**Planned Test Orders FY22-1 (IC No.1139.38)**

**Issuance Under EPA ICR No. 1139.12; OMB Control No. 2070-0033**

The following information is being provided in accordance with the terms of clearance for the information collection request (ICR) approved under the Office of Management and Budget (OMB) Control Number 2070-0033, which requires the Environmental Protection Agency (EPA) to provide OMB with prior notice and opportunity to review the Test Orders to be issued under the Toxic Substance Control Act (TSCA) Section 4 before EPA may issue the Test Orders under this ICR. Additional information about the collection activities, authority and specific requirements under TSCA and EPA implementing regulations, estimates and related methodologies, is provided in the ICR Supporting Statement that was approved in December 2020.

***A. What TSCA Priority Chemicals will be subject to the planned Test Order?***

EPA's Office of Pollution Prevention and Toxics (OPPT) is requesting clearance to issue a Test Order to manufacturers and processors of 1,2-Dichloropropane CAS 78-87-5; Docket Identification (ID) Number: EPA-HQ-OPPT-2018-0428).

***B. What are the Estimated Total Burdens and Costs for this planned Test Order?***

The total paperwork burden and cost for this specific Test Order request is estimated to be 265.5 hours and $22,250.30 as shown in the following table.

| Summary of Study Costs, Burden Costs and Hours for the Test Order in this IC | | | |
|---|---|---|---|
| **Chemical** | **Testing Costs ($)** | **Paperwork Burden Costs ($)** | **Paperwork Burden Hours** |
| 1,2-Dichloropropane (CAS 78-87-5) | $326,862.00 | $22,250.30 | 265.5 |

These figures reflect an overestimate because the methodology is based on the assumption that all of the companies will file Exemption Applications instead of Letters of Intent. In reality, however, some companies are likely to only submit a Letter of Intent. The range of burden and cost between Letters of Intent and Exemption Applications are provided below but the upper bound is used in the summary table above. In addition, the company could submit existing data to EPA to determine if the existing data fulfills the data needs and subsequently the testing requirement. If EPA makes the determination submitted existing data does preclude the need for conducting and submitting testing, the respondent's incurred costs would be lower.

***C. What activities are required for the Test Order?***

To respond to the Test Order, subject companies must undertake the following activities that may result in burden and costs such as:

- Providing company identification. This consists of identifying as a manufacturer, processor, or both, and in certain cases, may include requesting to modify their corporate identity.
- Providing an initial response to the test order.
- Developing and providing a study plan.
- Conduct testing. In certain cases, this may include collecting necessary samples, contracting out the analysis of samples and tests, management of a consortium.
- Providing a final report of study results to EPA.

The details of these activities are explained in Section D of this document. Requirements summarized here are set out in the Test Order and reflect the requirements enumerated in TSCA section 4 and EPA implementing regulations, as applicable. The activities based on these requirements are also described in the Generic ICR.

***D. Detailed Description of the Test Order Activities.***

*Company Identification*

EPA has attempted to identify the highest-level US corporate entity for purposes of issuing the Test Order. The highest-level US corporate entity is ultimately responsible for satisfying the obligations of the Test Order, although the highest-level US corporate entity may delegate its responsibilities under the Order to a U.S. subsidiary. As prescribed by the Test Order, within 30 calendar days of the effective date of the Test Order, a response is required at TSCAtestorders@epa.gov should companies wish to modify the name of the recipient or identify another US corporate entity in the corporate structure as the point of contact in place of the recipient named in the Test Order.

As prescribed by the Test Order, within 30 calendar days of the effective date of the Test Order, a response is required through EPA's Central Data Exchange (CDX) portal, informing the Agency whether the recipient will be responding to this Order as manufacturer or processor. The estimated burden and cost for the company identification is shown in Table D1.

**Table D1. Company Identification - Burden and Cost (2020$)**

| Activity | Managerial Burden (hrs.) per Response | Technical Burden (hrs.) per Response | Clerical Burden (hrs.) per Response | Respondents (Companies included in Test Order) | Responses per Respondent | Total Responses | Total Burden | Non-Labor Cost | Total Cost |
|---|---|---|---|---|---|---|---|---|---|
| Company Identification | 0.0625 | 0.1875 | 0 | 11 | 1 | 11 | 2.75 | $0.00 | $231.03 |
| **Total, Reporting** | **0.0625** | **0.1875** | **0** | **11** | **1** | **11** | **2.75** | **$0.00** | **$231.03** |
| **Total, Recordkeeping** | **0** | **0** | **0** | **0** | **0** | **0** | **0** | **$0.00** | **$0.00** |
| **Total, Company Identification** | **0.0625** | **0.1875** | **0** | **11** | **1** | **11** | **2.75** | **$0.00** | **$231.03** |

*Initial Response*

As prescribed by the Test Order, 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 company basis and assumes each company may decide to file an Exemption Application instead of a Letter of Intent. The new assumption is incorporated in order to ease the consolidation of activities involved with an initial response. EPA also assumes that each application would request the exemption from all of the testing.

As prescribed by the Test Order, within 45 calendar days of the effective date of the Test Order, a response is required through EPA's Central Data Exchange (CDX) portal informing the Agency which of the five options articulated in the Test Order the recipient has chosen to comply with the Test Order. Any CDX related burden and cost is covered in a different ICR and therefore not captured here. The estimated burden and cost for the initial response is shown in Table D2. Companies will either respond with a Letter of Intent or Exemption Application, they will not need to perform both. The lower estimates assume all companies submit Letters of Intent and the upper estimates assume all file Exemption Applications.

**Table D2. Initial Response - Burden and Cost (2020$)**

| Activity | Managerial Burden (hrs.) per Response | Technical Burden (hrs.) per Response | Clerical Burden (hrs.) per Response | Respondents (Companies included in TO) | Responses per Respondent | Total Responses | Total Burden | Non-Labor Cost | Total Cost |
|---|---|---|---|---|---|---|---|---|---|
| **Initial Response ("Letter of Intent")** | 0 | 1 | 0 | 11 | 1 | 11 | 11 | $0.00 | $885.50 |
| **Total, Reporting ("Letter of Intent")** | **0** | **1** | **0** | 11 | **1** | 11 | 11 | **$0.00** | $885.50 |
| **OR** | | | | | | | | | |
| **Exemption Application Submission** | 6 | 2 | 0 | 11 | 1 | 11 | 88 | $0.00 | $8,010.64 |
| **Recordkeeping** | 0 | 0 | 0.5 | 11 | 1 | 11 | 5.5 | $0.00 | $201.19 |
| **Total, Exemption Application** | **6** | **2** | **0.5** | **11** | **1** | 11 | **93.5** | **$0.00** | **$8,211.83** |
| **Total, Letter of Intent, Test Orders** | **0 to 6** | **1 to 2** | **0 to 0.5** | **11** | **1** | 11 | **11 to 93.5** | **$0.00** | **$885.50 to $8,211.83** |
| Assumes every company responds with either a letter of intent or an exemption application. | | | | | | | | | |

*Test Protocols*

EPA assumes that a consortium of the companies subject to the Test Order will provide the required data. As prescribed by the Test Order, after expressing an intent to provide information in the initial response, the Test Order recipients must submit a Study Plan to EPA for each test to be conducted. The Study Plan includes documents detailing the different types of tests, health effects, and endpoints covered in each chemical report.

EPA expects that companies will incur costs to participate in consortiums to manage testing requirements with shared responsibilities. Consortium management costs, which include activities such as, meetings, organizing payment for testing, and developing contracts for testing, are estimated at 15 percent of total laboratory costs. Costs are also included for technical experts working for the consortium by providing study review and site visits to the laboratory and are estimated at 10 percent of total laboratory costs. Table D3 lists the tests EPA will require of a company and the estimated burden and costs for testing and consortium management.

**Table D3. Required Tests – Unit Costs (2020$)**

| Test Guideline | Sample Collection Activities | | | | | Laboratory Costs | Consortium Management | Total, Testing Costs |
|---|---|---|---|---|---|---|---|---|
| | Managerial Burden (hrs.) | Technical Burden (hrs.) | Clerical Burden (hrs.) | Unit Burden (hrs.) | Total Labor Unit Cost | Total Non-Labor Unit Cost | Total Non-Labor Unit Cost | |
| OECD 222 | 0 | 8 | 0 | 8 | $644 | $20,975 | $5,244 | $26,863 |
| OCSPP 850.2200 | 0 | 8 | 0 | 8 | $644 | $8,858 | $2,215 | $11,717 |
| OCSPP 850.2300 | 0 | 8 | 0 | 8 | $644 | $230,111 | $57,528 | $288,283 |

Table D4 shows the tests required for the chemical. While both manufacturers and processors will receive the Test Order, processors should only conduct the consumer exposure tests for a given chemical. The Test Order for this chemical does not include any consumer exposure tests, therefore processors are not included.

**Table D4. Required Tests**

| Test Type | Test Protocol/Method | Manufacturers | Processors |
|---|---|---|---|
| Environmental Hazard | OECD 222 | X | |
| Environmental Hazard | OCSPP 850.2200 | X | |
| Environmental Hazard | OCSPP 850.2300 | X | |

*Study Plan*

As prescribed by the Test Order, 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 final study plan for each chemical is required at the beginning of the testing period. In general, confidential business information (CBI) substantiation to support confidentiality claims for relevant data elements throughout the testing period may be required. For this Order, EPA assumes that there will be no CBI confidentiality claims because chemical ID is known, and other data elements are expected not to be confidential for reasons of transparency. The estimated burden for preparing study plans is shown in Table D5.

**Table D5. Study Plan – Burden and Cost (2020$)**

| Activity | Managerial Burden (hrs.) | Technical Burden (hrs.) | Clerical Burden (hrs.) | Respondents | Responses per Respondent (# of tests in TO) | Total Responses | Total Burden | Non-Labor Cost | Total Cost |
|---|---|---|---|---|---|---|---|---|---|
| Study Plan | 0 | 3.9 | 0 | 1 | 3 | 3 | 11.7 | $0.00 | $941.85 |
| CBI Substantiation | 0 | 0 | 0 | 0 | 0 | 0 | 0 | $0.00 | $0.00 |
| **Total, Reporting** | **0** | **3.9** | **0** | **1** | **3** | **3** | **11.7** | **$0.00** | **$941.85** |
| **Total, Recordkeeping** | **0** | **0** | **0** | **0** | **0** | **0** | **0** | **$0.00** | **$0.00** |
| **Total, Study Plan** | **0** | **3.9** | **0** | **1** | **3** | **3** | **11.7** | **$0.00** | **$941.85** |
| Assumes companies form consortium and the consortium submits a study plan for each test. | | | | | | | | | |

*Test Results*

At the conclusion of each test, respondents are required to provide a final report, which must also undergo both corporate and laboratory review (which includes certified compliance with the applicable Good Laboratory Practice standards (GLPs). Recordkeeping is also expected for all final report transmittals.

**Table D6. Test Results - Burden and Cost (2020$)**

| Activity | Managerial Burden (hrs.) | Technical Burden (hrs.) | Clerical Burden (hrs.) | Respondents | Responses per Respondent (# of tests in TO/# of respondents) | Total Responses (# of Tests Included in TO) | Total Burden | Non-Labor Cost | Total Cost |
|---|---|---|---|---|---|---|---|---|---|
| Study Final Report | 0 | 40 | 0 | 1 | 3 | 3 | 120 | $0.00 | $9,660.00 |
| Study Corporate Review | 6 | 0 | 0 | 1 | 3 | 3 | 18 | $0.00 | $1,701.72 |
| Laboratory Review | 0 | 6 | 0 | 1 | 3 | 3 | 18 | $0.00 | $1,449.00 |
| **Total, Reporting** | **6** | **46** | **0** | 1 | **3** | **3** | **156** | **$0.00** | **$12,810.72** |
| **Total, Recordkeeping** | **0** | **0** | **0.5** | 1 | **3** | **3** | **1.5** | **$0.00** | **$54.87** |
| **Total, Test Results, Test Orders** | **6** | **46** | **0.5** | **1** | **3** | **3** | **157.5** | **$0.00** | **$12,865.59** |
| Assumes companies form consortium and the consortium submits the test results for each test. | | | | | | | | | |