LD7006260

HOUSE BILL NO. 725

Offered January 25, 1994

A BILL to amend the Code of Virginia by adding in Chapter 5.9 of Title 2.1 an article numbered 2, consisting of sections numbered 2.1-51.40:2 through 2.1-51.40:11, relating to regulation of biotechnology research; penalties.

Patrons—Hall, Abbitt, Almand, Ball, Cantor, Cox, Cranwell, Cunningham, Dickinson, Hull, Jones, D. C., Martin, Morgan, Moss, Reid, Rhodes, Shuler, Van Yahres and Watkins; Senators: Bell, Benedetti, Cross, Holland, E.M., Lambert, Marye, Russell and Stosch

Referred to Committee on General Laws

Be it enacted by the General Assembly of Virginia:

1. That the Code of Virginia is amended by adding in Chapter 5.9 of Title 2.1 an article numbered 2, consisting of sections numbered 2.1-51.40:2 through 2.1-51.40:11 as follows:

Article 2.

Virginia Biotechnology Framework.

§ 2.1-51.40:2. Purpose.

The purposes of this article are to establish a state regulatory scheme to ensure state participation in the federal Coordinated Framework for the Regulation of Biotechnology to protect human health and the environment and to stimulate the growth of the biotechnology industry within the Commonwealth. To do this, the Secretary of Commerce and Trade shall cooperate with federal authorities pursuant to the federal Coordinated Framework to assess the potential risks and effects of proposed planned introductions of genetically engineered organisms into the environment without undue governmental interference with the progress and commercial development of biotechnology within the Commonwealth. The General Assembly does not intend to create a regulatory scheme that duplicates federal regulatory efforts regarding biotechnology, or one that overly burdens biotechnology efforts within the Commonwealth. This article is intended to institute a process in which the Commonwealth can monitor the federal regulatory process and protect its interests in agriculture, public health, and the natural environment, as needed, by participation in the federal regulatory process.

§ 2.1-51.40:3. Definitions.

As used in this article:

"Affected localities" means the locality in which a planned introduction is proposed to be made and any locality within a three-mile radius of the location where the planned introduction is proposed to be made.

"Confidential business information" means information entitled to confidential treatment under subdivision A1 or A2 of § 2.1-51.40:8.

"Coordinated Framework" means the federal Coordinated Framework for the Regulation of Biotechnology set forth in 51 Fed. Reg. 23,302 through 23,350 (June 26, 1986), as amended by 52 Fed. Reg. 22,892 through 22,915 (June 16, 1987); 55 Fed. Reg. 31,118 through 31,121 (July 31, 1990); and 57 Fed. Reg. 6,753 through 6,762 (Feb. 27, 1992); and subsequent amendments to the federal Coordinated Framework for the Regulation of Biotechnology, as they may be issued from time to time.

"Department" means the department designated by the Secretary of Commerce and Trade to implement the requirements of this article for certain types or classes of regulated introductions. Where possible, the Secretary shall designate the department whose purpose most closely resembles the purpose of the federal regulator that will be responsible under the Coordinated Framework for reviewing and authorizing the regulated introduction.

"Federal regulator" means a federal department, agency, or other instrumentality of the federal government, or a designee of such federal instrumentality, which is responsible for regulating an introduction of a genetically engineered organism into the environment under the Coordinated Framework.

"Genetically engineered organism" means an organism (any organism such as animal, plant, bacterium, cyanobacterium, fungus, protist, or virus), altered or produced through genetic modification from a donor, vector, or recipient organism using modern molecular techniques such as recombinant deoxyribonucleic acid methodology, and any living organisms derived therefrom.

"Locality" means any county or municipality located within the Commonwealth of Virginia.

"Planned introduction into the environment" means the intentional introduction or use in this Commonwealth beyond the de minimis level of a genetically engineered organism anywhere except within an indoor facility which is designed to physically contain the genetically engineered organism,

including a laboratory, greenhouse, building, structure, growth chamber, or fermenter.

"Regulated introduction" means an introduction into the environment for which the Coordinated Framework requires that the person proposing to commence the introduction into the environment do one or more of the following:

1. Notify a federal regulator of the proposed introduction into the environment;

2. Secure the approval of or a permit or license from a federal regulator before commencing the introduction into the environment; or

3. Secure a determination by a federal regulator of the need for notification, approval, licensing or issuance of a permit by the federal regulator if the determination is part of a procedure specified in the Coordinated Framework.

§ 2.1-51.40:4. Exemptions.

A. The Department may waive part or all of the requirements under this article for a specified regulated introduction if the Department determines that the satisfaction of that requirement is not necessary to protect the public health or the environment.

B. The Department may exempt a class of regulated introductions from part or all of any requirement under this article if the Department determines that the satisfaction of those requirements or part thereof is not necessary to protect the public health or the environment.

C. Planned regulated introductions approved by a federal regulator pursuant to the federal Coordinated Framework prior to enactment of this article shall be exempt from the provisions this article.

§ 2.1-51.40:5. Notification.

Except as provided under § 2.1-51.40:4, no person may commence a regulated introduction unless the person:

1. Provides to the Department all of the following information within seven days after the person submits or should have submitted the information specified in subdivisions 1 a and 1 b of this section to a federal regulator, whichever is sooner:

a. A copy of all information which the person is required to submit to the federal regulator and which is not confidential information; and

b. A summary of any confidential information which the person submits or is required to submit to a federal regulator. The summary shall provide sufficient information to enable the Department to exercise its notice and comment functions under §§ 2.1-51.40:6 and 2.1-51.40:7, to provide public notice pursuant to § 2.1-51.40:6, and to prepare comments pursuant to § 2.1-51.40:7, and shall have minimal extraneous and irrelevant information. Likewise, the summary shall provide sufficient information to enable the locality in which the introduction is proposed to be made to exercise its comment function under § 2.1-51.40:7.

2. Provides such additional information, if any, as is necessary to enable the Department to fulfill any functions it undertakes, on a case-by-case basis, under § 2.1-51.40:7.

§ 2.1-51.40:6. Public notice.

Within fifteen days after receiving the information required under § 2.1-51.40:5, the Department shall publish notice and a brief description of the proposed planned introduction. Notice shall also be provided to any affected locality and to any person who has filed a written request to be notified of such planned introductions. Notice shall be given by publication one time in a newspaper having general circulation in each locality where the planned introduction is proposed to be made. In addition, subject to the provisions of this article regarding confidential business information, any documents submitted to the Department as required under § 2.1-51.40:5 shall be available for public inspection or copying at or near the site of the proposed planned introduction and at the offices of the Department.

§ 2.1-51.40:7. Comment.

A. The Department, and any affected locality may prepare formal comments on the regulated introduction for submission to the federal regulator for that regulated introduction. Such comments shall be submitted within the time established by the federal regulator for that regulated introduction, as determined by the applicable federal requirements or the Coordinated Framework. The comments shall address the criteria for the granting of approval of a permit or a license under the applicable requirement in the Coordinated Framework and for the protection of the public health and the environment.

B. To assist in the preparation of comments, the Department may do any or all of the following:

1. Hold an informational meeting on the proposed regulated introduction;

2. Provide an opportunity for the public to comment on the proposed regulated introduction;

3. Request any additional information necessary on the proposed regulated introduction from the person providing information under § 2.1-51.40:5;

4. Conduct a technical review of the proposed regulated introduction; and

5. Seek the assistance of the faculty and academic staff of any Virginia public college or university, the Department of Health, the Department of Agriculture and Consumer Services, the Department of

Environmental Quality, or any other appropriate state agency or organization, including but not limited to an institutional biosafety committee, in reviewing the proposed regulated introduction.

C. To assist in the preparation of comments, affected localities may do either or both of the following:

1. Hold an informational meeting on the proposed regulated introduction. When possible, that meeting shall be held in conjunction with an informational meeting held by the Department; and

2. Provide an opportunity for the public to comment on the proposed planned introduction.

§ 2.1-51.40:8. Confidential business information.

A. Except as provided in subsections B and C, the Department and any affected locality shall keep confidential any information received under this article if the person submitting the information notifies them that:

1. The federal regulator to whom the information has been submitted has determined that the information is entitled to confidential treatment and is not subject to public disclosure under the federal Freedom of Information Act, 5 U.S.C. § 552, as now or hereafter amended, or under the Coordinated Framework; or

2. The person submitting the information to the Department and any locality has submitted a claim to the federal regulator that the information is entitled to confidential treatment under the federal Freedom of Information Act or under the Coordinated Framework, and the federal regulator has not made a determination on that claim.

B. Subsection A shall not prevent the Department from using the information for the purposes of subdivision B4 or B5 of § 2.1-51.40:7, subject to the requirements of subsection D of this section.

C. The Department shall allow public access to any information which has been granted confidentiality under subsection A if either of the following occurs:

1. The person providing the information expressly agrees in writing to the public access of the information; or

2. After information has been granted confidentiality under subdivision A2, the federal regulator makes a determination that the information is not entitled to confidential treatment under the federal Freedom of Information Act or under the Coordinated Framework.

D. 1. The Department shall establish procedures to protect information required to be kept confidential under subsection A of this section. Under the procedures, the Department may not submit any information under subdivision B4 or B5 of § 2.1-51.40:7 to any person who is not an employee of the Department unless that person has signed an agreement which satisfies the requirements of subdivision 2 of this subsection.

2. Any agreement under subdivision 1 of this subsection shall provide that information which is the subject of the agreement is subject to confidential treatment; shall prohibit the release or sharing of the information with any other person except at the direction of the Department and in compliance with this article; shall acknowledge the penalties in § 59.1-338 of the Virginia Uniform Trade Secrets Act (§ 59.1-336, et seq.), as now and hereafter amended, and any other applicable law of the Commonwealth identified by the Department for the unauthorized disclosure of the information; and shall contain a statement that the person receiving the information, any member of his or her immediate family or any organization with which he or she is associated has no substantial financial interest in the regulated introduction which is the subject of the information. Any person submitting the information under § 2.1-51.40:5 may waive any of the requirements under this section.

§ 2.1-51.40:9. Enforcement.

The Department shall enforce §§ 2.1-51.40:5 and 2.1-51.40:8. Actions to enforce this article by injunctive and any other relief appropriate for enforcement may be filed in the circuit court of the City of Richmond or in any county or municipality where a violation occurred in whole or in part. In an enforcement action under this article, if it is determined that a person commenced a regulated introduction and did not comply with § 2.1-51.40:5, the court may enter an injunction directing the person to cease the regulated introduction and may order any additional action necessary to protect human health and the environment.

§ 2.1-51.40:10. Penalties.

A civil penalty of not more than $500 may be assessed by the Department against any person who violates any provision of this article. In determining the amount of the penalty, the Department shall consider the degree and extent of harm caused by the violation. No civil penalty may be assessed under this section unless the person has been given the opportunity for a hearing pursuant to the Virginia Administrative Process Act, (§ 9-6.14:1 et seq.). Any continuing failure to notify under § 2.1-51.40:5 shall constitute the same offense for purposes of imposing the above penalty.

§ 2.1-51.40:11. Local regulation.

No locality shall enact any regulation or ordinance regulating the planned introduction of genetically engineered organisms into the environment. No locality shall enact any regulation or ordinance

regulating biotechnology research activities, provided, however, that the siting of biotechnology research activities shall be subject to the zoning and land use laws and regulations of the political subdivisions in which such activities are conducted.

2. That §§ 2.1-51.38 through 2.1-51-40.1 shall be Article 1 of Chapter 5.9 of Title 2.1 of the Code of Virginia.