

## Regulations Have Affected the Seed Industry

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Agricultural innovations, such as improved plant varieties, are a product of research and development. Seeds embody the scientific knowledge needed to produce a new plant variety with desirable attributes, such as higher yield, greater disease resistance, or improved quality. To fully understand the nature of the seed industry, it is necessary to consider the regulations that affect the costs and benefits faced by public and private sector innovators, agricultural producers, and other agents in the seed market.

### Appropriability and Agricultural R&D

Some agricultural innovations are imperfectly appropriable, meaning that the innovation, or the knowledge embodied in the innovation, can be transmitted to, imitated by, or reproduced by prospective competitors with minimal difficulty or at a low cost, and with little or no obligation to compensate the innovators (Cohen and Levin, 1989, pp. 1090-1991). Plant breeders, in particular, face both the risk of imitation by competing seed firms and the risk of seed reproduction by farmers themselves. For example, once marketed, plant breeding innovations embodied in the seeds of improved self-pollinated varieties, such as wheat, can be easily adapted by competing seed firms into their own product lines without compensation to the innovators if property right protections are not available (Beach and Fernandez-Cornejo, 1994, p. 5). Once the seeds are sown, they can also be reproduced and used by farmers as seed for planting in subsequent years, again without compensation.

If innovators are unable to assert property rights over their innovations or the knowledge used in creating innovative products, they may be unable to realize the full rewards of their efforts. This effect may reduce the private incentives for further innovations. If the innovation provides social benefits, as is frequently the case with agricultural sector innovations, then limited private incentives may result in research underinvestment. The establishment of patent laws and other forms of enforceable legal protection, which provide innovators limited market power, thereby generating private incentives for research, offer a potential solution to this appropriability problem and its social consequences. Public investments in socially desirable research and development, particularly in areas in

which private incentives are inadequate, offer another possible solution.

### IPR Protection in the Seed Industry

Providing private incentives to innovators and inventors is a clear and longstanding priority in U.S. agriculture and industry. The U.S. Constitution charges the Congress with the responsibility of establishing laws that award innovators exclusive proprietary rights over their inventions and ideas for limited periods of time. The first intellectual property rights (IPR) legislation passed by Congress was the Patent Act of 1790, which protects the intellectual property rights of inventors, discoverers, and innovators, and establishes a framework through which they may obtain financial rewards through the functioning of the market system (see box on timeline of regulations). The Patent Act and its subsequent amendments, however, do not extend IPRs to new plant varieties; rather, they classify biological innovations, such as new plant varieties, as “products of nature” and exclude them from protection (Fuglie et al., 1996, p. 35).

In 1790, the lack of protection over plant varieties was of limited relevance to most farmers, breeders, and other agricultural sector participants because farmers of that era relied on nonhybrid varieties of seed for planting new crops. These plant varieties were seeded by the natural processes of pollination. Seeds from self-pollinating crops, such as wheat or cotton, could be saved from one crop harvest and planted for the next without the seed losing yield potential or vigor. Seeds from cross-pollinating crops, such as corn, could also be saved from one harvest and planted for the next. However, before the advent of hybrid varieties, farmers had to select more carefully among these seeds to maintain the desirable characteristics they wanted.<sup>1</sup>

The use of saved seeds to plant subsequent crops severely limited the extent to which innovators might realize the benefits of plant breeding efforts. In practical terms, it was nearly impossible for an innovator to maintain appropriability over nonhybrid seeds, thus

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<sup>1</sup> This genetic malleability of corn, on the other hand, meant that farmers could more easily select for characteristics they wanted on their own.

## Timeline of Regulations Related to Intellectual Property Rights to Plant Varieties

**1790.** The first intellectual property rights (IPR) legislation passed by Congress was the *Patent Act of 1790*, which protects the intellectual property rights of inventors, discoverers, and innovators and establishes a framework through which these individuals may obtain financial rewards through a functioning market system. The Patent Act and its subsequent amendments do not, however, extend IPRs to new plant varieties; rather, they classify biological innovations, such as new plant varieties, as “products of nature” and exclude them from protection.

**1883.** One of the oldest international IPR agreements is the *Paris Convention for the Protection of Industrial Property* of 1883, which seeks to harmonize patent regimes among its 100 signatory countries. However, the convention provides its members only limited property rights protection for innovation of plant varieties and biological processes for plant production.

**1930.** The first IPR legislation enacted to specifically address issues of plant breeding was the *Plant Patent Act of 1930 (PPA)*. Administered by the U.S. Patent and Trademark Office (PTO), the PPA provides patent protection over asexually or vegetatively reproduced plant varieties. The PPA also includes patent protection for spores, mutants, hybrids, newly found seedlings, or plants found in an uncultivated state, and extends property rights for a period of 17 years.

**1952.** The *Patent Act of 1952 (PA)* extends patent rights to agricultural innovations under a much more general category that includes “any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvements thereof.” Patent protection under the PA covers agricultural machinery, equipment, chemicals, production processes, and similar inventions, and is termed “utility patent protection.” More importantly, the PA’s broad definition of what may be entitled to patent protection leaves an important opening for covering innovations in biotechnology and genetic engineering.

**1961.** The International Convention for the Protection of New Varieties of Plants was adopted in Paris, France, with the objective of providing intellectual property rights to the breeders of new varieties of plants. The Convention established the *International Union for the Protection of New Varieties of Plants* (UPOV—*Union Internationale pour la Protection des Obtentions Végétales*), an intergovernmental organization headquartered in Geneva, Switzerland. The Convention was revised in 1972, 1978, and 1991. The 1991 revision attempts to expand protection to address new issues in agricultural biotechnology.

**1960s.** The American Seed Trade Association formed the Breeders’ Rights Study Committee to examine issues related to plant breeders’ property rights. This effort helped enact the Plant Variety Protection Act in December 1970.

**1970. The Plant Variety Protection Act (PVPA)** grants breeders a Certificate of Protection that gives them exclusive rights to market a new plant variety for 18 years from the date of issuance. These exclusive rights are subject to a research exemption and a farmer’s exemption.

**1971.** The Consultative Group on International Agricultural Research (CGIAR) is established as a key institution in the free international exchange of plant genetic materials. CGIAR, a global network of agricultural research centers, receives funding from multilateral agencies, governments of both industrialized and developing countries, and private foundations. Included within CGIAR’s charter is the coordination of efforts to preserve plant genetic material and distribute these resources to research institutions in member countries.

**1980.** Breeders’ rights were strengthened by the U.S. Supreme Court’s 1980 decision in *Diamond v. Chakrabarty*, which extends patent rights to genetically engineered microorganisms, an important tool and product of biotechnology.

**1983.** FAO member countries passed Resolution 8/83, the International Undertaking on Plant Genetic Resources (the Undertaking), to ensure free access to genetic material whether existing in the public domain or developed commercially.

**1985-88.** A series of rulings by the PTO’s Board of Appeals and Interferences widened the scope of patent protection for genetically engineered organisms by including plants and nonhuman animals. These rulings extend IPR to a wide range of new biotechnology products in the form of utility patents awarded under the PA. These products include seeds, plants, plant parts, genes, traits, and biotechnology processes.

**1994.** The *1994 amendment to the PVPA*, which went into effect in April 1995, brought the PVPA into conformity with international standards established by the International Union for the Protection of New Varieties of Plants and allowed the United States to ratify the 1991 International Convention for the Protection of New Varieties. Protection provided by Certificates of Protection extended from 18 to 20 years for most crops.

**2000.** A case involving Pioneer Hi-Bred brought before the U.S. Federal Court of Appeals reinforced plant breeders’ intellectual property protection through protection certificates issued under the PVPA or through utility patents awarded under the PA. This ruling extended the options available to plant breeders seeking to assert property rights over their innovations.

**2001.** FAO members approved an International Treaty on Plant Genetic Resource for Food and Agriculture growing out of the International Undertaking in November 2001, although the agreement is subject to ratification by member states.

limiting the role of an IPR regime where nonhybrid seeds play a central role in agriculture.

By the 1920s, the development of hybrid corn seed offered farmers an alternative to open-pollinated corn. Hybrids also proved beneficial to plant breeders: As long as the lineage of a hybrid remains known only to the breeder, the hybrid cannot be easily reproduced, thus providing the plant breeder with control and appropriability over the innovation. Moreover, seed saved and planted from the harvest of a hybrid crop tends to diminish in yield and vigor in subsequent harvests, thus ensuring breeders a continuous market for their seed so long as other higher performing hybrid seeds do not enter the market. The unique nature of hybrids led to extensive commercialization of the corn seed industry in the 1930s, even in the absence of a regulatory framework to protect new plant varieties.

The first IPR legislation passed to specifically address issues of plant breeding was the Plant Patent Act of 1930 (PPA). Administered by the U.S. Patent and Trademark Office (PTO), the PPA provides patent protection over asexually or vegetatively reproduced plant varieties. PPA specifically covers plants derived from parts of the parent other than its seeds or tubers, and thus covers plants that contain the exact genetic makeup as the parent plant. The protection includes spores, mutants, hybrids, newly found seedlings, or plants found in an uncultivated state and extends property rights for a period of 17 years (USITC, 1995, p. 16). Patent owners have the right to exclude others from reproducing their plants asexually or vegetatively and may enforce ownership through civil action brought against parties alleged to be infringing upon their patents. The PPA's explicit exclusion of plants that are sexually reproduced or propagated by tubers reflects the perception at the time that such varieties were not adequately identifiable, uniform, or stable enough to constitute varieties requiring patent protection.

The Patent Act of 1952 (PA) extended patent rights to agricultural innovations under a much more general category, which includes "any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvements thereof" (35 U.S.C. § 101, in USITC, 1995, p. 16). The PA also includes patent protection for agricultural machinery, equipment, chemicals, production processes, and similar inventions and is termed "utility patent protection." The protection and exclusionary rights offered under

the 1952 PA are, under many circumstances, significantly greater than similar protections and rights offered by the 1930 PPA and the 1970 Plant Variety Protection Act. More importantly, the PA's broad definition of what may be entitled to patent protection left an opening for covering innovations in biotechnology and genetic engineering.

Still, neither the 1930 PPA nor the 1952 PA contained language that extended IPR to seed- and tuber-propagated varieties. In the early 1960s, the American Seed Trade Association (ASTA) formed the Breeders' Rights Study Committee to examine the issue, an effort that contributed to the enactment of the Plant Variety Protection Act (PVPA) in December 1970 (USITC, 1995, p. 16).

The 1970 PVPA grants breeders a Certificate of Protection that gives them exclusive rights to market a new variety for 18 years from the date of issuance. These exclusive rights are subject to two exemptions: (i) a research exemption, which allows the use of the seed to develop new varieties; and (ii) a farmer's exemption, which allows a farmer whose primary occupation is growing crops for sale to save seed from a protected variety to plant on the farmer's land, and to sell from that seed to another farmer whose primary occupation also is to grow crops (Strachan, 1992). Saved seed that is sold under exemption (ii) must meet the applicable State seed laws and must be labeled to show the variety name as protected under the PVPA. Further, the PVPA does not extend protection to fungi, bacteria, and first-generation hybrids. Like the 1930 PPA, the 1970 PVPA is enforceable through the actions of a protected variety's owner. To enforce protection, an owner of a protected variety may bring civil action against parties allegedly infringing on his/her property rights, and would typically seek an injunction to prevent others from further violations (USDA, AMS, 2000a).

The 1994 amendment to the PVPA, which went into effect in April 1995, brought the PVPA into conformity with international standards established by the International Union for the Protection of New Varieties of Plants (UPOV)<sup>2</sup> and allowed the United States to ratify the 1991 International Convention for the Protection of New Varieties (Fuglie et al., 1996, p. 35). The amendment extends the length of protection

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<sup>2</sup> Acronym from the French *Union Internationale pour la Protection des Obtentions Végétales*.

provided by a Certificate of Protection from 18 to 20 years from the date of issuance for most crops (25 years for trees, shrubs, and vines) (USDA, AMS, 2000a). The amendment also prohibits farmers from selling saved seed of protected varieties without the permission of the variety owner (Fuglie et al., 1996, p. 35). In addition, the amendment extends protection to tuber-reproduced plants (such as potatoes). The amendment's introduction of an "essentially derived" plant variety category, which entitles such varieties to protection, is specifically designed to address technological advances made in biochemistry and genetic engineering that enable breeders to develop varieties that may differ on the basis of a single gene or micro-molecule within the DNA structure. The category extends the definition of distinctness to include varieties of GE plants for which the uniqueness exists at miniscule levels, thereby providing property rights to plant breeders over even the smallest of genetic manipulations of their varieties (USITC, 1995, p. 16; USC, 1970, § 2401, 2541).

The PVPA affords IPR to plant varieties that are demonstrably "new, distinct from other varieties, and genetically uniform and stable through successive generations" and includes protection for both nonhybrid and hybrid seeds (USDA, AMS, 2000a).<sup>3</sup> According to the PVPA, distinctness, a key determinant of a variety's potential for protection, may be based on "one or more identifiable morphological, physiological, or other characteristics (including any characteristics evidenced by processing or product characteristics, such as milling and baking characteristics in the case of wheat) with respect to which a difference in genealogy may contribute evidence" (USDA, AMS, 2001a).

The PVPA is administered by USDA's Plant Variety Protection Office (PVPO). The PVPO is responsible for scrutinizing applications for Certificates of Protection, including information on the variety's lineage, genealogy, and breeding methodology, as well as seed or cell-culture samples and other proof of the variety's distinctness, uniformity, and stability. Plant breeders applying for protection of new wheat varieties must also submit information on the milling and baking characteristics of the variety (USDA, AMS, 2000a). Applications may be submitted by both domestic and

foreign breeders seeking protection for their variety in the U.S. marketplace.

Breeders' rights were strengthened by the U.S. Supreme Court's 1980 decision in *Diamond v. Chakrabarty*, which extends patent rights to genetically engineered microorganisms, an important tool and product of biotechnology. In the case brought before the Supreme Court, the underlying question was whether a genetically engineered bacterium designed to digest and break down crude oil was a "product of nature" that was not covered by the Patent Act or whether it was a new invention for which a patent could be awarded. Among the arguments brought before the Court was the fact that patents had been previously awarded for compositions containing living organisms, such as microbial spores, vaccines, yeast compositions, and certain dairy products. Ultimately, the Supreme Court determined that GE microorganisms were, in fact, patentable (Schor, 1994, pp. 60-61). A series of rulings by the PTO's Board of Appeals and Interferences widened the scope of patent protection for genetically engineered organisms by including plants and nonhuman animals. These rulings extend IPR to a wide range of new biotechnology products in the form of utility patents awarded under the PA. Products protected under the rulings include seeds, plants, plant parts, genes, traits, and biotechnology processes (Fuglie et al., 1996, p. 35; USITC, 1995, p. 16).

Breeder's rights were extended further with the Supreme Court's 1995 decision in *Asgrow v. Winterboer*, which precluded farmers from selling protected seed without a license from the variety's owner for varieties developed before April 1995 and not covered by the PVPA's 1994 amendment. This decision, along with the PVPA amendment, addressed the issue of appropriability in terms of the threat posed to plant breeders not by competing firms but by farmers who save and reproduce nonhybrid seed from their own crops for resale purposes (Fuglie et al., 1996, p. 35).<sup>4</sup>

A more recent case involving Pioneer Hi-Bred brought before the U.S. Federal Court of Appeals in 2000 reinforced plant breeders' intellectual property protection through protection certificates issued under the PVPA

<sup>3</sup> This does not apply to open-pollinated corn because it would not be "genetically uniform and stable through successive generations."

<sup>4</sup> This case is particularly relevant to the issue of genetically engineered nonhybrids such as herbicide tolerant "Roundup Ready" soybeans. Monsanto, the largest producer of these varieties, required farmers purchasing the soybean seed to enter into contracts that specifically prevented them from saving seed for future planting.

or through utility patents awarded under the PA (*AgBiotech Reporter*, 2000). This ruling extended the options available to plant breeders seeking to assert property rights over their innovations.

Both legislative and judicial action have contributed to an IPR regime in the United States that provides an extensive set of incentives to developing new plant varieties: plant patents for asexually or vegetatively propagated varieties under the PPA; certificates of protection for sexually or tuber-propagated varieties under the PVPA; and utility patents under the PA. Although the number of plant patents issued under the PPA exceeds all other types of property protection awarded to plant innovators, the number of protection certificates and utility patents has increased significantly in recent years (Fuglie et al., 1996, pp. 36-37).

### IPR in the International Context

Although the U.S. IPR regime provides a comprehensive framework to protect plant breeders' rights and create incentives for plant breeding R&D, the relevance of the U.S. regime is better understood within an international context because the expansion of U.S. IPR has implications for genetic resource conservation worldwide. Historically, the United States and several other countries have facilitated the free exchange of plant genetic resources for research purposes as a means of increasing worldwide agricultural production and food security. However, the role of intellectual property rights in this context remains unclear and has been the subject of much international debate (USDA, ERS, 2000, p. 14).

A key institution in the free global exchange of plant genetic materials is the Consultative Group on International Agricultural Research (CGIAR), an international network of agricultural research centers established in 1971. CGIAR receives funding from multilateral agencies, governments of both industrialized and developing countries, and private foundations. Included within CGIAR's charter is the coordination of efforts to preserve plant genetic material and distribute these resources to research institutions in member countries. Historically, the free exchange of plant genetic resources has been important to the United States, not only because of its membership in CGIAR but also because of its need for access to genetic materials beyond U.S. borders. The relative lack of genetic diversity among indigenous plants makes the United States a "germplasm-deficient" country, and free exchange

ensures the United States continued access to genetic resources from other countries to support its extensive work in agricultural R&D (Day-Rubenstein and Heisey, 2001, p. 22). In fact, as a result of collection and breeding activities, the United States is currently a net supplier of plant germplasm to the rest of the world (Day-Rubenstein and Heisey, 2001, p. 18).<sup>5</sup>

The United States, however, is also committed to supporting plant breeders and private sector investment in plant breeding R&D, a commitment that is shared with many other countries. As a result, the United States is party to a number of international agreements and conventions designed to protect the rights of plant breeders. One such agreement, the Paris Convention for the Protection of Industrial Property (1883), seeks to harmonize patent regimes among its 100 signatory countries. However, the Paris convention provides only limited property rights protection for plant varieties and biological processes for plant production (Van Wijk, 1993, p. 17). The UPOV provides for a more explicit IPR regime to its 52 member states by extending protection to distinct, uniform, and stable plant varieties for a minimum of 15 years.<sup>6</sup> The 1991 Act of the UPOV convention attempts to expand protection to address new issues in agricultural biotechnology. For instance, the 1991 Act eliminates an exemption for essentially derived varieties, under which breeders who created new varieties by incorporating single genes into an existing protected variety did not require permission from the variety owner (Van Wijk, 1993, pp. 6-7). Out of 52 member states, only 23, including the United States, have become a party to the 1991 Act (UPOV, 2003).

The difficulty of balancing free access to plant genetic materials with protecting breeders' rights was apparent in 1983, when member countries of the United Nations Food and Agriculture Organization (FAO) passed Resolution 8/83, the International Undertaking on Plant Genetic Resources (the Undertaking), seeking to ensure free access to genetic material, whether existing in the

<sup>5</sup> For some quantitative results, see Smale and Day-Rubenstein (2002).

<sup>6</sup> UPOV is an intergovernmental organization headquartered in Geneva, Switzerland. UPOV was established by the International Convention for the Protection of New Varieties of Plants with the objective of protecting new varieties of plants through intellectual property rights. The Convention was adopted in Paris in 1961, and it was revised in 1972, 1978, and 1991. These revisions, or amendments, are referred to as the "1972 Act," "1978 Act," and "1991 Act" (UPOV, 2003).

public domain or developed commercially. As a result of objections from the United States and other FAO member countries, compliance with the resolution was deemed nonbinding on members. Disagreements arose during subsequent rounds of discussion on key issues related to plant breeding, such as compensating farmers, particularly in developing countries, for their contribution to past plant genetic improvements; protecting the rights of plant breeders over their inventions, ideas, and products; ensuring free and equitable access to genetic materials; and establishing programs to preserve diverse genetic resources for future use. Members approved an International Treaty on Plant Genetic Resource for Food and Agriculture growing out of the Undertaking in November 2001, although it is subject to ratification by member states (FAO, 2001).

The UN Convention on Biological Diversity (1992) also addressed issues relevant to plant breeding, such as the equitable use and preservation of plant genetic resources, although the convention's provisions relating to IPRs were found wanting by the United States and other members (Day-Rubenstein and Heisey, 2001, pp. 20-21; Van Wijk, 1993, pp. 26-27). The convention was signed by the United States in 1993 but has not been ratified by the U.S. Senate (Day-Rubenstein and Heisey, 2001, p. 22).

While FAO, the UN, and CGIAR efforts focus on preserving genetic diversity and, to the extent possible, making plant genetic material available worldwide, a new international regulatory regime is poised to establish a much stricter international IPR regime. The 1986 Uruguay Round of the General Agreement on Tariffs and Trade (GATT) established the framework for an initiative on trade-related aspects of intellectual property rights (TRIP). Under TRIP, member countries of the World Trade Organization (WTO) are required to update their IPR legislation to meet new international standards. These new standards include the protection of seed and plant varieties with patents or similar property rights (Day-Rubenstein and Heisey, 2001, p. 22). Moreover, the WTO's authority to sanction members for noncompliance with TRIP would enable the organization to more effectively enforce the initiative, resulting in a stronger international IPR regime that will reflect and support the present IPR regime in the United States.

## Regulation To Ensure Seed Quality

Along with the comprehensive framework designed to protect plant breeders' rights, the United States also

offers protections to farmers who purchase seed, directly or indirectly, from plant breeders. Because the quality of most seed cannot be determined by visual inspection, the risks associated with seed choice are high. U.S. farmers are protected by a comprehensive system to ensure seed quality.

Varietal registration, a key protection for farmers who purchase seed, provides a system for establishing a variety's genetic identity and its performance characteristics, such as yield or disease resistance. In the United States, plant breeders register varieties with Federal agencies responsible for awarding plant patents or protection certificates. These agencies can provide farmers with information on the characteristics of different varieties that might otherwise be overly complicated or difficult to obtain in the marketplace. U.S. plant breeders are not required to provide information on a variety's performance characteristics, which is typically ascertained through field tests (Tripp, 1998, p. 160). Field testing is mandatory, however, in cases involving the introduction of GE organisms.

Seed certification and quality testing also offer protection to farmers. Seed certification establishes the genetic purity of a seed, while quality testing ascertains such information as germination rates, moisture content, or seed size. Individual States oversee the process of seed certification through State agencies, such as agricultural extension services; State agricultural departments; or independent bodies, such as crop improvement associations. The certification system is not a rigorous process of mandatory testing; rather, seed companies are required to adhere to truthful labeling provisions that permit companies to sell seed as long as seed quality information is completely disclosed on the packaging. This labeling provision is considered highly effective (Tripp, 1998, p. 164).

## Environmental and Consumer Protection

Much like the laws that protect plant breeders' property rights and the interests of farmers, a regulatory framework provides protection for the environment and for consumers of agricultural commodities. These laws are particularly relevant in light of the expanding role of biotechnology in U.S. agriculture.

The Animal and Plant Health Inspection Service (APHIS) of the U.S. Department of Agriculture plays a central role in regulating the release of agricultural

biotechnology products into the environment. Such products, which include genetically engineered plants, microorganisms, and invertebrates, are considered “regulated articles.” Private firms and public institutions wishing to move or release these organisms must receive authorization from APHIS through either a notification or permit procedure. APHIS requires that the notifications and permit applications contain specific details about the organism’s genetic makeup and lineage, as well as the testing and safety measures designed to prevent the organisms from being disseminated from the test site or persisting beyond the duration of the test. In the case of permits, APHIS often imposes additional conditions to ensure confinement. APHIS determines whether to authorize the test, based on whether the release will pose a risk to agriculture or the environment. APHIS and State authorities maintain a continuing right to inspect test sites at any time (USDA, 2000b). 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, then the organism is “de-regulated.” At this point, the organism is no longer considered a regulated article and can be moved and planted without APHIS authorization.

APHIS is also responsible for plant quarantines, a function that is crucial to protecting the environment from the spread of disease or pests. APHIS enforces regulations that govern the import and export of plants and seeds and are designed to ensure that sanitary and phytosanitary threats do not affect U.S. agriculture or the agriculture sectors of U.S. trading partners. The agency is also responsible for imposing quarantines on areas within the United States where disease or pests pose a threat. APHIS authority to impose quarantines is particularly important with the increase in adoption of bioengineered crops and concerns over genetic exchanges among these crops, weeds, and other crops (Tripp, 1998, p. 171).

If a plant is engineered to produce a substance that “prevents, destroys, repels, or mitigates a pest,” then such substance is considered to be a pesticide and is subject to regulation by the U.S. Environmental Protection Agency (EPA) (Federal Register, November 23, 1994). The U.S. Food and Drug Administration (FDA) maintains regulatory control over all food applications of crops, including those crops that are developed through the use of biotechnology. Shoemaker et al. (2001, pp. 31-32) describe the EPA and FDA regulation of agricultural biotechnology products.