



EPA Celebrates Two Year Anniversary of New TSCA Law by Announcing Completion of Several Actions

TSCA, US EPA

By ROGER PEARSON, July 30, 2018

On June 22, then-EPA Administrator Scott Pruitt announced that his agency was celebrating the second anniversary of the 2016 revision of the Toxic Substances Control Act [the Frank R. Lautenberg Chemical Safety for the 21st Century Act] by announcing the completion of several initiatives required under the law. The announcement was one of the last made by Pruitt who resigned his position shortly thereafter.

The recently enacted EPA actions include the following:

Finalized Strategy for Animal Testing

On June 22, EPA released its **Strategic Plan to Promote the Development of Alternative Test Methods within the TSCA Program**¹⁾. Development of the strategic plan is required under section 4(h)(2)(A) of the new Act. The goal of the strategy is to reduce the level of testing in vertebrates for chemicals regulated under TSCA. The new strategy includes "alternative test methods," which are based on "reduction, refinement, and replacement of animal test methods;" and "strategies," which incorporate more than just toxicity tests methods to characterize harm. The alternative test methods and strategies together define a new term: "new approach methodologies (NAMs)."

Final Rule on Reporting Mercury Manufacturing and Imports

Also on June 22, EPA published a prepublication version of the final rule containing reporting requirements for applicable persons to provide information to assist in the preparation of an "inventory of mercury supply, use, and trade in the United States." Mercury for purposes of the rule is defined as "elemental mercury" and any "mercury compound." The final rule applies to any person who manufactures (including imports) mercury or mercury-added products or otherwise intentionally uses mercury in a manufacturing process. EPA will use data obtained from implementation of the rule in 2018 to prepare a 2020 mercury inventory. The reporting year is from January 1, 2018 through December 31, 2018 and the deadline for reporting is July 1, 2019.

The **final rule was published in the June 27 Federal Register**²⁾.

Guidance for State, Tribal, and Local Governments; Medical Personnel; and Emergency Responders on sharing Confidential Business Information

The new Act expanded the categories of people to whom EPA may disclose TSCA Confidential Business Information (CBI) by specifically authorizing EPA to disclose CBI to the above categories of individuals or organizations under certain conditions. **EPA has released three guidance documents**³⁾ each of which discusses the requirements for releasing CBI to one of the three categories.

Policy and Procedures for Assigning Unique Identifiers to Better Publically Track Information on Chemicals While Protecting CBI

When EPA approves a CBI claim for chemical identity, the agency is required to:

Assign a unique identifier to that chemical identity; Apply this unique identifier to other information or submissions concerning the same substance; and Ensure that any non-confidential information received by the Agency identifies the chemical substance using the unique identifier while the specific chemical identity of the chemical substance is protected from disclosure.

On June 27, Federal Register published the **Notice of Availability of the EPA policy on assigning unique identifiers**⁴⁾ .

Guidance on Structurally Descriptive Generic Names

EPA has created a guidance for **creating generic names for chemical substances**⁵⁾ whose specific chemical identities are claimed as CBI. This guidance will allow the agency to share more information with the public about the structure of chemical substances while protecting the confidential elements of the substance's specific chemical identity.

Resources for this article

1. Strategic Plan to Promote the Development of Alternative Test Methods within the TSCA Program

<https://prop65clearinghouse.com/documents/27747>

2. final rule was published in the June 27 Federal Register

<https://prop65clearinghouse.com/documents/27748>

3. EPA has released three guidance documents

<https://www.regulations.gov/document?D=EPA-HQ-OPPT-2017-0652-0023>

4. Notice of Availability of the EPA policy on assigning unique identifiers

<https://prop65clearinghouse.com/documents/27749>

5. creating generic names for chemical substances

<https://www.regulations.gov/document?D=EPA-HQ-OPPT-2018-0292-0001>