Farm Foundation
Issue Report

Economics of Regulation of Agricultural Biotechnologies

Consumer preferences, industry structure and economic forces shape the regulatory process

A decade after the general introduction of new agricultural biotechnology inputs, the technology remains engulfed in controversy that impacts the economics of regulation.

Some consumers are reluctant to accept products of the new technologies, which primarily benefit agricultural producers by offering the potential to reduce production costs. In some developed countries, genetically-modified (GM) commodities or products made with GM commodities have been banned from the market, or are selling at discounts relative to non-GM counter parts. Consumer resistance may lessen or disappear as agricultural biotechnology products with direct consumer benefits are created. Until then, consumer resistance complicates both regulatory and economic issues.

There are four broad issues regarding regulation of agricultural biotechnologies:

- How to improve the regulatory framework,
- Consumer attitudes toward agricultural biotechnology,
- Impacts of biotechnology regulation on markets, and
- Access to agricultural biotechnology in developing countries.

Regulatory framework

In the United States, the 1986 Coordinated Framework for Regulation of Biotechnology, and other legislation through which Congress regulates biotechnologies, disperse regulatory responsibility to multiple federal agencies:

- USDA's Animal and Plant Health Inspection Service (APHIS)
  - o Has jurisdiction over introduction of genetically engineered plants and veterinary biologics.
  - o Under the Plant Protection Act (PPA), grants permits for developing or importing GM organisms at the experimental stage.
  - o Regulates pesticide-tolerant crops only during experimentation.
- U.S. Environmental Protection Agency (EPA)
  - o Has jurisdiction over pesticides

engineered into plants, microbial pesticides and novel microorganisms.

- o Regulates distribution, sale, use and testing of pesticidal substances, including plant-incorporated protectants such as Bt, just as chemical pesticides have been regulated under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), or under the Toxic Substances Control Act (TSCA) if FIFRA does not apply.
- o Regulates pesticide products sold commercially.

• Department of Health and Human Services' Food and Drug Administration (FDA)

- o Has jurisdiction over food and feed uses of biotechnology.
- o Regulates foods and feed derived from new plant varieties.
- o Under the Federal Food, Drug and Cosmetic Act (FFDCA), enforces pesticide tolerances—as determined by EPA—on foods. If bio-engineered substances do not differ from substances currently found in food, FDA approval is not required, nor is it required that the product be labeled for bioengineered ingredients.

The result is that regulation of agricultural biotechnologies may differ greatly depending on the statute under which they are regulated. For example, GM crops that include a pesticidal substance will face a more demanding standard than those that do not because they are subject to the EPA market regulations of pesticides, rather than only the plant introduction regulations of APHIS. New economic analysis is needed that includes models of adoption behavior, profit effects, risk premiums and changes in conventional pesticide use associated with potential EPA decisions. At issue are the real and hypothetical risks to the environment and human health.

The underlying framework for biotechnology regulation lacks important features, including balanced pre-market versus post-market regulation, risk assessments that consider both positives and negatives, and economic considerations of benefits versus costs. The action of private firms and regulatory standards that are too stringent may be causing current regulations of agricultural biotechnology to be stricter than optimal.

The United States has a permissive approach to technology risk, while the European Union (EU) has a more precautionary approach. These differing perspectives create the potential for varied interpretations in regulatory testing. The impacts of these variations are likely to increase as GM technology is used to produce pharmaceutical or industrial chemicals in plants and animals.

In earlier years, most new agricultural technologies were developed in the public sector. Today, the private sector is a major research innovator. Critics contend regulators are too close to the industry they regulate, and industry is exercising excessive political clout on legislative activities. In response to the backlash against traditional views of government regulation, political action groups have formed around private interests. The relative strength, and ultimately the political power, of these groups are determined by their respective resources, the homogeneity of their members' interests, and their ability to control their members' behavior.

Consumer attitudes

Farmers and consumers are heterogeneous relative to agricultural biotechnology products. Understanding this heterogeneity is important to understanding farmers' adoption of the technologies, farmer compliance with refuge requirements and consumer acceptance and resistance to GM products. The agricultural biotechnology industry has developed and marketed input traits. Farmers have accepted these traits because they reduce expected costs of production and greatly reduce risks of chemical exposure to farm workers.

Pest resistance to GM-products and refuge management are important issues to farmers. Twenty percent of a producer's acreage in a Bt or pesticide-tolerant crop must be set aside to non-biotech crops. These refuges provide a breeding ground for Bt- and pesticide-vulnerable pests, slowing development of pest resistance to GM technology. Acreage of non GM-adopters also serves as a refuge. Empirical evidence suggests farmers' non-compliance is an issue. To date, resistance has been a minor problem, but that could change as farmers increase adoption of GM technologies.

Labeling for GM content in food products is controversial. In a recent

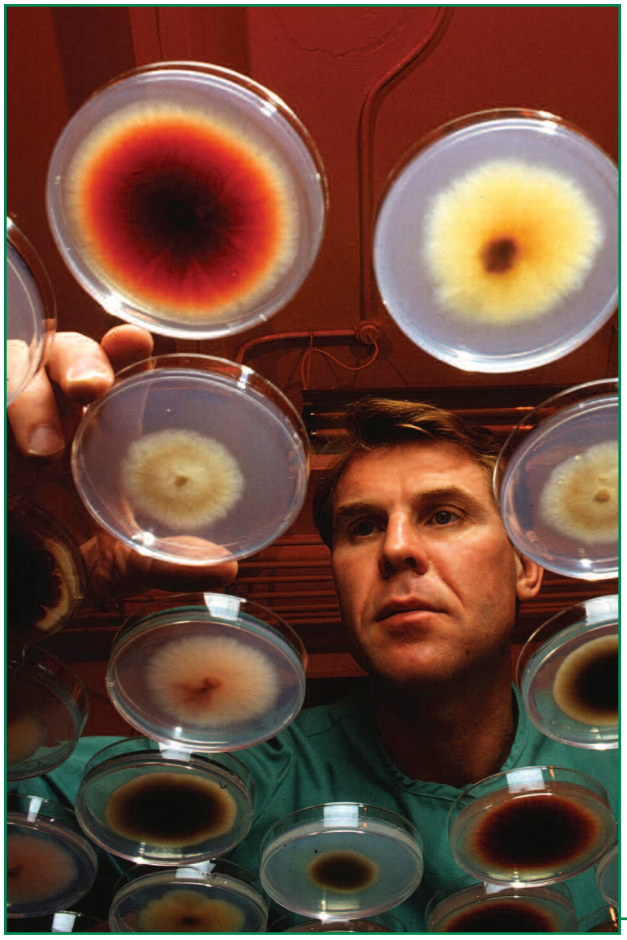
study, 87% of U.S. consumers and 99% of Norwegian consumers said GM labeling was extremely or somewhat important. This result is interpreted as preferences when labeling is costless. When told that GM labeling might increase food costs by 5%, the percentage of consumers in the U.S. and Norway indicating that labeling was extremely or somewhat important dropped by 44 percentage points. This indicates that consumer preferences for GM-labeling in Western developed countries is price responsive.

In the United States, labeling could be required under the Nutrition Labeling and Education Act of 1990, or under FDA food safety legislation. The Nutrition Labeling Act is explicit about the scientific evidence required to support the linkage of food intake to health outcomes. Current GM-food products do not meet this standard, except for golden rice. The United States has adopted the position that only GM products that are substantially different from their non-GM counterparts must be labeled. Currently, no GM products fall under this mandatory labeling requirement.

Voluntary labeling is possible, but has economic impacts. Producers of "superior" and likely higher-priced products benefit by identifying its type. Since some consumers may discount products that they know contain GM content, the "superior" product is non-GM. If labeling is voluntary, non-GM producers would have to bear the cost of labeling to attain the higher price, which they consider unfair. Labeling policies can also be used as non-tariff trade barriers, and the United States has raised this issue with the EU.

Market Impacts

The current regulatory framework for biotechnologies in the United States prevents efficient functioning of markets and denies or delays post-patent farmer and consumer benefits. The agricultural biotech industry is concentrated in three large U.S. and three foreign firms. The social contract is that an inventor reveals to others what he or she has invented and, in return, receives a monopoly on use of the invention for 20 years. With public-sector innovations, intellectual property rights have historically served primarily to allocate priority claims to discoveries, but need not be for income generation.



This all changed with the Bayh-Dole Act of 1980. It gave the income-generating right to a discovery or invention from federally-funded research to the non-federal partner. This Act strengthened the incentive of universities to patent and to license new inventions which has made university research more applied. Patents have a long history of protecting inventions and providing income streams to inventors in the private sector and their employers. Costly testing to meet federal regulatory requirements and infringement suits reduces the expected profits going to the original inventors and developers. When an invention goes off patent, other parties are free to enter the market with generic products.

Pesticide regulation demonstrates how Bt biotechnology regulation might be approached, as both are regulated under the same statutes. For chemical pesticides, post-patent competition can lead to 20% to 50% price reduction, even with only a 10% to 20% generic market penetration, and transfer profits from monopolistic developers under patent protection, to farmers and consumers when they gain access to generic products.

This annual transfer can amount to several times the competitive profits that exist in the industry after generic products are introduced. Thus, firms producing generic products that provide this competition can expect to receive only a fraction of the profits of early innovator companies, but they must engage in costly testing to satisfy federal regulatory requirements.

Under loopholes in FIFRA regarding the sharing of regulatory testing costs between market developers and generic entrants, the original entrant can manipulate the sharing process in a way that discourages and/or prevents entry by firms producing generic products. When this occurs, farmers and consumers never receive the major share of benefits from innovation to which they would otherwise be entitled under patent policy.

Furthermore, these regulatory costs create an entry barrier for small firms and an advantage for larger firms. That advantage has increased as antitrust policies have allowed mergers and acquisitions. Economies of scale in obtaining regulator compliance are a contributing factor to the emergence of a few dominant firms in the U.S. agricultural biotech industry. It would be expected that these firms would be astute in making political contributions to promote or protect their private interests.

Access for developing countries

Agricultural biotechnology has a potentially important dimension in developing countries. Some countries of Sub-Saharan Africa and parts of Asia totally missed the Green Revolution, and continue to face issues of poverty and food scarcity. Development of agricultural biotechnology is at a primitive stage in these countries, and policy makers are ill prepared to deal with the regulatory issues of such technologies.

Great potential exists for biotechnologies to help address hunger problems in Africa, but no development has taken place because of insignificant economic incentives for biotechnology developers. The six largest multinational agricultural biotechnology firms make money by selling GM traits through contracts that prevent second-generation use of seed stock. Companies will not risk profits to enter markets that lack a reliable system of contract enforcement.

The EU's conservative policies on agricultural biotechnology cost its society little as the input traits in current GM products are not well suited to EU crops. But the EU position has discouraged biotechnology development world-wide. Estimates are that the world has realized only about $1 billion of the $8 billion potential annual benefits from GM crops. China and India are two developing countries realizing large social benefits from GM products, especially Bt cotton.

Alternatives to regulation

One alternative to regulation is a commercial commodity grading system that includes a labeling policy supported by legally enforceable contracts. Even with product labeling, however, buyers and sellers face risks regarding tolerance levels and GM and non-GM segregation.

For a buyer, the risk is receiving product that should be rejected for exceeding minimum impurity levels to qualify as non-GM. The risk to the seller is having product rejected even though it is within tolerance standards. These risks are complicated by the potential for accidental commingling of product—an event that can occur at any location within the production and marketing system.

Other issues include whether non-GM and GM are meaningful grades, and whether the high cost of segregating product outweighs the benefits of the technology that necessitates it. Another issue is whether government regulatory programs, even in the United States, are too stringent, in light of the fact that not even one human health liability claim has been awarded against GM products.

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The Source

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