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The Cost of Biotechnology Regulation in the Philippines

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The Cost of Biotechnology Regulation in the Philippines

Modern agricultural biotechnologies, including Genetically Modified (GM) crops, have demonstrated their potential to provided significant benefits for developing countries. However, many developing countries lack functional and enabling regulatory processes that allow the release of GM crops into the environment. A suitable regulatory process has been deemed necessary by international agreements and national governments for the safety of those who consume genetically modified organisms (GMOs) as well as for the environment that might be affected by these products. Each nation needs a set of regulations that are both protective and efficient. In setting regulations, countries must be cautious but not overly restrictive unless they intend to delay or even forgo the benefits of the technology.

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 (Jafee 2006; Pray, Bengali, and Ramaswami 2005). Some of these costs involve direct expenditures made to comply with biosafety regulations while others are opportunity costs of benefits foregone from the product being delayed while advancing through regulatory processes needed for commercialization approval. In evaluating the potential net benefits of genetically modified crops, it is important to understand the magnitude of these costs, both for countries still in the process of designing their regulatory processes, and for those implementing their own.

Regulatory costs vary by country and for conditions specific to each GM event - defined as a combination of a specific crop and gene. For example, costs can be affected

if certain bio-safety tests for a product have already been conducted in other countries and are accepted in an evaluating country, the product has been developed and tested in the public versus the private sector, the product will be exported, and the product is consumed as a food as opposed to a feed or a fiber product. The products examined in this paper: *Bt* eggplant, *Bt* rice, ring-spot virus resistant (RVR) papaya, and multiple-virus resistant (MVR) tomato, in the Philippines, differ in the amount of previous bio-safety testing in other countries, in their export status, degree of private versus public involvement, and their importance in domestic food consumption.

This paper provides background on bio-safety regulatory issues, cost of compliance in selected countries, and policy issues faced by developing countries. It identifies and estimates the direct costs and opportunity costs of regulation for four transgenic products in the Philippines. It provides estimates of changes in economic surplus for those crops that incorporate the cost of compliance with bio-safety regulations and R&D costs. The implications of delaying the benefit stream due to regulatory delay are considered. Finally, lessons are drawn for the Philippines and other developing countries with respect to bio-safety issues.

The paper finds that direct regulatory costs while significant, are similar in magnitude or smaller than the research costs for technology development. However, both research and regulatory costs are overshadowed by even a relatively short delay in product release, which might be caused by an unexpected regulatory delay. The opportunity cost of benefits foregone due to non- or delayed approval during a bio-safety regulatory assessment are significant, and thus an important issue for debate and

reflection in developing countries contemplating the use of GM technologies.

Bio-safety Regulatory Regimes

During the earliest stages of the discovery and R&D process, the novelty of GM organisms led scientists and policy makers to design and implement regulatory processes that would ensure proper safety assessments and decision making. Bio-safety processes formalized in the Cartagena Protocol on Bio-safety, have now become pre-requisite for GM research and release into the environment. The Bio-safety Protocol focused on the potential effects of GMOs on the environment. Nevertheless, most bio-safety regulatory systems have broadened their scope of action to include food and feed safety and, in some cases, other considerations such as socio-economics and ethics.

Most bio-safety systems are sequential learning processes where the knowledge and data accumulated in a regulatory stage are used to decide whether the product advances to the next regulatory stage. The data and knowledge may be generated within the country or outside it for the specific application or for a related crop (i.e. potatoes and sweet potatoes). The task of the decision maker, in this case a national bio-safety authority, is to decide whether the data submitted are sufficient to demonstrate an established level of safety.

Previous Evidence on Cost of Compliance with Bio-safety Regulations

Estimates of the cost of compliance with bio-safety regulations in selected countries are presented in Table 1. These data do not include the cost of R&D or technology transfer to producers. It is clear that the cost of compliance varies across countries, crops, and traits.

These estimates do not take into account the time value of money, nor indicate the relative importance of the costs of compliance compared to other costs of commercializing a new technology in a particular country.

The total cost of compliance with bio-safety regulations is the sum of a set of distinct activities performed during a bio-safety assessment. These activities are undertaken to collect or generate data and information that will be used to judge specific safety attributes of a particular technology. The total cost of compliance with bio-safety regulations for three countries: the United States, India and China, are presented in Table 2. These cost estimates reflect the diverse philosophies and approaches to regulation in the selected countries.

Table 1. Cost of Compliance with the bio-safety regulations in selected countries[1]

Type of Crop (example)	Crop	Country	Event approved in Developed Countries	Estimated Costs of Bio-safety Regulations (US$)
Food Crop	Maize	India	Yes	500,000 - 1,500,000
	Maize	Kenya	Yes	980,000
	Rice	India	No	1,500,000- 2,000,000
	Rice	Costa Rica	No	2,800,00
	Beans	Brazil	No	700,000
	Mustard	India	No, have to seek approval in export markets	4,000,000
	Soybeans	Brazil	Yes	4,000,000
	Potatoes	South Africa	Yes	980,000
	Potatoes	Brazil		980,000
	Papaya	Brazil	Yes	
Non-Food Crop	Cotton	India	Yes	500,000 - 1,000,000
	Jute	India	No	1,000,000 - 1,500,000

1. Compilation presented in Falck Zepeda (2006) based on estimates from Quemada (2004), Odhiambo (2003), Sampaio(2002), Sittenfeld(2002), and Pray, Bengali and Ramaswamy (2004).

Regulators and the regulatory systems in the three countries may have differing views on the data and information needed to demonstrate reasonable safety. Note the smaller costs of meeting bio-safety rules in China as compared to India. This difference may also reflect assessment cost differences for the public as opposed to the private sector.

Table 2. Estimated Costs per Bio-safety Activities for U.S., India and China[1]

Activity	Cost Ranges USA (US$)	Cost estimates India (US$)	Cost estimates China (US$)
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 Approval		195,000	

1. Compilation presented in Falck Zepeda (2006) based on estimates for USA by Kalatzaidonakes, Alston and Bradford (2005); for India by Pray, Ramaswamy, and Bengali (2004); and for China, Pray et al. (2006).

Table 3. Cost of compliance with bio-safety regulations in Indonesia and the Philippines[1]

Country	Technology	Developer	Present value of cost (US$)
Philippines	Golden Rice	IRRI	104,698
	Bacterial blight resistant rice (Xa-21)	Phil-Rice	99,213
	Bt maize	Monsanto	1,690,000
Indonesia	Bt cotton	Monsanto	99,870
	Herbicide resistant cotton	Monsanto	112,480
	Bt rice	RCB-IIS / LIPI	64,730
	Drought tolerant sugarcane	PTPN XI Perseroan Terbatas Perkebunan Negara - Government Enterprise for Estate Crops	98,879
	Transgenic Citrus Resistant to CPVD	Udayana University	Abandoned

Note: Source: Falck Zepeda (2006).

Methods

The steps in the regulatory process and its direct costs and timing were defined for the Philippines through review of documents and interviews with government officials, researchers, and other experts in the regulatory process for biotech products 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 Bio-safety of the Philippines. The interviews helped identify circumstances in which bio-safety and other tests conducted in other countries are accepted and how that acceptance affects the costs. The costs and time associated with each of the following steps were assessed:

1. Preparing a project proposal for submission to the Institutional Bio-safety Committee (IBC),
2. Submitting a proposal to the IBC which conducts a risk/benefit assessment and then submits it to the National Committee on Bio-safety of the Philippines (NCBP),
3. NCBP 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,
4. Applying to the Bureau of Plant Industry (BPI) for contained testing and incorporation of regulated articles, conditional on endorsement by the NCBP,
5. Risk assessment by BPI,
6. Applying to BPI for a field testing permit after contained testing is complete and successful (tests relate to gene flow, food safety, toxicity, efficacy, and other environmental tests),
7. Single field and then multiple location field testing with each field evaluated separately once there is receipt of a field test permit, and
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: http://www.ncbp.dost.gov.ph/. 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.

Once estimates of the costs of these steps were collected, economic surplus models were run to evaluate the economic impacts of introducing each of the GM products. These models built upon previous studies by Yorobe (2006) for Papaya, Mamaril and Norton (2006) for rice, Mamaril (2005) for tomato, and Francisco (2006) for eggplant. The results of their analyses were duplicated. These authors' models assumed small open economies for papaya and rice and closed economies for tomato and eggplant. Assumptions in these models were then updated and regulatory costs were introduced in addition to research and development costs. The models were run allowing basic assumptions to vary, including regulatory costs and the time lags for regulatory steps. Assessment of net benefits under various scenarios allowed for calculation of opportunity costs associated with regulatory time lags.

Results

The major activities for which there are significant regulatory costs can be categorized into four groups: a) contained laboratory and screen house testing, b) confined field trials, c) multi-location field trials, and d) other commercialization costs (Table 4). Based on information from the sources described above, total estimated regulatory costs vary from $248,500 for papaya to $690,000 for rice (Table 5). The two field trial activities represent the majority of the 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. Details for each crop are given in Bayer (2007). Total estimated research costs are similar in size to regulatory costs, and vary from $120,000 for papaya (significant research results transferred in from abroad) to $890,000 for rice.

Table 4. Regulatory costs (US$) and time

	Cost/year	Years	Total cost
Bt eggplant			
Containment	90,000	2	180,000
Limited field trial	100,000	1	100,000
Multi-location field trial	100,000	1	100,000
Commercialization costs	95,000	1	95,000
MVR tomato			
Containment	90,000	2	180,000
Limited field trial	100,000	1	100,000
Multi-location field trial	100,000	1	100,000
Commercialization costs	95,000	1	95,000
Bt rice			
Containment	20,800	1	20,800
Limited field trial	446,700	1	446,700
Multi-location field trial	105,000	2	210,000
Commercialization costs	13,180	1	13,180
RSV papaya			
Containment	16,000	3	48,000
Limited field trial	43,300	2	86,600
Multi-location field trial	41,700	2	82,400
Commercialization costs	31,500	1	31,500

Table 5. Basic assumptions in economic surplus models

	Bt eggplant	MVR tomato	Bt rice	RSV papaya
Quantity (MTs)	182,750	152,690	10,500,000	159,000
Price (US$/MT)	200	215	180	363
Supply Elasticity	.5	.75	.95	.80
Demand Elasticity	-.80	-.45	-.30	-1.0
Change in yield %	40	67	2.4	77
Change in costs %	-16	-10	0	8
Prob. Of success %	70	50	100	83
Max adoption %	50	70	66	80
Years to first adopt	9	12	8	10
Years to max adopt	14	14	15	15
Total research cost	$580,000	$434,000	$888,729	$120,370
Total regulatory cost	$475,000	$475,000	$690,680	$249,500

RSV 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 are now in confined field trials. It is expected that regulatory costs for MVR tomato will follow a similar pattern to that of *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 occurred over a 3 year period. Confined screen house testing in the first year cost $20,800, while the second year contained field testing cost $446,700. Multi-location field testing is projected to cost $105,000 per year. Commercialization and public release were projected to cost $13,180 (Table 4).

A large set of assumptions is required for am economic surplus analysis, and several of the most important ones are listed in table 5. Rice production is substantial in the Philippines and adoption of *Bt* rice is projected to be significant despite a relatively

low impact on yield. According to the experts consulted, adoption is projected to be more gradual however, than for the other products, perhaps due to the small yield effect. Because *Bt* rice exists and is part way through the regulatory process, the experts were confident it would be a successful and gave it a probability of research success of 1. MVR tomato is the product that is farthest away from the market.

The net present value of benefits minus costs over 20 years, beginning from inception of the research (discounted at 5%), varied from $17 million for tomato, to $20milion for eggplant, to $220 million for rice, to $90 million for papaya (Table 6). A variety of sensitivity analyses were conducted, such as varying the elasticity of supply and the discount rate. They had predictable effects on benefits, such as smaller supply elasticity or a smaller discount rate increasing benefits significantly.

Table 6. Economic surplus results (US$)

	Bt eggplant	**MVR tomato**	**Bt rice**	**RSV papaya**
Total benefits	40,813,627	34,240,196	481,723,200	171,976,074
Consumer benefits	15,697,549	21,400,122	0	0
Producer benefits	25,116,078	12,840,073	481,723,200	171,976,074
NPV of benefits minus costs (at 0% Dis. rate)	39,758,627	33,331,196	480,143,791	171,606,204
NPV of benefits minus costs (at 5% Dis. rate)	20,466,196	16,748,347	220,373,603	90,765,793

However, the key sensitivity analyses were 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 7). Even when regulatory costs were doubled or quadrupled, effects on total net benefits in each case were small, less than 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 were 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 (Table 7). In each case, several million dollars were lost due to regulatory delay. A one year delay in the onset of benefits induced a 12% decrease in the projected NPV for *Bt* rice and up to a 36% decrease for MVR tomato. A three 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.

Table 7. Sensitivity analysis (NPV of benefits minus costs under varying assumptions on regulatory costs and time lags) (US$)(Discount rate = 5%)

	Bt eggplant	**MVR tomato**	**Bt rice**	**RSV papaya**
Baseline	20,466,196	16,748,347	220,373,603	90,765,793
Reg. costs				
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
Reg. 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

The potential sources of regulatory delays include the repetition of tests, review time by the NCBP, information requests by regulators, and lack of clarity with respect to the requirements of the NCBP. One example of a factor that can cause a time delay is an NCBP request of more information from a previous generation. Under the containment rules of the NCBP, it is required that each generation, Tn, of the plant be destroyed once any and all tests are completed and the next generation, Tn+1, has been produced. In the instance of an information request from the T0 generation when the scientists are testing the T3 generation, T3 then reverts to being the T0 generation and three more generations of the plant must be produced, 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 would be a loss of 3 years.

The duplication of tests is another potential source of time delay. An example of this is the agro-morphology, 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 the NCBP. An inherent delay is created by the NCBP review panel schedule, as it meets only once a 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.

An additional issue with regard to implications of the cost of compliance with bio-safety regulations is the potential “barrier to entry” they may create for small private

firms and even the public sector in developing countries. The cost of compliance with bio-safety regulations may be high enough that it deters a firm or institution from pursuing GM technologies, or to abandon or delay commercialization of potentially valuable products. Compared to large multinational corporations, neither small firms nor the public sector may have the cash flow and budget flexibility to absorb regulatory delays, during which financial resources spent on compliance with bio-safety regulations are frozen until a regulatory decision is made by the proper authority. For technologies that are public goods, especially those that are pro-poor, finding resources to pay for regulatory compliance is critical.

The uncertainty that surrounds a regulatory outcome may also serve as a deterrent to public sector institutions or small private forms to consider GM technologies as a potential solution to agricultural problems. Innovation may be unnecessarily stifled in a particular country unless it is careful to make certain that none of the steps in its regulatory process for GM products are trivial or unnecessary.

Conclusion

The key contributions of this paper are to document the nature and size of regulatory costs for different types of genetically modified crops in a developing country setting, 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* corn for commercialization, and has experience with bio-safety evaluations of commodity imports.

A study in India by Pray, Bengali, and Ramaswami previously found private regulatory costs for *Bt* cotton in the neighborhood of $2 million. That 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. Our results confirm their hypothesis, with regulatory costs running less than $1 million. Especially for products for which many of the basic laboratory bio-safety tests have already been completed elsewhere, such as in the RSV papaya case, direct regulatory costs do not appear to be prohibitive given the size of the benefits, assuming the benefits can be captured by those commercializing the product. Estimates presented in this paper indicate that the bigger constraint to release of transgenic products is the risk of regulatory time delays, which induces significant reduction in the level of benefits.

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