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**“Cost of Regulatory Approval for a New Biotech Product”**

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**ABSTRACT**

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. Informal estimates suggest that full deregulation of a biotech variety may cost \$5 to 15 million over and above development costs for a traditionally bred variety, but formal estimates of the costs of compliance with the regulatory system are lacking.

In this paper we make four contributions to knowledge concerning the private costs of complying with the regulatory approval system for agrifood biotechnologies. First, we describe and document the regulatory requirements and how they have evolved over time, including the details of the statutes, the regulatory agencies involved, and their typical practice in implementing and enforcing the laws. Second, we examine how such requirements translate into relevant costs of compliance, including both the direct expense and the opportunity cost in terms of time delays. Our estimates of compliance costs are based on reviews and analysis of dossiers submitted to regulatory agencies by universities and several major biotech companies (including Monsanto, Syngenta, and Dow, who agreed to cooperate and provide confidential information for this project), and interviews with regulatory affairs

practitioners and regulators.. Third, based on this work, we provide estimates of representative compliance costs for key biotechnologies, and we characterize the structure of compliance costs (e.g. key categories of costs, major differences in costs across separate types of dossier submissions, and potential sources of economies of scale and scope). Fourth, and finally, we examine the proposition that regulatory compliance costs have increased over time and will identify factors that might have caused such increases, if any.