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HOUSE BILL NO. 725**AMENDMENT IN THE NATURE OF A SUBSTITUTE**(Proposed by the House Committee on General Laws
on February 4, 1994)

(Patron Prior to Substitute—Delegate Hall)

A *BILL* to amend the Code of Virginia by adding a section numbered 2.1-51.39:2 and by adding in Title 2.1 a chapter numbered 48, consisting of sections numbered 2.1-769 through 2.1-778, relating to the Virginia Biotechnology Research Act; penalties.

Be it enacted by the General Assembly of Virginia:

1. That the Code of Virginia is amended by adding a section numbered 2.1-51.39:2 and by adding in Title 2.1 a chapter numbered 48, consisting of sections numbered 2.1-769 through 2.1-778, as follows:

§ 2.1-51.39:2. Virginia Biotechnology Research Act; responsibilities of the Secretary.

The Secretary of Commerce and Trade shall implement the provisions of the Virginia Biotechnology Research Act (§ 2.1-769 et seq.).

CHAPTER 48.**VIRGINIA BIOTECHNOLOGY RESEARCH ACT.**

§ 2.1-769. Purpose.

The purposes of this chapter 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 regulated 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 chapter 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.

§ 2.1-770. Definitions.

As used in this chapter:

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

"Confidential business information" means information entitled to confidential treatment under subdivision A1 or A2 of § 2.1-775.

"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 chapter 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 (DNA) methodology, and any living organisms derived therefrom.

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

"Planned introduction into the environment" means the intentional introduction or use in the 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,

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

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

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

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

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

70 § 2.1-771. Exemptions.

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

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

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

80 § 2.1-772. Notification.

81 Except as provided under § 2.1-771, no person may commence a regulated introduction unless the
82 person:

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

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

88 b. A summary of any confidential information which the person submits or is required to submit to a
89 federal regulator. The summary shall provide sufficient information to enable the Department to exercise
90 its notice and comment functions under §§ 2.1-773 and 2.1-774, to provide public notice pursuant to
91 § 2.1-773, and to prepare comments pursuant to § 2.1-774, and shall have minimal extraneous and
92 irrelevant information. Likewise, the summary shall provide sufficient information to enable the locality
93 in which the introduction is proposed to be made to exercise its comment function under § 2.1-774.

94 2. Provides such additional information, if any, as is necessary to enable the Department to fulfill
95 any functions it undertakes, on a case-by-case basis, under § 2.1-774.

96 § 2.1-773. Public notice.

97 Within fifteen days after receiving the information required under § 2.1-772, the Department shall
98 publish notice and a brief description of the proposed regulated introduction. Notice shall also be
99 provided to any affected locality and to any person who has filed a written request to be notified of
100 such regulated introductions. Notice shall be given by publication one time in a newspaper having
101 general circulation in each locality where the regulated introduction is proposed to be made. In
102 addition, subject to the provisions of this article regarding confidential business information, any
103 documents submitted to the Department as required under § 2.1-772 shall be available for public
104 inspection or copying at or near the site of the proposed regulated introduction and at the offices of the
105 Department.

106 § 2.1-774. Comment.

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

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

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

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

117 3. Request any additional information necessary on the proposed regulated introduction from the
118 person providing information under § 2.1-772;

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

120 5. Seek the assistance of the faculty and academic staff of any Virginia public college or university,
121 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 regulated introduction.

§ 2.1-775. 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 chapter 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 § 2.1-774, 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 § 2.1-774 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 chapter; 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 § 2.1-772 may waive any of the requirements under this section.

§ 2.1-776. Enforcement.

The Department shall enforce §§ 2.1-772 and 2.1-775. Actions to enforce this chapter 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 chapter, if it is determined that a person commenced a regulated introduction and did not comply with § 2.1-772, 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.

§ 2.1-777. Penalties.

A civil penalty of not more than \$500 may be assessed by the Department against any person who violates any provision of this chapter. 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 § 2.1-772 shall constitute the same offense for purposes of imposing the above penalty.

§ 2.1-778. Local regulation.

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

183 *regulation or ordinance regulating or prohibiting biotechnology research activities, provided, however,*
184 *that the siting of biotechnology research activities shall be subject to the zoning and land-use laws and*
185 *regulations of the political subdivisions in which such activities are conducted and the Uniform*
186 *Statewide Building Code (§ 36-97 et seq.), the Statewide Fire Prevention Code (§ 27-94 et seq.), local*
187 *public utility and public works ordinances and regulations of general application, and local tax*
188 *ordinances of general application.*