ENVIRONMENTAL PROTECTION AGENCY 6560-50

[EPA-HQ-OPPT-2011-0966; FRL- 9523-7]

Agency Information Collection Activities; Submission to OMB for Review and Approval; Comment Request; Tier 1 Screening of Certain Chemicals Under the Endocrine Disruptor Screening Program (EDSP) (Renewal)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (44 U.S.C. 3501 et seq.), this document announces that an Information Collection Request (ICR) has been forwarded to the Office of Management and Budget (OMB) for review and approval. The ICR, which is abstracted below, describes the nature of the information collection activity and its expected burden and costs.

DATES: Additional comments may be submitted on or before [insert date 30 days after publication in the Federal Register].

ADDRESSES: Submit your comments, referencing Docket identification (ID) number (No.) EPA-HQ-OPPT-2011-0966, to (1) EPA online using www.regulations.gov (our preferred method) or by mail to: Pollution Prevention and Toxics Docket, Environmental Protection Agency Docket Center (EPA/DC), Mailcode: 28221T, 1200 Pennsylvania Ave., NW., Washington, DC 20460, and (2) OMB by mail to: Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), Attention: Desk Officer for EPA, 725 17th Street, NW, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: William Wooge, (7203M), Office of Science Coordination and Policy (OSCP), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (202) 564-8476; fax number: (202) 564-

8482; e-mail address: *wooge.william@epa.gov*.

SUPPLEMENTARY INFORMATION:

EPA has submitted the following ICR to OMB for review and approval according to the procedures prescribed in 5 CFR 1320.12. On August 9, 2012 (77 FR 47640), EPA sought comments on this renewal pursuant to 5 CFR 1320.8(d), and the ICR submitted to OMB includes EPA's responses to the four comments that were received. Any additional comments on the revised ICR should be submitted to EPA and OMB within 30 days of this notice.

EPA has established a public docket for this ICR under Docket ID No. EPA EPA-HQ-OPPT-2011-0966, which is available online at http://www.regulations.gov, or in person at the OPPT Docket in the EPA/DC, EPA West Room 3334, 1301 Constitution Ave., NW., Washington, DC. The EPA/DC Public Reading Room is open from 8 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Reading Room is 202-566-1744, and the telephone number for the OPPT Docket is 202-566-0280. Use www.regulations.gov to submit or view public comments, access the index listing of the contents of the public docket, and to access those documents in the public docket that are available electronically. Once in the system, select "search," then key in the docket ID number identified for this ICR. Please note that EPA's policy is that public comments, whether submitted electronically or in paper, will be made available for public viewing in www.regulations.gov as EPA receives them and without change, unless the comment contains copyrighted material, confidential business information (CBI), or other information whose public disclosure is restricted by statute. For further information about the docket, go to www.regulations.gov.

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

ICR Numbers: EPA ICR No. 2249.03, OMB Control No. 2070-0176.

ICR Status: This is a request to renew an existing approved collection. This ICR is scheduled to expire on October 31, 2012. Under OMB regulations, the Agency may continue to conduct or sponsor the collection of information while this submission is pending at OMB. 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 for EPA's regulations in title 40 of the CFR, after appearing in the Federal Register, are listed in 40 CFR part 9 and included on the related collection instrument or form, if applicable.

Abstract: This is a renewal of an existing ICR covering the information collection activities associated with Tier 1 screening of 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 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 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 at http://www.epa.gov/endo.

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

associated with the issuance of and response to Tier 1 EDSP orders issued by 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, this ICR addresses the paperwork burden associated with the continuation of the activities over the next three years. As such, the paperwork burdens are adjusted to reflect the planned progression associated with the information collection activities covered by the ICR. In addition, EPA has restructured the ICR to incorporate a presentation of the activities and related burden in a way that would match what is used in the ICR submission system.

Burden Statement: The annual public reporting and recordkeeping burden for this collection of information is estimated to range between 204 and 4,919 hours per response. Burden is defined in 5 CFR 1320.3(b).

Respondents/Affected Entities: Entities potentially affected by this ICR are those that receive an EDSP test 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."

Frequency of Collection: On occasion.

Estimated No. of Respondents: 385.

Estimated Total Annualized Burden: 98,414 hours.

Estimated Total Annualized Cost: $6,301,807.

Changes in Burden Estimates: There is a decrease of 63,011 hours in the total estimated annualized burden compared with that currently approved by OMB (i.e., from 161,415 hours to 98,404 hours). This is an adjustment that reflects the planned progression of the collection activities associated with the initial chemicals to be screened under Tier 1 of the EDSP.

John Moses, Director, Collection Strategies Division

[FR Doc. 2012-26611 Filed 10/29/2012 at 8:45 am; Publication Date: 10/30/2012]