Office of Pollution Prevention and Toxics (OPPT)  
Environmental Protection Agency  
1200 Pennsylvania Ave. NW.  
Washington, DC 20460–0001.

October 9, 2012

Re: Renewal of Information Collection Request (ICR) to the Office of Management and Budget (OMB) entitled: “Tier 1 Screening of Certain Chemicals Under the Endocrine Disruptor Screening Program (EDSP)”; EPA ICR No. 2249.03 and OMB Control No. 2070–0176; EPA–HQ–OPPT–2011–0966

To Whom It May Concern:

These comments are submitted on behalf of People for the Ethical Treatment of Animals (PETA) and the Physicians Committee for Responsible Medicine (PCRM). The parties are national animal protection and scientific advocacy organizations representing more than three million members and supporters that share the 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.

This Renewal refers to the original ICR submitted on April 15, 2009 to OMB (EPA ICR No. 2249.01) and refers only to the 67 pesticide active ingredients and pesticide inert ingredients for which information requests have already been issued and addresses the paperwork burden for these same chemicals over the next three years. The ICR remains largely unchanged with the exceptions of 1) providing new burden estimates for collection of other scientifically relevant information (OSRI); 2) providing updated cost estimates for conducting the 11 Tier 1 assays; 3) providing updated burden estimates of the data generation and submission phases of the program. The original recipients of test orders for these 67 chemicals are currently in the data generation or submission phases; additional producers or manufacturers may receive catch-up orders in the future.

**OSRI Burden Estimate**

The Paperwork Reduction Act (PRA) ICR regulations require agencies to demonstrate that any proposed collection of information “is not duplicative of information otherwise accessible to the agency” and that it “has practical utility.”¹ In approving the original ICR

¹ 5 C.F.R. § 1320.5(d)(ii) and (iii).
for Tier 1 screening of List 1 chemicals, the OMB, under authority of the PRA, attached a notice of Terms of Clearance (TOC) directing 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 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.

While EPA has amended the Renewal to include estimates of OSRI costs, these costs do not appear to accurately reflect the numbers given in the 2010 CropLife America (CLA) survey\(^2\) of EDSP test order recipients upon which EPA claims to have based its numbers. Actual costs per chemical of preparing the OSRI submissions, as reported by survey participants for 33 chemicals, ranged from $8,280 to $151,620, with 27 chemicals costing $19,000 or more. In contrast, the Renewal estimates a cost per chemical of only $16,886 in Table 7. The wide disparity in costs reported in the CLA report is due largely to differences in the quality and length of OSRI reports, which varied considerably among test order respondents. These differences in OSRI reports can be traced back to a lack of clear guidance from EPA as to what existing studies would be acceptable for satisfying Tier 1 data requirements. As a result, some test order recipients invested considerable cost and effort in preparing OSRI submissions, while others spent little or no time. In any case, the actual cost of preparing and submitting OSRI in lieu of Tier 1 testing should be accurately estimated.

**Tier 1 Assay Costs**

With respect to updated Tier 1 assay cost estimates, EPA notes that it used estimates “provided by the EPA scientist overseeing the validation effort” for two of the assays, and a 2009 Cost Estimate Survey of commercial labs along with the 2010 preliminary burden estimate prepared by CLA\(^3\), and applies a factor to adjust for inflation. As of the date of this Renewal, many companies receiving the initial test orders have likely already completed the assays and have actual costs available. EPA should therefore use actual costs, as directed by OMB, rather than relying on two- and three-year old estimates.

In addition, the report states: “Our basis for being comfortable with these cost estimates is a peer-reviewed article that appeared in *Toxicological Sciences* entitled ‘Application of an Integrated Testing Strategy to the U.S. EPA Endocrine Disruptor Screening,’ which estimated the costs for the 11 assays to be $572,913.12. As indicated in Attachment F, the estimate provided by EPA is slightly higher at $637,184” (a citation for that article\(^4\) should

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\(^3\) Ibid.

be included). In citing this reference, EPA is applying a circular argument as the numbers presented in that article were cited from a draft 2010 OECD guidance document\(^5\) that used the same assay estimates from the 2009 cost estimate survey of commercial labs mentioned above. As such, the Tox Sci article numbers do not provide an independent check on the assay costs because they are derived from the same source.

**Updated Data Generation and Submission Paperwork Burden and Cost**

Again, as most test order recipients should be nearing the end of the process, it seems reasonable to suppose that costs based on actual experiences should be available to better estimate these values. Yet, EPA states that it estimates the paperwork burden as a percentage of the testing costs, based on a method derived in the 1980s. If the testing costs are not first accurately estimated, then the data generation paperwork costs are likely to be inaccurately estimated as well. EPA states it assumes 35% of the testing costs to be a reasonable cost of the paperwork activities associated with testing and submission. This should be compared to actual costs in cases where companies have completed all or most of their testing to see if this is a reasonable estimation.

**Practical Utility of the Data**

This Renewal attempts to update the cost and burden estimates for fulfilling data requirements under the original ICR; however, it does not adequately address the practical utility of this information. Unlike the original ICR, the Renewal now states that the Tier 1 data will be used, along with other information, in a weight-of-evidence analysis to: 1) determine whether a chemical has the potential to interact with the endocrine system; 2) determine what kind of Tier 2 testing may be appropriate; and 3) be used in risk characterization. The Renewal explains that a two-tiered screening and testing approach is designed to be less resource-intensive than requiring full testing of all chemicals, and while this is undoubtedly true, it does not address whether the Tier 1 and Tier 2 batteries currently being implemented are the most efficient means available for screening and assessment purposes. The Renewal should describe how the data obtained will be evaluated for utility and compared with developing assessment tools. For example, EPA has recently favorably compared the results from a subset of ToxCast assays to certain EDSP Tier 1 assays.\(^6\) Now that most of the Tier 1 assays have been performed for the first list of chemicals and given all that has occurred since the original ICR was written, such as issuance of OMB’s TOC, advances in endocrine toxicology, and the announcement of EDSP21, EPA should analyze the Tier 1 data and OSRI to the fullest extent possible and critically assess the current program to determine its effectiveness in identifying endocrine disruptors.

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Thank you for the opportunity to comment.

Sincerely,

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