VIRGINIA ACTS OF ASSEMBLY — CHAPTER

An Act to amend the Code of Virginia by adding in Chapter 65 of Title 3.2 an article numbered 13, consisting of sections numbered 3.2-6591, 3.2-6592, and 3.2-6593, relating to animal research; 3 4 alternative test methods; civil penalty.

[H 1087] 5 6

Approved

Be it enacted by the General Assembly of Virginia:

1. That the Code of Virginia is amended by adding in Chapter 65 of Title 3.2 an article numbered 13, consisting of sections numbered 3.2-6591, 3.2-6592, and 3.2-6593, as follows:

Article 13. Animal Research.

§ 3.2-6591. Definitions.

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As used in this article, unless the context requires a different meaning:

"Alternative test method" means a test method that (i) provides information of equivalent or better scientific quality and relevance than animal test methods, (ii) has been identified by a validation body and adopted by the relevant federal agency or program within an agency responsible for regulating the specific product or activity for which the test is being conducted, and (iii) does not use animals, or, when there is no test method available that does not use animals, uses the fewest animals possible and reduces the level of suffering or stress, to the greatest extent possible, of an animal used for testing. "Alternative test method" includes computational toxicology and bioinformatics, high-throughput screening methods, testing of categories of chemical substances, tiered testing methods, invitro studies, and systems biology and new or revised methods.

"Animal" means any live vertebrate nonhuman animal.

"Animal test method" means a process or procedure that uses animals to obtain information on the characteristics of a chemical or agent or the biological effect of exposure to a chemical or agent under specified conditions.

"Contract testing facility" means any partnership, corporation, association, or other legal relationship that tests chemicals, ingredients, product formulations, or products on behalf of another entity.

"Manufacturer" means any partnership, corporation, association, or other legal entity that produces chemicals, ingredients, product formulations, or products.

"Validation body" means an organization that seeks to facilitate development, validation, and regulatory acceptance of new and revised regulatory test methods that reduce, refine, or replace the use of animals in testing, such as the Interagency Coordinating Committee on the Validation of Alternative Methods or other similar organizations.

- § 3.2-6592. Manufacturers and contract testing facilities required to use alternative test methods when available.
- A. No manufacturer or contract testing facility shall use an animal test method when an alternative test method is available.
 - B. Nothing in this section shall prohibit the use of a test method that does not use animals.
- C. This section shall not apply to any manufacturer or contract test facility using an animal test method for the purpose of medical research related to the causes, diagnosis, treatment, control, or prevention of physical or mental diseases and impairments of humans and animals, or related to the development of devices or drugs, as those terms are defined in 21 U.S.C. § 321, biomedical products, or any other products regulated by the U.S. Food and Drug Administration, except for any product regulated under Subchapter VI of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 301 et seq.). Such medical research does not include the testing of an ingredient that (i) was formerly used in a drug; (ii) was tested for use in a drug using commonly accepted animal testing methods to characterize the ingredient and to substantiate its safety for human use; and (iii) is proposed for use in a product other than a biomedical product, medical device, or drug.

§ 3.2-6593. Enforcement; civil action; penalty.

The Attorney General may bring a civil action in the appropriate circuit court for injunctive relief to enforce the provisions of this article. Any person who violates any provision of this article may, upon such finding by an appropriate circuit court, be subject to a civil penalty of not more than \$5,000 and any court costs and attorney fees. Such civil penalties shall be paid into the state treasury.