

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.

#### What Information Collection Activity or ICR Does This Apply to?

Docket ID No. EPA-HQ-SFUND-2005-0008.

*Affected entities:* Entities potentially affected by this action are those which have a threshold planning quantity of an extremely hazardous substance (EHS) listed in 40 CFR Part 355, Appendix A and those which have a release of any of the EHS above a reportable quantity. Entities more likely to be affected by this action may include chemical manufacturers, non-chemical manufacturers, retailers, petroleum refineries, utilities, etc.

*Title:* Emergency Planning and Release Notification Requirements under Emergency Planning and Community Right-to-Know Act Sections 302, 303, and 304.

*ICR number:* EPA ICR No. 1395.07, OMB Control No. 2050-0092.

*ICR status:* This ICR is currently scheduled to expire on May 31, 2009. 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** when approved, are listed in 40 CFR part 9, 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 in certain EPA regulations is consolidated in 40 CFR part 9.

*Abstract:* The authority for these requirements is sections 302, 303, and 304 of the Emergency Planning and Community Right-to-Know Act (EPCRA), 1986 (42 U.S.C. 11002, 11003, and 11004). EPCRA established broad emergency planning and facility reporting requirements. Section 302 requires facilities to notify their state emergency response commission (SERC) that the facility is subject to emergency planning. This activity has been completed; this ICR covers only new facilities that are subject to this requirement. Section 303 requires the local emergency planning committees (LEPCs) to prepare emergency plans for facilities that are subject to section 302. This activity has been also completed; this ICR only covers any updates needed for these emergency response plans. Section 304 requires facilities to report to SERCs and LEPCs releases in excess

of the reportable quantities listed for each extremely hazardous substance (EHS). This ICR also covers the notification and the written follow-up required under this section. The implementing regulations and the list of substances for emergency planning and emergency release notification are codified in 40 CFR part 355.

On November 3, 2008 (73 FR 64452), EPA has revised some of the requirements in 40 CFR part 355, specifically, the requirements related to emergency planning notification. EPA is now requiring facilities to notify their LEPC within 30 days of any changes occurring at the facility that may be relevant to emergency planning. This revision should not impose any additional burden on facilities subject to emergency planning. Prior to the November 3, 2008 final rule, facilities were required to provide any changes to the LEPC promptly. This final rule now requires facilities to provide any changes within 30 days. Other revisions finalized on November 3, 2008 do not impose any burden on facilities subject to Section 302 and 304 requirements.

*Burden Statement:* The burden and costs stated below are from the current approved ICR. The average reporting burden for a limited number of existing facilities, to inform the LEPC of any changes at the facility that may affect emergency planning (1.50 hours). The average reporting burden for facilities reporting releases under 40 CFR 355.40 is estimated to average approximately 5 hours per release, including the time for determining if the release is a reportable quantity, notifying the LEPC and SERC, or the 911 operator, and developing and submitting a written follow-up notice. There are no record keeping requirements for facilities under EPCRA Sections 302-304. The total burden to facilities over three years is 229,473 hours at a cost of \$11.1 million.

The average burden for emergency planning activities is 21 hours per plan for LEPCs, and 16 hours per plan for SERCs. Each SERC and LEPC is also estimated to incur an annual record keeping burden of 10 hours. The total burden to LEPC and SERC over three years is 320,568 hours at a cost of \$8.1 million.

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 the Agency's estimate, which is only briefly summarized here:

*Estimated total number of potential respondents:* 84,215.

*Frequency of response:* Occasionally.

*Estimated total average number of responses for each respondent:* Once.

*Estimated total annual burden hours:* 183,347.

*Estimated total annual costs:* \$27,000 includes annualized capital or O&M costs.

#### 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. At that time, 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**.

Dated: December 5, 2008.

**Deborah Y. Dietrich,**

*Director, Office of Emergency Management.*

[FR Doc. E8-29469 Filed 12-11-08; 8:45 am]

**BILLING CODE 6560-50-P**

#### ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPP-2008-0414; FRL-8751-2]

**Agency Information Collection Activities; Submission to OMB for Review and Approval; Comment Request; Submission of Protocols and Study Reports for Environmental Research Involving Human Subjects; EPA ICR No. 2195.03, OMB Control No. 2070-0169**

**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 an Information Collection Request (ICR) has been forwarded to the Office of Management and Budget (OMB) for review and approval. This is a request to renew an existing approved collection. The ICR, which is abstracted below, describes the nature of the information collection and its estimated burden and cost.

**DATES:** Additional comments may be submitted on or before January 12, 2009.

**ADDRESSES:** Submit your comments, referencing Docket ID No. EPA-HQ-OPP-2008-0414, to (1) EPA online using [www.regulations.gov](http://www.regulations.gov) (our preferred method), by e-mail to [opp.ncic@epa.gov](mailto:opp.ncic@epa.gov), or by mail to: OPP Regulatory Public Docket (7502P), Office of Pesticide Programs (OPP), Environmental Protection Agency, 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:** Joseph Hogue, Field and External Affairs Division, Office of Pesticide Programs, (7506P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: 703-308-9072; fax number: 703-305-5884; e-mail address: [hogue.joe@epa.gov](mailto:hogue.joe@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 June 13, 2008 (73 FR 33811), EPA sought comments on this ICR pursuant to 5 CFR 1320.8(d). EPA received two comments during the comment period, which are addressed in the ICR. Any additional comments on this 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-HQ-OPP-2008-0414, which is available for online viewing at [www.regulations.gov](http://www.regulations.gov), or in person viewing at the OPP Regulatory Public Docket in Rm. S-4400, One Potomac Yard (South Building), 2777 S. Crystal Drive, Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305-5805.

Use EPA's electronic docket and comment system at [www.regulations.gov](http://www.regulations.gov), to submit or view public comments, access the index listing of the contents of the docket, and to access those documents in the docket that are available electronically. Once in

the system, select "docket search," then key in the docket ID number identified above. Please note that EPA's policy is that public comments, whether submitted electronically or in paper, will be made available for public viewing at [www.regulations.gov](http://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 electronic docket, go to [www.regulations.gov](http://www.regulations.gov).

**Title:** Submission of Protocols and Study Reports for Environmental Research Involving Human Subjects.  
**ICR numbers:** EPA ICR No. 2195.03, OMB Control No. 2070-0169.

**ICR Status:** This ICR is scheduled to expire on January 31, 2009. 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** when approved, are listed in 40 CFR part 9, 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 in certain EPA regulations is consolidated in 40 CFR part 9.

**Abstract:** In January 2006, EPA issued a final rule to amend the Federal Policy for the Protection of Human Subjects (also known as the Common Rule) at 40 CFR part 26. EPA's final rule significantly strengthened and expanded the protections for subjects of "third-party" human research (i.e., research that is not conducted or supported by EPA). Affected entities are required to submit information to EPA and an institutional review board (IRB) prior to initiating, and to EPA upon the completion of, certain studies that involve human research participants. The information collection activity imposed by this final rule consists of activity-driven reporting and recordkeeping requirements for those who intend to conduct research for submission to EPA under the pesticide laws. If such research involves intentional dosing of human subjects, these individuals (respondents) are required to submit study protocols to EPA and a cognizant local Human Subjects IRB before such research is initiated so that the scientific design

and ethical standards that will be employed during the proposed study may be reviewed and approved. Also, respondents are required to submit information about the ethical conduct of completed research that involved human subjects when such research is submitted to EPA.

This renewal ICR estimates the third party response burden from complying with the January 2006 final rule. Information is typically submitted by registrants of pesticide products to support the registration of their products. Responses to this collection of information are mandatory. The authority for this information collection is provided under section 25 of FIFRA and 40 CFR part 26.

**Burden Statement:** The annual public reporting and recordkeeping burden for this collection of information is estimated to average 598 hours per response for research involving intentional exposure of human subjects, and 12 hours per response for all other submitted research with human subjects. 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.

**Respondents/Affected Entities:** Pesticide registrants.

**Estimated Number of Responses:** 54.

**Frequency of Response:** On occasion.

**Estimated Total Annual Hour Burden:** 20,572.

**Estimated Total Annual Cost:** \$1,579,098, includes \$0 annualized capital or O&M costs.

**Changes in the Estimates:** There is an increase of 19,168 hours in the total estimated burden currently identified in the OMB Inventory of Approved ICR Burdens. This increase is an adjustment to the estimate, based on input received during the consultation process from entities that have submitted human subjects research since the implementation of the rule. The burden estimates in the previous (new) ICR were developed before the rule was

implemented, and were based on EPA's predictions of how long it would take study sponsors to prepare submissions. Based on the information provided in the consultation responses, it appears that the actual amount of time necessary to comply with the paperwork and recordkeeping requirements is higher than originally estimated.

Dated: December 8, 2008.

**John Moses,**

*Acting Director, Collection Strategies Division.*

[FR Doc. E8-29483 Filed 12-11-08; 8:45 am]

BILLING CODE 6560-50-P

## ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPPT-2008-0864; FRL-8393-4]

### Certain New Chemicals; Receipt and Status Information

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

**ACTION:** Notice.

**SUMMARY:** Section 5 of the Toxic Substances Control Act (TSCA) requires any person who intends to manufacture (defined by statute to include import) a new chemical (i.e., a chemical not on the TSCA Inventory) to notify EPA and comply with the statutory provisions pertaining to the manufacture of new chemicals. Under sections 5(d)(2) and 5(d)(3) of TSCA, EPA is required to publish a notice of receipt of a premanufacture notice (PMN) or an application for a test marketing exemption (TME), and to publish periodic status reports on the chemicals under review and the receipt of notices of commencement to manufacture those chemicals. This status report, which covers the period from October 20, 2008 through October 31, 2008, consists of the PMNs or expired, and the notices of commencement to manufacture a new chemical that the Agency has received under TSCA section 5 during this time period.

**DATES:** Comments identified by the specific PMN number or TME number, must be received on or before January 12, 2009.

**ADDRESSES:** Submit your comments, identified by docket identification (ID) number EPA-HQ-OPPT-2008-0864, 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 Bldg., Rm. 6428, 1201 Constitution Ave., NW., Washington, DC. Attention: Docket ID Number EPA-HQ-OPPT-2008-0864. 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-2008-0864. 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) website 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. For additional information about EPA's public docket, visit the EPA Docket Center homepage at <http://www.epa.gov/epahome/dockets.htm>.

**Docket:** All documents in the docket are listed in the docket index available in [www.regulations.gov](http://www.regulations.gov). To access the electronic docket, go to <http://www.regulations.gov>, select "Advanced Search," then "Docket Search." Insert the docket ID number where indicated and select the "Submit" button. Follow the instructions on the [www.regulations.gov](http://www.regulations.gov) website to view the docket index or access available documents. 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 Federal 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:** Colby Lintner, Regulatory Coordinator, Environmental Assistance Division, Office of Pollution Prevention and Toxics (7408M), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (202) 554-1404; e-mail address: [TSCA-Hotline@epa.gov](mailto:TSCA-Hotline@epa.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. General Information

###### A. Does this Action Apply to Me?

This action is directed to the public in general. As such, the Agency has not attempted to describe the specific entities that this action may apply to. Although others may be affected, this action applies directly to the submitter of the premanufacture notices addressed in the action. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

###### B. What Should I Consider as I Prepare My Comments for EPA?

1. *Submitting CBI.* Do not submit this information to EPA through [www.regulations.gov](http://www.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 that you mail to EPA, mark the outside of the disk or CD-ROM as CBI and then identify electronically