SUMMARY: Recent amendments to the Toxic Substances Control Act (TSCA) require EPA to develop a system to assign a “unique identifier” whenever it approves a Confidential Business Information (CBI) claim for the specific chemical identity of a chemical substance, to apply this unique identifier to other information concerning the same substance, and to ensure that any nonconfidential information received by the Agency identifies the chemical substance using the unique identifier while the specific chemical identity of the chemical substance is protected from disclosure. EPA previously requested comment on approaches for assigning and applying unique identifiers, and has developed an additional approach on which it now requests comment.

DATES: EPA will accept written comments and materials submitted to the docket on or before March 12, 2018.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA–HQ–OPPT–2017–0144, by one of the following methods:

- Hand Delivery: To make special delivery of boxed information, please contact the EPA Dockets Office, 401 M Street SE, Washington, DC 20460–0001.
- Email: Dockets@epa.gov.

B. What should I consider as I prepare my comments for EPA?

1. Submitting CBI. Do not submit this information to EPA through regulations.gov or email. 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 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.

2. Tips for preparing your comments. When preparing and submitting your comments, see the commenting tips at http://www.epa.gov/dockets/comments.html.

II. Background

A. TSCA Section 14 Requirement To Assign a “Unique Identifier”

The June 22, 2016, amendments to TSCA by the Frank R. Lautenberg Chemical Safety for the 21st Century Act added a requirement in TSCA section 14(g)(4) for EPA to, among other things, “assign a unique identifier to each specific chemical identity for which the Administrator approves a request for protection from disclosure.” EPA is required to use the “unique identifier assigned under this paragraph to protect the specific chemical identity in information that the Administrator has made public” and to “apply that identifier consistently to all information relevant to the applicable chemical substance,” including “any nonconfidential information received by the Administrator with respect to a...
chemical substance... while the specific chemical identity of the chemical substance is protected from disclosure.” 15 U.S.C. 2613(g)(4).

The requirements to assign a unique identifier and the unreconciled requirements concerning application of the unique identifier and protection of CBI are more fully discussed in the Federal Register document published previously. (See 82 FR 21386; May 8, 2017; hereafter “May 8 Federal Register document.”) EPA has noted drawbacks to each of the two alternative approaches discussed in the May 8 Federal Register document.

EPA has developed a third alternative approach for reconciling the competing requirements of TSCA section 14(g), and now invites public comment on this new alternative.

A brief explanation of CBI claims for chemical identity provides context for understanding the potential effects of applying a unique identifier. TSCA section 14 permits a person to assert a CBI claim to seek to protect from public disclosure certain information in a submission, including a specific chemical identity. A CBI claim for specific chemical identity is intended to protect from disclosure the existence of the chemical substance and/or the fact that the chemical substance is (or is intended to be) manufactured by any person for commercial purposes in the United States (note that under TSCA, the term “manufacture” includes import).

When a chemical identity on the TSCA Inventory (Inventory) is claimed as CBI, then the chemical substance is maintained on the confidential portion of the Inventory. Conversely, a specific chemical identity that appears on the public portion of the Inventory, and is therefore known to be (or have been) manufactured for commercial purposes in the United States, is generally not eligible for confidential protection (see, e.g., Chemical Data Reporting regulations at 40 CFR 711.30(b)). If another company reveals that they manufacture the substance for commercial purposes, such as in a non-CBI submission filed under TSCA, the chemical identity is no longer eligible for confidential protection, and a CBI claim for chemical identity would be denied upon evaluation. Because the meaning of a CBI claim for chemical identity is limited, companies that wish to protect other information in a submission (such as company identity or specific information regarding the use, function, or application of that chemical substance) should claim that specific information as CBI rather than (or in addition to) chemical identity.

B. Third Alternative Approach

Under this approach, EPA would assign one unique identifier (UID) per chemical substance. In most cases EPA would apply the UID to all non-confidential information concerning the same chemical substance, from any company. However, in a small number of cases, EPA would not apply the UID to some non-confidential documents, in order to preserve approved CBI claims for specific chemical identity where the non-confidential document itself does not undermine the CBI claim, but EPA’s application of the UID to that document would result in a linkage that does undermine the CBI claim. The basic criterion for application of the UID to submissions made by different submitters is that the Agency’s act of applying the UID must not disclose to the public the confidential specific chemical identity that the UID was assigned to protect.

Specifically, prior to applying a UID to public versions of documents concerning the same substance, and filed by different submitters, those documents would be reviewed for presence of the specific chemical identity. If the specific chemical identity (e.g., Chemical Abstracts Service (CAS) name or CAS number) appears in any of the documents, EPA would revisit the CBI claim in the remaining document(s) to assure that the claim is unexpired and otherwise still valid. If the CBI claim remains valid, EPA would not apply the UID to the document that reveals the specific chemical identity, in order to preserve the CBI claim in the other document(s) (if the claim has expired, been withdrawn, or appears no longer valid, EPA would act in accordance with section 14(f)(2)(B) and/or 14(g)(4)(D), as appropriate). All of the documents would be available to the public, and the specific chemical identity would be revealed in the document where it was not claimed as CBI—the document revealing the specific chemical identity would simply not be connected by the UID to the other document(s) where the specific chemical identity is CBI.

For example, Company A files a Premanufacture Notice (PMN) and later, a Notice of Commencement (NOC), claiming chemical identity as CBI to protect from disclosure the fact that the chemical is now being manufactured for commercial purposes in the United States and hence is being added to the Inventory. EPA approves the CBI claim and assigns a UID. Company A subsequently submits a section 8(e) notice concerning the same substance, claiming chemical identity as CBI again.

The UID is applied to that submission as well. Sometime later, Company B files a section 8(e) notice on the same substance, which it asserts is being used for research and development (R&D) purposes, but does not claim chemical identity as CBI. EPA revisits Company A’s original CBI claim and confirms that it is not expired, has not been withdrawn, and has not been denied. Company B’s submission does not reveal that the substance is on the Inventory or that it is in commerce (as other than an R&D substance). If EPA applied the UID to Company B’s submission, that act would link Company B’s section 8(e) notice to Company A’s NOC, revealing that the specific chemical identity in Company B’s section 8(e) notice is also the subject of an NOC and has therefore been manufactured for commercial purposes, and is on the Inventory. Thus, EPA’s linkage of the two documents through the applied UID—as opposed to any information contained in the non-confidential document itself—would undermine the previously approved CBI claim for chemical identity. EPA would not apply the UID to Company B’s submission in this case, to preserve Company A’s CBI claim.

By way of contrast, if Company B’s non-confidential section 8(e) notice itself revealed that the chemical substance was manufactured for commercial purposes in the United States—for instance, if the filing were an incident report relating to the commercial manufacture or use of that chemical substance, as opposed to an R&D exploration as originally described—then this would indicate that Company A’s CBI claim may no longer be valid, and EPA would reevaluate the prior CBI claim in accordance with TSCA section 14(f)(2)(B) and/or 14(g)(4)(D), as appropriate.

EPA expects that exceptions to application of the UID will be fairly rare. For example, in reviewing all non-confidential section 8(e) submissions submitted over the past 5 years that included a CAS number (such that Inventory status can be readily checked), EPA found that fewer than 4% of these submissions mentioned substances that are currently on the confidential portion of the TSCA Inventory. Further, on preliminary review (i.e., without completing a full CBI review and determination), it appeared that several of these submissions were under circumstances indicating that the original CBI claim may have been withdrawn or otherwise became invalid, suggesting that there may be even fewer exceptional cases...
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.


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


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