

once EPA revisits the original CBI claim(s).

EPA acknowledges that this approach would occasionally create the possibility that the application of the UID to submissions from two or more companies may alert each company to the other's manufacture of the same chemical substance. However, such disclosures frequently arise in the normal course of business under TSCA, independent of UID. One reason for this is that a single accession number is typically assigned to each Inventory substance, and the accession number is often used for subsequent reporting, *e.g.*, under the Chemical Data Reporting (CDR) rule. Accession numbers are also included alongside other regulatory information, such as relevant section 5 significant new use rule (SNUR) citations, reported in public databases, such as the Substance Registry Service (SRS), and in the Inventory file that EPA makes available to the public (confidential inventory chemicals are listed by PMN number, accession number, and generic name). (See <https://www.epa.gov/tscainventory/how-access-tscainventory>.) Anyone that has an accession number for a given confidential inventory substance can query the CDR database and learn whether other companies have manufactured the chemical in CDR-reportable amounts, or query the public Inventory to find out the PMN number of the original submission.

While not every company reports under the CDR for every chemical that they manufacture (for example, specialty chemical companies may be making relatively small quantities of a substance, for a specialized use, and may not meet the reporting thresholds for CDR), the fact that a chemical substance is on the Inventory can be revealed in other ways. For example, a company that intends to manufacture a chemical substance for commercial purposes may file a bona fide submission under 40 CFR 720.25 to determine whether the chemical substance is already on the Inventory. The response to the bona fide inquiry, where EPA tells the submitter whether a chemical substance is on the confidential portion of the Inventory, would indicate whether another company has manufactured the chemical substance for commercial purposes in the United States. Also, submitters of section 5 notices that are subsequently deemed to be invalid because the substance is already on the Inventory and thus not subject to section 5 reporting requirements are informed of the Inventory status and are provided the accession number.

This third alternative approach would avoid several problems that EPA has identified with assigning more than one UID to a single substance (see "Second Alternative Approach," May 8 **Federal Register** document (at 21389)). One such problem is that assigning more than one UID per chemical substance would work against one of the purposes of assigning UIDs, to "provide a specific reference identifier that protects the confidentiality claim to the specific chemical identity for the duration of the claim, while providing a way for the public to identify other filings pertaining to that substance." (See discussion in EPA's May 8 **Federal Register** document (at 21388).) In addition, it is unclear how multiple UIDs per chemical can be reconciled with the section 8(b)(7) requirement to publish and keep current a list of each confidential Inventory chemical, with its UID, accession number, generic name, and PMN number, where applicable. Any list that includes all of this information for each chemical would automatically link submissions from different companies by including all of the UIDs and/or by using the same accession number for multiple listings on the same chemical. (*i.e.*, if Chemical X has three UIDs, assigned to three different company claims, they would all be linked on this list, because Chemical X only has one accession number, and the list is supposed to include both accession number and UID.) It is also unclear to EPA how using one UID per chemical, per company, would operate in the case that a company or parts of a company changes ownership; how such UIDs would be applied to EPA-generated documents that are relevant to more than one submission; or how the multiple UIDs would be handled in the case that one company withdraws or permits its CBI claim to expire while the other does not. Using one UID per chemical, and applying that same UID to related documents in all but a very few exceptional cases, would avoid these issues.

C. Opportunity To Comment on Approach to Applying the Unique Identifier

EPA invites comment on the possible approach outlined above.

Authority: 15 U.S.C. 2613.

Dated: January 26, 2018.

Charlotte Bertrand,

Acting Principal Deputy Assistant Administrator, Office of Chemical Safety and Pollution Prevention.

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ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPP-2017-0687; FRL-9971-89]

Proposed Information Collection Request (EPA ICR No. 1204.13); Comment Request; Submission of Unreasonable Adverse Effects Information Under FIFRA Section 6(a)(2)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency is planning to submit an information collection request (ICR), "Submission of Unreasonable Adverse Effects Information under FIFRA Section 6(a)(2)" (EPA ICR No. 1204.13, OMB Control No. 2070-0039), to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act. Before doing so, EPA is soliciting public comments on specific aspects of the proposed information collection as described below. This is a proposed extension of the ICR, which is currently approved through September 30, 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.

DATES: Comments must be submitted on or before April 9, 2018.

ADDRESSES: Submit your comments, referencing Docket ID No. EPA-HQ-OPP-2017-0687 online using www.regulations.gov (our preferred method), by email to OPP_Docket@epa.gov, or by mail to: EPA Docket Center, Environmental Protection Agency, Mail Code 28221T, 1200 Pennsylvania Ave. NW, Washington, DC 20460.

EPA's policy is that all comments received will be included in the public 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.

FOR FURTHER INFORMATION CONTACT: Amaris Johnson, Field and External Affairs Division, Office of Pesticide Programs, (7506P), Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460; telephone number: (703) 305-9542; email address: johnson.amaris@epa.gov.

SUPPLEMENTARY INFORMATION:

Supporting documents which explain in detail the information that the EPA

will be collecting are available in the public docket for this ICR. The docket can be viewed online at www.regulations.gov or in person at the EPA Docket Center, WJC West, Room 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>.

Pursuant to section 3506(c)(2)(A) of the PRA, EPA is soliciting comments and information to enable it to: (i.) 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; (ii.) evaluate the accuracy of the Agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (iii.) enhance the quality, utility, and clarity of the information to be collected; and (iv.) 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. 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. At that time, EPA will issue another **Federal Register** notice to announce the submission of the ICR to OMB and the opportunity to submit additional comments to OMB.

Abstract: Section 6(a)(2) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) requires pesticide registrants to submit information to the Agency which may be relevant to the balancing of the risks and benefits of a pesticide product. The statute requires the registrant to submit any factual information that it acquires regarding adverse effects associated with its pesticidal products, and it is up to the Agency to determine whether or not that factual information constitutes an unreasonable adverse effect. In order to limit the amount of less meaningful information that might be submitted to the Agency, the EPA has limited the scope of factual information that the registrant must submit. The Agency's regulations at 40 CFR part 159 provide a detailed description of the reporting obligations of registrants under FIFRA section 6(a)(2).

Form Numbers: None.

Respondents/affected entities: Entities potentially affected by this ICR include

anyone who holds or has ever held a registration for a pesticide product issued under FIFRA Section 3 or 24(c). The North American Industrial Classification System (NAICS) is 325300 (Pesticide, Fertilizer and Other Agricultural Chemical Manufacturing).

Respondent's obligation to respond: Mandatory (FIFRA 6(a)(2)).

Estimated number of respondents: 1,452 (total).

Frequency of response: On occasion.

Total estimated burden: 301,118 hours (per year). Burden is defined at 5 CFR 1320.03(b).

Total estimated cost: \$19,999,815 (per year).

Changes in Estimates: There is an increase of 71,778 hours in the total estimated respondent burden compared with the ICR currently approved by OMB. This increase is due to the expectation that the number of responses will increase by 16% from 93,000 in the last ICR approval to approximately 108,000 for this ICR renewal. The increase is due to EPA's revised expectations regarding the number of incident reports that will be submitted to the Agency, which reflects historical information on the number of responses received. The increase in the number of incident reports has also prompted the need for additional information discussed in section 4 of the supporting statement. Since the last ICR was approved, the EPA has found it necessary to request additional data in certain subject areas under 40 CFR 159. First, due to a significant increase in the number of adverse incidents for spot-on domestic animal pet products from several registrants, EPA began requiring more standardized post-market surveillance reporting on adverse effects and submission of sales information, so the Agency can better evaluate incident rates. Second, the Agency requested additional information from the registrant of an herbicide to help explain circumstances for incidents of alleged tree and plant damage. Finally, new concerns about neonicotinoid pesticides and the loss of bee colonies led to EPA's request for more documentation from registrants for these products.

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

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

Dated: January 11, 2018.

Charlotte Bertrand,

Acting Principal Deputy Assistant Administrator, Office of Chemical Safety and Pollution Prevention.

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ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-ORD-2005-0530; FRL-9974-07-OEI]

Information Collection Request Submitted to OMB for Review and Approval; Comment Request; Application for Reference and Equivalent Method Determination (Renewal)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) has submitted an information collection request (ICR), "Application for Reference and Equivalent Method Determination (Renewal)" (EPA ICR No. 0559.13, OMB Control No. 2080-0005) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act. This is a proposed extension of the ICR, which is currently approved through February 28, 2018. Public comments were previously requested via the **Federal Register** on September 6, 2017 during a 60-day comment period. This notice allows for an additional 30 days for public comments. A fuller description of the ICR is given below, including its estimated burden and cost to the public. 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.

DATES: Additional comments may be submitted on or before March 12, 2018.

ADDRESSES: Submit your comments, referencing Docket ID Number EPA-HQ-ORD-2005-0530, to (1) EPA online using 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, and (2) OMB via email to oir_submission@omb.eop.gov.