

TESTIMONY OF
PHYSICIANS COMMITTEE FOR RESPONSIBLE MEDICINE
BEFORE THE
SENATE COMMITTEE ON ENVIRONMENT AND PUBLIC WORKS
AND
SUBCOMMITTEE ON SUPERFUND, TOXICS, AND ENVIRONMENTAL HEALTH
ON
THE SAFE CHEMICALS ACT, S.847

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Nancy Beck, PhD
Physicians Committee for Responsible Medicine
5100 Wisconsin Ave NW, Suite 400
Washington, DC 20016
nancybeck226@gmail.com

Chad Sandusky, PhD
Physicians Committee for Responsible Medicine
5100 Wisconsin Ave NW, Suite 400
Washington, DC 20016
csandusky@pcrm.org

The Physicians Committee for Responsible Medicine is a national non-profit group of over 125,000 doctors and laypersons advocating for preventive medicine and ethical standards in research and testing. We appreciate the opportunity to submit written testimony for the record.

We have provided legislative language aimed at ensuring that the legislation moves forward on the basis of the best available science. The use of cell-based, tissue-based and computational methods for chemical testing, rather than the use of animals, is critical to the legislation's ability to protect public health. Non-animal methods have the potential to provide more accurate and human-relevant information, much more quickly and affordably. While the extensive use of animals for chemical testing is a significant concern, it is one that has been largely ignored in the discourse on this legislation. We believe the language suggested below will help decrease reliance on animal use, and in turn, increase protection of public health.

SUGGESTIONS FOR S. 847:

SEC. 3. FINDINGS, POLICY, AND GOAL

CHANGE:

(b) POLICY. It is the policy of the United States that—

(6) to reduce the reliance on animal testing in hazard assessment;

~~(67)~~ to guarantee the right of the public and workers to know about the hazards and uses of chemical substances that the public and workers may be exposed to by maximizing public access to information on chemical safety and use; and

~~(78)~~ to strengthen cooperation between and among the Federal Government and State, municipal, tribal, and foreign governments

JUSTIFICATION: This is a goal of many in and outside Congress and is linked hand-in-hand with the ability to collect new human-relevant hazard data on thousands of substances in a timely manner.

SEC. 5. MINIMUM DATA SETS AND TESTING OF CHEMICAL SUBSTANCES

CHANGE:

'(d) Exemptions.-

'(2) Action by administrator. In accordance with paragraph (3) or (4), the Administrator shall exempt an applicant under paragraph (1), if, on receipt of the application, the Administrator determines that-

'(A) the chemical substance for which the application was submitted is equivalent to a chemical substance for which-

'(i) data has been submitted to the Administrator in accordance with a rule or order under subsection (a) or (b); or

'(ii) data is being developed in accordance with the rule or order; or
'(iii) data is being developed in accordance with another regulatory purpose; and
'(B) submission of data by the applicant for the substance would be duplicative of data that-
'(i) has been submitted to the Administrator in accordance with the rule or order under
subsection (a) or (b); or
'(ii) is being developed in accordance with the rule or order; or
'(iii) is being developed in accordance with another regulatory purpose.

JUSTIFICATION: All data, including that developed for other regulatory agencies, countries, or purposes outside of this Act, should be brought to bear to prevent duplicative testing.

SEC. 6. MANUFACTURING AND PROCESSING NOTICES.

CHANGE:

'(a) New Chemical Substances and New Uses of Chemical Substances.-

'(3) New uses of existing chemical substances that meet the safety standard.-

'(A) In general. For an existing chemical substance for which the Administrator has determined under section 6(b) that the manufacturers and processors of the chemical substance have established that the substance meets the applicable safety standard, no person may manufacture or process the chemical substance for uses, at production volumes, or in manners other than those the Administrator specified in the safety standard determination, unless-

'(i) the manufacturer or processor submits to the Administrator-

'(I) a notice of the intention of the manufacturer or processor to manufacture or process the substance for a new use, at a new production volume, or in such other manner as is inconsistent with a specified condition or term for that substance; and

'(II) ~~all~~ any necessary updates to the minimum data set as determined by the Administrator relevant to the new use, new production volume, or other new manner of manufacturing or processing;

JUSTIFICATION: This language makes it more likely that companies will enter into a conversation with the Agency about what new testing might be required, instead of assuming some tests must be done when, depending on the new use or production volume, this may not be the case. The goal is to avoid “one-size-fits-all” data collection.

CHANGE:

'(b) Submission of Data.-

'(1) In general. A person shall submit to the Administrator data in accordance with the rule or order at the time that notice is submitted under subsection (a), except as provided under subsection (b)(2), if the person is required to submit to the Administrator-

'(A) under subsection (a), a notice prior to beginning the manufacture or processing of a chemical substance; and

'(B) under section 4(b), test data for the chemical substance prior to the submission of the

notice.

'(2) Exceptions to minimum data set.-

'(A) A person may, upon application, request exception from specific requirements of the minimum data set described in section 4(a), either before or concurrent with submission of notice under subsection (a).

'(B) The administrator shall determine whether such exception(s) will be granted within 30 days of receipt of application, and make such this determination in accordance with section 30(b)(1) and section 30(e).

'(3) Availability. Subject to section 14, the Administrator shall make any test data submitted under paragraph (1) available on a publicly accessible Internet site.

JUSTIFICATION: This absolutely crucial change clarifies that Congress's intent is to avoid "one-size-fits-all" testing schemes in the new substances sector, just as is provided for in this Act for existing substances. It allows companies to apply for testing exceptions if there is reason to believe certain test are unnecessary for any relevant reason, such as existing data already in the EPA's possession, characteristics of the new substance, or information about related substances. As the Act is written now, companies must submit, animal- and resource-intensive toxicity data at the same time as they notify the EPA of their intent to manufacture the substance, prompting companies to conduct potentially unwarranted testing. This language creates an opportunity for dialog between the company and the EPA regarding the generation of data. At the same time it provides quick turnaround for both the agency and the company, and allows some flexibility to companies who wish to bring newer, potentially safer, chemicals to market but are concerned about the up front costs of traditional toxicity data generation.

CHANGE:

'(c) Content and Availability of Notice.-

'(1) Content. Notice under subsection (a)(1) shall include-

'(A) the declaration described in section 8(a)(2);

'(B) the minimum data set described in section 4(a) and considering subsection (b)(2); and

'(C) a statement that the chemical substance will meet the applicable safety standard.

JUSTIFICATION: Referring to changes in 6(b).

CHANGE:

'(d) Exemptions.-

'(2) ~~Equivalent~~ Similar chemical substances.-

'(A) In general. The Administrator shall, upon application, fully or partially exempt any person from the requirement to submit data under subsection (a) if, on receipt of an application, the Administrator determines that-

'(i) the chemical substance for which the application was submitted is ~~equivalent~~ structurally or toxicologically similar to a chemical substance for which data has been submitted to the Administrator as required by this Act; and

'(ii) submission of data by the applicant on the chemical substance would be duplicative of data which has been submitted to the Administrator in accordance with this Act.

JUSTIFICATION: Scientific support can be provided to show that two or more structurally or toxicologically very similar, but slightly different (i.e., not equivalent) substances have very similar toxicological properties, making testing of such substances duplicative.

SEC. 30. REDUCTION OF ANIMAL-BASED TESTING.

CHANGE:

'(a) In general. Tests on animals shall not be performed if another scientifically satisfactory method of obtaining the information sought, not entailing the use of an animal, is reasonably and practicably available. Testing on animals for the purpose of this Act shall be undertaken only as a last resort when all other data sources have been exhausted. Where adequate animal test data exist for a toxicological or ecotoxicological endpoint, further animal testing for the same endpoint shall not be required.'

JUSTIFICATION: Such a requirement is the best incentive to develop and use non-animal methods, which is crucial for ethical, scientific, and practical reasons alike. This language is similar to that enacted in other chemicals legislation worldwide (such as REACH in the European Union), and will help implement the National Academies' vision for "Toxicity Testing in the 21st Century", which envisions faster, cheaper, and more human relevant tests instead of currently relied-upon animal tests. More focused, strategic testing and the generation of more human-relevant data will also save EPA resources.

CHANGE:

'(c**b**) Interagency Science Advisory Board on Alternative Testing Methods.-

'(1) Establishment. Not later than 90 days after the date of enactment of the Safe Chemicals Act of 2011, the Administrator shall establish an advisory board to be known as the 'Interagency Science Advisory Board on Alternative Testing Methods' (referred to in this subsection and subsection (d**e**) as the ' Board').

'(2) Composition. The Administrator shall-

'(A) appoint the members of the Board, including, at a minimum, representatives of-

'(i) the National Institute of Environmental Health Sciences;

'(ii) the Centers for Disease Control and Prevention;

'(iii) the National Toxicology Program;

'(iv) the National Cancer Institute; ~~and~~

'(v) the National EPA-Tribal Science Council; and

'(vi) not fewer than 3 non-agency members with expertise in alternative testing methods; and

'(B) ensure that at least ½ of the members of the Board have specific scientific or practical expertise in the development or implementation of test methods that replace or reduce animal-

based testing; and

'(C~~B~~) ensure that no individual appointed to serve on the Board has a conflict of interest that is relevant to the functions to be performed, unless-

'(i) the individual promptly and publicly discloses the conflict; and

'(ii) the Administrator determines that the conflict is unavoidable.

JUSTIFICATION: The public sector contains individuals with years of expertise in the development and use of non-animal methods and alternatives to animal tests, and it is essential that the EPA consult this expertise in addition to federal agency representatives

CHANGE:

'(5) Report. Not later than 1 year after the date of enactment of the Safe Chemicals Act of 2011, and every 23 years thereafter, the Administrator, in consultation with the Board, shall publish in the Federal Register a list of testing methods that reduce the use of animals in testing under section 4.

JUSTIFICATION: The fast-developing scientific fields related to the development of non-animal toxicity tests require updates of a list of accepted testing methods more frequently than every 3 years.

CHANGE:

'(d~~e~~) Implementation of Alternative Testing Methods. To promote the development and timely incorporation of new testing methods that are not animal-based, the Administrator shall-

'(1) in consultation with the Board, and after providing an opportunity for public comment, develop a strategic plan to promote the development and implementation of alternative test methods and testing strategies to generate information used for safety standard determinations under section 6(b) that do not use animals, including toxicity pathway-based risk assessment, in vitro studies, systems biology, computational toxicology, bioinformatics, and high-throughput screening;

'(2) beginning on the date that is 2 years after the date of enactment of the Safe Chemicals Act of 2011 and every 2 years thereafter, submit to Congress a report that describes the progress made in implementing this section; ~~and~~

'(3) fund and carry out research, development, performance assessment, and translational studies to accelerate the development of test methods and testing strategies that are not animal-based for use in safety standard determinations under section 6(b); and

'(4) after an opportunity for public comment, establish policies within the administration of this Act that create incentives for the development of alternative test methods and the use of such methods, testing strategies, and other measures to reduce animal-based testing as described in this section.

JUSTIFICATION: Market and other incentives to develop and use non-animal toxicity tests, and the increased uptake of those tests, will save company and EPA resources, protect human health

by allowing the collection of data more quickly, and accomplish ethical societal goals.

SEC. 32. COOPERATION WITH INTERNATIONAL EFFORTS.

CHANGE:

(a) 'In cooperation with the Secretary of State and the head of any other appropriate Federal agency (as determined by the Administrator), the Administrator shall cooperate with international efforts as appropriate-

'(1) to develop a common protocol or electronic database relating to chemical substances; or

'(2) to develop safer alternatives for chemical substances; or

'(3) to harmonize testing methods and procedures.

JUSTIFICATION: International cooperation to harmonize testing methods and procedures saves businesses and governments millions of dollars and saves thousands of animals by preventing duplicative testing. Cooperating with other regulatory agencies' efforts to replace animal tests also saves research resources and encourages scientific progress.