

106TH CONGRESS
1ST SESSION

S. 1495

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 SENATE OF THE UNITED STATES

AUGUST 4, 1999

Mr. DEWINE introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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 Authoriza-
5 tion Act of 1999”.

1 **SEC. 2. INTERAGENCY COORDINATING COMMITTEE ON THE**
2 **VALIDATION OF ALTERNATIVE METHODS.**

3 (a) IN GENERAL.—The Interagency Coordinating
4 Committee on the Validation of Alternative Methods (re-
5 ferred to in this Act as “ICCVAM”) shall be sustained
6 as a permanent standing committee and continued to be
7 administered by the National Institute of Environmental
8 Health Sciences. The purposes of ICCVAM shall be to—

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

11 (2) eliminate duplicative efforts and share expe-
12 riences across Federal regulatory agencies;

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

15 (4) ensure that new test methods meet the
16 needs of Federal agencies; and

17 (5) reduce, refine, and replace the use of ani-
18 mals in testing.

19 (b) COMPOSITION.—ICCVAM shall be comprised of
20 a representative from each of the following agencies and
21 organizations:

22 (1) Agency for Toxic Substances and Disease
23 Registry.

24 (2) Consumer Product Safety Commission.

25 (3) Department of Agriculture.

26 (4) Department of Defense.

- 1 (5) Department of Energy.
- 2 (6) Department of the Interior.
- 3 (7) Department of Transportation.
- 4 (8) Environmental Protection Agency.
- 5 (9) Food and Drug Administration.
- 6 (10) National Institute for Occupational Safety
7 and Health.
- 8 (11) National Institutes of Health.
- 9 (12) National Cancer Institute.
- 10 (13) National Institute of Environmental
11 Health Sciences.
- 12 (14) National Library of Medicine.
- 13 (15) Occupational Safety and Health Adminis-
14 tration.
- 15 (16) Any other agency that develops, employs,
16 or regulates the use of animals in toxicity testing.

17 (c) SCIENTIFIC ADVISORY COMMITTEE.—

- 18 (1) ESTABLISHMENT.—In addition, the Na-
19 tional Institute of Environmental Health Sciences
20 shall establish a Scientific Advisory Committee to
21 assist ICCVAM and the National Institute of Envi-
22 ronmental Health Sciences. The Committee shall be
23 composed of at least one knowledgeable representa-
24 tive having a history of expertise, development, or

1 evaluation in alternatives to animal toxicological
2 tests, from each of the following interests:

3 (A) The personal care, pharmaceutical, in-
4 dustrial chemicals, agriculture, and any other
5 regulated industry.

6 (B) A national animal protection organiza-
7 tion established under section 501(e)(3) of the
8 Internal Revenue Code of 1986.

9 (2) MEMBERSHIP.— The National Institute of
10 Environmental Health Sciences shall also invite to
11 be members of the Scientific Advisory Committee
12 representatives from other stakeholder organizations
13 such as:

14 (A) An academic institution.

15 (B) A State government agency.

16 (C) An international regulatory body.

17 (D) A corporation developing or marketing
18 alternative test methodologies including con-
19 tract laboratories.

20 (d) DUTIES.—ICCVAM shall carry out the following
21 duties consistent with the protection of public health and
22 the environment and for the purpose of reducing, refining,
23 and replacing the use of animals in acute and chronic toxicological tests:
24

1 (1) Review and evaluate existing and new alter-
2 native methods, including batteries of tests and test
3 screens, which may be acceptable for specific regu-
4 latory uses, including the coordination of technical
5 reviews of proposed new or revised test methods of
6 interagency interest.

7 (2) Facilitate interagency and international
8 harmonization of acute chronic toxicological test pro-
9 tocols that encourage the reduction, refinement, or
10 replacement of animal tests.

11 (3) Facilitate, promote, and provide guidance
12 on development of validation criteria and processes
13 for new methods and help promote the acceptance of
14 such methods and awareness of accepted methods by
15 Federal agencies and other stakeholders.

16 (4) File formal recommendations with each ap-
17 propriate Federal agency identifying specific agency
18 guidelines, recommendations, or regulations for each
19 new test, battery of tests, test screen, or end point
20 reviewed by ICCVAM that may be appropriate for
21 the reduction, refinement, or replacement of an ani-
22 mal test required or recommended by that Federal
23 agency for compliance with that agency's specific
24 statutes, regulations, or guidelines. Tests may be

1 recommended for a certain class of chemicals within
2 that regulatory framework.

3 (5) Consider for review and evaluation, peti-
4 tions received from the public which identify a spe-
5 cific regulation, recommendation, or guideline, and
6 which recommend alternatives and provide scientific
7 evidence of the acceptability of the alternatives for
8 the purpose of carrying out the regulatory mandate
9 in question.

10 (6) Make final recommendations to agencies
11 and responses from agencies available to the public.

12 (7) Make an annual report to be made available
13 to the public on its progress to promote the regu-
14 latory acceptance of new and revised toxicological
15 tests.

16 **SEC. 3. APPLICATION.**

17 This Act shall not apply to regulations, guidelines,
18 or recommendations related to medical research. The term
19 “medical research” means research, including research
20 performed using biotechnology, related to the causes, diag-
21 nosis, treatment, or control of physical or mental impair-
22 ments of humans or animals. The term does not include
23 the testing of a product to determine its toxicity for the
24 purpose of complying with protocols, recommendations, or
25 guidelines for testing required, recommended, or accepted

1 by a Federal regulatory agency for a product introduced
2 in commerce.

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

4 (a) IDENTIFICATION OF TESTS.—Within 180 days
5 after the date of enactment of this Act, each Federal agen-
6 cy authorized to carry out a regulatory program which re-
7 quires or recommends acute or chronic toxicological test-
8 ing shall identify any regulation or industry-wide guideline
9 which specifically, or in practice requires, recommends, or
10 encourages the use of an animal acute or chronic toxicological
11 test and shall forward to ICCVAM a list of these
12 regulations, guidelines, and recommendations along with
13 the test or tests recommended or required.

14 (b) ALTERNATIVES.—Each Federal agency shall pro-
15 mote and encourage the development and use of alter-
16 natives to animal tests, including batteries of tests and
17 test screens, where appropriate, for the purpose of com-
18 plying with Federal regulations, guidelines, or rec-
19 ommendations, in each instance, and for each chemical
20 class, for which such tests are found to be effective for
21 generating data at least equivalent for hazard identifica-
22 tion or dose-response assessment purposes to the method
23 established under the current regulatory scheme.

24 (c) TEST VALIDATION.—Each Federal agency shall
25 ensure that any new acute or chronic toxicity test, includ-

1 ing animal tests and alternatives, is determined to be valid
2 for its proposed use prior to requiring, recommending, or
3 encouraging its application.

4 (d) **REVIEWS.**—Each Federal agency shall review any
5 formal recommendations from ICCVAM to promulgate
6 new regulations or draft new guidelines or recommenda-
7 tions to promote the ICCVAM recommendations and no-
8 tify ICCVAM in writing of its findings within 180 days
9 of receipt of the recommendations.

10 (e) **RECOMMENDATION ADOPTION.**—Each Federal
11 agency shall adopt the ICCVAM recommendations unless
12 each individual Federal agency determines that—

13 (1) the alternative is not adequate in terms of
14 biological relevance for the regulatory goal author-
15 ized by that agency;

16 (2) the alternative does not generate data at
17 least equivalent for the appropriate hazard identi-
18 fication or dose-response assessment purpose as the
19 method recommended by that agency;

20 (3) that agency does not employ, recommend,
21 or require testing for that class of chemical or for
22 the recommended end point; or

- 1 (4) the new test method is unacceptable for sat-
- 2 isfactorily fulfilling the test needs for that particular
- 3 agency and its respective congressional mandate.

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