POLICY BRIEF
VOLUME I, NO. 1

The Costs of Regulatory Delays for Genetically Modified Crops[1]

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I. INTRODUCTION

Regulatory approval times are increasing in many countries. The impact of unjustified regulatory delays due to inefficiencies, lack of coordination or unnecessary and redundant requirements can be devastating. Regulatory delays may especially affect the public sector and international R&D investments intended to address developing country productivity constraints. As the authors (Smyth et al., 2016, 173) indicate **“Future public-sector investment in agricultural research and development is at risk, given the increase in regulatory approval times for GM crops“**.

National and international public research systems focus on the development of public goods for developing countries. The public sector typically conducts R&D in crops and traits which may have significant social impacts but in markets that are insufficient to attract private sector investment. Impacts on public sector R&D investments will have significant impacts on food security and will likely result in investment re-allocation to other alternatives which may not be as effective in reducing productivity constraints (Smyth et al., 190).

Biosafety regulatory delays, often intended to hyper-regulate private sector products, may lead to the unintended consequence of pricing out public-sector institutions.The private sector typically has larger budgets and may be prepared to face higher regulatory costs and regulatory delays compared to the public. Even so, it also faces investments limits (Smyth et al., 189).

For continued investment in research and development in a given jurisdiction, technology developers from private and public sectors need a well-defined, timely and efficient commercialization pathway for innovative products. Regulations of (GM) crops with are not consistent with a science-based approach tend to complicate the regulatory review process, resulting in unanticipated, costly and increased regulatory time lags. The inclusion of socio-economic considerations in the regulatory review of GM products, which are often ill defined, further complicates the decision-making process. These factors collectively serve to paralyze the decision-making process while leaving regulatory decisions on many new varieties on hold. The increased regulatory approval time creates greater uncertainty for those who invest in agricultural research and development to the point, as the authors indicate that **“If the regulatory approval uncertainty increases enough, further investments in agricultural innovation are jeopardized” (Smyth et al., 173).**

[1] *Summary of Smyth, J., J.B. Falck Zepeda and K. Ludlow. 2016. The Costs of Regulatory Delays for Genetically Modified Crops. The Estey Journal of International Law and Trade Policy, Volume 17, Number 2 2016/pp .173-195 http://ageconsearch.umn.edu/record/253074/files/smyth-falck-zepeda-ludlow17-2lay.pdf*

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2. SUMMARY OF GM CROP BENEFITS

The earlier literature on GM crop benefits focused on economic benefits, in part, due to the type of crops and traits available. After 2000, the research focus began to shift to developing country needs and constraints. The debate on the impact of GM crops thus evolved into a consideration of developing country needs and constraints, and how the technology could be used to address them, such as food security, poverty alleviation, agriculture intensification and malnutrition. This paper briefly describes the case study, using insect resistant (Bt) cotton as an example. Although Bt cotton is not considered a food security crop, by the generally accepted definition, given its broad adoption by smallholders in developing countries and its status as an important cash crop, it can indirectly address many of the food security, poverty reduction and nutrition concerns.

In **India** during the 2001 field trials, farmers who planted Bt cotton increased their yields by an average of 58 percent and their expenses for pesticides dropped by 50 percent (Qaim, 2003). After four years of production, Bt cotton yields were higher by 37 percent, pesticide use dropped by 41 percent, Bt cotton households increased their incomes by 82 percent and households earning less than $2/day USD increased their income by 134 percent (Subramanian and Qaim, 2010). While critics suggested that increases in farmer suicides were due to Bt cotton, Gruère and Sengupta (2011) concluded that these events were not correlated. Further research by Qaim (2014) showed that the application of cotton pesticides decreased, resulting in cost savings for farmers, higher yields (24%) and higher profits (50%) with an estimated 27 million acres (10,926,512.34 hectares) planted to Bt cotton, generating a net income gain for farmers of $1 billion USD in 2012.

China is another country which has strongly adopted Bt cotton. A 1999 survey of cotton farmers in northern China (Pray et al., 2001) showed that while non-Bt farmers saved money on seed costs, they spent considerably more on pesticides and labor while Bt cotton farmers commonly reduced pesticide sprays from 12 applications per season to 3 or 4. In 2000 and 2001, it was determined that even with lower cotton prices, Bt cotton adopters increased their net income by $500/ha USD (Pray et al., 2002). After a decade of commercial production, bollworm insect infestation dropped not only in Bt cotton fields but in all cotton fields in parts of China; and insecticide applications dropped from 14kg/ha to 4kg/ha (Huang et al., 2010). These results have been supported by long term assessments such as Qiao (2015) and Pray et al. (2011).

Benefits of GM crops also are documented in **Africa**. In the Makhathini flats of **South Africa**, Bt cotton yields increased by 89 to 129 % as compared to conventional cotton in three growing seasons and added the equivalent of two to four months of wages (Bennet, Morse and Ismael, 2006) to farmers' pocketbooks. In **Sub Saharan Africa**, women spent 10 to 12 days less on weeding in families who planted GM herbicide tolerant corn, thus giving them time for other activities (Gouse 2013). In **Burkina Faso**, Bt cotton yields were 22 percent higher and the average economic return was more than double that of conventional cotton in the first three production years with 30,000 fewer cases of pesticide poisoning (Vitale, Vognan and Ouattarra, 2014).

Meta-analyses also have been conducted on the effects of GM crops. Carpenter (2010), examined yield comparisons between adopters and non-adopters from 168 studies and found that 124 reported yield increases, 32 reported no difference and 13 reported lower crop yields. Areal, Riesgo and Rodriguez-Cerezo (2013) compared 97 observations that compare production between GM and conventional crops, finding that GM crops out-performed conventional crops in both developed and developing countries. Klümper and Qaim (2014) reported the findings of their meta-analysis of 147 studies and found that with GM crops chemical use declined by 37 percent, yields increased by 22 percent and farmer profits increased by 68 percent.

3. METHODOLOGY

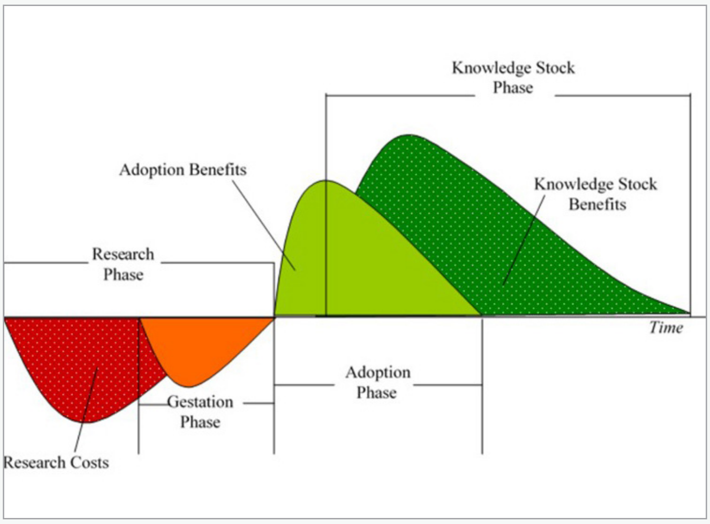
The authors (in page 181) used the four phases in the process of creating new crop varieties in their analysis, as seen in **Figure 1**.

- **Research phase** – "resources are spent to develop a crop variety that has commercially desirable characteristics"
- **Gestation lag of research** – "the number of years between making the investment and generating new technology or useful knowledge"
- **Adoption phase** – "the new variety is adopted and then later replaced by other varieties"
- **Depreciation phase or knowledge stock phase** – "innovations in the form of new varieties contribute to the stock of knowledge or germplasm, which continue to play a role long after the particular innovation has been supplanted by newer innovations"

In essence, the study conducted an analysis to determine what would be impact of increases in the size of the orange curve below the horizon (research costs) and an expansion in the number of years needed to complete the orange phase in **Figure 1**, by examining impacts on the green curve above the horizontal line. The sum of changes in the orange and green curve, provides an estimate of the net impact of research costs and adoption benefit changes.

Rather than expecting a reduction on regulatory decisions, regulatory lags have been increasing over time in different countries. A study by Jaffe (2005) shows that in the United States, regulatory approval time doubled from 5.9 months during the period 1994-1995 to 13.6 during 2000-2004. A study by EuropaBio (2011) documented that the approval time has almost doubled again in the United States by 2011 to 25 months. A study by Phillips McDougal (2011) estimated that the total time for varietal registration and regulatory affairs was 44.5 months for those varieties developed

Figure 1. Four phases of crop development and the path for R&D costs and benefits



Source: Adapted from Alston et al., 1995

BOX 1. DEFINITION OF TERMS

- **Discount rate** - an interest rate used to convert a future income stream to its present value *(https://stats.oecd.org)*
- **Meta-analysis** - the process or technique of synthesizing research results by using various statistical methods to retrieve, select, and combine results from previous separate but related studies *(http://www.thefreedictionary.com)*
- **Net present value (NPV)** - a measure used to help decide whether or not to proceed with an investment *(http://www.economist.com)*
- **Rate of Return (ROR)** - a way to measure economic success; it is calculated by expressing the economic gain (usually PROFIT) as a percentage of the CAPITAL used to produce it *(http://www.economist.com)*

before 2002, but this increased to 65 months by 2011. The Phillips McDougall study (2011) estimated that the total cost of obtaining variety approval for what is considered industry standard practice (cultivation approval in 1 to 2 countries, import approval in 5 to 7 countries and the involvement of 15 agencies) was $136 million USD. Smyth et al. (2016, p. 183) proposes that the concern while examining these data and trends in the seed development industry is **"that the commercialization of new traits will only be done by large multinational seed developers"**.

To estimate net present value (NPV) of an initial investment, the authors' study used scenarios with different required rates of return and other relevant assumptions. The study used the Phillips McDougall's (2011) report which documents a $136 million USD investment required from discovery to registration and deployment to farmers. The assumed rates of return (ROR) chosen were 20 percent, 50 percent, 75 percent and 100 percent, net cash flows were expressed as present values. A fixed real discount rate of 10 percent was used to estimate the net present value (NPV), and a set of even cash flow incomes for a period of ten years as the lifetime of the project, in order to meet the required return. While the even cash flows assumption during the life of the project is somewhat naïve – in most technology evaluations, cash flows vary throughout the life of the project- it allowed the study to focus on the net effect of time delays on investment outcomes while allowing the authors to conduct sensitivity analysis of the discount rates.

The regulatory delay scenarios were generated through computer simulations to calculate the investment risk by examining impacts of time on different required rates of return to an initial investment. The base assumptions used in the model have been described previously.

4. RESULTS AND POLICY RECOMMENDATIONS

Figure 2 shows the NPVs for the required rate of return (RORs) for a GM biotechnology investment which are also interpreted in **Table 1**. This implies that if a company requires a higher ROR for these investments, it is more likely to select those products with a higher market potential that will ensure the return on its investment. This is the rationale for focusing on core crops with better market potential such as corn, soybeans, cotton and canola. **Figure 3** shows that delays increase marginal losses which implies that technology developers would need to generate higher levels of returns and reduce time delays to ensure a company's financial well-being.

The authors conclude in their study that longer regulatory delays are associated with lower expected net present values and with higher investment risk. A policy implication is that reducing regulatory delays reduces investment risk and thus may make investments more attractive to investors. This result may be of interest to public sector institutions which may have projects with relatively lower economic returns but with significantly high social returns as is the case with many public goods.

The results of the analysis provide evidence of the causal relationship between increasing time delays, decreasing net present values of a technology and increases in financial/outcome risk. The data underscores the need for regulators, decision makers and developers to reduce time delays and to increase the efficiency of coordinating decision points along the product development cycle – for R&D, regulatory review, and compliance to optimize costs and time in delivering a product.

Figure 2. NPV investment change in GM biotechnology with regulatory delays

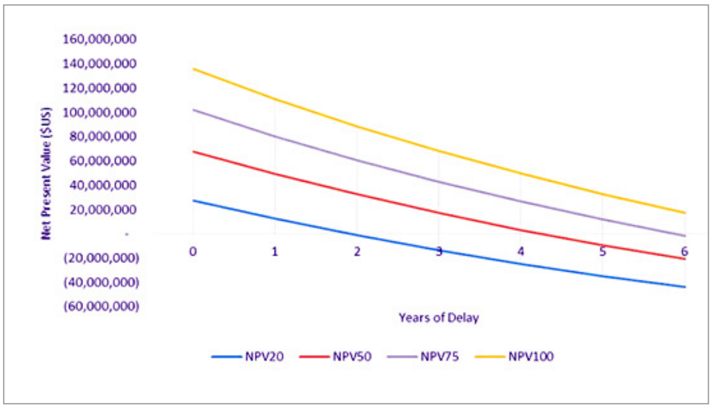
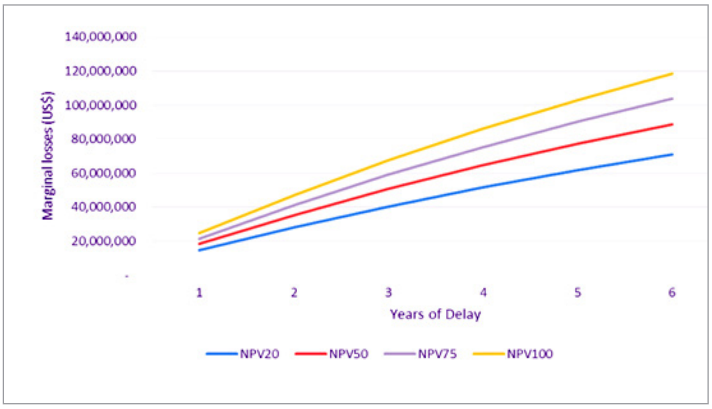


Table 1. Time delays that can be absorbed by companies

ROR	Time delay for company to abandon investment
20 percent	2 years
50 percent	4 years
75 percent	Less than 6 years
100 percent	More than six years

Figure 3. Marginal losses compared to the baseline of no delay with a ten-year life span and a discount rate of 10 percent



The situation becomes even more critical when considering the product development cycle for public sector crops, where increased regulatory delays and costs needed to develop a product can limit public sector capacity to address crops and traits of interest to developing countries. Given the public sector's limited experience with GM technologies, application of GM approaches in crops and traits of interest to developing countries (e.g. viral resistance in cassava) and the required regulatory review of resulting products, it is likely that the delays and costs will have a more significant impact to the public sector efforts in developing such technologies than products developed by the private sector for proven markets. Increases in regulatory costs and delays can thereby delay the accrued benefits even further. Furthermore, the public sector research would be more vulnerable to increases in regulatory costs because of its source and amount of funding. The impacts of these delays will, in turn, affect food security and other important development indicators, especially for those R&D innovations and investments which address constraints for which there are few options from which to draw alternatives to farmers in developing countries. As Smyth et al. (2016, p. 188) write: **"Unless caution is exercised, all unjustified delays due to problems with coordination and/or regulatory requirements beyond those necessary to ensure an accepted level of safety will likely make this situation worse and may drive public sector developers out of the R&D sector, particularly in developing countries."**

GM Crops and products have proven to give benefits to farmers and the agriculture sector of various countries. Increases in regulatory delays could hinder or even stop public sector R&D which are particularly intended to address needs in developing countries.

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