

106TH CONGRESS
2D SESSION

H. R. 4281

AN ACT

To establish, wherever feasible, guidelines, recommendations, and regulations that promote the regulatory acceptance of new or revised scientifically valid toxicological tests that protect human and animal health and the environment while reducing, refining, or replacing animal tests and ensuring human safety and product effectiveness.

106TH CONGRESS
2D SESSION

H. R. 4281

AN ACT

To establish, wherever feasible, guidelines, recommendations, and regulations that promote the regulatory acceptance of new or revised scientifically valid toxicological tests that protect human and animal health and the environment while reducing, refining, or replacing animal tests and ensuring human safety and product effectiveness.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “ICCVAM Authoriza-
5 tion Act of 2000”.

6 **SEC. 2. DEFINITIONS.**

7 In this Act:

8 (1) ALTERNATIVE TEST METHOD.—The term
9 “alternative test method” means a test method
10 that—

11 (A) includes any new or revised test meth-
12 od; and

13 (B)(i) reduces the number of animals re-
14 quired;

15 (ii) refines procedures to lessen or elimi-
16 nate pain or distress to animals, or enhances
17 animal well-being; or

18 (iii) replaces animals with non-animal sys-
19 tems or 1 animal species with a phylogenetically
20 lower animal species, such as replacing a mam-
21 mal with an invertebrate.

22 (2) ICCVAM TEST RECOMMENDATION.—The
23 term “ICCVAM test recommendation” means a
24 summary report prepared by the ICCVAM charac-

1 terizing the results of a scientific expert peer review
2 of a test method.

3 **SEC. 3. INTERAGENCY COORDINATING COMMITTEE ON THE**
4 **VALIDATION OF ALTERNATIVE METHODS.**

5 (a) IN GENERAL.—With respect to the interagency
6 coordinating committee that is known as the Interagency
7 Coordinating Committee on the Validation of Alternative
8 Methods (referred to in this Act as “ICCVAM”) and that
9 was established by the Director of the National Institute
10 of Environmental Health Sciences for purposes of section
11 463A(b) of the Public Health Service Act, the Director
12 of the Institute shall designate such committee as a per-
13 manent interagency coordinating committee of the Insti-
14 tute under the National Toxicology Program Interagency
15 Center for the Evaluation of Alternative Toxicological
16 Methods. This Act may not be construed as affecting the
17 authorities of such Director regarding ICCVAM that were
18 in effect on the day before the date of the enactment of
19 this Act, except to the extent inconsistent with this Act.

20 (b) PURPOSES.—The purposes of the ICCVAM shall
21 be to—

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

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

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

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

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

11 (c) COMPOSITION.—The ICCVAM shall be composed
12 of the heads of the following Federal agencies (or their
13 designees):

14 (1) Agency for Toxic Substances and Disease
15 Registry.

16 (2) Consumer Product Safety Commission.

17 (3) Department of Agriculture.

18 (4) Department of Defense.

19 (5) Department of Energy.

20 (6) Department of the Interior.

21 (7) Department of Transportation.

22 (8) Environmental Protection Agency.

23 (9) Food and Drug Administration.

24 (10) National Institute for Occupational Safety
25 and Health.

1 (11) National Institutes of Health.

2 (12) National Cancer Institute.

3 (13) National Institute of Environmental
4 Health Sciences.

5 (14) National Library of Medicine.

6 (15) Occupational Safety and Health Adminis-
7 tration.

8 (16) Any other agency that develops, or em-
9 ploys tests or test data using animals, or regulates
10 on the basis of the use of animals in toxicity testing.

11 (d) SCIENTIFIC ADVISORY COMMITTEE.—

12 (1) ESTABLISHMENT.—The Director of the Na-
13 tional Institute of Environmental Health Sciences
14 shall establish a Scientific Advisory Committee (re-
15 ferred to in this Act as the “SAC”) to advise
16 ICCVAM and the National Toxicology Program
17 Interagency Center for the Evaluation of Alternative
18 Toxicological Methods regarding ICCVAM activities.
19 The activities of the SAC shall be subject to provi-
20 sions of the Federal Advisory Committee Act.

21 (2) MEMBERSHIP.—

22 (A) IN GENERAL.—The SAC shall be com-
23 posed of the following voting members:

24 (i) At least 1 knowledgeable rep-
25 resentative 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); and

(III) a national animal protection organization established under section 501(c)(3) of the Internal Revenue Code of 1986.

(ii) Representatives (selected by the Director of the National Institute of Environmental Health Sciences) from an academic institution, a State government agency, an international regulatory body, or any corporation developing or marketing new or revised or alternative test methodologies, including contract laboratories.

(B) NONVOTING EX OFFICIO MEMBERS.—

The membership of the SAC shall, in addition to voting members under subparagraph (A), include as nonvoting ex officio members the agen-

1 cy heads specified in subsection (c) (or their
2 designees).

3 (e) DUTIES.—The ICCVAM shall, consistent with the
4 purposes described in subsection (b), carry out the fol-
5 lowing functions:

6 (1) Review and evaluate new or revised or alter-
7 native test methods, including batteries of tests and
8 test screens, that may be acceptable for specific reg-
9 ulatory uses, including the coordination of technical
10 reviews of proposed new or revised or alternative test
11 methods of interagency interest.

12 (2) Facilitate appropriate interagency and
13 international harmonization of acute or chronic toxi-
14 cological test protocols that encourage the reduction,
15 refinement, or replacement of animal test methods.

16 (3) Facilitate and provide guidance on the de-
17 velopment of validation criteria, validation studies
18 and processes for new or revised or alternative test
19 methods and help facilitate the acceptance of such
20 scientifically valid test methods and awareness of ac-
21 cepted test methods by Federal agencies and other
22 stakeholders.

23 (4) Submit ICCVAM test recommendations for
24 the test method reviewed by the ICCVAM, through
25 expeditious transmittal by the Secretary of Health

1 and Human Services (or the designee of the Sec-
2 retary), to each appropriate Federal agency, along
3 with the identification of specific agency guidelines,
4 recommendations, or regulations for a test method,
5 including batteries of tests and test screens, for
6 chemicals or class of chemicals within a regulatory
7 framework that may be appropriate for scientific im-
8 provement, while seeking to reduce, refine, or re-
9 place animal test methods.

10 (5) Consider for review and evaluation, peti-
11 tions received from the public that—

12 (A) identify a specific regulation, rec-
13 ommendation, or guideline regarding a regu-
14 latory mandate; and

15 (B) recommend new or revised or alter-
16 native test methods and provide valid scientific
17 evidence of the potential of the test method.

18 (6) Make available to the public final ICCVAM
19 test recommendations to appropriate Federal agen-
20 cies and the responses from the agencies regarding
21 such recommendations.

22 (7) Prepare reports to be made available to the
23 public on its progress under this Act. The first re-
24 port shall be completed not later than 12 months
25 after the date of the enactment of this Act, and sub-

1 sequent reports shall be completed biennially there-
2 after.

3 **SEC. 4. FEDERAL AGENCY ACTION.**

4 (a) IDENTIFICATION OF TESTS.—With respect to
5 each Federal agency carrying out a program that requires
6 or recommends acute or chronic toxicological testing, such
7 agency shall, not later than 180 days after receiving an
8 ICCVAM test recommendation, identify and forward to
9 the ICCVAM any relevant test method specified in a regu-
10 lation or industry-wide guideline which specifically, or in
11 practice requires, recommends, or encourages the use of
12 an animal acute or chronic toxicological test method for
13 which the ICCVAM test recommendation may be added
14 or substituted.

15 (b) ALTERNATIVES.—Each Federal agency carrying
16 out a program described in subsection (a) shall promote
17 and encourage the development and use of alternatives to
18 animal test methods (including batteries of tests and test
19 screens), where appropriate, for the purpose of complying
20 with Federal statutes, regulations, guidelines, or rec-
21 ommendations (in each instance, and for each chemical
22 class) if such test methods are found to be effective for
23 generating data, in an amount and of a scientific value
24 that is at least equivalent to the data generated from exist-

1 ing tests, for hazard identification, dose-response assess-
2 ment, or risk assessment purposes.

3 (c) TEST METHOD VALIDATION.—Each Federal
4 agency carrying out a program described in subsection (a)
5 shall ensure that any new or revised acute or chronic tox-
6 icity test method, including animal test methods and alter-
7 natives, is determined to be valid for its proposed use prior
8 to requiring, recommending, or encouraging the applica-
9 tion of such test method.

10 (d) REVIEW.—Not later than 180 days after receipt
11 of an ICCVAM test recommendation, a Federal agency
12 carrying out a program described in subsection (a) shall
13 review such recommendation and notify the ICCVAM in
14 writing of its findings.

15 (e) RECOMMENDATION ADOPTION.—Each Federal
16 agency carrying out a program described in subsection (a),
17 or its specific regulatory unit or units, shall adopt the
18 ICCVAM test recommendation unless such Federal agency
19 determines that—

20 (1) the ICCVAM test recommendation is not
21 adequate in terms of biological relevance for the reg-
22 ulatory goal authorized by that agency, or mandated
23 by Congress;

24 (2) the ICCVAM test recommendation does not
25 generate data, in an amount and of a scientific value

1 that is at least equivalent to the data generated
2 prior to such recommendation, for the appropriate
3 hazard identification, dose-response assessment, or
4 risk assessment purposes as the current test method
5 recommended or required by that agency;

6 (3) the agency does not employ, recommend, or
7 require testing for that class of chemical or for the
8 recommended test endpoint; or

9 (4) the ICCVAM test recommendation is unac-
10 ceptable for satisfactorily fulfilling the test needs for
11 that particular agency and its respective congres-
12 sional mandate.

13 **SEC. 5. APPLICATION.**

14 (a) APPLICATION.—This Act shall not apply to re-
15 search, including research performed using biotechnology
16 techniques, or research related to the causes, diagnosis,
17 treatment, control, or prevention of physical or mental dis-
18 eases or impairments of humans or animals.

19 (b) USE OF TEST METHODS.—Nothing in this Act
20 shall prevent a Federal agency from retaining final au-
21 thority for incorporating the test methods recommended
22 by the ICCVAM in the manner determined to be appro-
23 priate by such Federal agency or regulatory body.

24 (c) LIMITATION.—Nothing in this Act shall be con-
25 strued to require a manufacturer that is currently not re-

1 quired to perform animal testing to perform such tests.

2 Nothing in this Act shall be construed to require a manu-

3 facturer to perform redundant endpoint specific testing.

4 (d) SUBMISSION OF TESTS AND DATA.—Nothing in

5 this Act precludes a party from submitting a test method

6 or scientific data directly to a Federal agency for use in

7 a regulatory program.

Passed the House of Representatives October 17,
2000.

Attest:

Clerk.