6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPPT-2013-0171; FRL 9925-37-OEI]

Information Collection Request Submitted to OMB for Review and Approval; Comment Request; Tier 2 Data Collection for Certain Chemicals under the Endocrine Disruptor Screening Program (EDSP)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA has submitted the following information collection request (ICR) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act (PRA): "Tier 2 Data Collection for Certain Chemicals Under the Endocrine Disruptor Screening Program (EDSP)" and identified by EPA ICR No. 2479.01 and OMB Control No. 2070-New. The ICR, which is available in the docket along with other related materials, provides a detailed explanation of the collection activities and the burden estimate that is only briefly summarized in this document. EPA has addressed the comments received in response to the previously provided public review opportunity issued in the **Federal Register** on June 24, 2013, 78 FR 37803. With this submission, EPA is providing an additional 30 days for public review.

DATES: Comments must be received on or before [**INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER**].

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA-HQ-OPPT-2013-0171, to both EPA and OMB as follows:

- To EPA online using *http://www.regulations.gov* (our preferred method) or by mail

to: EPA Docket Center, Environmental Protection Agency, Mail Code 28221T, 1200 Pennsylvania Ave., NW, Washington, DC 20460.

• To OMB via email to *oira_submission@omb.eop.gov*. Address comments to OMB Desk Officer for EPA.

EPA's policy is that all comments received will be included in the docket without change, including any personal information provided, unless the comment includes profanity, threats, information claimed to be Confidential Business Information (CBI), or other information whose disclosure is restricted by statute. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

FOR FURTHER INFORMATION CONTACT: Jane Robbins, Office of Science Coordination and Policy (7201M), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (202) 564-6625; e-mail address: *robbins.jane@epa.gov*.

SUPPLEMENTARY INFORMATION:

Docket: Supporting documents, including the ICR that explains in detail the information collection activities and the related burden and cost estimates that are summarized in this document, are available in the docket for this ICR. The docket can be viewed online at *http://www.regulations.gov* or in person at the EPA Docket Center, West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC. The telephone number for the Docket Center is (202) 566-1744. For additional information about EPA's public docket, visit *http://www.epa.gov/dockets*.

ICR status: This ICR is for a new information collection activity.

Under PRA, 44 U.S.C. 3501 *et seq*., an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information, unless it displays a currently valid OMB control number. The OMB control numbers are displayed either by publication in the **Federal Register** or by other appropriate means, such as on the related collection instrument or form, if applicable. The display of OMB control numbers for certain EPA regulations is consolidated in 40 CFR part 9.

Abstract: This ICR covers the information collection activities associated with Tier 2 data collection activities for certain chemicals under EPA's EDSP. The EDSP is established under section 408(p) of the Federal Food, Drug, and Cosmetic Act (FFDCA) (21 U.S.C. 346a(p)), which requires 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 potential bioactivity in the estrogen, androgen, or thyroid hormone systems using a battery of assays. Substances that have potential bioactivity with estrogen, androgen or thyroid hormone systems may proceed to Tier 2, 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. Additional information about the EDSP is available through the Agency's Web site at *http://www.epa.gov/endo*.

This ICR addresses the information collection activities for those chemicals that were screened under Tier 1 of the EDSP and are now proceeding to testing under Tier 2 of the EDSP. The ICR covers the information collection activities associated with Tier 2 of the

EDSP. As such, this ICR addresses the paperwork activities associated with generating the data requested, and submitting the data to EPA pursuant to the order.

Respondents/Affected Entities: Those individuals and companies that receive an EDSP Tier 2 order issued by the Agency. Under FFDCA section 408(p)(5)(A), EPA "shall issue" EDSP test orders "to a registrant of a substance for which testing is required . . . or to a person who manufactures or imports a substance for which testing is required."

Respondent's obligation to respond: FFDCA section 408(p)(5) obligates test order recipients to respond.

Estimated total number of potential respondents: 100.

Frequency of response: On occasion.

Estimated total burden: 83,116 hours (per year). Burden is defined at 5 CFR 1320.3(b).

Estimated total costs: $5,861,023 (per year). This primarily represents estimated labor cost, with related administrative costs of $104. Given the nature of the activities, there are no costs estimated for capital investment or maintenance and operational costs.

Changes in the estimates: This is a request for a new approval from OMB.

Authority: 44 U.S.C. 3501 *et seq*.

Courtney Kerwin,
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Collection Strategies Division.
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