



BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPPT-2017-0559; FRL-9974-13]

TSCA Alternative Testing Methods Draft Strategic Plan; Notice of Availability and Notice of Public Meeting

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: As required by the Toxic Substances Control Act (TSCA), as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act in June 2016, EPA is developing, pursuant to TSCA section 4(h)(2)(A), a Strategic Plan to promote the development and implementation of alternative test methods and strategies to reduce, refine or replace vertebrate animal testing. The draft Strategic Plan will be available for comment until *[INSERT DATE 45 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]* and information obtained will be considered in the Agency's development of the final Strategic Plan which is required to be completed and published in June of 2018.

EPA is also holding a public meeting to obtain input on the Agency's draft Strategic Plan. Information obtained during this meeting will be considered in the Agency's development of the final Strategic Plan due in June of 2018.

DATES: The public meeting will be held on April 10, 2018 from 9:00 a.m. to 5:00 p.m.

Members of the public must register to make oral comments at the public meeting on or before April 3, 2018. Online requests to participate in the meeting must be received on or

before April 3, 2018. 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 meetings 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 accept written comments and materials submitted to the docket EPA-HQ-OPPT-2017-0559. The docket will remain open to receive comments and materials until [*insert date 45 days after date of publication in the **Federal Register***]. When submitting comments to the docket, please be as specific as possible, and please include any supporting data or other information.

ADDRESSES: The meeting will be held in the Ronald Reagan Building 1300 Pennsylvania Avenue, NW, Washington, DC 20004. The meeting will also be available by remote access for registered participants. For further information, see Unit I under **SUPPLEMENTARY INFORMATION**.

To participate in the meeting on April 10, 2018, you may register online (preferred) or in person at the meeting. To register online, go to <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/alternative-test-methods-and-strategies-reduce>.

Written comments, identified by the docket ID number EPA-HQ-OPPT-2017-0559 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:* Louis Scarano, Risk Assessment Division, Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (202) 564-2851, email address: scarano.louis@epa.gov. In addition, progress on this activity will be periodically updated at the following page on the OPPT website at <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca>.

For meeting logistics or registration contact: Klara Zimmerman, Abt Associates; telephone number: (301) 634-1722; email address: 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.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are required to conduct testing of chemical substances under the Toxic Substances Control Act (TSCA). Since other entities may also be interested, the Agency has not attempted to describe all the specific entities that may 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:

- Basic Chemical Manufacturers (NAICS code 3251);
- Resin, Synthetic Rubber, and Artificial Synthetic Fibers and Filament Manufacturers (NAICS code 3252);
- Pesticide, Fertilizer, and Other Agricultural Chemical Manufacturers (NAICS code 3255);
- Paint, Coating, and Adhesive Manufacturers (NAICS code 3255);
- Other Chemical Product and Preparation Manufacturers (NAICS code 3259); and Petroleum Refineries (NAICS code 32411).
- Animal Welfare Groups
- Environmental non-governmental organizations
- Toxicity testing laboratories (contract labs)
- Academic/non-profit groups involved in developing and using alternative toxicity test methods

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-2017-0559, 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>.

Meeting materials for the April 10, 2018 public meeting will be made available in the docket. (<http://www.regulations.gov>; docket number EPA-HQ-OPPT-2017-0559).

II. Background

On June 22, 2016, the Frank R. Lautenberg Chemical Safety for the 21st Century Act, which amended the Toxic Substances Control Act (TSCA), the nation's primary chemicals management law, was signed into law. Along with new requirements and deadlines for actions related to the regulation of new and existing chemicals in the U.S., the new law includes changes to TSCA section 4 (*Testing of Chemical Substances and Mixtures*). Specifically, a new section (4(h)) has been added entitled *Reduction of Testing on Vertebrates*.

TSCA section 4 (h)(2)(A) states that EPA must “...develop a strategic plan to promote the development and implementation of alternative test methods and strategies to reduce, refine, or replace vertebrate animal testing and provide information of equivalent or better scientific quality and relevance for assessing risks of injury to health or the environment...”.

The Strategic Plan must be completed by June 22, 2018. OPPT hosted a public meeting on November 2, 2017 in which a conceptual approach to this Plan was presented. The meeting materials and public comments received through January 10, 2018, when the comment period associated with the November 2, 2017 meeting closed, are available in the docket.

(<http://www.regulations.gov>; docket number EPA-HQ-OPPT-2017-0559). Meeting materials for the April 10, 2018 public meeting will be made available in the docket as well.

III. Meeting

A. Remote Access

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

B. Public Participation at the Meeting

Members of the public may register to attend the public meeting and may also register to provide oral comments, in person or remotely, on the day of the meeting, using one of the registration methods described under **ADDRESSES**. A registered speaker is encouraged to focus on issues directly relevant to the meeting's subject matter. Depending on time and number of people registered to speak, each speaker may be limited to no more than five minutes. A speaker must be registered in order to provide oral comments. To accommodate as many registered speakers as possible, speakers may present oral comments 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**. An Agenda for the meeting and supporting materials will be made available in the docket and on EPA's website in advance of the meeting.

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 online no later than April 3, 2018, 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. 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 meetings prior to its start.

B. *Required Registration Information*

Members of the public may register to attend as observers or to 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.

V. What Action is the Agency Taking?

EPA is publishing a draft strategic plan, and taking comments until [*insert date 45 days after date of publication in the **Federal Register***], to promote the use and development of alternative test methods and strategies to reduce, refine or replace vertebrate animal testing, which includes a list of new approach methodologies (NAMs) that are “scientifically reliable, relevant, and capable of providing information of equivalent or better scientific reliability and quality to that which would be obtained from vertebrate animal testing” along with criteria “for considering scientific reliability and relevance” of NAMs. See TSCA sections 4(h)(2)(C) and (D).

EPA is also holding a public meeting to obtain input on the Agency's draft Strategic Plan. Information obtained during this meeting will be considered in the Agency's development of the final Strategic Plan due in June of 2018.

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

Dated: March 5, 2018.

Charlotte Bertrand,

Acting Principal Deputy Assistant Administrator,

Office of Chemical Safety and Pollution Prevention.

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