18,030	$19,047
Annual Sales per Small Parent Company	$412,713,310		$11,821,104	
Cost-to-sales Ratio	0.004%	0.005%	0.153%	0.161%
Number of Companies Potentially Affected	7		4	

Processors

To estimate the impact of the collection of exposure-related data elements on processors, EPA is limited by the availability of data. As described above, EPA estimated the number of processors that may be impacted by the requirement using TRI submission data. However, data provided under the TRI program does not include information about a submitter's parent company or annual revenues.

For this screening-level analysis, EPA assumes the chemical substance processor industry shares many characteristics with the chemical substance manufacturing industry subject to the IUR rule. To the extent this is not the case, this analysis may over- or underestimate the impact of additional data elements on processors. Specifically, EPA assumes 3.89 manufacturing sites per global parent company. EPA also assumes 41.3 percent of global parent companies are considered small under an employment-based definition, and 24.8 percent are considered small under a sales-based definition. EPA further assumes 1.76 sites per small parent company under the employment-based definition, and 1.92 sites per small parent company under the sales-based definition, consistent with manufacturer information. Given the large number of companies identified as processors according to TRI submissions, EPA was unable to examine Dun & Bradstreet data to estimate annual parent company revenue for this analysis, so manufacturer revenue was used as a proxy. Therefore, this analysis provides only a preliminary estimate of impacts.

EPA divided the number of expected processor reports (1,500) by the average number of chemical substances for which a processor submitted TRI data (2.45) to obtain the estimated number of processors (612). EPA divided this number by 3.89 (the number of sites per global parent company) for an estimated 157 global parent companies. This number was then multiplied by 41.3 percent and 24.8 percent to estimate the number of small global parent companies (the number of companies potentially affected), under the employment-based definition and sales-

based definition, respectively. To calculate cost-to-sales ratios, EPA followed the same methodology for processors as described above for manufacturers. Results are presented in Table G-13

Table G-13: Derivation of Cost-to-Sales Ratios for Small Processors for Collection of Exposure-Related Data Elements

	Employment-based Definition		Sales-based Definition	
	3% Discount Rate	7% Discount Rate	3% Discount Rate	7% Discount Rate
Cost of Section 8(a) Rule	$8,510,161			
Total Annualized Costs	$2,222,780	$2,348,074	$2,222,780	$2,348,074
Total Number of Sites	612			
Annualized Costs per Site	$3,631	$3,835	$3,631	$3,835
Number of Sites per Small Parent Company	1.76		1.92	
Annualized Costs per Small Parent Company	$6,390	$6,750	$6,971	$7,364
Annual Sales per Small Parent Company	$412,713,310		$11,821,000	
Cost-to-sales Ratio	0.0015%	0.0016%	0.059%	0.062%
Number of Companies Potentially Affected	65		39	

Table G-13, under the employment-based definition, a small parent company affected by the rule on average has sales of more than $412.7 million. The annualized costs of the proposed IUR rule amendments per small parent company, however, are $6,750 at a seven percent discount rate, and even lower under a three percent discount rate. The cost-to-sales ratio for an average small company under the employment-based definition would be 0.0016 percent or less. Under the more conservative sales-based definition, small parent company sales are on average more than $11.8 million, with annualized costs associated with the proposed amendments of $7,364 or lower. The cost-to-sales ratio for an average small company under the sales-based definition would be 0.062 percent or less.

As described in Chapter 8, the Regulatory Flexibility Act does not define the terms “significant” or “substantial” analytically with regard to extent of economic impact and number of small entities affected. However, EPA typically defines a threshold as compliance costs of one percent of sales to establish whether the level of economic impacts faced by the small entities can be presumed as not significant (U.S. EPA, 2006). Using the highest annual cost shown in Table G-13, $7,364, a small company would have to have annual sales of less than $736,400 in order to have a cost-to-sales ratio larger than one percent.