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Biotechnology Product Development, Biosafety Regulation and Environmental Risk Assessment in the Philippines

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This study looks at the current biotechnology and biosafety situation in the Philippines. It assesses whether the country's biotechnology organizations are in a position to effectively perform biosafety regulation, protect intellectual property rights and respond to the accelerating pace of international biotechnology product development.

Based on a mixture of primary and secondary information, the study finds that biotechnology development is constrained by funding and resources. It also finds that, while biosafety guidelines and practices are relatively strong, there are a number of institutional weaknesses.

The study recommends measures to make biotechnology research and development more cost-effective and to improve biosafety in the country. Overall, the report calls for the Philippines to carefully balance the need for biotechnology regulation with the need for innovative biotechnology development.

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ACB	Asiatic Corn Borer
AFMA	Agriculture and Fisheries Modernization Act
AIA	Advanced Informed Agreement
AO	Administrative Order
BAFPS	Bureau of Agriculture and Fisheries Product Standards
BAI	Bureau of Animal Industry
BAR	Bureau of Agricultural Research
BAT	Biotechnology Advisory Team
BCH	Biosafety Clearing House
BCT	Biotechnology Core Team
BPI	Bureau of Plant Industry
BPD	Biotechnology Product Development
CL	Containment Level
CBD	Convention on Biological Diversity
CPB	Cartagena Protocol on Biosafety
DA	Department of Agriculture
DCs	Developing Countries
DENR	Department of Environment and Natural Resources
DILG	Department of Interior and Local Government
DNA	Deoxyribonucleic Acid
DOH	Department of Health
ELISA	Enzyme-linked Immunosorbent Assay
EO	Executive Order
FAO	Food and Agriculture Organization
FPA	Fertilizer and Pesticide Authority
GDP	Gross Domestic Product
GM	Genetically Modified
GMO	Genetically Modified Organism
HIPs	High Impact Projects
IBC	Institutional Biosafety Committee
IDRC	International Development Research Centre
IP	Intellectual Property
IP Code	Intellectual Property Code of the Philippines
IPR	Intellectual Property Rights
IRM	Insect Resistance Management
IRRI	International Rice Research Institute
ISAAA	International Service for the Acquisition of Agri-biotech Application
ISNAR	International Service for National Agricultural Research
IUCN	International Union for Conservation of Nature and Natural Resources
KI	Key Informant
LGUs	Local Government Units
LMO	Living Modified Organism
MTA	Material Transfer Agreement
NBF	National Biosafety Framework
NIH	National Institute of Health
NCBP	National Committee on Biosafety of the Philippines

NGO	Non-Government Organization
PBG	Philippine Biosafety Guidelines
PBRS	Philippine Biosafety Regulation System
PCARRD	Philippine Council for Agriculture, Forestry and Natural Resources Research and Development
PHILRICE	Philippine Rice Research Institute
PVPA	Plant Variety Protection Act
RA	Republic Act
RARC	Risk Assessment Review Cost
RFU	Regional Field Unit
R&D	Research and Development
SCUs	State Colleges and Universities
STRP	Scientific and Technical Review Panel
TRIPS	Trade-Related Aspects of Intellectual Property Rights
TWG	Technical Working Group
UNEP/GEF	United Nations Environment Programme/Global Environment Facility
UPLB	University of the Philippines Los Baños
USA	United States of America
WB	World Bank

BIOTECHNOLOGY PRODUCT DEVELOPMENT, BIOSAFETY REGULATIONS AND ENVIRONMENTAL RISK ASSESSMENT IN THE PHILIPPINES

Linda M. Peñalba
John A. Fajardo, Flordeliza A. Sanchez and Aida O. Grande

EXECUTIVE SUMMARY

The application of modern biotechnology is recognized as the potential answer to the growing problems of food security (i.e., the ability to provide adequate and affordable food), poverty and environmental degradation, particularly in developing countries. The challenge for these countries is how to benefit from the application of these technologies considering their lack of necessary biosafety regulation and intellectual property management capacity.

The aim of this study was to find out if the Philippine biosafety regulation system is effective, if it protects intellectual property rights (IPR) and if it has the capacity to respond to the potential increased pace in biotechnology product development.

The results of the study show that: (a) the current Philippine Biosafety Guidelines are consistent with the Cartagena Protocol on Biosafety (2000); (b) efforts are being made to enhance human resource and infrastructure capacity for research and development, and biosafety regulation; (c) due to resource limitations, research and development efforts focus on testing the applicability of technologies developed in other countries to local conditions. These studies are less costly but can contribute significantly to the knowledge and science on biosafety; (d) *Bt* corn[1], the first genetically modified crop approved for commercial release in the Philippines, underwent several stages of risk assessment before it was approved for commercial release; and (e) the intellectual property rights related to biotechnology are protected under the Intellectual Property Code of the Philippines (1997).

It can be concluded that in the Philippines, biosafety regulation and intellectual property management systems have been effective in regulating the use of biotechnology materials and in providing IRP protection. The Philippine Biosafety Regulation System can adequately cope with biosafety regulation requirements at the current level of agricultural biotechnology research and development in the country.

1.0 INTRODUCTION

Modern biotechnology is fast gaining importance as a tool to address food security concerns in the face of rapid population growth, increasing scarcity of natural resources and diminishing rates of productivity in agriculture using conventional technology (Quiam and von Braun 1998). The adoption rate for genetically modified (GM) crops is remarkably high compared to other technologies. Over a nine-year period**,** from 1996 – 2004, the global area for GM crops increased 47-fold, from 1.7 million hectares to 81.0 million hectares (James 2004). In 2003, six countries (United States-63%, Argentina-21%, Canada-6%,

[1] *Bt* corn (*Zea mays L.)* is genetically engineered to express genes from the soil bacterium *Bacillus thuringiensis* that encodes the insecticidal protein toxin Cry1Ab to resist corn borers.

Brazil-4%, China-4%, and South Africa-1%), four crops (maize, soybean, canola/rapeseed and cotton) and two traits (insect resistance and herbicide tolerance) accounted for 99 per cent of the global area planted with transgenic (GM) crops (FAO 2004; James 2003). James (2004) further noted that in 2004: (a) about 90 per cent of the farmer-adopters were resource-poor from developing countries (DCs); (b) the adoption rate of GM crops in developing countries increased by 35 per cent compared with only 11 per cent in industrialized countries; and (c) nine of the fourteen biotech mega-countries (growing 50,000 hectares or more of biotech crops) are DCs. The Philippines is among these nine biotech mega-countries.

Despite expectations that biotechnology can enhance agronomic, nutritional and marketing qualities of crops as well as reduce environmental damage caused by toxic agricultural chemicals, the product development process and the product itself are seen by some environment advocates as threats to the environment and society (FAO 2004). Unlike the high-yielding crop varieties disseminated under the Green Revolution (the 1960s to the 1970s), the products (such as GM crops) of the Gene Revolution (1996 to 2004) have raised public concern and encountered significant regulatory and market barriers due to the potential long-term risks that they may bring to human health and the environment. The common environmental and health concerns associated with transgenic crop cultivation are: (a) the possibility that transgenes will escape from cultivated crops into wild relatives; (b) the peril of unintentional introduction of allergens into food; and (c) pests becoming resistant, through time, to the toxins produced by GM crops (BioLife 2005).

According to Jaffe (2002), the keys to reaping the long-term benefits of agricultural biotechnology are: (a) a strong but not stifling biosafety regulation system; (b) well-trained human resources to undertake modern biotechnology research, conduct biosafety assessments and develop physical infrastructure facilities that meet biosafety standards; and (c) an intellectual property (IP) management system that can deter the illegal use of untested biotechnology materials. These aforementioned requirements, however, are frequently lacking in developing countries (Kowalski et. al. 2002).

However, it is observed that DCs may not benefit from this promising technology because: (a) global trends in biotechnology product development (BPD) do not address the needs of the poor (James 2003); (b) biotechnology research and development (R&D) requires huge investments that DCs cannot afford (James 2003); (c) DCs have poor regulatory capacity hence, they cannot effectively enforce biosafety regulation (James 2003); and (d) DCs have no IP management capability, therefore they cannot protect the intellectual property rights (IPRs) of technology developers (ISAAA 2003).

In the Philippines, modern biotechnology R&D started in the late 1970s. In anticipation of the need to set-up an institutional and policy framework to govern the use of genetically engineered crops, a group of scientists from the University of the Philippines Los Baños (UPLB) and the International Rice Research Institute (IRRI) drafted biosafety rules. This became the basis of Executive Order (EO) No. 430 issued in 1990, which in turn, created the National Committee on Biosafety of the Philippines (NCBP) and instituted the Philippine Biosafety Guidelines (PBG). Other related measures such as Department of Agriculture (DA) Administrative Order (AO) No. 8 of 2002 (Implementing Rules and Regulations for the Import and Release into the Environment of Plant and Plant Products Derived from the Use of Modern Biotechnology); the Republic Act (RA) 9168 of 2002 (The Philippine Plant Variety Protection Act (PVPA) of 2002); the DA AO No. 7 (Implementing Rules and Regulations of the Philippine Plant Variety Protection Act, 2002),

and RA 8293 of 1997 (Intellectual Property Code of the Philippines) were issued to enhance the Philippines' capacity to comply with international agreements such as the Cartagena Protocol on Biosafety (2002) and the Trade-Related Aspects of Intellectual Property Rights (TRIPS) (1994). However, while PBG mechanisms have been set-up, apparent gaps in the regulatory system have been observed.

For instance, the Department of Environment and Natural Resources is still in the process of designing a framework to address broader environmental concerns related to genetically modified organisms (GMO) and other modern biotechnology products. Furthermore, the alleged lack of proper consultation with local government unit (LGU) officials and the advocacy of non-governmental organisations (NGOs) against GMO were major sources of tension during the field trial of *Bt* corn, the first GM crop approved from for commercial release.

Biotechnology adoption is seen as a major element in the promotion of Philippine agricultural development. As a consequence, there has been an increase in the number and diversity of biotechnology products being proposed for commercialization. Since 2002, adoption of *Bt* corn has been promoted. *Bt* corn is a genetically engineered corn expressing the insecticidal CrylAb protein from *Bacillus thuringiensis*, a soil bacterium that has been used as microbial insecticide for the last 40 years. It accounts for 11.2 million hectares or 14 per cent of the total global transgenic crop area. It is planted in 13 countries and has been approved for commercial release for food and/or feed use in the USA, Canada, Argentina, South Africa, Spain, Honduras, Germany, the European Union, Japan, Russia, France, Australia and Switzerland (Ebora 2003 and BPI 2004).

This study proposed to find out the effectiveness of the Philippine biosafety regulation and intellectual property management systems in mitigating the possible environmental and health risks associated with GM crops.

2.0 OBJECTIVES OF THE STUDY

The aims of this study were:

a) to determine the prospects for biotechnology product development (BPD) in the Philippines;

b) to examine the effectiveness of Philippine biosafety regulatory mechanisms, the capacity of local institutions to implement biosafety guidelines, and the extent of environmental risk analysis conducted before the commercial release of *Bt* corn was approved;

c) to study the mechanisms used in intellectual property (IP) management in the Philippines and how these can be used to deter illegal importation and commercialization of untested biotechnology products and;

d) to recommend measures to further improve the Philippine biosafety regulation system (PBRS) and provide adequate safeguards to minimize environmental risks.

3.0 METHODOLOGY

Primary and secondary data were used in this study. Primary data was gathered through interviews with key informants (KIs) from state colleges and universities (SCUs), public R&D institutions, funding agencies, provincial and municipal agricultural offices, Institutional Biosafety Committees (IBCs), private seed companies, regulatory agencies, non-government organizations (NGOs) and farmers. Secondary data was gathered through the review of reports, policy papers, other relevant documents and biosafety guidelines from the various websites of international development organizations involved in biotechnology and biosafety (such as the Biosafety Information Network and Advisory Service-United Nations Industrial Development Organization (BINAS-UNIDO), Food and Agriculture Organization-Asian Biotechnology Network (FAO-Asia Bio-net), World Intellectual Property Organization (WIPO), National Academy of Agricultural Sciences (NAAS)-India, International Service for National Agricultural Research (ISNAR), Berekely Electronic Press (BEPRESS), and the Council for Biotechnology Information, DA, NCBP).

Several rounds of interviews were conducted. The first was to get preliminary data that would serve as a guide in finalizing the direction of the study and preparing the interview questions. The second round was to validate information drawn from the reports reviewed and assess the applicability and relevance of the principles and concepts proposed in the policy analysis; while the last round was to fill in data gaps. The preliminary findings of this study were presented to distinguished scientists and policy-makers in a round-table discussion to validate assumptions, conclusions and recommendations.

The prospects for biotechnology product development in the Philippines were assessed by analyzing public investment in agricultural biotechnology R&D as well as public and private R&D initiatives. The effectiveness of PBRS, on the other hand, was assessed by comparing PBG with selected biosafety regimes, the institutional capacity of regulatory agencies, the costs of regulation and compliance, and the extent of compliance of PBG with the Cartagena Protocol on Biosafety. The contents of the IP Code or RA 8293 and PVPA 2002 or RA 9168 were analyzed to determine if safeguards had been instituted to protect the IPR of technology developers and deter IPR infringement in accordance with the Trade-Related Aspects of Intellectual Property Rights.

The project design was based on the following conceptual framework:

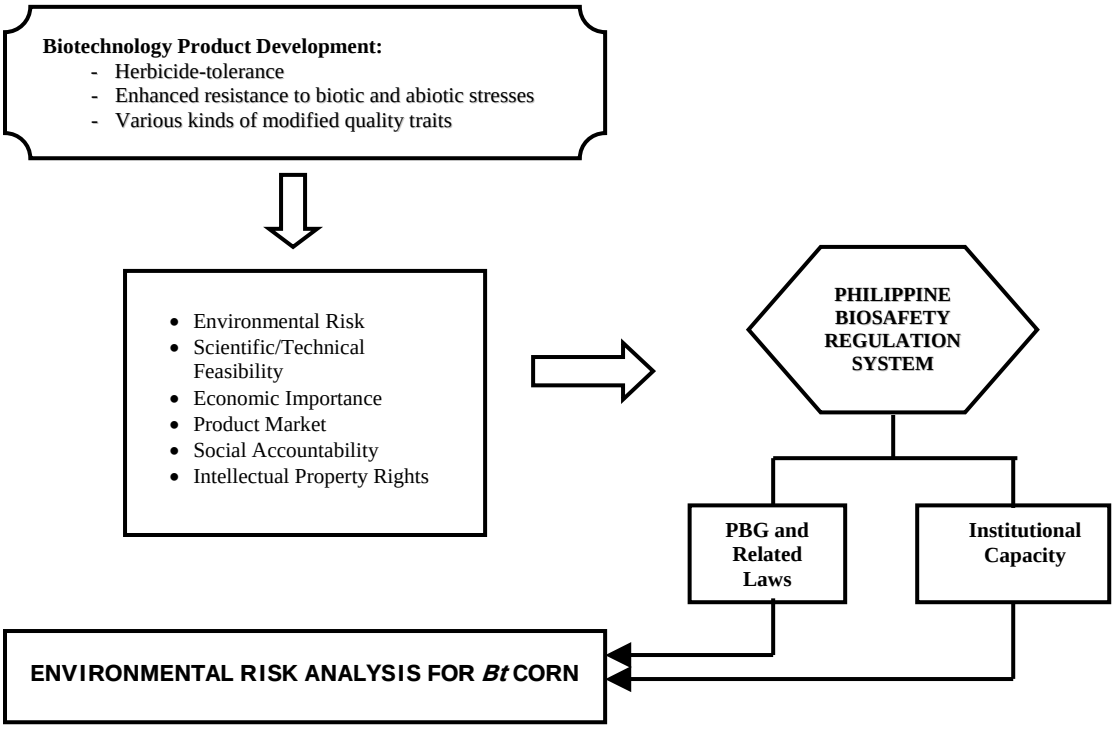

Figure 1. Conceptual framework of the study

4.0 FINDINGS

4.1 Prospects for Biotechnology Product Development

The responsible use of modern agricultural biotechnology is recognized by the Philippine government as a means of achieving food security, a sustainable environment and industrial development in the country. This has been highlighted in major policy pronouncements and the Agriculture Fisheries Modernization Act (AFMA) of 1997 which allocates four per cent of the Department of Agriculture's research and development budget for agricultural biotechnology research. Agricultural biotechnology product development in the Philippines is largely constrained by the low and unsustained level of investment in R&D, the lack of coordination among agricultural R&D institutions, and the limited capacity of local institutions to undertake state-of-the-art R&D (BAR 2001).

4.1.1 Low Public Sector Investment

From 1982 to 1992, public sector investment in agricultural R&D (which constitutes about 90 per cent of the total R&D budget) averaged only 0.3 per cent of the Gross Domestic Product (GDP). This is much lower than the four per cent recommended by the World Bank (WB) for developing countries (BAR 2001). A major provision of the AFMA 1997 specified that from 1998 to 2004, an amount equivalent to almost USD 20 million or four per cent of the proposed total annual R&D budget should be allocated to agricultural biotechnology R&D.

However, this legislated budget was not made fully available by the government to the research institutions. From 1998 to 2005, a total of 40 projects was funded by the two government funding agencies i.e., the Bureau of Agricultural Research (BAR) and the Philippine Council for Agriculture, Forestry and Natural Resources Research and Development (PCARRD) with a total budgetary requirement of PHP 103 million. However, only PHP 70.1 million (68%) was actually released. Moreover, budget releases were not sustained through the years (Table 1). As a consequence, the annual budgetary requirements of individual projects were not adequately met and project timetables were compromised.

Table 1. Annual budget released by BAR and PCARRD for agricultural biotechnology R&D (1998-2005)

Year	Budget by Funding Source (in million PHP)		Total
	BAR	PCARRD	
1998	*	0.9	0.9
1999	10.4	17.8	28.2
2000	11.9	8.0	19.9
2001	3.6	5.3	8.9
2002	4.6	2.3	6.9
2003	1.0	2.7	3.7
2004	0.6	*	0.6
2005	*	1.0	1.0
Total	**32.1**	**38.0**	**70.1**

Source: BAR (2003) and PCARRD (2005)

Note: * = no data

Given the limited funds, the funding agencies had to reassess their focus and give priority to the so-called high impact projects (HIPs) (BAR 2001). HIPs are considered of economic and social significance and are expected to generate results within two to three years. As a consequence of this prioritization strategy, basic agricultural biotechnology projects, which generally involve long product development periods, were not included among the priority projects.

Another indication of the limited financial support to biotechnology R&D is the small budgetary allocation for the research programs of the Philippine Rice Research Institute (PHILRICE), a major R&D institution that focuses on research on rice. PHILRICE has been working on various projects devoted to the development of rice varieties resistant to common pests and diseases such as bacterial leaf blight, sheath blight and blast, stem borer, and tungro, as well as salinity and drought. Each of these major projects was allotted only about PHP 150,000 (USD 3,000) annually. This small budgetary allotment has resulted in the slow pace of the research work.

4.1.2 Lack of Coordination

Fragmentation and duplication of functions and programs as well as the lack of coordination among agricultural R&D institutions were also observed. There are two government agencies involved in agricultural R&D planning and agenda setting as well as

public sector funding of agricultural R&D projects. These two institutions have some form of linkage but both of them independently set their own R&D agenda, receive and allocate R&D funds, and have their own network of regional research institutions.

These two agencies adopted a participatory approach in the formulation of their respective R&D agendas. Farmers were consulted to find out their technology needs, while scientists were consulted to determine the technical and scientific feasibility of using biotechnology to address their needs. Among the research areas prioritized were: (a) genetic engineering; (b) genomics; (c) application of various techniques in diagnostic kits development; (d) development of strains resistant to plant and animal pests and diseases; and (e) the use of microbial technology products which bring about significant environmental benefits like enhancing soil fertility, pest control, and rapid and effective waste degradation (Espino 2004; PCARRD 2003).

However, due to lack of local funding for agricultural R&D projects, many researchers try to access funds from external sources, primarily international donor agencies. As a consequence, local researchers are compelled to follow the priorities of the funding agencies regardless of whether or not these research projects would fall within the national R&D agenda.

A common strategy adopted by some researchers is to test the applicability of biotechnologies developed in other countries by entering into material transfer agreements (MTAs) with technology developers. To date, technologies that can prolong the shelf life of mango and papaya, enrich the Vitamin A content of rice (Golden Rice), and develop resistance to cotton bollworm as well as papaya ringspot virus have been accessed by Filipino researchers through MTAs. Studies to test the applicability of these technologies are funded by the Philippine government.

4.1.3 Limited Institutional Capacity

Records show that from 1990 to 2004, only eight public and 13 private institutions (NCBP 2004), and about 110 scientists (Varma 2004) were involved in the government's modern agricultural biotechnology R&D projects. Most of the public institutions were state colleges and universities (SCUs) that worked on a broad range of research problems involving plants, animals and microbials while most of the private institutions tested the adaptability of *Bt* corn to local conditions. About 65 per cent of the scientists were stationed at the University of the Philippines Los Baños (UPLB) and accounted for about 53 per cent of the agricultural biotechnology research proposals submitted to the biosafety regulation agencies for appropriate action.

The current human resource capability of public R&D institutions is much lower than the level required to implement the R&D agendas of BAR and PCARRD (BPI 2004). Moreover, only some of the research laboratories and greenhouses meet biosafety standards which compel researchers working on different research problems to share in the use of these facilities. Notwithstanding these limitations faced by local development planners, the institutional capacity of Philippine R&D institutions appears comparable to if not better than that of other Asian countries.

Varma (2004) conducted a study to compare the capacity-building needs of selected countries in the Asia-Pacific region and found that the Philippines has a "low" requirement in terms of human resources and infrastructure for R&D (Table 2). This study further shows that the Philippines has the same requirement level as that of China in terms of human resources and infrastructure development for R&D. On the other hand, it has "medium" requirements in terms of human resources and infrastructure for technology and development, which is slightly lower than that of China and Indonesia. Recent data (Varma 2004), however, indicates that China has further enhanced its biotechnology R&D capacity and has developed its own biotechnology products while the Philippines is still limited to the local application of technologies developed in other countries.

Local R&D institutions try to expand their R&D capabilities by working with international donor agencies and establishing partnerships with universities in North America and the Asia-Pacific region. Moreover, the UPLB is now offering Master's degree programs in modern biotechnology thereby providing opportunities for advanced degrees in the field.

Table 2. Capacity building needs of selected countries

Broad Areas	Specific Areas	China	Indonesia	Malaysia	Philippines	Vietnam
HRD	Research & Development					
	Technology & Development					
Infrastructure	Research & Development					
	Technology & Development					

Legend:

High Requirement	Medium Requirement	Low Requirement	No Requirement

Source: Varma 2004

4.2 The Philippine Biosafety Regulation System (PBRS)

4.2.1 The Philippine Biosafety Guidelines and Related Issuances

Biotechnology is seen by many scientists as a means of addressing the issues of food security and environmental degradation. However, biotechnology processes as well as products raise public health and environmental concerns, hence the need for biosafety regulation. It is feared that the genetic engineering process and the introduction of GMOs might cause: (a) the unintentional introduction of allergens and other anti-nutritional factors into foods; (b) the unintentional gene flow or transgenes escaping from GM crops to wild relatives and non-GMOs; (c) the emergence of new pests (like viruses); (d) adverse effects on non-target organisms (e.g., the monarch butterfly); and (e) transgenic (i.e., GM) plants to turn weedy.

Efforts to develop biosafety guidelines in the Philippines were initiated by UPLB and IRRI scientists whose research require the use of modern biotechnology to improve the productivity and sustainability of farming systems. The basic guiding principle was to

design guidelines that would supplement existing quarantine laws that could be applied to GMOs and which would make use of existing quarantine mechanisms. Towards this end, the researchers concerned reviewed the biosafety guidelines of Australia, Japan, the United Kingdom and the USA – National Institute of Health (NIH) and studied Philippine quarantine laws, especially those pertaining to the introduction of micro-organisms, plants and animals into the country and the movement of regulated organisms, plants and animals within the country (Ramirez 2004).

In October 1990, President Corazon C. Aquino signed Executive Order No. 430 constituting the National Committee on Biosafety of the Philippines (NCBP). Among the primary mandates of the NCBP are: (a) to formulate and supervise the implementation of a national biosafety guideline; (b) the identify and evaluate potential hazards involved in genetic engineering experiments and recommend measures to minimize risks; (c) to assist in the development of necessary technical expertise and facilities; and (d) to recommend the development of research programs to establish risk assessment protocols.

The NCBP is a multi-sectoral body composed of scientists, representatives of regulatory agencies and community or civil society representatives. It does not have field officers but relies instead on the personnel of the regulatory agencies in the monitoring of field trials and contained experiments.

The NCBP conducted nationwide consultations using the guidelines developed by the IRRI and UPLB as a working draft and came up with the Philippine Biosafety Guidelines (PBG) which were issued in 1991. The PBG contain the procedures and guidelines for the evaluation of project proposals of potentially hazardous biological work; the introduction, movement and field releases of regulated materials; and physico-chemical and biological containment procedures and facilities. These rules apply to both R&D works under contained (laboratory and greenhouse) experiments as well as field trials. Consistent with the mandate of the NCBP, the PBG outline the procedures for public consultation, creation of Institutional Biosafety Committees (IBCs), and the participation of scientists in the risk assessment process through the Scientific and Technical Review Panel (STRP).

The PBG were revised in 1993 and 1996 to take into account the lessons learned by the implementers and to outline the procedures to be installed in anticipation of field trials for GMOs and other biotechnology products that have passed the contained experiment stage. The 1996 version includes: (a) procedures for planned release applications and reviews; (b) monitoring and evaluation; (c) procedures for withdrawal of NCBP materials; and (d) penalties and sanctions.

Supplementary guidelines were issued on 3 April 2002 by the Department of Agriculture (DA) under Administrative Order 8 (DA AO 8) to set the policies for processing applications for the commercial propagation and importation of biotechnology materials. In view of the increasing number of applications for field trials, which was consistent with DA AO 8 and which the NCBP could no longer accommodate, the responsibility for risk assessment during field trials was transferred from the NCBP to the DA in July 2003.

In response to this new mandate, the DA created the Biotechnology Core Team (BCT) comprising representatives from the three bureaus of the Plant Industry (BPI), Animal Industry (BAI), and the Agriculture and Fisheries Product Standards (BAFPS) as well as the Fertilizer and Pesticide Authority (FPA). The BPI, which is in charge of looking

at general environmental impacts, heads the BCT. The BAI evaluates the safety of biotechnology materials/products in feed and animal vaccines while the BAFPS is concerned with the safety of biotechnology materials as food products. The FPA gets involved if the biotechnology material is a pest-resistant plant and assesses if it has any impact on protected and beneficial organisms. The BCT is assisted by the STRP which is made up of scientists with expertise in the fields of molecular biology, animal nutrition and plant protection.

Thus, under the current PBRS, two agencies are involved and have responsibility for environmental risk assessment. The Biotechnology Advisory Team (BAT), composed of representatives from the regulatory agencies, was also formed by the DA to give technical advice to the secretaries of the Departments of Agriculture, Environment and Natural Resources and Health concerned on the technical and scientific aspects of biosafety regulation. The NCBP, with the help of the IBCs concerned, has jurisdiction over contained (laboratory and greenhouse) experiments to ensure the safety of the biotechnology materials/products. On the other hand, supervision of field trials and approval for commercialization to determine the effect of the materials in an open environment and on the socio-economic conditions of farmers as well as post-approval monitoring to guard against potential development of insect resistance are undertaken by the DA-BCT.

4.2.2 The PBG and the Cartagena Protocol on Biosafety (CPB)

The CPB to the Convention on Biological Diversity (CBD) (2000) is the "international legally binding instrument on biosafety that…provides an international framework to reconcile the respective needs of trade and environmental protection with respect to biotechnology" and was adopted in January 2000 (CBD 2000).

The CPB envisions every country formulating a national biosafety framework (NBF) that would ensure: (a) safe transboundary movement of living modified organisms (LMOs); (b) protection of biodiversity especially with respect to indigenous peoples; (c) transparency; (d) credibility of the regulatory process; and (e) availability of measures to address liability and redress.

The identified tools to promote biosafety are:

a) biosafety clearing houses (BCHs)

b) advanced informed agreements (AIAs)

c) risk assessment and risk management frameworks based on precautionary principles

d) capacity-building (institutional resources and institutional capacity to operate BCHs and carry out AIAs and risk assessment)

e) public education, awareness and participation

f) review of policies and procedures at least every five years (Napompeth 2004)

It is worth noting that even though the PBG came before the CPB, it adopts the same fundamental principles of biosafety such as transparency, public participation and precautionary principles.

Following the adoption of the CPB, efforts to develop a conceptual framework that could guide individual countries in designing their biosafety guidelines were initiated by the International Service for National Agricultural Research (ISNAR), the Food and Agriculture Organization (FAO) and the United Nations Environment Programme/Global Environment Facility (UNEP/GEF). This was deemed necessary in order to harmonize biosafety regulations among countries that use biotechnology materials which would in turn ensure safe transboundary movement. These studies (MacLean et al. 2003; Jaffe 2002) were conducted to identify the essential features of an ideal biosafety regulation system. The results show that there is no single best approach or standard of biosafety regulation that can be adopted by different countries because of heterogeneity of factors (e.g., environmental, social, economic, cultural, political, financial and scientific) that should be considered in a country's national biosafety framework. These studies further show that, currently, there is no country with an ideal biosafety regulation system. Nevertheless, some features of the biosafety system of some countries can be adopted as models by those that are in the process of establishing their own biosafety systems.

Jaffe (2004) and McLean et al. (2002) noted some features that a biosafety regulation system should have in order for it to conform to the CPB. Using some of these indicators, the PBG were compared with the biosafety guidelines of other developing countries (Indonesia, Malaysia, Vietnam, Mexico and Norway) and two developed countries (USA and Japan). These countries were chosen because of their variance in the levels of socio-economic development and biotechnology product utilization.

4.2.3 Comparison of Biosafety Guidelines under Different Regulatory Regimes

Results of the comparison show that the PBG are comparable to and even better than the programs of other countries (Table 3). The PBG and the biosafety guidelines being used by the US generally comply with most of the requirements except that, like the other countries in the comparison, they do not include provisions for the assessment of the socio-economic implications of biotechnology applications. In addition, the common weaknesses of the other regulatory regimes are: (a) lack of transparency; (b) no post-approval monitoring; and (c) no outside scientific experts involved in risk assessment. Furthermore, the PBG have a strong legal basis. Executive Order 430 is supplemented by quarantine laws, DA AO 8 and its rules and regulations on implementation, the PVPA and the IP Code.

An analysis of the PBG shows that the rules and procedures set up to implement its provisions ensure science-based risk assessment, transparency and public participation. The other countries studied can use these rules and procedures and the PBG itself in formulating or revising their own biosafety guidelines to include these important factors. However, all the countries involved in the assessment should come together to develop the framework and methodology for socio-economic impact assessment.

Table 3. Comparison of biosafety guidelines under different regulatory regimes

Areas	Philippines	Indonesia	Malaysia	Vietnam	Japan	Norway	US	Mexico
Use of existing legislation	✓	✓	✓	✓	✓	✓	×	✓
Mandatory pre-market approval	✓	✓	✓	✓	✓	✓	✓	×
Established safety standards	✓	✓	✓	✓	✓	✓	✓	×
Transparency (regulatory process)	✓	×	×	×	✓	✓	✓	✓
Transparency (data)	✓	×	×	✓	×	×	✓	×
Public information (application)	✓	×	×	×	×	✓	✓	×
Use of external scientific experts	✓	✓	×	×	×	✓	✓	✓
Post-approval monitoring	✓	×	×	×	×	×	✓	×

The implementation of the PBG has evolved through the years. As more experience is gained by the regulators and the scientists through exposure to actual field conditions and literature, risk assessments have become more realistic and less stringent. Also, GMO evaluation has taken on a wider and deeper perspective. Gene flow and the effects on non-target organisms, biodiversity, ecosystems and the food chain have become important concerns in addition to toxicity, nutritional value and allergenicity (Ramirez 2004).

Moreover, the efficiency of regulators has improved over the years. The period for processing applications for field trials declined from eleven months (September 1998 to August 1999) in the case of MON 810 *B*t corn to five months (July to November 2002) in the case of the field trial application of *Bt* 11 maize and six months in the case of glyphosate-tolerant corn or NK 603 and *Bt* corn Herculex I (NCBP 2004). The shortened processing time is reflective of the regulators' learning curve.

Efforts to make the PBRS truly CPB-compliant are underway. The Philippines is among the many developing countries that receive assistance from the UNEP/GEF to formulate a national biosafety framework (NBF) based on the provisions of the CPB. Some structural and operational changes to the PBG have been introduced in the proposed NBF. Under the NBF, the National Committee on Biosafety of the Philippines (NCBP) will become a policy-making body and all the biosafety regulation tasks will be performed by the regulatory agencies i.e., the DA, Department of Environment and Natural Resources (DENR), and Department of Health (DOH).

Like the PBG, the NBF is consistent with the national policy to promote the safe and responsible use of biotechnology and the principles of sustainable development. The NBF expressly states that it adopts the precautionary principle, science-based, balanced approach to risk assessment by taking into consideration the potential risks and benefits of biotechnology application as well as the interests of major stakeholders. The other major features of the NBF that articulate the provisions of the CPB are those concerning availability of remedies through administrative and judicial proceedings and the inclusion of socio-economic, cultural, and ethical considerations.

However, some observers have noted that the NBF provision on the "socio-economic consideration" is wider than that of the CPB. The socio-economic considerations articulated in Article 26 of the CPB refer particularly to the impact of LMOs on biological diversity and the value to indigenous peoples. On the other hand, Section 2.5 of the NBF states that assessment of the socio-economic, ethical and cultural benefits and risks of modern biotechnology should take into account not only the indigenous people but also the farmers, women, small and medium enterprises, and domestic scientific community.

Furthermore, Section 5.4 (paragraphs 2 and 3) of the NBF states that "…NCBP shall issue guidelines relating to the conduct of social, economic, ethical, cultural and other assessments, as appropriate, particularly prior to decisions to commercialize products of modern biotechnology…these assessments shall be conducted separately from risk assessment and in a transparent, participatory and rigorous manner." These provisions show that in the proposed NBF, socio-economic impact assessment will be a prerequisite to approval for commercial release of a biotechnology material and will have the same weight as the environmental impact.

Various multi-sectoral groups participated in the formulation of the NBF. There are groups that strongly propose the adoption of the precautionary principle to enable maximum public health and environmental protection. However, there are also proponents of strictly science-based risk assessment and more liberal systems that will allow the commercial release of a biotechnology product as long as no harmful effects are observed, in order to encourage investments and maintain competitiveness in agriculture. However, neither of these groups expressed full satisfaction with the final form of the NBF.

4.2.4 Environmental Risk Assessment: The Bt Corn Experience

Bt corn event[2] MON 810, is the first genetically modified crop approved for commercial release in the Philippines and is the first biotechnology material that has so far gone through the entire biosafety regulation process. *Bt* corn contains the Cry1Ab gene from *Bacillus thuringiensis* var kurstaki which confers resistance to the Asiatic Corn Borer (ACB) insect (*Ostrinia furnacalis* Guenee).

In accordance with the PBG, the biosafety assessment of *Bt* corn underwent four stages: (i) the glasshouse trial phase in 1996 and 1997 (NCBP 2004); (ii) the limited field trial stage from 1999 to 2000 (NCBP 2004); (iii) the multi-location field trial phase from 2001 to 2002 (NCBP 2004); and (iv) the processing of the application before commercialization in 2002 (BPI 2004). Contained laboratory experiments which involved the identification and purification of the *Bt* gene were conducted in the U.S. because the Philippines lacked the financial sources and laboratory facilities to perform such lengthy (8-10 years) and costly experiments.

[2] An event is defined as the stable transformation — the incorporation of foreign DNA into a living plant cell — undertaken by a single institute (Cohen, 2005).

Glasshouse Trials

In the Philippines, the first study on the efficacy of *Bt* corn against ACB was conducted in 1996 by the UPLB in an IRRI laboratory using imported *Bt* corn seeds. This facility was classified by the NCBP as having met the highest containment level standard (i.e., containment level 4 or CL-4). In 1997, two more tests on the efficacy of *Bt* corn against ACB were also conducted at the IRRI. The risk assessment procedure as outlined in the PBG was used in evaluating these tests.

The risk assessment of the *Bt* corn glasshouse trial was done by the IBC, NCBP, and STRP based on the information supplied by the applicant (i.e., the technology developer) along with the supporting technical dossier as required under the PBG. Information in the proposal pertinent to risk assessment included: (a) the characteristics of *Bt* corn; (b) the characteristics of the host organism; (c) characteristics of the deoxyribonucleic acid (DNA) of the donor (in this case, *Bacillus thuringiensis*); (d) the origin and characteristics of the vector; (e) the construction method of *Bt* corn (the method used to introduce target genes into recipient cells); and (f) characteristics of *Bt* corn as breeding material (NCBP 2004). The results of risk assessments done in other countries were also used as bases in evaluating the potential risks to human health and the environment associated with *Bt* corn.

Among the environmental risk parameters evaluated during the contained experiments were: (a) the possibility of natural crossing to related and wild species; (b) the producibility (i.e., possibility of producing) of toxic substances; (c) 'weediness' potential (i.e., the possibility that the GM corn will become a weed); (d) effect on the environment (e.g., soil and water); and (e) potential to cause epidemics (NCBP 1990). On the other hand, the parameters used to determine the risks to human health were allergenicity, toxicity, pathogenicity, resistance to antibiotics, digestibility, and stability.

Several risk mitigation measures were taken to avoid or minimize the potential risks to research personnel and the potential escape of the transgenic material into the environment. These included the provision of information on:

a) containment capabilities of the laboratory/glasshouse

b) sterilization procedures

c) personnel's awareness of biosafety procedures

d) past history of biosafety in the laboratory/glasshouse

e) labeling/designation of "risk" areas

f) decontamination facilities

g) "biosafetiness" of equipment

h) data on markers available to track the *Bt* organism if it escaped into the environment (NCBP 1990)

Limited Field Trials

The NCBP was quite cautious in allowing the planting of *Bt* crops in open fields, hence, while building up its biosafety regulation capacity, it initially opted for a limited field trial before approving multi-location field trials. "Limited field trials" were then conducted to verify the efficacy of *Bt* corn against ACB under semi-controlled field conditions. This approval process involved another environmental risk assessment exercise undertaken by the IBC and the NCBP STRP (Palacpac and Agbagala 2000).

The risk assessment at the "limited field trials" stage was more thorough than during the glasshouse trial. In addition to the assessment of the potential risk to the environment, the safety of *Bt* corn when consumed as food or feed was evaluated in terms of possible allergenicity and toxicity effects to human health. The risk assessment was also based on the technical dossier submitted by the proponent/applicant. A list of countries that used *Bt* corn as food or feed was submitted along with the proposal to support the claim that *Bt* corn is safe for humans and livestock. Other parameters used in conducting the risk analysis and in identifying risk management measures included information on the: (a) parent (wild type) organism; (b) genetic constituents; (c) phenotype of organisms; and (d) attributes of the environment (NCBP 1998).

Several mitigating measures were implemented by the NCBP and DA-BPI during the "limited field trials" in 1999. These are described below.

a) Joint monitoring by the NCBP and DA-BPI.

b) The institution of liability measures whereby the proponents were required to sign an Oath of Undertaking that they would take full responsibility for whatever damage the field trials might cause to human health and the environment, and that they would abide by other conditions imposed by the government agencies and the LGUs concerned.

c) Close monitoring by the BPI-Plant Quarantine Office of the transport or movement of the *Bt* corn seeds from the quarantine office to the field trial sites to ensure that there would be no pilferage or unauthorized release of seeds.

d) Routine seed health testing of imported *Bt* corn seeds to verify if they were free from seed-borne insects and diseases.

e) Spatial and temporal isolation of field trial sites and detasseling of experimental crops.

As an added precautionary measure, the NCBP required that field trial sites should be accessible to hospitals that could provide medication to people who may suffer any unexpected effects of *Bt* corn.

Results of the enzyme-linked immunosorbent assay (ELISA) tests showed that non-*Bt* plants outside the field trial sites were free from the *Bt* gene, an indication that there was no gene flow to *Bt* corn relatives. It was further observed that growth stands of the corn plants were uniform, which means that there were no indications of new weeds creation; and that *Bt* corn did not have harmful effects on non-target organisms as shown by the presence of insects and other non-target organisms in the experimental areas. To be sure

that there would be no unauthorized use of seeds and plant materials, seeds that fell on the ground were allowed to germinate and these volunteer plants as well as plant remains were destroyed and plowed under.

Having learned from the MON 810 experience that multi-location field trials could adequately provide the necessary data, the NCBP decided to scrap the "limited field trials" phase of the risk assessment process. Therefore limited field trials were no longer required for succeeding GM corn products tested such as herbic, ide-tolerant NK603, and other ACB-tolerant corn varieties (i.e., Cry1F *Bt* corn and *Bt* 11).

Multi-location Field Trials

Multi-location field trials were required to test the performance of *Bt* corn under different local conditions. A total of 31 *Bt* corn multi-location field trials were conducted during the two cropping seasons (wet and dry) of the crop year 2001 – 2002 in various parts of the Philippines. These sites were selected based on biophysical conditions, distance from bodies of water, distance from highly populated areas, and the extent of ACB damage.

The same procedures and precautionary measures as those used during the limited field trials were applied in the multi-location field trials. Moreover, an ex-ante study to determine the socio-economic impact of *Bt* corn was undertaken during the same multi-location field trial period. The results of the multi-location field trials were used by the NCBP as additional bases for endorsing the proponents' applications for the commercial release of *Bt* corn.

Processing of Application for Commercial Release

After the successful multi-location field trials, the BCT and its STRP conducted the final stage of risk assessment by reviewing all the scientific and technical documents submitted by the proponents and the results of the contained experiments, limited field trials and multi-location field trials. It should be noted that all these documents had passed NCBP scrutiny. At this point in the risk assessment process, the BCT and its STRP were primarily concerned with the potential risks of the large scale use of *Bt* corn in an unrestricted environment. The concern was to make sure that *Bt* corn was safe to use as food or feed and that it would not pose a risk to people, animals and the environment.

Substantial equivalence tests which were used to evaluate and compare the compositional and nutritional aspects of corn line MON 810 with conventionally bred corn yielded the following results:

a) no significant difference in terms of nutritional composition (i.e., *Bt* corn can be used as a substitute for non-GM corn in food/feed preparations);

b) no sources of toxicants or allergens were found in *Bt* corn;

c) no significant difference in protein, fiber, fat, ash, and carbohydrate content; and

d) the fatty acid composition was comparable (BPI 2004).

Food and feed safety was assessed by the STRP using information gathered from countries that had approved the use of *Bt* corn in food and feed and from other studies conducted locally. Local studies showed that the growth performance and meat quality of broiler fed with *Bt* and non-*Bt* diets were comparable (Querubin 2003). On the other hand, based on feeding studies done in other countries, it was found that there was no trace of plant DNA or protein in the meat, milk, and eggs of livestock and poultry (BPI 2004). It was, however, recommended by the BCT-STRP that local feeding studies on hog and cattle be conducted.

Using information on the donor organism (*Bt*), scientists have observed that *Bt* corn is safe for humans, mammals and non-target organisms (Bernardo 2005). In the Philippines, *Bt* has been used as biological control pesticide against the diamond back moth for many years and there has been no evidence of harm to humans and other non-target organisms. Scientists have also stressed that *Bt* corn can be harmful only to organisms that possess the necessary *Bt* toxin receptor in the gut, and must be ingested to have an adverse effect. Humans, livestock and poultry are not susceptible to the *Bt* protein because there are no receptors of the protein in their intestinal cells. In any event, the human digestive tract is acidic which causes the degradation of the *Bt* toxin.

The potential environmental risks in terms of the consequences of outcrossing, weediness potential, and secondary and non-target effects were evaluated by the BCT-STRP using data on the host plant environment and reproductive biology of the host plant. It was concluded that gene transfer to wild relatives, i.e., tigbi, through hybridization will not occur because tigbi grasses are spatially, ecologically, temporally, and cytologically isolated. It was also found that weediness is not possible because seed dormancy, seed survival, and the time to maturity of *Bt* corn were comparable to the conventional corn variety (BPI 2004).

The adverse effects on non-target organisms, which were assessed by comparing the arthropod species present in *Bt* corn and non-*Bt* corn farms, were not observed. It was found that there were no differences in the population of green lacewing, spiders, coccinelid beetles, derbid planthoppers, leafhoppers, and earthworms between these two types of farms. No significant risks to soil organisms were identified because Cry1Ab protein easily degrades in the soil and *Bt* is a natural soil-borne microorganism. There were also no foreseen changes in agricultural practices as a result of *Bt* corn adoption (BPI 2004).

It can be noted that it took more than six years for MON 810 to be approved for commercial release. The long and meticulous risk assessment process and procedures reflect the NCBP's commitment to ensure biosafety, even if the biotechnology product being tested is already widely adopted in other countries. The processing time of current applications for commercial release has been shortened by at least one year because, as mentioned earlier, the "limited field trials" phase is no longer required under the NCBP's revised risk assessment procedures and because of the greater efficiency of the regulators. However, if the proposed socio-economic impact assessment is approved as a prerequisite to environmental risk assessment, it is expected that proposal processing time will become much longer.

Post-Approval Monitoring

Monitoring after the commercial release of *Bt* corn had been approved was needed in order to identify the potential effects of large-scale and long-term adoption of the technology such as the development of insect resistance. In this connection, the DA-BPI created a multi-sectoral Technical Working Group (TWG) on Insect Resistance Management (IRM) composed of agricultural technologists from the DA Regional Field Units (RFUs), the seed companies selling *Bt* corn and scientists from the academe. The IRM group was tasked with evaluating the proposed sites for pilot testing the "80-20 bag-in-a-bag" strategy[3], recommending mechanisms to ensure effective and efficient implementation of the pilot testing, facilitating capacity building activities and providing the necessary technical assistance in the pilot testing (DA Special Order No. 143, 2004).

The TWG adopts the 80-20 (high-dose-refuge) strategy. The high dose guarantees over 99 per cent protection from the Asiatic corn borer (ACB) – the refuge (the portion of the farm planted with non-Bt corn) serves as the source of *Bt* susceptible insects that may mate with any resistant insects emerging from *Bt* corn plants, thus maintaining population susceptibility. The establishment of a refuge can either be structured or unstructured. A structured refuge (80 per cent *Bt* corn and 20 per cent non-*Bt* corn in the planted area) will be recommended once a contiguous area planted with *Bt* corn reaches 200 hectares, or when *Bt* corn plantings reaches 95 per cent of the total corn area. An unstructured refuge is a diverse and scattered production system of *Bt* and non-*Bt* corn which is widespread in the Philippines given the predominance of small-sized corn farms (DA MC No. 17, 2003).

According to Bernardo (2005), the ACB is naturally bound to develop resistance in the near future. Hence, it is important to immediately implement the IRM strategy which is targeted at reducing the rate of development of insect resistance and prolonging the effective use of resistant plant varieties.

As part of the precautionary measures enforced by the DA-BPI, the permit to propagate or commercialize *Bt* corn was issued for only five years, but it can be renewed if no adverse effects are observed (DA AO 8, Section 10F, 2002). In this connection, the BPI requires the seed companies to regularly submit data relevant to the safety of *Bt* corn.

NGO Reaction to Introduction of Bt Corn

Despite the efforts of the regulatory agencies to ensure the safety of *Bt* corn to human health and the environment, some NGOs actively advocate against the use of GMOs in general and *Bt* corn in particular. Campaigns to oppose the introduction of *Bt* corn started during the first *Bt* corn limited field trial in 1999. Some NGOs demand that the safety of GMOs/*Bt* corn be assured not only before it is approved for commercial release but even before field testing. There are also NGOs that are totally against GMOs. However,

[3] Under the "80-20" IRM concept, 80 percent of the farm would be planted with *Bt* corn while the remaining 20 percent would be planted with non-*Bt* corn. The area planted with non-Bt corn would serve as the insect refuge for the *Bt* susceptible ACB. In the Philippines, corn seeds stocks are usually sold in 18-kg bags that contain seeds enough for a one-hectare farm. To make it easier for farmers to obtain both *Bt* and non-*Bt* corn seeds for use on a one-hectare farm, the 80-20 "bag-in-a-bag" concept was developed. This means that a bag containing four (4) kilograms of non-*Bt* corn will be packed inside a bag that contains 14 kilograms of *Bt* corn. The former will be used by the farmer in setting-up an insect refuge on his small farm.

scientists argue that the safety of any product, even those naturally or conventionally bred, cannot be guaranteed.

People's reaction to *Bt* corn field trials in the different provinces varied from high acceptance in Isabela to moderate acceptance in Camarines Sur and low acceptance in South Cotabato. The anti-GMO campaigns were very intense and influenced media practitioners, some farmers groups, and even local government officials in some provinces. For instance, local government resolutions banning GMOs were passed in two provinces in southern Philippines (Bohol and South Cotabato); some farmers destroyed field experiments; and criticisms about the risks associated with *Bt* were broadcasted over the radio.

It is recommended that the government and NGOs conduct a knowledge-based and case-to-case debate on the safety of a biotechnology material using common standards and parameters so as to thrash out issues objectively and scientifically, and inform the public properly. The Government should also make serious efforts to implement DA AO 8 (Section 10-K) which encourages the public to submit any new information on the harmful effects of MON 810 to the concerned regulatory agency for possible permit revocation.

4.2.5 Costs of Regulation and Compliance

Cost of Regulation

The cost of regulation refers to expenses incurred by regulatory agencies such as the NCBP and DA-BCT to implement the PBG. This includes salaries and wages of government personnel involved in the regulation process and the scientists who are members of the NCBP and STRP; the costs of conducting training, seminars/workshops to improve the capability of regulators as well as costs incurred in infrastructure development and the purchase of necessary equipment. The regulatory functions cover a range of activities from risk assessments in connection with contained experiment and field trials, to reviews of scientific documents and risk assessment reports and processing of applications for the importation of biotechnology material for propagation or direct use.

The cost of biosafety regulation in the Philippines appears to be low (approximately USD 3,000 in 2004) (NCBP 2004), but this does not reflect the true value of the services of the people and the facilities involved nor of the operational costs associated with biosafety regulation. There are two reasons for this seemingly low value. Firstly, most of the government personnel are involved in biosafety regulation on a part-time basis and it is difficult to accurately estimate the value of their time devoted to biosafety regulation. The salaries and operational expenses of these people, while performing biosafety regulation duties, are covered by their mother agencies. Secondly, the services of scientists who serve as NCBP and their STRP members as well as those who are invited by the NCBP to serve as STRP members are undervalued. NCBP members receive only a monthly travel allowance of PHP 2,000 (approx. USD 38) while STRP members are paid only PHP 6,000 (approx. USD 110) per application review which is way below their regular professional fee.

The NCBP's budget cannot be used as an accurate indicator of the cost of regulation nor of the efforts exerted by NCBP members to implement the PBG. The NCBP, as the

main regulatory body, operates on a very small budget that has declined rather than increased over the years. Its budgetary allocation dropped from about PHP 500,000 (approx. USD 20,000) in 1991 to only PHP 160, 000 (approx. USD 3,000) in 2004 despite the increase in the number of applications being processed by the agency. This amount covers the salaries of the NCBP Secretariat, which acts as the Biosafety Clearing House (BCH), the honorarium paid to NCBP members and the professional fees of its STRP members.

The Department of Agriculture, particularly the Biotechnology Core Team (BCT) and the Biotech Program also incurred costs related to biosafety regulation. From 2000 to 2004, the Biotech Program received a total grant of USD 7.5 million from both local and international donors, most of which was used for capacity building activities such as the training of regulators and STRP members and infrastructure development. Expenses incurred for capacity building can be considered as a one-time cost, the benefits of which can be enjoyed as long as the equipment is working, the trained personnel continue to perform biosafety regulation tasks, and the regulatory system is not changed.

According to key informants from the NCBP and DA, a realistic budget for the NCBP would be about PHP 5 million (approx. USD 100,000) per year. This could cover all the operational expenses of the government agencies involved in the implementation of the PBG. On the other hand, the estimated cost of processing an application for the use of a biotechnology material could range from about PHP 300,000 (approx. USD 5,500) for direct use to PHP 750,000 (approx. USD 14,000) for commercial propagation. This cost would cover the entire risk assessment procedure from contained/glasshouse experiments to multi-location field trials and final reviews of risk assessment results by the BCT.

Cost of Compliance

The cost of compliance refers to expenses incurred by the proponent/technology developer in complying with the PBG. It includes direct costs such as application fees paid when applying for necessary permits such as those for importation and commercial propagation of regulated materials; rental of contained facilities and field trial sites; costs of securing experimental sites; conducting public information and education campaigns; and other incidental expenses related to securing field trial permits from local government units.

The industry representatives could not provide estimates of the total costs because of the many “hidden costs” they incurred. Admittedly, the cost to obtain permits for the commercial release of *Bt* corn is higher than for conventionally bred hybrid seeds. Field trial sites are usually rented for about PHP 15,000 (approx. USD 275) per hectare per season which is almost equivalent to a farmer’s net income per cropping season from corn grown from regular hybrid seeds.

The NCBP and BPI did not charge the MON 810 proponents any risk assessment fee. This meant lower costs for the proponent but added burden to the already financially-strapped regulatory agencies. The issuance of DA AO No. 8 which transfers the responsibility for conducting risk assessment during the field trials stage from the NCBP to the BPI has caused the cost of compliance to increase. Section 17 of DA AO No. 8 (2002) authorizes the BPI to charge proponents a Risk Assessment Review Cost (RARC) to cover the cost of evaluating applications and petitions, and monitoring compliance with permit

conditions. This provision was operationalized in May 2003 with the issuance of the DA Memorandum Circular (MC) No. 9 (2003) that sets the schedule of fees for risk assessment.

The RARC is a one-time cost and varies according to the intended use of the biotechnology material being evaluated. Biotechnology materials intended for direct use as food or feed, or for processing into feed or food are charged an RARC of about PHP 140,000 (approx. USD 2,550) while those products that will eventually be released for commercial propagation are charged PHP 250,000 (approx. USD 4,550). Examples of biotechnology materials imported by the Philippines for direct use as food are potato (for french fries) and canola oil; and *Bt* corn as animal feed ingredients and for processing *Bt* cotton for fiber and cloth. On the other hand, materials for commercial propagation would include *Bt* corn which is sold as seeds to be planted by farmers.

Imposing the RARC is based on the need to augment limited government resources to cover expenses in conducting a comprehensive risk assessment review but "does not guarantee the issuance of a permit to the applicant..." (DA MC No.9, 2003). Risk assessment is a task newly assigned to the DA and is not funded under its regular budget. However, according to key informants from NCBP and R&D institutions, the DA-BCT need not incur costs in reviewing the same documents that have already been reviewed by the NCBP and upon which the latter established the biosafety of the biotechnology material concerned and recommended its importation or commercial release to the BPI.

Any new technology to be introduced could bring about social costs particularly if the technology has a negative outcome. Unexpected/unintended costs such as the loss of biodiversity, introduction of foreign pollutants into the environment, and potential gene transfer may be considered as social costs. A more liberal regulatory system that allows the local release of a biotechnology product already being used in other countries but not yet tested locally will reduce the costs of regulation and compliance but could result in higher social costs. This system is contrary to the precautionary principle and is not recommended for adoption.

In principle, the cost of meeting the regulatory requirements, which is proportional to the level of stringency of biosafety regulations, may have significant negative socio-political and environmental impacts. Excessive regulatory reviews may curtail interest in biotechnology R&D and application to such an extent that only a few large multinational companies will have the necessary resources to go through the entire process. Therefore, over-regulation may promote a situation that is a cause of concern to many: corporate control of agriculture. This trend is already clearly apparent and may result in the creation of a single or a few companies dominating world food production (Nap et al. 2003). On the other hand, relaxed regulations that allow rapid and easy approval of GMOs may not effectively protect citizens and the environment from potential harm. Policy-makers, therefore, have to carefully balance the costs and benefits of regulation (FAO 2003).

4.3 Intellectual Property Management

The development of a biotechnology product generally involves a long research process. Genetic engineering research requires the identification, isolation and testing of selected genes/characteristics to determine their stability and the potential harm that they may cause if released into the environment or taken in as food or feed. Each of the

experiments conducted generates new knowledge in terms of genetic characterization; methodology for identifying, isolating and testing these characteristics; and transformation events (genes that survive the selection process) that could qualify as a new discovery or new intellectual property.

The importance of technology transfer in enabling developing countries to benefit from modern biotechnology is recognized in the CPB. However, since modern biotechnology research is dominated by multinational companies based in developed countries and the technology has become proprietary in nature, technology transfer to developing countries is more difficult (ISAAA 2003). This is because in many developing countries, there are no intellectual property restrictions such that R&D tools as well as products appear unprotected (Binenbaum et al. 2000). Moreover, many developing countries lack the required IP management capacity and resources to perform product clearance analyses and evaluations needed to facilitate the legitimate import, use and/or export of technologically advanced products (Kowalski et al. 2002). Therefore, there is a strong need to build the (IP management) capacity of developing countries not only to assimilate and use such technologies but also to develop their own technologies and address related biosafety and IP management issues (Varma 2004).

In the Philippines, there are two laws on IP protection, i.e., the IP Code (1997) and the PVPA 2002. The IP Code contains a very broad definition of patents or patentable inventions or innovations (Section 21) and specifies that microorganisms, non-biological processes, and microbiological processes used for biotechnologies can be patented (Section 22). It further states that a law providing *sui generis* (unique*)* protection of plant varieties and animal breeds as well as a system of community intellectual rights protection may be enacted. In line with this, the PVPA 2002 was passed. It should be noted, however, that GM crops that do not exhibit distinct morphological characteristics are not patentable under this law.

Some biosafety regulation measures can be used as a means of IP protection and to prevent the illegal entry of untested biotechnology materials. For instance, among the scientific documents that the NCBP requires from the proponents as part of the risk assessment documentation is a deoxyribonucleic acid (DNA) construct or plasmid map of the biotechnology material that is proposed to be used. This document is also used by the NCBP-STRP in evaluating if the supporting scientific documents refer to the same DNA construct. Information on the DNA construct of such biotechnology material is encoded in the NCBP database. This information also serves as a reference in verifying the IPR claims of other applicants. This measure can be a potential deterrent to fraudulent claims of IPR by unscrupulous entities and may be institutionalized as a means of IPR protection. Appropriate policies can be formulated to ensure IP protection and prevent disclosure of classified business information.

The importation and deployment of GM products is monitored by the quarantine offices concerned (i.e., the BPI and BAI) of the DA. Product labeling is not required but as part of the DA's quarantine practice, the BPI requires importers of plants and plant products to submit detailed information on the kind of product they are importing. To determine if the imported material is genetically modified or not, the Quarantine Service reviews the attached documents and compares them with the list of GMOs exported by other countries. If found misdeclared, the product could either be shipped back to the point of origin or dumped, and the importer's accreditation, cancelled. A more scientific and accurate GMO detection method involving the use of a GMO detection kit or ELISA kit

can be adopted not only for the purpose of preventing the illegal entry of untested products but also to deter IPR infringement.

5.0 SUMMARY, CONCLUSIONS AND RECOMMENDATIONS

5.1 Biotechnology Research and Development

The prospects for biotechnology product development in the Philippines are largely constrained by low and unsustained investment by the public sector and negligible private sector investment in agricultural biotechnology R&D. The R&D agendas of the Bureau of Agricultural Research (BAR) and the Philippine Council for Agriculture, Forestry and Natural Resources Research and Development (PCARRD) which were prepared with the participation of major stakeholders, although reflective of the technological needs of the country and technically feasible, have not been fully implemented by the research institutions because of budget constraints.

The local R&D institutions take a practical stance in prioritizing research projects. Their R&D efforts are largely focused on local testing of technologies developed in other countries rather than on basic research. Local testing of patented technologies does not require huge technology/product development costs and yields immediate results. The use of these technologies is facilitated through material transfer agreements (MTAs) negotiated between the local R&D institution and the patent holder. On the other hand, despite budget constraints, PHILRICE has been able to continue its R&D activities to develop plant (rice) varieties resistant to biotic and abiotic stresses.

To systematize the process of prioritizing biotechnology application studies, it is important to: (a) have an updated inventory of all available biotechnologies that have potential application in the Philippines; (b) develop procedures that will guide researchers and research institutions in negotiating MTAs that will be beneficial to all parties concerned; and (c) strengthen linkages between R&D institutions to enhance infrastructure capabilities and steer scientists with advanced training in biotechnology into the biotechnology R&D mainstream.

Biosafety studies were done by transnational companies in partnership with local R&D institutions. Such partnerships involve the awarding of grants to researchers who will conduct the study. The long-term benefit of this partnership goes mainly to the private company that owns the patent for the product. Considering the potential benefits that will accrue to the private company after such products have been approved for commercial release in the Philippines, the R&D institution should negotiate better terms beyond the actual cost of conducting the experiments and study the feasibility of getting a share in the potential sales revenue that will be generated.

Notwithstanding the budget constraints, Filipino scientists should venture into studies that would not require a lot of resources but can contribute significantly to the knowledge and science on biosafety. The following list of suggested studies that were identified in this study based on the review of the CPB, PBG and the proposed NBF can be used by BAR and PCARRD in planning their research programs in the short to medium term.

a) Studies on the appropriate risk assessment protocol and the potential long-term effects of *Bt* corn. The results of this study could help the BPI reassess the environmental safety of *Bt* corn, which is due for review in 2007 (five years after the approval for commercial release).

b) A study to design a socio-economic impact assessment framework. This study is critical in determining the key decision points and decision-making standards for the integration of socio-economic considerations into the risk assessment process. The study must be able to provide decision-makers with information on the relative importance of socio-economic considerations vis-à-vis environmental risks in biosafety decisions. The results of this study will also be useful to the NCBP in the formulation of guidelines for conducting socio-economic studies, a task proposed under the National Biosafety Framework (NBF). In the proposed regulatory framework, evaluation of the socio-economic impact will be a prerequisite to the commercialization of a biotechnology product.

c) A study on the factors to be considered in and the methodology for assessing the socio-economic, cultural and ethical impacts of biotechnology. The importance of this kind of study was recognized by the International Development Research Centre (IDRC) and the International Union for Conservation of Nature and Natural Resources (IUCN) in a conference entitled "Setting a Research Agenda on Agricultural Biotechnology and Biosafety in Asia" held in Colombo, Sri Lanka in October 2004. It was further recognized that because of the differences in socio-economic conditions and cultures, the protocol for incorporating socio-economic, cultural and ethical considerations should be country-specific. This is one area of research that does not require a large budget but can benefit not only the Philippines but also other countries that are signatories to the CPB.

d) A comprehensive study on the socio-economic impacts of *Bt* corn. A few studies on the socio-economic impact of *Bt* corn have already been conducted in the Philippines. These studies used productivity, income, yield levels, cost effectiveness, net profitability, subsistence carrying capacity and global cost competitiveness as indicators (Yorobe et al. 2004; Gonzales 2002). However, these studies were done on a limited scale i.e., four sites and two seasons in the case of Yorobe et al. (2004) and ten sites and two seasons in the case of Gonzales (2002). A comprehensive study that evaluates all the identified potential benefits, including benefits to consumers, and costs (risks) purportedly associated with the application of a specific technology, such as *Bt* corn, based on data drawn from a substantial sample size could provide more concrete recommendations.

e) A study on the socio-economic implications of the 80-20 IRM strategy is an area that has strong policy implications. To prevent the ACB from developing resistance to *Bt*, scientists suggest that an ACB refuge be established once a 200-hectare contiguous area of *Bt* corn plantation has been reached. Under this concept, 20 per cent of the total area should be planted with non-*Bt* corn and serve as the insect refuge while the remaining 80 per cent should be planted with *Bt* corn. However, considering that corn farm size in the Philippines is small (average size is 1.2 ha), it is possible that a 200-hectare contiguous area may be owned by about 200 farmers. It is important to know how this IRM strategy can be implemented without causing adverse social, economic and equity effects. It would likewise be interesting to

study the effect of *Bt* corn on the socio-economic conditions of the non-*Bt* corn adopters whose farms will, in effect, become the insect refuge.

The environmental and socio-economic studies that have been conducted so far have been funded mostly by private seed companies or their allies and there are those who would question and challenge the objectivity of these organizations. While such doubts may be disputed, it would be more credible if such studies were funded and carried out by impartial bodies.

5.2 The Philippine Biosafety Regulation System (PBRS)

The PBG were found to be comparable in form and substance with the biosafety guidelines of other countries and most of the provisions conform to the CPB. In general, Philippine regulatory agencies are able to effectively implement the PBG but their operations, particularly those of NCBP, are difficult to sustain. The scientists who comprise the NCBP serve because of their strong commitment and concern for biosafety even if they do not receive remunerations commensurate with their qualifications. There is a need to allocate realistic budgets to the agencies involved in biosafety regulation and to institutionalize risk assessment principles and procedures to sustain the effectiveness of the PBRS.

The Institutional Biosafety Committees (IBCs) are critical nodes in the entire risk assessment process. Lapses in their performance could lead to a breakdown in the biosafety regulation process and pose a serious threat to public health and the environment. It was observed that even though the NCBP reviews the qualifications of proposed IBC members and monitors IBC activities, there are cases where the IBCs do not perform effectively. It has been observed that the IBCs in some research institutions do not monitor either the contained experiments or the field trials, nor keep the necessary records. In one case, the IBC chairperson did not know of on-going biotechnology research projects in his/her institution. The NCBP should monitor the IBCs more closely and set up an IBC Secretariat that could serve as the institution's biosafety clearing house.

Streamlining the regulatory process by adopting technologies already commercialized in other countries without the benefit of extensive field trials under local environmental conditions is being proposed by some groups. This is contrary to the precautionary principle and could result in higher social costs. While it could make new technology available within a short period of time and result in short-run benefits, it could also expose people to greater risks due to ignorance of appropriate risk management and precautionary measures. The enforcement of stringent biosafety regulation measures that are currently being practiced in the Philippines and other countries would still be more cost-effective in the long run.

The National Biosafety Framework (NBF) for the Philippines was formulated in 2004 to further improve the PBG. When approved, it will supercede the PBG. Its major difference with the PBG is the inclusion of a provision that requires the assessment of the "socio-economic, cultural and ethical impacts" as a prerequisite for approval of the commercial release of a biotechnology product. This provision is contrary to the opinion of some analysts who hold that socio-economic considerations are not part of biosafety issues and go beyond the intent of the CPB. Furthermore, since a socio-economic impact

assessment system is not yet in place, the NCBP should formulate the protocol immediately after the NBF takes effect, otherwise, no application for commercial release can be approved during the interim period.

Like the current PBG, the NBF is science-based, adopts the precautionary principle, promotes transparency and public participation, employs scientists as external reviewers in the risk assessment process, and is linked with the operations of the Philippine Quarantine Services. In the PBG, risk assessment is done primarily by the NCBP. However, in the proposed NBF, this task will be performed by the regulatory agencies (i.e., the DA, DENR and DOH) while the NCBP will only be a policy-making body. To be able to respond to the proposed revision in the risk assessment procedure, the DENR and DOH should come up with their own biosafety guidelines as soon as possible.

The level of human resource capacity for biotechnology R&D and biosafety regulation as well as the infrastructure facilities and the systems for data management and public information in the Asia-Pacific region is relatively low. Overall, the Philippines is next to China in terms of human resource capacity and ranks higher than Indonesia, Malaysia and Vietnam in this regard. In terms of infrastructure capability necessary for biotechnology research and biosafety regulation, the Philippines ranks third after China and Indonesia, but is in a better position compared with Malaysia and Vietnam. As far as regulatory mechanisms are concerned, the Philippines rates high in almost all aspects except for the labeling of GMOs and the appropriate Seed Act. Considerable efforts should be exerted by the Philippines along with other Asian countries in the areas of human resource development for R&D and regulatory system management, improvement of infrastructure facilities, and the formulation and implementation of regulatory mechanisms and policies for optimum utilization of biotechnology.

The establishment of the DA-Biotech Program and the DA's active partnership with local and international organizations as well as the cooperation, support and provision of the voluntary services of many scientists with vast experience in biotechnology R&D have contributed to the country's capacity building progress. However, for the Philippines to be able to keep up with the technological development pace worldwide, it should continue to pursue capacity building initiatives aggressively.

The Philippines' human resource development programs should focus on the following areas:

a) Advanced level training programs for improving the capabilities of scientific and technical personnel engaged in biotechnology research and risk assessment.

b) Training programs on risk assessment and risk management.

c) Training for legal experts to upgrade the regulatory mechanisms and enhance their capability to negotiate favorable MTAs.

d) Training for managers and professionals to implement biosafety guidelines.

e) Training to improve the capabilities of personnel working in the quarantine and food safety departments in detecting GMOs and enforcing IPR laws.

Furthermore, to meet the country's capacity building needs and improve its risk assessment protocol, the DA and NCBP should expand their linkages with donor agencies, universities and governments in the Asia-Pacific region as well as in the developed countries in carrying out biotechnology R&D projects, and share relevant data and information on biotechnology and biosafety with other countries.

Post-approval monitoring of potential environmental risks should be continuously implemented. The current post-commercialization monitoring is perceived to be weak because it focuses only on insect resistance and even that is not adequately performed. Only a few local government units (LGUs) monitor the use of *Bt* corn in their respective jurisdictions because most LGUs do not fully appreciate the importance of insect resistance management (IRM). On the other hand, the DA relies mostly on data submitted by the seed companies. Independent post-approval monitoring should be done to ensure that timely and appropriate risk management measures can be instituted.

A modification of the refuge approach to IRM was introduced by the IRM TWG in 2004 in the Philippines. Under the "80-20" IRM concept, 80 per cent of the farm would be planted with *Bt* corn while the remaining 20 per cent would be planted with non-*Bt* corn. In the Philippines, corn seeds that are available in the market are packaged in a bag of about 18 kilograms, which is suitable for a one-hectare farm. To make it easier for farmers to obtain both *Bt* and non-*Bt* corn seeds for use on their one-hectare farm, the 80-20 "bag-in-a-bag" concept was formed. Following this concept, a farmer has to set up an insect refuge on his small farm. This "bag-in-a-bag" strategy is not consistent with the DA IRM Technical Working Group guideline that ACB refuges are to be established only when a 200-hectare contiguous area of corn plantation is attained.

Farmers are against this 80-20 "bag-in-a-bag" strategy primarily because they do not want to sacrifice 20 per cent of their small earnings from their corn farms. If this approach is adopted, a more thorough analysis of the implications will have to be done to minimize the adverse effects on the already impoverished farmers. Moreover, public information campaigns will be necessary to make the farmers understand and appreciate the importance of adopting IRM strategies for their long-term benefit.

Likewise, the interface between the DA and LGUs in terms of IRM is also an issue. The provision of agricultural extension services to farmers is a function that was devolved to the LGUs by virtue of the Local Government Code (1991). However, some local executives do not give due importance to agriculture and therefore, do not allot sufficient resources for agricultural development and extension services. In other instances, the provincial or municipal agriculturists take a different position and pursue programs independent from that of the DA. Moreover, there are LGUs that really do not have the capacity to provide extension support to farmers. Policies have to be formulated to effectively implement IRM since its enforcement is constrained by the lack of authority of the DA over LGU agricultural officers and technicians, and the poor capacity of many LGUs in terms of financial and manpower resources.

The budgets allocated to the NCBP and other regulatory agencies do not reflect the actual costs of regulation. The lack of funds to finance the operational costs associated with risk assessment prompted the DA to collect RARC from the proponents. However, it was noted that since the risk assessment exercise is completed by the NCBP, there is no need for the BCT to repeat the process. This duplication of work can be avoided under the proposed NBF which unfortunately has not yet been approved. In the meantime, the NCBP

and DA-BCT should work together to streamline the whole procedure to avoid unnecessary delays and minimize the cost of regulation.

The PBRS can adequately cope with the biosafety regulation requirement of the current level of agricultural biotechnology R&D in the country. However, considering the global trends in agricultural biotechnology R&D and the increase in the number of MTA facilitated local R&D activities, corresponding structural and policy adjustments have to be made to further improve the PBRS.

5.3 Intellectual Property Management

Technology transfer to developing countries is now more difficult because biotechnology has now become proprietary in nature and most developing countries do not have intellectual property (IP) laws nor the capacity to implement them, if any. In the Philippines, there are two laws governing IP protection: the IP Code (1997), which contains a very broad definition of patents or patentable inventions or innovations (Section 21) and specifies that microorganisms, non-biological processes, and microbiological processes used for biotechnologies can be patented (Section 22); and the PVPA 2002, which allows plants with distinct, stable and uniform morphological characteristics to be patented. The law that provides IP protection for biotechnology products and processes is the IP Code but no mechanism to monitor infringement of IPR has yet been installed.

Two biosafety regulation measures are available to protect IP holders against fraudulent IPR claims. These are: (a) the use of information on DNA constructs filed at the NCBP which forms part of the NCBP database and (b) the use of GMO detection kits. Appropriate policies to use these biosafety regulation measures as IP protection strategies should be formulated to guard against disclosure of classified business information and equip quarantine service units with the necessary instruments.

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