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# Issues in Biotechnology Regulation and Its Effects on Industrial Structure

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This article analyzes research and development in genetically modified crops, the changing attitudes of regulatory agencies, and the impacts of these factors on the agri-biotech industry. It provides details on the deregulated products, including the timing of the process, the company involved, and the regulatory costs. If the product failed in the market, the article discusses major reasons for failures. The article will illustrate changes in the required time to deregulate for each product and how this timing has changed during the last 25 years. Additionally, it discusses that the increasing costs and risks in successfully developing, deregulating, and marketing a new product has forced small biotech companies to either exit from business or merge with other companies. Thus the number of companies conducting agri-biotech research has significantly decreased over time. The industry became smaller in firm numbers, but some companies became larger in size, presenting the possibility of reduced competition among firms. This reduced number of firms has likely contributed to a more narrow research focus for the industry.

***Key words:*** agri-biotech, regulation, industrial structure, United States.

## Introduction

Agricultural biotechnology consists of a set of tools that includes traditional breeding techniques and genetic engineering. Traditional biotechnology has been employed for hundreds of years in agriculture to improve qualitative and quantitative characteristics of plants and animals. Farmers and breeders used selective- and cross-breeding methods to develop new varieties with specific desirable characteristics. During the selective method, breeders choose traits with desired characteristics and propagate them repeatedly over several generations to develop a new variety. In most cases, the genes that contributed special characteristics were not explicitly identified, so the desired attributes were selected mostly through the trial and error method. The process is extremely time-consuming, often taking more than 15 years to bring a new product to market. Furthermore, this method has a number of limitations; one of the most notable is that the two species can be cross-bred only if they are closely related. For instance, if a breeder wants to develop an insect-resistant high-yield corn variety, it is necessary to find two corn varieties in which one of them is naturally resistant to insects and the other is capable of providing high yields. Thus if no varieties are naturally resistant to an insect, the traditional breeders cannot create a new variety that is resistant to that particular insect.

Modern gene technologies and a deeper understanding of DNA structures allow scientists to identify specific genes associated with desired characteristics and transfer the genes across species boundaries. This procedure—recombinant methodology—enables scientists to circumvent many problems faced in traditional breeding methodologies. One of the most important advantages of this method is that the specific desired characteristic gene does not necessarily come from closely related species, as is required in traditional breeding methods. Consequently, the usefulness of a desired characteristic can be transferred to many other varieties. Since only the targeted gene is separated and infused, the recombinant methodology can easily limit the non-targeted characteristics, which is another major problem in traditional breeding methodologies (Ministry of Foreign Affairs of Denmark [DANIDA], 2002).

The recombinant technological procedure accelerated developments of new transgenic products in many fields, including the pharmaceutical (e.g., monoclonal antibodies and vaccines), manufacturing (e.g., plastics and biofuels), and agricultural (e.g., resistant to biotic stress) sectors. Application of this technology in the agricultural sector has provided a number of benefits such as developing plants that are resistant to disease and pests, increasing shelf life of fruits and vegetables, producing plants that possess healthy fats and increased nutritive values, and increasing productivity. Despite all

**Table 1. Global area of biotech crops in 2013 by country (million hectares).**

| Rank | Country | Area | Biotech crops |
|---|---|---|---|
| 1 | United States | 70.1 | Maize, soybean, cotton, canola, sugar beet, alfalfa, papaya, squash |
| 2 | Brazil | 40.3 | Soybean, cotton, maize |
| 3 | Argentina | 24.4 | Soybean, cotton, maize |
| 4 | India | 11.0 | Cotton |
| 5 | Canada | 10.8 | Canola, maize, soybean, sugar beet |
| 6 | China | 4.2 | Cotton, papaya, poplar, tomato, sweet pepper |
| 7 | Paraguay | 3.6 | Soybean |
| 9 | South Africa | 2.9 | Maize, soybean, cotton |
| 8 | Pakistan | 2.8 | Cotton |
| 10 | Uruguay | 1.5 | Soybean, maize |
| 11 | Bolivia | 1.0 | Soybean |
| 12 | Philippines | 0.8 | Maize |
| 13 | Australia | 0.6 | Cotton, canola |
| 14 | Burkina Faso | 0.5 | Cotton |
| 15 | Myanmar | 0.3 | Cotton |
| 16 | Spain | 0.1 | Maize |
| 17 | Mexico | 0.1 | Cotton, soybean |
| 18 | Colombia | 0.1 | Cotton |
| 19 | Sudan | <0.1 | Cotton |
| 20 | Chile | <0.05 | Maize, soybean, canola |
| 21 | Honduras | <0.05 | Maize |
| 22 | Portugal | <0.05 | Maize |
| 23 | Czech Republic | <0.05 | Maize |
| 24 | Cuba | <0.05 | Maize |
| 25 | Slovakia | <0.05 | Maize |
| 26 | Costa Rica | <0.05 | Cotton, soybean |
| 27 | Romania | <0.05 | Maize |

*Source: James (2013)*

these advantages and potential to solve many of the most striking problems in the world, the technology has become one of the most critically challenged technologies in the history of agriculture.

This study focuses on the current status of agricultural biotechnology and how the current policies shaped biotechnology research and the agricultural industry in the United States. The regulatory process is outlined and the present industrial structure is presented. The policy implications of the intersection of the regulatory process and industrial structure are discussed at the end.

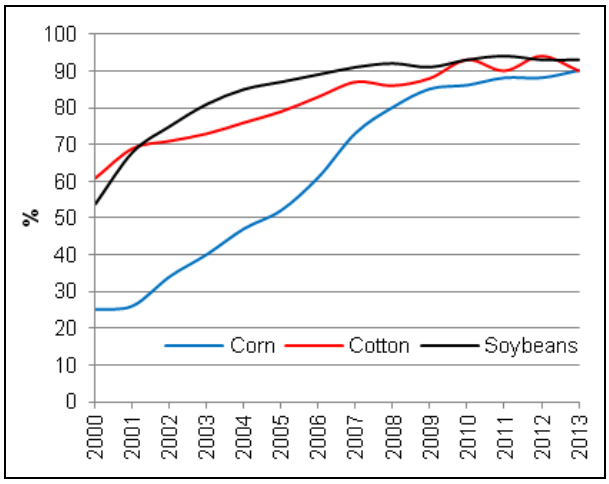


**Figure 1. US adoption of biotech varieties for corn, cotton, and soybeans since 2000 (in percentages).**
*Source: USDA APHIS (2014)*

## Adoption of Genetically Modified Crops

Currently 59 countries have granted approvals to use biotech crops for food or feed, yet only 27 countries grow genetically modified (GM) crops (Table 1). James (2013) states that about 175 million hectares of land in the world in 2013were planted with GM seed. The United States accounted for approximately 41% of the area; other major countries include Brazil (21%), Argentina (14%), Canada (7%), and India (6%). About 18 million farmers use GM seed, and 50% of them are from developing countries. The majority of the GM products are utilized for feed and fiber in the major industrialized countries. Table 1 shows that soybeans (11 countries), maize (15 countries), and cotton (13 countries) are the major transgenic crops grown in the world. The fourth-largest crop is canola (rape), but it is grown only in four countries (United States, Canada, Australia, and Chile). In terms of the share of the total area cultivated, soybeans and cotton are the most successful GM crops—in 2012, 81% of the total area of these crops grown globally were GM varieties.

The United States is the leading country in both adoption of GM products and research and development (R&D) in the recombinant technology. The success of adoption is mostly concentrated in field crops such as corn, cotton, and soybeans. Figure 1 shows the percentage of acres adopted by various corn, cotton, and soybean varieties in the United States. Major corn and cotton traits are insect resistance (Bt), herbicide tolerance (HT), and stacked (involve two or more genes); GM soybean seeds only offer the herbicide tolerance

trait. Despite high adoption rates, the technology adoption is mostly limited to these three crops.

Commodity crop traits are specifically developed to target a large number of farmers. The release of Bt and HT varieties were not engineered to increase yield directly; however, the traits reduce losses from pests and weed competition (Klotz-Ingram, Jans, Fernandez-Cornejo, & McBride, 1999). Thus the traits are well received by almost all farmers, and developers are eager to continue their efforts on these products. Current policies require millions of dollars to develop and successfully market a new biotech product. So it is important for the firm to develop a technology that will create enough revenue to cover the development costs. Therefore, biotech firms develop varieties that are grown on large areas and the crops are freely exported. Feed and fiber crops seem to be well suited for this venture.

A number of biotech companies invested many resources to develop more crop varieties other than the three field crops, but the firms were not successful with those products. Application of the technology in food products has been severely hampered by strong opposition in a number of affluent countries. Consumer attitudes toward the technology have been negative for a long time in Europe, Japan, and other major food-importing countries. Public agitation with the technology in the early 1990s was limited to small circles. However, as the first GM seeds arrived in Europe during the late 1996, the opposition to GM products severely intensified. Media and other interested organizations looked at GM products as inferior products, and these organizations campaigned extensively on the risks of GM products. In addition, during this period, Europe experienced a number of health scares involving contaminated blood (HIV), asbestos, BSE, and *Listeria*. Some consumers in wealthy countries are willing to pay an extra premium for non-GMO products, which sent a message to many developing countries that the GM products are inferior goods and not well suited for human consumption.

GM field crops are successful because these products do not pose any significant food-safety threat since the end use of these crops is for the most part as animal feed or industrial use. Buyers of feed crops are, in general, other farmers who are mostly comfortable with the technology. Fiber crops, such as cotton, are used in industrial production and therefore production technology causes no food-safety concerns. For these reasons, many biotech firms limited their research to commodity crops to recoup the research expenditures and to avoid confrontations with a hostile public.

## The Biotechnology Regulatory Process in the United States

The US Department of Agriculture's (USDA) Animal and Plant Health Inspection Service (APHIS), the US Environmental Protection Agency (EPA), and the US Department of Health and Human Services' Food and Drug Administration (FDA) oversee the development of agricultural biotechnology under the Coordinated Framework for Regulation of Biotechnology. APHIS has jurisdiction over the planting of GM plants and veterinary biology, EPA has jurisdiction over pesticides engineered into plants and microbial pesticides, and FDA has jurisdiction over food and feed uses of biotechnology. Under the authority of APHIS, the development of a new biotechnology product is subject to a three-stage regulatory process.

- Stage 1: The notification process. The applicant must show that the intended genetically-engineered (GE) plant satisfies six eligibility[1] criteria for notification. If the GE plant does not satisfy all six criteria, then the application must go to a permit process, which falls under APHIS regulations. The application must provide a detailed description of the tests already undertaken, including specific measures to reduce the risk of harm to other plants.
- Stage 2: Compliance with regulations. APHIS ensures that the research is conducted in accordance with the regulations. Compliance specialists and inspectors visit and audit the research sites thoroughly to see if there have been any complaints or infractions.
- Stage 3: Petition for determining non-regulated status. A GE plant developer can apply for non-regulated status if the GE plant is no longer subject to regulatory oversight under 7 CFR part 340. The petitioner must provide all data from the field trials (which were regulated by APHIS) to help the agency make its decision.

1. *(i) The organism is not listed as a noxious weed nor considered by APHIS to be a weed in the area of release; (ii) stable integration of genetic material; (iii) known function of genetic material that does not result in plant disease; (iv) characteristics of the gene and gene product; (v) does not pose significant risk of creating new plant viruses; and (vi) does not contain sequences from human or animal pathogens (USDA APHIS, 2011).*

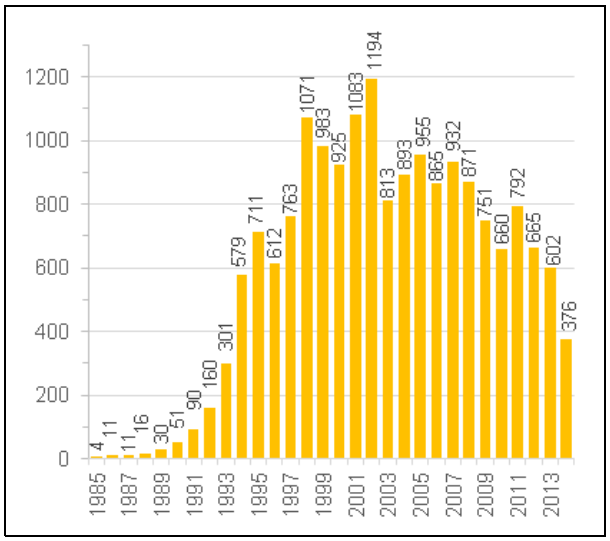


**Figure 2. Number of permits and notifications granted by APHIS to conduct research on genetically-engineered varieties, 1985-2014.**

*Source: USDA APHIS (2014)*

APHIS analyzes the data and prepares documentation that is required by the National Environmental Policy Act of 1969. All federal agencies must determine whether the GE product can pose any adverse environmental impacts. APHIS prepares either an environmental assessment (EA) or an environmental impact statement (EIS), and makes it available to the public for comment. After receiving and considering all comments, APHIS determines non-regulatory status if the GE product does not pose a plant pest risk. In addition to APHIS, the developers need to obtain non-regulated status from the Environmental Protection Agency (EPA) and Food and Drug Agency (FDA) before the product is commercialized.

The first petition was approved by the regulatory agencies in 1992 and the first GE product—the Flavr Savr Tomato—was commercially produced and marketed in 1994. The approval of this new product stimulated R&D in the subsequent years. Private investment in the field began to dominate R&D. Since 1985, APHIS has released 17,770 permits and notifications to conduct GE research. Data on permits and notifications indicate that the interest in R&D in GE technology is still high in the United States despite significant opposition to the technology in the major trading partner countries (Figure 2). A number of studies conducted in the first half of the last decade (e.g., Jaffe, 2005) point out that the enthusiasm for biotechnology research began to moderate in the late 1990s; however, it is still high.

**Table 2. Number of authorized sites and constructs and their percentage changes, for evaluation by APHIS.**

| Year | Number of authorized sites | Number of authorized constructs | Percentage change in authorized sites | Percentage change in authorized constructs |
|---|---|---|---|---|
| **1990** | 14 | 142 | 16.67 | 91.89 |
| **1991** | 10 | 226 | -28.57 | 59.15 |
| **1992** | 121 | 427 | 1,110.00 | 88.94 |
| **1993** | 455 | 870 | 276.03 | 103.75 |
| **1994** | 1,669 | 1,926 | 266.81 | 121.38 |
| **1995** | 3,690 | 2,666 | 121.09 | 38.42 |
| **1996** | 2,745 | 2,305 | -25.61 | -13.54 |
| **1997** | 3,427 | 2,650 | 24.85 | 14.97 |
| **1998** | 4,781 | 3,830 | 39.51 | 44.53 |
| **1999** | 4,134 | 3,502 | -13.53 | -8.56 |
| **2000** | 3,836 | 3,126 | -7.21 | -10.74 |
| **2001** | 5,831 | 3,208 | 52.01 | 2.62 |
| **2002** | 5,111 | 3,234 | -12.35 | 0.81 |
| **2003** | 2,910 | 2,650 | -43.06 | -18.06 |
| **2004** | 4,523 | 2,851 | 55.43 | 7.58 |
| **2005** | 4,939 | 3,042 | 9.20 | 6.70 |
| **2006** | 4,327 | 18,532 | -12.39 | 509.20 |
| **2007** | 3,623 | 63,217 | -16.27 | 241.12 |
| **2008** | 7,744 | 125,365 | 113.75 | 98.31 |
| **2009** | 6,751 | 217,502 | -12.82 | 73.49 |
| **2010** | 6,626 | 297,422 | -1.85 | 36.74 |
| **2011** | 10,128 | 385,501 | 52.85 | 29.61 |
| **2012** | 9,133 | 469,202 | -9.82 | 21.71 |

*Source: Fernandez-Cornejo, Wechsler, Livingston, and Mitchell (2014)*

The number of permissions granted to conduct biotech research increased significantly in the early stages of the development process, especially after the first GE crop was deregulated in 1992 (Figure 2). The number of released permits increased more than three-fold within the first two years, which suggests that biotech companies showed great interest in conducting field research. The positive trend continued until 2002; however, the number of permits granted by APHIS decreased by 32% in 2003. The number of permits released or the number of applications submitted for permits may not necessarily correlate to the actual research in the field because one permit can reflect multiple release sites and authorize many different gene constructs to be tested at each site. Data on the actual number of authorized sites and authorized constructs are presented in Table 2. It shows that there was about a 50% drop in the number of biotech research sites in 2003 compared to 2001. However,

**Table 3. Biotech crops deregulated by the United States as of May 2014.**

| Crops | 2000 and before | 2001-2011 | After 2011 |
|---|---|---|---|
| **Alfalfa** | 0 | 1 | 0 |
| **Beet** | 2 | 0 | 0 |
| **Canola** | 0 | 0 | 2 |
| **Chicory** | 1 | 0 | 0 |
| **Corn** | 15 | 11 | 8 |
| **Cotton** | 6 | 6 | 3 |
| **Flax** | 1 | 0 | 0 |
| **Papaya** | 1 | 1 | 0 |
| **Plum** | 0 | 1 | 0 |
| **Potato** | 5 | 0 | 0 |
| **Rapeseed** | 4 | 3 | 0 |
| **Rice** | 1 | 1 | 0 |
| **Rose** | 0 | 0 | 1 |
| **Soybean** | 5 | 3 | 7 |
| **Squash** | 2 | 0 | 0 |
| **Sugar beet** | 0 | 1 | 0 |
| **Tobacco** | 0 | 1 | 0 |
| **Tomato** | 11 | 0 | 0 |
| **Total** | **54** | **29** | **21** |

*Source: USDA APHIS (2014)*

the number of constructs in each research site increased. For instance, as shown in Table 2, the number of constructs per site was 4.3 in 2005; however, the number increased to 51.4 in 2012. The expanded research activities for each site provide the necessary data for researchers to analyze multiple research objectives with limited available resources.

Despite the high volume of R&D activities, US regulatory agencies have deregulated 104 varieties belonging to 18 different crops since the first transgenic crops came to the market in 1994 (Table 3). Regulatory agencies were busier approving GE technology until 2000. The early period (until 2000) had 54 varieties deregulated involving 13 different crops, while the 2001-2010 period had only 24 approvals (involving 10 crops). This slower rate of approvals might have forced firms to alter their business strategies. Since 2011, though, 21 traits have been deregulated. Jaffe (2005) noted that 62 petitions were submitted to USDA between 1994 and 2004 and the average decision times were 5.9 months for the first five years but 13.9 months for the last five years. According to the USDA, the major reason for decision delays was a shortage of personnel in the regulatory agency. This slowdown might indicate that the regulatory agencies wanted to delay the development of biotech products and allow market conditions to adjust to the new environment. Whatever the reason, these delays forced biotech firms to incur additional costs (increased opportunity costs) and change their strategies in order to be competitive in the market.

Deregulating a product does not guarantee success in the market. As noted earlier, most of the successful products are field crops, and the products introduced for human consumptions have mostly failed because either the products didn't perform very well in the field (tomato) or processing firms or major users of the product did not want to take the associated risks since the benefits for using biotech products over the traditional products were not significant (potato).

## Increasing Private-Sector Involvement in Agri-Biotech Research

New product development is particularly imperative for publicly-traded biotechnological firms since their success depends on the ability to produce higher profits and consistently bring new products to the marketplace. Thus the firms need to develop new products continually as their existing products mature and have lower profits due to competition from other firms. This short lifecycle for biotech products forces companies to innovate or find their profits falling. If a firm does not develop new innovative products before the maturity stage of the current product, it might lose its competitiveness as a leading innovator, thus providing competitors more opportunity to seize market share. Therefore, continual development of new products is necessary and firms must be able to allocate enough resources to conduct research.

In addition, firms need to have the ability to predict dynamic changes in the industry. Agricultural biotechnology is high tech, innovative, and can be easily influenced by a number of factors such as new developments in DNA technologies, regulatory policies, and consumers' acceptance. Therefore, biotechnology firms need to be aware of current developments in these factors and must be flexible enough to alter their business strategies accordingly.

Despite a decreasing number of approvals (released new varieties) and growing opposition to the technology, the amount of money spent by private investors to conduct research on seed and biotech products is on the rise. Figure 3 shows that private investors in the seed and biotech industry increased research expenditures from $507 million in 1995 to $1.05 billion in 2000—a 99% increase. In comparison, increases in private

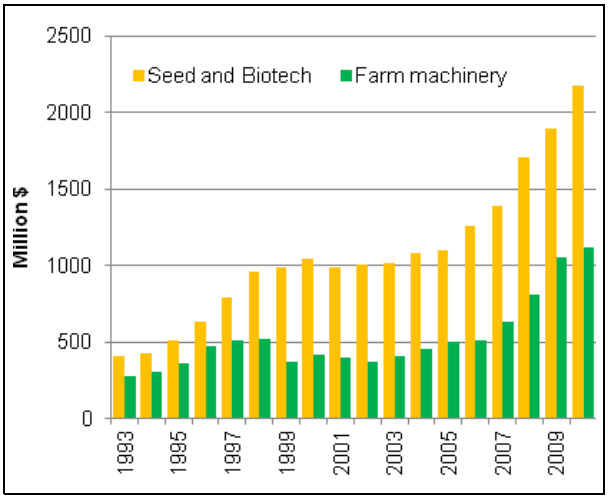


**Figure 3. Private investments in seed and biotech versus farm machinery.**
*Source: Fuglie et al. (2011)*

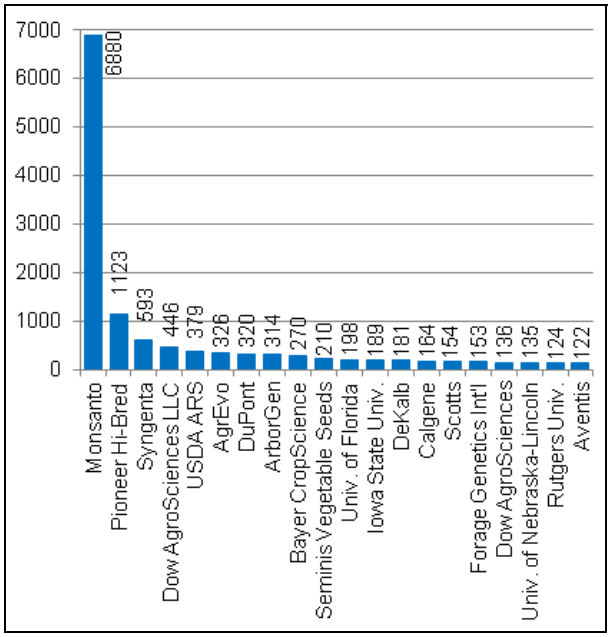


**Figure 4. Number of biotech research permits held by the top 20 institutions.**
*Source: USDA APHIS (2014)*

investments in the farm machinery and food industries during the same period were 3% and 40%, respectively (Fuglie et al., 2011). Obviously there was interest in biotechnology research in the private sector, and many people were optimistic and believed that investment in the GE technology might be lucrative.

Figure 4 shows the top 20 biotech institutions holding research permits in the United States. This figure illustrates that the biotechnology industry is strongly funded by private industry. Currently 324 institutions hold permits from APHIS, but the top 10 institutions hold 61.2% of the permits. USDA Agricultural Research Service is the only publicly-funded institution that holds more than 2% of the total. Monsanto is the largest firm, holding 38.8% of the permits, followed by Pioneer-Hi Bred international Inc., which holds 6.3%. This shows Monsanto's large influence on the industry.

Strong competition among product developing firms can reduce potential benefits and in some cases the whole R&D costs can be sunk costs. For example, if Monsanto and Pioneer compete to develop a new product at the same time, but Monsanto's product is better suited in the market, Pioneer could lose all its R&D expenditures, which are a sunk cost to Pioneer. Pioneer will certainly be less able to make future investments in R&D. To avoid such pitfalls, firms choose two strategies: (1) firms in the industry collaborate with each other so they are not competing directly and (2) one firm hinders other firms from producing similar products through buying or merging with the firms that hold biological patents. The latter strategy has been Monsanto's business strategy—the company merged with and acquired many small firms with biological patents.

Consequently, a few large biotechnology firms control most of the property rights and patents. Thus many small firms are not able to conduct R&D and then market their own products independently. Therefore, each firm calculates the risks and potential revenues associated with each new possible product carefully. Table 4 shows time, biotech firm names and number of varieties each firm has permission to sell in the United States. It shows that a large number of companies have developed products that were deregulated, but many of these companies no longer exist. Since 2011, 21 traits belonging to 9 companies have been deregulated by APHIS. Four biotech companies—Bayer (2), Monsanto (7), Pioneer (3), and Syngenta (3)—account for 15 of these 21 products. In effect, the agricultural biotechnology is a high-concentration industry.

## Regulatory Costs and Changes in Industrial Structure

The cost to develop new biotech products involves R&D costs, regulatory costs, and marketing costs. Research costs are expected to be lower as scientists gain more experience and have access to new information and improved technologies. As the technology progresses, one would think that the cost to deregulate new

**Table 4. Biotech crops deregulated by APHIS since 1992.**

| Time period | Company | Varieties that deregulated | Number of successfully deregulated articles |
|---|---|---|---|
| **1994-2013** | Monsanto | Soybean, corn, cotton, potato, rapeseed, tomato, alfalfa | 34 |
| **2004-2014** | Dow | Corn, soybean | 2 |
| **2005-2013** | Syngenta | Corn, cotton | 6 |
| **2014** | BASF | Soybean | 1 |
| **1998-2013** | Pioneer | Corn, soybean, canola | 8 |
| **2013** | Genective | Corn | 1 |
| **2013** | Stine Seed | Corn | 1 |
| **2006-2012** | Bayer | Cotton, rice | 4 |
| **2011** | Florigene | Rose | 1 |
| **2009** | University of Florida | Papaya | 1 |
| **2007** | ARS | Plum | 1 |
| **2004** | Mycogen/DOW | Cotton | 2 |
| **1998-2003** | Aventis | Cotton, rapeseed | 3 |
| **2002** | Vector | Tobacco | 1 |
| **2001** | Mycogen/DOW/Pioneer | Corn | 1 |
| **1999** | University of Saskatchewan | Flax | 1 |
| **1992-1997** | Calgene | Cotton, rapeseed, tomato | 9 |
| **1998** | Novaritis/Monsanto | Beet | 1 |
| **1995-1998** | AgrEvo | Corn, beet, rapeseed, rice, soybean | 10 |
| **1996-1997** | Dekalb | Corn | 1 |
| **1996-1997** | Dupont | Cotton, soybean | 2 |
| **1996** | Agritope | Tomato | 1 |
| **1996** | Cornell University | Papaya | 1 |
| **1996** | Northrup King | Corn | 1 |
| **1996** | Asgrow | Squash | 1 |
| **1996** | Plant Genetic System | Corn | 1 |
| **1995** | Cibaseeds | Cotton | 1 |
| **1995** | Zeneca & Petoseed | Tomato | 1 |
| **1994** | DNA Plant Tech | Tomato | 1 |
| **1994** | Upjohn | Squash | 1 |

*Source: USDA APHIS (2014)*

products would be lower as regulators and developers become more experienced and able to make decisions quicker and easier. However, regulatory costs depend on several factors, such as changes in regulatory policies and unexpected regulatory delays. Redenbaugh (2004) estimated that launching a transgenic biotech product costs between $3 million and $5 million, and the costs increase as time progresses and as approvals are sought on a worldwide basis. He observed that Monsanto spent about $65 million to develop its Round-Up Ready soybean seeds. In another study, Manalo and Ramon (2007) estimated the total cost to develop Bt corn (MON810) in the Philippines was $2.6 million, in which 67% was regulatory compliance and 33% was technology development costs. Kalaitzandonakes, Alston, and Bradford (2006) estimated that compliance costs for Bt corn in the United States was between $7 million and $15 million.

Bayer, Norton, and Falck-Zepeda (2010) estimated changes in the present value of net returns due to increased regulatory cost and delay. They show that the impact of regulatory costs are relatively small—for example, a quadruple increase in regulatory costs lead to a 7% decrease in net present value for multiple virus resistant (MVR) tomato, but a three-year regulatory delay leads to a 93% decrease in net present value using

a 5% discount rate. This shows that delays in regulatory approval play an important role in a firm's net returns and could have drastic effects on investment decisions.

The increasing regulatory costs and risks in successfully getting a product through development, approvals, and market introduction has forced small biotech companies to either exit from the business or merge with other companies. As a result, the number of companies conducting agricultural biotech research has significantly decreased over time. For example, between 1996 and 2006, the number of independent biotech companies decreased from 600 to 250. The industry became smaller in number, but some of its firms became larger in size, presenting the possibility of reduced competition among firms (for instance the big four biotech seed companies—Monsanto, DuPont/Pioneer Hi-Bred, Syngenta, and Dow AgroSciences—own 80% of the US corn market and 70% of the soybean).

Since 1990, global market concentration in agricultural input industries has increased significantly. For example, seed and biotechnology industry concentration (C4) was 32.5% in 2000, and it increased to 53.9% in 2009, which is an increase of 66%. Similar values exist for the agricultural chemicals—41% in 2000 and 62.5% in 2009, which is an increase of 52.4% (Fuglie et al., 2011). Major reasons for the growing concentrations are due to either a few firms expanding their sales much more than the industry average or firms acquiring and merging with other firms in the industry. Increased trade among countries, improved transportation facilities, and better marketing strategies has helped some firms to improve their sales. In addition, lower prices as a result of economies of scale allowed firms to increase their sale volume.

This reduced number of firms has contributed to a more narrow research focus for the industry. Firms with large resources are able to make the necessary investments in technological progress, whereas smaller, limited-resource firms and public institutions depend on collaborating or merging with the larger firms. For example, Monsanto acquired at least 25 independent companies between 1998 and 2007. The dominance of these few privately-funded firms has influenced the development of new products and the direction of the industry growth. The largest firms face little or no competition in the industry, and patent and copyright laws limit entries of new firms or growth of existing small firms. This is because current and future R&D mostly relies on previously patented gene constructs or methods, which provide effective protection for firms that are already established in the industry. The threats of new

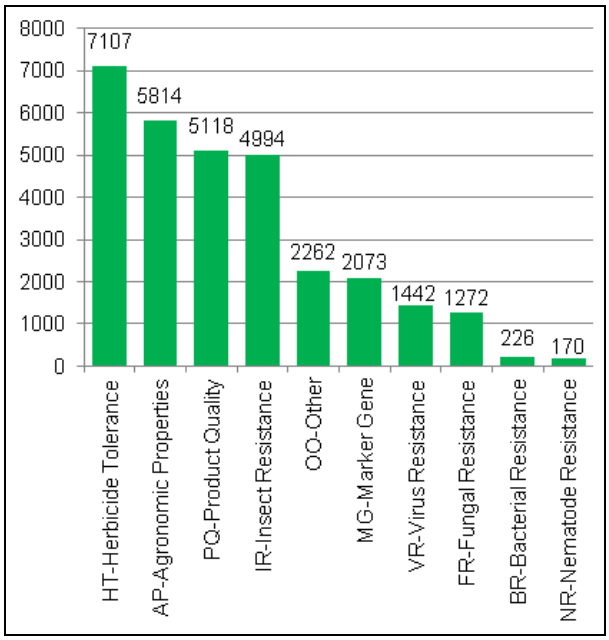


**Figure 5. Number of permits to conduct field research by category.**

*Source: USDA APHIS (2014)*

firm entry into biotech R&D and product development are efficiently negated by these barriers. This provides the largest, resource-rich firms freedom to operate and choose products that deliver maximum profits with minimum risks.

Even though biotechnology is a highly concentrated industry, there are still opportunities for many small firms in biotech research. Some small biotech companies conduct research and establish patents with the sole purpose of being purchased by a large multinational company. These small firms conduct research independently (or are even sometimes partially financed by the larger companies), however, the demand for their discoveries is driven from a few big multinational companies. This means the existence of small firms depends on delivering products and methods that are demanded by the big companies. Furthermore, slow regulatory approvals and other delays more likely deter small firms than large firms. The end result is that only a few firms decide what to produce and who will be the beneficiaries of these new products.

## Future Products and Consumer Perceptions

Figure 5 shows the number of permits to conduct field research in different phenotype categories, which reflect the firms' goal and the direction of biotechnology devel-

opment. The four most dominant categories are herbicide tolerance, agronomic properties (such as increased pathogen and stress resistance), product quality, and insect resistance. Firms are still strongly focused on input traits that do nothing to negate the strong opposition to the technology. As noted earlier, consumers see these products as low-valued products because they do not involve new product attributes that they value. A number of studies have been conducted to understand consumers' attitude toward the technology. These studies show that even after several years of GM experience, consumers still have a negative attitude towards the technology. Consumers see that most GM products in the market have input traits that help farmers to increase net returns, but these products provide no significant benefits or incentives for consumers. Thus consumers either want to pay less for the GM products or are willing to pay a higher premium for non-GM products (Carlsson, Frykblom, & Lagerkvist, 2007; Huffman, Rousu, Shogren, & Tegene, 2007; Mather et al., 2011).

Not all GM products are seen as negative. Huffman (2010) found that consumers are willing to pay an additional premium (19-26%) for a product with intragenic addition of vitamins over a plain-labeled product. Similar findings are observed in other products such as "Golden Rice," which has added vitamin A in the United States (Lusk, 2003); vitamin-A-fortified cassava in Brazil (Gonzalez, Garcia, & Johnson, 2009); and pest-resistant vegetables in India (Krishna & Qaim, 2008). These studies imply that consumers are willing to accept some specific GM products that are not available to them otherwise. However, biotech firms seem unable or unwilling to supply those products adequately. This might be one of the reasons that the technology is not well accepted among the public.

The inadequate supply of products implies that the market is not consistent with the socially preferred outcome, which is a clear characteristic of market failure. Another reason for market failure in biotech R&D is that a few firms have too much market power (high-concentration industry). In addition, a large number of small firms lack the market resources to capture sufficient benefits from R&D. Anti-trust regulations are in place to remedy some of the market power imbalances. However, the nature of the technology, the industrial structure, longer delays for approvals, and stricter regulatory protocols accentuate market failure conditions.

## Policy Implications of the Present Situation in Biotech

Policy-makers are in a difficult situation with respect to the biotechnology sector. Extensive and costly regulations erected to ensure that biotech products are safe for consumers and the environment lead to large firms that can afford the costs, delays, and risks of developing GE products. Furthermore, there is a market failure because the large firms currently dominating the industry are not actively developing consumer-desired characteristics into their products.

In the current industrial structure, large companies dictate the future through their own R&D and their collaborations and ultimate purchases of smaller firms that are developing new GE products. These purchases of small companies not only protects the large firms against competition by new products but also encourages small companies to develop new products that they will not take all the way through the approval process. Small, nimble biotech startups take the risks of product development through their lower operating costs, and the large companies get the technology when they purchase the smaller company. The large company then takes the product through the regulatory approval and marketing process. The danger is that this competitive structure leads to large, imperfectly competitive firms that might extract large profits from individuals who buy the seeds (and ultimately from those who purchase the resulting products).

Governments cannot easily change the regulatory system to help small biotech firms because the process is established for safety and security. The government could underwrite some of the R&D costs by firms and some do that through their funding of university research and their own research agencies. Yet these findings in the public domain are equally available to all entities, and large companies can afford to benefit from those discoveries. Governments could subsidize small firms directly (such as the Small Business Innovative Research program in the United States), but this will not likely happen on a large enough scale to allow small firms to hold on to new technology throughout the regulatory and market-development process. Yet governments need to make sure there is enough competition among the large firms so that users of biotech products are not exploited and that the products desired and needed by farmers and consumers are forthcoming.

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