Optional Questionnaire
Level of Effort for Recipients of Tier 1 Screening Orders

As a recipient of an Order for EDSP Tier 1 screening data, your feedback on the level of effort it took for you to respond to the Order would facilitate the Agency's review of the assumptions and estimates presented in the Information Collection Request (ICR) document approved by OMB (identified under EPA ICR No. 2249.01, and OMB Control No. 2070-[# will be inserted when obtained]). The Agency is required to review the estimates in that ICR in 2 years and seek public comment on revisions before a renewal ICR is submitted to OMB before the OMB approval expires. EPA would greatly appreciate your assistance in answering a few questions about your experiences related to the Order you received.

You are **not** required to complete this questionnaire, and any responses on returned questionnaires will only be considered in the Agency's review of the burden estimates used in developing the renewal request for this ICR. Responses provided will not be attributed to any individual or entity. We thank you in advance for answering the following questions as completely as you can.

As identified in the ICR that EPA prepared under the Paperwork Reduction Act, 44 USC 3501 *et seq.*, the public reporting burden for the information collection activities associated with Tier 1 screening of the first group of chemicals under the Endocrine Disruptor Screening Program (EDSP) is estimated to average [# will be inserted when ICR is approved] hours per Order. The details of this estimate, including the specific information collection activities and related estimated burden and costs, is provided in the ICR document, a copy of which is available in docket ID No. **EPA-HQ-OPPT-2007-1081**. The docket is available electronically at http://www.regulations.gov. A hard copy of the ICR is also available for public viewing at the OPPT Docket. The OPPT Docket is located in the EPA Docket Center (EPA/DC) at Rm. 3334, EPA West Bldg., 1301 Constitution Ave., NW., Washington, DC. The EPA/DC Public Reading Room hours of operation are 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding Federal holidays. The telephone number of the EPA/DC Public Reading Room is (202) 566–1744, and the telephone number for the OPPT Docket is (202) 566–0280. Docket visitors are required to show photographic identification, pass through a metal detector, and sign the EPA visitor log. All visitor bags are processed through an X-ray machine and subject to search. Visitors will be provided an EPA/DC badge that must be visible at all times in the building and returned upon departure.

✉ → Mail your completed questionnaire with your final response to the Order, or under separate cover to the Document Processing Desk (PRD-EDSP), Office of Pesticide Programs (7504P), U.S. Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, D.C. 20460.

1. Clarity of Instructions

1.1. Did you find that the Order clearly explained what you needed to do to respond to the Order?

❍ Yes. → Go to Question 1.2.
❍ No. Please provide a brief description of what you felt was not clear, along with any suggestions you may have for making it clearer, then go to Question 1.2.:

DRAFT

1.2. Was the Initial Response Form for Individual Order Recipients formatted clearly and logically so that you were able to complete it without difficulty?

❍ Yes. → Go to Question 1.3.
❍ No. Please provide a brief description of any difficulties, along with any suggestions you may have for making it clearer, then go to Question 1.3.:

1.3. Was the Initial Response Form for Consortium/Task Force formatted clearly and logically so that you were able to complete it without difficulty?

❍ Not applicable. → Go to Question 2.1.
❍ Yes. → Go to Question 2.1.
❍ No. Please provide a brief description of any difficulties, along with any suggestions you may have for making it clearer, then go to Question 2.1.:

2. Level of Effort – Estimates for Time, Activities and Cost

2.1. Can you provide an estimate for how much time (in terms of hours & minutes) it took for you to complete the information collection activities in the following table? How would you divide this time among the identified categories?

Activity (a)	Estimated Time (b)				
	N/A	Managerial	Technical	Clerical	Total
1) Read instructions in the Order					
2) Plan activities					
3) Submit the Initial Response to EPA (c)					
4) Read the applicable assay specific Test Guideline or Protocol, discuss revisions, if applicable					
5) If applicable, discuss revisions to the assay specific Protocol & prepare explanation for deviations.					
5) Submit the required Progress Report					
6) Compile and review the final data for submission					
7) Assemble the final submission package					
8) Maintain records associated with this Order.					
Total time estimates:					

(a) Activities described in more detail in section 4(b) of the ICR.
(b) Please provide time estimates in terms of hours and minutes that were used to complete the activity.
(c) This should include the burden to provide any additional material required to accompany the Initial Response.

2.2. Did you conduct tests in-house or hire an independent laboratory to generate new data in response to the Order?

❍ Not applicable. No new data was generated. → Go to Question 2.7.
❍ Conducted tests in house. → Go to Question 2.3.
❍ Hired an outside laboratory to conduct the tests. → Go to Question 2.3.

2.3. What did it cost you to conduct the tests in-house or to pay an independent laboratory? If you shared the total cost for a test with another Order recipient, what was your share of the cost?

Tier 1 Battery	Your costs for conducting the tests identified in the Order		
	You did the Test	You paid a Lab to do it	Your share
Amphibian Metamorphosis (Frog)			
Androgen Receptor Binding (Rat Prostate)			
Aromatase (Human Recombinant)			
Estrogen Receptor Binding			
Estrogen Receptor Transcriptional Activation (Human Cell Line (HeLa-9903))			
Fish Short-term Reproduction			
Hershberger (Rat)			
Female Pubertal (Rat)			
Male Pubertal (Rat)			
Steroidogenesis (Human Cell Line – H295R)			
Uterotrophic (Rat)			

2.4. What assumptions did you make in arriving at these costs?

2.5. What percentage of the test cost would you consider to be related to the paperwork activities[1] associated with conducting the test?

❍ 15%. ❍ 20%. ❍ 25%. ❍ 30%. ❍ 35%. ❍ 40%. ❍ _____

2.6. What assumptions did you make in arriving at this estimate?

2.7. Did you join forces with any of the other Order recipients by forming a Consortium or Task Force to respond to the Order?

❍ Not applicable. There were no other Order recipients. → Go to Question 3.1.
❍ Yes. → Go to Question 2.8.
❍ No. Please explain why not, then go to Question 3.1.:

[1] Paperwork activities include activities related to the information collection activities. In the context of tests, this includes reading the Test Guideline/protocol, preparing or planning to conduct the test, discussing protocol changes with EPA, completing records while conducting tests, generating reports while the test is being performed, preparing the final Study Report, and storing, filing, and maintaining the data/ Study Report. Paperwork activities do NOT include activities like the daily care and feeding of the test animals, marketing costs, profit margins included in the cost charged by a laboratory to perform the test or other costs not related to fulfilling the paperwork for the test.

2.8. How much time did you spend participating in activities associated directly with the Consortium or Task Force? _____ hours.

2.9. How did the Consortium or Task Force divide the work associated with managing the activities of the group?

❍ It was managed by an outside party, *e.g.*, someone who did not receive an Order (Trade Association, Consultant, etc.)
❍ One participant was assigned or took on the lead for managing the group's activities.
❍ The participants took turns managing the group's activities.
❍ Other, please describe:

2.10. How did the Consortium or Task Force divide the cost associated with managing the activities of the group?

❍ It was divided equally among participants.
❍ It was apportioned among participants based on their identified market share.
❍ Other, please describe:

2.11. How would you characterize your experience in using a Consortium or Task Force to respond to the Order?

❍ It was a positive experience and I would do it again because (provide brief explanation:)
❍ It was a positive experience, but I would NOT do it again because (provide brief explanation:)
❍ It was NOT a positive experience, but I would do it again because (provide brief explanation:)
❍ It was NOT a positive experience, and I would NOT do it again because (provide brief explanation:)

3. Use of Electronic Technology

3.1. Do you maintain records in an electronic format?

❍ Yes. → Go to Question 3.2.
❍ No. Please explain why not, then go to Question 3.2.:

DRAFT

3.2. Did you submit any information to EPA in an electronic format in response to this Order?

❍ Yes. → Go to Question 3.3.
❍ No. Please explain why not, then go to Question 3.3.:

3.3. Is your use of an electronic format for recordkeeping or reporting more or less burdensome than traditional paper-based methods?

❍ There is no meaningful difference. Please explain:
❍ MORE Burdensome. Please explain:
❍ Less Burdensome. Please explain:

3.4. In what ways could EPA enhance the use of electronic formats in the future?

☺ Thank you for providing this feedback to EPA.

→ Follow the instructions on page 1 for mailing EPA the completed Questionnaire.

DRAFT