Appendices

The appendices referenced in EPA ICR No. 1139.12; OMB Control No. 3070-0033 are listed below and this document is available in the public docket established for this ICR under docket ID number **EPA-HQ-OPPT-2015-0436** at http://www.regulations.gov.

Appendix A: Specific Legacy Assumptions Converted to Standardized Assumptions

Table A-1 depicts a detailed table of tests that has been historically part of ICR renewal methodology. In this revision, the assumption is simplified to a generic set of ten tests, with total costs at $1.6 million (Bureau of Labor Statistics (BLS), 2014; EPA, 2013b; Piccirillo, 2004). Of the ten tests in Table A-1, three tests are of long duration and seven are of short duration

In this ICR revision, the assumption is simplified to a generic set of seven screening-level tests, including five physiochemical tests, one environmental fate and degradation test, and one aquatic toxicity test, with a total cost of $58,177. These tests are listed in Table A-2 and the costs were estimated using test costs developed for OPPT's New Chemical Program, and are meant to serve as seven generic tests that may be performed at any point during the three-year period. Future ICR renewals can take into account the actual duration of tests and build a new generic frequency distribution accordingly.

Table A-1 Legacy TSCA Section 4 "Standard" Testing Battery Laboratory Costs (2014$), Per Chemical

Test Protocol Name	Protocol Number	Date of Estimate	Mean Cost Estimate (2014$)[a]	Validation Costs (2014$)
Algal Acute Toxicity	797.105	8/3/1990	$12,132.58	$4,398.95
Daphnid Acute Toxicity	797.13	4/25/1996	$11,965.05	$4,398.95
Fish Acute Toxicity	797.14	4/25/1996	$18,285.73	$4,398.95
Gene Mutations in Somatic Cells	798.53	8/16/1994	$25,366.24	$4,398.95

Test Protocol Name	Protocol Number	Date of Estimate	Mean Cost Estimate (2014$)[a]	Validation Costs (2014$)
Subchronic Oral Toxicity	870.31	9/3/2005	$167,921.14	$4,398.95
Prenatal Developmental Tox. (2 species)[b]	870.37	1/1/2010	$152,450.48	$10,683.16
Reproduction/Fertility Effects[b]	870.38	1/1/2010	$422,689.97	$10,683.16
Salmonella Reverse Mutation Assay	870.5265	9/16/1996	$9,792.46	$4,398.95
In vivo Bone Marrow Cytogenetics	870.5395	2/27/2005	$24,968.83	$4,398.95
Developmental Neurotoxicity[b]	870.63	1/1/2010	$754,982.00	$10,683.16
Subtotal			$1,600,554.48	$62,842.13
Total			**$1,663,397**	

Footnotes:

[a] Where multiple versions of a test have been assessed by EPA (e.g., covering different species or routes of exposure), the mean cost estimate is used. All testing costs are updated to 2014 dollars.

[b] Designated as "long duration" studies.

Sources:

1. U.S. Bureau of Labor Statistics. July 2014, Employment Cost Index Historical Listing - Volume V. Series: All Private Workers Total Compensation (not seasonally adjusted).
2. U.S. EPA. 2013. Office of Pollution Prevention and Toxics, Economic and Policy Analysis Branch. Filename: Standard Nano Test Costs 9-01-2013.xls.
3. Piccirillo 2004. Vincent Piccirillo, personal communication. September 20, 2004.

Table A-2 Updated TSCA Section 4 "Standard" Testing Battery Laboratory Costs (2018$), Per Chemical

Test Type	Corresponding EPA Guideline or Test ID	Test Cost (2018$)
Physicochemical Screening Tests		
Melting Point	830.7200	$1,600
Boiling Point	830.7550	$1,012
Vapor Pressure	796.1220	$3,065
log Kow	796.1950	$8,500
Water Solubility	830.7840	$11,800
Environmental Fate and Pathways		
Ready Biodegradation	835.3110	$9,900
Aquatic Toxicity		
Acute Toxicity to Daphnia	850.1010	$22,300
Total		$58,177

Appendix B: Overlap Model

In previous ICRs, estimates assumed that new actions occurred chronologically without consideration of overlap as shown in Figure 1. As a method to model such effects, EPA considers a scenario in which activities are run in sequence, compared to a scenario in which activities running with overlap. In conjunction with the change to the input value of “number of actions initiated each year” instead of a lumped input variable that contains overlap as well, the overlap model is developed as a factor to apply to the new input value which is the ratio of the overlap burden to the sequential burden (see the top panel of Figure 1). The purpose of the overlap factor is to account for burden from actions proceeding asynchronously and in parallel. Additionally, burden from actions with activities from previous ICR periods (carry-over activities) are captured. This appendix provides the details of developing the standardized overlap factor to apply in ICR burden estimation. Future ICR renewals can take into account the actual overlap and revise the model accordingly.

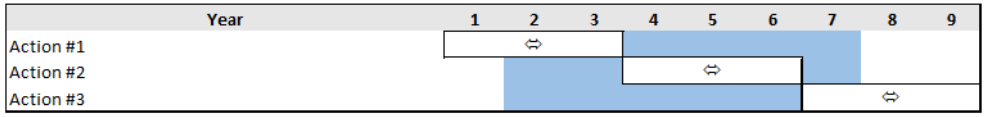
The overlap factor incorporated into this revised model is the ratio of burden that incorporates overlap considerations to the burden of that considers sequential implementation of the actions (see the bottom panel of Figure 1). The factor’s numerator and denominator are modeled considering that certain activities for the action fall in certain years over the time span of the action, depending on the assumptions. For example, for three rules occurring in sequence, there is one study plan in years one, three, and six. But for the model considering overlap, there is one study plan in years one, two, and three. An overlap factor greater than one accounts for the fact that the actions are proceeding asynchronously with activities for each contributing action overlapping, even though action initiations are staggered.

Previous ICR estimates model did not account for this overlap as a separate factor, and the model presented in Figure 1 provides a standardized method to be used with a simplified load variable for “number of actions initiated each year.” This generic model is based on assumptions of 1 rule with 1 chemical and 1 sponsor. After accounting for the burden associated with each type of activity under the nominal framework described in Section 5, the overlap factor (burden with overlap accounting divided by burden without overlap) is equal to 2.8.

For each chemical, the unit burden and cost estimates from the previous ICR remain the same under the revised model. These estimates are then adjusted by the overlap factor, as well as any other additional factors to consider such as the number of chemicals per action (see Table C-1 for assumptions) to estimate total burden and costs. In sum, the overlap model facilitates scaling up or down any of the unit-level burden and cost estimates based on changes to program inputs for “number of actions initiated per year.”

Figure 1. Overlap Factor Model to Account for Asynchronous, Parallel Activities under Separate Actions

No overlap factor – one concurrently running action, with three-year duration

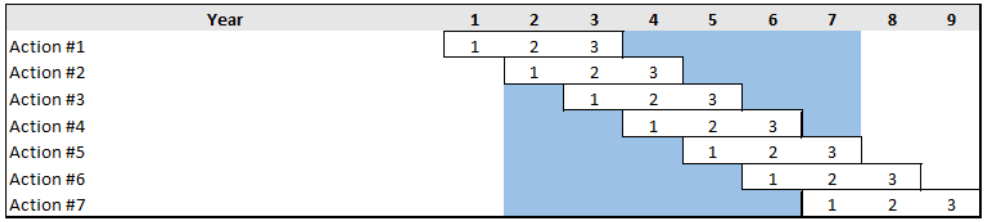


Number of Concurrently Running Actions

1	1	1	1	1	1	1			

Activity	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9	Total (Years 2-7)
Letter of Intent/Study Plans	1			1			1			2
Prepare Progress Report (for long duration studies)	2	2	1	2	2	1	2	2	1	10
Final Report - short duration studies	2	2	3	2	2	3	2	2	3	14
Final Report - long duration studies			3			3			3	6
Robust Summaries			1			1			1	2
TOTAL	5	4	8	5	4	8	5	4	8	34

Overlap factor – concurrently running actions, with a new one each year and each with a three-year duration



Number of Concurrently Running Actions

1	2	3	3	3	3	3			

Activity	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9	Total (Years 2-7)
Letter of Intent/Study Plans	1	1	1	1	1	1	1	0	0	6
Prepare Progress Report (for long duration studies)	2	4	5	5	5	5	5	3	1	29
Final Report - short duration studies	2	4	7	7	7	7	7	5	3	39
Final Report - long duration studies	0	0	3	3	3	3	3	3	3	15
Robust Summaries	0	0	1	1	1	1	1	1	1	7
TOTAL	5	9	17	17	17	17	17	12	8	96

Appendix C: Derivation of Program Input Information

The Fees for the Administration of the Toxic Substances Control Act rule (2018) basis for "number of expected actions under full implementation" for TSCA section 4 are derived using data from TSCA High Production Volume (HPV) TSCA section 4 actions (EPA, 2018b, 2018c). The metrics of ICR renewals are not as specific as the metrics of the Fees rule, as they reflect prospective generic assumptions to be used in ICR renewals every three years. Updating the standardized assumptions of the ICR revision based on experience, and mapping results to the conditions of the Fees rule produces the results in Table C-1. The structure of the assumptions in the ICR differ from those of the Fees rule, but on balance provide overstated burden estimates. The assumption that the testing is conducted over three years (instead of two years for rules and ECAs, or one year for test orders) understates the burden. However, other assumptions more than compensate, leaving the estimates overstated:

- One sponsor per chemical (instead of four)
- 10 tests per chemical (instead of seven)
- Overlap Factor of 2.8 (derived based on three years with each new action staggered by one year)

Table C-1: Translating Fees Rule information to ICR Bases

	Fees Rule				ICR			
Type of Action	Number of Actions Initiated Per Year (New Actions)	Associated Number of Chemicals[1]	Number of Sponsors per Chemical Tested	Notes on Overlap, Action Duration, and Tests Per Chemical	New Actions per Year	Associated Number of Chemicals	Duration; Overlap Factor[2]	Simplifying Assumptions (Standardized for all types of actions)
Test Rule	0.5	7	4	One new action every other year and 2 year durations per action; 7 tests per chemical	0.5	7	3 years 2.8 overlap factor	• 1 sponsor per chemical • 7 tests per chemical tested
Test Order	10	7	4	No overlap, as duration is one year or less; 7 tests per chemical	10	7	3 years 2.8 overlap factor	
Enforceable Consent Agreement	0.5	7	4	One new action every other year and 2-year durations per action; 7 tests per chemical	0.5	7	3 years 2.8 overlap factor	

Footnotes:

[1] The assumption of 7 chemicals per action is used in several calculations in the Fees Rule EA, including the section 4 industry opportunity costs

(Section 5.1.2) and the number of small businesses (Section 3.4.2.A). However, the justification for the program cost estimates states that each TSCA section 4 action covers one to five chemicals (Section 3.2.2).

[2] See Figure 1 for a visual rendering.

Appendix D: ICs for TSCA Section 4 Actions Under a Generic ICR

Note that this is a generic ICR, and as such, EPA is requesting generic clearance for the types of activities discussed in this ICR. EPA intends to submit to OMB for review and approval individual Information Collections (ICs) for specific collections of information. For more information about generic ICRs, see OMB's website on Federal Collection of Information: *https://www.whitehouse.gov/omb/information-regulatory-affairs/federal-collection-information/*

Section 4 generic ICR will be $90 million dollars. The $90 million dollars was estimated by assuming one batch of Test Orders each year of approximately $30 million dollars each. Representative historical data is not available to refine this estimate or indicate if $30 million per Test Order batch is high or low. At this time, EPA's best estimate is to assume that future Test Orders will be similar in burden.

The testing battery being requested with future Test Order ICs, impacts non-labor laboratory costs and not the labor burden on industry.

Appendix E: Additional Information on Methodology

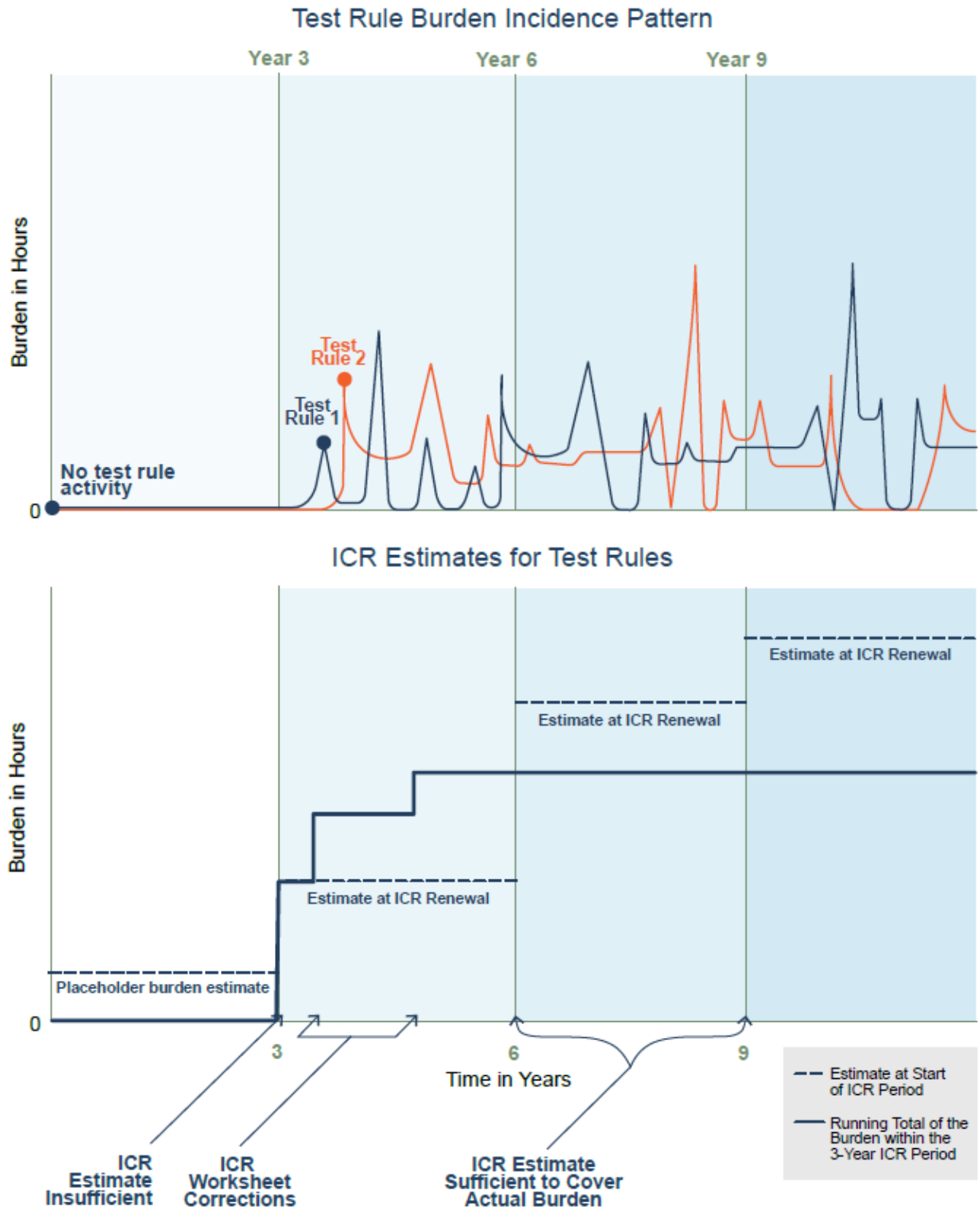
Note that it is particularly challenging to design the burden estimate calculations for TSCA section 4 ICR revisions. Any given action contains its own unique set of testing specifications. There may be one or more chemicals—or even a family of chemicals involved. The tests are specific to the chemical(s) and action, with highly varied counts of tests, test durations, and cost per test.

New issues addressed in this ICR revision are workflow effects and updates in ICR renewals to reflect regulatory conditions. EPA reviewed workflow during an ICR period and considered the nature of the workflow effects on burden for TSCA section 4 actions. Workflow effects include:

- The nature of burden incidence for respondents to TSCA section 4 actions is intermittent and irregular.
- Activities do not occur on a set calendar schedule, but rather on an incidental basis, depending on the details of the particular action.
- Once an action is initiated, a number of activities of differing frequencies follow.
- The timeline for a single action's related activities can stretch out over multiple years, as tests can be conducted over an extended period of time.

The overall magnitude of the burden for the ICR is determined by the sum effect of all actions' requirements with associated activities. However, for purposes of this methodology discussion, only one type of action is considered – test rules. Error: Reference source not found Figure 2 presents the nature of burden incidence in real time (top section) compared to levels of burden estimated in ICR renewals (bottom section). Note that at the times that a larger than anticipated burden is incurred, EPA program staff must prepare and submit a worksheet correction to OMB, as depicted for two incidents in Error: Reference source not found between Years 3 and 6. Although worksheet corrections are a standard procedure for updating the OMB inventory, to the extent that known effects for TSCA section 4 actions can be anticipated in the ICR revision, EPA believes such effects should be included in the ICR revision's burden and cost estimates.

Figure 2. Comparison of Actual Burden to ICR Estimates for One Type of TSCA Section 4 Action (Test Rules)



EPA also reviewed the issue of updating burden estimates to reflect anticipated regulatory conditions for the upcoming ICR renewal period. Historically, EPA has taken a "placeholder" approach in which a set of generic assumptions are used for calculations, with the understanding that actual conditions can appreciably differ. Periodically—typically during ICR Renewals—updates to counts for number of actions and number of chemicals tested per action (or simply "number of chemicals tested within a type of action") are applied to estimates to reflect the intensity of the regulatory conditions. For purposes of this methodology discussion, these updates are referred to as "load projections," which differ from methodology changes to standardized estimates and generic assumptions.[1]

In this stage of the methodology evolution, EPA makes changes to methodology to address the two of overlap estimation and load projections. EPA implements a new standardized estimate for overlap, the overlap model. The model constitutes a new standardized estimate designed to capture the activity patterns shown in Figure 1, as applicable to the requirements of TSCA section 4 actions. EPA is also revising the definition for load projection updates to the number of chemicals undergoing testing in new actions initiated annually. Further details are provided below.

As an overview of methodology components, the standardized estimates and generic assumptions of ICR estimates (defined to meet Objective 1—reflect the nature of the information collection) must be highly inclusive of the considerations in Figure 1, including the complexity of multiple activities of varying frequencies associated with activities per single chemical tested, as well as the complexity of multiple actions (of the same type) in effect asynchronously. To better address Objective 2—provide ease in future updates, the dynamics of carry-over and overlap on total burden are separated from load projection for the ICR period and handled in a standardized overlap model. The new definition for load projection as number of new rules initiated per year with an average of number of chemicals undergoing testing or more simply, chemicals newly tested in TSCA section 4 actions. This change in methodology replaces the complex load projection that requires EPA program staff to consider both factors (load projection and overlap) lumped together. The next section provides a comprehensive summary of methodology features by objective.

Objective 1—reflect the nature of the information collection—is met by extending work from previous ICR renewals to improve upon the standardized estimate. The key estimate is a standardized unit burden that is generic for test rules, test orders, and ECAs. The unit burden contains activities bundled according to a chemical undergoing testing in a TSCA section 4 action. The unit of analysis for this unit burden chemical tested is a TSCA section 4 action pertaining to the overall submission from a sponsor for the rule, order, or ECA. Prior to this ICR revision (EPA, 2016, 2018a), key features include:

- Define response unit as "per chemical tested within an action (e.g., test rules, test orders, ECAs)." Bundling activities to a basis of "per chemical" combines activities of

[1] For example, see this ICR revision's updates in Table 4.

irregular occurrence and differing frequencies to a single metric. This feature shifts the analytical focus away from individual activities and considers a sponsor's overall submission as a bundle of activities, providing a roll-up for the submission. The bundled approach has several advantages. In bundling activities, the irregular frequencies are appropriately weighted across the whole submission. Analysts do not have to repeatedly revisit calculations activity-by-activity. The method minimizes sources of error and document production costs.[2] Additionally, the resultant unit burden estimates are useful for communication purposes, as shown, for example in Table 2's total burden estimate.[3]

- Apply the standardized unit burdens per submission for use in multiple types of actions (rules, orders, ECAs).
- Simplify with the standardized unit burden with generic assumptions:
    - One sponsor per chemical, and
    - Battery of seven tests per chemical with an associated cost at $58,177 (see details in Appendix A)

As a new enhancement in this ICR revision, EPA employs a model for overlap to account for carry-over burden from previous ICR periods plus the additive effect of concurrent actions' burden effects on the total burden (see illustration in Error: Reference source not found). EPA is using a standardized estimate for overlap derived based on three years' duration per action with each new action staggered by one year, which leads to an overlap factor of 2.8 (see details in Appendix B). When the factor is applied, for example, the number of chemicals tested in a TSCA section 4 action is multiplied by 2.8 to account for the effect of staggered intermittent burden as portrayed in Figure 2Error: Reference source not found. Use of this new model adds to the list of key features above:

- Account for carry-over and overlap effects separately from new action initiations/load projections.

Objective 2—provide ease in future updates—is related to the new model for overlap described above. Historically, load projections for the ICR required the program staff to consider overlap dynamics as part of the specification set for "number of actions (i.e., rules) per year" and "number of chemicals per action."[4] The input is rather subjective, requiring a

[2] In the 2013 ICR renewal, EPA overestimated burden hours associated with test rules due to a misinterpretation about the frequencies for of activities. Instead of using different, variable numbers for the count of annual responses, EPA applied an erroneous high constant value frequency across all activities, resulting in overstatement by more than 500,000 hours (EPA, 2013a, 2018a). The standardized bundle is developed to address the root cause of this error, which involves confusion about the specific frequency that applies to a given activity (see Table and Table). Estimates are vulnerable to this type of error in methodologies that depart from the standardized bundle and organization of ICs by type of TSCA section 4 action.

[3] To the extent that all associated activities can be grouped in the same bundle, a more intuitive overall unit of analysis is provided with a slate of associated methodology improvements (see Nielsen & Day, 2018).

[4] For example, the previous ICR supporting statements read: "In this ICR TSCA section 4 test rule or order activity is partially due to anticipated activity from rules promulgated prior to this ICR period. Such test rules are still generating responses from sponsors because testing projects can have protracted timelines and/or can encounter delays. Additionally, potential new rules and/or orders promulgated in the next three years are considered as part

knowledge of specific rules in progress at the same time as considering potential future rules and probability of implementation. In this ICR revision, the input metric is simplified, for example, to “number of rules initiated each year” and “average number of chemicals per (new) rule” without need to consider carry-over and overlap which is handled via a standard overlap model.

Objective 3—enable minimal changes during the ICR period—is accomplished by making the estimate comprehensive and sufficiently inclusive of all known considerations for the three-year ICR renewal period. The continued implementation of key principles employed in previous ICR renewals, plus accounting for overlap specifically (as described for Objective 1), the use of concise metrics for updating load projections work in concert to assure that Objective 3 is met.

The revised methodology of this ICR revision reflects a continued shift to standardized estimates and generic assumptions in recognition that the estimates are being used to provide a placeholder function in the OMB burden inventory pending possible further revision based on data from TSCA section 4 actions. In future ICR renewals, when loads projections are updated, the standardized estimates and generic assumptions can be revised (i.e., calibrated) to better reflect the actual conditions and EPA experience (e.g. number of tests per chemical undergoing testing, test durations, and test costs). In this plan for continued methodology revisions with updates to standardized estimates and generic assumptions, EPA provides accurate burden estimates, but avoids conveying a false sense of precision in ICR estimates themselves.

Beyond methodology enhancements, this ICR revision contains analyses for purposes specific to changes anticipated in the upcoming ICR period:

- Analysis of the conditions used for the Fees for the Administration of the Toxic Substances Control Act rule (2018) and translation to load projections for this ICR (provided in Appendix C)
- Incorporation of new activities related to the Lautenberg Act requirements
  - Respondent substantiation of confidentiality claims
  - Agency reviews of confidentiality claims

For reference, the respondent burden estimates are organized in this section according to the following types of information collection activities:

- CDX Registration for e-Reporting
- Initial Response, Test Rules
- Study Plan, Test Rules
- Test Results, Test Rules
- Initial Response, Test Orders
- Study Plan, Test Orders

of this ICR’s scope. For purposes of estimates for this ICR period, EPA assumes that all effects amount to the equivalent activity of issuing two rules/orders annually with five chemicals per rule.”

- Test Results, Test Orders
- Voluntary Initial Contact, ECAs
- Study Plan, ECAs
- Test Results, ECAs
- Voluntary Robust Summaries for Test Rules, Test Orders
- Voluntary Data Submissions
- Testing Costs (Non-Labor Costs)

Appendix F: Specific Data Items Requested

EPA may require any type of health or environmental effects testing necessary to address unanswered questions about the effects of the chemical. Regarding testing pursuant to TSCA section 4(a)(1), EPA need not limit the scope of testing required to the factual basis for the TSCA section 4(a)(1)(A)(i) or 4(a)(1)(A)(ii) findings, as long as EPA finds that there is insufficient information and experience upon which the effects of the manufacture, distribution in commerce, processing, use, or disposal of such substance or mixture or of any combination of such activities on health or the environment can reasonably be determined or predicted, and that testing is necessary to develop the information. This approach is explained in more detail in EPA's statement of policy for making findings under TSCA section 4(a)(1)(B) in the Federal Register of May 14, 1993 (58 FR 28736, 28738-39; FRL-4059-9). Note that the TSCA sections that were previously enumerated as 4(a)(1)(A) and (B) are now enumerated as 4(a)(1)(A)(i) and 4(a)(1)(A)(ii), respectively.

In addition to submitting the specified information to EPA, respondents may also need to submit a letter of intent, study plans and progress reports, or an exemption application. Respondents must also maintain certain records related to the testing.

The specific requirements and procedures governing testing ECAs, test rules, and exemption from test rules are found in 40 CFR part 790. The requirements regarding Good Laboratory Practice standards (GLPs) are found in 40 CFR part 792, the various test guidelines that are incorporated into the individual test rules are in 40 CFR parts 795 through 799, and the chemical specific testing requirements are in 40 CFR part 799.

The following is an overview of the specific requirements for each type of activity:

Test Rules – EPA may promulgate a rule describing what type of testing must be performed on the chemical and specifying specific test guidelines that have been published by the EPA or alternative methods proposed by industry and approved by EPA as test methods. In combination with the GLPs requirements, these guidelines or methods provide the TSCA-mandated standards (TSCA section 4(d)) for development of adequate and reliable information. Records concerning information developed according to these standards must be retained for a minimum of ten years, as described in GLP standards. Information collections under TSCA section 4(c) are designed to reduce the burden of duplicative testing under test rules. As such, test rules generally require testing of only a single representative chemical and all chemicals subject to the test rule are assumed to be equivalent to it.

Test Orders – EPA may promulgate an order describing what type of testing must be performed on the chemical and specifying specific test guidelines that have been published by the EPA or alternative methods proposed by industry and approved by EPA as test methods. In combination with the GLPs requirements, these guidelines or methods provide the TSCA-mandated standards (TSCA section 4(d)) for development of adequate and reliable

information. Records concerning information developed according to these standards must be retained for a minimum of ten years, as described in GLP standards. Information collections under TSCA section 4(c) are designed to reduce the burden of duplicative testing. As such, test orders generally require testing of only a single representative chemical and all chemicals subject to the test order are assumed to be equivalent to it.

Enforceable Consent Agreements (ECAs)– EPA may negotiate an ECA under which manufacturers agree to conduct specific testing and submit the information to EPA. The ECA describes what type of testing is to be performed on the chemical and which test guidelines need to be followed to generate the information sought.

As with test rules, the test guidelines have either been published by EPA or another organization (e.g., OECD), or involve alternative methods proposed by industry and approved by EPA as test methods. In combination with the GLPs requirements, these guidelines or methods provide the TSCA-mandated standards (TSCA section 4(d)) for development of adequate and reliable information. Records concerning information developed according to these standards must be retained for a minimum of ten years, as described in GLP standards. Information collections under TSCA section 4(c) are designed to reduce the burden of duplicative testing. As such, test rules and ECAs generally require testing of only a single representative chemical and all chemicals subject to the ECA are assumed to be equivalent to it.

Testing Exemption Applications – TSCA section 4 allows an entity subject to a test rule or test order to apply for an exemption from the testing requirement if that testing will be, or has been, conducted by another party. Any manufacturer or processor subject to a test rule or order may submit an application to EPA for an exemption from performing any or all of the tests required under the test rule or order. The exemption application process and requirements for test rules are set out in 40 CFR Part 790, Subpart E. The exemption application, which generally must be filed within thirty days after the effective date of the test rule, must identify the test rule, the chemical, and the Chemical Abstract Service Registration Number (CASRN) of the test substance on which the application is based, and the specific testing requirement(s) from which an exemption is sought, along with the basis for the exemption request. An exemption application will generally be approved if a letter of intent to conduct the testing has been received from another party; if a study plan submitted by another party has been approved; or if the data needs identified in the test rule have been satisfied by another party. A procedure is provided for the appeal and hearing of the denial of an exemption application. Exemptions are also only relevant for testing requirements in test rules.

Voluntary Data Submissions – Unrelated to any test rule or other testing requirement or agreement, chemical manufacturers may voluntarily submit data to EPA at any time. Historically, voluntary data submissions have been provided as paper submissions. However, these submissions may be provided electronically through CDX, and it is anticipated that such submissions would be provided electronically in the future when applicable. Should submitters

decide to do so, EPA simply asks that submitters follow the same procedures for preparing their package and completing their submission as test rule respondents. Since such data submissions are entirely voluntary and based on decisions in which EPA is not a participant, EPA can only provide a general estimate of potential burden and costs associated with such submissions, guided generally by past such submissions, which have been rare. In doing so, EPA believes that the potential costs and burdens for such voluntary submissions are captured in this information collection request.

Appendix G: Respondent Burden and Cost Methodology

This section presents the relevant unit burdens of the information collection activities to respondents in terms of the time required by companies to perform the activities as outlined in the introductory section of this document. Unless otherwise stated, assumptions presented in section 5 use information from the previous ICR (EPA, 2018a). As an initial step to organize information according to the submission's response unit of per chemical, activities are bundled according to the chemical being tested. In this presentation EPA explains, from the respondents' point of view, all the activities associated with a TSCA section 4 submission (generically) for test rules, test orders, and ECAs. Thereafter, estimates are derived and presented according to those types of activities.

From the average respondent's perspective, any given TSCA section 4 action may require a variety of activities, depending on the specifics of the action with regard to the chemical to be tested, tests required, and timing of the tests. The collection of these activities per chemical constitutes the definition of a submission for purposes of analysis in this document. G-1 presents a generic version of the collection of activities per chemical tested. For the seven tests under each action, some activities occur in the initial year, and some are spread out throughout the three-year period. Table G-2 presents the annual burden and cost for a single chemical tested in a generic standardized TSCA section 4 action. Note that the result of Table G-2 is used in reporting average respondent burden. In the following sections, unit burdens by collection activity type are presented in Section 5(b), with associated universe information and total burdens presented in Section 5(c). For a comprehensive list of activity-level burdens with applicable labor categories used to construct G-1 and the tables in Section 5(b), see Error: Reference source not found.

Table G-1. TSCA Section 4 Actions – Activities per Chemical Undergoing Testing Over Three Years and Annually

Activity[2]	TSCA Section 4 Action				
	Total Counts Three Year Period	Year 1	Year 2	Year 3	Average Per Year[4]
Initial Response Letter of Intent OR Voluntary Request to Negotiate a Consent Agreement for ECAs	1	1			0.333
Interim Reports					
Study Plans	1	1			0.333
CBI Substantiation	1	1			0.333
Final Reports					
Studies	7	2	2	3	2.333
Laboratory Review	7	2	2	3	2.333
Recordkeeping	7	2	2	3	2.333
(Voluntary) Robust Summaries	1			1	0.333

General Note:
This information is presented as an overview and for use in Section 5. Note that the activities listed above include a mix of required and voluntary activities. Certain activities are not included in this table because they are not relevant to the core bundle of activities associated with a testing submission. Excluded activities are associated with: CDX, Exemption Applications, Voluntary Submissions, and Testing Costs (Non-Labor Costs).

Footnotes:
[1] Additional detail is provided in Error: Reference source not found, which lists detailed activities and applicable labor categories (i.e., managerial, technical, clerical).
[2] Note that a response is defined as the collection of related activities involving a battery of seven tests all of which pertain to a chemical undergoing testing.
[4] Averages per year are rounded as shown for use in calculations in subsequent burden tables.

Table G-2. Generic TSCA Section 4 Action Annual Comprehensive Unit Burden and Unit Cost (2018$) for Test Rules, Test Orders, and ECAs

	Frequency of Occurrence (Average Per Year)	Unit Burden per Chemical (hours)	Unit Cost per Chemical
Initial Response			
Letter of Intent	0.333	0.333	$25.41
OR			
Voluntary Request to Negotiate a Consent Agreement for ECAs			
Interim Reports			
Study Plans	0.333	12.987	$991.17
CBI Substantiation[1]	0.333	1.215	$94.22
Final Reports			
Studies, including Corporate Review	2.333	107.318	$8,243.28
Laboratory Review	2.333	13.998	$1,068.33
Voluntary Robust Summaries	0.033	0.400	$30.50
Total, Reporting		**136.251**	**$10,452.91**
Total, Recordkeeping (Final Reports)	**2.333**	**1.167**	$57.49
TOTAL, Test Rules, Test Orders, ECAs		**137.418**	**$10,493.15**
Notes:			

1. This information is presented as an overview and for use in Section 5. Note that the activities listed above include a mix of required and voluntary activities. Certain activities are not included in this table because they are not relevant to the core bundle of activities associated with testing. Excluded activities are associated with: CDX, Exemption Applications, Voluntary Submissions, and Testing Costs (Non-Labor Costs).
2. Error: Reference source not found lists detailed associated activities and applicable labor categories (i.e., managerial, technical, clerical); Error: Reference source not found provides wage rates. Costs listed in this table are all labor costs.
Footnotes:
[1] Drawn from the burden and cost report for the final TSCA Inventory Notification Requirements rule (EPA, 2017) with adjustments for number of applicable data elements and the list of substantiation questions.

Respondents incur burden and costs in activities associated with e-reporting. Activities that are needed to facilitate electronic submission include CDX registration and CDX electronic signature; the unit burden for each of these activities is 0.180 hours and 0.350 hours of technical burden, respectively, as shown in Table G-3.

Table G-3. CDX Registration Annual Unit Burden and Cost (2018$)

Activity	Unit Burden				Unit Cost		
	Managerial Burden (hours)	Technical Burden (hours)	Clerical Burden (hours)	Unit Burden (hours)	Labor Unit Cost [1]	Non-Labor Costs	Unit Cost
CDX Registration	0.000	0.180	0.000	0.180	$13.74	$0.00	$13.74
CDX Electronic Signature	0.000	0.350	0.000	0.350	$26.71	$0.00	$26.71
Total, Reporting	**0.000**	**0.530**	**0.000**	**0.530**	**$40.45**	**$0.00**	**$40.45**
Total, Recordkeeping	**0.000**	**0.000**	**0.000**	**0.000**	**$0.00**	**$0.00**	**$0.00**
Total, CDX Registration and e-Reporting and Recordkeeping	**0.000**	**0.530**	**0.000**	**0.530**	**$40.45**	**$0.00**	**$40.45**

Footnotes:
[1] Unit costs are estimated by multiplying the clerical, technical, and managerial burdens by the corresponding wage rates in Error: Reference source not found.

The letter of intent is an initial response made by respondents after EPA promulgates a test rule and it formally acknowledges that the respondent intends to sponsor required testing under the rule. An entity subject to a test rule may apply for an exemption from one or all of the testing requirements imposed in a test rule if that testing will be, or has been, performed by another entity subject to the rule.

It is difficult to predict how many exemption applications might be submitted to EPA in any one year. EPA changes this assumption to a per-chemical basis at three per chemical undergoing testing, or one annually.[5] The new assumption is incorporated for ease of future maintenance as the number of exemptions is expected to vary according to the number of chemicals tested in actions (see also Table G-1). EPA also assumes that each application would request exemption from all tests.

[5] For details of the assumption, see discussion in Section 5(c), and Error: Reference source not found 4.

Table G-4. Initial Response, Test Rules - Annual Per Chemical Unit Burden and Cost (2018$)

Activity	Unit Burden								
	Managerial Burden (hours)	Technical Burden (hours)	Clerical Burden (hours)	Unit Burden (hours)	Frequency of Occurrence (Average Per Year)	Adjusted Unit Burden (hours)	Labor Unit Cost [1]	Non-Labor Cost	Unit Cost
Letter of Intent	0.000	1.000	0.000	1.000	0.333	0.333	$25.41	$0.00	$25.41
Total, Reporting	**0.000**	**1.000**	**0.000**	1.000	**0.333**	**0.333**	**$25.41**	**$0.00**	**$25.41**
Total, Recordkeeping	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**	**$0.00**	**$0.00**	**$0.00**
Total, Letter of Intent, Test Rules	**0.000**	**1.000**	**0.000**	**1.000**	**0.333**	**0.333**	**$25.41**	**$0.00**	**$25.41**
OR									
Prepare Exemption Application	0.000	2.000	0.000	2.000	1.000	2.000	$152.64	$0.00	$152.64
Corporate Review	6.000	0.000	0.000	6.000	1.000	6.000	$480.54	$0.00	$480.54
Total, Reporting	**6.000**	**2.000**	**0.000**	**8.000**	**1.000**	**8.000**	**$633.18**	**$0.00**	**$633.18**
Total, Recordkeeping	**0.000**	**0.000**	**0.500**	**0.000**	**1.000**	**0.500**	**$17.25**	**$0.00**	**$17.25**
Total, Exemption Application, Test Rules	**6.000**	**2.000**	**0.500**	**8.500**	**1.000**	**8.500**	**$650.43**	**$0.00**	**$650.43**

Footnotes:
[1] Unit costs are estimated by multiplying the clerical, technical, and managerial burdens by the corresponding wage rates in Error: Reference source not found.

After the initial response has occurred, test sponsor respondents must provide a study plan to EPA. The study plan includes documents detailing the different types of tests, protocols to be followed, health effects, and endpoints to be covered in each chemical report. One study plan for each chemical is required at the beginning of the testing period.

CBI substantiation to support confidentiality claims for relevant data elements for the overall submission throughout the testing period (see list of transactions in Table G-1) must be provided in conjunction with the study plan transmittal. The CBI substantiations address chemical identity (chemID) and other data elements.

Table G-5. Study Plan, Test Rules – Annual Per Chemical Unit Burden and Cost (2018$)

Activity	Unit Burden								
	Managerial Burden (hours)	Technical Burden (hours)	Clerical Burden (hours)	Unit Burden (hours)	Frequency of Occurrence (Average Per Year)	Adjusted Unit Burden (hours)	Labor Unit Cost[1]	Non-Labor Cost	Unit Cost
Study Plan	0.000	39.000	0.000	39.000	0.333	12.987	$991.17	$0.00	$991.17
CBI Substantiation[2]	1.184	2.465	0.000	3.649	0.333	1.215	$94.22	$0.00	$94.22
Total, Reporting	**1.184**	**41.465**	**0.000**	**42.649**	**0.333**	**14.202**	**$1,085.39**	**$0.00**	**$1,085.39**
Total, Recordkeeping	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**	**$0.00**	**$0.00**	**$0.00**
Total, Study Plan, Test Rules	**1.184**	**41.465**	**0.000**	**42.649**	**0.333**	**14.202**	**$1,085.39**	**$0.00**	**$1,085.39**

Footnotes:
[1] Unit costs are estimated by multiplying the clerical, technical, and managerial burdens by the corresponding wage rates in Error: Reference source not found.
[2] Drawn from the burden and cost report for the final TSCA Inventory Notification Requirements rule (EPA, 2017a) with adjustments for number of applicable data elements and the list of substantiation questions. For CBI substantiation questions see *What to Include in CBI Substantiations - Sample substantiation templates* (EPA, 2017b).

At the conclusion of each test, respondents are required to provide a final report, which must also undergo both corporate and laboratory review. Recordkeeping is also required for all final report transmittals.

Table G-6. Test Results, Test Rules – Annual Per Chemical Unit Burden and Cost (2018$)

Activity	Unit Burden								
	Managerial Burden (hours)	Technical Burden (hours)	Clerical Burden (hours)	Unit Burden (hours)	Frequency of Occurrence (Average Per Year)	Adjusted Unit Burden (hours)	Labor Unit Cost[1]	Non-Labor Cost	Unit Cost
Study Final Report	0.000	40.000	0.000	40.000	2.333	93.320	$7,122.18	$0.00	$7,122.18
Study Corporate Review	6.000	0.000	0.000	6.000	2.333	13.998	$1,121.10	$0.00	$1,121.10
Laboratory Review	0.000	6.000	0.000	6.000	2.333	19.998	$1,068.33	$0.00	$1,068.33
Total, Reporting	**6.000**	**46.000**	**0.000**	**52.000**		**121.316**	**$9,311.61**	**$0.00**	**$9,311.61**
Total, Recordkeeping	**0.000**	**0.000**	**0.500**	**0.500**	**2.333**	**1.167**	**$40.24**	**$0.00**	**$40.24**
Total, Test Results, Test Rules	**6.000**	**46.000**	**0.500**	**52.500**		**122.483**	**$9,351.85**	**$0.00**	**$9,351.85**

Footnotes:
[1] Unit costs are estimated by multiplying the clerical, technical, and managerial burdens by the corresponding wage rates in Error: Reference source not found.

As with test rules, the letter of intent is an initial response made by respondents in response to test orders and it formally acknowledges that the respondent intends to sponsor required testing under the order. An entity subject to a test order may apply for an exemption from one

or all of the testing requirements imposed in a test order if that testing will be, or has been, performed by another entity subject to the order.

In either case, it is difficult to predict how many exemption applications might be submitted to EPA in any one year. EPA changes this assumption to a per-chemical basis at three per chemical undergoing testing, or one annually.[6] The new assumption is incorporated in order to ease the consolidation of activities involved with an initial response (see Table 4). EPA also assumes that each application would request the exemption from all of the testing.

Table G-7. Initial Response, Test Orders - Annual Per Chemical Unit Burden and Cost (2018$)

Activity	Unit Burden								
	Managerial Burden (hours)	Technical Burden (hours)	Clerical Burden (hours)	Unit Burden (hours)	Frequency of Occurrence (Average Per Year)	Adjusted Unit Burden (hours)	Labor Unit Cost[1]	Non-Labor Cost	Unit Cost
Letter of Intent	0.000	1.000	0.000	1.000	0.333	0.333	$25.41	$0.00	$25.41
Total, Reporting	**0.000**	**1.000**	**0.000**	**1.000**	**0.333**	**0.333**	**$25.41**	**$0.00**	**$25.41**
Total, Recordkeeping	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**	**$0.00**	**$0.00**	**$0.00**
Total, Letter of Intent, Test Orders	**0.000**	**1.000**	**0.000**	**1.000**	**0.333**	**0.333**	**$25.41**	**$0.00**	**$25.41**
OR									
Prepare Exemption Application	0.000	2.000	0.000	2.000	1.000	2.000	$152.64	$0.00	$152.64
Corporate Review	6.000	0.000	0.000	6.000	1.000	6.000	$480.54	$0.00	$480.54
Total, Reporting	**6.000**	**2.000**	**0.000**	**8.000**	**1.000**	**8.000**	**$633.18**	**$0.00**	**$633.18**
Total, Recordkeeping	**0.000**	**0.000**	**0.500**	**0.500**	**1.000**	**0.500**	**$17.25**	**$0.00**	**$17.25**
Total, Exemption Application, Test Orders	**6.000**	**2.000**	**0.500**	**8.500**	**1.000**	**8.500**	**$650.43**	**$0.00**	**$650.43**

Footnotes:
[1] Unit costs are estimated by multiplying the clerical, technical, and managerial burdens by the corresponding wage rates in Error: Reference source not found.

After the initial response has occurred, respondents must provide a study plan to EPA. The study plan includes documents detailing the different types of tests, health effects, and endpoints covered in each chemical report. One study plan for each chemical is required at the beginning of the testing period.

CBI substantiation to support confidentiality claims for relevant data elements throughout the testing period (see list of transactions in G-1) must be provided in conjunction with the study plan transmittal. The CBI substantiations address chemID and other data elements.

[6] For details of the assumption, see discussion in Section 5(c), and Table 4.

Table G-8. Study Plan, Test Orders – Annual Per Chemical Unit Burden and Cost (2018$)

Activity	Unit Burden								
	Managerial Burden (hours)	Technical Burden (hours)	Clerical Burden (hours)	Unit Burden (hours)	Frequency of Occurrence (Average Per Year)	Adjusted Unit Burden (hours)	Labor Unit Cost [1]	Non-Labor Cost	Unit Cost
Study Plan	0.000	39.000	0.000	39.000	0.333	12.987	$991.17	$0.00	$991.17
CBI Substantiation[2]	1.184	2.465	0.000	3.649	0.333	1.215	$94.22	$0.00	$94.22
Total, Reporting	**1.184**	**41.465**	**0.000**	**42.649**	**0.333**	**14.202**	**$1,085.39**	**$0.00**	**$1,085.39**
Total, Recordkeeping	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**	**$0.00**	**$0.00**	**$0.00**
Total, Study Plan, Test Orders	**1.184**	**41.465**	**0.000**	**42.649**	**0.333**	**14.202**	**$1,085.39**	**$0.00**	**$1,085.39**

Footnotes:
[1] Unit costs are estimated by multiplying the clerical, technical, and managerial burdens by the corresponding wage rates in Error: Reference source not found.
[2] Drawn from the burden and cost report for the final TSCA Inventory Notification Requirements rule (EPA, 2017a) with adjustments for number of applicable data elements and the list of substantiation questions. For CBI substantiation questions see *What to Include in CBI Substantiations - Sample substantiation templates* (EPA, 2017b).

As with test rules, at the conclusion of each test, respondents are required to provide a final report, which must also undergo both corporate and laboratory review. Recordkeeping is also required for all final report transmittals.

Table G-9. Test Results, Test Orders – Annual Per Chemical Unit Burden and Cost (2018$)

Activity	Unit Burden								
	Managerial Burden (hours)	Technical Burden (hours)	Clerical Burden (hours)	Unit Burden (hours)	Frequency of Occurrence (Average Per Year)	Adjusted Unit Burden (hours)	Labor Unit Cost[1]	Non-Labor Cost	Unit Cost
Study Final Report	0.000	40.000	0.000	40.000	2.333	93.320	$7,122.18	$0.00	$7,122.18
Study Corporate Review	6.000	0.000	0.000	6.000	2.333	13.998	$1,121.10	$0.00	$1,121.10
Laboratory Review	0.000	6.000	0.000	6.000	2.333	13.998	$1,068.33	$0.00	$1,068.33
Total, Reporting	**6.000**	**46.000**	**0.000**	**52.000**		**121.316**	**$9,311.61**	**$0.00**	**$9,311.61**
Total, Recordkeeping	**0.000**	**0.000**	**0.500**	**0.500**	**2.333**	**1.167**	**$40.24**	**$0.00**	**$40.24**
Total, Test Results, Test Orders	**6.000**	**46.000**	**0.500**	**52.500**		**122.483**	**$9,351.85**	**$0.00**	**$9,311.61**

Footnotes:
[1] Unit costs are estimated by multiplying the clerical, technical, and managerial burdens by the corresponding wage rates in Error: Reference source not found.

The request to negotiate a consent agreement is an initial contact made by respondents interested in participating in negotiations for an Enforceable Consent Agreement. The request consists of a letter notifying EPA of the party's intent to participate.[7]

Table G-10. Voluntary Initial Contact, ECAs – Annual Per Chemical Unit Burden and Cost (2018$)

Activity	Unit Burden								
	Managerial Burden (hours)	Technical Burden (hours)	Clerical Burden (hours)	Unit Burden (hours)	Frequency of Occurrence (Average Per Year)	Adjusted Unit Burden (hours)	Labor Unit Cost[1]	Non-Labor Cost	Unit Cost
Request to Negotiate	0.000	1.000	0.000	1.000	0.333	0.333	$25.41	$0.00	$25.41
Total, Reporting	**0.000**	**1.000**	**0.000**	**1.000**	**0.333**	**0.333**	**$25.41**	**$0.00**	**$25.41**
Total, Recordkeeping	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**	**$0.00**	**$0.00**	**$0.00**
Total, Voluntary Initial Contact, ECAs	**0.000**	**1.000**	**0.000**	**1.000**	**0.333**	**0.333**	**$25.41**	**$0.00**	**$25.41**

Footnotes:
[1] Unit costs are estimated by multiplying the clerical, technical, and managerial burdens by the corresponding wage rates in Error: Reference source not found.

After the voluntary initial contact has occurred, respondents must then provide a study plan to EPA. The study plan includes documents detailing the different types of tests, health effects, and endpoints covered in each chemical report. One study plan for each chemical is required at the beginning of the testing period.

CBI substantiation to support confidentiality claims for relevant data elements throughout the testing period (see list of transactions in Table G-1) must be provided in conjunction with the study plan transmittal. The CBI substantiations, address chemID and other data elements.

Table G-11. Study Plan, ECAs – Annual Per Chemical Unit Burden and Cost (2018$)

Activity	Unit Burden								
	Managerial Burden (hours)	Technical Burden (hours)	Clerical Burden (hours)	Unit Burden (hours)	Frequency of Occurrence (Average Per Year)	Adjusted Unit Burden (hours)	Labor Unit Cost[1]	Non-Labor Cost	Unit Cost
Study Plan	0.000	39.000	0.000	39.000	0.333	12.987	$991.17	$0.00	$991.17
CBI Substantiation[2]	1.184	2.465	0.000	3.649	0.333	1.215	$94.22	$0.00	$94.22
Total, Reporting	**1.184**	**41.465**	**0.000**	**42.649**	**0.333**	**14.202**	**$1,085.39**	**$0.00**	**$1,085.39**
Total, Recordkeeping	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**	**$0.00**	**$0.00**	**$0.00**
Total, Study Plan, ECA	**1.184**	**41.465**	**0.000**	**42.649**	**0.333**	**14.202**	**$1,085.39**	**$0.00**	**$1,085.39**

Footnotes:
[1] Unit costs are estimated by multiplying the clerical, technical, and managerial burdens by the corresponding wage rates in Error: Reference source

[7] As a point of reference, respondents conduct this transaction after EPA has determined that developing information on a chemical substance or mixture through a consent agreement is appropriate and invites interested parties to participate in negotiations by publishing a notice in the Federal Register.

not found.
[2] Drawn from the burden and cost report for the final TSCA Inventory Notification Requirements rule (EPA, 2017a) with adjustments for number of applicable data elements and the list of substantiation questions. For CBI substantiation questions see *What to Include in CBI Substantiations - Sample substantiation templates* (EPA, 2017b).

As with test rules and test orders, at the conclusion of each test, ECA respondents are required to provide a final report, which must also undergo both corporate and laboratory review. Recordkeeping is also required for all final report transmittals.

Table G-12. Test Results, ECAs – Annual Per Chemical Unit Burden and Cost (2018$)

Activity	Unit Burden								
	Managerial Burden (hours)	Technical Burden (hours)	Clerical Burden (hours)	Unit Burden (hours)	Frequency of Occurrence (Average Per Year)	Adjusted Unit Burden (hours)	Labor Unit Cost[1]	Non-Labor Cost	Unit Cost
Study Final Report	0.000	40.000	0.000	40.000	2.333	93.320	$7,122.18	$0.00	$7,122.18
Study Corporate Review	6.000	0.000	0.000	6.000	2.333	13.998	$1,121.10	$0.00	$1,121.10
Laboratory Review	0.000	6.000	0.000	6.000	2.333	13.998	$1,068.33	$0.00	$1,068.33
Total, Reporting	**6.000**	**46.000**	**0.000**	**52.000**		**121.316**	**$9,311.61**	**$0.00**	**$9,311.61**
Total, Recordkeeping	**0.000**	**0.000**	**0.500**	**0.500**	**2.333**	**1.167**	**$40.24**	**$0.00**	**$40.24**
Total, Test Results, Test Orders	**6.000**	**46.000**	**0.500**	**52.500**		**122.483**	**$9,351.85**	**$0.00**	**$9,351.85**

Footnotes:
[1] Unit costs are estimated by multiplying the clerical, technical, and managerial burdens by the corresponding wage rates in Error: Reference source not found.

EPA estimates that ten percent of the studies completed for TSCA Section 4 testing actions will be accompanied by a robust summary, yielding one robust summary per chemical each year.[8]

Table G-13. Voluntary Robust Summaries for Test Rules, Test Orders, and ECAs – Annual Per Chemical Unit Burden and Cost (2018$)

Activity	Unit Burden								
	Managerial Burden (hours)	Technical Burden (hours)	Clerical Burden (hours)	Total Unit Burden (hours)	Frequency of Occurrence (Average Per Year)	Adjusted Unit Burden (hours)	Total Labor Unit Cost [1]	Total Non-Labor Cost	Total Unit Cost
Robust Summary	0.000	12.000	0.000	12.000	0.033	0.400	$30.50	$0.00	$30.50
Total, Reporting	**0.000**	**12.000**	**0.000**	**12.000**	**0.033**	**0.400**	**$30.50**	**$0.00**	**$30.50**
Total, Recordkeeping	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**	**$0.00**	**$0.00**	**$0.00**

[8] Historically, robust summaries have been developed in order to standardize how the technical information is presented and summarized. Robust summaries have been adopted voluntarily and used by data submitters outside EPA programs.

Total, Robust Summaries (Voluntary)	**0.000**	**12.000**	**0.000**	**12.000**	**0.033**	**0.400**	**$30.50**	**$0.00**	**$30.50**
Footnotes: [1] Unit costs are estimated by multiplying the clerical, technical, and managerial burdens by the corresponding wage rates in Error: Reference source not found.									

EPA conservatively assumes that a voluntary submission consists of a final report for one chemical, as shown in Table G-14. The description of this assumption is slightly revised from previous ICRs for simplification purposes.[9]

Table G-14. Voluntary Data Submissions – Annual Per Chemical Unit Burden and Cost (2018$)

Activity	Unit Burden								
	Managerial Burden (hours)	Technical Burden (hours)	Clerical Burden (hours)	Unit Burden (hours)	Frequency of Occurrence (Average Per Year)	Adjusted Unit Burden (hours)	Labor Unit Cost[1]	Non-Labor Costs	Unit Cost
Paper Submission of Final Reports	0.000	0.000	10.000	10.000	1.000	10.000	$345.00	$14.62	$359.62
Total, Reporting	**0.000**	**0.000**	**10.000**	**10.000**	**1.000**	**10.000**	**$345.00**	**$14.62**	**$359.62**
Total, Recordkeeping	**0.000**	**0.000**	**1.000**	**1.000**	**1.000**	**1.000**	**$34.50**	**$0.00**	**$34.50**
Total, Voluntary Data Submissions	**0.000**	**0.000**	**11.000**	**11.000**	**1.000**	**11.000**	**$379.50**	**$14.62**	**$394.12**
Footnotes: [1] Unit costs are estimated by multiplying the clerical, technical, and managerial burdens by the corresponding wage rates in Error: Reference source not found.									

Testing costs include laboratory costs and administrative costs. For purposes of this ICR, as in past ICRs, EPA assumes that the tests specified in a standard testing battery of seven tests are all likely to be performed on each chemical, although the specific tests actually performed could differ depending on specific circumstances and testing needs. Estimates include non-labor costs for analytical chemistry method development and validation where it was judged that such method development would be necessary to conform to good laboratory practices. Tests are assigned costs based on typical costs cited by industry experts and compiled by EPA. The overall laboratory costs of the "standard" testing battery (per chemical) is estimated at $58,177, (see Appendix A for further detail).

In addition to laboratory costs, there are also costs for consortium management and costs for technical experts. Consortium management costs, which includes activities such as identifying manufacturers, meetings, organizing payment for testing, developing contracts for testing, and

[9] Robust summaries are removed from the description because the voluntary data submission in a non-standard submission with contents largely unknown. Inclusion of an assumption about robust summary produces unnecessary complications in Agency burden estimates.

employing toxicologists who may be hired to provide technical expertise, are estimated at 15 percent of total laboratory costs. Costs for technical experts working for the consortium by providing study review and site visits to the laboratory are estimated at 10 percent of total laboratory costs.

Table G-15. Testing Costs (Non-Labor Costs) – Annual Per Chemical Unit Burden and Cost (2018$)

Activity	Unit Burden								
	Managerial Burden (hours)	Technical Burden (hours)	Clerical Burden (hours)	Total Unit Burden (hours)	Frequency of Occurrence (Average Per Year)	Adjusted Unit Burden (hours)	Total Labor Unit Cost [1]	Total Non-Labor Cost	Total Unit Cost
Laboratory Costs	0.000	0.000	0.000	0.000	0.333	0.000	$0.00	$19,392.33	$19,392.33
Consortium Management	0.000	0.000	0.000	0.000	0.333	0.000	$0.00	$2,908.85	$2,908.85
Technical Experts	0.000	0.000	0.000	0.000	0.333	0.000	$0.00	$1,939.23	$1,939.23
Total, Testing Costs (Non-Labor Costs)	**0.000**	**0.000**	**0.000**	**0.000**	**0.333**	**0.000**	**$0.00**	**$24,240.41**	**$24,240.41**

Footnote:
[1] Unit costs are estimated by multiplying the clerical, technical, and managerial burdens by the corresponding wage rates in Error: Reference source not found.

Table G-16. Activity-Level Unit Burdens and Costs (2018$) by Activity and Type of Action

Activity	Unit of Analysis	Managerial Burden (hours)	Technical Burden (hours)	Clerical Burden (hours)	Activity-Level Unit Burden (hours)	Average Wage Rate	Labor Costs	Per-Activity Non-Labor Costs	Total per-Activity Cost
		a	b	c	d = a + b + c	e	f = d x e	g	h = f + g
CDX									
CDX Registration	Registration	0.000	0.180	0.000	0.180	$76.33	$13.74	$0.00	$13.74
CDX Electronic Signature	Registration	0.000	0.350	0.000	0.350	$76.31	$26.71	$0.00	$26.71
Initial Response (Test Rules, Test Orders, ECAs)									
Letter of Intent	Chemical	0.000	1.000	0.000	1.000	$76.32	$76.32	$0.00	$76.32
Request to Negotiate	Chemical	0.000	1.000	0.000	1.000	$76.32	$76.32	$0.00	$76.32
Alternate Initial Response (Test Rules, Test Orders)									
Prepare Exemption Application	Application	0.000	2.000	0.000	2.000	$76.32	$152.64	$0.00	$152.64
Corporate Review	Review	6.000	0.000	0.000	6.000	$80.09	$480.54	$0.00	$480.54
Recordkeeping	Record	0.000	0.000	0.500	0.500	$34.50	$17.25	$0.00	$17.25
Standardized Core Activities (Test Rules, Test Orders, ECAs)									
Study Plan (ten tests)[1]	Chemical	0.000	39.000	0.000	39.000	$76.32	$2,976.48	$0.00	$2,976.48

CBI Substantiation[2]	Substantiation	1.184	2.465	0.000	3.649	$77.54	$282.96	$0.00	$282.96
Biannual Progress Report (Long Duration Studies)	Report	0.000	8.000	0.000	8.000	$76.32	$610.56	$0.00	$610.56
Final Report (Short Duration Studies)	Report	0.000	40.000	0.000	40.000	$76.32	$3,052.80	$0.00	$3,052.80
Final Report (Long Duration Studies)	Report	0.000	80.000	0.000	80.000	$76.32	$6,105.60	$0.00	$6,105.60
Corporate Review (Short Duration Studies)	Review	6.000	0.000	0.000	6.000	$80.09	$480.54	$0.00	$480.54
Corporate Review (Long Duration Studies)	Review	9.000	0.000	0.000	9.000	$80.09	$720.81	$0.00	$720.81
Laboratory Review	Review	0.000	6.000	0.000	6.000	$76.32	$457.92	$0.00	$457.92
Recordkeeping	Record	0.000	0.000	0.500	0.500	$34.50	$17.25	$0.00	$17.25
Voluntary Robust Summaries (Test Rules, Test Orders, ECAs, Voluntary Data Submissions)									
Robust Summary	Chemical	0.000	12.000	0.000	12.000	$76.32	$915.84	$0.00	$915.84
Voluntary Data Submission[3]									
Paper Submission of Final Reports	Chemical	0.000	0.000	10.000	10.000	$34.50	$345.00	$14.62	$359.62
Recordkeeping	Record	0.000	0.000	1.000	1.000	$34.50	$34.50	$0.00	$34.50
Testing Costs (ten tests) [4]									
Laboratory Costs	Chemical	0.000	0.000	0.000	0.000	-	$0.00	$1,663,397.00	$1,663,397.00
Consortium Management	Chemical	0.000	0.000	0.000	0.000	-	$0.00	$249,509.55	$249,509.55
Technical Experts	Chemical	0.000	0.000	0.000	0.000	-	$0.00	$166,339.70	$166,339.70

Footnotes:

[1] For test rules or orders and testing agreements, the estimates of this ICR Revision are developed for a battery of ten tests per chemical (see Table A-1 for list of tests; see Table 4 for activity frequencies per chemical). For labor costs, with the exception of the activity "Study Plans," the activity-level burdens of this table are unaffected by the number of tests. However, for the activity, "Study Plans" involving different test counts, the activity-level (and chemical-level) unit burden estimate for "Study Plans" is obtained by multiplying the number of tests by 3.9 hours per test-per chemical to obtain hours per chemical.

[2] Drawn from the burden and cost report for the final TSCA Inventory Notification Requirements rule (EPA, 2017a) with adjustments for number of applicable data elements and the list of substantiation questions

[3] Voluntary Submissions are the only type of TSCA Section 4 submission that are not required to be submitted electronically. Paper and postage costs for final reports and robust summaries are estimated under "Per-Activity Supply Cost." These costs assumed that a voluntary submission contains: ten final reports averaging 35 pages, plus a cover letter and robust summary, totaling 352 pages. Paper costs at $0.0112 per page total $3.94 (Staples, 2019). Postage via 2-day FedEx Ground for the 0.4 lb package totals $10.68 (FedEx, 2019).

[4] For test rules or orders and testing agreements, the estimates of this ICR Revision are developed for a battery of ten tests per chemical (see Table A-1 for list of tests). For testing costs, the activity-level (and chemical-level) unit burden is obtained based on the laboratory costs. Consortium management is estimated as 15 percent of laboratory costs, and technical experts is estimated as 10 percent of laboratory costs.

Table G-17. Industry Wage Rates (2018$)

Labor Category	Data Series[a]	Date	Wage	Fringe Benefit	Fringes as % Wage	Overhead % wage [b]	Fringe + Overhead Factor [c]	Hourly Loaded Wages [d]
			(a)	*(b)*	*(c) =(b)/(a)*	*(d)*	*(e)= (c)+(d)+1*	*(f)=(a)×(e)*
Managerial	BLS ECEC, Private Manufacturing industries, "Mgt, Business, and Financial"	Dec-18	$48.73	$23.08	47%	17%	1.64	$80.09
Professional / Technical	BLS ECEC, Private Manufacturing industries, "Professional	Dec-18	$44.35	$24.43	55%	17%	1.72	$76.32

	and related“							
Clerical	BLS ECEC, Private Manufacturing industries, “Office and Administrative Support”	Dec-18	$20.77	$10.20	49%	17%	1.66	$34.50

Footnotes:

[a] Source: *Employer Costs for Employee Compensation Historical Supplementary Tables: December 2006 – March 2019*. All rates are rounded to the nearest cent.

[b] An overhead rate of 17 percent is used based on assumptions in *Wage Rates for Economic Analysis of the Toxics Release Inventory Program* (Rice, 2002), and the *Revised Economic Analysis for the Amended Inventory Update Rule: Final Report* (EPA, 2002).

[c] The inflation factor of “1” in the formula for calculating the fringe + overhead factor means wage data are not escalated to reflect inflation.

[d] Wage data are rounded to the closest cent in this analysis.