REPORT OF THE
SECRETARY OF COMMERCE AND TRADE ON

A VIRGINIA BIOTECHNOLOGY RESEARCH ACT

TO THE GOVERNOR AND
THE GENERAL ASSEMBLY OF VIRGINIA

HOUSE DOCUMENT NO. 31

COMMONWEALTH OF VIRGINIA
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1994

COMMONWEALTH of VIRGINIA

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November 1, 1993

TO: The Honorable Lawrence Douglas Wilder
Members of the General Assembly of Virginia
Chairmen of the House Appropriations Committee and the Senate Finance Committee

House Joint Resolution 516, agreed to by the General Assembly in 1993, requests the Secretary of Commerce and Trade to "conduct a study of the value of enacting a biotechnology research act for the benefit of human endeavor, including agriculture, health care and environmental protection."

As directed by this joint resolution, I hereby submit the enclosed report which includes the findings of the study that was conducted in response to HJR 516.

I wish to express my appreciation to the many individuals who served on the study group and to others who also assisted my office in carrying out the request of the General Assembly for this important study.

Respectfully submitted,

Cathleen A. Magennis
Secretary of Commerce and Trade

CAM/klc

Enclosure

EXECUTIVE SUMMARY

In response to 1993 HJR No. 516 the Secretary of Commerce and Trade initiated a study on the value of enacting a Virginia biotechnology regulatory framework. A committee made up of scientists, business persons, regulators, economic development and university officials, and environmental specialists appointed by the Secretary completed its work and submitted the following report and model legislation on September 1.

The study identified the existing federal, state and local framework for oversight and regulation of biotechnology research, development and commercialization in Virginia. It examined regulatory actions taken by other states and sought options that would be both protective of human health and the environment, and cost-effective and timely. The Committee concluded that an appropriate balance between the protection afforded by the federal rules and the desire of concerned localities and citizens to be involved in the regulatory process was an important objective. This can best be served by a state regulatory approach that relies on the federal Coordinated Framework while also providing notification to the public and creating a participatory role for localities and citizens.

Specifically, the Committee agreed that codification of a responsible and non-burdensome regulatory framework for biotechnology research was a necessary foundation for successful development and recruitment of the industry in Virginia, and made three recommendations:

- Accept the federal Coordinated Framework for Regulation of Biotechnology as the state's substantive policy of oversight and regulation.

- Conduct an outreach/education effort to build understanding and support before General Assembly consideration of the legislation.

- Codify the Commonwealth's position as a responsible partner with the federal government to assure regulatory uniformity, improve notification and communication, give proof of Virginia's interest in developing the industry, and assure protection of public health and the environment.

The Commonwealth faces an opportunity to craft a leadership role in biotechnology from both a business attraction and an environmental protection standpoint. Already, some 40 or more companies, university research centers, agricultural producers, and other organizations in Virginia are engaged in biotechnology research and development activities, with commercialization on the horizon.

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INTRODUCTION

House Joint Resolution 516, 1993 (Appendix A), patroned by Delegate Franklin P. Hall of Richmond (69th District) and co-patroned by 16 other members of the General Assembly, requested that the Secretary of Economic Development (now Commerce and Trade) conduct a study of the value of enacting a biotechnology research act for the Commonwealth. The field of biotechnology is rapidly creating jobs and revenues for jurisdictions across the nation. It has enormous potential to benefit many fields of human endeavor, including agriculture, health care, and environmental protection.

Present and pending research in Virginia makes this study most timely. Already, some 40 or more companies, university research centers, agricultural producers, and other organizations in Virginia are engaged in biotechnology research and development activities, with commercialization on the horizon. As more biotechnology organizations become interested either in expanding or in locating in the Commonwealth, the climate for research, testing, and, ultimately, commercialization of their products will significantly influence the benefits to the Commonwealth from this activity. While some of the Commonwealth's future efforts will focus on attracting outside industry to locate here, it will also be important to support existing businesses already established.

Biotechnology in the broad sense is a group of technologies that utilize living organisms to make or modify products, to improve plants or animals, or to develop microorganisms for specific uses. The term biotechnology, in a narrower sense and often modified by "new," may be defined as a useful technology enabling the precise transfer of specific genetic information from one organism to another, as well as precise modification in the expression of genetic information within an organism, to create desirable end results (see Appendices D & E). After nearly two decades of research and development, biotechnology has an exemplary safety record. A report from a 1992 international meeting to review field tests with genetically engineered organisms concluded "...hundreds of field experiments in many countries have been reported, and so far no harmful events to our environment were detected. No adverse consequences have resulted from work for more than 15 years in laboratories and in over 500 field releases." Nonetheless, the need to proceed with caution in the application of this science remains a priority with the public.

A biotechnology research act was perceived to be necessary and beneficial for economic development in this area because it would communicate to the public and the biotechnology industry, both within and outside the Commonwealth, that Virginia has a definitive policy and framework for the regulation of biotechnology. The study thus focused on determining the operational components of a Virginia

policy and framework for biotechnology regulation and, if appropriate, drafting proposed legislation. The study first identified the existing federal, state and local framework for oversight and regulation of biotechnology research, development and commercialization, in Virginia. It then examined regulatory actions taken by other states in the biotechnology arena and considered the need, if any, for similar regulation in Virginia. The study sought options that would be both protective of human health and the environment, and cost-effective and timely.

APPROACH

As directed by the Secretary, the Chairman of the Scientific Advisory Committee of the Virginia Biotechnology Research Park assembled a working group with representatives from private industry, Virginia life science research institutions and academic researchers, Virginia's Center for Innovative Technology, the Virginia Department of Environmental Quality, the Virginia Department of Economic Development, an environmental safety specialist, and environmental regulatory law specialists. Representatives also joined the Committee from the Virginia Department of Agriculture and Consumer Services and the Virginia Department of Health. A complete list of Committee members is attached as Appendix F.

The Committee held several meetings in 1993 and divided its work into drafting this report and proposed legislation.

The Committee approached issues, as directed by the Secretary, with a unified perspective: to encourage development of this valuable industry by protecting public health and the environment. As Carl Feldbaum, president, Biotechnology Industry Organization, has noted, "...the biotech industry acknowledges the need for responsible government regulation and companies to work closely with government agencies to assure that regulation keeps pace with knowledge despite the fact that it's expensive and delays the availability of products. But the public has a right to know, to be reassured about safety and efficacy." (in *USA Today*, 6/22/93) The Committee sought to achieve both goals.

FINDINGS—GENERAL

Need for Further Outreach/Education about Biotechnology Regulation

A regulatory climate which (a) addresses protection of public health, safety, and the environment, (b) provides a framework of certainty for industry and the public, and (c) is cost-efficient and timely, will best foster future economic growth. Citizens who may be concerned about businesses or organizations involved with any new technology such as biotechnology look to government for reassurance the activities are taking place with adequate oversight to protect public health and the environment. Experience has also shown that, like other industries, the biotechnology industry prefers an established policy or procedure in place for oversight, rather than being faced with the uncertainty created by the absence of such a statement. Likewise, it is desirable to maintain uniformity and consistency of regulation within the Commonwealth.

It is important to keep the regulatory arena flexible, allowing a track record in Virginia to be established over time, and supplementing the track record already formed in other states. Because other entities (i.e., citizens and localities) are likely to play an important and active role in the regulation of biotechnology, the Committee concluded that their participation in the policy development process is important. This need for participation extends to localities where field research/planned introductions may take place or where contained facilities may be located. Including these constituents in the decision-making process affords an opportunity to demonstrate that support of this industry is in the Commonwealth's best interest and will enable an informed citizenry to develop confidence in the benefits biotechnology can offer society.

FINDINGS—SPECIFIC

1. Existing Federal, State, and Local Regulatory Framework Relative to Biotechnology Research, Development and Commercialization in Virginia

At the federal level, the Coordinated Framework for Regulation of Biotechnology was announced in the Federal Register in 1986, amended in 1987 and 1990, and supplemented in 1992. This framework is a comprehensive policy covering oversight, guidelines and regulations of the U.S. Department of Agriculture (USDA), the Environmental Protection Agency (EPA), the Food and Drug Administration (FDA), the National Institutes of Health (NIH), the National Science Foundation (NSF), and the Occupational Safety and Health Administration (OSHA), among others. The underlying premise of the Coordinated Framework is that existing statutes provide a basic network of agency jurisdiction which addresses both research and product marketing in a manner that assures reasonable safeguards are in place to address public health and environmental concerns. An operational summary of the Coordinated Framework is attached as Appendix B.

Within Virginia, an internal task force at the Virginia Department of Agriculture and Consumer Services recommended in 1990 that, with regard to biotechnology, the agency rely on the federal regulatory structure rather than creating duplicative state regulations. The agency made that recommendation because both existing federal and state laws pertaining to land use and environmental protection—including emissions, water quality, and hazardous waste management—regulate businesses generally, without referencing biotechnology specifically.

The Committee recognized the hierarchical nature of oversight, starting with existing federal guidelines and regulations that cover both the research process and the end products. States and localities serve as responsible partners with the federal government in the administration of these rules. Beyond the regulatory role, states may also undertake steps to foster economic development and serve as a clearinghouse for legislative and economic information pertaining to the biotechnology industry.

In light of the Committee's conclusion that the existing federal Coordinated Framework more than adequately protects public health and the environment, the Committee recommends that any Virginia policy and biotechnology regulatory structure rely on, as much as possible, that framework. Nonetheless, the Committee recognizes that others, such as citizens and localities, may want to participate actively in the regulatory process. Currently, the federal Coordinated Framework, acting alone, may not provide interested persons with adequate opportunity to participate in that process. Therefore, the Committee recommends that their interests also

be considered, without compromising the intent of the federal Coordinated Framework, when formally adopting a Virginia regulatory structure.

2. Need for Consolidation, Uniformity, and/or Additional Regulation, Oversight, Reporting, or Monitoring of Biotechnology Research, Development and Commercialization

Virginia faces an opportunity to craft a leadership role in biotechnology from both a business attraction and an environmental protection standpoint. With the rapid growth of the biotechnology industry along the East Coast, it is important that the state take steps to capitalize on that opportunity. The Commonwealth of Virginia has a favorable economic climate, labor force and tax structure to attract biotechnology business, and Virginia universities are research leaders in agriculture, health care, and related fields essential for supporting the biotechnology industry.

Though some have expressed concern that laws and regulations in each of the 50 states would create a confusing patchwork, that is mild compared with the confusing patchwork of regulation that might occur if every locality enacted its own ordinances. The federal Coordinated Framework has been the starting point for other state mechanisms, thus offering a precedent for Virginia's direction. Not only does it adequately protect human health and the environment, it also provides a single, credible system within the Commonwealth and a consistent, stable and predictable regulatory environment for both existing and prospective biotechnology activities. Such an approach recognizes the Commonwealth's desire to be sensitive to both economic development and environmental safety interests. Without adding a duplicative layer of bureaucracy at significant additional cost to the citizens of the Commonwealth, adoption of the Coordinated Framework confirms the state's existing practice of conforming with federal requirements. Should additional regulation be deemed necessary or desirable for a specific sector of the biotechnology industry in the future, the General Assembly may choose to take appropriate action at a later date.

The Committee has chosen not to address situations where a multistate response may be needed, while recognizing that such situations may exist and may be considered in the future. Within the framework of existing environmental regulation, mechanisms for interstate cooperation and collaboration (such as the Chesapeake Bay Commission, the Appalachian Regional Commission, or the Tennessee Valley Authority) may fulfill that role, or serve as a model should the need arise.

As stated above, the Committee concluded that the federal Coordinated Framework adequately addresses concerns related to the biotechnology industry, and its regulation of biotechnology activities in Virginia likely is sufficient without supplementation with state requirements. On the other hand, the Committee recognized the potential interests of localities and citizens, among others, to participate in

the regulation of activities within Virginia to an extent broader than that currently provided within the federal Coordinated Framework. Therefore, the Committee has developed a draft of legislation for consideration, submitted as Appendix C, that balances these two conclusions.

3. Regulatory Actions by Other States Relative to Biotechnology Research, Development and Commercialization

Each state that has addressed biotechnology regulation has selected approaches best suited for the needs of that particular state, while still acknowledging that the federal rules are at the top of the oversight hierarchy. States have taken one of three general approaches states take towards oversight of biotechnology: 1) specific and comprehensive new legislation and regulations; 2) amended existing legislation and creation of notification requirements; or 3) no revised legislation, with the focus on federal rules. Virginia's neighbor, North Carolina, addressed regulation of this industry by forming a 27-member Advisory Committee that developed legislation over a 10-month period, giving the North Carolina Department of Agriculture regulatory authority over planned introductions into the environment, and creating an interagency review board to issue permits for activities for which individual permits are not required. California, with several state laws already in existence that duplicated the federal regulatory review process, determined that existing authority was adequate to regulate biotechnology products and processes without enacting any new state regulation specific to these technologies. Other states have revised existing legislation to require notification of a state agency when a federal permit has been requested. There is also an interstate biotechnology group, the steering committee of which is chaired by North Carolina.

The Committee reviewed the regulatory systems of many states. It concluded that enacting specific new legislation, such as North Carolina's, would not provide additional protection to that afforded by the federal Coordinated Framework and would unnecessarily deplete state resources. On the other hand, the Committee concluded that focusing *solely* on the federal rules, as in Wisconsin or Hawaii, would not adequately involve concerned localities and citizens in the regulatory process. Therefore, the Committee concluded that an appropriate balance between those interests is to adopt a state regulatory approach that relies on the federal Coordinated Framework while also providing notification to the public and creating a participatory role for localities and citizens. The proposed draft legislation embodies the substantive views of the Committee.

RECOMMENDATIONS AND CONCLUSIONS

1. The Committee unanimously recommends that the Commonwealth accept the federal Coordinated Framework for Regulation of Biotechnology, as amended by Agency Rules, Policies, and Actions as they occur, as the substantive policy for oversight and regulation of biotechnology in Virginia.

2. The Committee recognizes that other constituents—especially local governments and citizens—also hold perspectives on the future of biotechnology in Virginia. The Committee thus recommends that an outreach/education process be initiated before the General Assembly considers legislation.

3. A draft statute is submitted for discussion as Appendix C and may be considered for presentation to the 1994 General Assembly, keeping in mind that further revisions may be made as a result of additional input in the outreach/education process. Consistent with the Committee's first recommendation, the draft legislation creates a notification obligation on the part of those engaging in biotechnology activities. This notification will enable the Commonwealth and its localities to participate and provide input whenever biotechnology research or commercial activity is required to be reviewed under federal law or regulations. Codifying the Commonwealth's position as a responsible partner with the federal government will: (a) assure uniformity throughout the state; assure notification to the state and to local governments, where required, for regulated introductions; (b) enhance and clarify communication between the federal, state and local levels of government; (c) establish that the state is both informed and interested in developing the industry; and (d) assure protection of public health and the environment.

APPENDIX A

1993 SESSION

LD9178260

HOUSE JOINT RESOLUTION NO. 516

Offered January 25, 1993

Requesting the Secretary of Economic Development to conduct a study of the value of enacting a biotechnology research act for the benefit of economic development for Virginia in various fields of human endeavor, including agriculture, health care and environmental protection.

Patrons—Hall, Ball, Cantor, Cox, Cunningham, J.W., Hargrove, Martin, Reid, Rhodes, Watkins and Wilder; Senators: Benedetti, Cross, Lambert, Marsh, Russell and Stosch

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Referred to the Committee on Rules

WHEREAS, it is the policy of the Commonwealth to encourage, stimulate and support economic development and the expansion of the Commonwealth's economy through its policies; and

WHEREAS, it is the policy of the Commonwealth to promote, improve, identify, encourage, and promote new approaches to economic development throughout Virginia; and

WHEREAS, the field of biotechnology is rapidly becoming an economic benefit to jurisdictions across the nation; and

WHEREAS, the biotechnological field has an enormous potential to benefit many fields of human endeavor, including agriculture, health care, and environmental protection; and

WHEREAS, the Commonwealth of Virginia has a favorable economic climate and tax structure to attract the biotechnology business to the Commonwealth; and

WHEREAS, Virginia universities are research leaders in agriculture, health care, business, and related services which are essential for supporting the biotechnology industry; now, therefore, be it

RESOLVED by the House of Delegates, the Senate concurring, That the Secretary of Economic Development initiate a study to determine the feasibility and operational components of a biotechnology regulatory framework and model legislation for a biotechnology research act in Virginia.

The University of Virginia, Virginia Commonwealth University and Virginia Polytechnic Institute and State University shall provide necessary support staff for the purposes of this study.

All agencies of the Commonwealth shall provide reasonable assistance at the request of the Secretary for the furtherance of this study.

The Secretary of Economic Development may include participation by other interested individuals during the study; and, be it

RESOLVED FURTHER, That the Secretary of Economic Development complete the work and submit the findings to the Governor, the 1994 Session of the General Assembly and the Chairmen of the House Appropriations Committee and the Senate Finance Committee as provided in the procedures of the Division of Legislative Automated Systems for processing legislative documents.

APPENDIX B

SUMMARY OF FEDERAL COORDINATED FRAMEWORK FOR THE REGULATION OF BIOTECHNOLOGY

The federal Coordinated Framework can best be summarized from a product basis, since the basic premise is that regulation is "product," not "process" based. That is, the applicable guideline or regulation depends on the agency that currently handles the commercial approval of the marketable product. Oversight of research and development is mainly by the funding agency, under the over-arching NIH Guidelines for Research Involving Recombinant DNA Molecules, which are based on the process of genetic modification. These guidelines are essentially a codification of good laboratory practices for microbiological research in which physical and biological containments are recommended for use, depending on the risk of the organism(s). (See end of this Appendix for a list of these agencies and their abbreviations.)

Contained Research, Any Organism and Purpose

- Federal funding agencies—NIH, NSF, USDA/S&E—are the responsible agencies.
- NIH Guidelines for Research Involving Recombinant DNA Molecules as recommended by the RAC after discussion in public meetings.
- Compliance required by all federal agencies for receipt of funding for rDNA research.
- Non-federally funded research voluntarily follows Guidelines.
- Most approvals are done by a local institutional Committee, known as the IBC, which includes public members.

Foods/Food Additives, Human Drugs, Medical Devices, Biologics, Animal Drugs

- Responsible agency is FDA.
- NIH Guidelines apply for Federally funded research; voluntary otherwise.
- Large Scale Fermentation Guidelines are included in NIH Guidelines.
- Human Gene Therapy currently reviewed and approved by NIH-RAC, and by FDA.
- FDA has approved several biotechnology-produced drugs and medical devices.
- FDA has issued a policy statement in 1993 describing principles for reviewing plants used as foods and derived from new plant varieties, including where biotechnology was used.

Plants, Animals and Animal Biologics

- Responsible federal agency is USDA.
- NIH Guidelines apply for federally-funded research; voluntary otherwise.
- USDA/ABRAC recommended guidelines to researchers and regulators for agriculturally-used organisms, including fish and aquatic species.
- USDA/APHIS under FPPA and PPQ have permitting requirements for shipment of plant pathogens.
- APHIS Rules address shipping/movement permits for rDNA organisms.
- APHIS Rules require permits for introduction into the environment.
- USDA/APHIS/BBEP issue permits for field tests with genetically engineered plants.
- Permits are required; 1993 short notification scheme for six familiar crops.
- APHIS Veterinary Services has approved engineered animal vaccines.
- USDA/FSIS issued policy for uses of experimental transgenic animals.

Microorganisms used as Pesticides

- Responsible federal agency is EPA.
- NIH Guidelines for federally-funded, contained research; voluntary otherwise.
- 1986 Policy in the Coordinated Framework applies. If released into the environment, EPA has primary responsibility, with co-review by USDA/APHIS for plant-pests.
- FIFRA applies depending on whether microorganism is intrageneric/intergeneric, whether pathogenic or non-pathogenic, and whether indigenous or nonindigenous.
- EPA acts currently through policy statements, and has not yet issued new regulations.
- Reviews information, decides whether Experimental Use Permit is required.
- Policies and actions discussed by an Advisory Committee in meetings open to public.

Microorganisms used for Environmental Purposes

- Responsible federal agency is EPA.
- 1986 Policy in the Coordinated Framework applies.
- NIH Guidelines for federally-funded, contained research; voluntary otherwise.
- TSCA applies for microorganisms used for environmental and industrial applications.

Abbreviations

ABRAC—Agricultural Biotechnology Research Advisory Committee
APHIS—Animal and Plant Health Inspection service (USDA)
BBEP—Biotechnology, Biologics, and Environmental Protection (USDA)
EPA—Environmental Protection Agency
FDA—Food and Drug Administration
FIFRA—Federal Insecticide, Fungicide, and Rodenticide Act
FPPA—Federal Plant Pest Act
FSIS—Food Safety Inspection service (USDA)
IBC—Institutional Biosafety Committee
NIH—National Institutes of Health
NSF—National Science Foundation
PPQ—Plant Protection and Quarantine (APHIS)
RAC—Recombinant DNA Advisory Committee (NIH)
TSCA—Toxic Substances Control Act
USDA—United States Department of Agriculture
S&E—Science and Education

APPENDIX C

DRAFT

VIRGINIA BIOTECHNOLOGY RESEARCH ACT

§ 1. Purpose.

The purposes of this Act 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 stimulate the growth of the biotechnology industry within the Commonwealth. To do this, the [designated Cabinet-level Department within the Virginia state government (the "Department")] 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 Act 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. Definitions.

As used in this Act:

(a) "Confidential business information" means information entitled to confidential treatment under paragraphs (1) or (2) of subsection (a) of section 7.

(b) "Coordinated Framework" means the federal Coordinated Framework for the Regulation of Biotechnology set forth in 51 Fed. Reg. 23,302 to 23,350 (June 26, 1986), as amended by 52 Fed. Reg. 22,892 to 22,915 (June 16, 1987); 55 Fed. Reg. 31,118 to 31,121 (July 31, 1990); and 57 Fed. Reg. 6,753 to 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.

(c) "Department" means the [designated Cabinet-level Department within the Virginia state government].

(d) "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.

(e) "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.

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

(g) "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.

(h) "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.

§ 3. Exemptions.

(a) The Department may waive part or all of the requirements under section 4 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 section 4 if the Department determines that the satisfaction of that requirement or part thereof is not necessary to protect the public health or the environment.

(c) Planned regulated introductions previously approved by a federal regulator pursuant to the federal Coordinated Framework shall be exempt from the provisions of § 4 unless the Department concludes that protection of the public health or of the environment requires otherwise.

§ 4. Notification.

Except as provided under section 3, no person may commence a regulated introduction unless the person

(a) Provides to the Department and the locality in which the introduction is proposed to be made all of the following information within 7 days after the person submits or should have submitted the information specified in paragraphs (1) and (2) of subsection (a) of this section to a federal regulator, whichever is sooner:

(1) A copy of all information which the person is required to submit to the federal regulator and which is not confidential information; and

(2) 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

sections 5 and 6, to provide public notice pursuant to section 5, and to prepare comments pursuant to section 6, 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 section 6.

(b) Shall provide 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 section 6.

§ 5. Public Notice.

Within 15 days after receiving the information required under section 4, the Department shall publish notice and a brief description of the proposed planned introduction. Notice shall also be provided 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 Act regarding confidential business information, any documents submitted to the Department as required under section 4 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.

§ 6. Comment.

The Department, the locality in which the 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 (collectively, "affected localities"), 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.

(a) 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 section 4;

(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.

(b) 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.

§ 7. 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 Act if the person submitting the information notifies them that:

(1) The federal regulator to which 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 subsections (4) or (5) of subsection (a) of section 6, subject to the requirements of subsection (d) of this section. Any person receiving such information is subject to the penalty specified under section 9 for the unauthorized release of such information.

(c) The Department and any locality 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 paragraph (2) of subsection (a) of this section, 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 subsections (4) or (5) of subsection (a) of section 6 to any person who is not an employee of the Department unless that person has signed an agreement which satisfies the requirements of paragraph (2) of this subsection (d).

(2) Any agreement under paragraph (1) of this subsection (d) 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 Act, shall acknowledge the penalties in the Virginia Uniform Trade Secrets Act, Va. Code § 59.1-338, 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 section 4 may waive any of the requirements under this section.

§ 8. Enforcement.

The Department shall enforce sections 4 and 7. Actions to enforce this Act 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 Act, if it is determined that a person

commenced a regulated introduction and did not comply with section 4, 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.

§ 9. Penalties.

A civil penalty of not more than ten thousand dollars ($10,000) may be assessed by the Department against any person who violates any provision of this Act. 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, Va. Code §§ 9.6.14:1 to 9-6.14:25. Each day of release in violation of this Act shall constitute a separate offense.

§ 10. 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.

APPENDIX D

BIOTECHNOLOGY AND EXAMPLES OF ITS USES

There isn't just one technology that makes up modern biotechnology. Rather, it is a **group of technologies** that, in a broad sense, utilize "living organisms (or parts of organisms) to make or modify products, to improve plants or animals, or to develop micro-organisms for specific uses."

Some of these processes have been in use in various forms for several millennia. They include **fermentation** of bacteria and yeasts—brewing beer, and baking bread—and **crop improvement** techniques which, since primitive times, have helped farmers increase yield when they select seeds from the best plants from the current year's harvest to plant crops for the next year.

More recently, since 1973, when scientists first successfully transferred DNA from one cell to another, it has been common to refer to the **"new" biotechnologies.**

Biotechnology is involved with specific **genes**, the basic building blocks of living organisms. Each gene allows specific traits to occur. When specific genes are transferred between certain species, the original gene's useful trait occurs in the receiving organism.

Nationally, **more than 1,200 U.S. companies, with about 79,000 employees,** are currently engaged in some aspect of biotechnology, an 11 percent increase since 1991. They serve product development needs in agriculture, chemical and environmental applications, therapeutic drugs/vaccines and human diagnostic solutions. Research and development expenses currently represent $4.9 billion nationally.

Agricultural biotechnology techniques are tailored to produce plants that resist insect pests, disease and herbicides; make their own fertilizer; use nutrients or energy more efficiently; and develop new, more accurate diagnostic tests for farm animal diseases. With the help of microorganisms, **food biotechnology** already produces bread, cheese, yogurt, beer, wine, whiskey, pickles, sauerkraut, and soy sauce, among others.

Alternative biological methods such as **bioremediation** and **biotreatment** are being researched and employed for ongoing waste treatment and disposal problems. Bioremediation uses natural as well as recombinant microorganisms to break down toxic and hazardous substances in the environment. Biotreatment is a broader term referring to all biological treatment processes.

Biopharmaceuticals utilize recombinant DNA technology and cell fusion to develop new proteins that can restore the body's natural, disease-fighting and functional mechanisms. These drugs take aim at such life-threatening diseases as cancer, AIDS and diabetes.

Bioprocessing generally refers to separation and purification techniques, instrumentation, and "downstream" processing required to prepare a product in final form for delivery to the marketplace.

*The **Biotechnology Industry Organization,** a private association recently formed by the merger of the Industrial Biotechnology Association and the Association of Biotechnology Companies, has published numerous backgrounders and booklets describing biotechnology. The federal government's **Office of Technology Assessment** has also published a number of reports about the current and potential applications of biotechnology. The above information is drawn from those sources.*

APPENDIX E

SELECTED REFERENCES AND ADDITIONAL READINGS

Public Perception and Participation

• *Biotechnology: Public Perception and Regulatory Policy in North Carolina.* Presentation to the American Chemical Society by Dr. Adrianne Massey, Educational Programs Manager, North Carolina Biotechnology Center, 1990.

Federal Oversight

• *Federal Register: Coordinated Framework for Regulation of Biotechnology,* June 26, 1986 (Vol. 51, No. 123), with Amendments and Supplements: June 16, 1987 (Vol. 52, No. 115), July 31, 1990 (Vol. 55, No. 147), and February 27, 1992 (Vol. 57, No. 39).

• *Oversight and Regulation of Biotechnology Research.* D.R. MacKenzie, USDA, and Anne K. Vidaver, University of Nebraska. Agricultural Experiment Station, Purdue University, 1991.

Comparative State Information

• Other State Statutes: Hawaii, Illinois, Maine, Minnesota, Nebraska, North Carolina, Oklahoma, Utah, Washington, West Virginia, Wisconsin.

• *State Case Histories on Biotechnology Oversight.* Edited by Susanne L. Huttner, Ph.D., University of California, & Roger H. Smith, Ph.D., New Jersey Department of Environmental Protection. University of California Systemwide Biotechnology Research and Education Program, 1990.

North Carolina:

• *Advisory Committee on Biotechnology in Agriculture: Process, Conclusions, Legislation and Regulations.* North Carolina Biotechnology Center, Summer 1990.

• *North Carolina's Genetically Engineered Organisms Act,* Education Program, fact sheet. North Carolina Biotechnology Center, November 1990.

California:

• *Guidance for State Governments on Oversight of Biotechnology.* Prepared from a workshop following 2nd National Conference on Federal and State Regulation of

Biotechnology, University of California Systemwide Biotechnology Research and Education Program, September, 1990.

• *Biotechnology: A Primer for California Communities.* California Department of Commerce, August, 1989.

General

• *Promoting Biotechnology in the States: A Guide for State and Local Officials.* Prepared by the State Government Relations Committee, Biotechnology Industry Organization, 1993.

• *Strengthening Collaboration in Biotechnology: International Agricultural Research and the Private Sector.* Proceedings of a Conference in Rosslyn, VA, Bureau for Science and Technology, Office of Agriculture, Agency for International Development, April, 1988.

• *Genetically Modified Organisms: Guidelines and Regulations for Research.* Anne Vidaver, University of Nebraska, & Sue Tolin, Virginia Polytechnic Institute and State University, Encyclopedia of Microbiology, Volume 2, 1992.

APPENDIX F

VIRGINIA BIOTECHNOLOGY RESEARCH ACT STUDY COMMITTEE

Dr. William L. Dewey, *Chairman*—Vice President for Research & Graduate Affairs, Virginia Commonwealth University, and Chairman, Scientific Advisory Committee, Virginia Biotechnology Research Park

b j Altschul, APR—Public Relations Counselor and current Master's candidate in public relations at University of Maryland College of Journalism; staff associate to CIT for the Biotechnology Research Act Study Committee

R. Joel Ankney—Attorney, Hunton & Williams

Dr. Dean W. Broga—Director, Environmental Health and Safety, Virginia Commonwealth University

Dr. Bernard J. Caton—Director, Policy , Budget & Administration, Virginia Department of Environmental Quality

Wm. Philip Eggborn—Program Manager, Office of Plant Protection, Virginia Department of Agriculture & Consumer Services

S. Brian Farmer—Attorney, Mezzullo & McCandlish; Secretary, Virginia Biotechnology Association

Frank Fulgham—Supervisor, Field Operations, Office of Plant Protection, Virginia Department of Agriculture & Consumer Services

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Patrick O'Hare—Attorney, Hazel & Thomas

Robert E. Olson—Executive Vice President, Virginia Biotechnology Research Park

Marvin H. "Skip" Schuelke—President, Schuelke & Associates Biomedical; Chairman, Virginia Biotechnology Association

Mark E. Smith—Executive Assistant, Government and Community Relations, Office of the President, Virginia Commonwealth University

Dr. Sue A. Tolin—Professor of Plant Pathology, Department of Plant Pathology, Physiology & Weed Science, Virginia Tech

Dr. Ram K. Tripathi—Toxicologist, Bureau of Toxic Substances, Virginia Department of Health

Dr. Tracy Wilkins—Professor of Agricultural Biotechnology, and Director, Center for Biotechnology, Virginia Tech; President, TransPharm, Inc., and TechLab, Inc.

Dr. Terry Woodworth—Associate Director, Center for Innovative Technology, Institute of Biotechnology

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