

9. EPA. Harmonized Test Guidelines. Available online at <http://www.epa.gov/ocsp/pubs/frs/home/guidelin.htm>.

#### List of Subjects

Environmental protection, Chemicals, Endocrine disruptors, Pesticides and pests, Safe drinking water, Reporting and recordkeeping.

Dated: September 28, 2010.

**Stephen A. Owens,**

*Assistant Administrator, Office of Chemical Safety and Pollution Prevention.*

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## ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPPT-2007-1081; FRL-8849-3]

### Agency Information Collection Activities; Proposed Collection; Comment Request; Addendum for the Second List of Chemicals; Tier 1 Screening of Certain Chemicals Under the Endocrine Disruptor Screening Program (EDSP); EPA ICR No. 2249.02, OMB Control No. 2070-0176

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice.

**SUMMARY:** In compliance with the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), this document announces that EPA is planning to submit a request an addendum to an existing approved Information Collection Request (ICR) to the Office of Management and Budget (OMB). This addendum simply covers the burden for a new list of chemicals to receive and respond to EDSP Orders. The activities articulated in the original ICR are not changing. This ICR addendum, entitled "Addendum for the Second List of Chemicals; Tier 1 Screening of Certain Chemicals Under the Endocrine Disruptor Screening Program (EDSP)" and identified by EPA ICR No. 2249.02 and OMB Control No. 2070-0106. Before submitting the ICR to OMB for review and approval, EPA is soliciting comments on specific aspects of the proposed information collection.

**DATES:** Comments must be received on or before January 18, 2011.

**ADDRESSES:** Submit your comments, identified by docket identification (ID) number EPA-HQ-OPPT-2007-1081, by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the on-line instructions for submitting comments.
- *Mail:* Document Control Office (7407M), Office of Pollution Prevention

and Toxics (OPPT), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Hand Delivery:* OPPT Document Control Office (DCO), EPA East, Rm. 6428, 1201 Constitution Ave., NW., Washington, DC. Attention: Docket ID Number EPA-HQ-OPPT-2007-1081. The DCO is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the DCO is (202) 564-8930. Such deliveries are only accepted during the DCO's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

*Instructions:* Direct your comments to docket ID number EPA-HQ-OPPT-2007-1081. EPA's policy is that all comments received will be included in the docket without change and may be made available on-line at <http://www.regulations.gov>, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through [www.regulations.gov](http://www.regulations.gov) or e-mail. The [www.regulations.gov](http://www.regulations.gov) Web site is an "anonymous access" system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through [www.regulations.gov](http://www.regulations.gov), your e-mail address will be automatically captured and included as part of the comment that is placed in the docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD-ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

*Docket:* All documents in the docket are listed in the docket index available at <http://www.regulations.gov>. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available electronically at <http://www.regulations.gov>, or, if only available in hard copy, 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 legal 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.

#### FOR FURTHER INFORMATION CONTACT:

William Wooge, (7201M), 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](mailto:wooge.william@epa.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. What should I consider when I prepare my comments for EPA?

##### A. Considerations Under the Paperwork Reduction Act (PRA)

Pursuant to section 3506(c)(2)(A) of PRA, EPA specifically solicits comments and information to enable it to:

1. 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.
2. Evaluate the accuracy of the Agency's estimates of the burden of the proposed collection of information, including the validity of the methodology and assumptions used.
3. Enhance the quality, utility, and clarity of the information to be collected.
4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses. In particular, EPA is requesting comments from very small businesses (those that employ less than 25) on examples of specific additional efforts that EPA could make to reduce the paperwork

burden for very small businesses affected by this collection.

#### B. Tips for Preparing Your Comments

You may find the following suggestions helpful for preparing your comments:

1. Explain your views as clearly as possible and provide specific examples.
2. Describe any assumptions that you used.
3. Provide copies of any technical information and/or data you used that support your views.
4. If you estimate potential burden or costs, explain how you arrived at the estimate that you provide.
5. Provide specific examples to illustrate your concerns.
6. Offer alternative ways to improve the collection activity.
7. Make sure to submit your comments by the deadline identified under **DATES**.
8. To ensure proper receipt by EPA, be sure to identify the docket ID number assigned to this action in the subject line on the first page of your response. You may also provide the name, date, and **Federal Register** citation.

#### C. Submitting CBI

Do not submit CBI to EPA through regulations.gov or e-mail. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD-ROM that you mail to EPA, mark the outside of the disk or CD-ROM as CBI and then identify electronically within the disk or CD-ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

#### III. What information collection activity or ICR does this action apply to?

**Affected Entities:** Entities potentially affected by this ICR are those individuals and companies that receive an EDSP test order issued by the Agency. Under FFDCA § 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." Using the North American Industrial Classification System (NAICS) codes, the Agency has determined that potential respondents to this ICR may include, but is not limited to: Chemical

Manufacturers and Processors (NAICS code 325), and Pesticide, Fertilizer, and Other Agricultural Chemical Manufacturing (NAICS code 3253), Producers & Formulators of Pesticide Products (NAICS code 32532); Producers of Antifouling Paints (NAICS code 32551); Producers of Antimicrobial Pesticides (NAICS code 32561); Producers of Nitrogen Stabilizers (NAICS code 32531); and Producers of Wood Preservatives (NAICS code 32519).

**Title:** Addendum for the Second List of Chemicals; Tier 1 Screening of Certain Chemicals Under the Endocrine Disruptor Screening Program (EDSP).

**ICR numbers:** EPA ICR No. 2249.02, OMB Control No. 2070-0176.

**ICR status:** This is an ICR addendum to an approved information collection activity. 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 number for this ICR will be displayed by publication in the **Federal Register** and by inclusion of a Paperwork Reduction Notice on the related collection instrument, *i.e.*, test orders, forms, *etc.*

**Abstract:** This ICR addendum covers the information collection activities associated with Tier 1 screening of the second group of chemicals under the EDSP. The EDSP is established under section 408(p) of the Federal Food, Drug, and Cosmetic Act (FFDCA), which requires endocrine screening of all pesticide chemicals and was established in response to growing scientific evidence that humans, domestic animals, and fish and wildlife species have exhibited adverse health consequences from exposure to environmental chemicals that interact with their endocrine systems.

The EDSP, which was established in 1998, consists of a two-tiered approach to screen all pesticide chemicals for potential endocrine disrupting effects. The purpose of Tier 1 screening (referred to as "screening") is to identify substances that have the potential to interact with the estrogen, androgen, or thyroid hormone systems using a battery of assays. The purpose of Tier 2 testing (referred to as "testing"), therefore, is to identify and establish a dose-response relationship for any adverse effects that might result from the interactions identified through the Tier 1 assays. Additional information about the EDSP is available through the Agency's Web site at <http://www.epa.gov/scipoly/ospendo/index.htm>.

EPA is submitting a request for an addendum to an approved ICR, EPA ICR No. 2249.01 and OMB Control No.

2070-0176 to OMB. This addendum simply covers the burden for a new list of chemicals to receive and respond to EDSP Orders. The activities articulated in the original ICR are not changing.

**Burden Statement:** The annual public reporting and recordkeeping burden for this collection of information is estimated to average 1002.7 hours per response. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements which have subsequently changed; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information.

The ICR provides a detailed explanation of this estimate, which is only briefly summarized here:

**Estimated total number of potential respondents:** 1,840.

**Frequency of response:** On occasion.

**Estimated total average number of responses for each respondent:** Two or three responses per chemical: An initial response, a consortium response, and the final data submission. All respondents will provide an initial response, and some respondents may provide a second response if they lead a consortium only those that generates the data will complete the final data submission.

**Estimated total annual burden hours:** 232,600 hours.

**Estimated total annual costs:** \$17,056,342.82.

#### IV. What is the next step in the process for this ICR?

EPA will consider the comments received and amend the ICR as appropriate. The final ICR package will then be submitted to OMB for review and approval pursuant to 5 CFR 1320.12. EPA will issue another **Federal Register** notice pursuant to 5 CFR 1320.5(a)(1)(iv) to announce the submission of the ICR to OMB and the opportunity to submit additional comments to OMB. If you have any questions about this ICR or the approval process, please contact the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

**List of Subjects**

Environmental protection, Reporting  
and recordkeeping requirements.

Dated: September 28, 2010.

**Stephen A. Owens,**

*Assistant Administrator, Office of Chemical  
Safety and Pollution Prevention.*

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