Status of Biotech Field Trial Activity

312 distinct APHIS notifications submitted (292 acknowledged; 18 denied/withdrawn/void; 24 currently in effect)

54 distinct APHIS permit applications submitted (48 issued; 6 denied/withdrawn/void; 2 currently in effect)

2 APHIS permits issued for varieties of tobacco mosaic virus (TMV) engineered to produce compounds for pharmaceutical production

1 APHIS permit issued for a variety of corn engineered to produce compounds for industrial applications

19 crops total for which APHIS notifications and/or permit applications were submitted

Most APHIS notifications and permit applications submitted for biotech varieties of corn, cotton, and tobacco

Other crops include: potatoes, rapeseed, soybeans, squash, tomatoes, and wheat
Biotech Activity and Legislative Status

**Biotech Activity and Interest**
North Carolina has long been active in attempting to attract more biotechnology firms and spark economic development based on agricultural biotechnology, with a major focus on biotech tobacco. One of the major debates in North Carolina has been about the use of biotech tobacco to produce pharmaceutical substances. Some are concerned that the pharma tobacco could contaminate conventional tobacco through out-crossing or accidental commingling. The North Carolina Farm Bureau has spoken out, both about the potential benefits of biotechnology, including offering alternative uses for tobacco, and the need for guidelines for the handling of biotech tobacco.\(^{503}\) No permit applications have been submitted to APHIS to field test pharma tobacco in North Carolina, but such permits have been issued in other states, and permits for other types of biotech tobacco, such as insect- or herbicide-resistant varieties, have been granted for North Carolina.\(^{503}\)

The North Carolina Department of Agriculture and Consumer Services is interested in helping North Carolina reap the economic benefits of biotech tobacco, while not jeopardizing the market for conventional tobacco strains. To that end, the department is playing a key role in the development of protocols for the identity preservation and containment of commercialized biotech and nonbiotech tobacco, which producers could voluntarily adopt. The protocols are being developed under the auspices of the National Association of State Departments of Agriculture and would involve a certification procedure that could verify genetic purity and product integrity.\(^{504}\)

For more details, see “Biotech Tobacco in North Carolina: A State-Driven Initiative to Ensure Identity Preservation of Commercialized Biotech Crops and their Conventional Counterparts” in Section IV.

**Regulatory Legislation**
Although North Carolina does not currently have specific statutory authority to regulate biotech crops and foods, the now-defunct Genetically Engineered Organisms Act provided North Carolina with a parallel process for issuing field test permits separate from APHIS permits from 1989 until 1995 (106 N.C. Gen. Stat. § 765 et seq. [2003]). The act created a ten-member Genetic Engineering Review Board, which had authority to review applications for the field testing of biotech crops in North Carolina and establish advisory committees to help with the review. The act gave the board power to add additional restrictions and measures to permits as well as deny,

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503 From information gathered on May 12, 2004, from Information Systems for Biotechnology 2004(f).
504 Dickerson 2004.
suspend, modify, or revoke the permits. The act also established penalties for violating any part of the law or any rule of the Board. Although providing for a separate state permitting process, the act did include the caveat that North Carolina was not seeking to duplicate federal regulations, specifying that the board had the option of issuing a permit “based on the federal review and approval of the proposed release if the board determines that federal regulation of the release sufficiently protects agriculture, public health, and the environment in North Carolina.” For more details, see “Filling the State Legislative Gap: Biotech-Specific Regulatory Statutes in North Carolina, Minnesota, and Iowa.”

Only one piece of legislation addressing the regulation of agricultural biotechnology has been introduced since 2001. The bill, which failed, would have required individuals taking part in business dealings involving biotech tobacco to obtain a license from the North Carolina commissioner of agriculture. Some stakeholder groups tried, but failed, to pass legislation that would have prevented the commercial planting of biotech tobacco in the state.

Nonregulatory Legislation
As far back as 1982, North Carolina’s General Assembly established the nonprofit North Carolina Biotechnology Center to support biotechnology research, development, and commercialization. The state offers investment tax credits for individuals investing in the biotechnology industry (105 N.C. Gen. Stat. § 419 et seq. (2003)). The Golden LEAF Foundation, a nonprofit group that receives one-half of its funds from North Carolina’s tobacco settlement with cigarette manufacturers, provides grants for economic development activities, including those involving biotechnology. A pending bill would give the University of North Carolina funds to establish a biomanufacturing training center and emphasizes the need for more growth in industries such as those developing pharma crops (SB943).

An anti-crop-destruction bill passed in North Carolina in 2001 that holds individuals liable for double the amount of damages they cause (HB218).

506 Pew Initiative on Food and Biotechnology 2004(c).
507 Dickerson 2004.
508 North Carolina Biotechnology Center n.d.
510 Pew Initiative on Food and Biotechnology 2004(c).
**REGULATORY AUTHORITY, AGENCIES, AND RESOURCES**

### RELEVANT STATUTORY AUTHORITY

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<th>Biotech-Specific Regulatory Statutes</th>
<th>Other Potential Statutory Authority Over Biotech Field Trials</th>
<th>Other Potential Statutory Authority Over PIPs</th>
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### AGENCIES AND PROGRAMS

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<td>None</td>
<td>North Carolina Department of Agriculture &amp; Consumer Services – Plant Industry Division, Plant Protection Section, Biotechnology Services</td>
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<td>North Carolina Department of Agriculture &amp; Consumer Services – Food and Drug Protection Division and Meat &amp; Poultry Inspection Service</td>
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<td>North Carolina Department of Environmental and Natural Resources – Division of Environmental Health</td>
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### RESOURCES

North Carolina Department of Agriculture and Consumer Services budget: $50,000,000
Budget for plant health protection: $3,600,000 (state-appropriated only)
Narrative description of budget for biotech crops and foods component: Approximately $25,000–$30,000