Planned Test Orders FY21-1 (IC No.1139.13)

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

December 22, 2020

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 the following priority chemicals selected for Risk Evaluation:

No.	Priority Chemical	Link to Docket for TSCA Section 6 Risk Evaluation Scoping Documents
1.	o-Dichlorobenzene (CAS 95-50-1)	Docket number: EPA-HQ-OPPT-2018-0444
2.	p-Dichlorobenzene (CAS 106-46-7)	Docket number: EPA-HQ-OPPT-2018-0446
3.	trans-1,2-Dichloroethylene (CAS 156-60-5)	Docket number: EPA-HQ-OPPT-2018-0465
4.	1,1 Dichloroethane (CAS 75-34-3)	Docket number: EPA-HQ-OPPT-2018-0426
5.	1,2 Dichloroethane (CAS 107-06-2)	Docket number: EPA-HQ-OPPT-2018-0427
6.	1,1,2 Trichloroethane (CAS 79-00-5)	Docket number: EPA-HQ-OPPT-2018-0421
7.	1,2 Dichloropropane (CAS 78-87-5)	Docket number: EPA-HQ-OPPT-2018-0428
8.	triphenyl ester (TPP) (CAS 115-86-6)	Docket number: EPA-HQ-OPPT-2018-0458
9.	4,4'-(1-Methylethylidene)bis[2, 6-dibromophenol] (TBBPA) (CAS 79-94-7)	Docket number: EPA-HQ-OPPT-2018-0462

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 1,878 hours and $22,786,731 as summarized in the following table.

Summary of Study Costs, Burden Costs and Hours for the Test Order in this IC			
Chemicals	**Laboratory Costs ($)**	**Paperwork Burden Costs ($)**	**Paperwork Burden Hours**
o-Dichlorobenzene (CAS 95-50-1)	$517,693	$13,298.75	173.52
p-Dichlorobenzene (CAS 106-46-7)	$726,499	$13,831.75	180.405
trans-1,2-Dichloroethylene (CAS 156-60-5)	$462,849	$13,298.75	173.52
1,1 Dichloroethane (CAS 75-34-3)	$776,175	$11,699.75	152.865
1,2 Dichloroethane (CAS 107-06-2)	$2,465,335	$17,562.75	228.6
1,1,2 Trichloroethane (CAS 79-00-5)	$1,437,197	$13,831.75	180.405
1,2 Dichloropropane (CAS 78-87-5)	$755,103	$12,232.75	159.75
triphenyl ester (TPP) (CAS 115-86-6)	$5,393,635	$21,293.76	276.795
4,4'-(1-Methylethylidene)bis[2, 6-dibromophenol] (TBBPA) (CAS 79-94-7)	$10,252,246	$27,156.76	352.53
Totals:	**$22,786,731**	**$144,207**	**1,878**

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 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.

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 D1. 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 D1. Initial Response - Burden and Cost (2019$)

Activity	Managerial Burden (hours) per Response	Technical Burden (hours) per Response	Clerical Burden (hours) per Response	Respondents (Companies included in Test Order)	Responses per Respondent	Total Responses	Total Burden	Non-Labor Cost	Total Cost
Initial Response ("Letter of Intent")	0	1	0	81	1	81	81	$0.00	$6,173.01
Total, Reporting ("Letter of Intent")	**0**	**1**	**0**	**81**	**1**	**81**	**81**	**$0.00**	**$6,173.01**
OR									
Exemption Application Submission	6	2	0	81	1	81	680	$0.00	$51,959.88
Recordkeeping	0	0	0.5	81	1	81	42.5	$0.00	$1,340.15
Total, Exemption Application	**6**	**2**	**0.5**	**81**	**1**	**81**	**722.5**	**$0.00**	**$53,300.03**
Total, Letter of Intent, Test Orders	**0 to 6**	**1 to 2**	**0 to 0.5**	**81**	**1**	**81**	**81 to 722.5**	**$0.00**	**$6,477.85 to $55,932.13**

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 consortium 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.

Table D2 lists the tests EPA may require of a company depending on the chemical they manufacture (or import) and their unit costs. For the National Institute for Occupational Safety and Health (NIOSH) 1003 and NIOSH 1013 test methods, EPA developed an estimate of the costs per sample for 1, 3, and 10 samples. The median costs per sample for 10 samples are $71 and $70 per sample respectively. For purposes of this analysis, EPA assumes companies will be charged $71 per sample for NIOSH 1003 and $70 per sample for NIOSH 1013, though several companies may need to submit more than 10 samples and may negotiate a lower per sample cost based on volume.

Table D2. Required Tests – Unit Costs (2019$)

Test Type	Test Guideline	Test Name	Estimated Non-Labor Unit Cost
Inhalation	NIOSH 1003*	Hydrocarbons, halogenated 1003	$10,022
Inhalation	NIOSH 1013*	Propylene dichloride 1013	$7,679
Inhalation	Enclosure E	Inhalation Sample Protocol for Flame Retardants	$97,283
Dermal	Enclosure F	Dermal Hand Wipe Samples - Solvents	$64,580
Dermal	Enclosure G	Dermal Hand Wipe Samples - Flame Retardants	$97,283
Dermal	OECD# 428	Skin Absorption: In Vitro Method	$47,392
Eco Hazard	OPPTS# 850.4500	Algal Toxicity	$21,924
Eco Hazard	OECD 225	Sediment-Water Lumbriculus Toxicity Test Using Spiked Sediment	$51,267
Eco Hazard	OECD 233	Sediment-Water Chironomid Life-Cycle Toxicity Test Using Spiked Water or Spiked Sediment	$108,019
Eco Hazard	OPPTS 850.4400	Aquatic Plant Toxicity Test Using Lemna spp.	$42,579
Eco Hazard	OECD 222	Earthworm Reproduction Test (Eisenia fetida/Eisenia andrei)	$20,475
Eco Hazard	OPPTS 850.1735	Spiked Whole Sediment 10-Day Toxicity Test, Freshwater Invertebrates	$25,629

***Laboratory costs for this test vary depending on the number of samples needed. The laboratory costs shown in this table were estimated by taking the average laboratory cost per site for summary purposes.**

#Organization for Economic Cooperation and Development (OECD) and EPA's Office of Prevention, Pesticides and Toxic Substances (OPPTS).

Table D3 shows which flame retardants and solvents are subject to which test. While both manufacturers and processors will receive the Test Order, processors should only conduct the facility specific occupational exposure tests for a given chemical.

Table D3.

Required Tests by Chemical

		o-Dichlorobenzene		*p*-Dichlorobenzene		*Trans*-1,2-Dichloroethylene		1,1 Dichloroethane		1,2 Dichloroethane		1,1,2 Trichloroethane		1,2 Dichloropropane		Triphenyl ester (TPP)		4,4'-(1-Methylethylidene)bis[2, 6-dibromophenol] (TBBPA)	
Test Type	Test Guideline	Mfr.	Proc.	Mfr.	Proc.	Mfr.	Proc.	Mfr.	Proc.	Mfr.	Proc.	Mfr.	Proc.	Mfr.	Proc.	Mfr.	Proc.	Mfr.	Proc.
Inhalation	NIOSH 1003*	X	X	X	X	X	X	X	X	X	X	X	X						
Inhalation	NIOSH 1013*													X	X				
Inhalation	Enclosure E*															X	X	X	X
Dermal	Enclosure F*	X	X	X	X	X	X	X	X	X	X	X	X	X	X				
Dermal	Enclosure G*															X	X	X	X
Dermal	OECD 428	X		X		X		X		X		X		X		X		X	
Eco Hazard	OPPTS 850.4500															X			
Eco Hazard	OECD 225															X		X	
Eco Hazard	OECD 233	X		X				X				X		X		X		X	
Eco Hazard	OPPTS 850.4400															X		X	
Eco Hazard	OECD 222															X			
Eco Hazard	OPPTS 850.1735	X		X															

*Indicates facility specific test.

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 D4. The estimates shown below are per test (Table D4).

Table D4. Study Plan – Burden and Cost (2019$)

Activity	Managerial Burden (hours)	Technical Burden (hours)	Clerical Burden (hours)	Respondents (Chemicals included in Test Order)	Responses per Respondent	Total Responses	Total Burden	Non-Labor Cost	Total Cost
Study Plan	0	3.9	0	9	1	9	35.1	$0	$2,674.97
CBI Substantiation	0	0	0	0	0	0	0	$0	$0.00
Total, Reporting	**0**	**3.9**	**0**	**9**	**1**	**9**	**35.1**	**$0**	**$2,675**
Total, Recordkeeping	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**$0**	**$0**
Total, Study Plan	**0**	**3.9**	**0**	**9**	**1**	**9**	**35.1**	**$0**	**$2,675**

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. The estimates shown below are per test. This is an overestimate because each chemical is not subject to every test included in this Test Order, but the burden was calculated this way for simplification purposes and to provide an upper bound for industry burden and cost.

Table D5. Test Results - Burden and Cost (2019$)

Activity	Managerial Burden (hours)	Technical Burden (hours)	Clerical Burden (hours)	Respondents (Chemicals included in Test Order)	Responses per Respondent	Total Responses (Number of Tests Included in Test Order)	Total Burden	Non-Labor Cost	Total Cost
Study Final Report	0	40	0	9	1.33	12	879.84	$0	$67,052.61
Study Corporate Review	6	0	0	9	1.33	12	131.976	$0	$10,757.36
Laboratory Review	0	6	0	9	1.33	12	131.976	$0	$10,057.89
Total, Reporting	**6**	**46**	**0**	9	**1.33**	**12**	**1,143.79**	**$0**	**$87,867.86**
Total, Recordkeeping	**0**	**0**	**0.5**	9	**1.33**	**12**	**11.00**	**$0**	**$363.92**
Total, Test Results, Test Orders	**6**	**46**	**0.5**	**9**	**1.33**	**12**	**1,154.79**	**$0**	**$88,231.78**