I

103D CONGRESS
2D SESSION

# H. R. 5222

To provide for nonanimal acute toxicity testing by the Federal Government.

---

IN THE HOUSE OF REPRESENTATIVES

OCTOBER 6, 1994

Mr. LANTOS (for himself, Mr. ACKERMAN, Mr. BEILENSON, Mr. BROWN of California, Mr. DEFAZIO, Mr. DELLUMS, Mr. GEJDENSON, Mr. HAMBURG, Mr. HOCHBRUECKNER, Mr. JOHNSON of South Dakota, Mr. JOHNSTON of Florida, Mr. KLECZKA, Mr. MANTON, Mr. MINETA, Mr. MORAN, Mr. NEAL of Massachusetts, Mr. RAVENEL, Ms. ROYBAL-ALLARD, Mr. SHAYS, Mr. SWETT, Mr. SWIFT, and Mr. TOWNS) introduced the following bill; which was referred to the Committee on Energy and Commerce

---

# A BILL

To provide for nonanimal acute toxicity testing by the Federal Government.

*Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,*

**SECTION 1. SHORT TITLE.**

This Act may be cited as the ''Consumer Products Safe Testing Act''.

**SEC. 2. FINDINGS AND POLICY.**

(a) FINDINGS.—The Congress finds that—

(1) nonanimal acute toxicity tests have been developed in recent years that have shown a level of reliability sufficient for the reduction or replacement of animal acute toxicity tests such as the Draize test for many products regulated by the Federal Government;

(2) many manufacturers have found nonanimal acute toxicity tests to be adequate for evaluating the safety of products for the purposes of complying with Federal regulations or guidelines;

(3) the Federal Government has discouraged the use of these alternatives through regulations that mandate or encourage the use of animal acute toxicity tests, or by not prescribing other, less costly, more accurate and humane alternatives;

(4) many manufacturers are reluctant to use nonanimal tests without encouragement from the Federal Government; and

(5) private industry and the consumer will benefit from the promotion of alternative methods of testing when these alternatives are as accurate and more humane than animal tests.

(b) POLICY.—Federal departments and agencies shall encourage the development and use of product testing procedures that accurately reflect the acute health effects on

humans of certain products, including consumer products and products containing hazardous or toxic substances, but which do not rely upon animals.

**SEC. 3. FEDERAL ACTION.**

(a) REVIEW OF REGULATIONS, GUIDELINES, OR RECOMMENDATIONS CONCERNING THE DRAIZE TEST AND OTHER ANIMAL ACUTE TOXICITY TESTS.—Not later than one year after the date of enactment of this Act, each Federal department or agency head shall—

(1) review and evaluate any regulation, guideline, or recommendation issued by that department or agency which requires, recommends, or encourages the use of the Draize or other animal acute toxicity test for the purpose of evaluation of the safety of a regulated product;

(2) review and evaluate nonanimal alternatives with the potential for partial or full replacement of the Draize or other animal acute toxicity test for some or all of the products regulated; and

(3) promulgate regulations, guidelines, or recommendations that specify a nonanimal acute toxicity test or battery of tests should be used instead of an animal acute toxicity test unless that Federal department or agency head determines that the nonanimal acute toxicity test or battery of such tests

is less likely to predict the acute health effects on humans of a product than the animal acute toxicity test.

(b) ANIMAL ACUTE TOXICITY TESTS.—If a determination is made that no nonanimal acute toxicity test or battery of tests is as likely to predict the human reaction to the regulated product as the Draize or other animal acute toxicity test, the appropriate Federal department or agency head shall publish in the Federal Register an explanation of all options considered and the justification for continuing the animal acute toxicity test, which shall be subject to public comment.

(c) PERIODIC REVIEW OF ANIMAL ACUTE TOXICITY TESTING REGULATIONS.—At least every 2 years (beginning 3 years after the date of enactment of this Act), each Federal department or agency head, after considering the most recent technological advances available, shall determine whether continued use of any animal acute toxicity test is justified. If a Federal department or agency head determines that such use is justified, then that Federal department or agency head shall publish an explanation and justification of such continued use in the Federal Register, which shall be subject to public comment.

**SEC. 4. APPLICATION.**

This Act shall not apply to regulations, guidelines, or recommendations related to medical research.

**SEC. 5. DEFINITIONS.**

For purposes of this Act:

(1) ANIMAL.—The term ''animal'' means any vertebrate.

(2) ANIMAL ACUTE TOXICITY TEST.—The term ''animal acute toxicity test'' means an acute toxicity test on animals, including (but not limited to) the Draize eye or skin irritancy test, LD–50 test, approximate lethal dose test, and the limit test.

(3) FEDERAL DEPARTMENT OR AGENCY HEAD.—The term ''Federal department or agency head'' means the head of a Federal department or agency who—

(A) has authority to promulgate regulations, guidelines, and recommendations with respect to procedures to be used in the safety testing by manufacturers of products, including consumer products, veterinary products, and products containing hazardous or toxic substances; or

(B) licenses or approves products, labeling requirements or the transportation of products based on the results of these tests.

(4) MEDICAL RESEARCH.—The term ''medical research'' means research related to the causes, diagnosis, treatment, or control of physical or mental impairments of humans or animals. The term does not include the testing of a product to determine its toxicity for the purpose of complying with protocols, recommendations, or guidelines for testing required, recommended, or accepted by a Federal regulatory agency for a product introduced in commerce.

(5) NONANIMAL ACUTE TOXICITY TEST.—The term ''nonanimal acute toxicity test'' means an acute toxicity test not conducted on animals. Such tests include (but are not limited to) cell culture, computer modeling, protein alteration, and chorioallantoic membrane techniques.

○