

## **Prepublication Copy Notice:**

The EPA Administrator signed the following *Federal Register* document on June 22, 2017:

Title: **Guidance to Assist Interested Persons in Developing and Submitting Draft Risk Evaluations Under the Toxic Substances Control Act; Notice of Availability**

Action: **Notice.**

FRL: 9964-25

Docket No.: **EPA-HQ-OPPT-2017-0341**

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Once the official version of the document publishes in the *Federal Register*, the prepublication version of the document posted on the agency's internet will be replaced with a link to the document that appears in the *Federal Register* publication. At that time, you will also be able to access the on-line docket for this *Federal Register* document at <http://www.regulations.gov>.

For further information about the docket and, if applicable, instructions for commenting, please consult the ADDRESSES section in the front of the *Federal Register* document.

**ENVIRONMENTAL PROTECTION AGENCY**

**[EPA-HQ-OPPT-2017-0341; FRL-9964-25]**

**Guidance to Assist Interested Persons in Developing and Submitting Draft Risk**

**Evaluations Under the Toxic Substances Control Act; Notice of Availability**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice.

**SUMMARY:** As required by the Toxic Substances Control Act (TSCA), which was amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act in June 2016, EPA is announcing the availability of a guidance document, entitled “Guidance to Assist Interested Persons in Developing and Submitting Draft Risk Evaluations Under the Toxic Substances Control Act”. This guidance document is intended to assist interested persons, or external parties, in developing and submitting draft risk evaluations to be considered by EPA under TSCA. The guidance document addresses the science standards, the data quality considerations, and the steps of the risk evaluation process that external parties should follow when developing draft risk evaluations for consideration by EPA.

**FOR FURTHER INFORMATION CONTACT:** *For technical information contact: Iris Camacho, Risk Assessment Division, Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (202) 564-1229; email address: TSCA-externalparty@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. General Information***A. Does this Action Apply to Me?*

You may be potentially affected by this action if you are interested in developing and submitting a draft chemical specific risk evaluation to the Agency for consideration under TSCA. Since there are a number of entities that may be interested, the Agency has not attempted to describe all the specific entities and corresponding NAICS codes for entities that may be interested in or affected by this action.

*B. How can I get copies of this document and other related information?*

The docket for this action, identified by docket identification (ID) number EPA-HQ-OPPT-2017-0341, is available online at <http://www.regulations.gov> or in person at the Office of Pollution Prevention and Toxics Docket (OPPT Docket), Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW., Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPPT Docket is (202) 566-0280. Please review the visitor instructions and additional information about the docket that is available at <http://www.epa.gov/dockets>.

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

This action implements TSCA section 26(l)(5), 15 U.S.C. 2601 *et seq.*

**II. Background**

On June 22, 2016, the “Frank R. Lautenberg Chemical Safety for the 21st Century Act” was signed into law, thereby amending the 1976 Toxics Substances Control Act. One

of the key features of the amended law is the requirement that EPA prioritize and assess existing chemicals, and manage identified unreasonable risks. Through a combination of new authorities, a risk-based assessment mandate, deadlines for action, and minimum throughput requirements, TSCA effectively creates a process by which EPA will conduct risk evaluation and management of existing chemicals. The law also requires EPA to develop guidance to assist external parties in submitting draft risk evaluations for EPA consideration under TSCA. To facilitate that consideration, the guidance is required, at a minimum, to address the quality of the information submitted and the process to be followed in developing the draft risk evaluations.

The guidance avoids being prescriptive as to EPA's approaches – and consequently the guidance that EPA would provide to external parties – will likely evolve over time, and new relevant guidance documents will be developed as necessary. EPA's goal is to ensure that external parties have flexibility to use the best available science by adapting and keeping current with changing science. The guidance may be refined, updated, or superseded in the future to capture the latest changes to the risk evaluation process resulting from Agency experience, advances in science, and future guidance which may be developed or updated.

EPA expects external party draft risk evaluations to be of the same high quality as those developed by EPA. To that end, the guidance discusses the science standards, data quality considerations, and the steps of the risk evaluation process that external parties should follow when developing draft TSCA risk evaluations. Having these key factors in the risk evaluation process laid out in the guidance will foster predictability by transparently communicating EPA's expectations.

### **III. What Action is the Agency Taking?**

EPA is announcing the availability of a guidance document, entitled "Guidance to Assist Interested Persons in Developing and Submitting Draft Risk Evaluations Under the Toxic Substances Control Act". This guidance document is intended to assist interested persons, or external parties, in developing and submitting draft risk evaluations to be considered by the EPA Administrator under TSCA.

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.

This final document has been determined to be an EPA Significant Guidance Document per the OMB Bulletin definition and is 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.

**Authority:** 15 U.S.C. 2601 *et seq.*

Dated: June 22, 2017.

E. Scott Pruitt,

*Administrator.*