

New approach methodologies and the context of use under the amended Toxic Substances Control Act (TSCA)

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Toxic Substances Control Act (TSCA)

New Chemical Substances (NCS)

Determination that the NCS:

1. “presents”,
2. “information is insufficient”,
3. “may present”,
4. “substantial quantities” or “significant or substantial exposure”, or
5. “not likely to present”

“an unreasonable risk of injury to health or the environment”

Existing Chemical Substances (ECS)

Prioritization of the ECS as:

1. “low-priority substance”, or
2. “high-priority substance” (HPS)

Risk evaluation on HPS and determination whether it:
“presents an unreasonable risk of injury to health or the environment”

Review of new and existing chemical substances at EPA

- Risk-based determinations/evaluations must be based on:
 - The best available science, and
 - The weight of the scientific evidence
 - “Without consideration of costs or other non-risk factors”
- EPA assesses a wide variety of potential human health and environmental effects associated with the known, intended and reasonably foreseeable conditions of use for new and existing chemical substances.

Types of data utilized for new and existing chemical substance reviews

- New chemical substances
 - Submitters must provide all data in their possession or control related to health and environmental effects
 - EPA may require the development of new information relating to the new chemical substance
- Existing chemical substances
 - EPA must first take into account reasonably available existing information
 - EPA may then require the development of new information relating to the existing chemical substance

Section 4(h) of the Amended TSCA: Reduction of Testing on Vertebrates

- Section 4(h)(1) - “The Administrator shall reduce and replace, to the extent practicable, scientifically justified, and consistent with the policies of this title, the use of vertebrate animals in the testing of chemical substances or mixtures...”

And, for voluntary testing is regulated by 4(h)(3):

- Section 4(h)(3)(A) – “Any person developing information for submission under this title on a voluntary basis and not pursuant to any request or requirement by the Administrator shall first attempt to develop the information by means of an alternative test method or strategy identified by the Administrator pursuant to paragraph (2)(C), if the Administrator has identified such a test method or strategy for the development of such information, before conducting new vertebrate animal testing.”

The Use of NAMs under the Amended TSCA

- OPPT has utilized various NAMs to exclude chemical substances from specific chemical categories (*e.g.*, polymer lung overload)
 - On April 1, 2020, EPA issued a proposed rule to revoke a significant new use rule (SNUR) for a new chemical substance, based on the results of a biosolubility study. See: <https://www.govinfo.gov/content/pkg/FR-2020-04-01/pdf/2020-06442.pdf>
 - The original SNUR would have required a subchronic inhalation toxicity study in order to use the chemical substance in a manner inconsistent with the original new chemical substance submission

General Questions & Answers

- Q: What approaches will OPPT consider in support of making a risk determination on a chemical substance?
 - A: OPPT maintains a list of alternative test methods to animal testing; see: <https://www.epa.gov/chemicals-under-tsca/updates-epa-list-alternative-test-methods-animal-testing>
- Q: Will OPPT “accept” data for a method that is not on the list of alternative test methods?
 - Yes, EPA will consider any/all data; however, EPA will review for reliability (quality) and relevance. EPA encourages submitters to consult with EPA BEFORE conducting any testing and has a process for doing so. Pre-submission meeting information is here: <https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/filing-pre-manufacture-notice-epa>