



BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPP-2017-0440; FRL-9966-08]

Agency Information Collection Activities; Proposed Renewal of an Existing Collection; Comment Request

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (PRA), this document announces that EPA is planning to submit an Information Collection Request (ICR) to the Office of Management and Budget (OMB). The ICR, entitled: “Plant-Incorporated Protectants; CBI Substantiation and Adverse Effects Reporting,” and identified by EPA ICR No. 1693.09 and OMB Control No. 2070-0142, represents the renewal of an existing ICR that is scheduled to expire on May 31, 2018. Before submitting the ICR to OMB for review and approval, EPA is soliciting comments on specific aspects of the proposed information collection that is summarized in this document. The ICR and accompanying material are available in the docket for public review and comment.

DATES: Comments must be received on or before **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA-HQ-OPP-2017-0440, by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you

consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

- *Mail*: OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at

<http://www.epa.gov/dockets/contacts.html>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Ryne Yarger, Field and External Affairs Division (7506P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 605-1193; email address: yarger.ryne@epa.gov.

SUPPLEMENTARY INFORMATION:

I. What Information is EPA Particularly Interested in?

Pursuant to PRA section 3506(c)(2)(A) (44 U.S.C. 3506(c)(2)(A)), 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.

II. What Information Collection Activity or ICR Does this Action Apply to?

Title: Plant-Incorporated Protectants; CBI Substantiation and Adverse Effects Reporting.

ICR number: EPA ICR No. 1693.09.

OMB control number: OMB Control No. 2070-0142.

ICR status: This ICR is currently scheduled to expire on May 31, 2018. 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 Code of Federal Regulations (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 for certain EPA regulations is consolidated in 40 CFR part 9.

Abstract: This ICR addresses the two information collection requirements described in regulations pertaining to pesticidal substances that are produced by plants (plant-incorporated protectants) and which are codified in 40 CFR part 174. A plant-incorporated protectant (PIP) is defined as “the pesticidal substance that is intended to be produced and used in a living plant and the genetic material necessary for the production of such a substance.” Many, but not all, PIPs are exempt from registration requirements under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Registrants sometimes include in a submission to EPA for registration of PIPs information that they claim to be CBI. CBI is protected by FIFRA and generally cannot be released to the public. For most pesticide registration applications, the current CBI regulations at 40 CFR part 2 require that claimants substantiate their CBI claims for their own records when the claim is made, and subsequently provide the substantiation to EPA only if requested. However, under 40 CFR part 174, whenever a registrant claims that information submitted to EPA in support of a PIP registration application contains CBI, the registrant must substantiate such claims to EPA when they are made. In addition, 40 CFR part 174 also requires manufacturers of PIPs that are otherwise exempted from registration requirements to report any adverse effects of the PIP to the Agency within 30 days of when the information is first obtained. Such reporting will allow the Agency to determine whether further action is needed to prevent unreasonable adverse effects to human health or the environment.

Burden statement: The annual public reporting and recordkeeping burden for this collection of information is estimated to average 21.5 hours per CBI substantiation and 7 hours per adverse effects reporting response. Burden is defined in 5 CFR 1320.3(b).

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 here:

Respondents/Affected Entities: Entities potentially affected by this ICR include producers and importers of PIPs. The NAICS codes for respondents under this ICR include: 325320 (Pesticide and other Agricultural Chemical Manufacturing), 325414 (Biological Products (except Diagnostic) Manufacturing), 422910 (Farm Supplies Wholesalers), 422930 (Flower, Nursery Stock, and Florist's Suppliers), 541710 (Research and Development in the Physical, Engineering, and Life Sciences), and 611310 (Colleges, Universities, and Professional Schools).

Estimated total number of potential respondents: 24.

Frequency of response: On occasion.

Estimated total average number of responses for each respondent: 1.

Estimated total annual burden hours: 518 hours.

Estimated total annual costs: \$41,892. There are no non-burden hour paperwork costs, e.g., investment or maintenance and operational costs, included in this information collection.

III. Are There Changes in the Estimates from the Last Approval?

There is an increase of 86 hours in the total estimated respondent burden compared with that identified in the ICR currently approved by OMB. This increase reflects EPA's updating of burden estimates for this collection based upon historical information on the number of CBI substantiations per year. Based upon revised

estimates, the number of CBI substantiations per year has increased from 20 to 24, with a corresponding increase in the associated burden. This change is an adjustment.

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** document 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 person listed under **FOR FURTHER INFORMATION CONTACT**.

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

Dated: August 17, 2017.

Louise P. Wise,

Acting Assistant Administrator,

Office of Chemical Safety and Pollution Prevention.