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Cost of Compliance with Biotechnology Regulation in the Philippines: Implications for Developing Countries

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Direct and opportunity costs of regulation are presented for four transgenic products in the Philippines: Bt eggplant, Bt rice, ring-spot-virus-resistant papaya, and virus-resistant tomatoes. Understanding the magnitude of these costs is important for evaluating potential net benefits of genetically modified crops, both for countries that are designing their regulatory procedures and for those implementing them. Results indicate that direct regulatory costs are significant but generally smaller than technology development costs. However, the cost of foregone benefits stemming from even a relatively brief delay in product release, which might be due to unexpected regulatory delays, overshadows both research and regulatory costs. Regulatory systems must ensure that none of the steps in its regulatory process for GM products that are required to protect public safety and the environment are omitted, but unnecessary steps are costly. Direct regulatory costs appear to be declining within countries as they gain experience with more products.

Key words: agricultural biotechnology, biosafety, genetically modified crops, GMO, regulatory costs.

Modern agricultural biotechnologies, including genetically modified (GM) crops, have significant potential in developing countries (Qaim & Matuschke, 2005; Ramasamy, Selvaraj, Norton, & Vijayragahavan, 2007), but relatively few products have been commercialized there to date (Atanassov et al., 2004). Although there are many reasons for the slow spread of GM products in developing countries, including inadequate intellectual property rights and market concerns, a major reason has been ill-defined bio-safety regulations and the time and costs associated with moving a product through the regulatory process (Pray, Bengali, & Ramaswami, 2005).

Many developing countries simply lack functional and enabling biosafety regulatory processes that guide proper scientific risk assessments before the safe release of GM crops into the environment. International agreements and national governments require a functional regulatory process to ensure environmental and food/feed safety of genetically modified organisms (GMOs). Each nation needs regulations that are both protective and efficient. In setting regulations, countries must be cautious but not unreasonably so based on scientific evidence lest they forgo the benefits of the technology.

High compliance costs can limit the ability of public sector institutions and small private enterprises to commercialize technologies of public interest (McElroy, 2004; Pew Initiative on Food and Biotechnology, 2004). Costs associated with implementing a regulatory process for a specific transgenic product can be a significant portion of the total costs of bringing the product to market (Jaffe, 2006; Kalaitzandonakes, Alston, & Bradford, 2006; Pray et al., 2005). Some of these costs involve direct expenditures made to comply with biosafety regulations, while others are opportunity costs of benefits foregone due to delays while the product advances through the regulatory process. In evaluating the potential net benefits of genetically modified crops, the magnitude of these costs must be understood, both by countries in the process of designing their regulatory processes, and by those implementing them.

Regulatory costs vary by country and for conditions specific to each GM event—defined as a combination of a specific crop and gene insertion. Several issues affect regulatory costs. For example, cost may decrease if the evaluating country accepts specific biosafety tests for a product already conducted in another country. Different cost structures may occur depending on whether products are developed and tested in the public versus the private sector, are export products, or are consumed as a food, feed, or fiber.

With these considerations in mind, the regulatory costs of four products in the Philippines are examined: Bt eggplant, Bt rice, papaya ring-spot virus-resistant (PRSV) papaya, and multiple-virus-resistant (MVR) tomato. These products differ in terms of previous biosafety tests completed in other countries, export status, degree of private versus public involvement, and importance in domestic food consumption. First, background

Table 1. Cost of compliance with the biosafety regulations in selected countries.

	Crop	Country	Event approved in developed countries	Estimated cost of compliance with biosafety regulations (US$)
Food crop	Maize	India	Yes	500,000 - 1,500,000
	Maize	Kenya	Yes	980,000
	Maize	Philippines	Yes	1,700,000
	Rice	India	No	1,500,000 - 2,000,000
	Rice	Costa Rica	No	2,800,00
	Beans	Brazil	No	700,000
	Mustard	India	No	4,000,000
	Soybeans	Brazil	Yes	4,000,000
	Potatoes	South Africa	Yes	980,000
	Potatoes	Brazil	Yes	980,000
	Papaya	Philippines	Yes	145,000
Non-food crop	Cotton	India	Yes	500,000 - 1,000,000
	Jute	India	No	1,000,000 - 1,500,000
	Cotton	Indonesia	Yes	100,000 - 112,000

Note. Data from Falck-Zepeda (2006) based on estimates from Pray et al. (2005); Quemada (2003); Sampaio (2002); Sittenfeld (2002); Yorobe and Laude (2009), Manalo and Ramon (2007).

information is provided on biosafety regulatory issues, cost of compliance in selected countries, and policy issues faced by developing countries. Second, direct costs are identified, as well as opportunity costs of regulation for the four transgenic products. Third, changes in net economic benefits for these GM crops are calculated, incorporating the cost of compliance with biosafety regulations and R&D costs. The economic implications of delaying the benefit stream due to regulatory delay are considered. Finally, lessons are drawn for the Philippines and for other developing countries with respect to biosafety and biotechnology decision-making.

Biosafety Regulatory Regimes

From the earliest stages of research on specific GM organisms, scientists and policy makers have attempted to design and implement regulatory processes that ensure their proper safety assessment. Biosafety processes formalized in the Cartagena Protocol on Biosafety have now become a pre-requisite for GM research and any release of GM products into the environment. The Biosafety Protocol focuses on the potential effects of GMOs on the environment, although most biosafety regulatory systems have broadened to include food and feed safety and, in some cases, socio-economic considerations and ethics.

Most biosafety systems are sequential learning processes in which the decision whether to advance a product to the next regulatory stage uses knowledge and data accumulated up to the point where the developer submits the application dossier. The developer can generate data and knowledge in country, use data generated elsewhere, or in some cases use data from a related crop (i.e., potato and sweet potato). Countries differ in the extent to which they accept data from other countries. The task of the decision maker—such as a national biosafety or other competent authority—is to decide whether the data submitted are sufficient to demonstrate an established level of safety.

Existing Estimates of the Cost of Compliance with Biosafety Regulations

Estimates of the cost of compliance with biosafety regulations in selected countries are presented in Table 1. The data do not include costs of R&D or technology transfer. They do not consider the time value of money, nor indicate the relative importance of the compliance costs compared to other costs associated with commercializing a new technology. Compliance costs in Table 1 differ by country, crop, and trait. Some of the estimates are ex ante and may reflect optimistic expert opinions.

Total cost of compliance with biosafety regulations is the sum of several distinct activities. These activities are undertaken to collect or generate data and information that can be used to judge specific safety attributes of a technology. Estimates of the total cost of compliance with biosafety regulations broken down by category are presented in Table 2 for three countries: the United States, India and China. Costs included are for

Table 2. Estimated costs of biosafety activities in US, India, and China (US$).

Activity	Cost in US	Cost in India	Cost in China
Molecular characterization	300,000 - 1,200,000		
Toxicology (90-day rat trial)	250,000 - 300,000		14,500
Allergenicity (Brown Norwegian rat study)		150,000	
Animal performance and safety studies	300,000 - 840,000		
Poultry feeding study		5,000	
Goat feeding study—90 days		55,000	
Cow feeding study		10,000	
Fish feeding study		5,000	
Anti-nutrient			1,200
Gene flow		40,000	11,200
Impact on non-target organisms			11,600
Baseline and follow-up resistance studies		20,000	
Protein production/characterization	160,000 - 1,700,000		
Protein safety assessment	190,000 - 850,000		
Non-target organism studies	100,000 - 600,000		
ELISA development, validation, and expression	400,000 - 600,000		
Composition assessment	750,000 - 1,500,000		
Agronomic and phenotypic assessment	130,000 - 460,000	30,000 - 205,000	
Socio-economic studies		15,000 - 30,000	
Facility/management overhead costs	600,000 - 4,500,000		
Total cost of approval	**3,180,000 - 12,550,000**	**195,000**	**53,000 - 90,000**

Note. Data from Kalaitzandonakes et al. (2005) for the US; from Pray et al. (2005) for India; and from Pray, Ramaswami, Huang, Hu, Bengali, and Zhang (2006) for China.

compliance with biosafety regulations and do not include R&D, product development, or commercialization expenses.[1] These cost estimates reflect diverse philosophies and approaches to regulation in different countries and depend on whether the technology developers are from the public (China) or private (United States, India) sector. For example, costs of public sector field trials are not included in the China estimates. Regulators and the regulatory systems in the three countries also differ on the data and information needed to demonstrate reasonable safety. For example, the costs of meeting biosafety rules in China are less than in India.

A study in India by Pray et al. (2005) found private regulatory costs for Bt cotton to be in the neighborhood of $2 million. The study notes, however, that public sector regulatory costs can be lower, in part because the private sector must contract with the public sector for some of the regulatory steps. Results presented below confirm their findings, with regulatory costs estimated at less than $1 million for public sector releases. For many of the products we examine, basic laboratory biosafety tests have already been completed elsewhere, such as for PRSV-resistant papaya. Estimated direct regulatory costs do not appear to be prohibitive given the size of the benefits, assuming product developers can capture the benefits of product deployment. However, costs may increase significantly if regulatory authorities require additional testing beyond what scientists and experts judge to be sufficient to demonstrate safety. The opportunity cost of money invested in biosafety compliance will also increase if regulatory processes incur significant delays.

Methods

Mapping the Regulatory Pathway in the Philippines

We reviewed documents and interviewed government officials, researchers, and other experts in the regulatory process for biotech products to help define the regula-

1. *In some cases, activities during research and product development serve multiple objectives (i.e., data from a confined field trial may be collected for both safety and efficacy purposes), and thus strict separation across regulatory, research, and product development costs is somewhat arbitrary.*

tory process in the Philippines. Those interviewed included: (a) scientists and experts from the Institute of Plant Breeding at the University of the Philippines-Los Baños, The International Rice Research Institute, and the Philippine Rice Research Institute, and (b) regulators from the Department of Science and from the National Committee on Biosafety of the Philippines. The interviews helped identify circumstances in which biosafety and other tests conducted in other countries are accepted and how that acceptance affects the costs. We assessed the costs and time for each of the following regulatory compliance steps.

1. Preparing a project proposal for submission to the Institutional Biosafety Committee (IBC)
2. Submitting a proposal to the IBC, which conducts a risk/benefit assessment and then endorses it to the National Committee on Biosafety of the Philippines (NCBP)
3. Applying to the NCBP for a permit to conduct contained testing
4. Applying to the Department of Agriculture, Bureau of Plant Industry (DA-BPI) for a field testing permit after contained testing is complete and successful (tests related to gene flow, food safety, toxicity, efficacy, and other environmental tests), conditional on endorsement by the NCBP
5. BPI creates a Scientific and Technical Review Panel (STRP) concurrent with public notification by the IBC, and the STRP evaluates potential adverse effects to humans and the environment
6. Risk assessment by STRP and the BPI-Core Biotechnology Team (BPI-BCT)
7. Conducting a single field test and then multiple location field testing with each field evaluated separately once there is receipt of a field test permit
8. Obtaining a permit for release for propagation and commercialization

Each step in the regulatory process allows for increased exposure of the transformed product to people and to the environment. A detailed description of the regulatory process can be found on the Department of Science and Technology's NCBP website[2] and is summarized in Chapter 1 in Norton and Hautea (2009). The NCBP is primarily responsible for regulating the development and release of transgenic products until the point in the process in which the products have contact with the environment. At that point, the regulatory responsibility shifts to the Bureau of Plant Industry.[3]

Economic Surplus Models Augmented with Inclusion of the Cost of Compliance

Economic surplus models were run for each of the four GM crops to evaluate the impacts of introducing these technologies in the Philippines. These models built on those in previous studies by Yorobe (2006) for papaya, Mamaril and Norton (2006) for rice, Mamaril (2005) for tomato, and Francisco (2006) for eggplant. Modifications included more specific accounting for regulatory lags and the cost of compliance with biosafety regulations.

The equations included in the models, following Alston, Norton, and Pardey (1995), depict specific markets in the Philippines and whether the benefits accrue to consumers, producers, or innovators. We also estimated the net present value (NPV) and internal rate of return (IRR) of net benefits. Net benefits were defined as the sum of changes in annual total economic surplus minus R&D and regulatory costs. We assumed a small open economy for papaya and rice and a closed economy for tomato and eggplant. The Philippines has active trade in rice and papaya, but the volume is small relative to world markets, and it trades little of its tomato and eggplant production. The counterfactuals in the surplus models were current varieties, as one reason these traits were chosen for transgenic research was the difficulty in addressing them through conventional breeding in a reasonable period of time.

Economic surplus models have a well documented set of limitations and require numerous assumptions (Alston et al., 1995). Therefore the models were run allowing basic assumptions to vary, including regulatory costs and time required for regulatory steps. Assessment of net benefits under various scenarios allowed for calculation of opportunity costs associated with regulatory time lags. We assumed that each scenario started in 2005, except for papaya which started in 2003. The adaptive R&D stage lasted from 3-7 years depending on the product, and the biosafety regulatory assessment stage was assumed to last 6-8 years. Adoption was

2. *http://www.ncbp.dost.gov.ph/.*

3. *The NCBP and the BPI regulate bioengineered crops under the authority of Executive Order (EO) 430 of 1990 (superceded by EO 514 of 2007) issued by the Office of the President of the Philippines and DA Administrative Order 8 Series of 2002 (DA-AO 9) of the Plant Quarantine Act.*

assumed to follow a sigmoid pattern, with a maximum adoption rate that varied by scenario.

Estimation of Supply Shifts

In the economic surplus models used in this article, the parameter K measures the vertical shift of the supply curve as a proportion of the pre-innovation price, while Z measures the reduction in price relative to the initial (pre-innovation) price. Formulas for estimating changes in producer, consumer, and total surplus use the parameters K and Z, which are calculated as

$$K_{t,i} = \left[\left[\frac{\Delta Y_{t,i}}{\varepsilon_i} + \frac{\Delta C_{t,i}}{(1+\Delta Y_{t,i})} \right]\right] \times R_i \times A_{t,i} \text{ and} \quad (1)$$

$$Z_{t,i} = \frac{K_{t,i}\,\varepsilon_i}{\varepsilon_i\,\eta_i} = -\frac{P_1 - P_0}{P_0}. \quad (2)$$

For every year t and crop i, $K_{t,i}$ is the proportionate shift of the supply curve relative to the pre-innovation price, $\Delta Y_{t,i}$ is the expected yield difference between the GM crop and its conventional counterpart, ε_i is the elasticity of supply, $\Delta C_{t,i}$ is the cost difference between the GM crop and its conventional counterpart, $R_{t,i}$ is the probability of R&D success, and $A_{t,i}$ is the adoption rate. We did not include a potential technology fee that might be charged to farmers because the technologies are likely to be provided by the public sector.

Estimating Consumer, Producer, and Total Surplus

The formulas for estimating changes in producer, consumer, and total surplus in the closed economy model for year t and crop i are

$$\Delta CS_{t,i} = P_0\,Q_0\,Z_{t,i}\,(1 + 0.5\,Z_{t,i}\,\eta_i), \quad (3)$$

$$\Delta PS_{t,i} = P_0\,Q_0\,(K_{t,i} - Z_{t,i})\,(1 + 0.5\,Z_{t,i}\,\eta_i), \text{ and} \quad (4)$$

$$\Delta TS_{t,i} = P_0\,Q_0\,K_{t,i}\,(1 + 0.5\,Z_{t,i}\,\eta_i). \quad (5)$$

The formulas for estimating changes in producer, consumer and total surplus in the small-open economy model are:

$$\Delta CS_{t,i} = 0 \quad (6)$$

$$\begin{aligned}\Delta PS_{t,i} = \Delta TS_{t,i} &= P_w\,Q_0\,K_{t,i}\,(1 + 0.5\,K_{t,i}\,\varepsilon_i) \\ &= P_0\,Q_0\,K_{t,i}\,(1 + 0.5\,K_{t,i}\,\varepsilon_i),\end{aligned} \quad (7)$$

where $\Delta CS_{t,i}$ is the change in consumer surplus, $\Delta PS_{t,i}$ is the change in producer surplus, $\Delta TS_{t,i}$ is the change in total surplus, ε_i is the elasticity of supply, η_i is the elasticity of demand, P_0 is the pre-innovation price, Q_0 is the pre-innovation quantity produced, P_w is the world price, and $Z_{t,i}$ and $K_{t,i}$ are defined above.

Estimating Change in Net Benefits

The equation to calculate undiscounted total net benefits (N_t^B) is

$$N_{t,i}^B = \Sigma_{t=1}^{n}\,(\Delta PS_{t,i} + \Delta CS_{t,i} - C_{t,i}^{\mathrm{RD}} - C_{t,i}^{Reg}), \quad (8)$$

where $C_{t,i}^{\mathrm{RD}}$ is the cost of research and development, and $C_{t,i}^{Reg}$ is the cost of regulations in year t and crop i. The NPVs were calculated by discounting the streams of net benefits at 5%.

Results

We can categorize the major activities for which there are significant regulatory costs into four groups: (a) contained laboratory and green house testing; (b) confined field trials; (c) multi-location field trials; and (d) other costs prior to commercialization, such as those incurred to obtain permits (Table 3). Based on information from the sources described above, estimated R&D costs vary from $129,600 for papaya to $888,750 for rice, while total regulatory costs vary from $249,500 for papaya to $690,680 for rice. The two field-trial activities represent the majority of the regulatory costs. Scientists and other experts projected the time required for each step. The number of years for each regulatory activity differs by commodity due to factors such as differing stages in which the technologies were received by scientists in the Philippines and the length of time it takes to obtain one generation of the crop.

PRSV-resistant papaya, MVR tomato, and Bt eggplant are being developed and tested by researchers and scientists at the University of the Philippines-Los Baños. Transformed papaya and eggplant have undergone confined field trials. MVR tomato is not as far along in the regulatory process, but should follow a similar pattern to Bt eggplant. Bt rice has been developed and tested at the Philippine Rice Research Institute (PhilRice) located in Nueva Ecija. Much of the regulatory activity on Bt rice has occurred over a 3-year period. Confined screen-house testing in the first year cost $20,800, while the second year confined field-testing cost $446,700. Scientists project multi-location field-testing costs at $105,000 per year. Projected cost

Table 3. Estimated R&D costs and costs of compliance with biosafety regulations.

	Cost/year (US$)	Activity duration (years)	Total (US$)
	Bt eggplant		
R&D costs	40,000 - 100,000	6	240,000 - 600,000
Regulatory costs			
Laboratory/greenhouse	90,000	2	180,000
Confined field trial	100,000	1	100,000
Multi-location field trial	100,000	1	100,000
Commercialization costs	95,000	1	95,000
Total *regulatory* costs			**475,000**
	MVR tomato		
R&D costs	62,000	7	434,000
Regulatory costs			
Laboratory/greenhouse	90,000	2	180,000
Confined field trial	100,000	1	100,000
Multi-location field trial	100,000	1	100,000
Commercialization costs	95,000	1	95,000
Total *regulatory* costs			**475,000**
	Bt rice		
R&D costs	296,250	3	888,750
Regulatory costs			
Laboratory/greenhouse	20,800	1	20,800
Confined field trial	446,700	1	446,700
Multi-location field trial	105,000	2	210,000
Commercialization costs	13,180	1	13,180
Total *regulatory* costs			**690,680**
	PRSV-resistant papaya		
R&D costs	32,400 - 41,700	4	129,600 - 166,800
Regulatory costs			
Laboratory/greenhouse	16,000	3	48,000
Confined field trial	43,300	2	86,600
Multi-location field trial	41,700	2	83,400
Commercialization costs	31,500	1	31,500
Total *regulatory* costs			**249,500**

Note. Data are from interviews with scientists and regulators in the Philippines. In each case, the multi-location field trial involved two sites and two seasons during the year. It was part of a broader variety trial that involved more sites and years. The costs of these other trials are not included here as they would have been incurred anyway.

for commercialization and public release is $13,180 (Table 3).

Regulatory cost estimates for PRSV-resistant papaya are lower than those for other transgenic products in the literature discussed earlier in this article. Some of the lower costs in the Philippines are due to the fact that the products submitted for regulatory approval have passed the regulatory processes in other countries and the Philippines' regulatory system allows submission of such data. Our estimates are slightly lower than those by Yorobe and Laude (2009), who estimated direct regulatory costs of $365,000 for PRSV-resistant papaya in the Philippines in 2008.

A set of the base assumptions used for the economic surplus analysis is presented in Table 4. Rice production is substantial in the Philippines and adoption of Bt rice is projected to be significant despite a relatively low yield increase. According to the experts, however, adoption is projected to be more gradual than for the other products, perhaps due to the small yield effect. Because

Table 4. Basic assumptions in the economic surplus models.

	Bt eggplant	MVR tomato	Bt rice	PRSV-resistant papaya
Quantity (MT)	182,750	152,690	10,500,000	159,000
Price (US$/MT)	200	215	180	363
Supply elasticity	0.5	0.75	0.95	0.80
Demand elasticity	-0.80	-0.45	-0.30	-1.0
Change in yield (%)	40	67	2.4	77
Change in costs (%)	-16	-10	0	8
Probability of success (%)	70	50	100	83
Maximum adoption (%)	50	70	66	80
Years to first adoption	9	12	8	10
Years to max adoption	14	14	15	15

Table 5. Results from net benefit analysis (US$).

	Bt eggplant	MVR tomato	Bt rice	PRSV-resistant papaya
Change in total surplus	40,813,627	34,240,196	481,723,200	171,976,074
Change in consumer surplus	15,697,549	21,400,122	0	0
Change in producer surplus	25,116,078	12,840,073	481,723,200	171,976,074
Total R&D and regulatory costs	1,055,000	909,000	1,579,430	368,870
NPV of change in net benefits (using a 0% discount rate)	39,758,627	33,331,196	480,143,791	171,606,204
NPV of change in net benefits (using a 5% discount rate)	20,466,196	16,748,347	220,373,603	90,765,793

Note. Change in net benefits is defined as total benefits estimated using the economic surplus model minus total research and regulatory costs. NPV is calculated with a discount rate of 5%.

Bt rice exists and is partially through the regulatory process, the experts were confident it would be successful and gave it a probability of research success of 1. MVR tomato is the product that is farthest away from the market.

The NPV of benefits minus costs over 20 years, beginning from inception of the research (discounted at 5%), varied from $17 million for tomato, $20 million for eggplant, $220 million for rice, and $90 million for papaya (Table 5). We conducted sensitivity analyses to examine the effect of varying the elasticity of supply and the discount rate. A smaller price elasticity of supply or a smaller discount rate increases benefits significantly.

Key sensitivity analysis was used to evaluate the effects of increasing regulatory costs and altering the time required for regulatory approval and, hence, adoption of the technologies by farmers (Table 6). Effects on total net benefits in each case were small, even with quadruple increases in regulatory costs. The results indicated less than a US$1 million change in NPV in most cases. The decrease in the NPV—with respect to the baseline—varied from a 1% decrease for the rice and papaya technologies to a 7% decrease in the case of MVR tomato. These losses are small compared to the losses (opportunity costs) that were incurred when commercialization was delayed by 1, 2, or 3 years due to regulatory delays beyond the expected timeframe (see Table 6). In each case, several million dollars were lost due to regulatory delay. A 1-year delay in the onset of benefits resulted in a 12% decrease in the projected NPV for Bt rice and up to a 36% decrease for MVR tomato. A 3-year regulatory delay would decrease the NPV compared to the baseline by 34% for Bt rice and 93% for MVR tomato. A combined increase in the cost of regulations and a regulatory delay would increase losses even more, albeit by a small proportion. The basic Excel spreadsheets used for the analysis are available from the authors for anyone desiring to duplicate or conduct additional sensitivity analyses.

As delays in regulatory approval are so important in terms of their effect on the NPV of benefits to society, what might be the sources of such delays? Some of the potential sources include test repetition, slow review time, and requests by regulators for additional information—especially beyond information required to demonstrate safety—and lack of clarity with respect to the

Table 6. Sensitivity analysis of the Net Present Value (NPV) of benefits minus costs under varying assumptions on regulatory costs and time lags (US$).

	Bt eggplant	MVR tomato	Bt rice	PRSV-resistant papaya
Baseline NPV of change in net benefits	20,466,196	16,748,347	220,373,603	90,765,793
	NPV with changing cost of biosafety compliance			
75% higher	20,550,612	16,529,580	219,976,847	90,633,007
200% higher	20,128,529	16,164,968	219,315,587	90,411,698
400% higher	19,435,196	15,581,590	218,257,570	90,097,124
	NPV with changing regulatory time lag			
1 year longer	14,707,235	10,656,533	193,926,128	66,362,939
2 years longer	8,931,527	4,854,806	168,738,056	46,060,500
3 years longer	4,242,285	1,110,757	144,749,416	29,540,365

Note. Discount rate for the NPV calculation is 5%.

regulatory requirements. Another source is political interference in the biosafety regulatory process.

One example of a factor that can cause a time delay in the case of the Philippines is the potential request by the NCBP for more information from a previous generation undergoing testing. Under the containment rules, it is required that each generation of the plant, T_n, be destroyed once all tests are completed and the next generation, T_{n+1}, has been produced. If there is an information request from the T_0 generation when the scientists are testing the T_3 generation, T_3 then reverts back to the T_0 generation and the developer has to produce three more generations of the plant product, resulting in a time loss of three growing seasons. With a 3-month growing season, the result would be a loss of one year. In the case of a 1-year growing season such as with papaya, the result could be a loss of three years.

Test duplication is another potential source of time delay in the Philippines. An example of this is the agromorphology requirement (or parent to progeny test) that is being duplicated by separate tests. A lack of clarity in terms of regulatory requirements creates time delays by encouraging scientists to gather extra information in anticipation of possible later requests by regulators. This information gathering of course increases the cost of compliance and total development costs. Another example is the inherent delay created by the NCBP review panel schedule, as it meets only once per month. Each time the NCBP requests information about a product under review, there is a delay of at least one meeting, implying a delay of at least one month. In many cases this delay can be avoided by the attendance of a researcher at the NCBP meeting so he or she can answer questions the panel may have about the product that do not require further testing.

Implications for Developing Countries

Other developing countries can learn from the regulatory experience in the Philippines. To date, the Philippines has approved GM products for importation as food/feed in six crops and approved confined field trials for three crops, yielding 51 events assessed for biosafety issues in the country (AGBIOS, 2010). The Philippines has one of the more advanced and experienced regulatory systems in developing countries. Even in such a highly functional system, however, items remain to be refined to ensure functional, enabling, and protective biosafety systems (Jaffe, 2006). Other developing countries should consider issues discussed in this article when deliberating their own biosafety issues. Biosafety regulatory systems are themselves learning processes, as they regulate a rapidly changing product—biotechnology.

A high cost of compliance with biosafety regulations may deter a small firm or public-sector institution from pursuing GM technologies, or may cause them to abandon or delay commercialization of potentially valuable products. Compared to large multinational corporations, these firms or the public sector may have less financial flexibility to absorb regulatory delays, during which funds spent on compliance with biosafety regulations are sunk costs until the regulatory authority renders its decision.

Beyond the impact of regulatory delays, uncertainty in terms of time needed to complete the biosafety regulatory process may also deter public-sector institutions or small private firms from considering GM technologies as a potential solution to agricultural problems.

It is essential that regulatory systems ensure that all steps are in place to guarantee biosafety. They must also work to ensure that none of the steps in the regulatory

process for GM products is unnecessary for demonstrating safety or efficacy. The various activities conducted for research, product development, and regulatory compliance can be complementary, and hence there are potential gains for regulators and developers, especially for public-sector and small private institutions, to coordinate their activities. Biosafety assessment can support product development while ensuring product safety.

Even with the most sophisticated regulatory process in place for GM crops, in the end, political considerations often come into play. Those considerations can affect decisions by regulatory committees or even surface after the regulatory process has been completed. For example, on February 9, 2010, the Government of India placed a moratorium on commercial release of Bt eggplant despite its having met the existing requirements of a rigorous regulatory system (Inform, 2010). Because Bt eggplant would have been the first GM vegetable crop released in a developing country, the Indian Environment Minister who issued the moratorium felt that India had to be extremely cautious (Inform, 2010). Thorough testing for biosafety is essential, but this article illustrates that extreme caution can come at a sizable cost.

Concluding Comments

The key contributions of this article are to document the nature and size of regulatory costs for different types of genetically modified crops in the Philippines, estimate opportunity costs of delays for comparative purposes, and summarize potential impacts of several different transgenic products. The Philippines is an excellent case study because the country has several GM products already undergoing the regulatory testing and approval process, has already released Bt maize for commercialization, and has experience with biosafety evaluations of commodity imports.

Regulatory costs also appear to be declining within countries as they gain experience with more products, even if the regulatory framework is constant. Changes to any regulatory framework can introduce benefits or costs. Estimates in this article indicate that the largest potential constraint to commercialization of transgenic products is regulatory delay, which may significantly reduce their net benefits.

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