



## **ENVIRONMENTAL PROTECTION AGENCY**

**[EPA-HQ-OPPT-2016-0658; FRL-9955-38]**

### **New Chemicals Review Program under the Amended Toxic Substances Control Act; Notice of Public Meeting and Opportunity for Public Comment**

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

**ACTION:** Notice.

**SUMMARY:** EPA is holding a meeting to update the public on changes to the New Chemicals Review Program under the Toxic Substances Control Act as amended by the Frank R. Lautenberg Chemical Safety for the 21<sup>st</sup> Century Act (TSCA). EPA will describe its review process for new chemicals under the amended statute, as well as discuss issues, challenges, and opportunities that the Agency has identified in the first few months of implementation. The meeting will provide interested parties with an opportunity to provide input on their experiences with the New Chemicals Review Program, including submittal of pre-manufacture notices (PMNs), microbial commercial activities notices (MCANs), and significant new use notices (SNUNs) under section 5 of the law. Information obtained during these meetings will be considered as the Agency works to implement the new requirements and increase efficiency in its review process under TSCA.

**DATES:** The meeting will be held on December 14, 2016 from 9:00 a.m. to 3:00 p.m. Requests to participate in the meeting must be received on or before December 13, 2016. On-site registration will be permitted, but seating and speaking priority will be given to those who pre-register by the deadline.

To request accommodation of a disability, please contact the meeting logistics person listed under **FOR FURTHER INFORMATION CONTACT**, preferably at least 10 days prior to the meeting, to give EPA as much time as possible to process your request.

EPA will hear oral comments at the meeting, and will accept written comments and materials submitted to the docket on or before January 14, 2016.

**ADDRESSES:** The meeting will be held at The Ronald Reagan Building and International Trade Center, Polaris Room, 1300 Pennsylvania Avenue Northwest, Washington, DC 20004. The meetings will also be available by remote access for registered participants. For further information, see Unit III.A. under **SUPPLEMENTARY INFORMATION**.

To participate in the meeting, identified by docket identification (ID) number EPA-HQ-OPPT-2016-0658, you may register online (preferred) or in person at the meeting. To register online, for the meeting, go to <https://tscanewchemicals.eventbrite.com>.

Written comments, identified by the docket ID number, EPA-HQ-OPPT-2016-0658, can be submitted 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 in general is available at <http://www.epa.gov/dockets>.

**FOR FURTHER INFORMATION CONTACT:**

*For technical information contact:* Greg Schweer, Chemical Control Division (7405M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (202)564-8469; email address: [schweer.greg@epa.gov](mailto:schweer.greg@epa.gov).

*For meeting logistics or registration contact:* Klara Zimmerman, Abt Associates; telephone number: (301) 634-1722; email address: [Klara\\_Zimmerman@abtassoc.com](mailto:Klara_Zimmerman@abtassoc.com).

*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](mailto:TSCA-Hotline@epa.gov).

**SUPPLEMENTARY INFORMATION:**

**I. General Information**

*A. Does this Action Apply to Me?*

This action is directed to the public in general, and may be of interest to a wide range of stakeholders including chemical manufacturers, processors and users, consumer product companies, non-profit organizations in the environmental and public health sectors, state and local government agencies, and members of the public interested in the

environmental and human health assessment and regulation of chemical substances. Since others also may be interested, the Agency has not attempted to describe all the specific entities that may be 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 ID number EPA-HQ-OPPT-2016-0658, is available at <http://www.regulations.gov> or 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 available at <http://www.epa.gov/dockets>. Documents and meeting information will also be available at the registration website and on EPA's new chemicals website at <https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca>.

## **II. Background**

On June 22, 2016, President Obama signed into law the Frank R. Lautenberg Chemical Safety for the 21<sup>st</sup> Century Act, which amended the TSCA Act of 1976. A number of statutory changes have enhanced the EPA's authority to evaluate chemicals and make determinations regarding their unreasonable risk to health and the environment prior to commercialization. Specifically, under section 5 of the amended TSCA, there are new requirements and additional determinations that EPA must make. These requirements provide EPA new authority to review and determine risk associated with the

manufacturing and processing of new chemicals.

*Background on EPA's New Chemicals Review Program.* EPA's New Chemicals Review Program has and will continue to help manage the potential risk to human health and the environment from chemicals new to the marketplace. The program functions as a "gatekeeper" that can identify conditions, up to and including a ban on production, to be placed on the use of a new chemical before it is entered into commerce. Under section 5 of TSCA, anyone who plans to manufacture (including import) a new chemical substance for a non-exempt commercial purpose, is required to provide EPA with notice before initiating the activity. Additionally, EPA must also be notified before chemical substances are used in new significant uses. Pursuant to the amended law, EPA is now required to make an affirmative determination as to whether or not the new use or new chemical presents, may present, or is not likely to present an unreasonable risk of injury to health or the environment, or, alternatively, if there is insufficient information to allow for a determination. This amendment went into effect immediately after the law was signed by the President and has resulted in significant changes for both the EPA's New Chemicals Review Program and those manufacturers submitting notices, including manufacturers of the notices under review on June 22, 2016. EPA has worked to keep manufacturers informed of these changes and hopes to continue this dialogue during this public meeting.

Additional information on the revisions to TSCA can be found at

*<https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/frank-r-lautenberg-chemical-safety-21st-century-act>.*

### **III. Meeting**

#### *A. Remote Access*

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

#### *B. Public Participation at the Meeting*

Members of the public 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. Each speaker is allowed no more than 5 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. Persons registered to speak (as well as others) may submit written materials to the docket as described under **ADDRESSES**.

### **IV. How Can I Request to Participate in this Meeting?**

#### *A. Registration*

To attend the meeting in person or to receive remote access, you must register no later than December 13, 2016, using one of the methods described under **ADDRESSES**. 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 125 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.

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

Dated: November 21, 2016.

Maria J. Doa,

*Director, Chemical Control Division, Office of Pollution Prevention and Toxics.*

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