



U.S. EPA Strategic Plan to Promote the Development and Implementation of Alternative Test Methods

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Presenter biography

Louis J. Scarano, Ph.D. Louis has been a toxicologist with the US Environmental Protection Agency since 1998. While at EPA, he has worked in the Office of Pollution Prevention and Toxics (OPPT) as well as the Office of Pesticide Programs. Prior to joining the EPA, he spent 12 years working in hazard/risk assessment in the public (Massachusetts Dept. of Food and Agriculture, Pesticide Bureau), private (Environ); and non-profit (the International Life Sciences Institute, or ILSI) sectors. He has a B.S. in Biology, an M.S. in Environmental Science, and a Ph.D. in Public Health.

Presentation abstract

On June 22, 2016, the Toxic Substances Control Act (TSCA) was amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act. The EPA Office of Pollution Prevention and Toxics (OPPT) is responsible for carrying out the mandate of TSCA to regulate new and existing industrial chemicals in the U.S. The amended law includes a new subsection that requires the EPA to develop a Strategic Plan to promote the use and development of alternative test methods and strategies to reduce, refine or replace vertebrate animal testing (Section 4 (h), *Reduction of Testing on Vertebrates*).

This presentation will provide an overview of the draft Strategic Plan for the reduction of testing in vertebrates for chemicals regulated under TSCA which was made public on March 7th, 2018 (available at <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/alternative-test-methods-and-strategies-reduce>).

The organizing framework for the EPA's strategy to reduce vertebrate animal testing relies heavily on what have been termed new approach methodologies (NAMs). The EPA recognizes that this Strategic Plan necessarily describes a multi-year process with incremental steps for adoption and integration of NAMs that are appropriate and fit-for-purpose for making TSCA decisions (e.g., identifying candidates for prioritization, prioritization, and risk evaluation). NAMs would include methods that evaluate hazard (human health and environmental), exposure, and environmental fate as well as different approaches to integrate NAMs for decision making; i.e., adverse outcome pathways, (AOP), integrated approaches to testing and assessment (IATA) and defined approaches (DA).

The Strategic Plan has three core components: (1) *identifying, developing and integrating* NAMs for TSCA decisions; (2) *building confidence* that the NAMs are scientifically reliable and relevant for TSCA decisions; and (3) *implementing* the reliable and relevant NAMs for TSCA decisions. The EPA has identified seven current/near-term (<3 years) needs and activities. Completing these activities will result in moving towards four intermediate-term (3-5 years) objectives. The EPA's long-term goal is to move towards making TSCA decisions (conducting prioritization activities and risk evaluations for new and existing chemicals) with NAMs in order to reduce and eventually eliminate vertebrate animal testing for TSCA.