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Regulatory Barriers to the Development of Innovative Agricultural Biotechnology by Small Businesses and Universities

Since the early 1980s, American taxpayers have invested heavily in public, university, and small business developers of crops and foods improved using biotechnology.

- The return on this investment is disappointingly thin.
- In theory, scientifically sound regulations serve the public good by assuring a reasonable degree of product safety while not unduly stifling innovation.
- This report analyzes the current U.S. regulatory system for genetically engineered (GE) crops, compares it with those of major trading partners, and considers various aspects of agricultural biotechnology regulation.

Much of the enabling technology for agricultural biotechnology was developed in academic or other public institutions.

- Many of the earliest field trials with GE plants were conducted by the public sector and academics at various universities, and some of the earliest commercialized crops receiving regulatory approval were from academia.
- Despite foundational contributions requiring considerable public resource commitments for GE crop innovation and development, the academic institutions and small private entities have been almost entirely excluded from the agricultural biotechnology market.

There is ample evidence that GE in plant breeding is of benefit to farmers, to consumers, and to the environment.

- When the USDA surveyed farmers, asking why they choose GE varieties, farmers said that GE crop benefits include higher yields, reduction in pesticide use, and more flexibility in managing weeds and other pests.
- The net reduction in pesticide use and safer foods—as well as major environmental benefits, the preservation of topsoil, and reduction in greenhouse gas emissions—are outcomes consumers support.

The export market, and its labyrinthine maze of regulations, remains an immense barrier to commercialization of GE crops and foods, especially to smaller companies and academics not familiar with the export structure and documentation requirements.

- European Union regulations are characterized by an ambiguous definition of genetically modified organism, an expeditiously flexible interpretation of the “Precautionary Principle,” and an unnecessarily comprehensive case-by-case approach to environmental risk assessment.
- Although Canada’s “plant with novel traits” policy is often hailed as the “scientifically sound” example for others, the policy is not without problems or controversy.
- China has a unique regulatory system combining both scientifically sound and politically motivated, scientifically unsound elements.

If regulatory compliance is difficult for large companies, small businesses and public institutions have almost no chance to commercialize safe, effective, and innovative GE crops and foods.

- The unnecessarily complicated, onerous, and unscientific regulatory system presents a near insurmountable barrier.
- Our current system denies potential benefits to farmers, consumers, and the environment, with no corresponding increase in safety, and unduly restricts innovation by public and private sector developers.
- Until regulations align with the stated public policy goal of reasonably assuring safety and regulating commensurate with the degree of risk posed, public, academic, and small business entities will continue to be frustrated in using these safe tools to deliver useful products to farmers and consumers.

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