

TABLE 2—LINURON HUMAN HEALTH AND ECOLOGICAL RISK ASSESSMENTS

Registration review case name and No.	Docket ID No.	Chemical review manager and contact information
Linuron, 0047	EPA-HQ-OPP-2010-0228	Katherine St. Clair, stclair.katherine@epa.gov , 703-347-8778.

III. How should comments, data and information be submitted?

EPA is providing another opportunity under 40 CFR 155.53(c) for interested parties to provide comments and input concerning the Agency’s draft human health and ecological risk assessments for the chemicals identified in this document. Such comments and input could address, among other things, the Agency’s risk assessment methodologies and assumptions, as applied to a draft risk assessment. The Agency will consider all comments received during the public comment periods and make changes, as appropriate, to a draft human health and/or ecological risk assessment. EPA will then issue a revised risk assessment, explain any changes to the draft risk assessment, and respond to comments.

As indicated in the November 29, 2016 **Federal Register** document, anyone may submit data or information in response to this document. To be considered during a pesticide’s registration review, the submitted data or information must meet the requirements enumerated in that document. To submit comments, or access the dockets, please follow the detailed instructions provided under **ADDRESSES** in the **Federal Register** document of November 29, 2016. If you have questions, consult the persons listed under **FOR FURTHER INFORMATION CONTACT**.

Authority: 7 U.S.C. 136 *et seq.*

Dated: February 2, 2017,

Yu-Ting Guilaran,

Director, Pesticide Re-Evaluation Division, Office of Pesticide Programs.

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ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPPT-2017-0144; FRL-9961-30]

Assignment and Application of the “Unique Identifier” Under TSCA Section 14; Notice of Public Meeting and Opportunity To Comment

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: Recent amendments to the Toxic Substances Control Act (TSCA)

require EPA 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 or submissions 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 is requesting comment on approaches for assigning and applying unique identifiers. In addition, EPA invites all interested parties to attend a public meeting to provide oral comment.

DATES: Meeting Date: The public meeting will be held from 1 p.m. to 4 p.m. on May 24, 2017.

Meeting Registration: You may register online (preferred) or in person at the meeting. To register online, for the meeting, go to: <https://tsc-unique-identifier.eventbrite.com>. Advance registration for the meeting must be completed no later than May 22, 2017. On-site registration will be permitted, but seating and speaking priority will be given to those who pre-register by the deadline.

Comments: EPA will hear oral comments at the meeting, and will accept written comments and materials submitted to the docket on or before July 7, 2017.

ADDRESSES: Meeting: The meeting will be held at the Ronald Reagan Building and International Trade Center, in the Horizon Ballroom, located at 1300 Pennsylvania Avenue Northwest, Washington, DC 20004. The meeting will also be available by remote access for registered participants. Registered participants will receive information on how to connect to the meeting prior to its start.

Comments: Submit your comments, identified by docket identification (ID) number EPA-HQ-OPPT-2017-0144, 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:** Document Control Office (7407M), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, 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>.

Meeting.

FOR FURTHER INFORMATION CONTACT: For technical information contact: Jessica Barkas, Environmental Assistance Division, Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460-0001; telephone number: (202) 250-8880; email address: barkas.jessica@epa.gov.

To request accommodation of a disability, please contact Jessica Barkas, preferably at least 10 days prior to the meeting, to give EPA as much time as possible to process your request.

For general information contact: The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554-1404; email address: TSCA-Hotline@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be affected by this action if you have or expect to submit information to EPA under TSCA. Persons who would use unique identifiers assigned by the Agency to seek information may also be affected by this action. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Manufacturers, importers, or processors of chemical substances (NAICS codes 325 and 324110), e.g., chemical manufacturing and petroleum refineries.

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 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.

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”

TSCA, as amended June 22, 2016, by the Frank R. Lautenberg Chemical Safety for the 21st Century Act, includes a requirement in 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 “clearly link the specific chemical identity to the unique identifier in such information to the extent practicable.” 15 U.S.C. 2613(g)(4).

The full requirements of TSCA section 14(g)(4) are as follows:

EPA must:

1. Develop a system to assign a unique identifier to each specific chemical identity for which the Administrator approves a request for protection from disclosure, which shall not be either the specific chemical identity or a structurally descriptive generic term. § 14(g)(4)(A)(i).

2. Apply that identifier consistently to all information relevant to the applicable chemical substance. § 14(g)(4)(A)(ii).

3. Annually publish and update a list of chemical substances, referred to by their unique identifiers, for which claims to protect the specific chemical

identity from disclosure have been approved, including the expiration date for each such claim. § 14(g)(4)(B).

4. Ensure that any nonconfidential information received by the Administrator with respect to a chemical substance included on that list while the specific chemical identity of the chemical substance is protected from disclosure under TSCA section 14 identifies the chemical substance using the unique identifier. § 14(g)(4)(C).

5. For each claim for protection of a specific chemical identity that has been denied by the Administrator or expired, or that has been withdrawn by the person who asserted the claim, and for which the Administrator has used a unique identifier assigned under § 14(g)(4) to protect the specific chemical identity in information that the Administrator has made public, clearly link the specific chemical identity to the unique identifier in such information to the extent practicable. § 14(g)(4)(D).

B. Assigning the Unique Identifier

The identifier cannot be the specific chemical identity, or a structurally descriptive generic term. TSCA section 14(a)(4)(A)(i). Consequently, EPA must develop a system to assign such identifiers for each substance for which it makes a final determination approving a CBI claim for specific chemical identity. EPA is considering using a numeric identifier, which will incorporate the year the claim was approved. Including this date will facilitate tracking of the expiration of the CBI claims for specific chemical identity made in that document, pursuant to TSCA section 14(f)(3). EPA considered using a pre-existing identifier, specifically accession numbers, but language in TSCA section 8(b)(7)(B) suggests that accession numbers were intended to be distinct from the unique identifier (15 U.S.C. 2607(b)(7)(B)), and expanding the use of accession numbers beyond their current use and purpose could be confusing (accession numbers are currently assigned following a notice of commencement of commercial manufacture or import under section 5, and identify chemicals that are or were formerly on the confidential portion of the TSCA Inventory, while the unique identifier is an outcome of a CBI determination under section 14—at this stage, very few chemicals with accession numbers have been subject to this new CBI review requirement, so the fact that a substance is identified using an accession number would not indicate anything reliable about whether chemical identity claims concerning the

substance had been reviewed (let alone when they might expire)).

C. Application of the Unique Identifier

Once the unique identifier is assigned, section 14(g)(4)(A)(ii) requires that EPA apply it to “all information relevant to the applicable chemical substance.” Section 14(g)(4)(C) instructs that any nonconfidential information received with respect to the chemical substance “while the specific chemical identity of the chemical substance is protected from disclosure,” identify the chemical substance using the unique identifier. In addition, section 14(g)(4)(D) requires that after the underlying CBI claim for specific chemical identity expires, is denied by EPA, or is withdrawn, specific chemical identity be “clearly link[ed]” to the unique identifier in public documents that previously used the unique identifier to “protect the specific chemical identity in information that the Administrator has made public.”

The two general requirements, (1) applying the unique identifier to other, non-confidential information concerning that substance (section 14(g)(4)(A)(ii) and (C)); and (2) “while the specific chemical identity is protected from disclosure,” using the unique identifier in a manner that would “protect the specific chemical identity in information that the Administrator has made public,” (section 14(g)(4)(C) and (D)), do not appear to be completely reconciled in the statute. EPA has identified several situations where applying the same unique identifier to every instance where information pertaining to the same chemical substance is reported under TSCA could cause CBI, including specific chemical identity, to be revealed.

The intent of Congress with respect to the protection of confidential chemical identities is explicit in the legislative history: “The Committee expects that redactions or the use of approved generic names or unique identifiers will be employed to meaningfully inform the public without comprising [sic] trade secrets.” H.R. Rep. No.114–176, at 30 (2015). Yet the specific instructions in section 14(g)(4) regarding assigning, applying, publishing and using the unique identifier would in some cases seem to disclose the very CBI that Congress has directed EPA to protect. Following is a more detailed discussion of the statutory provision. EPA desires comment on how to reconcile the different objectives of the provision.

TSCA section 14(g)(4)(A)(ii) states that EPA shall apply the unique identifier “consistently to all

information relevant to the applicable chemical substance.” Section 14(g)(4)(C) states that EPA shall “ensure that any nonconfidential information . . . with respect to a chemical substance” for which a unique identifier has been assigned “identifies the chemical substance using the unique identifier.” Reading these words in isolation suggests that a particular chemical substance would have a single unique identifier, assigned the first time EPA makes a final determination concerning a CBI claim to protect the specific chemical identity of that substance, and applied to public versions of other filings pertaining to that substance. Section 14(g)(4)(A)(ii) and (C). Further, if the CBI claim is later denied, expires, or is withdrawn, EPA is required (to the extent practicable) to clearly link the specific chemical identity to the unique identifier in any information that it has made public that used the unique identifier to protect the specific chemical identity. § 14(g)(4)(D). The purpose of the unique identifier is 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.

However, having a single unique identifier that is publicly applied to every submission containing that chemical identity and used for every instance in which there is nonconfidential information concerning that chemical substance may cause CBI to be revealed to one or more other parties (or the public at large), in some circumstances the specific chemical identity that EPA has determined is entitled to confidential treatment, and which was intended to be protected as noted in section 14(g)(4)(C) and (D).

If documents concerning the same substance, submitted by different companies, at different times, and for different purposes, were to always be assigned the same unique identifier, then each company could learn that the substance was marketed in the United States by another company, and possibly learn of new uses and other information concerning the substance. Thus, one of the rationales for a CBI claim for specific chemical identity, *i.e.*, that the chemical substance is manufactured for commercial purposes in the United States, might be disclosed to competitors, undermining the protection of that specific chemical identity that is part of the purpose for section 14(g)(4).

Example 1: Company A files a Premanufacture Notice (PMN) and later commences import of Chemical X, for

which its CBI claim for chemical identity is approved by EPA, resulting in Chemical X being placed on the confidential portion of the TSCA Inventory. Company B subsequently files a notice of substantial risk under TSCA section 8(e) on the same substance, which it is utilizing for research and development, also claiming chemical identity as CBI. EPA approves this claim and assigns the same unique identifier.

By connecting submissions from different companies with the unique identifier, Company B can determine the confidential information that Chemical X is in US commerce (without having to submit and meet the terms of a *bona fide* request under 40 CFR 720.25). Both companies can now determine that another company has an active interest in the same chemical. Both companies also can determine any non-CBI information about the other company, uses, or other information that might be in the other submission.

Further, if the specific chemical identity is not uniformly claimed as CBI in all such submissions, applying the unique identifier to a submission with a non-confidential chemical identity effectively destroys the CBI claim for chemical identity in all other documents that use the same unique identifier. *E.g.*, in Example 1, if Company B chose to *not* claim chemical identity as CBI in its section 8(e) filing regarding an R & D use, and EPA applied the unique identifier to the section 8(e) submission, this submission could be readily linked to Company A’s submission, and the confidential chemical identity in Company A’s submission would be revealed to the public, along with the fact that Chemical X is in commerce in the United States.

There are additional circumstances where the action or inaction of one company could cause the CBI of another company to be revealed:

Example 2: EPA receives and approves Company A’s CBI claim for chemical identity in a Notice of Commencement (NOC). The substance is placed on the confidential portion of the Inventory and a unique identifier is assigned. Subsequently, Company B files a bona fide notice concerning the same substance. Company B does not claim chemical identity as CBI. In accordance with section 14(g)(4)(C), EPA applies the unique identifier to the public version of the bona fide submission.

Applying the unique identifier to the *bona fide* submission effectively discloses the identity of Company A’s chemical, and reveals that the substance

is in US commerce. Because it is now not a secret that the substance is in US commerce, the substance would be removed from the confidential portion of the Inventory, and all information concerning uses, company identity, and other information that was not claimed as CBI in the underlying PMN, NOC, and the *bona fide* notice could be linked together, potentially further disclosing information about the chemical that the other company may have claimed as confidential.

Alternative Approaches

Following are two alternative approaches to applying the unique identifier to other submissions for the same chemical substance to meaningfully inform the public without compromising trade secrets. These approaches are intended to give the greatest possible effect to the language of section 14(g)(4) concerning the application of the unique identifier to related submissions, while (also in accordance with section 14(g)(4)) maintaining the EPA-approved confidentiality of certain chemical identities. EPA invites comments on applying the unique identifier to all submissions containing a particular chemical substance and on these alternative approaches, as well as suggestions for other possible approaches.

First Alternative

There are readings of section 14(g)(4) that may avoid or ameliorate what are otherwise contradictory instructions. For example, section 14(g)(4)(C) may plausibly be read as instructing EPA to ensure that any non-confidential information received by EPA concerning a confidential chemical substance should identify the substance using *only* the unique identifier, so long as the confidential identity remains protected from disclosure. In this way, the public (including other companies) could identify the various submissions concerning a particular chemical, but could not identify the specific chemical.

However, the fact that information not claimed as confidential would need to be treated as such might be viewed as inconsistent with policy (as reflected in the FOIA and in TSCA amendments) to limit CBI protection to relatively narrow set of circumstances. This option also presents a number of implementation challenges. For example, this approach would require EPA to carefully screen incoming, non-CBI submissions against its list of confidential chemical names, and to treat as CBI information to which no such claim was made, a process that carries considerable risk of error.

Further, the facts of a specific case may affect whether the original, unaltered and non-CBI submissions could be prevented from release pursuant to a Freedom of Information Act (FOIA) request. Finally, screening and redacting submissions in this way may be such a burden on EPA resources as to be impracticable.

Second Alternative

Under this approach, unique identifiers, once assigned, are applied to other submissions concerning that chemical substance, but only those that are submitted by the *same* person/company. Additional submissions concerning the same substance that are submitted by a different company would be assigned a different unique identifier. The unique identifier would not be applied to or associated with non-confidential information if the effect of that application would be to reveal the identity of an approved confidential chemical that is otherwise protected from disclosure under section 14. The public would be able to link some submissions on the same chemical, but not necessarily all submissions on that chemical.

The public could use generic identities and the identities provided in non-confidential filings to group together submissions on similar chemicals, but would not be able to tell, with certainty, whether filings bearing different unique identifiers pertain to the same chemical or two different chemicals with generically similar structures. This option at least partly fulfills the intent to link information concerning the same substance, while maintaining the approved confidentiality claims of each submitter, until such claims are withdrawn, expire, or are subsequently denied by EPA. At that time, EPA would then append or otherwise make known to the public the specific identity that corresponds to the unique identifier used in such filings, in accordance with section 14(g)(4)(D).

EPA notes that this alternative is consistent with EPA's history of reconciling ambiguities and apparent contradictions concerning TSCA confidentiality. Since the inception of TSCA, the Agency has needed to balance the requirements and interests in protecting confidentiality with the requirements and interests in public disclosure of chemical information. For example, in the preamble to the final rule establishing the initial TSCA Inventory, EPA discussed an apparent conflict between TSCA sections 8(b) and 5(a)'s requirements to include certain chemical identities on the Inventory (to

publish a list of "each chemical substance which is manufactured in the United States," including "each chemical substance which any person reports under section 5"), and section 14's requirement that information exempt from disclosure under FOIA exemption 4 (5 U.S.C. 552(b)(4)) not be disclosed except in accordance with section 14(a) and (b). 42 FR 64573 (December 23, 1977). EPA ultimately resolved this apparent conflict by attempting to balance the competing concerns (informing the public and defining what is a new chemical under TSCA, versus protecting CBI and trade secrets) by creating a confidential portion of the Inventory, and setting up the bona fide inquiry process to permit limited disclosure of CBI to individual companies seeking to determine whether they are required to file a PMN.

Another example can be found in the preamble to the final rule implementing section 12(b) of TSCA, the export notification requirements. 45 FR 82847 (December 16, 1980). Section 12(b) requires EPA to report certain specific chemical identities to certain foreign governments under specified circumstances. Section 14(b) prohibits disclosure of information claimed as CBI except under specified circumstances, such that it appeared that EPA could not report the information required under section 12(b) without violating section 14. Reasoning that because the statute must be interpreted to give the fullest possible effect to both sections, EPA concluded that section 12(b) requires the notification to foreign governments, even if the chemical identity is confidential, but prohibits disclosure of such confidential information to other persons. Otherwise, the notification required by section 12(b) would be meaningless and not carry out the purpose of the section.

D. Opportunity To Comment on Approach To Applying the Unique Identifier

In addition to general comments on the possible approaches outlined above, EPA invites comment on other suggested approaches.

III. Meeting

A. Remote Access

The meeting will be accessible remotely for registered participants. Registered participants will receive information on how to connect remotely to the meeting prior to its start.

B. Public Participation at the Meeting

Anyone may register to attend the meeting as observers and may also register to provide oral comments on the day of the meeting. A registered speaker is encouraged to focus on issues directly relevant to the meeting's subject matter. Based on level of interest in speaking, each speaker may be limited to five minutes to provide oral comments. To accommodate as many registered speakers as possible, speakers may present oral comments only, without visual aids or written material.

C. Submitting Written Materials

Anyone may submit written materials to the docket as described under **ADDRESSES**.

IV. How can I request to participate in the meeting?

A. Registration

To attend the meeting in person or to receive remote access, you must register no later than May 22, 2017, using the method described under **DATES**. While on-site registration will be available, seating will be on a first-come, first-served basis, with priority given to early registrants, until room capacity is reached. The Agency anticipates that approximately 150 people will be able to attend the meeting in person. For registrants not able to attend in person, the meeting will also provide remote access capabilities; registered participants will be provided information on how to connect to the meeting prior to its start.

B. Required Registration Information

Members of the public may register to attend as observers or speak if planning to offer oral comments during the scheduled public comment period. To register for the meeting online, you must provide your full name, organization or affiliation, and contact information to the on-line signup. Do not submit any information in your request that is considered CBI. Requests to participate in the meeting, identified by docket ID No. EPA-HQ-OPPT-2017-0144, must be received on or before May 22, 2017.

Authority: 15 U.S.C. 2613.

Dated: April 21, 2017.

Louise P. Wise,

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

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