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The Cost of Product Development of Bt Corn Event MON810 in the Philippines

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The estimated total cost of developing Bt corn MON810 in the Philippines is $2.6 million (128 million Philippine pesos) at 2004 discounted prices. This includes the entire process of product development, from concept initiation done in the US in 1985 to implementation of post-commercial approval requirements in 2004. Lindahl pricing was employed to allocate the share of total relevant cost incurred in the US to the Philippines. Costs were converted into corresponding 2004-year equivalents and capitalized using literature-recommended values to reflect base-year real monetary value. The biggest costs were incurred in the conduct of post-commercial application activities followed by the 17 multi-location field trials across the country. Project spending was highest in 2002 when field trials and supporting studies were being completed and the product stewardship plan was being developed. The study discovered that two-thirds of total cost went into activities conducted in compliance and support of government regulatory requirements.

Key words: Bt corn MON810, Department of Agriculture (DA), insect resistance management (IRM), Lindahl factor, National Committee on Biosafety of the Philippines (NCBP), product development, Scientific and Technical Review Panel (STRP).

Introduction

Although optimism is high for the potential of genetic engineering to overcome many hindrances in healthcare delivery, environmental amelioration, efficiency of industrial processes and agricultural production, associated safety issues need to be addressed in order to optimize the derived benefits to society. This is where the intervention of biosafety regulation comes in to serve as a safety check for biotech products in development. But while regulation may provide a comfort level of safety, high regulatory costs involved in compliance with a biosafety system can hamper product delivery. In many developing countries, excessive regulatory requirements imposed by some biosafety assessors may inhibit technology transfer (Zepeda, Cohen, & Komen, 2003). The trade-off between cost of regulation and safety assurance is evident: on one hand, increasing biosafety regulation may be desirable as an added safety check; on the other hand, excessive regulation–and consequently, the extra costs involved–tends to stifle product delivery, thus incurring the opportunity cost of benefits to society. Harrington, Morgenstern, and Nelson (1999) relate this cost trade-off by defining the cost of a good as the maximum value of the opportunities foregone in obtaining that good.

Cost of Pharmaceutical Innovation

Estimating the cost of technological innovation has been done to a significant extent in the area of pharmaceutical products. Schnee (1972) estimated the cost of a research and development (R&D) project reported by one firm covering the period 1950-1967, although the estimate did not include pre-clinical costs and costs attributed to unsuccessful projects. The total estimated R&D cost of $534,000 (in current dollars) was derived simply through the average development cost and time reported by one large firm. The Tufts Center for the Study on Drug Development produced three comprehensive studies on the average cost of developing new drugs. The first study was released as early as 1979. These costs were updated in 1991, and then again in 2003. The Tufts Center studies by Hansen (1979), DiMasi, Hansen, and Grabowski (1991), and DiMasi, Hansen, Grabowski, and Lasagna (2003) estimated drug development costs using a representative sample from a list of drugs that entered clinical trials in predefined time spans. Other early studies differed in approach by using either case studies or aggregate data, often disregarding costs incurred in abandoned projects. DiMasi et al. (2003) claimed that it is difficult to estimate the cost from aggregated annual data because the R&D process often extends for a decade or more and the drug development process often changes.

In the studies conducted by DiMasi, Hansen, and Grabowski (1991) and DiMasi, Hansen, Grabowski, and Lasagna (2003), the full cost of drug R&D integrates the capital outlays expended on projects that failed. For each study, the opportunity cost of capital was computed at a constant discount rate spread over the total development time. The recent study of DiMasi, Hansen, and Grabowski (2003) employed a baseline value computed using a weighted real cost-of-capital for each firm. Other components in the estimation procedures are the period of regulatory review and the attrition rate (or conversely, success rate from testing to approval). DiMasi, Hansen and Grabowski (2003) estimated the average out-of-pocket cost per new drug at $403 million (in 2000 dollars). Capitalizing this to the time of market approval at a real discount rate of 11% accrues to a total of $802 million (in 2000 dollars). The estimated total cost is more than a three-fold increase of the estimate derived in the 1991 study at only $231 million (in 1987 dollars). In an analysis in *Nature*, Frantz (2003) blames the high costs of clinical development to trial requirements and inefficiencies. Adams and Brantner (2004) cite in particular regulatory policy as one of several factors that can influence the cost of development.

While Hansen and DiMasi included only self-originated drugs in the data, Wiggins (1987) also included costs from licensed-in drugs. Unlike in the Hansen (1979) and DiMasi (1991, 2003) studies, preclinical costs and costs attributed to treatment of unsuccessful projects are implicit in Wiggins's data. The discount rate used for out-of-pocket expenses remained either the same, as with Hansen, or comparable with other studies. Although the estimate derived by Wiggins is very close to the results of Hansen when compared at a single reference year, it has been recommended that Wiggins's analysis should have used a shorter development time for licensed-in drugs (US Congress, 1993). Data suggest that development times for approved licensed-in drugs are substantially shorter than the development times for approved self-originated products, implying that cost to the licensee is lower.

Like Wiggins, the study by Grabowski and Vernon (1990) used annual aggregate R&D data. However, the difference in modified R&D time profile and a higher discount rate resulted in a higher estimated average cost.

In summary, all of the studies on estimating cost of pharmaceutical innovation begin with an estimation of out-of-pocket expenditures for each phase of the R&D process. Duration to complete each phase is then determined, which will be used for capitalization of cash outlay. Attrition rate for projects in each phase of development may or may not be considered, but this holds an important implication on who will ultimately bear the expended capital on failed projects.

A study on drug evaluations runs parallel to the motivation of this study. The US system of drug approval minimizes the "Type I" error, i.e., the probability of approving drugs that are not safe or effective. Intriligator (1996) claims that too much emphasis on Type I error disregards the chance of committing a "Type II" error, or the error of rejecting drugs that are, in fact, safe and effective. Consequently, the first error type raises the cost of drug testing and protracts the R&D period before a safe and effective drug is made available in the market. He further asserted that this system can result in the loss of significant benefits to society when the sale of drugs that are safe and effective is prohibited.

Stages in Developing Genetically Modified (GM) Crops and the Associated Costs

Research and development of GM crops overlaps biosafety considerations with no clear delineation. The ultimate goal is to produce a plant that exhibits desirable novel characteristics by introgressing a laboratory-constructed gene. Introgression is the instance of integrating the gene construct to the host plant. Between and within each of the R&D stages, biosafety checks are already integrated, all of which require resources.

After a particular practical problem is defined, the first step in the development of GM crops is gene discovery. To be able to enhance a certain plant by adding a new characteristic not inherent to the plant, a gene that expresses that characteristic must be sourced. The gene is usually found in other organisms. In the case of borer-resistant corn, the gene responsible for the resistance was obtained from the soil bacterium *Bacillus thuringiensis* (Bt). It is often the case that the gene of interest is discovered first before it finds any practical applications. When the gene is found, the gene construct is made. The introgression process may be done through a biolistic accelerator (more commonly known as "gene gun") or through a vector plasmid of the tumor-inducing bacterium *Agrobacterium tumefaciens*. After a selection procedure is made to determine which plantlets have successfully integrated the novel gene, the genetically enhanced plant is now ready for laboratory or greenhouse testing, confined field trial, multi-location field trials when desired and finally, commercialization.

At each phase of a GM project development, costs are incurred. Aside from the resources expended on

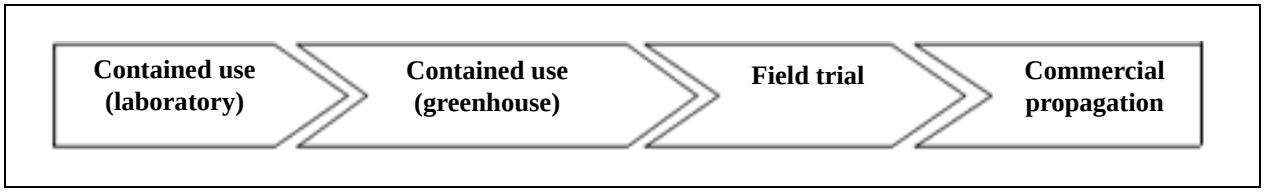

Figure 1. Succession of phases of GM crop biosafety approval in the Philippines.

activities that are organic to R&D, costs are also involved in expenditures for biosafety checks. A battery of tests is conducted to evaluate the safety of the protein product or the entire GM plant for humans, animals and the environment. The more stringent the regulatory process is, the more safety studies are required, and the longer it takes for the GM plant to reach commercialization. Biosafety processes are, by definition, precautionary (Zepeda, 2005). How precautionary a biosafety process is significantly contributes directly to the total cost of development.

Compliance with the formal regulatory process also involves significant attendant costs. Aside from the collection and reproduction of technical dossier and other overhead costs, activities germane to compliance, such as convening of institutional biosafety committees, field trial set-up and visits and publication of public information sheets (PIS), also contribute to the total cost.

The cost of developing a GM crop from the research stage to market approval is also largely influenced by the biosafety system that a country adopts. While a biosafety decision takes into consideration the safety of the regulated GM crop in terms of food, feed and environmental safety, a biotechnology policy decision may also involve all other aspects such as social, ethical and moral considerations (Zepeda, 2005). Assuming that a GM crop has already addressed the biosafety concerns, when the framework of a biotechnology decision process makes it more difficult for the crop to be considered as acceptable by imposing other requirements, then the total cost of development will consequently escalate.

The GM Crop Development Process: Case Study for Bt Corn MON810

The Philippine Biosafety System

Compared to most regulatory evaluations conducted to establish the safety of a technological innovation, the process required for genetically enhanced organisms (also called genetically modified organisms, or GMOs) is probably more stringent. All relevant safety aspects and probable risks associated with a genetically enhanced organism are scrutinized by regulators in order to gain knowledge upon which decisions for approval or disapproval are based. In the Philippines, the regulatory system to establish biosafety is conducted in a step-by-step fashion: the organism is subjected to a series of successive stages, each one being a prerequisite to the next. Each stage intends to incrementally introduce the organism from confinement (laboratory experiments) to the open environment (commercial propagation), provided safety considerations are satisfied at each level.

Figure 1 demonstrates the phase-by-phase biosafety assessment of a GM crop. Monsanto Philippines' Bt corn event MON810 underwent this process, finally being granted the permit for commercial propagation on December 4, 2002.

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 concerned with the field release and commercialization.

The primary function of the NCBP, a multi-agency and multi-disciplinary committee, is to identify and evaluate potential hazards involved in initiating genetic engineering experiments and recommend measures to minimize risks. Any individual or organization planning to conduct contained experiments on genetic modification needs to seek NCBP approval through an Institutional Biosafety Committee (IBC). Through this process, preliminary biosafety evaluation is already conducted 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. 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 the environment. Concurrent with the review by the STRP are public notifications of the proposal and solicitation of comments.

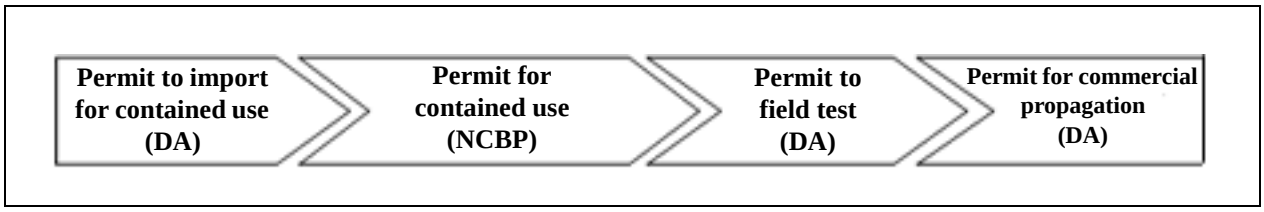

Figure 2. Succession of permits of GM crop biosafety approval in the Philippines.

An individual or organization planning to release a GM plant into the environment needs to subject the regulated article to the biosafety assessment procedure as defined in the DA's Administrative Order No. 8 series of 2002 (AO 8). Science-based risk assessment is carried out case-by-case and on the basis of the transformation event. The types of permits issued under AO 8 are classified according to the intended use of the regulated article: (1) importation for contained use, (2) field testing, (3) release for propagation, and (4) importation for direct use as food, feed or for processing.

AO 8 policy for commercial propagation stipulates that no regulated article will be released unless (1) field testing showed that the GM crop will not pose any significant risks to the environment, (2) food and/or feed safety studies showed that the GM crop will not pose any significant risks to human and animal health, and (3) a permit for propagation has been secured from the DA. If the GM crop is a *plant-incorporated protectant* (PIP), as is the case for Bt corn, it must also be duly registered with the Fertilizer and Pesticide Authority (FPA).

Figure 2 illustrates the sequence of permits necessary for the eventual propagation of a regulated article.

When new information on a regulated plant becomes available, the principles of risk assessment articulated in AO 8 allow a provision for re-evaluation of the level of risks or an amendment to the risk management strategies prescribed in the permit. In the case of Bt corn, the identified risk of the target insect developing resistance to the crop is being mitigated by an insect resistance management (IRM) strategy. Similar risk-mitigating measures are also conducted for other GM plants approved for commercial propagation.

History of Developing Bt Corn MON810 in the Philippines

A year after Bt corn MON810 was first commercially planted in the US in 1996, Cargill Philippines, in collaboration with the University of the Philippines at Los Baños (UPLB) submitted a proposal to the NCBP to conduct contained experiments (greenhouse study) on Bt corn. The NCBP approved the project proposal based on the UPLB IBC report, STRP recommendation, public comments favorable to the application and available relevant scientific literature that supported the study. Upon approval, the planting material was imported by Cargill USA and then planted in the greenhouse of the International Rice Research Institute (IRRI) during the dry season of 1998. The final report of the confined testing was submitted to the NCBP in 1998, which was to be used in the application for the confined field trial (CFT).

The NCBP, DA and STRP evaluated the proposed field testing activity. As required, part of the evaluation is the solicitation of public participation through the process of information dissemination activities such as stakeholder consultations and public hearings. During this time, NCBP members conducted on-site visits to be able to formulate guidelines and procedures on the safe conduct of the experiment before the actual activity was undertaken. In February 1999, Cargill was incorporated into Agroseed, making the latter the new study collaborator of UPLB.

About ten months after receiving the proposal, the NCBP decided to grant the permit and in December 1999, the confined field trial started. Meanwhile, a coalition of cause-oriented groups initiated public demonstrations against the conduct of the filed trials in certain parts of the country. A proposed site in Southern Luzon was eventually abandoned because of intensified anti-biotech activities in the area. But the confined field trial was satisfactorily completed in March 2000 and the terminal report was submitted in July of the same year. Results of the confined trial were used in preparation for the ensuing application for multi-location field trials. During this time, Agroseed was absorbed by Monsanto.

Through the 40 IBCs that it created all over the country, Monsanto filed the application for permit to conduct the multi-location field trials (MFT). Approval to conduct the 10-site field testing of Bt corn covering two seasons was granted in February 2001. Safety and risk assessments for each field test site were required to be evaluated separately by government. In July 2001,

the planting for the wet season trials in seven selected sites commenced.

During the field testing, anti-GMO groups continued with their activities to forestall the trials. One particular episode happened in August 2001 when they organized an uprooting protest activity at the field trial site in a province in Mindanao. As a result, the trial at this site was discontinued. This event had a big implication on the cost of regulatory compliance because stronger security measures had to be deployed in other sites, including the field trials conducted in the ensuing dry season.

From March to June 2002, the dry season trials in 10 selected sites were conducted. The report summarizing the results of the 17 trials was submitted to government in July for evaluation. On August 27, the government issued its certificate of completion of the MFT; and on September 3, Monsanto applied for a permit to propagate the regulated article on a commercial scale.

Monsanto had satisfactorily completed the biosafety and risk assessment process until the MFT level. With the application for commercial propagation, full biosafety assessment has to be conducted to assure that the plant is safe for humans, animals and the environment. The DA's Bureau of Plant Industry (BPI) evaluated the environmental safety aspect of the regulated article. Food safety was evaluated by the Bureau of Agriculture and Fisheries Product Standards (BAFPS) and feed safety was evaluated by the Bureau of Animal Industry (BAI). Since the article is a plant-incorporated protectant, it was also assessed by the Fertilizer and Pesticide Authority (FPA). Aside from these, external safety reviews by three members of the STRP were separately conducted. Public participation also formed part of the evaluation process with the solicitation of comments through the publication of the PIS in two newspapers of national circulation.

Even though this proved to be a learning experience for the government regulators, the evaluation process was accomplished within the 90-day time frame. By December 3, a consensus of the technical evaluators favorably endorsed the GM crop for commercialization. This served as the basis for the DA summary report, which concluded that:

1. MON810 is safe to humans, animals, and nontarget organisms; and is as nutritious as ordinary corn.
2. MON810 is safer than chemical insecticides.
3. MON810 is very effective in controlling the Asiatic corn borer.
4. The Bt gene is inherited like any ordinary corn gene.

On December 4, 2002, Monsanto Philippines' Corn event MON810–the transformation event of the gene that confers resistance to the Asiatic corn borer (ACB)–became the first GM plant to gain approval for commercial propagation in the country. It took five years, three months and 16 days to complete the process and satisfy the requirements of the Philippine biosafety system.

However, the product development of Bt corn MON810 continued even after it was granted commercial approval in December 2002 since the permit contained an explicit condition for the technology proprietor to implement an insect resistance management (IRM) strategy for Bt corn. Even before applying for the permit to propagate the Bt corn, Monsanto had already conducted technical studies and consultation meetings on appropriate IRM strategies in anticipation of this requirement. With other industry players, Monsanto embarked on the full implementation of the enhanced national IRM strategy for Bt corn. The DA exercised its supervisory functions over the implementation of the IRM strategy and industry monitoring of any resistance development.

Methodology for Estimating the Product Development Cost

Ex Post Study

The paper is an ex post study on the cost of developing Bt corn MON810 in the country. An ex post study evaluates a project or program after the institution has been in operation and the component activities have already been carried out. Since the GM crop under consideration is already fully developed and adopted, this study employs an ex post assessment. Thus, assessments are made based on actual implementation experiences. This study benefited from data gathered on actual costs incurred during the different development phases of the project, from product conceptualization to in situ product testing and post-application product stewardship.

The Timeframe: 1985 to 2004

In estimating the cost of developing the Monsanto GM crop, the study considered the timeframe starting from the initial stages of product development in the 1980s and culminating in 2004 when the post-market regulatory system for product stewardship was fully implemented.

The process to develop Bt corn MON810 started with product conceptualization. However, it was in the mid-1980s when activities were formally initiated in the US to develop the concept into a concrete product, beginning with tests performed in the laboratory and greenhouse for gene discovery, genetic transformation, production of tissues and line selection. In the early 1990s, MON810 was tested in field trials in the US and Canada. Data collected from these trials demonstrated that MON810 was not different from conventional maize varieties except that it was effective in controlling the corn borer. Environmental clearance in the US was obtained in 1995 while food and feed safety approval was acquired in 1996, paving the way for commercial release in the same year.

Technical and commercial development of the GM crop in the Philippines started in the late 1990s with the greenhouse trial in 1997. In December 2002, the permit for commercial planting was granted. However, as mentioned, the costs of developing the product did not end right then, due to the requirement for the development and implementation of the IRM strategy. Thus in 2003, Monsanto started with the full implementation of its *post-commercial application* (PCA) regulatory activities, particularly its stewardship program in the implementation of the IRM strategy. At present, Monsanto is continuously carrying out the same post-commercial activities on product stewardship. However, the cost of regulatory compliance is not as steep as before, since development of the basic system had already been completed and laid down in 2004. Activities in 2005 and beyond are simply implementation and minor refinements of the system already in place.

Economic and Financial Tools of Analysis

The study employed economic and financial tools of analysis–particularly (1) itemized project costing deflated in constant terms, (2) cost-of-capital estimates using real discount rates, (3) multiple currency valuation, and (4) Lindahl pricing–to come up with a cost estimate that is closest to the real market cost of developing the product, using 2004 as the base year.

The entire *cost structure*–with (1) component items and activities arranged by general type, year and phase plus (2) their respective item costs given in (a) current terms in the year when the cost was incurred, and in (b) the currency actually used based on the country where the expenditure was undertaken–was laid neatly in a matrix (Table 1). This allowed the researchers ease of reference to component items vis-à-vis the total project cost as well as data analysis both from a micro and macro perspective.

Table 1. The initial cost structure.

Area/activity	Item cost PhP	US$	Year
Laboratory/greenhouse (US)			
Item 1			
Item 2			
Item 3			
Greenhouse (Phil.)			
Item 1			
Item 2			
Item 3			
Confined field trial			
Item 1			
Item 2			
Item 3			
Multi-location field trials			
Item 1			
Item 2			
Item 3			
Commercial propagation			
Item 1			
Item 2			
Item 3			
Post-commercial application			
Item 1			
Item 2			
Item 3			

Using data from the GDP deflator for the Philippines and the US, each component cost was adjusted in constant terms to the base year 2004. When the complete project development cycle stretches across several years, as is the case for Bt corn MON810, itemized project costing deflated in constant terms allows an accurate measure of the total project cost in terms of its *real* monetary value established around the specified base year. This renders the different item costs comparable at the time of assessment.

Estimation of the total cost of development should also consider the cost of capitalization, which will depend on the lag between the initial investments in developing the product and the realization of returns. The gap between investments and returns should be taken into account by capitalizing the stream of costs and returns to a date that according to DiMasi, Hansen, and Grabowski (2003) is standard at the date of commercial approval. For the MON810 case, since the

approval was obtained in December 2002 wherein no significant commercial planting was undertaken at this late time of the year, the effective year by which discounting was set is 2003, the same year when Bt corn planting was carried out on a commercial scale. In applying the methodology to this study, each component cost was capitalized (discounted) at the appropriate discount rates. The discount rate is the expected return that the company forgoes during initial investments based on an equivalent investment portfolio in an alternative financial instrument. Discounting measures the scarcity value of money, or its opportunity cost – the rate of return which the funds would have earned in its best available alternative use.

For expenditure items incurred in the US, this study employed the updated estimate of DiMasi, Hansen, and Grabowski (2003) and used a uniform 11% real cost-of-capital discount rate, which was based on a representative group of US-based pharmaceutical firms. Biotech R&D has similar characteristics to pharmaceutical R&D in terms of its initial stages, incremental out-of-pocket expenses, investment risks and lag time profile. Due to these similarities, the real discount rate that DiMasi estimated for the pharmaceutical industry is deemed applicable for the agricultural biotech industry in the US as well.

For expenditure items incurred in the Philippines, the study used a variable real discount rate per annum which is computed based on the (nominal) social discount rate–recommended by the Philippine National Economic Development Authority (NEDA) at 15%–less the current inflation rate during the year of expenditure (Philippine NEDA, 2004).

The cost structure was then subjected to multiple currency valuation by converting dollar-based expenditures to their peso equivalent and vice versa using *Bangko Sentral ng Pilipinas* data on exchange rates. This is necessary because Bt corn MON810 was already developed as a complete product in the US before being introduced in the Philippines. Expenditures for those activities conducted in the US during the early product development phase were transacted in U.S dollars, while succeeding expenditures on activities for the commercial development of the product in the Philippines were dealt in Philippine pesos. Thus, with multiple currency valuations, the study was able to come up with a robust cost structure despite the different currencies used to bring and develop the product in the Philippines.

Computation of the Lindahl Factor

One major problem the researchers faced in developing the Bt corn cost structure was how to attribute the costs incurred in the US – 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.

These core activities assume the nature of a public good. Benefits derived from initial expenditures incurred in the US for Bt corn conceptualization, design and development, which account for a significant portion of the total cost structure, accrue also to the other countries where the GM crop will be commercialized in the future. The knowledge capital that is produced in the US for MON810 was a public good that also benefited Monsanto scientists in the Philippines and other countries. Moreover, the cost of *replication* and *refinement*–those activities conducted in the Philippines and other countries to commercially develop Bt corn–is relatively much less than those for the core activities. It is for these reasons that the core activities become non-rival and non-excludable and become a public good.

The question now is: How do we account for (or allocate) the costs of these core activities when we try to isolate the costs of developing Bt corn MON810 solely for the Philippines? An economically sound approach is to use the concept of Lindahl pricing and adapt it to our particular case. In 1919, Swedish economist Eric Lindahl proved that, based on willingness to pay, different prices for different people would result in optimal levels of public goods and would distribute costs in the fairest way possible (Detering, 2001).

Adapting the principle of Lindahl price, we proportionately distribute 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 US that will be attributed to the total cost of developing Bt corn event MON810 solely for the Philippines.

By the principle of Lindahl pricing, the share of the Philippines to total costs incurred in conducting the core

activities is based on the share of the country to total (world) benefits from planting the Bt corn. Benefit from the commercial planting of Bt corn is measured in terms of its value of production, both actual (past) and expected (future).

However, data on actual Bt corn values of production (both for the world and for the Philippines) are not readily available and can only be indirectly obtained from existing Food and Agriculture (FAO) and Monsanto data on corn hectarage, production, yield, and prices using the following derived formulas.

Given:

1) Corn hectarage
   a) World: H_T (from FAOSTAT)
   b) Bt corn: H_{bt} (from Monsanto)
2) Corn production
   a) World: C_T (from FAOSTAT)
3) Corn yield
   a) World: Y_T (from FAOSTAT)
   b) Bt corn yield advantage: β = assumed constant at 25% based on literature
4) Corn prices
   a) World: P (from FAOSTAT)

Derived Formulas:

Total corn hectarage: (Bt and non-Bt corn hectarage)

$$H_T = H_{bt} + H_{nbt} \tag{1}$$

Share of Bt corn to total corn hectarage:

$$\alpha = \frac{H_{bt}}{H_T} \tag{2}$$

Total corn production: (Bt and non-Bt corn production)

$$C_T = C_{bt} + C_{nbt} \tag{3}$$

Average corn yield:

$$\begin{aligned} Y_T &= \frac{C_T}{H_T} \\ &= \frac{C_{bt}}{H_T} + \frac{C_{nbt}}{H_T} \\ &= \left(\frac{C_{bt}}{H_{bt}} * \frac{H_{bt}}{H_T}\right) + \left(\frac{C_{nbt}}{H_{nbt}} * \frac{H_{nbt}}{H_T}\right) \end{aligned} \tag{4}$$

Given Equations 1 and 2, then:

$$Y_T = Y_{bt}\alpha + Y_{nbt}(1-\alpha) \quad \text{or}$$
$$\alpha Y_{bt} = Y_T - Y_{nbt}(1-\alpha) \tag{5}$$

Average Bt corn yield$_1$:

$$Y_{bt} = \frac{Y_T}{\alpha} - Y_{nbt}\frac{(1-\alpha)}{\alpha} \tag{6}$$

Given Bt corn yield advantage:

$$\beta = \frac{Y_{bt} - Y_{nbt}}{Y_{nbt}} \quad \text{or} \quad Y_{nbt} = \frac{Y_{bt}}{1+\beta} \tag{7}$$

Hence, with Equations 6 and 7:

$$Y_{bt} = \frac{Y_T}{\alpha} - \left(\frac{Y_{bt}}{1+\beta}\right)\left[\frac{(1-\alpha)}{\alpha}\right]$$

$$Y_{bt} + \left(\frac{Y_{bt}}{1+\beta}\right)\left[\frac{(1-\alpha)}{\alpha}\right] = \frac{Y_T}{\alpha}$$

$$Y_{bt}\left[1 + \frac{(1-\alpha)}{\alpha(1+\beta)}\right] = \frac{Y_T}{\alpha}$$

$$Y_{bt}\left[\frac{\alpha(1+\beta)+(1-\alpha)}{\alpha(1+\beta)}\right] = \frac{Y_T}{\alpha} \tag{8}$$

Average Bt corn yield$_2$:

$$Y_{bt} = \frac{Y_T(1+\beta)}{\alpha(1+\beta)+(1-\alpha)} \quad (9)$$

With Bt corn production:

$$C_{bt} = H_{bt} * Y_{bt} \quad (10)$$

And value of production, world:

$$V_T = C_T * P \quad (11)$$

Therefore, value of production, Bt corn:

$$V_{bt} = C_{bt} * P \quad (12)$$

Having derived the past annual values of Bt corn production for the Philippines and the world, forecasting methods are used to project both values of production in the future at 2004 net present value (NPV). According to industry sources, YieldGard (the trade name of Bt corn MON810) will be commercially available until an enhanced Bt corn product (YieldGard 2) is introduced in the market and becomes well accepted. This is taken into consideration in the forecasts. The respective total values of production are then obtained by simply adding the actual and forecasted values of Bt corn production for the country and for the world. Finally, we get the imputed Lindahl factor for the Philippines–computed at 0.7306% (see Table 2)–from the ratio of these two totals.

With the Lindahl factor considered in our computation, we now have the final cost structure as shown in Table 3.

Table 2. Bt corn actual and projected values of production, world and the Philippines.

	Bt corn value of production, US$ (2004 NPV)	
Year	World ($V_{bt\text{-}World}$)	Philippines ($V_{bt\text{-}Phil}$)
1997	563,323,019	-
1998	2,573,103,099	-
1999	3,161,209,017	-
2000	2,965,057,780	-
2001	3,226,818,180	-
2002	4,558,471,196	46,859
2003	5,505,574,429	4,512,628
2004	7,754,944,884	23,896,302
2005	6,602,676,674	16,018,148
2006	6,596,083,213	48,545,963
2007	6,527,771,420	59,777,718
2008	6,409,776,352	75,711,867
2009	6,252,385,939	91,008,083
2010	6,064,365,452	96,852,148
2011	4,377,688,463	69,914,739
2012	2,962,451,812	47,312,422
2013	1,781,888,506	28,458,003
2014	803,796,215	12,837,186
Total	78,687,385,652	574,892,066
	Lindahl factor	**0.7306%**

The Cost of Development of Bt Corn Event MON810

Cost of Development by Major Activity Grouping

The cost of developing Bt corn event MON810 in the Philippines – from the US laboratory testing to the post approval stewardship stage – is estimated at $2,607,793 at 2004 discounted prices.

Table 4 shows the costs in terms of major activity groupings. Laboratory and greenhouse activities conducted in the US in the 1980s and 1990s, mostly in the form of experiments and scientific studies, accounted for about $200,000. 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 US-based activities alone would have reached $29 million.

Laboratory and greenhouse activities conducted in the Philippines only amounted to about $57,000. These activities simply complemented those already conducted in the US, 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.

Cost for the single-site confined field trial (CFT) is about $170,000. Contrasting this to the total costs of about $888,000 incurred for the conduct of the multi-location field trials (MFT) in 17 sites–or an average of $52,000 per site–the unit cost of conducting the latter

Table 3. The final cost structure.

Area/activity	Item cost		Year	GDP deflator (2004=100)	Exchange rate	Real discount rate	Lindahl factor	Discounted cost at 2004 prices	
	PhP	US$						PhP	US$
Laboratory/ greenhouse (US)									
Item 1									
Item 2									
Item 3									
Greenhouse (Phil.)									
Item 1									
Item 2									
Item 3									
Confined field trial									
Item 1									
Item 2									
Item 3									
Multi-location field trials									
Item 1									
Item 2									
Item 3									
Commercial propagation									
Item 1									
Item 2									
Item 3									
Post-commercial application									
Item 1									
Item 2									
Item 3									
Total									

experiment is cheaper by roughly 70%. Here we can appreciate the advantage of economies of scale. Conducting simultaneous multi-location field trials costs 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 $316,000. A significant portion of this amount (close to 85% or $267,000) 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 $5,300 government fee paid (at the 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.

Post-application activities amounted to more than $965,000, the set of activities garnering the lion's share in the total expenditure pie. The two items entailing the most significant costs are the conduct of IRM activities across the country and the production of promotional and information, education and communication (IEC) materials.

Cost of Development by Phase

By phase of development, the order observed in terms of decreasing share to the total development cost (at 2004 discounted prices) is as follows: (1) post commercial activities, (2) multi-location field trials, (3) commercial

Table 4. Cost of developing Bt corn event MON810 in the Philippines by major activity grouping at 2004 discounted prices.

		Discounted cost at 2004 prices			
		PhP		US$	
Area/activity	Lindahl factor	(without Lindahl)	(with Lindahl)	(without Lindahl)	(with Lindahl)
Laboratory/greenhouse (US)	0.00731	**711,705,874**	**5,199,741**	**29,025,063**	**212,058**
1980s studies	0.00731	95,274,121	696,075	5,120,244	37,409
1990s studies	0.00731	616,431,753	4,503,666	23,904,819	174,649
Greenhouse (Phil)	1.00000	**1,988,113**	**1,988,113**	**57,362**	**57,362**
1997 Lab/greenhouse	1.00000	922,638	922,638	31,307	31,307
1998 Lab/greenhouse	1.00000	1,065,476	1,065,476	26,055	26,055
Confined field trial	1.00000	**7,009,088**	**7,009,088**	**169,718**	**169,718**
1999 trials	1.00000	3,762,657	3,762,657	96,259	96,259
2000 trials	1.00000	3,246,431	3,246,431	73,459	73,459
Multi-location field trial	1.00000	**44,379,128**	**44,379,128**	**887,774**	**887,774**
2000 activities	1.00000	7,392,247	7,392,247	167,269	167,269
2001 activities	1.00000	16,120,342	16,120,342	316,131	316,131
2002 activities	1.00000	20,866,539	20,866,539	404,375	404,375
Commercial propagation	1.00000	**16,312,461**	**16,312,461**	**315,853**	**315,853**
2002 studies	1.00000	13,793,309	13,793,309	267,302	267,302
2002 activities	1.00000	2,204,703	2,204,703	42,725	42,725
PIS	1.00000	26,975	26,975	523	523
Application Fee	1.00000	287,474	287,474	5,304	5,304
Post-commercial application	1.00000	**53,088,637**	**53,088,637**	**965,028**	**965,028**
2003 activities	1.00000	14,052,274	14,052,274	259,253	259,253
2004 activities	1.00000	11,265,589	11,265,589	201,028	201,028
2003 promo material	1.00000	15,203,283	15,203,283	280,488	280,488
2004 promo material	1.00000	12,567,490	12,567,490	224,260	224,260
Total		**834,483,302**	**127,977,169**	**31,420,798**	**2,607,793**

application, (4) confined field trial, (5) US laboratory and greenhouse (with the Lindahl factor considered), and (6) Philippines greenhouse. This can be observed in Table 5.

Cost of Development by Year of Expenditure

Table 6 shows the stream of costs in terms of year of expenditure – measured at current prices and without factoring in the cost of capitalization. Costs were not discounted and were taken at current prices from the year when the cost was incurred. This was done so as to compare the amount of expenditure between different points in time at their prevailing price levels and then observe the general trend of the time series.

The series started in 1985, when expenditures for the initial phase of product development in the US were first reported. A nine-year hiatus is observed before the next set of laboratory and greenhouse activities was undertaken. Year-after-year expenditures are incurred from 1994 until 2004, the year when the system for post-application monitoring was fully implemented in the Philippines. Particular for the country, it took 20 years for Bt corn MON810 to traverse the complete cycle of full product development.

Figure 3 is a historical plot of the time series. The trend is generally increasing until 2002 and then declines thereafter. We notice a modest upward spike in 1995 brought about by the conduct of most of the costly experimental studies in the US; i.e. molecular characterization, compositional assessment, protein safety assessment, non-target organism studies, agronomic and phenotypic assessments, ELISA development, validation and expression analysis, animal performance and safety studies, environmental fate, and facility costs.

Table 5. Cost of developing Bt corn event MON810 in the Philippines by phase of development at 2004 discounted prices.

Phase	Discounted cost at 2004 prices (US$)	Percent share (%)
Lab/greenhouse (US)	212,057.86	8.13
Greenhouse (Phil.)	57,362.13	2.20
Confined field trials	169,717.60	6.51
Multi-location field trials	887,773.99	34.04
Commercial application	315,853.39	12.11
Post-commercial activities	965,028.12	37.01
Total	**2,607,793.08**	100.00

Table 6. Cost of developing Bt corn event MON810 in the Philippines by year of expenditure at current prices.

Year	Cost at current prices (US$)	Percent share (%)
1985	3,653.01	0.18
1994	4,895.04	0.23
1995	56,950.47	2.73
1996	1,680.39	0.08
1997	12,758.00	0.61
1998	12,758.00	0.61
1999	53,230.37	2.55
2000	154,288.72	7.39
2001	226,225.06	10.84
2002	583,061.90	27.94
2003	513,838.62	24.63
2004	463,265.74	22.20
Total	**2,086,605.34**	100.00
2005	38,413.08	---

A steady increase is then observed from 1998 to 2001. The amount for 2002 is significant in that close to 28% of the entire cost was incurred during this year. This was when the last stages of the multi-location field trials, as well as the local biosafety and socioeconomic studies, were undertaken. From 2002 to 2004, a slight but steady decline is observed.

The table (Table 6) and corresponding graph (Figure 3) also show the amount spent by Monsanto for MON810 in 2005. Here we see a very steep drop in the pattern of expenditure (represented by the dotted lines in the graph). The year 2004 marks the period when full product development has been achieved. Activities from 2005 and beyond are simply for product stewardship and continuous product marketing.

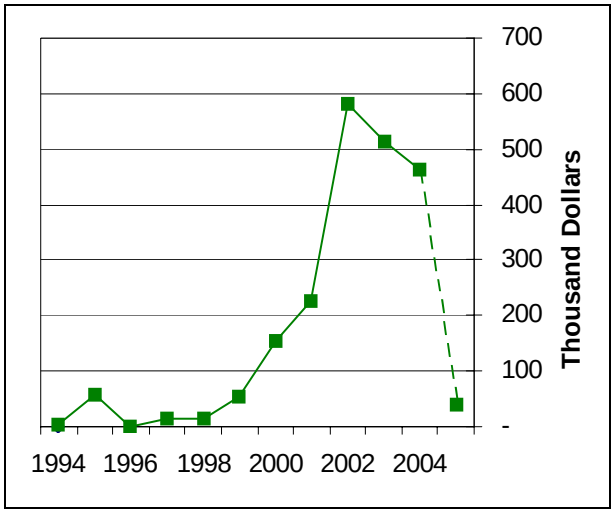

Figure 3. Cost of developing Bt corn event MON810 in the Philippines by year of expenditure (excluding 1985) at current prices.

Cost of Development by Core Function

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. However, as may be observed in Figure 4, when individual activities were defined as to their primary objective and strictly classified according to their core function, it was discovered that two-thirds of the total cost went into activities conducted largely for the purpose of compliance and support to government regulatory requirements.

Indeed, did regulatory compliance eat up too much of the total cost of developing the Bt corn? The costs estimated in this study show patterns of spending that can be used as a rough guide for estimating the cost of developing a new GM crop in the Philippines. The study is especially helpful if one is to appreciate that many of these novel crops are being developed by public research institutions in developing countries. Pardey and Beintema (2001) found that for these countries, public investments accounted for 95% of total costs spent for agricultural R&D from 1976 to 1995. Most of the work is devoted to a wide range of nationally important crops which the private sector will not venture into because of limited expected returns. Moreover, the main objectives of these products include servicing the special needs and concerns of local community stakeholders and contributing to national development goals.

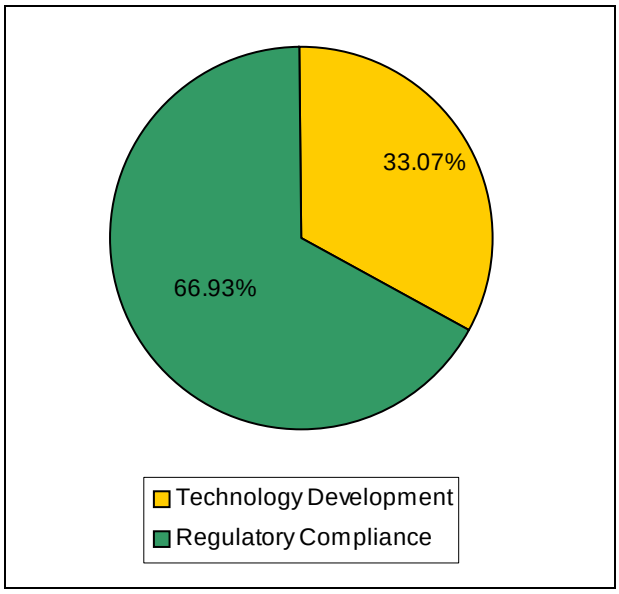

Figure 4. Percent share to total cost of activities as to core function: Technology development (R&D) vs. regulatory compliance (or approval).

Conclusion

Initial data from other crops being developed in the Philippines and other countries show that the cost of development is not as expensive as that for Bt corn MON810. The comparatively steep cost of developing MON810 in the Philippines may be explained by the fact that the technology is relatively new when it was being developed in the 1990s, thus government and the technology developer had to take extra steps to ensure the highest level of safety before bringing the product into the market. Particular to the Philippines, Bt corn was the first GM crop that was applied for commercial propagation. As such, many studies – both required and not required by government – were conducted in support of Monsanto's application.

Related to this point, some observers claim that many of the biosafety regulatory requirements set in place are too stringent, going beyond the scope of scientifically supported principles of biosafety assessment. Likewise, since demonstration of agronomic performance was required, the company used this opportunity to test the crop across space and time–the 17-site field trials spanning two seasons were conducted to reflect the different geo-climatic conditions of the Philippines. Although this served as an incidental opportunity to demonstrate the bioefficacy of Bt corn MON810 to stakeholders, socio-economics is not a rudimentary concern of biosafety.

While an overly stringent regulatory system may have increased the total cost of Bt corn development, the computed item costs for some component activities could also be an underestimate of its real monetary value. Greenhouse activities were conducted through the participation of UPLB and IRRI, which allowed for free use of established infrastructure for technology development and biosafety compliance. It was thus advantageous for the technology developer to have formed this collaborative agreement.

The pioneering work undertaken in the development of Bt corn MON810 can serve as a model for the Philippines and similarly situated countries where significant activities are currently being carried out in the development of domestically important GM crops. Technology developers, particularly public research institutions, can learn to anticipate the level of effort and attendant costs involved so that project proposals are prepared with the proper resources allocated for the entire project duration. Government agencies, on the other hand, can appreciate the dynamic nature of GM crop development and learn to adapt the evolving regulatory system in place that could harmonize competing value claims so that safe GM crops can be developed and exploited in the service of the national interest.

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