Response to Comments on the
Public Review Draft of the Renewal for
Information Collection Request (ICR), entitled:
Tier 1 Screening of Certain Chemicals Under the Endocrine Disruptor Screening Program (EDSP)
(77 FR 47640, August 9, 2012)

EPA ICR No.: 2249.03
OMB Control No.: 2070-0176
Docket ID No.: EPA–HQ–OPPT–2011–0966

October 22, 2012

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I. Introduction

The EPA's Endocrine Disruptor Screening Program (EDSP) was established under §408(p) of the Federal Food, Drug, and Cosmetic Act (FFDCA),[1] which required the EPA to develop a chemical screening program using appropriate validated test systems and other scientifically relevant information to determine whether certain substances may have hormonal effects. The EDSP consists of a two-tiered approach to screen chemicals for potential endocrine disrupting effects. The purpose of Tier 1 screening is to identify substances that have the potential to interact with the estrogen, androgen, or thyroid hormone systems using a battery of assays. Substances that have the potential to interact with estrogen, androgen or thyroid systems will proceed on to Tier II, which is designed to identify any adverse endocrine-related effects caused by the substance, and establish a quantitative relationship between the dose and that endocrine effect for risk assessment. Additional information about the EDSP is available through the agency's Web site at http://www.epa.gov/endo.

This "Response to Public Comments" document specifically addresses public comments that the EPA received on the renewal of the existing information collection request (ICR) (EPA ICR No. 2249.03) under the Paperwork Reduction Act (PRA),[2] covering the information collection activities associated with Tier 1 screening of chemicals under the EPA's (EDSP) and currently approved through October 31, 2012.

The ICR renewal addresses the information collection activities only for the initial list of chemicals screened under Tier 1 of the EDSP, and covers the full range of information collection activities

[1] See attachment A to the ICR.
[2] 44 USC 3501 et seq.

associated with the issuance of and response to Tier 1 EDSP orders issued by the EPA. The initial list was established in 2009, and consists of 67 pesticide active ingredients (PAIs) and pesticide inerts.

As the renewal of an ongoing information collection activity approved under the PRA, the draft ICR renewal covers the paperwork burden associated with the continuation of these activities over the next three (3) years. As such, the paperwork burdens were adjusted to reflect the planned progression associated with the information collection activities covered by the ICR.

Under the existing ICR, the EPA issued the Tier 1 EDSP orders to the identified pesticide registrant and inert manufacturers, and received the initial responses from those order recipients. However, as stated in the EDSP Policies and Procedures (Attachment B), the EPA will continue to issue "catch-up" orders for a period of 15 years to companies who enter the marketplace after the issuance of the initial orders in 2010. An up-to-date matrix with information on the status of the orders issued and responses received for those chemicals is available on the agency's Web site at http://www.epa.gov/endo. To facilitate consortia formation, the EPA also makes a list of the order recipients for each chemical publicly available. It is available at the same web address as above.

Although the information collection activities were not being changed by this ICR renewal, only limited activities remain to be completed at this stage of the program. The limited remaining ongoing information collection activities relate primarily to data submission, and to those activities associated with "catch-up" orders. In calculating the overall burden, the EPA assumes that all future "catch-up" order recipients will join existing data submitters. Therefore, no new data generators will be created. Thus, any changes in the calculation of the burdens and costs associated with data generators (IC#1 and IC#2) are moot.

II. Commenters

The following four unique entities filed comments on the draft renewal to the ICR:

Commentor #(1)	DCN (2)	Commenter Name (3)	Affiliate
1	EPA-HQ-OPPT-2011-0966-0012	Bayer CropScience Endocrine Drive Team	Bayer CropScience LP
2	EPA-HQ-OPPT-2011-0966-0013	Clare Thorpe, Senior Director Human Health Policy	CropLife America (CLA) and Endocrine Policy Forum (EPF)
3	EPA-HQ-OPPT-2011-0966-0014	Scott Slaughter	Center for Regulatory Effectiveness (CRE)
4	EPA-HQ-OPPT-2011-0966-0015	Patricia L. Bishop, Research Associate, Regulatory Testing Division and Kristie Sullivan, Director, Regulatory Testing Issues	People for the Ethical Treatment of Animals (PETA) and Physicians Committee for Responsible Medicine (PCRM)

Key
(1) This is the number that is used in this document to refer to this particular commenter.
(2) This is the number that is used to identify this comment in the docket at http://www.regulations.gov.
(3) This is the name of the individual or entity that submitted the comments, along with their affiliation, if provided.

These four commenters provided similar comments that can be grouped into specific topic or subject categories. This document is organized according to the topic or subject categories:

A. General ICR
B. Paperwork Related Activities
C. Calculation Methodologies
D. Other Topics

III. Comments and Responses

A. General ICR

General Comment: The EPA has not followed the OMB terms of clearance the agency agreed to with the existing ICR. (Commenters # 1, 2, 3, and 4)

Additional Detail: Commenter 4 stated, "In approving the original ICR for Tier 1 screening of List 1 chemicals, the OMB, under authority of the PRA, attached a notice of Terms of Clearance (TOC) directing the EPA to demonstrate the maximum practical utility of the information collection and evaluate the sufficiency of OSRI on these chemicals prior to requiring industry to screen additional chemicals. OMB also went on to request that the EPA provide a report re-estimating the burden of this information collection based on the responses to the Tier 1 test orders, including the use of cost-sharing and data compensation, the submission and acceptance of existing data and OSRI, and description of any instances in which submission of OSRI was deemed insufficient to satisfy the testing order."

Agency Response: The EPA fully intends to follow the terms of clearance as additional information becomes available. For example, the report on the re-estimation of the burden is partly dependent on an optional survey (requested by OMB) of EDSP Tier 1 order recipients that were mailed along with the orders the EPA issued for EDSP List 1. Keep in mind that the EPA is still receiving EDSP List 1 Tier 1 data at the time of the writing of this document. This survey is, again, optional and so far, no surveys have been returned to the agency with any significant information germane to a re-estimation report. This lack of returned surveys notwithstanding, the EPA has re-estimated the cost of the EDSP Tier 1 Battery in conjunction with a study of laboratory capacity of contract laboratories that conduct the EDSP Tier 1 Battery. The ICR supporting statement was previously updated to reflect the updated burden and cost estimates. A copy of the laboratory capacity study has been placed in the docket under Docket ID No. EPA-HQ-OPPT-2007-1081 and is available at http://www.regulations.gov.

With regards to submission and acceptance of existing data and OSRI, the EPA revised the ICR supporting statement to include a line item to estimate the burdens and costs associated specifically with OSRI submission. The estimated burdens and costs associated with this submission of OSRI are based on the report submitted during the public comment period by Commenter 2 under Docket ID No. EPA-HQ-OPPT-2007-1081-0037 and is available at http://www.regulations.gov.

Furthermore, the EPA has developed a guidance document titled, "*Weight-of-Evidence Guidance Document: Evaluating Results of EDSP Tier 1 Screening to Identify Candidate Chemicals for Tier 2 Testing*." The availability of this document for public comment was announced in a FR Notice on November 4, 2010 (FR 75 67963) under Docket ID No. EPA-HQ-OPPT-2010-0877. The guidance document was revised based on the public comments received and an amended document was placed in the same docket. Standard Evaluation Procedures (SEPs) for all 11 EDSP Tier 1 Assays are available at http://www.epa.gov/endo/pubs/toresources/seps.htm. These SEPs were internally peer reviewed at the agency.

General Comment: The EPA has not demonstrated practical utility. (Commenters # 1, 2, 3 and 4)

Additional Detail: Commenter 1 stated the EPA should "evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility."

Agency Response: The EPA disagrees with this comment. The draft ICR Renewal Supporting Statement explained the utility of the data generated by each assay and its intended use in decision-making, as well as the estimated cost and burden for each assay. In fact, the EPA has already considered the potential interaction of a chemical with the endocrine system in making certain pesticide registration decisions. For example, the EPA considered data from prototypes of the assays included in the current EDSP Tier 1 screen, along with other existing data, in preparing the risk assessments of procymidone[3] and vinclozolin[4].

B. Paperwork Related Activities

General Comment: The EPA should better calculate the costs and burdens associated with the submission of OSRI and the data entry spreadsheet templates (DESTs). (Commenters # 1, 2, 3 and 4)

Additional Detail: Commenter 3 stated, "CLA/EPF notices that the activities associated with evaluating regulatory and literature data in the context of endocrine disruption potential and providing justifications for waivers based upon OSRI were not specifically included in EPA's request. We believe that this information should be included in detail because it represents a significant effort by test order recipients. In addition, this information was specifically requested by OMB." Commenter 2 specifically added "while the Supporting Statement does mention the study profile templates, it does not appear that the burden estimates included in the ICR account for Data Entry Spreadsheet Templates (DESTs)."

Agency Response: The EPA agrees with the comment. However, as the EDSP List 1 order cycle is nearing its final phases, the agency does not expect any additional OSRI or DEST submissions (one of the base assumptions in the ICR renewal). The EPA will revise the costs and burdens associated with the submission of OSRI and DESTs in future EDSP ICR Supporting Statements using properly vetted supporting information.

C. Calculation Methodologies

General Comment: The EPA should re-estimate the costs and burdens associated with the submission of EDSP Tier 1 data specifically related to the base cost of the 11 assays contained in the EDSP Tier 1 Screening Battery. (Commenters # 1, 2, 3 and 4)

Additional Detail: Commenter 2 noted an improvement in the agency's estimation of the cost of the 11 assays that comprise the EDSP Tier 1 Screening Battery but stated the "EPA's estimate of the costs is still too low." Commenter 2 went on to add, "The EPF has

[3] To access the documents related to the procymidone decision, go to http://www.epa.gov/pesticides/reregistration/procymidone/.
[4] To access the documents related to the vinclozolin decision, go to http://www.epa.gov/pesticides/reregistration/vinclozolin/.

recently collected available time and cost estimates from many of its members, for the conduct of individual studies as well as the technical, managerial and clerical activities related to preparing, submitting and archiving the studies and associated documents such as Weight-of-Evidence papers, submission letters and transmittal documents. Recognizing that some of the EDSP List 1 work is still ongoing, we plan to make the industry data collection and analysis available to the EPA when the collection and analysis is complete. At completion of this exercise, we will be better able to comment on the accuracy of the EPA's current estimates; the EPF burden information should be available in time for the EPA to take them into account before issuing a List 2 ICR. While this collection effort is incomplete and there is a range of cost per chemical experienced by test order recipients, enough information is available to state that the EPF estimates the cost per chemical to be approximately $1 million. The EPA's estimate is approximately 15% too low."

Agency Response: The EPA will review and consider any detailed information related to this issue when it is submitted. The agency has based all estimates on currently vetted information. All estimates are adjusted for inflation and represent an average.

D. Other Topics

General Comment: Enhance the quality, utility and clarity of the information collected. (Commenters # 1, 2, 3 and 4)

Additional Detail: Commenter 1 specifically added, "on a technical level, the quality of information collected depends heavily on the clarity and/or transparency of the EPA protocols and standard evaluation procedures (SEPs) and the timeliness of communicating these to respondents."

Agency Response: The EPA agrees and will make every effort to improve clarity and timeliness.

General Comment: The current battery does not take into account animal welfare. (Commenters # 3 and 4)

Additional Detail: Commenter 3 stated, "Continuing with the current EDSP tests would be a waste of time, money and animal lives." Commenter 4 added their organization and membership shared a "common goal of promoting reliable and relevant regulatory testing methods and strategies that protect human health and the environment while reducing, and ultimately eliminating, the use of animals."

Agency Response: The agency is currently working diligently to move towards the use of computational techniques to reduce our reliance on animal testing. The EDSP has prepared a workplan entitled, "*Endocrine Disruptor Screening Program for the 21st Century: (EDSP21 Work Plan)*" which goes into further detail regarding the EPA's strategy to move towards use of validated 21st Century toxicology tools. The EDSP21 plan can be found on the EDSP website at http://www.epa.gov/endo/pubs/edsp21_work_plan_summary%20_overview_final.pdf. Until the agency has new validated tools to use, we must rely on the current EDSP Tier 1 Screening Battery.