18. The United States approach for fostering new biological technologies and ensuring their safety

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This section addresses the regulation of genetically engineered (GE) products and biotechnology as exemplary of a system for delivering innovative new products and assuring safety with public involvement. Biotechnology has been integral to the record productivity the US Department of Agriculture (USDA) has seen in major crops. In the United States, the regulation of GE and biotechnology products involves three agencies: APHIS, the FDA and the EPA. Each agency has different responsibilities, though their regulatory domains often overlap. As a result, there is a high level of collaboration and cooperation across agencies, with each decision based on scientific fact and experimental data. GE crops, in particular, have had significant impact upon sustainability within the United States. These crops have had measurable beneficial economic and environmental effects on GE and non-GE producers alike. Going forward, we need to facilitate the transfer of scientific knowledge and innovation between the public and private sectors, through Intellectual Property (IP) protection and public-private partnerships.

This section addresses the regulation of genetically engineered (GE) products and biotechnology as exemplary of a system for delivering innovative new products and assuring safety with public involvement. It also discusses the complexities of this regulation, as well as the mechanisms through which biotechnology contributes to sustainability within the United States. Finally, the section addresses the intellectual property issues within the context of technology transfer between public and private sectors.

Background

Agriculture is a priority for the US economy. Rural prosperity is essential for a healthy agricultural sector, and a healthy agricultural sector, in turn, is essential for rural prosperity. Given the fact that different forms of agriculture have different rural footprints, the USDA supports all forms, including not only biotechnology, but organic and non-GE production, as well. Keeping people on farms and maintaining the health of rural communities is very important to the department. Nevertheless, biotechnology and GE-based agriculture comprise a vital component of our agricultural system.

Increasing population, wealth and energy use have recently spurred a global surge in consumption of food commodities. In response, the USDA has focused its future research on several high priority thematic areas, including climate change, bio-energy, food safety and global food security, along with nutrition and childhood obesity. Several of our objectives directly relate to the use of biotechnology, which will be essential to addressing these issues.

Within the US context, biotechnology has been integral to the record productivity we have seen in some of our major crops, including maize, cotton and soybeans. Biotechnology has been rapidly adopted by farmers, its safety record has been exemplary, and it has helped raise awareness of the importance of environmental stewardship in agriculture.

Indeed, it will likely be impossible to achieve our goals for production of bio-fuels without the most advanced technologies, including biotechnology. These technologies will also be critical to addressing climate change and reducing greenhouse emissions.

Regulation of biotechnology in the United States

The US regulatory system on biotechnology was introduced in 1986, with the Coordinated Framework for Regulation of Biotechnology. This system was developed under a process that was led by the White House, and involved discussions among various government agencies, as well. Its development was underpinned by the work of the US National Academy of Sciences, which found that the types of risks associated with crops produced using GE are not different from those associated with other products. As a consequence, the National Academy of Sciences determined that US regulation should be based on the end use of products, and that it should be conducted on a case-by-case basis. This work also revealed that adequate regulation of biotechnology-based products could be facilitated through existing US laws.

Three agencies are involved in this regulation: The USDA's Animal and Plant Health Inspection Service (APHIS), the Environmental Protection Agency (EPA) and the Food and Drug Administration (FDA). APHIS is responsible for protecting agriculture against

pests and diseases, the EPA is charged with ensuring the safe use of pesticides, and the FDA is responsible for food and drug safety. In several areas, the regulatory domains of each agency overlap. Indeed, products are frequently regulated by more than one agency.

Extensive coordination and collaboration among regulatory officials and agencies are crucial to this process. Within the United States, regulations have been updated numerous times to keep pace with scientific advancement. All product decisions are based on scientific evidence. It is also worth noting that as time has gone on, we have adopted new market tools to deal with ancillary issues not covered under our regulatory framework. For example, parts of the USDA have developed the capacity to evaluate test methods used to detect the presence of GE products, and to verify that laboratories are proficient in using them.

The USDA conducts oversight of nearly all field trials concerning GE plants. All field trials must receive USDA approval, and must be designed in a manner that guarantees biological confinement. This ensures that tested organisms will not persist in the environment, and that there will be no impact on non-target organisms outside of the test. When an applicant has enough information to demonstrate that a given organism will not pose danger to agricultural and human environments, and that it will not pose any plant-pest risks, he or she can petition the agency for "deregulated status." The agency will then conduct an environmental analysis process based on the supplied data, though it may request additional information, if needed. The public also has the opportunity to provide input during this process. Depending upon the conclusions drawn from this initial analysis, more complex and elaborate analyses may be required, as outlined under federal law.

This process demands information on a broad range of topics. Applicants must supply all relevant experimental data, including any data that may be unfavourable, as mandated by law. These data must also include comparisons to conventional crops. If a petition is approved and a product is deregulated, that product can be grown and marketed without further GE-specific oversight from APHIS. Deregulation, however, does not guarantee that the product will not undergo concurrent EPA or FDA review.

The EPA is responsible for the regulation of pesticidal microorganisms and any plant-produced pesticidal substances. If a plant were to produce the insecticidal toxin BT, for example, the EPA would regulate that substance as a pesticide. The agency also sets tolerance levels for the safe use of various conventional pesticides. If any herbicide is used in coordination with an herbicide-tolerant plant, the EPA will regulate the use of the herbicide in conjunction with that plant.

Regardless of whether a pesticidal substance is applied to, or produced by a plant, there is a wide range of information that must first be examined. Each product needs to be characterised, and its effects on human health, ecological impacts and environmental consequences must be evaluated. For certain insecticidal substances produce by a plant (e.g. BT proteins), the EPA also requires plans for resistance management, in the event that insects develop resistance to that insecticide. In addition, the EPA's responsibility with respect to these substances covers not only environmental effects, but impacts on food and feed safety, as well.

The FDA is responsible for ensuring that foods produced through GE are as safe as conventional foods. The types of issues addressed for GE products are the same as those addressed for conventional foods, including toxicity and allergens, food composition, nutritional value, and intended use. The FDA also conducts consultations with product

developers. Formally, these consultations are considered voluntary, though it is very unlikely that a company would bring a product to market without first consulting the FDA. These consultations typically include significant dialogue between regulators and developers.

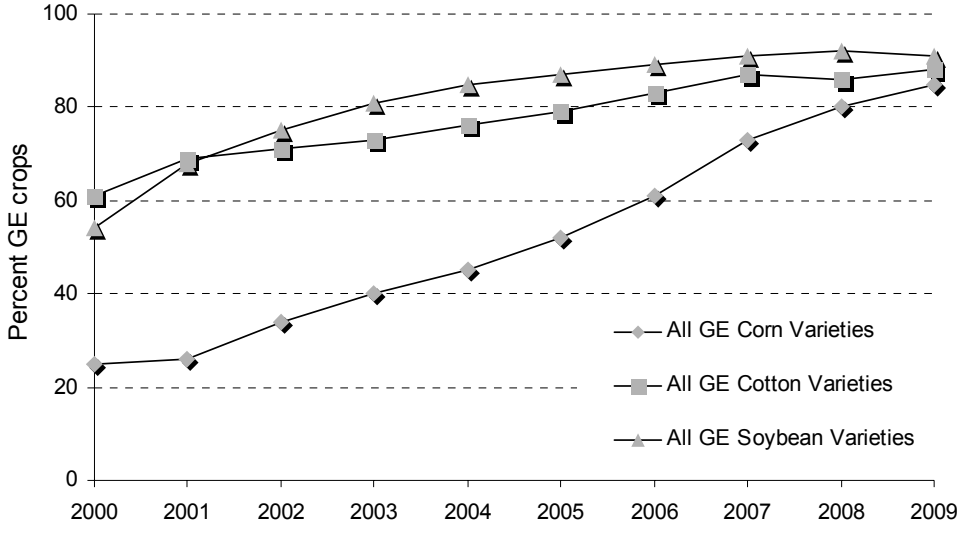
In short, all foods must meet same safety standard under the Food, Drug and Cosmetic Act, regardless of whether or not they are derived from GE organisms.

Impact of GE crops on farm sustainability in the United States

Last year, the National Academy of Sciences published an important report examining the ways in which biotechnology has contributed to sustainability in the United States. These effects encompass environmental and economic impacts, on both GE and non-GE producers, alike.

Adopters of biotechnology have benefited from improved weed control, reduced losses from insect pests, reduced expenditures on pesticides and fuel, increased worker safety, greater flexibility in farm management and lower risk of yield variability. As a result, these products have been rapidly adopted over the course of the last decade, as demonstrated in Figure 18.1

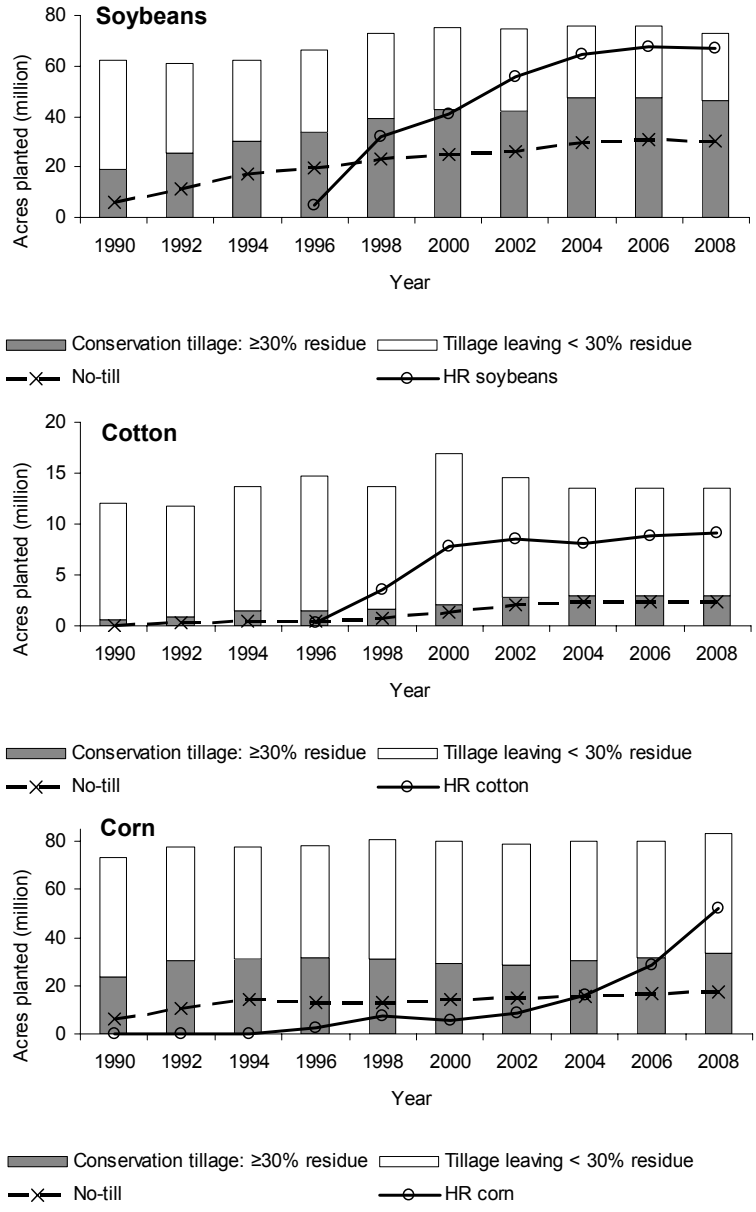
Figure 18.1. Nationwide acreage of GE soybean, corn and cotton crops as a percentage of total acreage of these crops



Source: USDA-NASS (2001, 2003, 2005, 2007, 2009b).

Herbicide-resistant crops have been associated with the complementary use of conservation tillage practices (Figure 18.2). These practices have improved soil retention and have also led to conjecture that surface water quality has improved. Data on water quality, however, remain incomplete.

Figure 18.2. Trends in conservation tillage practices



Source: CTIC, 2009; USDA-FRS, 2009.

Economic effects on non-GE producers are generally more complicated and poorly understood. It is clear, however, that purchasing decisions of GE producers have an effect on those of non-GE producers. To date, there is no quantitative estimate of the economic impact on livestock producers, though it should be noted that we have observed landscape-level effects on pests, with the growth of pest-resistant biotech crops reducing pest pressures on non-GE crops grown nearby. At one point before the commercialisation of GE papayas, for example, non-GE papayas in Hawaii could not be grown, due to viral loads in the region. Now, however, it is possible to grow both. In addition, segregated markets for non-GE products have arisen, in part, due to increased demand from a segment of the population that wishes to avoid GE products altogether.

Recently, the United States has deregulated three products that have received more public scrutiny: an herbicide-tolerant alfalfa, high amylase corn and an herbicide-tolerant sugar beet, which has received partial deregulation. APHIS is currently reviewing petitions for additional products, including some that will address climate change and may introduce nutritional improvements.

Some of these products approvals (including the herbicide-tolerant alfalfa and herbicide-tolerant sugar beet mentioned above) have come in face of legal challenges. The decisions made with regard to these products are based on a thorough scientific review as described above through the Coordinated Framework, but these legal challenges have indeed slowed down the approval process, while increasing costs for both government regulators and developers. None of these legal challenges, however, has questioned the findings of safety regarding these products; rather, they have focused on details of the process under which the decisions were reached. The upshot is that the approval process continues, and legal challenges will undoubtedly continue, as well.

The Secretary of Agriculture has identified a need for increased dialogue among stakeholders with a range of differing interests, in order to discuss approaches to future technological advances. In particular, the Secretary has revived the Advisory Committee on Biotechnology and 21st Century Agriculture, which is charged with providing practical recommendations for bolstering coexistence in US agriculture. The President of the United States, meanwhile, has recently issued executive orders calling for improved regulation across government, greater reliance upon scientific experience, and increased collaboration and coordination among agencies.

Facilitating innovation

United States law allows for a variety of forms of Intellectual Property (IP) protection for GE agricultural products, including patent and plant variety protections. There are a variety of mechanisms to facilitate the transformation of public sector technologies into products commercialised by private sector. Congress has passed laws to facilitate the process of transferring technology from the public to the private sector.

Public-private partnerships (PPPs) have also helped facilitate this process, and, going forward, will become increasingly important in the development of new technology. Because many important developments come from groundbreaking public sector research, strengthening the pathway for product development through the public sector will be critical. Additionally, the first patents on biotechnology-based products are about to expire within the next few years. The transition to a marketplace with generic products will likely raise new IP, economic and stewardship issues.

Note

1. Agricultural Research Service, US Department of Agriculture, United States.