Rapid Change and Pace of R&D Activity Characterize the Seed Industry and Technology Providers

The U.S. commercial seed market is the world's largest—with an estimated annual value of $5.7 billion per year in the late 1990s—followed by China at $3 billion and Japan at $2.5 billion (Fernandez-Cornejo, 2004). Moreover, the U.S. seed market is growing (in quantity and value), mainly because farmers have been increasing purchases of seed and reducing the planting of saved seed. Growth in the seed market has been particularly rapid for major field crops—corn, soybeans, cotton, and wheat—that together constituted two-thirds of the seed market value in 1997.

The U.S. seed industry began a transformation in the 1930s, with the introduction of commercially viable hybrid seeds. These hybrids were higher yielding than nonhybrid varieties but degenerative, so farmers had to purchase new seed every year to maintain the high yields. Further changes were motivated by the strengthening of intellectual property rights (IPR) protection, mainly during the 1970s and 1980s, which increased returns to research and offered a greater incentive for private companies to invest in seed development. The two principal forms of legal protection are plant variety protection (PVP) certificates issued by the Plant Variety Protection Office of USDA and patents issued by the U.S. Patent and Trademark Office. Both grant private crop breeders exclusive rights to multiply and market their newly developed varieties. However, patents provide more control since PVP certificates have a research exemption allowing others to use the new variety for research purposes. Agricultural biotechnology patents, mostly dealing with some aspect of plant breeding, have outpaced the general upward trend in patenting throughout the U.S. economy. During 1996-2000, 75 percent of over 4,200 new agricultural biotech patents went to private industry (King and Heisey).

Enhanced protection of intellectual property rights brought rapid increases in private research and development (R&D) investments and changes in market concentration in the U.S. seed industry. R&D expenditures on plant breeding for many major crops shifted from mainly public to mainly private. Private spending on crop variety R&D increased fourteenfold between 1960 and 1996 (adjusted for inflation), while public expenditures changed little (Fernandez-Cornejo, 2004).

As the amount of private capital devoted to R&D in the seed industry grew rapidly, the number of private firms engaged in plant breeding also grew, until peaking in the early 1990s. Subsequently, the seed industry consolidated, with fewer firms capable of sustaining the research investment needed to develop new seed varieties. Mergers and acquisitions created a seed industry structure dominated by large companies with primary investments in related sectors, such as pharmaceutical, petrochemical, and food (Fernandez-Cornejo, 2004).[2]

In the early 1980s, developments in biological sciences created an additional incentive for private firms to increase their investment in R&D and seed production. As the first products of crop biotechnology were tested on a large scale in the 1980s, the seed industry's structure underwent additional

[2]Some firms evolved in the 1990s toward developing "life sciences" complexes organized around the development of products such as agricultural chemicals, seeds, foods and food ingredients, and pharmaceuticals based on applications of related research in biotechnology and genetics. However, most of those life sciences companies have since divested their agricultural operations after "failing to realize adequate returns on their investments" (Shoemaker et al., 2003, p.32; Fernandez-Cornejo, 2004, p.42).

transformation. Companies sought to achieve economies of scale to offset the high costs of biotechnology R&D through an extensive process of mergers, acquisitions, and joint ventures. Chemical and seed businesses combined to take advantage of strong demand complementarities between products (Just and Hueth, 1993). For example, the herbicide glyphosate and soybean seeds tolerant to glyphosate are sold by the same firm. As a consequence of the merger activity, the seed industry became more concentrated. By 1997, the share of U.S. seed sales (including GE and conventional varieties) controlled by the four largest firms providing seed of each crop reached 92 percent for cotton, 69 percent for corn, and 47 percent for soybeans (table 1).

Table 1
Estimated U.S. seed market shares for major field crops, 1997

Company	Corn	Soybean	Cotton
Pioneer Hi-Bred	42.0	19.0	
Monsanto[1]	14.0	19.0	11.0
Novartis	9.0	5.0	
Delta & Pine Land[2]			73.0
Dow Agrosciences/Mycogen	4.0	4.0	
California Planting Seed Distributors			6.0
All-Tex			2.0
Four largest total	69.0	47.0	92.0

[1]Monsanto acquired DeKalb in 1997 and Asgrow in 1998.
[2]The merger proposed between Monsanto and Delta & Pine Land in 1998 was called off in December 1999.
Source: Fernandez-Cornejo, 2004.

From the Laboratory to the Field

A critical part of new variety development is field-testing to ensure that the desired traits will perform under production conditions. The release of new GE varieties of organisms into the environment is regulated through field release permits and monitored by USDA's Animal and Plant Health Inspection Service (APHIS) (see box, "Regulatory Oversight"). The number of field releases of plant varieties for testing purposes provides a useful indicator of R&D efforts on crop biotechnology.

By early April 2005, nearly 11,600 applications had been received by APHIS since 1987 and more than 10,700 (92 percent) had been approved (Virginia Polytechnic Institute and State University, 2005). Approvals peaked in 2002 with 1,190 (fig. 1). Most applications approved for field testing involved major crops, particularly corn with nearly 5,000 applications approved, followed by soybeans, potatoes, cotton, tomatoes, and wheat (fig. 2). Applications approved between 1987 and early April 2005 included GE varieties with herbicide tolerance (3,587), insect resistance (3,141), improved product quality (flavor, appearance, or nutrition) (2,314), virus resistance (1,239), and agronomic properties like drought resistance (1,043) and fungal resistance (647) (fig. 3).

Regulatory Oversight

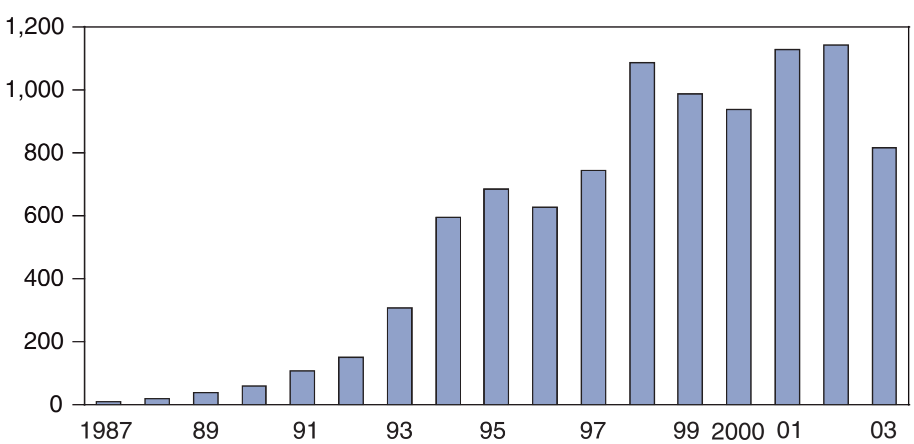
Before commercial introduction, genetically engineered crops must conform to standards set by State and Federal statutes (USDA, 2005). Under the Coordinated Framework for the Regulation of Biotechnology, Federal oversight is shared by the U.S. Department of Agriculture (USDA), the U.S. Environmental Protection Agency (EPA), and the U.S. Food and Drug Administration (FDA).

USDA's Animal and Plant Health Inspection Service (APHIS) plays a central role in regulating field-testing of agricultural biotechnology products. Through either a notification or permit procedure, such products, which include genetically engineered plants, microorganisms, and invertebrates, are considered "regulated articles." APHIS determines whether to authorize the test, based on whether the release will pose a risk to agriculture or the environment. After years of field tests, an applicant may petition APHIS for a determination of nonregulated status in order to facilitate commercialization of the product. If, after extensive review, APHIS determines that the unconfined release does not pose a significant risk to agriculture or the environment, the organism is "deregulated." At this point, the organism is no longer considered a regulated article and can be moved and planted without APHIS authorization (USDA, 2004).

If a plant is engineered to produce a substance that "prevents, destroys, repels, or mitigates a pest," it is considered a pesticide and is subject to regulation by EPA (*Federal Register*, November 23, 1994). FDA regulates all food applications of crops, including those crops that are developed through the use of biotechnology, to ensure that foods derived from new plant varieties are safe to eat. A more complete description of the EPA and FDA regulations of GE products may be found in EPA (2003) and FDA (1992, 2005).

Though the current regulatory system is considered to be effective, USDA, EPA, and FDA continuously look forward and make necessary changes to address new trends and issues of the future. For example, USDA's APHIS has made updates in 1993 and 1997 and is currently considering the need for additional changes in the regulations (USDA, 2004). The National Academy of Sciences also issued a report that made recommendations suggesting that regulation "could be improved further" by making the process more "transparent and rigorous" by enhanced scientific peer review, solicitation of public input, and "more explicit presentation of data, methods, analyses, and interpretations" (NRC, 2003).

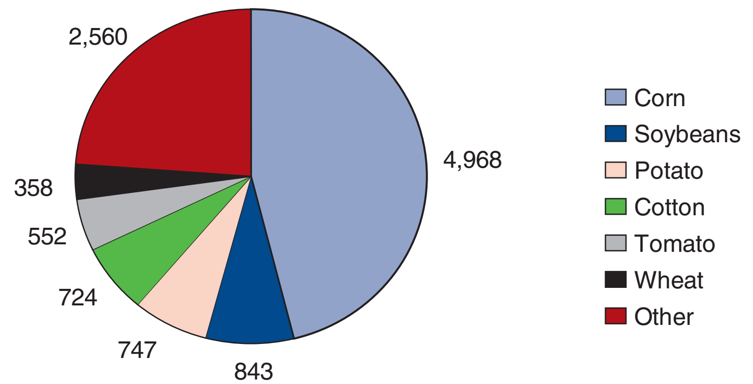
Figure 1
Permits for release of GE varieties approved by APHIS



Source: Virginia Polytechnic Institute and State University, 2005.

Figure 2

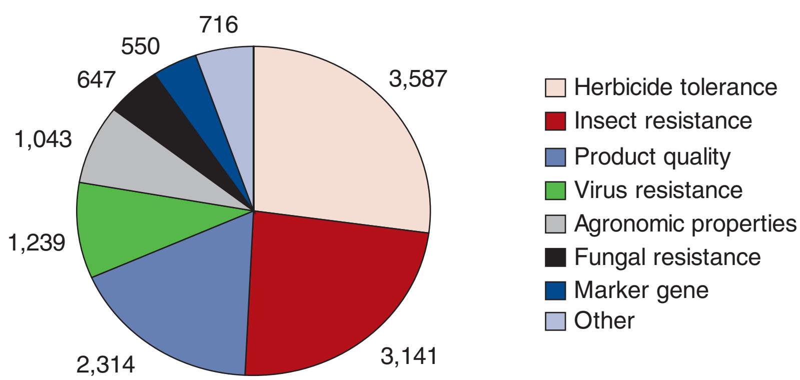
Total number of permits approved by APHIS, by crop



Source: Virginia Polytechnic Institute and State University, 2005.

Figure 3

Total number of permits approved by APHIS, by GE trait



Source: Virginia Polytechnic Institute and State University, 2005.

APHIS approvals for field testing also provide an indication of products that are in development and that may come "through the pipeline" in the future (table 2). In addition to crops with improved pest management traits, approvals include crops with traits that provide viral/fungal resistance, favorable agronomic properties (resistance to cold, drought, salinity, more efficient use of nitrogen), enhanced product quality (delayed ripening, increased protein and oil content, modified starch content, nutraceuticals (added vitamins, iron, antioxidants such as beta-carotene), and pharmaceuticals. Additional information may be found in Runge and Ryan and in Pew Initiative on Food and Biotechnology (2001).

After extensively field-testing a GE variety, an applicant may petition APHIS to deregulate (grant nonregulated status) the variety. If, after extensive review, APHIS determines that the new variety poses no significant risk

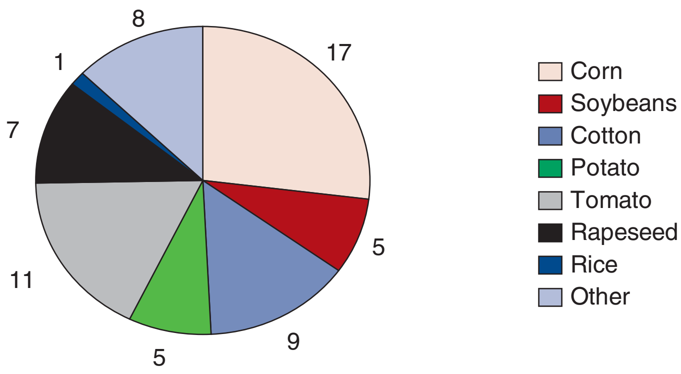
Table 2
Biotech crops currently available and in development in the United States

Crop	Input traits				Output traits	
	Herbicide tolerance	Insect resistance	Viral/fungal resistance	Agronomic properties[9]	Product quality[11]	Nutraceuticals; pharmaceuticals; industrial[13]
Corn	C	C[5]	D	D	D	D
Soybeans	C	D		D	D	
Cotton	C	C[6]		D	D	
Potatoes		W[7]	D	D	D	D
Wheat	C[2]		D			
Other field crops[1]	C[3] D[4]	D	D	D	D	D
Tomato, squash, melon			D	D	W[12] D	D
Other vegetables	D				D	
Papaya			C[8]			
Fruit trees			D		D	
Other trees				D[10]	D	
Flowers					D	

C = Currently available; D = In various stages of development and testing; W = Withdrawn from the market.
Sources: Virginia Polytechnic Institute and State University; USDA, APHIS; Colorado State University; Shoemaker et al.; Pew.
[1]Includes barley, canola, peanuts, tobacco, rice, alfalfa, etc.
[2]Monsanto discontinued breeding and field-level research on its GE Roundup Ready wheat in 2004.
[3]Canola.
[4]Barley, rice, sugar beets.
[5]Bt corn to control the corn borer commercially available since 1996; Bt corn for corn rootworm control commercially available since 2003.
[6]Bt cotton to control the tobacco budworm, the bollworm, and the pink bollworm, commercially available since 1996.
[7]Bt potatoes, containing built-in resistance to the Colorado potato beetle, were commercially introduced in 1996 and withdrawn in 1999.
[8]In the mid 1990s, researchers at Cornell University and at the University of Hawaii developed two virus-resistant varieties of GE papaya. First commercial plantings were made in 1998. The new varieties were proved successful in resisting a viral epidemic and were planted on more than 30 percent of Hawaii's papaya acreage in 1999.
[9]Resistance to cold, drought, frost, salinity; more efficient use of nitrogen; increased yield.
[10]Modified lignin content (for example, to reduce cost of paper making from trees).
[11]Includes delayed ripening; increased protein, carbohydrate, fatty acid, micronutrient, oil, and modified starch content; enhanced flavor and texture (fruits and vegetables); color (cotton, flowers); fiber properties (cotton); gluten content; natural decaffeination; and low phytase.
[12]Tomato genetically engineered to remain on the vine longer and ripen to full flavor after harvest; currently withdrawn from the market (Colorado State University, 2004).
[13]Includes increased vitamin, iron, beta-carotene content; antibodies, vaccines; specialty machine oils.

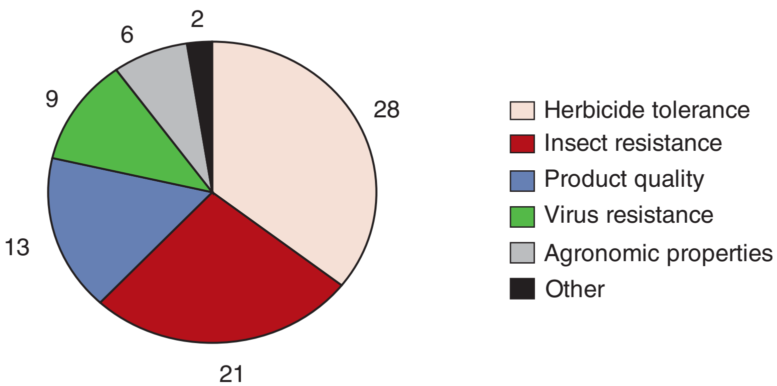
to agriculture or the environment, permission is granted (see box, "Regulatory Oversight"). As of April 2005, APHIS had received 103 petitions for deregulation and had granted 63 (fig. 4). Thirty-six percent of the released varieties have herbicide-tolerance traits, 27 percent have insect-resistance traits, and 17 percent have product-quality traits (fig. 5).

Figure 4
Petitions for deregulation approved by APHIS, by crop



Source: Virginia Polytechnic Institute and State University, 2005.

Figure 5
Petitions for deregulation approved by APHIS, by GE trait



Source: Virginia Polytechnic Institute and State University, 2005.