

test method specified in a regulation or industry-wide guideline which specifically, or in practice requires, recommends, or encourages the use of an animal acute or chronic toxicological test method for which the ICCVAM test recommendation may be added or substituted.

(b) Alternatives

Each Federal agency carrying out a program described in subsection (a) of this section shall promote and encourage the development and use of alternatives to animal test methods (including batteries of tests and test screens), where appropriate, for the purpose of complying with Federal statutes, regulations, guidelines, or recommendations (in each instance, and for each chemical class) if such test methods are found to be effective for generating data, in an amount and of a scientific value that is at least equivalent to the data generated from existing tests, for hazard identification, dose-response assessment, or risk assessment purposes.

(c) Test method validation

Each Federal agency carrying out a program described in subsection (a) of this section shall ensure that any new or revised acute or chronic toxicity test method, including animal test methods and alternatives, is determined to be valid for its proposed use prior to requiring, recommending, or encouraging the application of such test method.

(d) Review

Not later than 180 days after receipt of an ICCVAM test recommendation, a Federal agency carrying out a program described in subsection (a) of this section shall review such recommendation and notify the ICCVAM in writing of its findings.

(e) Recommendation adoption

Each Federal agency carrying out a program described in subsection (a) of this section, or its specific regulatory unit or units, shall adopt the ICCVAM test recommendation unless such Federal agency determines that—

- (1) the ICCVAM test recommendation is not adequate in terms of biological relevance for the regulatory goal authorized by that agency, or mandated by Congress;
- (2) the ICCVAM test recommendation does not generate data, in an amount and of a scientific value that is at least equivalent to the data generated prior to such recommendation, for the appropriate hazard identification, dose-response assessment, or risk assessment purposes as the current test method recommended or required by that agency;
- (3) the agency does not employ, recommend, or require testing for that class of chemical or for the recommended test endpoint; or
- (4) the ICCVAM test recommendation is unacceptable for satisfactorily fulfilling the test needs for that particular agency and its respective congressional mandate.

(Pub. L. 106-545, § 4, Dec. 19, 2000, 114 Stat. 2723.)

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.

§ 285I-5. Application

(a) Application

Sections 285I-2 to 285I-5 of this title shall not apply to research, including research performed using biotechnology techniques, or research related to the causes, diagnosis, treatment, control, or prevention of physical or mental diseases or impairments of humans or animals.

(b) Use of test methods

Nothing in sections 285I-2 to 285I-5 of this title shall prevent a Federal agency from retaining final authority for incorporating the test methods recommended by the ICCVAM in the manner determined to be appropriate by such Federal agency or regulatory body.

(c) Limitation

Nothing in sections 285I-2 to 285I-5 of this title shall be construed to require a manufacturer that is currently not required to perform animal testing to perform such tests. Nothing in sections 285I-2 to 285I-5 of this title shall be construed to require a manufacturer to perform redundant endpoint specific testing.

(d) Submission of tests and data

Nothing in sections 285I-2 to 285I-5 of this title precludes a party from submitting a test method or scientific data directly to a Federal agency for use in a regulatory program.

(Pub. L. 106-545, § 5, Dec. 19, 2000, 114 Stat. 2724.)

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.

§ 285I-6. Methods of controlling certain insect and vermin populations

The Director of the Institute shall conduct or support research to identify or develop methods of controlling insect and vermin populations that transmit to humans diseases that have significant adverse health consequences.

(July 1, 1944, ch. 373, title IV, § 463B, as added Pub. L. 108-75, § 3, Aug. 15, 2003, 117 Stat. 902.)

SUBPART 13—NATIONAL INSTITUTE ON DEAFNESS AND OTHER COMMUNICATION DISORDERS

§ 285m. Purpose of Institute

The general purpose of the National Institute on Deafness and Other Communication Disorders (hereafter referred to in this subpart as the “Institute”) is the conduct and support of research and training, the dissemination of health information, and other programs with respect to disorders of hearing and other communication processes, including diseases affecting hearing, balance, voice, speech, language, taste, and smell.

(July 1, 1944, ch. 373, title IV, § 464, as added Pub. L. 100-553, § 2(4), Oct. 28, 1988, 102 Stat. 2769, and Pub. L. 100-607, title I, § 101(4), Nov. 4, 1988, 102 Stat. 3049; amended Pub. L. 100-690, title II, § 2613(b)(2), Nov. 18, 1988, 102 Stat. 4238.)

CODIFICATION

Pub. L. 100-553 and Pub. L. 100-607 contained identical provisions enacting this section. See 1988 Amendment note below.