

Union Calendar No. 578

106TH CONGRESS
2^D SESSION

H. R. 4281

[Report No. 106-980]

To establish, wherever feasible, guidelines, recommendations, and regulations that promote the regulatory acceptance of new and revised 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.

IN THE HOUSE OF REPRESENTATIVES

APRIL 13, 2000

Mr. CALVERT (for himself, Mr. LANTOS, Mr. BROWN of Ohio, Mr. CAMPBELL, Mrs. CAPPS, Mr. COSTELLO, Mr. DELAHUNT, Mr. DEUTSCH, Ms. ESHOO, Mr. FRANK of Massachusetts, Mr. GILCHREST, Mr. GILMAN, Mr. GOSS, Mr. HORN, Mr. HYDE, Mr. MARKEY, Mr. GARY MILLER of California, Mr. PALLONE, Mr. PORTER, Mr. QUINN, Ms. RIVERS, Mr. SENSENBRENNER, Mr. SHAYS, Mr. SMITH of New Jersey, Mr. TOWNS, Mr. UDALL of Colorado, Mr. WAXMAN, Mr. WELDON of Pennsylvania, and Ms. WOOLSEY) introduced the following bill; which was referred to the Committee on Commerce

OCTOBER 16, 2000

Additional sponsors: Mr. WEXLER, Mr. GEJDENSON, Mr. RAHALL, Mr. BILBRAY, Mr. GALLEGLY, Mr. GREENWOOD, Mr. METCALF, Mr. RAMSTAD, Mr. GOODLING, Mr. WHITFIELD, Mr. ENGLISH, Mr. CANADY of Florida, Mr. DOYLE, Mr. KUCINICH, Ms. PELOSI, Mr. COOK, Mrs. MALONEY of New York, Mr. BLUMENAUER, Mr. NADLER, Mr. GEORGE MILLER of California, Mr. DEAL of Georgia, Mr. STARK, Mr. BAIRD, Mr. EVANS, Mr. ACKERMAN, Mr. DIXON, Mr. HALL of Texas, Mr. CAPUANO, Mr. LEVIN, Mr. HOBSON, Mr. DEFazio, Mr. BONIOR, Mr. SWEENEY, Mr. TIERNEY, Mr. HINCHEY, Ms. BALDWIN, Mr. BERMAN, Mrs. JOHNSON of Connecticut, Mr. LOBIONDO, Mr. SAXTON, Mr. ENGEL, Mr. SHERMAN, Mr. ABERCROMBIE, Mr. HASTINGS of Washington, and Mr. OXLEY

OCTOBER 16, 2000

Reported with an amendment, committed to the Committee of the Whole
House on the State of the Union, and ordered to be printed

[Strike out all after the enacting clause and insert the part printed in italic]

[For text of introduced bill, see copy of bill as introduced on April 13, 2000]

A BILL

To establish, wherever feasible, guidelines, recommendations,
and regulations that promote the regulatory acceptance
of new and revised 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 Authorization*
5 *Act of 2000”.*

6 **SEC. 2. DEFINITIONS.**

7 *In this Act:*

8 (1) *ALTERNATIVE TEST METHOD.*—*The term “al-*
9 *ternative test method” means a test method that—*

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

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

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

4 (iii) replaces animals with non-animal sys-
5 tems or 1 animal species with a phylogenetically
6 lower animal species, such as replacing a mam-
7 mal with an invertebrate.

8 (2) *ICCVAM TEST RECOMMENDATION.*—The
9 term “*ICCVAM test recommendation*” means a sum-
10 mary report prepared by the *ICCVAM* characterizing
11 the results of a scientific expert peer review of a test
12 method.

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

15 (a) *IN GENERAL.*—With respect to the interagency co-
16 ordinating committee that is known as the Interagency Co-
17 ordinating Committee on the Validation of Alternative
18 Methods (referred to in this Act as “*ICCVAM*”) and that
19 was established by the Director of the National Institute
20 of Environmental Health Sciences for purposes of section
21 463A(b) of the Public Health Service Act, the Director of
22 the Institute shall designate such committee as a permanent
23 interagency coordinating committee of the Institute under
24 the National Toxicology Program Interagency Center for
25 the Evaluation of Alternative Toxicological Methods. This

1 *Act may not be construed as affecting the authorities of such*
2 *Director regarding ICCVAM that were in effect on the day*
3 *before the date of the enactment of this Act, except to the*
4 *extent inconsistent with this Act.*

5 (b) *PURPOSES.—The purposes of the ICCVAM shall be*
6 *to—*

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

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

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

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

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

17 (c) *COMPOSITION.—The ICCVAM shall be composed of*
18 *the heads of the following Federal agencies (or their des-*
19 *ignees):*

20 (1) *Agency for Toxic Substances and Disease*
21 *Registry.*

22 (2) *Consumer Product Safety Commission.*

23 (3) *Department of Agriculture.*

24 (4) *Department of Defense.*

25 (5) *Department of Energy.*

1 (6) *Department of the Interior.*

2 (7) *Department of Transportation.*

3 (8) *Environmental Protection Agency.*

4 (9) *Food and Drug Administration.*

5 (10) *National Institute for Occupational Safety*
6 *and Health.*

7 (11) *National Institutes of Health.*

8 (12) *National Cancer Institute.*

9 (13) *National Institute of Environmental Health*
10 *Sciences.*

11 (14) *National Library of Medicine.*

12 (15) *Occupational Safety and Health Adminis-*
13 *tration.*

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

17 (d) *SCIENTIFIC ADVISORY COMMITTEE.—*

18 (1) *ESTABLISHMENT.—The Director of the Na-*
19 *tional Institute of Environmental Health Sciences*
20 *shall establish a Scientific Advisory Committee (re-*
21 *ferred to in this Act as the “SAC”) to advise ICCVAM*
22 *and the National Toxicology Program Interagency*
23 *Center for the Evaluation of Alternative Toxicological*
24 *Methods regarding ICCVAM activities. The activities*

1 *of the SAC shall be subject to provisions of the Fed-*
2 *eral Advisory Committee Act.*

3 (2) *MEMBERSHIP.—*

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

6 (i) *At least 1 knowledgeable representa-*
7 *tive having a history of expertise, develop-*
8 *ment, or evaluation of new or revised or al-*
9 *ternative test methods from each of—*

10 (I) *the personal care, pharma-*
11 *ceutical, industrial chemicals, or agri-*
12 *culture industry;*

13 (II) *any other industry that is*
14 *regulated by the Federal agencies speci-*
15 *fied in subsection (c); and*

16 (III) *a national animal protection*
17 *organization established under section*
18 *501(c)(3) of the Internal Revenue Code*
19 *of 1986.*

20 (ii) *Representatives (selected by the Di-*
21 *rector of the National Institute of Environ-*
22 *mental Health Sciences) from an academic*
23 *institution, a State government agency, an*
24 *international regulatory body, or any cor-*
25 *poration developing or marketing new or*

1 *revised or alternative test methodologies, in-*
2 *cluding contract laboratories.*

3 *(B) NONVOTING EX OFFICIO MEMBERS.—*

4 *The membership of the SAC shall, in addition to*
5 *voting members under subparagraph (A), include*
6 *as nonvoting ex officio members the agency heads*
7 *specified in subsection (c) (or their designees).*

8 *(e) DUTIES.—The ICCVAM shall, consistent with the*
9 *purposes described in subsection (b), carry out the following*
10 *functions:*

11 *(1) Review and evaluate new or revised or alter-*
12 *native test methods, including batteries of tests and*
13 *test screens, that may be acceptable for specific regu-*
14 *latory uses, including the coordination of technical re-*
15 *views of proposed new or revised or alternative test*
16 *methods of interagency interest.*

17 *(2) Facilitate appropriate interagency and inter-*
18 *national harmonization of acute or chronic toxic-*
19 *ological test protocols that encourage the reduction,*
20 *refinement, or replacement of animal test methods.*

21 *(3) Facilitate and provide guidance on the devel-*
22 *opment of validation criteria, validation studies and*
23 *processes for new or revised or alternative test meth-*
24 *ods and help facilitate the acceptance of such scientif-*
25 *ically valid test methods and awareness of accepted*

1 *test methods by Federal agencies and other stake-*
2 *holders.*

3 (4) *Submit ICCVAM test recommendations for*
4 *the test method reviewed by the ICCVAM, through ex-*
5 *peditious transmittal by the Secretary of Health and*
6 *Human Services (or the designee of the Secretary), to*
7 *each appropriate Federal agency, along with the iden-*
8 *tification of specific agency guidelines, recommenda-*
9 *tions, or regulations for a test method, including bat-*
10 *teries of tests and test screens, for chemicals or class*
11 *of chemicals within a regulatory framework that may*
12 *be appropriate for scientific improvement, while seek-*
13 *ing to reduce, refine, or replace animal test methods.*

14 (5) *Consider for review and evaluation, petitions*
15 *received from the public that—*

16 (A) *identify a specific regulation, rec-*
17 *ommendation, or guideline regarding a regu-*
18 *latory mandate; and*

19 (B) *recommend new or revised or alter-*
20 *native test methods and provide valid scientific*
21 *evidence of the potential of the test method.*

22 (6) *Make available to the public final ICCVAM*
23 *test recommendations to appropriate Federal agencies*
24 *and the responses from the agencies regarding such*
25 *recommendations.*

1 (7) *Prepare reports to be made available to the*
2 *public on its progress under this Act. The first report*
3 *shall be completed not later than 12 months after the*
4 *date of the enactment of this Act, and subsequent re-*
5 *ports shall be completed biennially thereafter.*

6 **SEC. 4. FEDERAL AGENCY ACTION.**

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

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

1 *lent to the data generated from existing tests, for hazard*
2 *identification, dose-response assessment, or risk assessment*
3 *purposes.*

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

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

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

21 (1) *the ICCVAM test recommendation is not ade-*
22 *quate in terms of biological relevance for the regu-*
23 *latory goal authorized by that agency, or mandated*
24 *by Congress;*

1 (2) *the ICCVAM test recommendation does not*
2 *generate data, in an amount and of a scientific value*
3 *that is at least equivalent to the data generated prior*
4 *to such recommendation, for the appropriate hazard*
5 *identification, dose-response assessment, or risk as-*
6 *essment purposes as the current test method rec-*
7 *ommended or required by that agency;*

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

11 (4) *the ICCVAM test recommendation is unac-*
12 *ceptable for satisfactorily fulfilling the test needs for*
13 *that particular agency and its respective congress-*
14 *sional mandate.*

15 **SEC. 5. APPLICATION.**

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

21 (b) *USE OF TEST METHODS.—Nothing in this Act*
22 *shall prevent a Federal agency from retaining final author-*
23 *ity for incorporating the test methods recommended by the*
24 *ICCVAM in the manner determined to be appropriate by*
25 *such Federal agency or regulatory body.*

1 (c) *LIMITATION.*—*Nothing in this Act shall be con-*
2 *strued to require a manufacturer that is currently not re-*
3 *quired to perform animal testing to perform such tests.*
4 *Nothing in this Act shall be construed to require a manufac-*
5 *turer to perform redundant endpoint specific testing.*

6 (d) *SUBMISSION OF TESTS AND DATA.*—*Nothing in*
7 *this Act precludes a party from submitting a test method*
8 *or scientific data directly to a Federal agency for use in*
9 *a regulatory program.*

Amend the title so as to read: “A bill 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.”.

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