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**The Cost of Compliance with Biosafety Regulations in Indonesia and The Philippines****Identifier**

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## **The Cost of Compliance with Biosafety Regulations in Indonesia and The Philippines<sup>1</sup>**

Jose Falck-Zepeda, Jose Yorobe, Abraham Manalo, Godfrey Ramon, Bahagiawati Amirsuhin, Erna M. Lokollo, Sutrisno, Supriyati, Patricia Zambrano

The rate of development and diffusion of biotechnology innovations including genetically modified organisms in agriculture has increased in recent years. This is indirectly evidenced by the increasing area dedicated to the commercial or pre-commercial planting of transgenic crops in several countries including the Philippines, Indonesia and others (James, 2005). Additionally, the benefits realized from the introduction of agricultural biotechnology in some countries have motivated some developing countries to invest in the creation of other biotechnology innovations, which are in the development and/or biosafety regulatory evaluation and approval stages (Atanassov, et al, 2004). Biosafety regulations rose from the concern of scientists and decision makers over the novelty and limited information available related to the biosafety profile of GM biotechnologies. Several countries, particularly those who signed and ratified the Cartagena Protocol, enacted regulations for assessing, managing and communicating the risk assessment and posterior decision making for Genetically Modified crops (Mendoza, 2005).

One issue of concern for decision and policy makers may be that the compliance with biosafety regulations increases the cost and time needed for these technologies to be

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eventually commercialized in the market<sup>1</sup>. However, the previous statement needs to be firmly set within the context of technology investments and strategic decision making. Common to all innovations, the R&D needed to create modern biotechnology innovations and its posterior deployment to farmers, is a long and costly endeavor. The seemingly high cost of developing and deploying GM innovations is not – and should not be – the only focus for the decision makers' analysis. Rather, the need arises to focus attention in contrasting (high) costs of R&D (including biosafety) with the expected level benefits that may accrue to farmers through the use of the technology. In essence implies contrasting the cost of R&D and compliance with regulations and technology transfer, to the benefits of adopting the technology in a (hopefully strategic) investment analysis framework.

This paper is structured as follows: First we describe the current status of biotechnology and biosafety in both countries. Second we present the data collected for the cost of compliance with biosafety regulations and development in Indonesia for potatoes resistant to fungi/nematodes, insect resistant cotton, drought tolerant sugarcane and insect resistant rice bioinnovations.<sup>2</sup> In the Philippines we collected data on the delayed ripening papaya, insect resistant (Bt) maize, Golden Rice and bacterial leaf blight resistant (Xa21) rice. These technologies highlight cross-cutting issues that include different traits, crops, institutional and governance issues, and stage of technological development. Finally we proceed to draw a set of policy and biosafety decision making implications to be addressed by regulatory bodies in both countries. We expect that these case studies will contribute to understanding the economics of biosafety regulations and

thus lead to refinements of the current functioning regulatory process in The Philippines and Indonesia that in turn will contribute improving further their efficiency. The ultimate goal of any review of a regulatory system is identifying ways to attain cost containment; that is, achieving an efficient and socially accepted level of biosafety while minimizing cost (Jaffe 2006). Across countries, this cost will depend to a large extent on the adopted regulatory framework which in turn varies significantly given the diverse environment, resources, capacities, culture, and societal concerns.

### **Methodology**

Estimating the cost of compliance with biosafety regulations and total cost of product development will always be controversial. There are significant methodological questions regarding attribution of costs and use of generally accepted standard accounting practice in the estimation of such costs. Issues, such as inclusion of the cost of failed technologies during the R&D and regulatory process to be charged to successful technologies sold to consumers, calculating the opportunity financial cost to society are also controversial; yet are standard practice in accounting.

The most controversial aspect, however, of estimating the cost of regulation of GM technologies (or of any regulated technology) is determining whether a particular activity is a biosafety compliance cost versus a product development cost. Alternatively, this issue can be framed within the question of whether a specific activity is necessary (or sufficient) to demonstrate safety or was done to fulfill other development objectives. There is simply no clear cut rule that allows the analyst to identify costs into one category or the other, in fact there are several alternatives, which are equally controversial.

Most analysts choose a set of heuristics (“rules of thumb”) that guide the process of determining whether a particular activity falls under regulatory compliance and thus assign a cost of regulation. In this sense, we choose to base our methodology partially in the process described by DiMasi (2003a, 2003b), those followed by the Activity Based Accounting methodologies used by the firm KPMG (KPMG 2000)<sup>3</sup> in their study to evaluate cost recovery of biosafety regulations in Australia, and other studies examining the cost of compliance with biosafety regulations (Kalatzaidonakes et al 2005, Pray, et al 2006). The basis of these approaches is to identify activities (and element within activities that drive cost) first and then attach cost estimations when possible.

The process described above is necessary particularly with changing and/or evolving regulatory environments, where it may be necessary to modify the way the cost structure is reported. Regulatory regimes, including activities requested or deemed necessary by the regulatory authority- may change over time. Having the flexibility and the ability to re-estimate regulatory and development costs is indispensable in this type of costing efforts with regulatory regime changes or when there is significant disagreement whether a particular activity is biosafety or R&D.

We thus followed a three step procedure: 1) Identify all the activities done during the product development process including the R&D, regulatory and technology transfer stages<sup>4</sup>, 2) Establish the set of biosafety activities explicitly required by biosafety laws, regulations and guidelines, 3) Establish a set of biosafety activities not included in step two but that may have been required (through formal or informal communications by the

Regulatory body in charge of the biosafety assessment process), 4) Assess expert and/or stakeholder opinion of what category a particular technology fall into.

We used a very simple set of heuristics: 1) Activities included in steps two and three that have been identified from step one may be counted as regulatory activities, 2) Activities identified in step four as regulatory, but that are not in Steps two or three, will not be considered as regulatory.

Note that the process (and heuristics) described above do not answer the question of whether a particular activity is actually needed to demonstrate safety of a particular technology. To take into consideration the question of whether an activity is needed to demonstrate safety, an alternative process is to determine what is the minimum information set needed to demonstrate safety versus what is required by the regulatory body and/or submitted by the proponent. This process calls for identification of a minimum information set needed to demonstrate safety, determination of attributes that will describe safety and the standard by which to judge achievement of safety. The minimum information set ideally should reflect society's values and is agreed upon accepted process by society.

Biosafety evaluations and approvals are typically made at the national level and thus the consensus build-up of the minimum information set has to be done at the national level. Ideally, national level efforts should be coordinated with those at the regional and international level to take advantage of regional and international efficiencies while performing biosafety assessments. There is, however, no internationally accepted minimum biosafety information set for food/feed and

environmental safety available yet, although there are some efforts currently underway<sup>5</sup>. Convergence to a biosafety decision making process involves settling on a conceptual framework and approaches that guides biosafety assessments. We present our results with the understanding that if an efficient information set is eventually identified we will be able to re-estimate our results promptly.

### *Study Protocol*

The case studies estimating the cost of biotechnology in Indonesia and The Philippines were implemented using sets of common questionnaires and templates common to all countries where similar studies are being done, modified for the context in both countries. Besides the estimation of the cost of compliance with biosafety regulations and R&D for the specified technologies, we also gathered data on human resources available for R&D and the current status of biosafety and biotechnology in both countries.

Interviews were conducted team leader scientists, coordinators of the national regulatory committee and the respective scientific/technical committees involved with regulatory affairs and their supporting staff. We also reviewed all available documentation including executive/administrative orders, laws, regulations and other publicly available materials. When possible we also reviewed available written contracts concerning publicly and privately delivered services to the applicants, such as those for conducting experiments.

The technologies chosen for this study were based on a sample from all technologies included in both the Next Harvest study (Atanassov, et al. 2004), other



reports (Bahagiawati et al, 2003; Mulya et al, 2003) and initial discussion with scientists and regulators. We strived to sample technologies that are currently in the regulatory evaluation process or are within a range of 3-5 years of entering the regulatory process.

#### *Related studies*

Table 1 presents some of the exploratory studies that have examined the agro-biotechnology regulatory costs and processes for several commodities and countries. The regulatory costs varied across commodities and countries ranging from US\$ 53,556 for Bt eggplant in India to US\$ 2.25 million for viral resistant rice in Costa Rica. Whether these compliance costs are low or high is arbitrary and subjective unless compared to an appropriate benchmark of an efficient regulatory system. Falck-Zepeda (2006) lists some of the studies completed since then, including those in India and China (Pray, et. al, 2005; Pray, et. al, 2006). Table 2 disaggregates the cost by activity and by country. As a first step in the policy analysis process, it is better to initially understand the structure of the regulatory process and the costs involved before decisions on whether high regulatory costs have stifled biotechnology innovation can be made.

The regulatory processes across countries also differed influencing to a large extent the level of costs. Some governments, for example China, have been sensitive to criticisms over the time taken for regulatory assessments and of the costs of regulations and thus have implemented revisions of the regulatory process and in some cases modified the process in order to attempt costs reductions. Pray, et al. (2006) presents an example where the process to conduct confined field trials was indeed modified in China.

The cost evaluation used in some of the studies in the literature, particularly in the developing countries where the regulatory framework is just evolving is more of the ex-ante type hence, costs are derived from 'best guess' estimates. For the ex-post studies, the approach simply follows the collection of cost data for complying with the regulation. The later costs studies typically examine the real-resource compliance costs and do not include other social costs like government sector regulatory costs, social welfare losses, transitional and indirect costs (Falck-Zepeda, 2003).

The cost of compliance may also vary with the type of institution undertaking the regulatory compliance. Pray, et al. (2005, 2006) indicated that regulatory cost incurred by private companies is usually higher than those by the public sector. A plausible explanation is that in the public sector, costs are usually underestimated due to nominal amounts of charges on tests and salaries and/or preferential or subsidized cost charges to the public sector. According to Pray, et al. (2005, 2006), in China, the cost of approval of a new GM field crop event between private companies and the government differed by about US\$ 30,000 and the cost per trial for private firms is typically about three times more than the costs by government research institutes.

These results available in the literature showcase the need to utilize robust, consistent and rigorous methodology to estimate the cost of regulations. In addition the methodology chosen will need to be flexible enough to accommodate a changing regulatory environment that may affect activities performed to demonstrate safety and/or to obtain regulatory approval by the appropriate regulatory agency. The technologies

discussed in this paper and our estimations of the total cost of development for Indonesia and The Philippines can be found in Tables 3 and 4.

### **Cost of Compliance with biosafety regulations in Indonesia**

#### *Drought-Resistant Transgenic Sugarcane (PTPN XI)*

In 2003, PTPN XI registered the transgenic sugarcane to BFSC through BFSTT, to evaluate its phenotype and invasiveness at the containment facility in ICABIOGRAD. Evaluation of the stability of the transgene was simultaneously carried out in greenhouses and laboratories at PTPN XI. Authorization for the confined field trials were granted by the regulatory body in 2003, and was implemented in two locations in East Java (Jatiroto and Asembagus). By 2005, the total expense paid by PTPN XI to fulfill these regulatory requirements was IDR 178 million (Table 5).

#### *Transgenic Rice Resistant to Stem Borers (Indonesian Institute of Science)*

After 7 years of development, the resulting transgenic plants were subjected to a confined field trial in 2003. That year, the Bt-rice was also registered to get approval for commercial released. The approval process began with an authorization from Indonesian regulatory agencies for conducting confined field trial studies in West Java. The confined field trials were held in Sukamandi, Karawang, Pusakanegara, and Indramayu. The field study was carried out in 3 years to evaluate the effect of Bt toxin carried by the transgenic plants on non-target species, especially insect predators and soil microbes. On 2006, there will be more studies on gene flow from the transgenic rice (Table 6).

Table 6 showed that up to 2004, Indonesian Institute of Science has spent IDR 226 million (PV IDR 266 million), which equal to US \$ 24,200 (PV US \$ 29,000).

According to Dr. Inez S. Loedin (Personal Communication), IIS would need an additional IDR 470 million to complete all the requirements of the approval processes listed in Table 6. The additional fund would be required for gene flow studies, multi-location testing, and facilitating meetings of regulatory bodies to evaluate the collected data from the aforementioned studies.

*Bt-Cotton Resistant to Bollworm (Monsanto)*

Indonesia was the first country in South East Asia that approved commercial field releases of transgenic plants. To obtain a permit to release their Bt-cotton, the Monsanto had to comply with the regulatory processes by conducting evaluations and research on the Bt-cotton at the containment facility owned by the ICABIOGRAD. The approval for a limited field release at 7 districts in South Sulawesi was obtained in 2001. The total of direct cost spent to complete the process was approximately IDR 919 million (PV IDR 974 million) or approximately US \$ 93,000 (PV US \$ 99,800), as summarized in Table 7. The time spent on additional research and assessments was merely 2-3 years. It took less than a year to attain a safe for environment status from the technical regulatory body in Indonesia, but it took longer to actually get the permit from the national regulatory body and the Minister of Agriculture. A limited permit was finally issued provide that 1) The permit was only valid for 1 year, 2) Bt cotton could only be planted at 7 districts in the province of South Sulawesi, 3) The release must be monitored by an appointed team, 4) Harvested seeds and other byproducts must not be used for feed nor food, 5) The permit would be reevaluated if some unintended negative consequences that can harm the environment and human health were found.

In 2001, about 6,639 farmers planted the Bt-cotton over 4,363 hectare area with an average yield of 1.2 tons/hectare. By 2002, the plantation area increased to 5,124 hectares and 10,424 farmers were involved. The average yield also increased to 2.2 tons/hectare, which was 2-3 times higher than the average yield of non-transgenic cotton varieties (Bermawie et al, 2003). However, Monsanto decided not to continue the plantation of Bt-cotton in 2003 and beyond.

#### *Roundup-Ready (NK603) Corn*

Monsanto started the application process for the herbicide-resistant corn in 2002. Originally, there were two roundup-ready corn applied for approval: RR GA21 and RR NK603. However, Monsanto subsequently decided to focus on RR NK603 for the Indonesian market. Table 8 shows that since 2002 the company has spent around IDR 81 million (PV IDR 133 million), which equal to US \$ 8,700 (PV US \$ 14,000). Until this paper was written, a release permit has not been issued for RR NK603. It is expected that more research and evaluations would need to be carried out to get the approval, which means that around IDR 953 million or US \$ 106,000 would be needed to pay for the whole regulatory processes.

#### **Cost of compliance with biosafety regulations in The Philippines**

The costs estimates up to these regulatory stages have been obtained from a series of interviews with PhilRice and IRRI scientists in late 2005 and early 2006. For the multi-location field trials and commercialization stages, the costs were derived from interviews with the regulators. Since there has been no experience from these regulatory

stages for rice, the estimates are conservative and drawn practically from their experiences in the commercialization of Bt corn and RR corn.

### *Golden Rice*

Golden Rice is a product of genetic engineering where a daffodil or maize gene was introduced into the traditional rice seeds to produce a yellow orange rice that contains beta-carotene. The name is coined from the yellow color of the grain which results from the introduction of the daffodil or maize gene. The technology was developed by scientists at the University of Freiburg using the donation of intellectual property licenses from a number of private companies (Barry, 2005). In October 2004, Syngenta donated to the Rice Humanitarian Board in Switzerland new Golden Rice seeds and lines for research and development. The Syngenta Golden Rice 1 (SGR1) was first received in the Philippines in December 2004. Through backcrossing, the Golden Rice genes have been introgressed into popular rice varieties in the Philippines<sup>6</sup> at IRRI. More recently, a new strain of Golden Rice called SGR2 containing significantly higher levels of beta-carotene than SGR,1 has been developed (Alfonso, 2004). Due to the high prevalence of Vitamin A deficiency (VAD) in children, pregnant and lactating women, there is now a growing interest to commercialize Golden Rice in the Philippines. This technology is still under evaluation in screen houses at IRRI and PhilRice to produce stable lines.

The regulation for the Golden Rice was more of a ‘learning by doing’ approach as the event has not yet been approved in any country and the regulation itself was just evolving in the country. However, regular consultations with all the stakeholders were

also undertaken by the regulators in establishing the necessary protocol to meet a satisfactory biosafety level. Table 9 presents the estimated cost of regulatory compliance to date for the Golden Rice event is US\$ 134,456 (US\$104,698). The laboratory and screen house evaluation costs were the actual costs incurred as the GMO is presently in this regulatory stage at the CL4 facility at IRRI and CL2 facility at PhilRice. The event selection alone costs about US\$ 2,000 per event. The cost at this stage comprised 16 percent of the total while the confined field trial cost was estimated to be the largest (44 %). For food safety, in our interviews regulators and scientists consulted indicated that data for allergenicity/toxicity tests will probably be required for this event, although a strong possibility exists for the regulatory body to accept data generated elsewhere.

One interesting issue is bioavailability. There is significant disagreement amongst scientists and regulators whether this constitutes a product development or is a regulation induced activity. As we do not have any strong opinion one way or the other, we simply adopt a conservative stance and assume that bioavailability is part of product development and for now is not a cost of compliance with biosafety regulations. This situation will change if any regulatory body requests data on bioavailability from developers. Then based on our heuristics, whether it is required or not to demonstrate safety, we will count it as cost of compliance with biosafety regulations<sup>7</sup>.

There is presently no agency conducting toxicity and allergenicity studies in the country hence, the cost quoted here was taken from data collected in India by Pray, et al. (2005). The estimates from India are somewhat inflated as the Indian regulatory required repeated replicates of these tests in different species and over time. However,

note that if we used data from the Kalatzaidonakes et al. (2004 and 2005) study we would obtain much higher estimates of cost.

The multi-location evaluation cost was estimated to be similar with the Xa21 event given the same protocol. The major regulatory cost item at this stage is conducting the field trials in several sites. The risk assessment cost may be estimated as small, however it may increase as regulators require additional tests or information on the event, e.g. socio-economic impact evaluation. The commercialization costs amounts to US\$ 2,517. In both multi-location and commercialization stages, the application include the costs for logistics and other support services of the approving agency. The regulatory cost at the post-commercialization stage is minimal compared with Xa21 as only two years of field monitoring was considered.

Aside from the direct costs, the large capital investment needed to comply with the biosafety regulation must also be taken into consideration in the design of the regulation. For small private companies, the significant capital outlay may provide disincentives to do research and produce novel transgenic products. In order to comply with regulations, both IRRI and PhilRice have constructed new facilities and improved their laboratories to meet the biosafety level required by the regulation for Xa21 and Golden Rice. Table 6 presents the capital investments incurred by the two institutions at current prices.

#### *The Bacterial Blight Resistant Rice (Xa21)*

Bacterial blight is one of the most destructive diseases of rice in the world causing as much as 20-30 percent of rice yield losses in some areas of Asia (Gueco, et. al., 2000).



As early as 1987, there was already a growing concern to develop bacterial blight resistance in rice and tests for new genes showing resistance have emerged. In 1990, a dominant gene for resistance to bacterial blight was successfully transferred to the cultivated variety 'IR24' and was designated as Xa21. This cloned gene was also used to transform an elite indica rice variety IR72 into transgenic rice resistant to bacterial blight

The seed materials used to screen test bacterial blight resistance using IR72 were obtained from the defunct International Laboratory for Tropical Agricultural Biotechnology (ILTAB) in California, USA. It was given through a material transfer agreement without cost. The screen testing was done for two seasons of crop year 1998-99 and it was approved for confined trial testing by NCBP in 2001. These trials were already conducted at PhilRice for two seasons in 2002-03 and for one season at IRRI in 2005. After the project was started and data collected, we found out that the genetically modified rice resistant to bacterial blight will not be commercialized, as the new strain also resistant to bacterial blight has already been developed through conventional breeding, which implies a much cheaper development cost. Innovators will not pursue further development of the genetically modified Xa21 event. We present our estimations for the bacterial blight rice to provide information for future development of rice innovations in The Philippines.

Table 10 shows the cost of compliance with biosafety regulations for the Xa21 rice. The total cost of regulation of the Xa21 rice is about US\$ 127,577 current values and US\$99,213 (at 2000 constant prices) with the laboratory and screen house evaluations accounting for 19 percent of the total cost. This activity was started in 1998-

99 with the agro-morphological and laboratory evaluation at PhilRice. The main cost items at this stage are the laboratory costs for the molecular analysis (to include PCR, and Southern Blot tests) and personal services.

*Insect resistant (Bt) Maize*

Table 11 present estimates on the insect resistant maize using the Bt gene (MON810) developed by Monsanto. One major problem the researchers faced in developing the Bt corn cost structure was how to attribute the costs incurred in the United States – those studies and activities conducted from the gene discovery phase to the first set of laboratory and greenhouse experiments – to the total product development cost for the Philippines. These items were basically the core activities necessary to develop the Bt crop from a mere concept to a finished physical product, with the attendant development costs. Once the physical product has been realized, future activities in further technology development and biosafety regulation compliance were geared towards the commercial development of the product in those countries where Bt corn MON810 would be later introduced.

An economically sound approach is to use the concept of Lindahl pricing and adapt it to our particular case. Adapting the principle of Lindahl price, we distribute proportionately the cost of producing a public good based on the share to total benefits derived by each entity from its utility. Thus, in our particular case, the Lindahl factor is used to determine that portion of the costs of the core activities conducted in the U.S. that will be attributed to the total cost of developing Bt corn event MON810 solely for the

Philippines (Expanded discussion of the Lindahl factor and pricing can be found in Manalo and Ramon (2007))

The cost of developing Bt corn event MON810 in the Philippines – from the U.S. laboratory testing to the post approval stewardship stage – is estimated at PhP 127,977,169 (or US\$ 2,607,793) at 2004 discounted prices. Table 11 shows the costs in terms of major activity groupings. Laboratory and greenhouse activities conducted in the U.S. in the 1980s and 1990s, mostly in the form of experiments and scientific studies, accounted for about 5.2 million pesos. The sum is small relative to the total cost of development because of the Lindahl factor that was considered in the cost attribution. Based on the computation, the Philippines accounts for only 0.73% of the total expenditures incurred for these activities. Without Lindahl pricing, the cost of the U.S.-based activities alone would have reached PhP 712 million (or US\$ 29 million).

Laboratory and greenhouse activities conducted in the Philippines amounted to about 2 million pesos only. These activities simply complemented those already conducted in the U.S., thus the relatively small amount. The product developers also earned additional savings from the use of laboratory and greenhouse facilities of the International Rice Research Institute (IRRI) free of charge, in the spirit of the IRRI-UPLB cooperation.

Costs for the single-site confined field trial (CFT) reached 7 million pesos. Contrasting this to the total costs of about 44.38 million pesos incurred for the conduct of the multi-location field trials (MFT) in 17 sites – or an average of 2.61 million pesos per site – the unit cost of conducting the latter experiment is cheaper by more than 60%. If

we are to factor out the cost of capitalization, the unit costs of conducting each experiment in their respective current years is about PhP 5.15 M for CFT and PhP 2.2 M for MFT. Here we can appreciate the advantage of economies of scale. Conducting simultaneous multi-location field trials cost relatively much less per unit compared to the conduct of a single-site field test.

Costs incurred for the application for commercial propagation amounted to about 16.31 million pesos. A significant portion of this amount (close to 85% or 13.79 million pesos) came from the nine biosafety and socioeconomic studies outsourced to independent scientists and conducted in support of the commercial application. Also worth noting is the PhP 287 thousand government fee paid (at 2004 discount cost) for the permit application. Due to financial constraints, the DA follows the principle of full cost recovery, whereby the transaction costs involved in processing the permit application is passed entirely to the applicant.

The overlapping nature between technology development on one hand and regulatory compliance on the other may be evident in many activities conducted in developing the Bt corn. When individual activities were defined as to their primary objective and strictly classified according to their core function, it was discovered that two-thirds (66.9%) of the total cost in Table 11 can be allocated to activities conducted largely for the purpose of compliance to government regulatory requirements. Thus the estimate cost of compliance with biosafety regulations in The Philippine for the MON810 maize was roughly 1.7 million dollars over the approval period.

*Delayed Ripening Papaya*

Delayed ripening is a desirable trait as it prolongs the shelf life while reducing damage during transport. Although the Philippines is the 8<sup>th</sup> largest producer of papayas in the world, its level of exports is relatively small. A major explanatory factor is the papaya ringspot virus and post harvest losses. Post-harvest losses in papaya production can occur at any point in the warehousing, marketing, and distribution channel. There are several factors that contribute to post-harvest losses of the highly perishable fresh papayas, from physical damage due to mishandling and long transport to spoilage due to occasional surplus in the market. However, a contributing factor to all of these and a major factor itself is physiological decay of the fruit due to over-ripening.

Table 12 presents the results of our estimation of the total cost of development for the delayed ripening papaya. This includes research, development and regulatory costs grouped together. We continue the process of separating these totals into individual components, but more work is needed to provide dis-aggregated numbers. This technology is particularly exciting from a developing country perspective as a significant share of the R&D has been done in country. However, there have been several contributory (in terms of financing and capacity strengthening) agencies including ACIAR (Australian Centre for International Agricultural Research), University of Queensland, and Philippines Public sector organizations. This makes separating costs even more difficult as there are multiple sources and types of funding.

Without discounting, the total estimated cost of developing the transgenic delayed ripening papaya in the Philippines amounted to US\$869,432.51 or equivalently PhP39,964,165 in 2005 values. The stream of component costs covered the period of 1997 to

2008 – 12 years of work that started in the laboratory and will end upon gaining regulatory approval. Time frames overlap between laboratory phase and greenhouse phase since major expenses (for construction) on the latter already started by the end of 2001. On the other hand, activities related to pre-commercial application and commercial application will be conducted simultaneously with the field testing.

More than half of the total cost was expended during the 1997-2001 period under activities conducted in the laboratory. Percentage expenses for the succeeding phases taper down consistently to 22.3 (greenhouse), 16.2 (field trial), and 8.8 (pre/commercial application). Activities conducted during the laboratory phase accounted for 52.7% of the total cost at US\$520,217. It was during this time when significant investments in equipments and human development were made, significantly contributing to the total cost. Activities under the pre-commercial application and commercial application consist mostly of those that will be done in compliance to regulatory requirements, namely payment of processing fees and conduct of IEC activities. A socio-economic study and a market feasibility plan will also be conducted in support of the application for commercialization. A significant component included the same item is the cost of converting the transgenic line into a hybrid variety.

## **Discussion**

The relatively high levels of expenses needed to conduct biotechnology R&D can be seen in equipment investments needed to perform biotechnology R&D. For example, one DNA sequencer alone may cost about US\$ 1 million and this is already significantly higher than the R&D budget of some national research organizations in developing

countries. Of course this particular equipment (and others) not only needs to be depreciated amongst the many GM technologies to be evaluated, but also amongst other types of biotechnologies where this machine will be used extensively (marker assisted selection and other techniques). Research organizations may be able to access expensive equipment through leasing or renting time for using these machines in other organizations. This strategy has been used quite successfully in The Philippines. However, the fact remains that the initial investments to purchase expensive R&D equipment is a barrier to entry for smaller organizations and the public sector as they are sunk costs once investments are made. In the end, investment costs in building, equipment and other capital investments should be evaluated as closely as possible in order to maximize society's benefits as rigorously as possible, with the major objective of answering the question of whether this particular investment is needed to demonstrate safety.

The regulatory cost estimates for the Xa21 and the Golden Rice may be low relative to the costs incurred by private companies that may range from US\$ 100,000 to US\$ 4 million for food and non-food crops (Pray, et. al., 2005), however the goal, objective and scope of private R&D is usually different. Costs estimates presented here are comparable with the regulatory costs of public sector produced events in China and Bt eggplant in India (Pray, et. al., 2006). It is however, expected that these regulatory costs will decline in the future as these rice technologies are approved in other countries. Some of the more expensive tests can be done in other countries where it is less costly, or information generated in one country (or within the same country) may be used in others to guide the biosafety assessment of the same event. In addition, the regulatory system

may reduce the minimum information set by identifying activities that either does not contribute any more information to the determination of safety or where a specific risk consideration may have been identified as not contribution to the risk profile of the technology. Costs will generally be reduced as regulators become more experienced as more events pass through the regulatory process, assuming that there is no change in the laws and/or regulations that guide the regulatory process.

An example of the cost changes expected as regulatory systems gain experience is that of the biotechnology laboratories at IRRI and PhilRice that have been approved by the Philippines regulatory system to undertake research on regulated materials such as GMOs. The CL2 and CL4 in these two institutes are low and high level containment facilities required for biotechnology research work. On the one hand, these investments may be necessary to ensure biosafety and minimize negative externalities for some crops and traits, these investments will need to be depreciated and its value attributed to all the technologies in the R&D pipeline that may make use of the contained evaluation facilities.

On the other hand, although large investments needed to establish these contained facilities may become major constraint for a public research institution, isolation facilities may be rendered obsolete in the long –run as the regulatory process may deem that the current state of knowledge and familiarity with specific crops and/or traits eliminate the need for performing biosafety assessments under contained situations. Important concept from a regulatory standpoint is to always establish the link between the level of



regulatory effort and the level of risk that the technology candidate for release represents to humans and the environment.

The costs presented here are direct costs incurred by the public institutions representing costs associated with technical and administrative procedures to comply with the biosafety regulations. Since these are public institutions, the costs may not pose to be a major constraint in the regulatory compliance but, more important is the speed by which these technologies are commercialized.

### **Concluding remarks**

Innovation has and will continue to be part of the sustainable development process in all countries of the world. As with any aspect of human activity, the use of innovations implies a certain amount of risk. Pursuing technologies with zero risk is not only unattainable, but may even be undesirable as societies may forego promising technologies that could address specific productivity constraints, particularly in developing countries. Thus, the need arises to establish regulatory systems that are commensurate to the potential risk of the technology, that are flexible enough to adapt to gains in knowledge and experience, that are transparent and fair, and that take into consideration all aspects of a broad and inclusive decision making process. Biosafety thus becomes a process that considers all costs, benefits and risks of prospective technologies, within the scope of overall sustainable agricultural and economic development. The biosafety process itself needs to have a “golden standard” of best practices in terms of data requirements, evaluation methodologies and analysis, but with a clear safety standard that needs to be met, complete understanding of how to judge how much data is

sufficient and/or necessary to make a decision, to be carried out in a time delimited and predictable process. We believe that this set of characteristics, along with those included in Jaffe's 2006 paper, defines a functional and pragmatic biosafety system.

## Footnotes

<sup>1</sup> The main concern is for the potential of large (and in some cases excessive or unneeded) investments in biosafety assessments may stifle innovation, in some cases, making valuable GM technologies unavailable for commercialization. In this situation, cost of compliance with biosafety regulations may become an entry barrier to biotechnology products particularly for the public sector and small private firms (Falck-Zepeda, et. al 2003). While regulations may be a necessary condition for the assessment of biosafety, excessive and overly stringent conditions increase the cost of the technology relative to the benefit received from an incremental level of safety. The high cost of regulation may thus become a disincentive to the adoption by farmers (particularly poor small-holder) if it has an effect on prices for the new product.

<sup>2</sup> We collected data on the cost of development of viral resistant citrus at Udayana University, however the lead scientist indicated that the research team will not pursue the technology any further as they do not have the financial resources to comply with biosafety regulations. They rather opted pursuing other non-regulated approaches to attending the productivity constraint.

<sup>3</sup> KPMG describes its approach succinctly as “The methodology used to develop a costing system for the Office of Gene Technology Regulator (OGTR) is based on the requirements of sound cost accounting practice as embodied in such tomes as the standard Horngren, Foster & Datar - Cost Accounting - a managerial emphasis...”

<sup>4</sup> The separation into stages is blurry, as a particular activity make accomplish both an R&D and a regulatory objective. We do not press too much this issue, rather we use these stages as an expository tool to describe the innovation process.

<sup>5</sup> One can always argue that for environmental safety the minimum standard is the Cartagena Protocol itself and its member deliberations. In contrast, Codex Alimentarius may become such standard for food/feed safety. The only limitation of these two documents is that they are not sufficiently detailed to identify a minimum biosafety set or have not been finalized yet. This information may have to be gleaned from international efforts done by scientists, or may have to be done at the national level.

<sup>6</sup> Such as like the PSB Rc82 and Mabango 1 at PhilRice and IR64 and IR36.

<sup>7</sup> If bioavailability of Golden Rice or any other nutritionally enhanced product were to be required in the Philippines (or elsewhere) as part of the regulatory process, we consulted with the Food and Nutrition Research Institute of the Department of Science and Technology of The Philippines to obtain an estimate of the cost of conducting a bioavailability test on this particular technology. The Institute indicated to us that it has the capability to undertake the bioavailability study for 1.3 million pesos (approximately US \$26,000). However, this may be a significant underestimate as the range of variation of these tests in other countries is from XXXX to YYYY US\$. Note that if bioavailability and for toxicity/allergenicity were to be included in our estimates, the cost for these two tests would have accounted for almost one-third of the regulatory cost at this stage.

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## Tables

**Table 1. Cost of Compliance with the National Biosafety Regulatory Framework**

Type of Crop (example)	Crop	Country	Event approved in Developed Countries	Estimated Costs of Biosafety 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

Note: Compilation presented in Falck Zepeda (2006) based on estimates from Quemada(2004), Odhiambo(2003), Sampaio(2002), Sittenfeld(2002). India data from a study by Pray, Bengali and Ramaswamy (2004).

**Table 2. Estimated Costs per Biosafety Activities for U.S., India and China**

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 (ea.)		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	

Note: Source of USA estimates is Kalatzaidonakes, Alston and Bradford (2005); India estimates from Pray, Ramaswamy, and Bengali (2004).China from Pray et al. (2006).



**Table 3. Actual and Present Value of R&D Activities to construct a GM technology in Indonesia**

Technology	Institution	Year R&D	1,000s IDR		1,000s US\$		Collaborative Agreements and Strategic Alliances involved in R&D of Technology
			Actual Total Cost	PV Total Cost	Actual Total Cost	PV Total Cost	
Potato Resistance to Fungi / Nematode	Bogor Agricultural University	1994-2004	1,481,887	2,470,043	317.6	650.9	Experiments were conducted at Plant Research International (PRI), Wageningen University, The Netherlands (the materials and equipments were subsidized)
Transgenic Citrus Resistant to CPVD	Department of Plant Pathology, Faculty of Agriculture, Udayana University (Denpasar)	1997-2004	3,108,406	5,572,552	370.2	641.4	Parts of R&D done at Nagoya University (Japan). Research funded by a grant from JSPS (Japan). Collaborating institutions include Brawijaya University (Indonesia), Gajah Mada University (Indonesia) and Bioscience Center, Nagoya University (Japan).
Sugarcane Drought Tolerant	PTPN XI Perseroan Terbatas Perkebunan Negara - Government Enterprise for Estate Crops	1999-2002	1,380,359	2,272,024	154.8	255.1	Private company Ajinomoto sponsored R&D by donating equipments and chemicals valued at around 600 million IDR (US\$61,000).
Insect resistant (Bt) rice	RCB-IIS / LIPI	1996-2002	2,925,009	7,149,026	522.5	1,466	The research were funded by the Rockefeller in the first 5 years besides funded by Indonesian government Indonesian Institute for Rice Research (IIRR) and AARD
Insect resistant (Bt) cotton	Monsanto	n.a.	n.a.	n.a.	n.a.	n.a.	Gene technology developed in the U.S.
Herbicide resistant maize	Monsanto	n.a.	n.a.	n.a.	n.a.	n.a.	Gene technology developed in the U.S.

Notes: n.a. = not available/applicable, Present Value (PV) for 2005 with interest rate of 18%, The GM citrus resistant to CPVD was discontinued as the university (still) does not have the resources to comply with biosafety regulations and proceed to commercialization approval.

**Table 4. Actual and Present Value of R&D Activities to construct a GM technology in The Philippines**

Technology	Institution	Years R&D	1,000s Pesos		1,000s US\$		Collaborative Agreements and Strategic Alliances involved in R&D of Technology
			Actual Total Cost	PV Total Cost	Actual Total Cost	PV Total Cost	
Delayed ripening papaya	Institute of Plant Breeding (IPB), College of Agriculture, University of the Philippines Los Baños (UPLB)						University of Queensland in Brisbane, Department of Science and Technology-Philippines, Australian Centre for International Agricultural Research (ACIAR), Philippine Council for Agriculture, Forestry and Natural Resources Research and Development (PCARRD).
Golden rice	IRRI	1999-2002& Beyond	n.a.	n.a.	n.a.	n.a.	Golden Rice Network, Syngenta, ETH-Zurich, University of Freiburg Germany, Rockefeller Foundation
Bacterial leaf blight (Xa21) rice	PhilRice	1990-2002	n.a.	n.a.	n.a.	n.a.	ILTAB
Insect resistant (Bt) maize <sup>1</sup>	Monsanto	1997-2002	-	85,655	-	1,384	Technology developed mostly in the U.S. , transferred to The Philippines

Note: n.a.=not available/applicable. <sup>1</sup> Cost included here are the development costs in the Philippines and an allocation of R&D activities done in the US through the use of the Lindahl factor charged to the Philippines.

**Table 5. Cost of Compliance with Biosafety Regulations of Drought Tolerant GM Sugarcane in Indonesia**

Year	Activity	Total actual cost (million IDR)	Total PV (million IDR)	Total actual cost (US \$)	Total cost PV (US \$)
2003	Dossier filling for risk assessment	4	7,8	470	905
2003	Containment facility Test at ICABIOGRAD	8	13,1	933	1,534
2003	Gene stability and plant phenotype at PTPN XI' green-house	50	69,6	5,834	8,123
2004	Confined Field trials (plant phenotype, drought tolerance, sugar content etc) in East Java	58	68,4	6,455	7,617
2005	Confined Field trials (plant phenotype, drought tolerance, sugar content etc) in East Java	58	58,0	5,961	5,961
	<b>TOTAL EXPENDITURES (COST)</b>	<b>178</b>	<b>216,9</b>	<b>19,649</b>	<b>24,139</b>
	Estimated future expenses :				
?	Gene-flow				
?	Non-target species				
?	Food safety				
?	Feed safety				
?	Data evaluation				
	<b>Total</b>				

*Note: IDR= Indonesia Rupiah, ? =activities not done, expected in the near future.*

**Table 6. Cost of Compliance with Biosafety Regulation of GM Rice Insect Resistant (Stemborers) Rice in Indonesia**

Year	Activity	Total actual cost (million IDR)	Total PV cost (million IDR)	Total actual cost (US \$)	PV Total Cost ( US \$)
2001-2002	Dossier filling for risk assessment	6	9.8	650	1,060
2003-2005	Non target impact (insects and others)	130	166.1	14,790	18,940
2003-2005	Non target impact – soil microorganisms	900	90.0	9,250	9,250
	<b>TOTAL EXPENDITURES (COST)</b>	<b>266</b>	<b>266.0</b>	<b>24,250</b>	<b>29,250</b>
	Estimated future expenses :				
?	Gene-flow	50	42.4	5,140	4,350
?	Multi location trials	400	287	41,110	29,520
?	Non-target impacts	10	8.5	1,030	870
?	Gene-flow	10	722	1,030	740
	<b>Total</b>	<b>696</b>	<b>611</b>	<b>73,000</b>	<b>64,730</b>

Notes= 1) ?= estimated cost as the activity has not yet been done.

**Table 7. Cost of Compliance with Biosafety Regulations of GM Insect Resistant Cotton to Bollworms Using the Bt Gene in Indonesia (Monsanto)**

Year	Activity	Total actual cost (million IDR)	PV Total Cost (million IDR)	Total actual cost (US \$)	PV Total Cost (US \$)
1998	Dossier for risk assessment	10.0	16.4	1,010	1,660
	Morphological characteristic (containment facility at ICABIOGRAD)	16.0	26.3	1,620	2,660
1999	Confined Field Trials	30.0	41.8	3,840	5,350
2000	Multi-location trials	140.0	165.2	16,400	19,360
	Technical Team meeting fee	10.0	11.8	1,170	1,380
2001	EIA(environment Impact Assessment)-Gene Flow	125.0	125.0	12,180	12,180
	EIA-Non target impact	193.0	193.0	18,800	18,800
	EIA-soil microbes	395.0	395.0	38,480	38,480
	<b>TOTAL EXPENDITURES (COST)</b>	<b>919.0</b>	<b>974.5</b>	<b>93,500</b>	<b>99,870</b>

Notes: EIA=Environmental Impact Assessments, Present Value (PV) for 2005, with interest rate of 18%.

**Table 8. Cost of Compliance with Biosafety Regulations for Herbicide Resistant Corn (RR NK603 from Monsanto) in Indonesia**

Year	Activity	Actual Total Cost (million IDR)	PV Total Cost	Actual Total Cost (US \$)	PV Total Cost
2002	Dossier for risk assessment	10.0	16.4	1,080	1,770
2002	Morphological characteristic				
	1. Non target impact, invasiveness in contained facilities	16.0	26.3	1,730	2,840
	2. Limited trial at 3 locations	30.0	49.3	3,240	5,320
2002	Dossier for food safety	10.0	16.4	1,080	1,770
2002	technical meeting (twice)	15.0	24.6	1,620	2,660
	<b>TOTAL EXPENDITURES (COST)</b>	<b>81.0</b>	<b>133.1</b>	<b>8,750</b>	<b>14,370</b>
	Estimated future expenses :				
?	1. Multi-location trials (10 units, 2 seasons, app 9 million)	180.0	180.0	18,530	18,530
?	2. Variety released Team meeting to evaluate multi-location trials data	15.0	15.0	1,540	1,540
?	3. Confined Field Trials				
	a. EIA-Gene Flow	125.0	125.0	12,870	12,870
	b. EIA-Non target impact	193.0	193.0	19,870	19,870
	c. EIA-soil microbes	395.0	395.0	40,660	40,660
?	4. Feed safety studies (fish, poultry)	15.0	15.0	1,540	1,540
?	5. Additional Technical meeting (3 times)	30.0	30.0	3,090	3,090
	<b>TOTAL</b>	<b>1,034</b>	<b>1,086</b>	<b>106,850</b>	<b>112,480</b>

Notes: Present Value (PV) for 2005 with interest rate of 18%, ?= not yet determined

**Table 9. Cost of Compliance with Biosafety Regulations for the Golden Rice in the Philippines**

Year	Activity	Actual Total Cost (US \$)	PV Total Cost (US\$)
2004	Application Lab/ Screen house	109	84
2004-	Lab Tests	7,628	5,877
idem	Screen house evaluation	23117	17810
idem	Application confined field trials	115	83
idem	Lab. Tests	1,201	936.03
2005-	Confined Field trial (2 seasons)	3,063	2,753
2006			
idem	Toxicity tests	36,938	32,329
	<b>TOTAL EXPENDITURES (COST)</b>	<b>66,253</b>	<b>55,312</b>
	Estimated future costs		
?	Application Multi Location trials	3,011	2181
?	Multi-loc trials	28,774	20,836
?	Bureau Plant Industry Monitoring	10,397	7,529
?	Application commercialization	3,476	2,517
?	Post commercialization monitoring	22,544	16,324
	<b>TOTAL</b>	<b>134,456</b>	<b>104,698</b>

Note: PV is in 2000 prices. Source of basic data: IRRI, Philrice, NCBP, BPI

**Table 10. Cost of Compliance with Biosafety Regulations Bacterial Leaf Blight Resistant Rice (Xa21) in the Philippines**

Year	Activity	Actual Total Cost (US \$)	PV Total Cost (US\$)
1998	Application Lab/ Screenhouse	138	144
1998- 1999	Lab tests	14,473	15,045
1998- 1999	Screen house evaluation	3,181	3,307
2001	Application field trials	100	88
2002- 2003	Lab tests	2,313	1,992
2002- 2003	Field trials (2 seasons)	5,907	5,162
?	Application multi-loc trials	1,285	931
?	Multi-loc trials	28,774	20,836
?	BPI Monitoring	10,397	7,529
?	Risk Assessment	1,726	1,250
?	Application commercialization	1,749	1,267
?	Risk assessment commercialization	1,726	1,250
?	Application post-commercialization	1,749	1,267
?	Field monitoring	54,059	39,145
	<b>TOTAL</b>	<b>127,577</b>	<b>99,213</b>

Note: PV is in 2000 prices. Source of basic data: IRRI, Philrice, NCBP, Bureau of Plant Industry-Philippines, PhilRice will not pursue this GM technology as there is a similar resistance pathway using conventional means. This is the best estimate from scientist and regulators assuming that the technology would have moved forward.

**Table 11. Cost of Compliance with Biosafety Regulations for Insect Resistant (Bt-MON810) Maize in the Philippines**

Year	Activity	Philippine Pesos (without Lindahl)	Philippine Pesos (with Lindahl)	US\$ (without Lindahl)	US\$ (with Lindahl)
1980s	U.S. lab/greenhouse studies	95,274,121	696,075	5,120,244	37,409
1990s	U.S. lab/greenhouse studies		4,503,666	23,904,819	174,649
		616,431,753			
1997	Lab/Greenhouse	922,638	922,638	31,307	31,307
1998	Lab/Greenhouse	1,065,476	1,065,476	26,055	26,055
1999	Confined field trial	3,762,657	3,762,657	96,259	96,259
2000	Confined field trial	3,246,431	3,246,431	73,459	73,459
2000	Multi-location field trial	7,392,247	7,392,247	167,269	167,269
2001	Multi-location field trial	16,120,342	16,120,342	316,131	316,131
2002	Multi-location field trial	20,866,539	20,866,539	404,375	404,375
2002	Commercial propagation - RP Studies	13,793,309	13,793,309	267,302	267,302
2002	Commercial propagation – socioeconomic studies	2,204,703	2,204,703	42,725	42,725
2002	Public information survey	26,975	26,975	523	523
2002	Application fee commercial propagation	287,474	287,474	5,304	5,304
2003	Post commercialization	14,052,274	14,052,274	259,253	259,253
2004	Post commercialization	11,265,589	11,265,589	201,028	201,028
2003	Post commercialization promotional materials	15,203,283	15,203,283	280,488	280,488
2004	Post commercialization promotional materials	12,567,490	12,567,490	224,260	224,260
	Total	834,483,302	127,977,169	31,420,798	2,607,793

Note: Lindahl factor was 0.00731 for Lab and greenhouse work done in the U.S., Expanded version of this table appears in Manalo and Ramon (2007)

**Table 12. Total Cost of Development of a Delayed Ripening Papaya in The Philippines**

Phase	Period Covered	Cost (2005 Ph.P)	Cost (2005 US\$)	Percent Share*
Laboratory	1997-2001	21,069,997.60	520,216.92	52.7
Greenhouse	2001-2005	8,930,583.76	168,831.21	22.3
Field Test	2006-2008	6,457,078.14	116,883.34	16.2
Pre/Commercial Application	2006-2008	3,506,506.39	63,501.03	8.8
Total	1997-2008	39,964,165.90	869,432.50	100.0

Note: Ph.P=Philippines Pesos



## **Annex. Status of Biosafety Assessments and Systems in Indonesia and the Philippines**

Both Indonesia and The Philippines have recently approved new biosafety laws that update or replace older legislation. The new biosafety law in both countries was drafted with the stated intent in both countries' regulatory systems to become fully compliant with the Cartagena Protocol. Formal approval and public release of the new laws in both countries coincided with the implementation of our data collection. As the regulatory system needs a long period of time to draft guidelines, standard operating procedures and other documents that govern implementation of the new law, therefore the data on the cost of compliance with biosafety regulations presented in this paper are based on the older laws, regulations and guidelines. The expectation in both countries is that the process under their new law is likely to have additional activities and/or potentially expand the focus of existing ones. This development may increase the regulatory lag and the overall cost of compliance with biosafety regulations, even as a change induced by the time cost of money invested due to the expanded regulatory lag.

### *Indonesia biosafety regulations*

The first Indonesia biosafety regulation of GMO (Ministerial Decree No. 85 *Kpts/hk.330/9/1997*) was released in 1997 by the Ministry of Agriculture. To implement the decree, the government created the Biosafety - Food Safety Commission whose function is to Government on the safe release of agricultural biotechnology product considering human health and/or environment. The Biosafety - Food Safety Commission was supported by a Technical Team consisting of experts in the plant biotechnology

representing different national institutes and universities. The technical team formulated a series of guidelines for the release of genetically-engineered organism. These include general and specific guidelines for genetically engineered plants, microbes and animals.

The 1997 decree was later revised in in 1999 by a Joint Decree drafted by four Ministries (*Joint Decree SKB4M*): the Ministry of Agriculture, the Ministry of Health, the Ministry of Forestry and Estate, and the State Ministry of Food and Horticulture (Herman, 1999). Joint Decree *SK4BM* was later revised to comply with the Cartagena Protocol that had been ratified by Indonesia in 2004 through Law no. *21/2004*. The new revision of this decree was in a law format signed by the President, not by the Ministries. This is Law no. *21/2005* which was released in May 2005. However, the guidelines and other implementing documents for this regulation has not been finished yet. Until this process is completed, Indonesia continues to use law *SKB4M* to evaluate and assess the biosafety and food safety of GMOs.

Interesting to note that several applications for risk assessment of GM plants have been evaluated by the technical team, some of them have been determined to be environmentally safe. Some of the technologies reviewed by the regulatory system came from multi-national companies such as Monsanto, Dupont, and from national research institutes. Most of the technologies from national research institutes entered the regulatory process mostly to obtain approvals for research purposes (i.e. permits for conducting research). The research performed would allow building knowledge of gene function either in greenhouse or under confine field trials. Worthwhile noting that for most proponents the decision has not been made whether they will go for the

commercialization, even while submitting an application for research purposes. This decision typically will be based on initial research results.<sup>viii</sup>

### *Philippines biosafety regulations*

Two government institutions are mandated to carry out the biosafety system outlined above: the National Committee on Biosafety of the Philippines (NCBP) and the Philippine Department of Agriculture (DA). At present, the NCBP is concerned with contained use (confined laboratory and greenhouse experiments on the regulated article) while the DA is with the field release and commercialization.

Executive Order No. 430 (EO430), issued by the President of the Philippines in October 15, 1990, created the NCBP and identified the scope of its functions. On the other hand, the DA supplemented the Plant Quarantine Act of 1978 by issuing Administrative Order No. 8 (AO8) on April 2002 to regulate plants and plant products derived from the use of modern biotechnology. These two policies provide the structure of the Philippine biosafety system.

The NCBP constitutes the National Committee on Biosafety of the Philippines. The primary function of the Committee is to identify and evaluate potential hazards involved in initiating genetic engineering experiments and recommend measures to minimize risks. The NCBP is a multi agency regulatory body which drafted the Biosafety Guidelines in 1990 (later revised in 1998), requiring the creation of Institutional Biosafety Committees (IBC). Through this process, preliminary biosafety and risk evaluation is done at the IBC level. If the IBC deems that associated risks, if any, are minimal or can be mitigated, it endorses the project proposal to the NCBP Secretariat

Upon receipt of the proposal from the NCBP Secretariat, the NCBP appoints at least three experts, collectively called the Scientific and Technical Review Panel (STRP), from its roster of independent scientists to evaluate potential adverse effects of the project to human health and environment. Concurrent with the review by the STRP are public notifications of the proposal and solicitation of comments.

#### Footnotes

<sup>viii</sup> This is a major difference between the public and private sectors in terms of how they structure their research processes. The private sector will typically try to identify as early as possible those technologies that will indeed go to commercialization and have (somewhat) well defined plans for technology transfer. This behavior is a partial result of the added cost and complexity of biosafety processes required for commercialization. The public sector may even reach pre-commercialization stages without a clear plan for technology transfer (Atanassov, et al. 2003).