

EPA's Implementation of Lautenberg Chemical Safety Act

Alternative Testing Methods Under the Amended TSCA

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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 (see <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/frank-r-lautenberg-chemical-safety-21st-century-act>). 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 § 4 (*Testing of Chemical Substances and Mixtures*). Specifically, a new section (4 (h)) has been added entitled *Reduction of Testing on Vertebrates*.

TSCA § 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. The next few pages contains the full language of Section 4(h) of the amended TSCA.

In developing a goal statement for the TSCA Strategic Plan, the Agency recognizes the recent developments in the creation of a vision/objectives of a national 3R's strategy and roadmap, coordinated by a large, US federal agency-wide congressionally-mandated committee on alternative test methods (the Interagency Coordinating Committee on the Validation of Alternative Methods, or ICCVAM)¹. Several major offices in the Agency are involved in this effort (the Office of Pesticide Programs [OPP²], the Office of Research and Development [ORD], the Office of Science Coordination and Policy [OSCP] as well as the Office of Pollution Prevention and Toxics [OPPT]). In addition, the Agency recognizes similar efforts in other parts of the world, specifically Europe (through initiatives of the European Chemicals Agency, or ECHA), Canada (with the newly announced Canadian Centre for Alternatives to Animal Methods³), other organizations under the umbrella of the International Cooperation on Alternative Test Methods (ICATM⁴), and member countries and stakeholders of the Organization for Economic Cooperation and Development (OECD).

Keeping these efforts in mind, the following goal statement is proposed for the TSCA Strategic Plan. It is a direct quote from the amended TSCA and captures the spirit and intent of both the ICCVAM vision for a national strategy and international regulatory and research efforts:

¹ ICCVAM URL: <https://ntp.niehs.nih.gov/pubhealth/evalatm/iccvam/index.html>

² OPP Strategic Vision for Alternative Test Methods URL: <https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/strategic-vision-adopting-21st-century-science>

³ Canadian Centre URL: <http://www1.uwindsor.ca/vpri/canadian-centre-for-alternatives-to-animal-methods-0>

⁴ ICATM URL: <https://ntp.niehs.nih.gov/pubhealth/evalatm/iccvam/international-partnerships/index.html#About-ICATM>

“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 of chemical substances or mixtures.” (Direct quote of amended TSCA – Section 4(h)(2)(A))

SEC. 4. TESTING OF CHEMICAL SUBSTANCES AND MIXTURES.

(Note: Text for sections a through g are not presented):

(h)Reduction of Testing on Vertebrates. —

(1) In General —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 under this title by—

(A) prior to making a request or adopting a requirement for testing using vertebrate animals, and in accordance with subsection (a)(3), taking into consideration, as appropriate and to the extent practicable and scientifically justified, reasonably available existing information, including—

- (i) toxicity information;
- (ii) computational toxicology and bioinformatics; and
- (iii) high-throughput screening methods and the prediction models of those methods; and

(B) encouraging and facilitating—

- (i) the use of scientifically valid test methods and strategies that reduce or replace the use of vertebrate animals while providing information of equivalent or better scientific quality and relevance that will support regulatory decisions under this title;
- (ii) the grouping of 2 or more chemical substances into scientifically appropriate categories in cases in which testing of a chemical substance would provide scientifically valid and useful information on other chemical substances in the category; and
- (iii) the formation of industry consortia to jointly conduct testing to avoid unnecessary duplication of tests, provided that such consortia make all information from such testing available to the Administrator.

(2) Implementation of Alternative Testing Methods—To promote the development and timely incorporation of new scientifically valid test methods and strategies that are not based on vertebrate animals, the Administrator shall—

(A) not later than 2 years after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, 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 of chemical substances or mixtures through, for example—

- (i) computational toxicology and bioinformatics;
- (ii) high-throughput screening methods;
- (iii) testing of categories of chemical substances;
- (iv) tiered testing methods;
- (v) in vitro studies;
- (vi) systems biology;
- (vii) new or revised methods identified by validation bodies such as the Interagency Coordinating Committee on the Validation of Alternative Methods or the Organization for Economic Co-operation and Development; or

- (viii) industry consortia that develop information submitted under this title;
 - (B) as practicable, ensure that the strategic plan developed under subparagraph (A) is reflected in the development of requirements for testing under this section;
 - (C) include in the strategic plan developed under subparagraph (A) a list, which the Administrator shall update on a regular basis, of particular alternative test methods or strategies the Administrator has identified that do not require new vertebrate animal testing and 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;
 - (D) provide an opportunity for public notice and comment on the contents of the plan developed under subparagraph (A), including the criteria for considering scientific reliability and relevance of the test methods and strategies that may be identified pursuant to subparagraph (C);
 - (E) beginning on the date that is 5 years after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, and every 5 years thereafter, submit to Congress a report that describes the progress made in implementing the plan developed under subparagraph (A) and goals for future alternative test methods and strategies implementation; and
 - (F) prioritize and, to the extent consistent with available resources and the Administrator's other responsibilities under this title, carry out performance assessment, validation, and translational studies to accelerate the development of scientifically valid test methods and strategies that reduce, refine, or replace the use of vertebrate animals, including minimizing duplication, in any testing under this title.
- (3) Voluntary Testing—
- (A) In General—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.
 - (B) Effect of Paragraph—Nothing in this paragraph shall, under any circumstance, limit or restrict the submission of any existing information to the Administrator.
 - (C) Relationship to Other Law—A violation of this paragraph shall not be a prohibited act under section 15.
 - (D) Review of Means—This paragraph authorizes, but does not require, the Administrator to review the means by which a person conducted testing described in subparagraph (A).