

## **Amendment to the Supporting Statement for the Information Collection Request (ICR):**

Title: **Tier 1 Screening of Certain Chemicals Under the Endocrine Disruptor Screening Program (EDSP)**

EPA ICR No.: **2249.01**; OMB Control No.: **2070-(tbd)**

Docket ID No.: **EPA-HQ-OPPT-2007-1081**

### **Overview:**

In the current ICR, the estimated total number of potential respondents is **390**. In describing the method for estimating this number, the Agency indicated on page 14 of the supporting statement that it intended to search external sources to identify other potential manufacturers and importers of the listed chemicals. Subsequent to submitting the ICR on April 15, 2009, EPA used a contractor's assistance to complete such a search of external public sources of information to identify other potential manufacturers and importers of the listed chemicals. This amendment provides an adjustment to the estimated number of potential Order recipients and the corresponding calculations. The chemicals listed in the April ICR, the activities described, methodologies used, and per activity burden estimates are not changed in this amendment.

### **Amended Potential Number of Respondents:**

The estimated number of potential Order recipients identified to date for each of the 67 chemicals is provided in Attachment A2 to this amendment. The estimated number of potential respondents for this ICR is assumed to include all of the potential recipients of an Order. Each Order recipient has several options for their initial response, which in turn specifically identifies the remaining activities applicable to them. Although several of those initial response options may be considered satisfaction of that recipient's activities under the Order, the ICR assumes that each recipient will either take the lead to submit the data, or will actively participate in a consortium. In addition, although the Agency has identified only one Order recipient for 15 of the 67 chemicals, and has identified that a total of 45 of the 67 chemicals have 5 or fewer Order recipients, the Agency has retained the assumption that all Order recipients will participate in the consortium activities. These and the other assumptions in the ICR are intended to ensure that the estimate provided remains conservative. The Agency expects to be able to amend these assumptions when the ICR is renewed based on its experience with issuing the Orders, and information on the initial responses provided by the Order recipients.

As in the original supporting statement, it is important to note that this estimate for the potential number of order recipients is based on currently available information. To account for the potential need to issue additional orders to recipients not currently identified, the Agency has projected the possibility that as many as 20 additional orders might be issued subsequently. The estimated number of potential "catch-up orders" is not changed.

The adjusted estimated total number of potential Order recipients is changed from 390 to **769**. To illustrate the change, which carries through to the number of respondents used in several tables as the multiplier, Table 1 of the ICR is amended as follows:

**Table 1 - Estimated Number of Potential Order Recipients (Respondents)**

Potential Respondent Category	Estimated Number of Respondents			
	Pesticide Registrants	Manufacturers/ Importers	Catch-Up Orders	Total
Order Recipients	<del>297</del> <b>219</b>	<del>463</del> <b>530</b>	20	<del>390</del> <b>769</b>
Data Generators/Submitters	58	9	0	67
Consortium Participants	<del>449</del> <b>161</b>	<del>454</del> <b>521</b>	20	<del>323</del> <b>702</b>

**Added Optional Level of Effort Questionnaire:**

During the OMB review of the ICR, it was suggested that the Agency more actively solicit feedback from the Order recipients on their individual level of effort for responding to the Order. This feedback would facilitate the Agency’s review of the burden estimates and activities described in the ICR so that they may be refined when the ICR is reviewed prior to its scheduled renewal. Table 17 provides an estimated per respondent burden and costs for the activities associated with responding to this optional questionnaire.

**Table 17 – Estimated per Respondent Burden & Costs for [Optional Questionnaire](#)**

Activities	Burden (hrs.)			Costs (\$)		
	Technical (a)	Clerical (b)	Total (c)	Technical (d)	Clerical (e)	Total (f)
				\$76.92/hr.	\$33.60/hr.	
1) Read Questionnaire	0.2	0.2	0.4	15.38	6.72	22.10
2) Prepare Responses	1.0	0.0	1.0	76.92	0	76.92
3) Submit Questionnaire to EPA	0.0	0.5	0.5	0	16.80	16.80
<b>Totals:</b>	1.2	0.7	1.9	92.30	23.52	115.82
Hourly rates are based on Table 5 in the ICR.						
Total Costs in (f) = (a) x (d) + (b) x (e)						

Since responding to this questionnaire is completely voluntary for the respondents, the Agency has assumed that at least half of the Order recipients might choose to respond. As such, the total potential burden is estimated to be 730 (1.9 hrs x 384), with an estimated cost of \$44,475 (\$115.82 x 384). Annualized over the three years of the ICR, the annual potential burden is 243 (730 ÷ 3), with an estimated annual cost of \$14,825 (\$44,475 ÷ 3).

These estimates are being added as a separate IC to the total burden, see revised Table 16 below.

**Amended Respondent Burden Estimates:**

The estimated respondent burden for each of the paperwork activities described in Table 2 in section 4(b) of the ICR, disaggregated by the labor category listed in Table 4, are presented in Table 6 of the ICR and are not adjusted for purposes of this

amendment. Using the respondent categories and numbers presented in Table 1, Tables 7 & 8 are amended to present the adjusted estimated respondent burden for each category of respondent.

<b>Table 7 – Estimated Burden Hours by Activity for Pesticide Registrant</b>			
<b>Activity (a)</b>	<b>Estimated Burden (b)</b>	<b>Estimated # Respondents (c)</b>	<b>Total Burden Hours (d)</b>
1) Read instructions	24	219	5,256
2) Plan activities	90	219	19,710
3) Submit an initial response to EPA (b)	47	219	10,293
4) Read and discuss the protocol	181	58	10,498
5) Participate in Consortium	171	161	27,531
6) Generate the data (c)	2,101	58	121,858
7) Submit Progress Report	32	58	1,856
8) Compile and review the final data for submission	239	58	13,862
9) Complete paperwork to assemble the submission package	32	58	1,856
10) Submit final data to EPA	5	58	290
11) Maintain records	86	219	18,834
<b>Total burden:</b>	<b>3,008</b>		<b>231,844</b>
(a) Activities described in more detail in section 4(b) of this ICR, which are disaggregated based on labor category.			
(b) Per chemical burden taken from the total column in Table 6.			
(c) Number of potential respondents from Table 1, pesticide registrant column.			
(d) Total = (b) x (c)			

<b>Table 8 – Estimated Burden Hours by Activity for Manufacturers/Importers</b>			
<b>Activity (a)</b>	<b>Estimated Burden (b)</b>	<b>Estimated # Respondents (c)</b>	<b>Total Burden Hours (d)</b>
1) Read instructions	24	530	12,720
2) Plan activities	90	530	47,700
3) Submit an initial response to EPA (b)	47	530	24,910
4) Read and discuss the protocol	181	9	1,629
5) Participate in Consortium	171	521	89,091
6) Generate the data (c)	2,101	9	18,909
7) Submit Progress Report	32	9	288
8) Compile and review the final data for submission	239	9	2,151
9) Complete paperwork to assemble the submission package	32	9	288
10) Submit final data to EPA	5	9	45
11) Maintain records	86	530	45,580
<b>Total burden:</b>	<b>3,008</b>		<b>243,311</b>
(a) Activities described in more detail in section 4(b) of this ICR, which are disaggregated based on labor category.			
(b) Per chemical burden taken from the total column in Table 6.			
(c) Number of potential respondents from Table 1, manufacturer/importer column.			
(d) Total = (b) x (c)			

As indicated previously, EPA's estimate for "catch-up" Orders as presented in Table 9 remains unchanged.

Table 10 is amended to present the adjusted total estimated respondent burden.

Activity (a)	Estimated Burden (b)	Estimated # Respondents (c)	Total Burden Hours (d)
1) Read instructions	24	769	18,456
2) Plan activities	90	769	69,210
3) Submit an initial response to EPA (b)	47	769	36,143
4) Read and discuss the protocol	181	67	12,127
5) Participate in Consortium	171	702	120,042
6) Generate the data (c)	2,101	67	140,767
7) Submit Progress Report	32	67	2,144
8) Compile and review the final data for submission	239	67	16,013
9) Complete paperwork to assemble the submission package	32	67	2,144
10) Submit final data to EPA	5	67	335
11) Maintain records	86	769	66,134
<b>Total burden:</b>	<b>3,008</b>		<b>483,515</b>

(a) Activities described in more detail in section 4(b) of this ICR, which are disaggregated based on labor category.  
(b) Per chemical burden taken from the total column in Table 6.  
(c) Number of potential respondents from Table 1.  
(d) Total = (a) x (b)

### ***Amended Respondent Cost Estimates:***

The estimated respondent cost for each of the paperwork activities is presented in Table 11 and remains unchanged. The estimated costs for delivering the data to the Agency are also unchanged. Table 12 is amended to present the estimated total respondent costs for the initial group of chemicals expected to undergo Tier 1 screening under the EDSP.

Activity	Estimated Costs (\$)	Estimated Respondents	Total \$ (rounded)
1) Read instructions	2,166.48	769	1,666,023
2) Plan activities	8,204.40	769	6,309,184
3) Submit an initial response to EPA (b)	4,169.40	769	3,206,269
4) Read and discuss the protocol	14,883.72	67	997,209
5) Participate in Consortium	13,707.48	702	9,622,651
6) Generate the data (c)	141,511.00	67	9,481,237
7) Submit Progress Report	2,291.70	67	153,544
8) Compile and review the final data for submission	18,825.24	67	1,261,291
9) Complete paperwork to assemble the submission package	2,291.70	67	153,544
10) Submit final data to EPA	378.06	67	25,330
11) Maintain records	3,929.28	769	3,021,616
12) Delivery Costs	10.55	67	25,330
<b>Total costs:</b>	<b>\$212,369.01</b>		<b>\$ 35,923,228</b>

### ***Amended Total Burden and Cost Estimates:***

Table 16 provides a breakdown of the total annualized burden and cost estimate in terms of the grouping required by OMB, i.e., distinct information collections (ICs).

ICs	Per Chemical (b)		Totals (c)	
	Burden Hrs.	Costs \$	Burden Hrs.	Costs \$
Reporting	974	\$69,480	139,127	\$10,967,204
Recordkeeping (d)	29	\$1,310	22,045	\$1,007,205
<b>Sub-total EDSP:</b>	1003	\$70,790	161,172	\$ 11,974,409
Optional Questionnaire (e)	0.63	\$39	243	\$14,825
<b>Total:</b>	1004	\$70,829	161,415	\$11,989,230

(a) Burden hours and costs are annualized by dividing them by 3.  
(b) For per chemical burden see Table 6, i.e., total burden minus line item 11 (3,008-86) ÷ 3, and for costs see Table 11, i.e., total cost minus line item 11 (212,369 – 3,929) ÷ 3. Line item 11 in both tables represents recordkeeping.  
(c) For total respondent burden see Table 10, i.e., total burden minus line item 11 (483,515-66,134) ÷ 3, and for costs see Table 12, i.e., total cost minus line item 11 (35,923,228-3,021,616) ÷ 3.  
(d) For per chemical see Table 6, for totals see line item 11 in both table 10 & 12 represents recordkeeping, which is ÷ 3.  
(e) Per chemical burden & costs comes from Table 17 (1.9 ÷ 3) and (\$115.82 ÷ 3), and total burden & costs come from the text below Table 17.

The total burden hours for respondents calculated for this ICR involves activities that are expected to occur over the next 3 years. Since the timing of these activities is not specific enough to accurately divide them by year, the Agency has assumed a 3 year duration of equal effort to calculate the annual burden and costs for this ICR. As such, the total annual respondent burden and costs for this ICR is simply divided by 3 to get an estimated annualized burden of approximately **161,415 hours** and an annualized cost of approximately **\$ 11,989,230**.

### ***Amended Burden Statement for this ICR:***

The estimated per respondent paperwork burden to comply with this information collection activity is 3,008 hours, with an estimated cost of \$212,369. The optional questionnaire is estimated to be an additional burden of 1.9 hours and \$115.82 per questionnaire.

Annualized over three years, the respondent burden is 1,003 hours, and the cost is \$70,790. The total annualized estimated paperwork burden for this ICR is **161,415 hours** (which includes the questionnaire) and an annualized cost of approximately **\$ 11,989,230** (with the questionnaire).

### ***Minor Amendments to the Initial Response Forms:***

The Agency has amended both of the Initial Response Forms to include a separate line item to reflect a response option discussed in the final Procedures document and Order template regarding the submission of other scientifically relevant information to address the Order. The revised forms allow the respondent to provide a separate response to indicate if other scientifically relevant information is cited or submitted to address (A) a particular assay (i.e., in part 2.1. of the revised form), or (B) to satisfy the Order as a whole (i.e., in part 2.2. of the revised form).

September 10, 2009

The last sentence in the "Paperwork Reduction Act Notice" was amended on both forms to reference the part on the form that provides the mailing & delivery addresses. The Agency revised the "See attached documentation" statement to clarify that the check box is intended to serve as a confirmation or reminder for the respondent to attach the required documentation. Previously the wording of the check box implied that attaching the required documentation was optional, which conflicted with the instructions in the Order that indicated certain documentation was required to substantiate the response.

Finally, the parenthetical used in the address for the submissions was revised to reflect an internal Agency revision to the name of the Division, i.e., "SRRD" was changed to "PRD," and to make other minor wording changes.

The revised Forms are in Attachments B2 and C2.

### ***Minor Amendments to the Order Templates:***

Corresponding revisions have also been made to the Order Templates that were attached to the ICR dated April 15, 2009. For example, revisions to the templates include inserting the citation for the published List of Chemicals, adding a reference to the new optional survey, and cleaning up internal references to sections within the Order and phrasing in the ICR.

The revised Templates appear in Attachments D2 and E2.

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### **Attachments to this Amendment:**

This amendment and the accompanying attachment listed below can be found in the docket for this ICR and are accessible electronically through [www.Regulations.gov](http://www.Regulations.gov), under Docket ID Number: **EPA-HQ-OPPT-2007-1081**.

<u>Attachment</u>	<u>Description</u>
A2	Updated Estimate for Number of Potential Recipients of EDSP Tier 1 Orders/DCIs as of September 3, 2009
B2	Amended Initial Response Form for Individual Order Recipients (As of September 8, 2009).
C2	Amended Initial Response Form for Consortium/ Task Force (As of September 8, 2009).
D2	Amended FFDCA 408(p) Order Template for Pesticide Inert Ingredients (As of September 8, 2009).
E2	Amended FFDCA 408(p) Order Template for Pesticide Registrants (As of September 8, 2009).
F2	Optional Level of Effort Questionnaire