

Prepublication Copy Notice:

The EPA Administrator signed the following *Federal Register* document on June 21, 2018:

Title: **Guidance on Expanded Access to TSCA Confidential Business Information; Notice of Availability**

Action: **Notice**

FRL: **FRL-9979-75**

Docket No.: **EPA-HQ-OPPT-2017-0652**

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ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPPT-2017-0652; FRL-9979-75]

Guidance on Expanded Access to TSCA Confidential Business Information; Notice of Availability

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The amendments to the Toxic Substances Control Act in June 2016 expanded 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 three guidance documents that address this requirement.

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 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 maintains a list of Significant Guidance Documents at <http://www.epa.gov/regulations/guidance/> as called for by the Office of Management and Budget's (OMB) Final Bulletin for Agency Good Guidance Practices (<https://www.gpo.gov/fdsys/pkg/FR-2007-01-25/pdf/E7-1066.pdf>). Please be aware that the EPA list of Significant Guidance Documents does not include every guidance document issued by EPA and only encompasses those documents that are "significant" as defined by OMB's Bulletin.

These final documents have been determined to be EPA Significant Guidance Documents per the OMB Bulletin definition and are included on the EPA list of significant guidance documents. OMB's Bulletin directs agencies to allow for the public to submit comments on any Significant Guidance Document that appears on the Agency's list of significant guidance documents. EPA allows for public comments to be submitted through the Agency's electronic docket and commenting system at <http://www.regulations.gov>. Please note that although you may receive an acknowledgement that EPA has received your comment, you may not receive a detailed response to your comment. Your feedback is nevertheless important to EPA and will be forwarded to the appropriate program for consideration.

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 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. The comment period closed on May 11, 2018. No comments were received.

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, TSCA section 14(d) as amended 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 or person authorized to make medical or health care decisions on behalf of the 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 requestors only need to sign an agreement and submit a statement of need if the person who made the claim so requests, following the notification required under TSCA section 14(g)(2)(C)(ii).

III. Response to Public Comments

EPA previously collected public comment on draft versions of the three guidance documents (83 FR 11748 (March 16, 2018)). Thirteen relevant comments were received, from state governments and government organizations (3), tribal governments (2), industry (3), a utility group (1), a fire fighters' organization (1), and medical, health and environmental groups (3). Most commentary on the guidance documents concerned EPA's request processing time; the scope of some definitions in the 14(d)(5) and (d)(6) documents; requested additional means through which to request or access information; suggested revisions to a provision in the confidentiality agreements included in the 14(d)(5) and (d)(6) documents; or requested that EPA establish a contact available for emergency requests after business hours. A Response to Comments document is available in the docket for this action.

IV. References

The following is a listing of the documents that are specifically referenced in this document. The docket includes these documents and other information considered by EPA, including documents that are referenced within the documents that are included in the docket, even if the referenced document is not physically located in the docket. For assistance in locating these other documents, please consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

EPA. 2018. Response to Comment Document for TSCA Section 14(d) Guidance Documents.

V. 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 guidance documents qualify as significant under Executive Order 12866 (58 FR 51735, October 4, 1993). As such, the 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 guidance and provides EPA's estimates for the related burden and costs. The comment period closed on May 11, 2018. No comments were received. The final ICR 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

Consistent with the EPA Policy on Consultation and Coordination with Indian Tribes, the EPA consulted with tribal officials during the development of this action. EPA

coordinated and engaged with tribal partners early in the process during the development of the guidance documents as well as continued to conduct outreach to tribes during the release of the draft guidance documents. In addition, EPA held a tribal consultation with tribes that requested further information. The Agency plans to continue to work with our tribal partners to introduce the guidance and provide a forum for open dialogue with tribes.

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 announcing the availability of guidance concerning obtaining access to CBI under 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.

VI. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 et seq. does not apply because this action is not a rule as that term is defined in 5 U.S.C. 804(3).

Administrator signature for the document identified under FRL-9979-75 (18T-0141) and
SAN 6410 is on
Page **10** of **10** total pages.

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

Dated: 6/21/2016

A handwritten signature in blue ink, appearing to read "E. Scott Pruitt", written over a horizontal line.

E. Scott Pruitt

Administrator.