

reduce or eliminate the use of animals in acute or chronic safety testing;

(4) to establish criteria for the validation and regulatory acceptance of alternative testing and to recommend a process through which scientifically validated alternative methods can be accepted for regulatory use;

(5) to communicate the results of research to government agencies, to medical, scientific, and regulatory communities, and to the public; and

(6) to integrate related activities of the Department of Health and Human Services.

(July 1, 1944, ch. 373, title IV, §463A, as added Pub. L. 103-43, title XIII, §1301(a), June 10, 1993, 107 Stat. 169.)

§ 2851-2. Definitions

In sections 2851-2 to 2851-5 of this title:

(1) Alternative test method

The term “alternative test method” means a test method that—

(A) includes any new or revised test method; and

(B)(i) reduces the number of animals required;

(ii) refines procedures to lessen or eliminate pain or distress to animals, or enhances animal well-being; or

(iii) replaces animals with non-animal systems or one animal species with a phylogenetically lower animal species, such as replacing a mammal with an invertebrate.

(2) ICCVAM test recommendation

The term “ICCVAM test recommendation” means a summary report prepared by the ICCVAM characterizing the results of a scientific expert peer review of a test method.

(Pub. L. 106-545, §2, Dec. 19, 2000, 114 Stat. 2721.)

CODIFICATION

Section was enacted as part of the ICCVAM Authorization Act of 2000, and not as part of the Public Health Service Act which comprises this chapter.

§ 2851-3. Interagency Coordinating Committee on the Validation of Alternative Methods

(a) In general

With respect to the interagency coordinating committee that is known as the Interagency Coordinating Committee on the Validation of Alternative Methods (referred to in sections 2851-2 to 2851-5 of this title as “ICCVAM”) and that was established by the Director of the National Institute of Environmental Health Sciences for purposes of section 2851-1(b) of this title, the Director of the Institute shall designate such committee as a permanent interagency coordinating committee of the Institute under the National Toxicology Program Interagency Center for the Evaluation of Alternative Toxicological Methods. Sections 2851-2 to 2851-5 of this title may not be construed as affecting the authorities of such Director regarding ICCVAM that were in effect on the day before December 19, 2000, except to the extent inconsistent with sections 2851-2 to 2851-5 of this title.

(b) Purposes

The purposes of the ICCVAM shall be to—

(1) increase the efficiency and effectiveness of Federal agency test method review;

(2) eliminate unnecessary duplicative efforts and share experiences between Federal regulatory agencies;

(3) optimize utilization of scientific expertise outside the Federal Government;

(4) ensure that new and revised test methods are validated to meet the needs of Federal agencies; and

(5) reduce, refine, or replace the use of animals in testing, where feasible.

(c) Composition

The ICCVAM shall be composed of the heads of the following Federal agencies (or their designees):

(1) Agency for Toxic Substances and Disease Registry.

(2) Consumer Product Safety Commission.

(3) Department of Agriculture.

(4) Department of Defense.

(5) Department of Energy.

(6) Department of the Interior.

(7) Department of Transportation.

(8) Environmental Protection Agency.

(9) Food and Drug Administration.

(10) National Institute for Occupational Safety and Health.

(11) National Institutes of Health.

(12) National Cancer Institute.

(13) National Institute of Environmental Health Sciences.

(14) National Library of Medicine.

(15) Occupational Safety and Health Administration.

(16) Any other agency that develops, or employs tests or test data using animals, or regulates on the basis of the use of animals in toxicity testing.

(d) Scientific Advisory Committee

(1) Establishment

The Director of the National Institute of Environmental Health Sciences shall establish a Scientific Advisory Committee (referred to in sections 2851-2 to 2851-5 of this title as the “SAC”) to advise ICCVAM and the National Toxicology Program Interagency Center for the Evaluation of Alternative Toxicological Methods regarding ICCVAM activities. The activities of the SAC shall be subject to provisions of the Federal Advisory Committee Act.

(2) Membership

(A) In general

The SAC shall be composed of the following voting members:

(i) At least one knowledgeable representative having a history of expertise, development, or evaluation of new or revised or alternative test methods from each of—

(I) the personal care, pharmaceutical, industrial chemicals, or agriculture industry;

(II) any other industry that is regulated by the Federal agencies specified in subsection (c) of this section; and

(III) a national animal protection organization established under section 501(c)(3) of title 26.