



ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPPT-2017-0652; FRL-9974-82]

Draft Guidance on Expanded Access to TSCA Confidential Business Information; Notice of Availability and Comment Request

RIN 2070-ZA19

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The amendments to the Toxic Substances Control Act in June 2016 expand the categories of people to whom EPA may disclose TSCA confidential business information (CBI) by specifically authorizing EPA to disclose TSCA CBI to state, tribal, and local governments; environmental, health, and medical professionals; and emergency responders, under certain conditions, including consistency with guidance that EPA is required to develop. This document announces the availability of and solicits comments on three draft guidance documents that address this requirement. These documents are available in the docket for public review and comment.

DATES: Comments must be received on or before [*INSERT DATE [30] DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER*].

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA-HQ-OPPT-2017-0652, 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>.

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.

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. Executive Summary

A. What Action is EPA Taking?

As directed by TSCA, EPA has developed draft guidance for each of three new expanded TSCA CBI access provisions. The guidance documents cover the content and form of the agreements and statements of need required under each provision, and include some basic logistical information on where and how to submit requests to EPA. EPA invites comment from prospective guidance users and other stakeholders concerning these draft guidance documents.

B. What is the Agency's Authority for Taking this Action?

TSCA section 14(c)(4)(B) requires that EPA develop guidance concerning the "content and form of the statements of need and agreements required" under TSCA section 14(d)(4), (5), and (6). 15 U.S.C. 2613.

C. Does this Action Apply to Me?

You may be potentially affected by this action if you are a state, tribal, or local government, or are employed by a government (federal, state, local, or tribal) or in the private sector and your duties concern: chemical regulation; chemical-related law enforcement; diagnosing or treating chemical exposures; and/or chemical spill, incident, accident, or emergency response, including injury to humans or the environment. You may also be affected by this action if you have or may in the future submit information to EPA that you claim qualifies as TSCA CBI.

D. What are the Potential Incremental Economic Impacts of Taking this Action?

The potential incremental economic impacts that are associated with the information collection activities contained in the guidance documents are enumerated in the Information Collection Request (ICR) entitled "Guidance on Expanded Access to TSCA Confidential Business Information" (EPA ICR No. 2570.01 and OMB Control No. 2070-(new)), which published in the **Federal Register** on March 12, 2018 (83 FR 10719) (FRL-9975-24). The annual public reporting and recordkeeping burden for this collection of information is estimated to average 14.8 hours and cost about \$868 per response.

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

1. *Submitting CBI.* Do not submit CBI to EPA through regulations.gov or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI 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

Enacted on June 22, 2016, the Frank R. Lautenberg Chemical Safety for the 21st Century Act (P.L. 114-182), changed and expanded many parts of TSCA (15 U.S.C. 2601 *et seq.*). Among these changes, amended TSCA section 14(d) expands the categories of people who may now access TSCA CBI. TSCA CBI is information submitted to EPA under TSCA, for which a business has made a claim of business confidentiality which has not been withdrawn by the business, expired, or denied by EPA. There are three new provisions expanding access to CBI, each under certain conditions:

- Under TSCA section 14(d)(4), 15 U.S.C. 2613(d)(4), EPA may disclose CBI to state, tribal, and local governments;
- Under TSCA section 14(d)(5), 15 U.S.C. 2613(d)(5), EPA may, in non-emergency situations, disclose CBI to a health or environmental professional employed by a Federal or state agency or tribal government, or to a treating physician or nurse; and
- Under TSCA section 14(d)(6), 15 U.S.C. 2613(d)(6), EPA may in the event of an emergency disclose CBI to a treating or responding physician, nurse, agent of a poison control center, public health or environmental official of a state, political subdivision of a state, or tribal government, or to a first responder (including any individual duly authorized by a Federal agency, state, political subdivision of a state, or tribal government who is trained in urgent medical care or other emergency procedures, including a police officer, firefighter, or emergency medical technician).

The conditions for access vary under each of the new provisions, but generally include the following;

- The requester must show that he or she has a need for the information related to their employment, professional, or legal duties;
- The recipient of TSCA CBI is prohibited from disclosing or permitting further disclosure of the information to individuals not authorized to receive it (physicians/nurses may disclose the information to their patient); and
- EPA generally must notify the entity that made the CBI claim at least 15 days prior to disclosing the CBI. There is an exception for disclosures in emergency situations, which require that EPA make the notification as soon as practicable (see TSCA section 14(g)(2)(C)(ii)).

In addition, under these new provisions, requesters are generally required to sign an agreement and may be required to submit a statement of need to EPA. Emergency requesters only need to sign an agreement and submit a statement of need if the entity who made the claim so requests, following the notification required under TSCA section 14(g)(2)(C)(ii).

III. Draft Documents for Public Review

Draft Implementing Guidance.

The Agency developed three separate draft guidance documents corresponding to each of the new authorities in TSCA section 14(d)(4), (5), and (6). The conditions for access vary under each of the new provisions, but generally include the following: requesters must show that they have a need for the information related to their employment, professional, or legal duties; recipients of TSCA CBI are prohibited from disclosing or permitting further disclosure of the information to individuals not authorized to receive it (physicians/nurses may disclose the information to their patient); and except in emergency situations EPA must notify the entity that made the CBI claim at least 15 days prior to disclosing the CBI. In addition, under these new provisions, requesters (except in some emergency situations) are required to sign an agreement and may be required to submit a statement of need to EPA. In accordance with the requirements of TSCA section 14(c)(4)(B), each guidance document covers the content and form of the agreements and statements required under each provision and include information on where and how to submit requests to EPA.

IV. Statutory and Executive Order Reviews

Additional information about these statutes and Executive Orders can be found at <https://www.epa.gov/laws-regulations/laws-and-executive-orders>.

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review

OMB has determined that these draft guidance documents qualified as significant under Executive Order 12866 (58 FR 51735, October 4, 1993). As such, the draft documents were submitted to OMB for review under Executive Orders 12866 and 13563 (76 FR 3821, January 21, 2011). Any changes to the documents that were made in response to OMB recommendations have been documented in the docket for this action as required by section 6(a)(3)(E) of Executive Order 12866.

B. Paperwork Reduction Act (PRA)

In the **Federal Register** on March 12, 2018 (83 FR 10719) (FRL-9975-24), EPA announced the availability of and solicited comment on the draft ICR entitled “Guidance on Expanded Access to TSCA Confidential Business Information” (EPA ICR No. 2570.01 and OMB Control No. 2070-(new)). The ICR identifies the information collection activities contained in the draft guidance and provides EPA’s estimates for the related burden and costs. The ICR, after addressing comments received, will be submitted to OMB for review and approval under the PRA, 44 U.S.C. 3501 *et seq.*

C. Regulatory Flexibility Act (RFA)

This action is not subject to the RFA, 5 U.S.C. 601 *et seq.* The RFA applies only to rules subject to notice and comment rulemaking requirements under the Administrative Procedure Act (APA), 5 U.S.C. 553, or any other statute. This action is not subject to the APA but is subject to TSCA, which does not require notice and comment rulemaking to take this action.

D. Unfunded Mandates Reform Act (UMRA)

This action does not contain an unfunded mandate of \$100 million or more as described in UMRA, 2 U.S.C. 1531-1538, and does not significantly or uniquely affect small governments. As such, the requirements of UMRA sections 202, 203, 204, or 205, 2 U.S.C. 1531–1538, do not apply to this action.

E. Executive Order 13132: Federalism

This action does not have federalism implications. It will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132 (64 FR 43255, August 10, 1999).

F. Executive Order 13175: Consultation and Coordination with Indian Tribal Governments

This action does not have tribal implications because it will not have any effect on tribal governments, on the relationship between the Federal government and the Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes, as specified in Executive Order 13175 (65 FR 67249, November 9, 2000).

G. Executive Order 13045: Protection of Children from Environmental Health Risks and Safety Risks

EPA interprets Executive Order 13045 (62 FR 19885, April 23, 1997), as applying only to those regulatory actions that concern environmental health or safety risks that EPA has reason to believe may disproportionately affect children, per the definition of “covered regulatory action” in section 2–202 of Executive Order 13045. This action is not subject to Executive Order 13045 because it does not establish an environmental standard intended to mitigate environmental health risks or safety risks.

H. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use

This action is not a “significant energy action” as defined in Executive Order 13211 (66 FR 28355, May 22, 2001), because it is not likely to have a significant adverse effect on energy supply, distribution, or use. This action is proposing service fees for TSCA, which will not have a significant effect on the supply, distribution or use of energy.

I. National Technology Transfer and Advancement Act (NTTAA)

Since this action does not involve any technical standards, NTTAA section 12(d) (15 U.S.C. 272 note) does not apply to this action.

J. Executive Order 12898: Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations

EPA believes that this action does not have disproportionately high and adverse human health or environmental effects on minority populations, low-income populations and/or indigenous peoples, as specified in Executive Order 12898 (59 FR 7629, February 16, 1994). This action does not affect the level of protection provided to human health or the environment.

Authority: 15 U.S.C. 2613(c).

Dated: March 12, 2018,

Charlotte Bertrand,

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

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