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The Costs of Regulatory Delays for Genetically Modified Crops

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The timely and efficient commercialization of innovation is one of industry's principal needs if it is to invest in research and development within a given jurisdiction. Increasing regulatory requirements are resulting in longer regulatory approval times, and in some cases where socio-economic considerations are now part of the regulatory approval process, the regulatory system has been put into gridlock, unable to approve new varieties. This increased regulatory approval time creates increased uncertainty for those that invest in agricultural research and development. If the regulatory approval uncertainty gets too high, further investment in agricultural innovation is jeopardized. Several regulatory delay scenarios are modeled, highlighting the investment risk that is established. The article concludes that future public sector investment in agricultural research and development is at risk, given the increase in regulatory approval times for GM crops.

Keywords: decision-making, food security, innovation, investment, uncertainty

1. Introduction

The lack of institutional capacity at an international regulatory level has created a trans-Atlantic gap in the risk assessment and commercialization of, and benefits from, genetically modified (GM) crops. For the most part, the Americas are global leaders in the research and development, risk assessment and commercialization of GM crops and foods, and in realizing quantifiable benefits from them. Thirteen out of the 28 countries growing GM crops and 7 of the 11 countries growing over one million hectares of GM crops annually are in the Americas (James, 2014). Risk assessments of GM products are science-based in most of these countries, with some countries including socio-economic considerations as part of their risk assessment process, but the crucial result is that the variety approval processes are consistent, efficient and timely, with approval times of two to two and a half years for the leading (in terms of regulatory efficiency) countries (EuropaBio, 2011). Based to a large degree on the regulatory inefficiency for GM products in Europe, BASF relocated all of its agricultural research activities from Europe to the Americas in 2012 (BASF, 2012). This decision by BASF illustrates that there is a substantial cost due to regulatory inefficiency.

The increase in global commerce and trade in the last 20 to 30 years has created the present day scenario, at least for agriculture, where the efficiency of a domestic regulatory system is now a crucial part of a multinational firm’s investment strategy. Regulatory efficiency is such an important factor that some industry executives have privately indicated that the greatest competition for research and development (R&D) project investment is not in gaining an advantage over other multinational firms, but domestic subsidiaries of their own firm. For example, Brazil’s regulatory approval time for new GM varieties is shorter than that of Canada, therefore the Brazilian subsidiary of a multinational seed technology development firm would have a stronger investment proposal due to the shorter time for regulatory approval of the resulting variety than would the corresponding Canadian subsidiary.

Innovations in agriculture established the criteria for the creation, development and growth of civilizations and cultures (Diamond, 1997). Without innovative methods and techniques to feed growing populations, the establishment and advancement of mankind would not have been possible. Modern day society is faced with a dilemma that is going to require considerable innovation and investment in agriculture: how to feed a global population of nine billion (or more) by the year 2050. The severity of this dilemma is crystallized by the following quote from the Deputy–Director General of the Food and Agriculture Organization (FAO):

"Agricultural production needs to increase by 70 percent worldwide, and by almost 100 percent in developing countries, in order to meet growing food demand" (Tutwiler, 2011). FAO (2010) estimates that annual crop yield increases of 2 percent are needed to sustain the planet's existing population. Current yield increases for corn, rice and wheat average 1.2 percent and have been steadily declining for the past 30 years. Meanwhile, there is considerable evidence of serious underinvestment in agricultural R&D over recent decades (Alston, Beddow and Pardey, 2009; James, Pardey and Alston, 2008). Even if investment could be increased to eventually backfill the current shortfall, there are considerable lags – often in the 25 year–plus range – between when investments are made and productivity increases are fully manifest (Alston, 2010).

The application of genetic science to plant breeding continues to advance, with plant breeders using increasingly refined biotechnologies to develop new varieties. Those regulatory agencies that struggled with (and still do in many jurisdictions) managing the regulation of first generation GM varieties will undoubtedly face daunting challenges regarding the regulation of new crop varieties developed by third generation technologies. The importance of these technologies and investment in them was highlighted in the 2012 Gates Foundation's Annual Letter. Agricultural research is highlighted as one of the crucial areas that deserves greater attention both from increased public and private investment into research on new crop varieties and the techniques used to develop them. The letter observes that "… we can find out precisely which plant contains what gene conferring a specific characteristic. This will make plant breeding happen at a much faster clip" (Gates Foundation, 2012). Clearly, there is a global need to improve the regulatory capacity and efficiency of biosafety frameworks in many nations such that developing world countries can have greater options regarding the production of food.

If development potentials offered by biotechnology and GM crops are to have any positive impacts on food security, regulatory systems are going to need to change and to improve. This article identifies the quantifiable benefits created to date from the commercialization of GM crops and then examines the potential cost due to regulatory delays. The article is structured as follows. Section 2 provides the summary of existing benefits, with section 3 undertaking the methodological assessment. Section 4 discusses the policy implications, with section 5 offering some concluding thoughts.

2. Summary of GM Crop Benefits

From 2000 the debate and research into biotechnology shifted heavily towards the potential and actual impacts on resource-constrained and food-insecure parts of the world. This discussion and research has contributed to a body of evidence about the ubiquitous and transformative capacity of the technology and the opportunity cost of truncated or delayed application and use.

The 2002 commercialization of Bt cotton in India, with its millions of small landholders, provides an excellent opportunity to assess the impacts of GM crop adoption on developing-world farmers. Qaim (2003) assessed the potential impacts of Bt cotton adoption in India (based on 2001 field trials), noting that prior to the commercialization of Bt cotton, farmers were losing an estimated 50-60 percent of yields due to insect pests. The analysis found that yields increased by an average of 58 percent and pesticide costs dropped by 50 percent. Subramanian and Qaim (2010) extended this research and reported that after four years of production, Bt cotton yields were 37 percent higher and pesticide use had dropped by 41 percent. Additional socio-economic benefits were also measured, with the most noticeable impact being increased hired female labour. Subramanian and Qaim estimated that Bt cotton–adopting households had increased their incomes by 82 percent and households that were defined by FAO as vulnerable (i.e., income of <$2/day) had increased their incomes by 134 percent.

Following several years of Bt cotton adoption in India, reports from biotechnology critics began to suggest that increases in farmer suicides were due to Bt cotton adoption. Gruère and Sengupta (2011) researched Bt cotton adoption and farmer suicides. Innovation adoption was not homogenous across states, and their meta-analysis revealed the commercialization of Bt cotton was plagued by counterfeit seeds, lack of agricultural extension and knowledge dissemination and variation in seed quality. In their research into farmer suicides and Bt cotton adoption, Gruère and Sengupta showed that when the pre–Bt cotton suicide rate was projected, the actual suicide rate was considerably lower. In two strongly GM cotton–adopting states suicide rates did not decline to the same level as in other cotton producing states. Analysis of the underlying factors revealed abnormally low precipitation in some years reduced yields, while general household indebtedness was a contributing factor. The authors concluded that Indian cotton farmers' suicides were not correlated with Bt cotton adoption.

Further research by Qaim (2014) shows that the application of cotton pesticides has fallen between 0.95-1.3 kg/acre of active ingredient. This results in a cost savings of 879-1284 rupees. In India pesticides are applied to cotton by farmers walking through the field using a backpack sprayer, in most cases with little to no protective clothing. Millions of cases of acute pesticide poisonings are reported every year. The adoption of Bt cotton has reduced the number of cases of pesticide poisoning, saving the Indian Ministry of Health millions of rupees. Not only have the environment and farmer health benefited, but so too have the yields and profitability of Bt cotton adopters. While Bt cotton adopters do pay a higher price for the seed, this is more than offset by the 24 percent increase in yield when compared to non–Bt cotton. Profits rose even more dramatically, by an estimated 1877 rupees per acre, or 50 percent. In 2012, it was estimated that 27 million acres were planted to Bt cotton, generating a net gain for farmers of US$1 billion.

China has invested heavily in biotechnology and is a strong adopter of GM cotton. Based on a 1999 survey of cotton farmers in northern China, Pray et al. (2001) provided the first insights into the impacts of Bt cotton. Their research measured the economic, income distribution, environmental and health effects. While not easy to quantify due to farmer-to-farmer sales and seed saving from year to year, the authors estimated that early adoption ranged from 8-27 percent. The authors highlighted that while non-Bt farmers saved money on seed costs, they spent considerably more on pesticide purchases and labour. When other production costs were factored in, non–Bt cotton producers experienced a loss in net income. The authors estimated that approximately 85 percent of the benefits of adoption accrued to the farmers, with industry receiving 6 percent and the balance going to government seed agencies. The most substantial impact from Bt cotton adoption may well be from the environmental and health benefits resulting from reduced pesticide applications. The adoption of Bt cotton allowed farmers to spray less frequently, in some instances dropping from 30 applications per season to 3, but more commonly from 12 to 3-4.

Pray et al. (2002) extended their original 1999 survey data with new 2000 and 2001 data. This period was one of rapid change as the Chinese government removed the cotton purchase monopoly of the state run Cotton & Jute Corporation, allowing the price of cotton to fluctuate with the market. A New Seed Law was passed, allowing private seed companies to operate and charge market prices for their seed. The increased Bt cotton adoption reduced market prices for cotton, resulting in some benefits being passed on to consumers through lower prices for cotton and yarn. Even with the lower cotton prices, adopters increased their net income by US$500/ha.

Huang et al. (2010) updated the Chinese Bt cotton story following a decade of commercial production. Based on the authors' analysis, they documented a drop in bollworm infestations, not only in Bt cotton fields but in all cotton fields in parts of China. In some non–Bt cotton fields, the amount of insecticide in kilograms per hectare dropped from in excess of 40 to less than 10. Across the entire sample region insecticide applications dropped from 14kg/ha to 4kg/ha.

Bennett, Morse and Ismael (2006) identified Bt cotton as the first commercial GM crop produced in Sub-Saharan Africa (SSA), first approved in 1998. One strongly adopting region was the Makhathini Flats area of the KwaZulu Natal province of South Africa, where the typical farm size is between one and three hectares. Cotton is a valuable cash crop and typically accounts for most of the land allocation. By 2002, an estimated 92 percent of smallholder cotton producers had adopted Bt cotton. Given male labour migration patterns at this time, it was estimated that 60 percent of the smallholder producers were female. The authors obtained production records for three growing seasons, showing that Bt cotton yielded substantially higher (89-129 percent) than conventional cotton, especially under adverse climates. The authors noted that the average daily wage in the area was SAR10-15, making the extra Bt cotton revenue equivalent to two to four months of wages.

Another interesting finding from the South African smallholder GM crop research is the substantial labour savings reported by GM herbicide tolerant (HT) maize–adopting farmers. Numerous studies in Africa have shown the devastating effects uncontrolled and less than optimally controlled weeds can have on crop yields (Chikoye, Schulz and Ekeleme, 2004; Joubert, 2000; Shetto and Kwiligwa, 1998; Atera, 2012). Poor weed control is often cited as the single biggest contributor to low maize yields for African smallholder farmers. The number of necessary weedings following planting is the principal limiting factor to African farm sizes (Kent, Johnson and Becker, 2001). More efficient use of a post-emergent, broad-spectrum herbicide would have a positive effect on weed control effectiveness and therefore on yield and area under crops and thus food security and nutrition. GMHT crop adoption has allowed such usage to occur and in some developing countries has resulted in increased ease of management and off-farm income (Fernandez-Cornejo, Hendricks and Mishra, 2005; Gardner, Nehring and Nelson, 2009; Hurley, Mitchell and Frisvold, 2009).

An interesting impact is the potential saving on weed control labour by female family members in households that have adopted GMHT maize. In SSA’s labour-intensive production systems, a decreased need for manual weed control will result in a reduced need for family and/or hired manual labour. This benefit is realized especially by female farmers and female household members because manual weeding is predominantly a female activity. Based on three seasons of research involving small landholder adopters of GM crops in South Africa, Gouse (2013) found that female GMHT maize adopters spent 10-12 days less in the field doing arduous weed pulling and hoeing than their conventional maize–planting counterparts.

The only other nation in Africa to have sustained GM crop production is Burkina Faso, where Bt cotton was approved in 2009. In comparing yields over the first three production years, Vitale, Vognan and Ouattarra (2014) found that Bt cotton yields were 22 percent higher than those of conventional cotton. Input costs were found to be virtually identical, with Bt cotton seed costing $US361/ha while conventional seed cost $US355. The higher seed costs for Bt cotton were offset by the higher insecticide costs for conventional cotton producers. Over the three years, the average economic return per hectare was more than double that of conventional cotton, with returns of $US151/ha for Bt cotton and $US70 for conventional cotton. Health benefits were also found to be substantial, with an estimated 30,000 fewer reported cases of pesticide poisoning.

Argentina has been a major adopter, with GM soybean production beginning in 1996 and Bt cotton in 1998. Nearly all of the GM soybeans produced in Argentina have been modified to be herbicide tolerant, and in 2009 adoption was estimated at 99 percent, with the economic impact of adoption in 2009 estimated at US$302 million, while the cumulative impact was US$3.87 billion (Brookes and Barfoot, 2010). Qaim and Traxler (2005) studied the 2001 farm-level and aggregate effects of GM soybean production, finding that producers captured 16 percent of the benefits and consumers captured 35 percent, with the technology developers capturing the remainder.

The distribution of GM crop benefits has been subject to rigorous review (table 1). Numerous studies have been undertaken with the results reported. The studies use a variety of models, so the numbers reported below should not be taken as benchmarks, but it is the range of returns and the general sense of distribution that are of interest. Clearly, benefits accrue to more than just the technology developer and the adopting producers; society benefits as well. The social benefits include some that go to the non-adopters. Soybeans have had the greatest number of studies, with roughly one-quarter to one-third of the benefits accruing to consumers.

In addition to the above commodity-specific analyses, there have been several important GM crop meta analyses undertaken. The first, by Carpenter (2010) examined yield comparisons between adopters and non-adopters from 168 studies, finding 124 reporting yield increases, 32 reports of no differences and 13 of lower GM crop yields. Finger et al. (2011) examined 203 peer reviewed publications, finding that yield increases exist due to reduced pest pressures (both insect and weed). Reduced chemical applications contribute to the economic benefits, but are reduced marginally by the higher seed costs for GM seed inputs. 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. In a wider assessment of literature that included journal articles, government reports as well as industry and organization reports, Klümper and Qaim (2014) reported the findings of their meta analysis of 147 studies. They found that with GM crops chemical use declined by 37 percent, yields increased by 22 percent and farmer profits increased by 68 percent.

Table 1 Distribution of Benefits from GM Crops*

Country	Year	Total benefit ($US Millions)	Share of total benefits (Percentage)			
			Farmers	Innovators	Consumers	Net ROW**
Canola						
Canada[a]	2005-07	1192	-	-	-	-
Canada[b]	2014	-	43%	48%	5%	4%
Soybeans						
USA[c]	1997	437	29%	18%	17%	28%
USA and Argentina[d]	1997	206	16%	49%	35%	-
USA[e]	1997	310	20%	68%	5%	6%
USA[f]	1999	804	20%	45%	10%	26%
USA and Argentina[d]	2001	1230	13%	34%	53%	-
Argentina[g]	1996-2010	65153	72%	7%	21%	-
Global[h]	1996-2010	46000	55%	14%	31%	-
Maize						
USA[i]	2001	334	50%	31%	NA	NA
Spain[j]	2003	2	60%	40%	-	-
Argentina[g]	1996-2010	5375	68%	20%	11%	-
Cotton						
USA[e]	1997	164	37%	45%	18%	-
China[k]	1999	140	98%	2%	-	-
India[l]	2001	315	67%	33%	-	-
Argentina[g]	1996-2010	1834	96%	4%	-	-

Notes: * adapted from Fernandez-Cornejo and Wechsler, 2014; ** rest of the world (consumers and producers).
Sources: a: Gusta et al., 2011; b: Smyth and Phillips, 2014; c: Falck-Zepeda, Traxler and Nelson, 2000; d: Qaim and Traxler, 2005; e: Price et al., 2003; f: Moschini, Lapan and Sobolevsky, 2000; g: Trigo, 2011; h: Alston, Kalaitzandonakes and Kruse, 2014; i: Wu, 2002; j: Demont and Tollens, 2004; k: Pray et al. 2001; l: Qaim, 2003.

3. Methodology

The process of creating new crop varieties can be described in four phases, as shown in figure 1. During the first phase, or the research phase, resources are spent to develop a crop variety that has commercially desirable characteristics. This process strongly depends on the stocks of human capital, knowledge and germplasm available as inputs into the creation of a new variety. The attribution of the cost of creating these important stocks is difficult. As a result, the creation of these stocks is often considered to be a set of sunk costs independent of the particular research program. The whole study of research spillovers would be important if these costs were to be attributed. At the end of the research phase a new variety is created.

There are many years between the research expenditure to develop a new variety and the variety reaching any end user. Research itself takes a number of years to produce any tangible product. Even after a variety with potential has been created, it must be tested both internally and by external regulatory agencies before it can be licensed for sale. This period is referred to as the "gestation lag of research" and is defined as the number of years between making the investment and generating new technology or useful knowledge. In practice, the gestation lag is difficult to estimate, because the expenditure to create a new variety is often spread over many years. For instance, a new variety released in year T may have involved research and development expenditure in years T-2 to T-8. To get around this problem of multiple gestation lags most studies have estimated a single gestation lag, which represents the lag between the weighted mean time of expenditure and the commercialization of a licensed variety. It is at this crucial stage that the time of regulatory delay has the potential to become so substantial that the orange curve is larger than both green curves combined, thus resulting in the end of investment in the project or technology.

The third relevant period for estimating the returns to research is the adoption phase. During this phase the new variety is adopted and then replaced by other varieties. The typical pattern is low adoption in the first year of introduction, growing to peak adoption in two more years, then slowly being replaced by other, newer varieties. In terms of economic impact the variety has its largest annual impact in the year when the adoption rate reaches its peak.

The final research stage is the depreciation phase or knowledge stock phase. Research often creates a new process or new germplasm. These innovations provide a very important base upon which subsequent research is built. Thus, 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. For instance, the first semi-dwarf wheat varieties are no longer used but some of the germplasm from these varieties continues to be in many of the varieties grown today. Although durable, the contribution to the stock of germplasm is not permanent and depreciates over time. One of the common reasons cited for depreciation is that pests in the environment eventually adapt themselves to attack a particular germplasm, and so new germplasm is required.

In the most basic of theoretical senses, what we are trying to determine is if the orange curve below the time horizon increases in figure 1, what impact does this have on the green curves above the horizon? Since the commercialization of GM crops began in 1995, a number of scholars have investigated the impact of the regulatory system on the agri-food sector. Present regulatory systems were designed to adjust for the commercialization of the first generation of GM crops. This regulatory approach is slowing considerably as the regulatory system is faced with commercializing products that are second and third generation. Jaffe (2005) reported that in spite of no new traits being regulated, the length of time associated with the United States Department of Agriculture (USDA) consultation process had more than doubled between the period 1994-99 and the period 2000-04. The average number of months to get regulatory approval in the United States in the 1994-99 period was 5.9 months, and in the period 2000-04 it took 13.6 months. A 2011 report released by EuropaBio that examined regulatory approval times in Brazil, Canada, the European Union and the United States documented that the average time to approve a GM crop in the United States had risen to 25 months (EuropaBio, 2011).

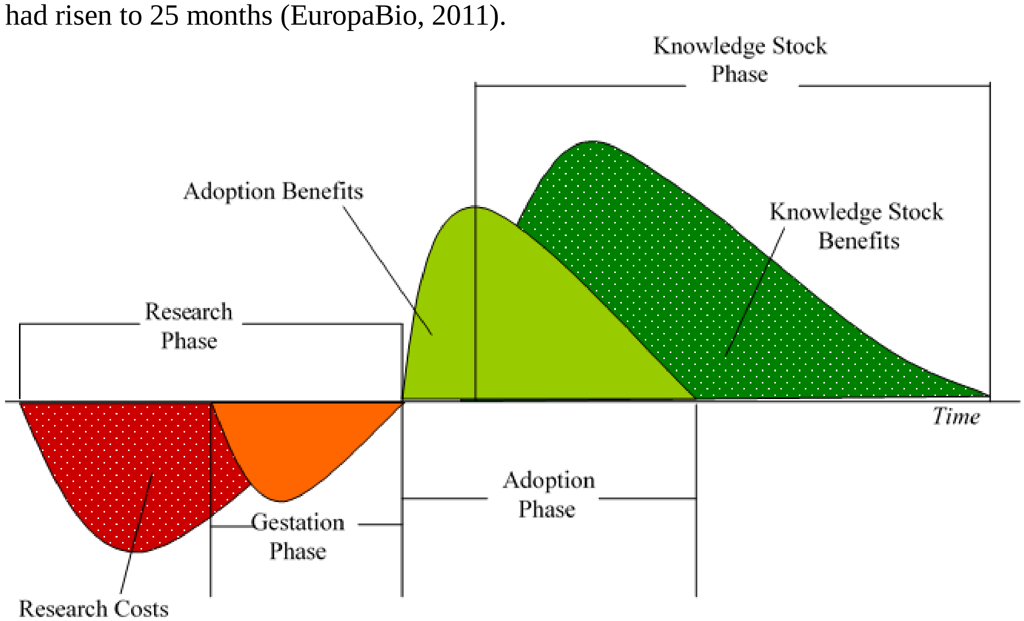

Figure 1 Four phases of crop development and the path for R&D costs and benefits.
Source: adapted from Alston et al., 1995

Two studies have examined the complex issue of crop regulation costs. The first was a study done by Pray et al. (2005) that examined the cost of biosafety regulations for the approval of Bt cotton in India. This process involved officials with Monsanto and their Indian seed partner company, Mahyco, working with officials from three different committees in the Indian regulatory system. Pray et al. identified two cost categories, pre-approval and post-approval. The pre-approval costs included costs for feeding studies for a wide variety of animals, poultry and fish, pollen flow, impacts on soil, and socio-economic considerations. The cost for this category was estimated to be US$1.8M. The post-approval costs were for three studies, on socio-economic issues, pest management and chemical resistance. These costs were estimated to be US$200,000. A second study was by Kalaitzandonakes, Alston and Bradford (2007) and examined the cost of regulatory approval for insect resistant (IR) corn and herbicide tolerant (HT) corn in the ten key markets. These key markets were defined as the major producing and importing countries and were listed as Argentina, Australia, Canada, China, the EU, Japan, Korea, the Philippines, Taiwan and the United States. The cost categories that were examined covered studies in the range of animal toxicity, non-target organisms, protein assessment, phenotypic and stewardship. The cost for approval of IR corn was estimated in the range of US$7-15.4M, while the estimated cost for HT corn was US$6.2-14.5M.

An industry report prepared by Phillips McDougall (2011) identified that the average number of months it took for a GM event to receive regulatory approval in 2011 was 65 months, up from 49 months in the 2008-2012 period.[2] The total cost of receiving variety approval in key markets was estimated to be US$136M. The concern within the seed development industry is that the commercialization of new traits will only be done by large multinational seed developers.

Clearly, the time required to grant regulatory approval for GM crops is increasing. This is in spite of the fact that virtually all of the plant varieties undergoing regulatory approval still contain the same two traits, herbicide tolerance and insect resistance. In some instances it may be that these traits are stacked into the same variety. Additional time required to regulate traits that have been regularly approved over the past 20 years is disconcerting. If science-based regulatory systems are taking longer to make regulatory decisions, inclusion of socio-economic considerations (SECs) would dramatically compound the problem. The following section examines the potential cost of including SECs into biosafety regulatory frameworks.

4. Model

Understanding the impacts of delays on the benefits of GM biotechnology investments is of critical importance to decision-makers. To gain an understanding of the effect of delays on decision-making we estimated the net present value of an initial investment with different required rates of return and other assumptions. We make use of the Phillips McDougall (2011) study, which estimated the cost of R&D, regulatory approval and all activities necessary to deliver a GM technology to farmers. The Phillips McDougall report documents a US$136 million investment from discovery to registration and deployment to farmers. To this effect we estimated the net present value (NPV) for an investment of US$136M with different required rates of return (RORs). The assumed RORs chosen were 20 percent, 50 percent, 75 percent and 100 percent, expressed as present values. This implies a required return of US$27M, US$68M, US$102M and US$136M in present values at the time of investment. In previous research, Smyth, McDonald and Falck-Zepeda (2014) estimated NPVs for a GM biotechnology investment with required rates of return of 20 percent and 50 percent. Subsequent conversations with industry showed that, in practice, private companies may require higher rates of return. Thus, for this research, we chose to increase the ROR to 75 percent and 100 percent to reflect private company practice.

We used a fixed discount rate of 10 percent to estimate the 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. The latter is a somewhat naïve assumption as returns are usually not linear during the life of a project. Returns usually depend on the rate of adoption/disadoption of a GM technology and thus the effective life cycle of the project. Furthermore, a ten-year lifespan may not be appropriate for every single GM technology. However, these assumptions allowed us to focus on the net effect of time delays on investment outcomes, allowing us to conduct sensitivity analysis of the discount rates.

We introduced a stochastic distribution for the discount rate using a PERT distribution as in Smyth, McDonald and Falck-Zepeda (2014) in order to conduct stochastic simulations to estimate return variability. The PERT distribution was described with a mean equal to 9.5 percent, a minimum of 5 percent, a maximum of 12 percent and having a standard deviation of 1.27 percent. We used the stochastic simulation software @Risk, repeating the estimation of NPV 10,000 times while saving outcomes in a Monte Carlo setting, in order to calculate mean and standard deviations for all required rates of return and thus obtain estimates of risk.

5. The Impact of Delays on Biotechnology Investments

Figure 2 shows the NPVs for the required RORs for a GM biotechnology investment. These estimates are for the static mean values for each required rate of return and year of delay. Losses shown in figure 2 are a reflection of the time value of money due to time delays. 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 what has been observed to date in terms of crop emphasis, as this is the rationale for focusing on core crops with better market potential such as corn, soybeans, cotton and canola.

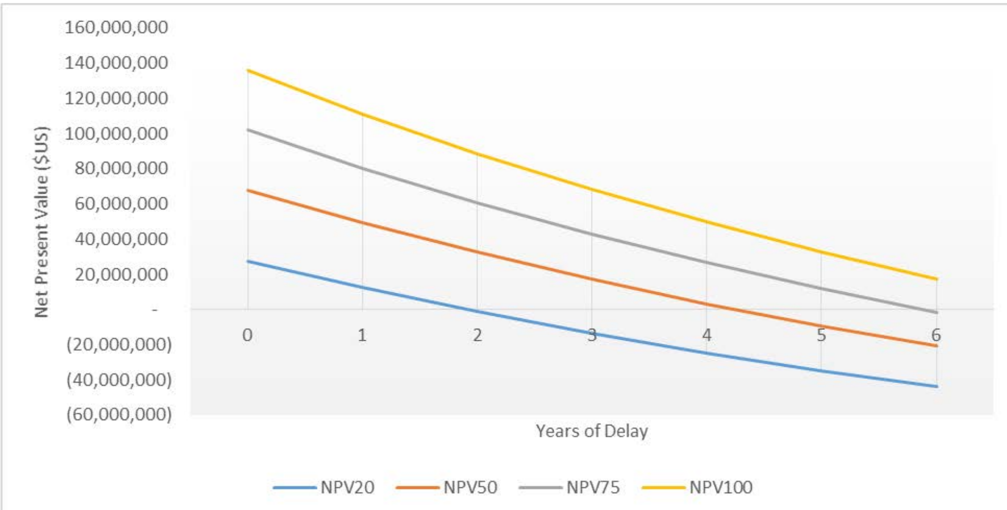

Figure 2 NPV investment change in GM biotechnology with regulatory delays.

A key point from figure 2 is how fast the NPV goes negative with the ROR of 20 percent. The implication is that the company would have to discontinue this investment after a two-year delay. In the case of an ROR of 75 percent, a company is likely to abandon the investment after a little less than six years, and for the ROR of 100 percent the time frame is likely to be over six years. This implies that higher levels of ROR may allow more time delay flexibility by increasing the amount of delay that may be allowed. A further implication is that investments with lower RORs are not likely to be chosen for further development.

Taking into consideration the initial investment of US$136M and these estimations, the results seem to indicate that a biotechnology company will require a high rate of return, especially when the product development pipeline may face uncertainty in terms of delays and compliance with regulatory and registration procedures. This implies that a company has to achieve a level of net income or cash flows, otherwise the investment is not financially sound, and thus this type of investment is indeed one where financial risk is a consideration.

Figure 3 shows the marginal losses compared to the baseline of no delay with the assumptions used in the estimation of NPV for the required rate of returns. As can be seen, results from these estimations show that for every ROR (e.g. estimated NPV with a required 20 percent ROR), every year of delay increases marginal losses due to delays. In turn, for every time period of delay (e.g. year 1) a higher ROR curve (e.g. NPV 100 compared to NPV 20) has a higher marginal loss. This result reinforces the idea that for the same amount of investment (US$136M), a biotechnology company will likely be required to generate higher levels of returns from an investment and to reduce time delays as much as possible if it wants to keep an annual stream of benefits to meet the required rate of return and thus ensure financial success over the lifetime of a product. We expect that products with shorter life spans will tend to reinforce the notion of having higher rates of return even more.

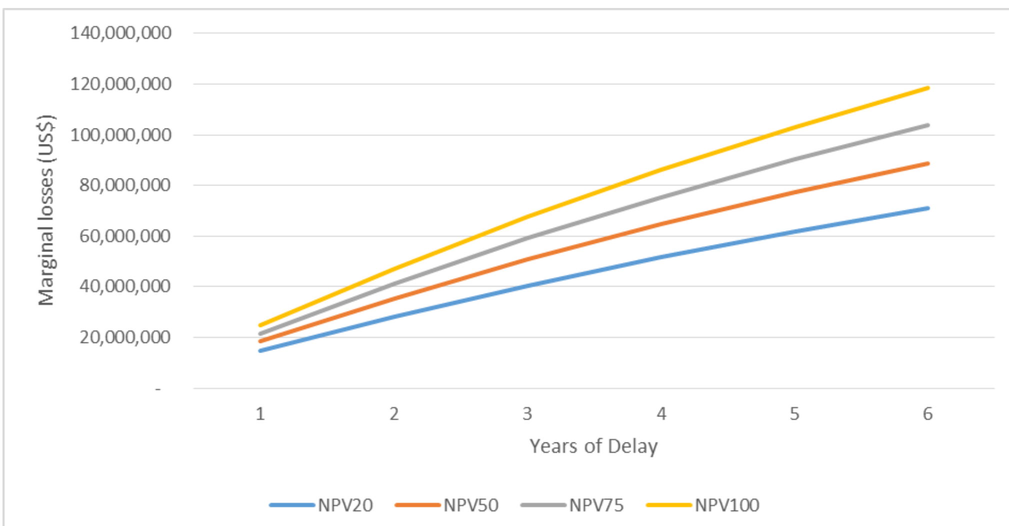

Figure 3 Marginal losses compared to the baseline of no delay with a ten-year life span and a discount rate of 10 percent.

Figures 4a and 4b show the results from the 10,000 iterations for the stochastic simulations conducted in @Risk for the NPVs with a required rated of return of 20 percent and 100 percent, respectively, and the impact of delays on NPV. As expected, the dispersion around the mean for both curves as measured by the standard deviation around the mean increases over time but with a lower expected NPV over time. The higher the years of delay, the lower the expected NPV and the higher the dispersion around the mean, and thus risk. Delays increase risk for the investing company. In other words, reducing delays in the outset of income and/or cash flows over time reduces risk.

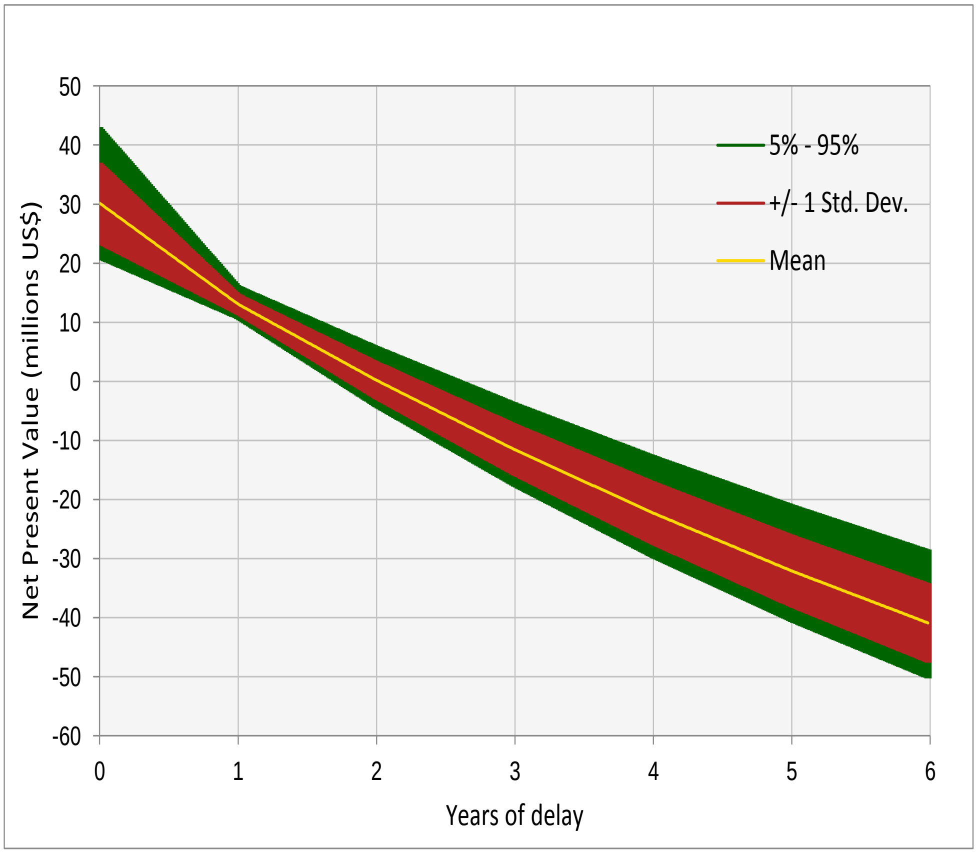

Figure 4a NPV with a required rate of return of 20 percent.

6. Policy Implications

GM biotechnologies are subject to a portfolio of activities before release to farmers. This would obviously include the R&D necessary to discover, research and develop such technology. Once a commercial technology is identified, then GM biotechnologies have to comply with biosafety, registration and other regulatory procedures before release. From the standpoint of a company, and taking into consideration the results from our analysis identifying evidence supporting the relationship between time delays and decreases in net present values of a technology and an increase in financial/outcome risk, it is important for developers to reduce time delays and to increase the coordination between activities to ensure not only compliance but also cost and time efficiency in delivering a product.

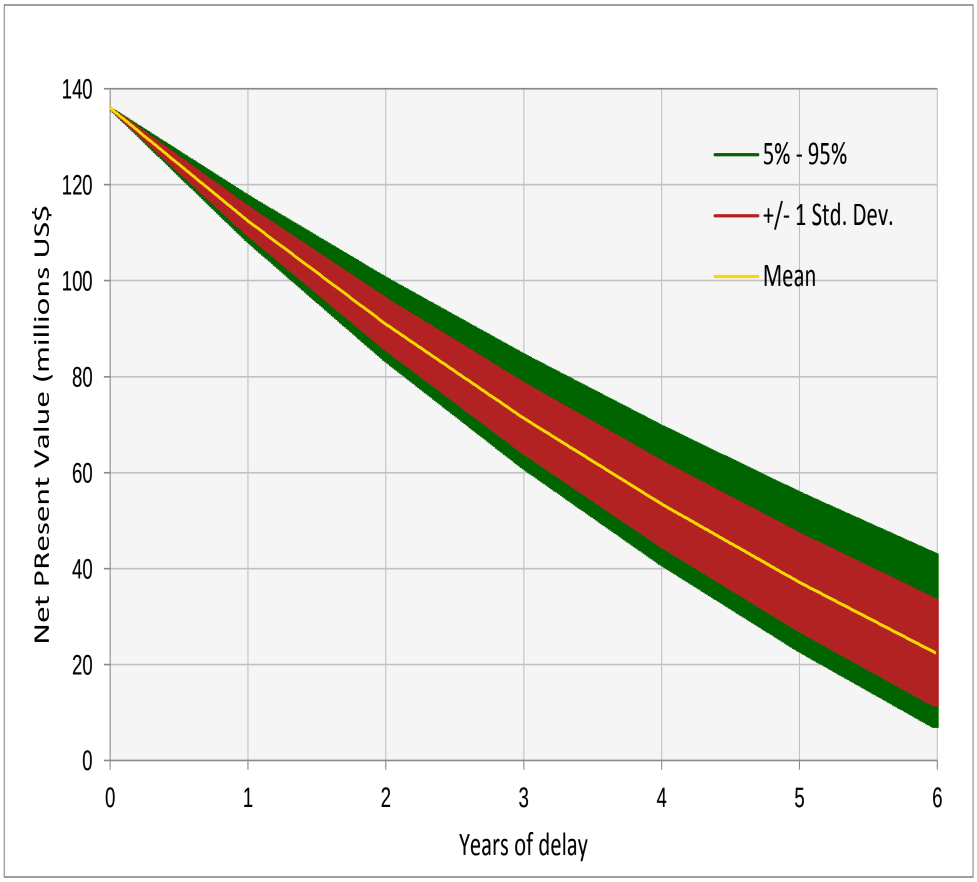

Figure 4b NPV with a required rate of return of 100 percent.

Private companies are not the only ones developing GM biotechnologies, especially in developing countries. Public sector institutions are developing a diverse portfolio of crops and traits of interest to and for developing countries (Chambers et al., 2014; Falck-Zepeda et al., 2009; Atanassov et al., 2004). Taking into consideration the relatively high level of investment necessary to develop a technology and the identified higher levels of returns necessary to justify investment, there is evidence that the public sector developers who are likely to be developing public goods may be disadvantaged in terms of securing the necessary funds to conduct basic R&D and to meet the higher rates of return needed for this type of investment.[3]

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. This is a public-good investment problem, in which public and private development investors need to intervene in order to ensure development of appropriate GM biotechnologies for developing countries.

Some developing countries may choose to pursue those GM biotechnologies where the bulk of R&D, including discovery, construct optimization and some (or all) commercial event selection and production may have been done elsewhere, as they may not have all the necessary resources to start from discovery. This will likely be a situation where license and intellectual property negotiation will need to occur to ensure technology transfer between developer and recipient country. Examples of this type of technology transfer include Golden Rice, Water Efficient Maize for Africa, and Fungal Resistant Bananas in Uganda.[4]

7. Conclusions

Private sector R&D regarding new technologies is better equipped to weather a regulatory delay due to the inclusion of socio-economic considerations as part of biosafety regulations than is public sector R&D. However, as verified above, even the deeper pockets of private sector research have limits. A two-year delay reduces the NPV of a private sector investment into a new GM crop variety by about one-third. As established by Ludlow, Smyth and Falck-Zepeda (2014), the lack of SEC methodologies to undertake this type of assessment makes two-year delays the expected minimum amount of time required to complete an SEC assessment. It is extremely doubtful that any corporation would consider making an investment into the development of a new GM crop with the regulatory uncertainty created by the inclusion of SECs into a biosafety regulatory framework. Evidence of this is abundant in the European Union: 20 years ago, the EU accounted for one-third of the global agricultural R&D, and now it accounts for slightly less than 10 percent. This is clear evidence that the incorporation of SECs into the EU's crop approval process has driven investment risk so high that firms are no longer willing to take this level of risk and have reallocated their agricultural investment resources into countries that have functioning regulatory systems. Based on the EU experience, any country that intends to incorporate SECs into its crop regulatory approval process should expect to experience a decrease in private agricultural R&D investments.

Even more concerning is the devastating impact a two-year delay from SEC assessments will have on public sector variety development projects. A great deal of the international research collaborations presently being undertaken combine the efforts of philanthropic organizations, private technology development companies and national agricultural research centres in developing countries. Even at the best of times, national agricultural research centres in developing countries function on the scarce fiscal resources available. Faced with a prospect of a two-year delay due to SEC assessments, such centres will have no choice but to halt the further development of innovative crop technologies, further increasing food insecurity. The research conducted by national agricultural research centres is commonly focused on traditional crop types that constitute considerable acreage, though not enough to attract multinational firm investments. Jeopardizing these R&D investments will have a catastrophic effect on efforts to enhance food security in developing countries, as the sole source of research on improving traditional crops will face uncertainty that may result in an investment reallocation.

The substantive argument is that the cost and/or the time required for compliance introduce uncertainty into the regulatory approval process and thus have the potential of reducing (or in some cases postponing) investments in R&D and thus, eventually decreasing innovation. Regulatory uncertainty may imply that firms have an incentive to divert resources to more productive uses, or to divert resources to activities or projects that are non-regulated but which may yield reduced returns on investment. This may be particularly important for small firms and for the public sector (especially) in developing countries.

If serious efforts are going to be made to respond to FAO's 2010 challenge of feeding a 2050 world, then one of the most crucial ways of doing so is to remove the regulatory barriers that will be created by the development and implementation of SEC-based biosafety regulatory frameworks. The inclusion of SECs into the approval process for products of biotechnology, such as GM crops, is a clear and costly impediment to successfully improving food security in developing countries. In fact, based on the arguments laid out above, SECs are the single biggest barrier that presently exists to innovation and improving food security in developing countries. Those that continue to advocate and argue for the inclusion of SECs into developing country regulatory frameworks are essentially positioning themselves to be in favour of existing food insecurity scenarios.

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[2] Firms were surveyed about the actual and expected costs for the 2008-2012 period in 2011. The 49-month figure represents the time in the 2008-2010 period, as firms also provided data for their experiences in 2011.

[3] Public good research provides vast social benefits, and this is particularly the case when it comes to investing in agricultural R&D (Alston et al., 1995; Pardey and Alston, 2012; Gray and Dayananda, 2014). Not only are higher yielding and superior agronomic varieties not released, but the economic spinoffs that result from higher agricultural incomes are also foregone. The ripple effect of this reduced agricultural income is then distributed across the nation's entire economy.

[4] The social cost is magnified in examples of staple crops in developing countries, particularly where the staple crop provides the majority of the daily nutritional intake. Not only are nutritional requirements not enhanced, but the lack of such technologies perpetuates the daily challenges of food insecurity. An additional lost social benefit from the increased regulatory delay is the continuation of existing labour intensive farming practices, such as hoeing and weeding in the hot sun.