

# **Compliance Costs of Regulation in the Development & Adoption of Biotech Crops**

*Submitted by Julian Alston and Kent Bradford, University of California, Davis, and Nicholas Kalaitzandonakes, University of Missouri*

Alston: Julian@primal.ucdavis.edu  
Bradford: KJBradford@ucdavis.edu  
Kalaitzandonakes: KalaitzandonakesN@missouri.edu

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## **Executive Summary**

The regulatory approval process for new biotech crop varieties is said to be slow and expensive, presenting important barriers to the development and commercialization of new cropping technologies. For some crops these barriers may be prohibitive, resulting in technological orphans. Alternative approaches to regulating new crop biotechnologies could be less expensive, but to date the private and social costs of the current regulatory system have not been analyzed or measured, let alone compared with alternatives. In fact prior to this research, estimates of the compliance costs for the full deregulation of a biotech crop had not been available as such information had been closely guarded by biotechnology developers.

This project has contributed to the knowledge concerning the private costs of complying with the current regulatory approval system for agrifood biotechnologies by: (a) surveying the regulatory requirements in the United States and elsewhere and explaining how they translate into relevant costs of compliance; (b) describing the structure of such compliance costs and characterizing their key dimensions; (c) providing estimates of representative compliance costs for specific crop biotechnologies which were based on reviews and analyses of dossiers submitted to regulatory agencies by major biotech firms.

## **Project Findings**

The techniques of biotechnology have been available for almost 30 years and have been used to enhance crop performance and quality for more than 20 years. Since 1996, over 1 billion cumulative acres of bioengineered soybeans, maize, cotton, and canola have been grown around the world. In spite of this apparent success, many observers have been disappointed at the rate of development and commercialization of new biotech crops. Indeed, the accumulating evidence suggests that agrobiotechnology innovation and product development have recently slowed down, and high compliance costs for regulatory approval have been cited as a key reason.

While it is increasingly apparent that agrobiotechnology innovation has recently slowed down, the specific reasons for the trends are not clear. Possible causal factors include market resistance and trade barriers as well as high and rising regulatory costs, but the relative importance of these

factors is not known. In particular, there is little empirical evidence to either support or refute the hypothesis that high (and possibly increasing) regulatory compliance costs are to blame. The purpose of this project was to develop a detailed understanding of the process of regulatory compliance in the United States and quantify the associated costs of compliance.

Compliance costs for this project were derived from accounting data supplied by four major agricultural biotechnology companies specific for traits that have gone from field trial to final commercialization. Quantifying costs across both firms and traits required some standardization/categorization of costs. To identify these general categories of compliance costs lead scientists and regulatory affairs practitioners were interviewed on the basics of regulatory submissions. Representative dossiers for various novel corn and soybean traits, submitted over the past fifteen years, were also obtained and analyzed.

Based on the information derived from interviews and dossier analysis, compliance costs, both variable and quasi-fixed, were organized into 14 categories. In order to provide representative figures for each of these categories, compliance costs were standardized along certain key dimensions (trait, crop, and countries petitioned). Along these lines, compliance costs incurred by leading biotech developers seeking deregulation of herbicide-tolerant and insect-resistant corn in ten key countries which include the top producers (e.g., the United States, Canada, Argentina, and the EU) and the top importing countries (e.g., Japan and South Korea) were reported (see tables below).

<b>Compliance Costs for Insect Resistant Corn -- in \$1000s</b>	
<b>Cost Categories</b>	<b>Range of Costs Incurred</b>
Preparation for Hand-off of Events into Regulatory	20 – 50
Molecular Characterization	300 - 1,200
Compositional Assessment	750 - 1,500
Animal Performance and Safety Studies	300- 845
Protein Production and Characterization	162 - 1,725
Protein Safety Assessment	195 – 853
Non-Target Organism Studies	100 – 600
Agronomic and Phenotypic Assessments	130 – 460
Production of Tissues	680 - 2,200
ELISA Development, Validation and Expression Analysis	415 – 610
EPA Expenses for PIPs (EUP, tolerances, etc.)	150 – 715
Environmental Fate Studies	32 – 800
EU Import (detection methods, fees)	230-405
Canada Costs	40-195
Stewardship	250-1,000
Toxicology (90 day rat) – when done	250-300
Facility & Management Overhead Costs	600-4,500
<b>Total</b>	<b>7,060-15,440</b>

**Compliance Costs for Herbicide Tolerant Corn -- in \$1000s**

<b>Cost Categories</b>	<b>Range of Costs Incurred</b>
Preparation for Hand-off of Events into Regulatory	20-50
Molecular Characterization	300-1,200
Compositional Assessment	750-1,500
Animal Performance and Safety Studies	300-845
Protein Production and Characterization	620-1,725
Protein Safety Assessment	195-855
Agronomic and Phenotypic Assessments	130-460
Production of Tissues	680-2,200
ELISA Development, Validation and Expression Analysis	415-610
Herbicide Residue Study	105-550
EU Import (detection methods, fees)	230-405
Canada Costs	40-195
Stewardship	165-1,000
Toxicology (90 day rat) –when done	250-300
Facility & Management Overhead Costs	560-4,500
<b>Total</b>	<b>6,180-15,510</b>

A number of conclusions were drawn from the compliance costs reported in the study. First, there is a wide variance in the compliance costs incurred by biotech developers. Some firm-level differences in the individual cost categories and total compliance costs are the result of differential accounting and budgeting practices among firms. However, these differences are also attributable to the variable strategies followed by biotech developers as they pursue deregulation of their innovations. These strategies are shaped by the developers' expectations of the appropriate number and types of field trials and analytical tests and assessment studies that are likely to satisfy the various national regulators. Similarly compliance costs can vary drastically depending on the number of events advanced by the developers through various regulatory stages in order to minimize uncertainty.

Second, among all variable compliance cost categories, four dominate: (1) production of tissues, (2) compositional assessment, (3) protein production and characterization, and (4) molecular characterization. Indeed, these four cost categories represent almost 60% of all variable costs.

Third, overhead costs for facilities and management are also very significant as they represent between 10 and 20% of the total compliance costs for various firms. Clearly, such costs are most challenging to measure as facilities and regulatory management are shared across multiple traits and events for various crops, all being advanced in parallel at their individual development speeds. Overhead costs also include regulatory outreach and other relevant activities. Our preliminary assessment indicates that large biotech firms that experiment with numerous crops and traits do not have discernible fixed cost advantages and hence we could not detect any economies of scale and scope. This may be the result of the regulatory slow-down that has occurred in recent years, suggesting that, at least temporarily, a larger than necessary management and facility capacity is being maintained by larger biotech firms. It may also be the result of the more significant regulatory outreach efforts sustained by larger biotech firms. Finally, it might be simply the outcome of the limited variance in the firm size studied here or other data limitations.

Fourth, the gap in the compliance costs between insect-resistant and herbicide-tolerant corn is lower than expected. Indeed, it appears that over time firm strategies on how to develop regulatory dossiers for those two traits have converged and so have the relevant compliance costs incurred.

Finally, the compliance costs incurred by biotech developers and reported here appear to be quite high, considering that they represent only part of the regulatory burden of novel biotech crops. Specifically, only direct compliance costs are reported here, counted as such by most biotech developers only after a formal assessment process with strict standards known as “good laboratory practices” has commenced. Informal pre-regulatory safety assessments of various discovered proteins and events are regularly carried out but are normally budgeted as R&D costs. Similarly, indirect private compliance costs from unnecessary and unexpected regulatory delays are not presented here. These costs include increased expenditures (e.g., for seed inventories that are carried over), foregone profits from delays in commercialization, costs for channeling and segregating biotech crops away from certain markets in cases of partial approvals, and others. Such indirect regulatory costs are likely significant but more difficult to estimate than direct ones.

### **Equipment Purchases**

None

### **Journal Articles:**

Kalaitzandonakes, N., J. Alston, and K. Bradford. “Compliance Costs for Regulatory Approval of New Biotech Crops,” *Nature Biotechnology*, 25(5), 509-11, 2007.

### **Book chapters:**

Bradford, K.J., J.M. Alston, and N. Kalaitzandonakes. Regulation of Biotechnology for Specialty Crops. In Regulating Agricultural Biotechnology: Economics and Policy. R. Just, et al., eds. Springer, p. 683-97, 2006.

Kalaitzandonakes, N., J.M. Alston, and K. J. Bradford. Compliance Costs for Regulatory Approval of New Biotech Crops. In Regulating Agricultural Biotechnology: Economics and Policy. R. Just, et al., eds. Springer, p. 37-57, 2006.

## **Presentations:**

Kalaitzandonakes, N. “Economics and Policy of Agrifood Biotechnology.” Invited presentation at the 2<sup>nd</sup> Symposium for Agricultural Biotechnology Risk Analysis (AGRA) Research, Food and Drug Administration and Environmental Protection Agency, College Park, Maryland, December 5-6, 2007.

Kalaitzandonakes, N. “Measuring the Costs of Biosafety Regulation and the Potential Impacts on Biotechnology Research and Development.” Invited presentation at the 9th Biannual International Symposium on the Biosafety of Genetically Modified Organisms, Jeju Korea, September 24-29, 2006.

Kalaitzandonakes, N. “Biotechnology Approval and Compliance Costs” in the Biotechnology Pre-Conference Workshop at the *26th Conference of the International Association of Agricultural Economists*, Queensland, Australia, August 11, 2006.

Kalaitzandonakes, N. “Empirical Measures of Compliance Costs in Biotech Regulation” at the *Symposium for Agricultural Biotechnology Risk Analysis Research organized by EPA/FDA/USDAAPHIS*, Washington, D.C., December 2005.

Kalaitzandonakes, N. “The Costs of Biotech Regulation” at the *World Conference on Biotechnology: Implications and Realities, hosted by the Congress of Racial Equality, the United Nations*, New York, NY, January 2005.

Kalaitzandonakes, N., “Cost of Regulatory Approval for a New Biotech Product –NC 1003 and Farm Foundation Conference on the Economics of Regulation of Agricultural Biotechnologies, Washington DC, March 10-12, 2005