Developing the National Biosafety Framework for the Philippines

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Contents

Preface

In May 2000, the Philippines signed the Cartagena Protocol on Biosafety to the Convention on Biological Diversity (CBD), the first treaty under the Convention that seeks to protect biological diversity from the potential risks that may be posed by living modified organisms (LMOs), or what are commonly referred to as genetically modified organisms (GMOs), resulting from modern biotechnology. The Protocol, regarded as the new legal environment instrument of the 21st century, creates an enabling environment for the environmentally sound application of biotechnology, making it possible to derive maximum benefits from the potential that biotechnology has to offer, while minimizing the possible risks to the environment and to human health.

Modern biotechnology is increasingly being accepted as a fact of life. We recognize and accept its potentially huge benefits and risks. We recognize its strategic role in global and national development in the 21st century, but we should not overlook its possible environmental effects on the conservation and sustainable use of biological diversity.

The Philippines is the first ASEAN country to formulate biosafety regulations with the issuance of Executive Order No. 430, creating the National Committee on Biosafety of the Philippines (NCBP) in 1990. The NCBP has had a wealth of experience regulating biosafety in the Philippines. In 2002, the Department of Agriculture (DA) issued Administrative Order No. 8, Series of 2002, “Rules and regulations for the importation and release into the environment of plants and plant products derived from the use of modern biotechnology.” Although many believe that the current systems are functional and working well, there is consensus that such systems must be strengthened, including the capabilities of the different regulatory and implementing agencies, the research institutions, civil society organizations, and the private sector.

In 2002, the Philippines received a grant from the UNEP-GEF) to develop a National Biosafety Framework (NBF). The NBF hopes to strengthen current biosafety systems and respond to a global regime on biosafety by building on existing national policies, integrating and updating and/or revising these policies to come up with a framework that is consistent with the Cartagena Protocol. Technical and legal data were gathered and multi-stakeholder consultations were conducted in support of the development of this framework. It has not yet been officially adopted but there is consensus that it should be pursued to its completion. This publication presents these data and the process in developing the framework. We hope that it will serve as an information and education tool for building capacities to address the issues concerning modern biotechnology and biosafety.

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DEMETRIO L. IGNACIO, JR.
DENR Undersecretary
for Policy and Planning
Chairperson, NCC-NBFP

THERESA MUNDITA S. LIM
OIC, Director PAWB/NEA

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List of Acronyms and Abbreviations

AFMA	Agriculture and Fisheries Modernization Act
AGILE	Accelerating Growth, Investments, and Liberalization with Equity (AGILE)
AIA	advanced informed agreement
AMBIONET	Asian Maize Biotechnology Network
APEC	Asia-Pacific Economic Cooperation
ASEAN	Association of Southeast Asian Nations
BAFPS	Bureau of Agriculture and Fisheries Products Standards
BAI	Bureau of Animal Industry, DA
BAT	Biotechnology Advisory Team, DA
BAR	Bureau of Agricultural Research, DA
BBTV	banana bunchy top virus
BCH	Biosafety Clearing House
BCP	Biotechnology Coalition of the Philippines
BFAD	Bureau of Food and Drugs, DOH
BFAR	Bureau of Fisheries and Aquatic Resources, DA
BPI	Bureau of Plant Industry, DA
BIOTECH	National Institute of Molecular Biology and Biotechnology, UPLB
CBD	Convention on Biological Diversity
CLSU	Central Luzon State University
CMMYT	International Maize and Wheat Center
CODA	Cotton Development Authority
COP	Conference of the Parties
CPB	Cartagena Protocol on Biosafety or the Protocol
DA	Department of Agriculture
DA-Biotech	Department of Agriculture Biotechnology Project Implementation Unit
DAMC	DA Memorandum Circular
DAP	Development Academy of the Philippines
DENR	Department of Environment and Natural Resources
DFA	Department of Foreign Affairs
DILG	Department of Interior and Local Governments
DNA	deoxyribonucleic acid
DOH	Department of Health
DOST	Department of Science and Technology
DTI	Department of Trade and Industry
ECA	environmentally critical area
ECC	Environmental Compliance Certificate
ECP	environmentally critical project
EGW	Experts' Group Workshop

EIA	environmental impact assessment
EIS	environmental impact statement system
ELISA	enzyme-linked immunosorbent assay
EMB	Environment Management Bureau, DENR
EMS	Environmental Management System
ERDB	Ecosystems Research and Development Bureau
FAO	Food and Agriculture Organization
FASPO	Foreign Assisted and Special Project Office, DENR
FMB	Forest Management Bureau, DENR
FPA	Fertilizer and Pesticide Authority, DA
GATT`	General Agreement on Tariffs and Trade
GEF	Global Environment Facility
GM	genetically modified
GMO	genetically modified organism
GRAS	generally regarded as safe
IAEA	International Atomic Energy Agency
IAS	invasive alien species
IBC	Institutional Biosafety Committee
IBMB	Institute of Biotechnology and Molecular Biology
IBS	Institute of Biological Sciences, UPLB
ICC	indigenous cultural communities
ICCP	Inter-governmental Committee for the Cartagena Protocol on Biosafety
ICLARM	International Center for Living Aquatic Resources Management (Now World Fish Center)
ILSI	International Life Sciences Institute
IMFJ	International Medical Foundation of Japan
IPs	indigenous peoples
IPB	Institute of Plant Breeding, UPLB
IPP	Investment Priority Plan
IPRA	Indigenous Peoples Rights Act
IRRI	International Rice Research Institute
ISAAA	International Service for the Acquisition of Agri-biotech Applications
LIKAS	Lingap sa Kalusugan ng Sambayanan Inc.
LLDA	Laguna Lake Development Authority, DENR
LMB	Land Management Bureau, DENR
LMOs	living modified organisms
LSU	Leyte State University
MARDI	Malaysian Agricultural Research Development Institute
MGB	Mines and Geosciences Bureau, DENR
MSI	Marine Science Institute, UP Diliman
NAST	National Academy of Science and Technology
NBB	National Biosafety Board
NBF	National Biosafety Framework
NBFP	National Biosafety Framework Project
NCBP	National Committee on Biosafety of the Philippines
NCC	National Coordinating Committee
NEA	National Executing Agency
NEDA	National Economic Development Authority
NGO	non-government organization
NIBMB	National Institute of Biotechnology and Molecular Biology, UP Manila
NIMBB	National Institute of Molecular Biology and Biotechnology,

	UP Diliman
NIPAS	National Integrated Protected Areas System
NFRI	National Fisheries Research Institute
NMIC	National Meat Inspection Commission
NPGRL	National Plant Genetic Resources Laboratory
NRCP	National Research Council of the Philippines
NSRI	Natural Sciences Research Institute
OECD	Organization for Economic Cooperation and Development
PAWB	Protected Areas and Wildlife Bureau, DENR
PCA	Philippine Coconut Authority
PCARRD	Philippine Council for Agriculture, Forestry and Natural Resources Research and Development, DOST
PCASTRD	Philippine Council for Advanced Science and Technology Research and Development, DOST
PCBs	polychlorinated biphenyls
PCC	Philippine Carabao Center
PCHRD	Philippine Council for Health Research and Development, DOST
PCR	polymerase chain reaction
PHES	potentially harmful exotic species
PhilAAS	Philippine Association for the Advancement of Science
PhilRice	Philippine Rice Research Institute
PHILSURIN	Philippine Sugar Research Institute
PLRV	potato leaf roll virus
PNRI	Philippine Nuclear Research Institute,DOST
PPT	phosphinothricin
PO	people's organization
R&D	research and development
RA	risk assessment
RDE	research and development extension
rDNA	recombinant deoxyribonucleic acid
RNA	ribonucleic acid
SEAMIC	Southeast Asian Medical Information Center
SEARCA-BIC	Southeast Asia Regional Center for Graduate Study in Agriculture-Biotechnology Information Center
SPS	Sanitary and Phytosanitary
STRP	Scientific Technical Review Panel
TAMA	Traditional and Alternative Medicine Act
UNEP	United Nations Environment Programme
UP Diliman	University of the Philippines Diliman
UPLB	University of the Philippines Los Banos
UP Manila	University of the Philippines Manila
USA	United States of America
USAID	United States Agency for International Development
USDA	United States Department of Agriculture
USFDA	United States Food and Drug Administration
WASP	Women Association of Scientists in the Philippines
WTO	World Trade Organization
ZYMV	zucchini yellow mosaic virus

List of Tables

List of Figures

List of Annexes

Executive Summary

The Philippines is a beneficiary of the United Nations Environment Programme/Global Environment Facility (UNEP/GEF) Global Project on Development of National Biosafety Frameworks, which aims to prepare countries for the entry into force of the Cartagena Protocol on Biosafety.

A national biosafety framework (NBF) for the Philippines was developed following an assessment of biotechnology and biosafety in the Philippines. An extensive technical and legal review of Philippine experience on biosafety regulation was undertaken. Inventories were conducted on the current uses of modern biotechnology; existing legal instruments, capacity building activities, and expertise within the country.

The global perspective on modern biotechnology was analyzed in terms of advances made on recombinant microorganisms including viruses, animals, and plants. Development of recombinant plants was more advanced and was highly regulated with 60 transformation events in 15 types of plants approved by the regulatory system of USA, Canada, and other countries.

The Philippines has several research and development (R&D) projects geared towards developing transgenic crops. Modern biotechnology techniques are basically used to address pest problems, postharvest concerns, and quality improvement in crops. Most of genetically engineered products, particularly pharmaceuticals, enzymes, food, and feed preparations, as well as plants used in the country are imported from other countries. Aside from these biotechnology products, exotic species and varieties are also introduced to Philippine agriculture, forestry, and fisheries sectors. Institutions and expertise are available and sufficiently equipped and capable of performing work on modern biotechnology.

Philippine government policies are supportive of the safe use of modern biotechnology. A thorough review of legal instruments related to biotechnology and biosafety was conducted, particularly those that address public health and safety, food security, environmental protection, treaty obligations, rights and obligations of stakeholders, and legal remedies/penalties. The experience of the Philippines in regulating biosafety applications through the National Committee on biosafety of the Philippines (NCBP) guidelines and Department of Agriculture Administrative Order (DA-AO) No. 8 was recognized. Analysis of the gaps, needs, and constraints of the existing instruments was done to recommend changes at appropriate levels to make the legal framework more responsive and effective.

Based on the data gathered and analysis made, an NBF was developed through a multi-stakeholder consultation process. Policies, rules, and regulations were consolidated and integrated into one framework so as to provide clarity, transparency, and predictability to biosafety decision making in the Philippines. The framework does not substitute for rules and regulations that relevant government agencies must issue in the exercise of their current powers and jurisdiction. It is intended to guide such exercise by the concerned agencies, and in particular, mandates coordination among them where appropriate and applicable. The framework contains general principles and minimum guidelines that the relevant agencies are expected to follow and which their respective rules and regulations must conform with.

The framework is not a substitute for legislation that must eventually be enacted to deal with the challenge of maximizing benefits and managing risks posed by modern biotechnology. Such legislation is necessary to provide more permanent rules, institutions, and funding to adequately deal with this challenge.

I. Introduction

In January 2000, an agreement was reached at the Cartagena Protocol on Biosafety (hereafter referred to as the Protocol), a supplemental agreement to the Convention on Biological Diversity (CBD). The Protocol aims "to contribute in ensuring an adequate level of protection in the field of the safe transfer, handling, and use of living modified organisms (LMOs), resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, and specifically focusing on transboundary movements."

In November 2000, the 16th GEF Council initiated the strategy of assisting countries in preparation for the entry into force of the Protocol (GEF/C.16/4). The main objectives of the strategy include assisting countries in implementing the Protocol through the development and implementation of their NBFs; promotion of information sharing and collaboration, especially at the regional and sub-regional levels; and promotion of

collaboration with other organizations to assist in capacity building for the implementation of the Protocol.

It was during this period that the GEF Council also approved the UNEP/GEF Global Project on developing NBFs. To date, the UNEP/GEF has assisted up to more than 100 eligible countries in preparing their NBFs, as well as in promoting regional and sub-regional collaboration and exchange of experiences on issues relevant to biosafety. The Philippines is one of the eligible countries, which received such assistance, being a full party to the CBD and having signed the Protocol on May 24, 2000. The Philippines, however, has yet to ratify the Protocol.

1.1 OBJECTIVES AND ACTIVITIES

The main objective of the National Biosafety Framework Project (NBFP) is to evaluate/review existing national policies on modern biotechnology/biosafety; and to integrate and update and/or revise these policies to come up with an NBF that is consistent with the relevant provisions of the Protocol. In this manner, the country will be better prepared to meet its obligations under the Protocol upon ratification.

To achieve these objectives, the NBFP was tasked to complete the following activities:

(1) Assessment and Inventory of Biotechnology/Biosafety

An assessment and survey of biotechnology and biosafety in the Philippines was conducted to carry out and produce an inventory of the following: (1) current use of modern biotechnology; (2) existing legislation or legal instruments related to biotechnology/biosafety; (3) active or planned national projects for capacity building related to the safe use of biotechnology; (4) relevant experts within the country; and (5) a report on existing sub-regional biosafety frameworks and mechanisms for harmonization of risk assessment/management. A report analyzing the results of the inventory gaps, needs, and priorities was prepared.

(2) Development and Generation of a National Biosafety Database

Based on the results of the assessment and inventory, a National Biosafety Database will be developed and generated. This database will be linked to the Biosafety Clearing (BCH) of the CBD.

(3) Development of an NBF for the Philippines

As a major output of the project, an NBF was developed and prepared through a series of multi-stakeholder consultative workshops at the regional and national levels. The NBF will consist of a regulatory system, an administrative system, a decision-making system, and mechanisms for public participation and information, consistent with the country's needs and priorities and the provisions of the Protocol.

Recognizing, however, that the introduction of potentially harmful exotic species (PHES) is a biosafety issue, information and data on the introduction of exotic species to Philippine agriculture, forestry, and fisheries were also generated.

1.2 METHODOLOGY

An extensive technical and legal review of Philippine experience on biosafety regulation and implementation was undertaken by technical and legal experts engaged by the PAWB/National Executing Agency (NEA). In conducting the technical review, primary and secondary data were used. Statistical data were obtained from the Department of Agriculture (DA) - Bureau of Plant Industry (BPI), Bureau of Animal Industry (BAI), Bureau of Fisheries and Aquatic Resources (BFAR), and the Department of Health (DOH) - Bureau of Food and Drugs (BFAD).

An inventory of modern biotechnology and biocontrol R&D projects and their implementing institutions were obtained from NCBP; Philippine Council for Agriculture, Forestry and Natural Resources Research and Development (PCARRD); Philippine Council for Advanced Science and Technology Research & Development (PCASTRD); Philippine Council for Health Research & Development (PCHRD); DA -Bureau of Agricultural Research (DA-BAR), DA-BFAR, and St. Luke's Medical Center. The web pages of different R&D institutions were also accessed. Applications for biosafety permits were obtained from NCBP and BPI.

Proposed and current training and capability-building programs related to modern biotechnology were obtained from the DA-Biotech Program Implementing Unit and the Biotechnology Coalition of the Philippines (BCP). Other non-government organizations (NGOs), people's organizations (POs), and

public institutions were invited to submit their capacity-building programs and only those who submitted were included in this report. A database on experts was generated from the directory of members of the National Research Council of the Philippines (NRCP) and the National Academy of Sciences (NAST), which was also accessed through *http:www/pinoyfarmer.com/experts*. A review of literature on the biosafety issues on biotech crops and how they apply to the Philippines was based on position letters obtained from the DA and position papers written by expert bodies. Interviews with regulators were also conducted in the course of the technical review.

The legal review consisted of an assessment of international, regional, and national legal documents. The purpose of which was to identify gaps in the Philippine biosafety legal regime as well as to identify best practices applicable to the country.

The technical and legal information gathered were analyzed and used to develop a working draft of an NBF. The working draft was then subjected to an expert and peer review process in October 2003 before a regional workshop draft was produced and subjected to regional consultations in January 2004. Throughout the expert review and regional consultation process, comments were solicited and received from various stakeholders. Simultaneously, individual meetings were held with concerned departments and agencies with the purpose of addressing their specific concerns about the draft NBF. Based on the results of the regional consultations, a national workshop draft was produced and subsequently subjected to a national multi-stakeholder and multi-disciplinary consultation in March 2004.

The NBF was again revised based on the results of the national workshop and further deliberated on by the National Coordinating Committee (NCC) of the NBFP. The members of this Committee include representatives from key stakeholders - government agencies such as the Department of Environment and Natural Resources (DENR), Department of Interior and Local Governments (DILG), Department of Foreign Affairs (DFA), Department of Trade and Industry (DTI), Department of Science and Technology (DOST), DA, DOH, NCBP, NGO, and industry sectors.

The present NBF draft is a product of several consultative meetings of the NCC, taking into account the results of various consultations and positions of the various key departments of government. It was endorsed in August 2004 by then DENR Secretary Elisea Gozun to the Secretaries of the DA, DOST, DOH, DTI, DILG, and DFA for their Department's concurrence and/or endorsement for approval by the Office of the President, or for further comments, if any. Full concurrence and endorsement for approval have been received from the Secretaries of DOH and DFA. Additional comments were received from DILG, DA, DTI, NCBP, and DOST. The present draft is a work in progress pending final discussion on the comments received and concurrence by other Departments.

II. Situational Background

Biological systems have been used by man for many economic activities, especially for food production. With the advent of modern biotechnology, the 21st century has been predicted to rely more and more on biological systems to provide goods and services to support progressive economic activities, maintain a healthy environment, and sustain human health. The introduction of new species/varieties/strain of organisms is a traditional practice in agriculture, forestry, and fisheries. These new organisms may directly increase farm productivity such as the use of new chicken strains in poultry production, serve a new purpose as the use of fast-growing species in reforestation, or are used to improve the germplasm of existing varieties/strain. Efforts to reduce dependence on chemical substances to manage pests have ushered in the use of biocontrol agents, some of which are new introductions from one country to another. However, the increasing use of novel and exotic biological systems have also brought isolated incidences of species and strain introductions that has brought more problems and/or changed ecosystems.

Genetically engineered organisms are new varieties of crops or strains of animals and microorganisms that have acquired novel traits through the direct integration of a gene into their genetic material by laboratory means rather than the natural method of pollen transfer or sperm-egg fertilization. While genetically engineered organisms provide benefits, the novelty of the trait may also pose risks, change the relationship of this organism with other components of the ecosystem, and may eventually change the ecosystem permanently. In addition, the novelty of the technique has raised health concerns such as the random integration of the new gene could change levels of toxicants, anti-nutrients, allergens, and nutritional components or that the integration could trigger the production of a latent toxin, anti-nutrients, or allergens. The rapid adoption of transgenic crops indicates that these crops could dominate world food supply.

To protect itself from the unintended effects of introductions of new organisms, a country must adopt biosafety measures to recognize and predict the probability and extent of their possible adverse effects; and adopt mitigating measures to prevent the occurrence and/or minimize damage.

This section presents an overview of the practice and extent of exotic species introduction and use in the Philippines; the use of modern biotechnology from a global and national perspective; and the policy and legal instruments on biotechnology and biosafety.

2.1. EXOTIC SPECIES INTRODUCTION AND USE IN PHILIPPINE AGRICULTURE, FORESTRY, AND FISHERIES

Philippine agriculture, forestry, and fisheries still employ the introduction of new species/varieties/strain of organisms as a productivity tool.

Most of Philippine major crops are introductions (Table 1) with centers of origin like South America. Of 22 major crop species currently cultivated, only banana and abaca are indigenous to the Philippines and the rest are either indigenized, early, or recent introductions. Although banana is indigenous to the Philippines, multinational companies that started the commercial growing of bananas introduced this variety from South America in the world trade. Cultivated rice originated from India and must have been brought to the Philippines by various ethnic

Table 1. The centers of origin of Philippine major crops[1].

Crop	Origin[1]	Date of introduction of cultivation[2]	Area (ha)
Rice	India	No record	~ 4,046,000
Coconut	No agreement	No record	~ 3,120,000
Corn	Mexico	Spanish period	~ 2,395,000
Banana	Philippines/Southeast Asia	Indigenous	~ 398,000
Sugarcane	New Guinea	1,000 BC	~ 386,000
Cassava	Mexico	Spanish period	~ 206,000
Mango	Indo-Burma region	No record	~ 143,000
Coffee	Ethiopia/Arabia	Spanish period	~ 137,000
Sweet potato	Mexico through Hawaii and Guam	16th century	~ 122,000
Abaca	Philippines	Indigenous	~ 107,000
Rubber	South America	1910	~ 78,000
Pineapple	South America	16th century	~ 45,000
Tobacco	North America	Spanish period	~ 41,000
Mongo	India/Indo-Burma	-	~ 36,509
Peanut	South America	Spanish period	~ 27,057
Eggplant	India	-	~ 21,000
Calamansi	China	-	~ 20,000
Tomato	South America	Spanish period	~ 17,000
Cacao	Central/South America	Spanish period	~ 12,000
Onion	Southwestern Asia	-	~ 10,000
Cabbage	Mediterranean region	-	~ 8,000
Garlic	Central Asia	-	~ 6,000

Halos, 2003

settlers and traders; thus accounting for the variation in traditional rice varieties. There is disagreement over the origin of coconut because it is widely spread along the seacoast of many countries. Corn is a Spanish introduction as well as the cassava, coffee, tomato, and many other crops. There is anthropological evidence that sweetpotato varieties were brought by various ethnic settlers that acquired these plants originally from the Americas through Polynesia and other varieties (camote line) were introduced by the Spaniards in the 16th century.

Introduced species usually have limited genetic bases, especially the recent introductions. To undertake a good breeding program, this genetic base is often expanded by the continuing introduction of new varieties from other countries, especially from the center of origin where the variation is the greatest. The introduction of new varieties and plant species for agriculture is an ongoing commercial activity. Hybrid corn, rice varieties, and vegetable seeds (Table 2) are annually imported from seed companies whose business is the breeding of new varieties. Also, many of the

Table 2. Number of species regularly imported for agricultural production and their country source.

Agricultural use	No of species	Country source
Major grains	2	
Corn (hybrid)		India, Thailand, Indonesia, USA, Japan
Rice		India, China, Indonesia, Bhutan, Turkey
Plantation crops	4	Israel, Belgium, Honduras, USA, Korea, France
Vegetables/spices, fruiting annuals	39	Argentina, Australia, Denmark, Hong Kong, India, Indonesia, Israel, Italy, Japan, Korea, Netherlands, New Zealand, South Africa, Taiwan, Thailand, USA
Ornamentals	21+++	Australia, Canada, Central America, China, Colombia, Ecuador, Germany, Israel, Japan, Korea, Malaysia, Netherlands, Singapore, Spain, Taiwan, Thailand, USA

Halos, 2003

temperate vegetables like onions, cabbage, carrots, and cauliflower do not produce seeds in this country and therefore their seeds must be regularly imported. Many ornamental plants are also introduced into the country due to constant changes in demand.

In addition to these species that are regularly imported as planting materials, more than 30 species of assorted fruit trees, ornamentals, and vegetables are imported occasionally.

Similarly, the Philippine poultry and livestock industry is highly dependent on imported genetic materials with annual imports of eggs, day-old chicks, and breeding stocks of hogs (Table 3). Imported eggs and day-old chicks are either used directly to grow broilers/layers or are bred to produce the next crop of chickens. All commercial broilers and layers are imported strains: Babcock, HNN Nick Chick, Hi-Ye, Hi-Sex, Hubbard, HY Line, Hybro, Lohmann, Ross, Shaver, Starbro, and Sasso. A new introduction is a free-range chicken, Kabir. Breeds of hogs include Landrace, Meat Master, Duroc, Yorkshire, Large White, Seghers, and Pietrain imported from Australia, USA, and Europe. Cattle are relatively recent introductions and many improved breeds are recent imports also. The carabao is being improved with the introduction of water buffaloes from India and Bulgaria, but the native strains remain predominant. Goats, sheep, horses, deers, pythons, pigeons, fancy chickens, ducks/swans, guinea pigs, rabbits, turtles, ostriches,

Table 3. Number of head/pieces of poultry and livestock genetic materials imported annually into the country (1998-2002, Bureau of Animal Industry, x 1000).

Type/Year	1998	1999	2000	2001	2002
Day-old chicks	1,076	2,182	1,542	2,296	2,225
Broiler (GP/PS)[1]	840	1,859	1,360	2,166	-
Layer	237	322	182	131	-
Hatching eggs	-	2,941	327	1,167	45
Hogs	1.7	1.2	1.5	2.1	1.2
Cattle					
Feeder	186	253	195	102	121
Breeder	0.7	0.8	2.0	0.03	0.5
Gamefowl		6.5	4.6	8.2	

[1]GP/PS – grandparent/parental stock
Halos, 2003

flamingoes, parrots, pumas, iguanas, crocodiles, and hedgehogs are also imported, but in smaller quantities.

In forestry, the major reforestation tree species like falcata, ipil-ipil, kakawate, yemane, and mahogany are all introduced. The falcata (*Peraserianthes falcataria* L. Nielsen) originated from the Moluccas, New Guinea, Birmark Archipelago, and was first planted as reforestation species in Bukidnon. Ipil-ipil (*Leucaena leucocephala* Lam de Wit) has its center of origin in Guatemala. The Spaniards introduced the common shrubby form into the country in the early 1600s and the "giant" Salvador type in the 1970s. Kakawate (*Gliricidia sepium* Jacq Kunth ex Walp.) originated from the coast of Central America and was introduced by the Spaniards in the early 1600s. Yemane (Gmelina *arborea*), was introduced in 1960, is distributed from Pakistan, India, Sri Lanka, and South China through the Malesian archipelago to Australia, Fiji, New Zealand, and New Caledonia. Mahogany (*Swietenia macrophylla* King), introduced in 1910 by the Americans, is a native of tropical America. Species and provenance trials have been the norm in reforestation research introducing into the country several *Eucalyptus* and *Acacia* species from Australia and Sabah, *Pinus* species from Central America and the Caribbean, and teak from neighboring countries.

For the fishery sector, tilapia, the major inland aquaculture species, has been introduced in the 1950s and new strains for genetic improvement are imported as well. Despite extensive cultivation, tilapia has not been found to populate waterways and crowd out other fish species. There are 24 freshwater aquarium species regularly imported (Table 4) and 31 species for aquaculture, game, and aquarium already established in the country (Table 5).

Table 4. Live aquarium fishes regularly imported into the Philippines and their country sources (Bureau of Fisheries and Aquatic Resources, 2003).

Common/Species name	Country source
Angelfish, Pterophyllum scalare	Taiwan
Australian arowana, Scleropage jardini	Hongkong, China, Taiwan
Bala shark, Balantiocheilus melanopterus	Thailand
Balzanii, Geophagus balzanii	Malaysia
Black belt, Vieja maculicauda	United States of America (U.S.A.)
Black moor, Carassius auratus	Hongkong
Black neon tetra, Hyphessobrycon herbertaxelrodi	Taiwan
Blood parrot, Cichlasoma sp.	Taiwan
Cardinal tetra, Paracheirodon hypsauchen	Taiwan
Clown knife fish, Notopterus mikereeki	Taiwan, Thailand
Color glass fish, Chanda wolfili	Taiwan, Thailand
Convict cichlid, Archocentron nigrofaciatus	U.S.A.
Discus, Symphysodon aequifasciata	Taiwan
Dwarf gouramy, Colisa lalia	Malaysia, Taiwan
Frontosa cichlid, Cyphotilapia frontosa	Taiwan, Tanzania
Golden severum, Heros severus	Taiwan
Gold fish, Carassius auratus	Hongkong, Malaysia, Taiwan
Guppy, Poecilia reticulata	Malaysia
Iridescent shark (catfish), Pangasius sp.	Thailand
Midas cichlid, Amphilopus citrinellus	U.S.A.
Neon tetra, Paracheirodon innesi	Hongkong, Taiwan
Oscar fish, Astronotus ocellatus	Taiwan, China
Pearl gouramy, Trichogaster leeri	Taiwan
Pearlscale cichlid, Herichthys carpinte	Hongkong, China
Quetzal, Vieja synspilum	U.S.A.
Red cap, Carassius auratus	Hongkong, China
Red oranda, Carassius auratus	Hongkong, China
Red-fin (Rainbow) Shark, Epalzeorhynchus (Labeo) frenatus	Thailand
Red telescopic, Carassius auratus	Hongkong
Silver arowana, Osteoglossum bicirrhosum	Hongkong, Taiwan, China
Silver dollar, Metynnis hypsauchen	Taiwan
Striped deepwater cichlid, Bentochromis tricoti	Tanzania
Surinamensis, Geophagus surinamensis	Malaysia, U.S.A.
Three-spot cichlid, Amphilophus trimaculatus	U.S.A.

Halos, 2003

Table 5. Fishes introduced and cultured into the Philippines (Fishbase, 2003).

Species	Type
Anabas testudineus	aquarium/aquaculture fish
Aristichtichthys nobilis	aquaculture fish
Barbonymus gonionotus	aquaculture fish
Carassius auratus auratus	aquarium/aquaculture/game fish
Carassius carassius	aquaculture/game fish
Catla catla	aquaculture/game fish
Channa striata	aquaculture fish
Cirrhinus cirrhosus	aquaculture/game fish
Clarias batrachus	aquarium/aquaculture fish
Clarias gariepinus	aquaculture/game fish
Colossoma macropomum	potential use in aquaculture
Ctenopharyngodon idellus	aquaculture/game fish
Cyprinus carpio	aquaculture/game fish
Gambussia affinis	aquarium fish
Helostoma temminckii	aquarium/aquaculture/game fish
Hypopthalmichthys molitrix	aquaculture fish
Ictalurus punctatus	potential use in aquaculture/game
fishLabeo rohita	aquaculture/game fish
Lepomis cyanellus	aquaculture fish
Lepomis macrochirus	aquarium/game fish
Micropterus salmoides	aquaculture/game fish
Misgurnus anguillicaudatus	aquarium/aquaculture fish
Oreochromis mossambicus	aquarium/aquaculture/game fish
Oreochromis niloticus	aquaculture fish
Oreochromis spilurus spilurus	potential use in aquaculture
Osphronemus goramy	aquarium/aquaculture fish
Pangasius hypophthalmus	potential use in aquaculture
Tilapia zillii	potential use in aquaculture
Trichogaster leerii	aquarium/aquaculture fish
Trichogaster pectoralis	aquarium/aquaculture fish
Trichogaster trichopterus	aquarium/aquaculture fish

Halos SC, 2003

Biological control agents are also common introductions in agriculture. *Trichogramma* spp., the wasp used to control the Asiatic corn borer, was introduced in the 1970s.

The mechanisms by which new introductions can reduce biodiversity are competition, predation, hybridization, disease transmission, and habitat alteration. Competition for the same niche or for the same food source between the new introduction and the native organisms may result with the new introduction overwhelming the native species. Traits such as rapid reproductive capacity in all organisms and rapid spread of seeds and production of allelopathic substances in plants

confer advantage over competing species. Predation of native organisms by a newly introduced animal often leads to the loss of a native species that could not reproduce rapidly enough to replace lost populations. Hybridization between the new introduction and its native relatives can reduce diversity if hybrids tend to be more competitive over their parents. Or, the hybrids are preferred and tend to be selected by other forces in the area. Disease transmission can also result to loss of biodiversity if the new introduction carries with it some pest or parasite of which it is tolerant but to which the native species in the area would succumb to. New species may attract their own set of pests, symbionts, and other interacting organisms; thereby resulting to a changed ecosystem. This habitat alteration can lead to the loss of the native species growing in the area.

There are already known instances of new introductions that have not resulted in economic benefit but have resulted instead to adverse environmental and economic consequences in the Philippines. The deliberate introduction of the "golden kuhol" (*Pomacea canaliculata*) to improve human nutrition and serve as a source of added income is an example of a species introduction gone awry. The rapid growth of this snail and its preference for young rice seedlings has spelled lost income to farmers. This snail, a native of South America, was introduced through Taiwan between 1982–1984 by a private individual, but government soon picked it up as a livelihood project. By 1986, this pest was reported to have damaged 300 ha of rice fields in Cagayan Valley . This snail continues to infest 11% of the irrigated rice fields and appears to have displaced the native species. Farmers spent US$23 million worth of imported molluscicides from 1980 to 1998 for controlling this pest[3].

The water hyacinth (*Eichornia crassipes* Mart Solms), originally from tropical America and introduced as an ornamental plant in 1912[4], has since become a very obnoxious weed, clogging waterways, covering swampy areas, and crowding out other species in the area. A look over the airplane window as one approaches the Manila airport will show the number of water inlets that flows to Pasig River clogged and rendered impassable by water hyacinth. Another introduced plant species that has since become a weed[5] is the castor oil plant, *Ricinus communis* L., originally from tropical Africa and introduced as a plantation crop. However, the environmental havoc caused by the water hyacinth does not compare with that of the castor oil plant.

The introduction of some aquatic species appears to result in biodiversity losses. The Thai catfish (*Clarias batrachus*), introduced in 1972, was noted to have crowded out the native catfish (*Clarias macrocephalus*) in its native habitat. Unfortunately, the tough flesh of the Thai catfish makes it unacceptable to consumers. The African catfish (*Clarias gariepinus*), introduced as aquaculture species in the 1985, appears to have the same effect on the native species, but it is more acceptable to consumers. Lately, an aquarium catfish species, the janitor fish (*Plecostomus hypostomus*), introduced in the 1990s, appears to be developing into a pest in Laguna Lake. Fishermen claim that this fish destroys fishnets and competes for food with the more valuable food fish species.[2] Likewise, the African snail, introduced as a food species by the Japanese, has turned into a vicious garden pest.

Among the introduced tree species, ipil-ipil and kakawate can be seen to have spread wild around the country. There is no measure of any negative impact of these species and they behave like pioneer species. However, the introduction of the Giant ipil-ipil has promoted infestation by a new insect pest, *Psyllid sp*. This new pest has checked the rapid spread of the Giant ipil-ipil. Early in its introduction, ecologists warned that this type of ipil-ipil could develop into a weed because it was claimed to be more pest-resistant than the existing dwarf types. The kakawate, on the other hand, was introduced as a nurse tree to the cacao; but today they can be seen in gregarious stands. Other introduced species that appear to thrive without human intervention include the Indian tree and neem.

San Valentin noted that insect pests may have been introduced with the entry of new forest species. Some biocontrol agents introduced to control agricultural and forestry pests have been reported to cause the demise of non-target species related to the pest. Spores from some fungal biocontrol agents have been associated with allergies. One bionematicide was suspected to cause an eye disease. One fungal composting agent was associated by a farmer to have caused the rotting of the posts of his house.

The continuing introduction of new varieties of cultivated major crops is not known to have resulted in any adverse environmental effect except the continuing loss in cultivation of old and inefficient varieties. The conservation of these disappearing varieties is the mandate of the National Plant Genetic Resources

Laboratory of the University of the Philippines Los Baños (UPLB) and members of the recently organized Plant Genetic Resources RDE (research and development extension) Network. These agencies maintain gene banks of Philippine crops and their relatives.

Except for the possible entry of new strains of pathogens along with the annual import of genetic stocks of poultry and livestock, no problem of uncontrolled reproduction and spread has been encountered. The population of native chickens remains high. Native chickens and improved progenies at 72 million outnumbered the number of broilers and layers as of October 2002. However, concern has been raised on the loss of old hog breeds and strains. The changed structure of the hog industry in the Philippines triggered the loss of the older hog breeds. There is an ongoing effort however, by the BAI and PCARRD to collect and maintain old breeds and strains of pigs and chickens.

Nevertheless, there are more useful introductions than harmful ones and this experience should assist us in developing a system of culling out potentially harmful introductions. Introduced crops that remained in cultivation and farm animals have not developed as pests. Crops and farm animals are grown in highly managed ecosystems. These crops must be culturally managed in order to survive. The foreign breeds of poultry and livestock are kept in poultry houses and growing pens, respectively, requiring strict growing conditions. That is, cultivated crops and introduced foreign strains of chicken and breeds of livestock do not thrive without human intervention. Hence, these do not become feral and cannot effect changes in unmanaged ecosystem.

2.2 MODERN BIOTECHNOLOGY IN A GLOBAL PERSPECTIVE

Many economic activities, especially in agriculture and medicine, make use of biological systems. Techniques in agriculture such as cross-pollination to make healthy, disease-resistant crop varieties; fermentation techniques used in making wine, beer, soy sauce and vinegar; as well as the use of organic fertilizers, biopesticides, antibiotics to improve yield of crop, poultry and aquaculture are all classified as traditional biotechnology. The 21st century has been predicted to rely more and more on biological systems through the use of information found in the genetic material or deoxyribonucleic acid (DNA). The processes of modern biotechnology or

recombinant DNA (rDNA) technology are used to provide goods and services to support progressive economic activities, maintain a healthy environment, and sustain human health.

Products of rDNA are referred to as genetically modified organisms (GMOs), transgenics, genetically engineered, or bioengineered organisms and in the Protocol as LMOs. Genomics and proteomics are also classified into modern biotechnology since they are techniques based on the knowledge of the DNA and ribonucleic acid (RNA). Genomics refer to techniques that look at the organization of total genomic make-up of organisms, the sequence of bases, the sequence of genes, and the spatial and functional relationships of genes. Proteomics refer to the total proteins in cells of organisms, their structure, how they function, how they are controlled, and how they relate to each other to make the whole organism. The structures of proteins determine their function and protein structure is determined directly by the DNA. Since the technique of rDNA was developed in 1973, various modern biotech organisms have been developed and placed into practical use.

The Cartagena Protocol on Biosafety defines modern biotechnology as the "application of in vitro nucleic acid techniques, including rDNA and direct injection of nucleic acid into cells or organelles, or the fusion of cells beyond the taxonomic family that overcome natural physiological reproductive or recombination barriers, and that are not techniques used in traditional breeding and selection."

2.2.1 Recombinant microorganisms including viruses

Microorganisms have been genetically engineered to produce pharmaceuticals, food, feed, and industrial enzymes; detoxify environmental pollutants; produce substances that can replace environmentally polluting products; and replace environmentally degrading industrial processes and products. Bacteria, yeasts, filamentous fungi, and viruses have been genetically engineered for these purposes.

Many bioengineered pharmaceuticals are derived from human genes and can not be

ethically produced any other way. The bacterium, *Escherichia coli,* is the first genetically engineered organism put in commercial use for the production of human insulin in 1982. Since then, a number of human therapeutic proteins have been manufactured by using *E. coli* and *Saccharomyces cereviseae*. Table 6 lists some known recombinant microorganisms and some of their pharmaceutical products in medical use.

Aside from pharmaceuticals, many food enzymes currently in use are produced by recombinant microorganisms[7] (Table 7). It is claimed that more than 90% of all cheeses produced in the world today are produced by using recombinant chymosin. Another major use of food enzymes is in the clarification of fruit juices. Most of these recombinant microorganisms are classified GRAS (generally regarded as safe) to ensure product safety.

New food-grade microorganisms are undergoing development to improve the nutritional and health value of fermented as well as non-fermented foods of dairy and soy origin referred to as microbial nutriceuticals. The new microbial strains are enhanced producers of low-energy sugars, digestion-

Table 6. Some recombinant microorganisms used to manufacture pharmaceuticals.

Organism	Product	Product use
Escherichia coli	Human insulin	Therapy for diabetes
	Interleukin-2 (IL-2)	Cancer therapy
	Alpha and gamma interferon	Cancer and viral infection therapy
	Tumor necrosis factor	Causes disintegration of tumors
	Somatotropin (Human growth hormone)	Corrects growth deficiencies in children
	Epidermal growth factor	Heals wounds, burns, ulcers
	Prourokinase	Anti-coagulant, heart attack therapy
Colony-stimulating factor	Counteracts adverse effects of Taxol	Chemotherapy Treatment of ovarian and breast cancer
Saccharomyces cereviseae	Superoxide dismutase	Minimizes damage caused by oxygen-free radicals
	Hepatitis B vaccine	Protection from Hepatitis B infection
	Alpha and gamma interferon	Cancer and viral infection therapy
Pichia pastoris	Prourokinase	Anti-coagulant, heart attack therapy

Halos, 2003

Table 7. Food enzymes produced by genetically engineered microorganisms.

Enzyme	Genetically engineered microbe
á-Acetolactate decarboxylase	*Bacillus subtilis* with *B brevis* gene
á-Amylase	*Bacillus subtilis* with *B stearothermophilus* gene
á-Amylase	*Bacillus subtilis* with *B megaterium* gene
á-Amylase	*Bacillus licheniformis* (self-cloned)
á-Amylase	*Bacillus licheniformis* with *B stearothermophilus* gene
Catalase	*Aspergillus niger* with *Aspergillus gene*
Chymosin A	*Escherichia coli* with calf gene
Chymosin B	*Aspergillus awamori* with calf gene
Chymosin B	*Kluyveromyces lactis* with calf gene
Cyclodextrin glucosyl transferase	*Bacillus licheniformis* with *Thermoanaerobacter* gene
â-Glucanase	*Bacillus subtilis(B amyloliquefaciens)* with *Bacillus* gene
â-Glucanase	*Trichoderma reesei* with *Trichoderma* gene
Glucose isomerase	*Streptomyces lividens* with *Actinoplanes* gene
Glucose isomerase	*Streptomyces rubiginosus with Streptomyces* gene
Glucose oxidase	*Aspergillus niger* with *Aspergillus gene*
Lipase, triacylglycerol	*Aspergillus oryzae* with *Rhizomucor* gene
Lipase, triacylglycerol	*Aspergillus oryzae* with *Thermomyces* gene
Maltogenic amylase	*Bacillus subtilis* with *B stearothermophilus* gene
Pectinesterase	*Aspergillus oryzae* with *A. aculeatus* gene
Protease	*Aspergillus oryzae* with *Rhizomucor* gene
Protease	*Bacillus amyloliquefaciens* with *Bacillus* gene
Protease	*Bacillus licheniformis* with *Bacillus* gene
Pullulanase	*Bacillus licheniformis* with *Bacillus* gene
Pullulanase	*Klebsiella planticola* with *Klebsiella* gene
Xylanase (hemicellulase)	*Aspergillus oryzae* with *Aspergillus* gene
Xylanase (hemicellulase)	*Aspergillus oryzae* with *Thermomyces* gene
Xylanase (hemicellulase)	*Aspergillus niger var awamori* with *Aspergillus* gene
Xylanase (hemicellulase)	*Aspergillus niger* with *Aspergillus* gene
Xylanase (hemicellulase)	*Bacillus subtilis* with *Bacillus* gene
Xylanase (hemicellulase)	*Bacillus licheniformis* with *Bacillus* gene
Xylanase (hemicellulase)	*Trichoderma reesei* with *Trichoderma* gene

Halos, 2003

stimulating oligosaccharides, and essential B vitamins. They may also have specific enzymes that hydrolyse anti-nutritional factors.

The health-promoting strains will be developed by using traditional strains of lactic acid bacteria and propionic acid bacteria, or be genetically engineered *Lactococcus lactis*, *Lactobacillus plantarum,* and *Streptococcus thermophilus*. The cultures will be used directly in fermented dairy or soy products or in fermentative production of nutraceutical ingredients[8].

Bioremediation is another active area in the genetic engineering of microbes. In fact, the first GMO that received a patent in the USA is a genetically engineered microbe for cleaning

up oil spills in seas. Some of the early microorganisms being developed are intended to detoxify environmental pollutants such as polychlorinated biphenyls (PCBs) (Table 8). Baculo-viruses or viruses that infect insects are being developed to replace chemical insecticides used in agriculture. These viruses must be introduced freely into the environment in order to take effect.

2.2.2 Recombinant Animals

There are only two recombinant animals in commerce. One is the oncogenic or Harvard mouse that is used in cancer research. The other is recently announced — an aquarium fish from Taiwan. However, researches in animal genetic engineering are many. Recombinant farm animals are being designed to improve meat quality such as reduction in fat content and increase in muscle tissue. An animal designed to reduce environmental pollution is the EnviroPig, a recombinant pig, which contains in its saliva the enzyme phytase that digests phytate in grains. The digestion of phytate enables the pig to utilize the phosphorus in feeds; thereby reducing the phosphorus content of manure. Phosphorus leaching into the ground water that feeds into

Table 8. Genetically engineered microorganisms for agriculture and bioremediation.

Species	Modification	Use
Pseudomonas putida	Strategy combines the killing function based on fusion of modified *lac* promoter to *gef* killing gene of *E. coli* with the regulatory system of the degradative pathway for 3-methylbenzoate	Bioremediation - chemical induction of suicide as a biological containment principle for the biodegradation of xenobiotics
Pseudomonas putida PaW[8]	Sac I fragment from *Alcaligenes eutrophus* plus growth-controlling plasmid	Biologically contained bioremediation agent for degrading 3-chlorobenzoate
Rhizobium leguminosarum biovar *viciae*	Tagged with *laz* Z reporter cartridge	Monitoring of inoculant
Azospirillum brasilense	Tagged with *gus*A	Monitoring of inoculant
Baculoviruses *Autographa californica ('Ac)*MNPV *Bombyx mori* (Bm) NPV	Added pesticidal genes: Insect-specific neurotoxin gene from scorpion, mite, hornet, spider	Biocontrol

river, lakes, and other water bodies has indirectly caused eutrophication. Biopharming or the production of pharmaceuticals in farm animals is also an active area of research. The production of therapeutic proteins in fermentation by using microbes and mammalian cells is an expensive and a technically difficult process; the production of these compounds in animal milk is hoped to avoid these difficulties.

Several fish species have been genetically engineered to improve productivity and these include the Atlantic salmon, Pacific salmon, Coho salmon, Chinook salmon, Medaka fish, tilapia, channel catfish, rainbow trout, and northern pike. The genetically engineered Atlantic salmon is currently undergoing review for possible commercial production.

2.2.3 Recombinant plants

Genetically engineered crops have generated much controversy such that the term GMO is now attributed by lay persons solely to genetically engineered crops. Nevertheless, the adoption of biotech crops has been unprecedented in the history of agriculture, from 1.7 million ha in 1996 to 52.8 million ha in 2002 (Figure 1). The annual expansion in hectarage is about 10% in the last few years (Clive James, 2002).

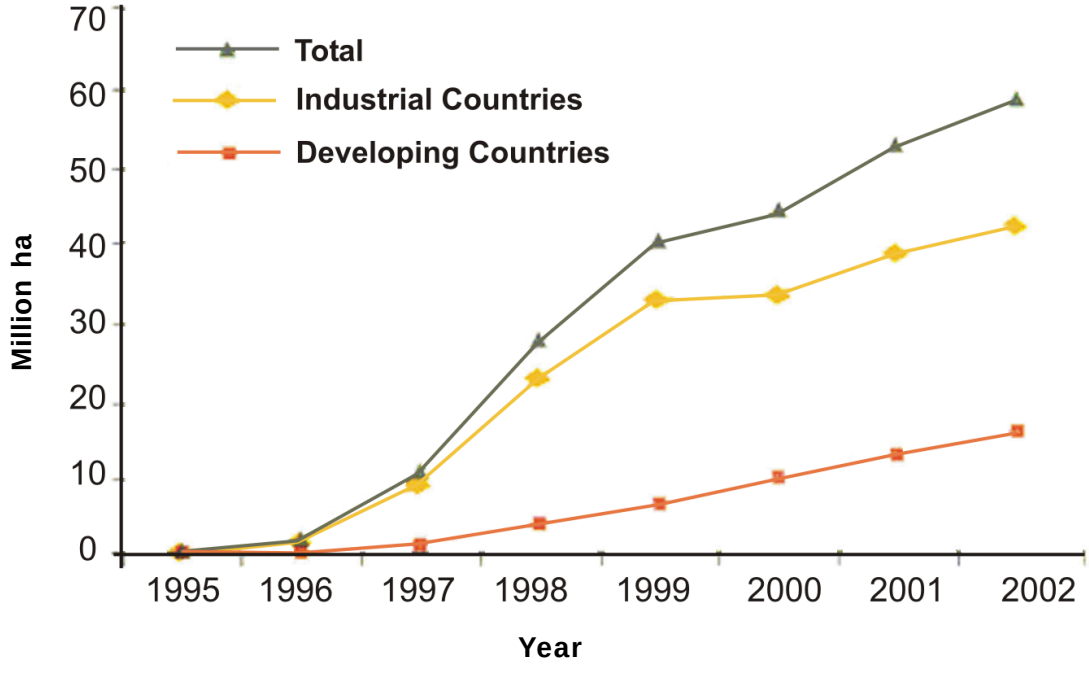


Figure 1. Global areas of transgenic crops, 1996–2002.

Transgenic crops are highly regulated. In the development of a transgenic variety, data on its safety as food and feed if used for these purposes and its introduction into the farming environment is generated. As per recommendation of the Organization for Economic Cooperation and Development (OECD) in 2000, countries must undertake risk assessment to address the following issues when transgenic crops are intended for propagation:

I. Background information
   A. The Crop family
      1. Potential for outcrossing and weediness of the novel crop/ variety
      2. Environmental consequences of introduction of transformed variety
   B. Description of the transformation system and plasmids utilized
   C. Donor genes and molecular biology of traits/transformation events
   D. Detailed description of the phenotype of novel variety

II. Bioefficacy data

III. Environmental safety of the novel variety - gene flow, effect on non-target species, exposure to active ingredients, speed of soil degradation

IV. Food and feed safety of the novel variety – toxicity, allergenicity, animal feeding trials, safety and nutritional value of introduced proteins, similarity to equivalent traditionally derived foods-composition, nutritional value, levels of toxicants and anti-nutrients

This strict regulation does not allow the entry into the market of recombinant food crops containing toxic or allergenic proteins, whether these are the direct products of the introduced gene(s) or due to changes in the plant from the genetic engineering process. This regulation does not also permit the entry into production of recombinant crops that could adversely affect the environment, specifically biodiversity.

The USA had earlier allowed for split approvals for crop plants, approving the Starlink *Bt* corn for feed and processing use but not for food use. However, this variety was later detected in foods containing corn, creating fear and confusion. The approval was withdrawn due to the inability of the technology developer to restrict its use to feed and processing. The USA is no longer issuing split approvals.

There are 60 transformation events in 15 transgenic crops approved by the regulatory system of USA, Canada, and other countries (Table 9).

Transformation event refers to one instance of DNA entering a cell and getting its protein product made by the plant derived from the cell. Apparently, not all of these

Table 9. Recombinant crops, new traits acquired, and number of transformation events.

Crop	New trait acquired (Number of transformation events)
Argentine canola	Phosphinothricin (PPT) herbicide tolerance, specifically glufosinate ammonium (3) Modified seed fatty acid content, specifically high laurate levels and myristic acid production (1) Oxynil herbicide tolerance, including bromoxynil and ioxynil (1) Pollination control system: male sterility; fertility restoration; PPT herbicide tolerance, specifically glufosinate ammonium (5) Glyphosate herbicide tolerance (2)
Carnation	Modified flower color; Sulfonylurea herbicide tolerance, specifically triasulfuron and metsulfuron-methyl (1) Modified flower color; Sulfonylurea herbicide tolerance, specifically triasulfuron and metsulfuron-methyl (1)
Chicory	Male sterility; PPT herbicide tolerance, specifically glufosinate ammonium (1)
Cotton	Resistance to lepidopteran pests including, but not limited to, cotton bollworm, pink bollworm, tobacco budworm (1) Oxynil herbicide tolerance, including bromoxynil and ioxynil (1) Resistance to lepidopteran insects; oxynil herbicide tolerance, including bromoxynil (1) Glyphosate herbicide tolerance (1)
Flax	Sulfonylurea herbicide tolerance, specifically triasulfuron and metsulfuron-methyl
Maize	Glyphosate herbicide tolerance (3) Resistance to corn root worm (Coleopteran, *Diabrotica sp.*) (1) Resistance to European corn borer (*Ostrinia nubilalis*); glyphosate herbicide tolerance (1) Male sterility; PPT herbicide tolerance, specifically glufosinate ammonium (3) Resistance to European corn borer (*Ostrinia nubilalis*); PPT herbicide tolerance, specifically glufosinate ammonium (4) PPT herbicide tolerance, specifically glufosinate ammonium (2) Resistance to European corn borer (*Ostrinia nubilalis)* (1) Resistance to European and Asiatic corn borer (*Ostrinia nubilalis)* (1)
Melon	Delayed ripening
Papaya	Resistance to viral infection, papaya ringspot virus (PRSV)
Polish Canola	Glyphosate herbicide tolerance (1)
Potato	Resistance to Colorado potato beetle (*Leptinotarsa decemlineata*, Say) (2)

Table 9. (Continued).

Crop	New trait acquired (Number of transformation events)
	Resistance to Colorado potato beetle (*Leptinotarsa decemlineata*, Say); resistance to potato leafroll luteovirus (PLRV) (1)
	Resistance to Colorado potato beetle (*Leptinotarsa decemlineata*, Say); resistance to potato virus Y (PVY) (1)
Rice	PPT herbicide tolerance, specifically glufosinate ammonium (1)
Soybean	Glyphosate herbicide tolerance (1)
	Modified seed fatty acid content, specifically high oleic acid expression (1)
	PPT herbicide tolerance, specifically glufosinate ammonium (4)
Squash	Resistance to viral infection, watermelon mosaic virus (WMV) 2, zucchini yellow mosaic virus (ZYMV) (1)
	Resistance to viral infection, cucumber mosaic virus (CMV), watermelon mosaic virus (WMV) 2, ZYMV (1)
Sugar Beet	PPT herbicide tolerance, specifically glufosinate ammonium (1)
	Glyphosate herbicide tolerance (1)
Tomato	Delayed ripening (5)
	Resistance to lepidopteran pests including, but not limited to, cotton bollworm, pink bollworm, tobacco budworm (1)

Halos, 2003

transformation events are grown in commercial scale. For example, of the six transformation events approved for soybean, only one, RR soybean or glyphosate-tolerant soybean is planted in commercial scale. There are only seven of the 16 approved transformation events in corn that are planted in commercial scale. Another *Bt* corn 176 is also being phased out. However, this list does not include the transformation events developed by Chinese R&D institutions and which are planted also in commercial scale: several transformation events of *Bt* cotton, virus-resistant tomato (Peking University), improved shelf-life tomato (CCAU), flower color-altered petunia (Peking University), and virus-resistant sweet pepper (Peking University). Countries that approve and grow these genetically modified (GM) crops in large areas are shown in Table 10.

Major transgenic crops are glyphosate herbicide-tolerant soybean, *Bt* corn, herbicide-tolerant canola, herbicide-tolerant corn,

Table 10. Increase in global area (million ha) of transgenic crops by country, 2001–2002.

Country	2001	2002	% Change
USA	35.7	39.0	+9
Argentina	11.8	13.5	+14
Canada	3.2	3.5	+9
China	1.5	2.1	+40
South Africa	0.2	0.3	+50
Australia	0.2	0.1	-50
India	-	<0.1	
Romania	<0.1	<0.1	
Spain	<0.1	<0.1	
Uruguay	<0.1	<0.1	
Mexico	<0.1	<0.1	
Bulgaria	<0.1	<0.1	
Indonesia	<0.1	<0.1	
Columbia	-	<0.1	
Honduras	-	<0.1	
Germany	<0.1	<0.1	
Total	52.6	58.7	+12

Clive James, 2003

Bt cotton, herbicide-tolerant cotton, *Bt* herbicide-tolerant cotton, and *Bt* herbicide-tolerant corn (Table 11).

2.3 THE PHILIPPINE BIOTECHNOLOGY AND BIOSAFETY SCENARIO

2.3.1 Use of biotechnology and biotechnology products

Pharmaceuticals

Drug manufacturers using recombinant organisms are all based outside the Philippines. There is a continuing development of this technology to produce medical products not only in developed countries, but also in some developing countries like Cuba. From 1982 to 2002, a total of 235 biotech pharmaceuticals have been approved by the United States Food and Drug Administration (USFDA) . There are about 40 of these products presently prescribed by doctors in the Philippines (Table 12).[9]

Commodity imports

The USA is the leading producer of transgenic crops. Countries producing transgenic crops

Table 11.Major transgenic crops and area planted in 2002.

Crop Transgenic	Area planted (million ha)	%
Herbicide-tolerant soybean	36.5	62
Bt corn	7.7	13
Herbicide-tolerant canola	3.0	5
Herbicide-tolerant corn	2.5	4
Bt cotton	2.4	4
Herbicide-tolerant cotton	2.2	4
Bt herbicide-tolerant cotton	2.2	4
Bt herbicide-tolerant corn	2.2	4
Total	58.7	100

Halos, 2003

Table 12. Pharmaceutical products prescribed in the Philippines, which are derived from genetically engineered organisms.

Declared as rDNA products	Use	No of commercial preparations
rHuman Tissue Plasminogen Activator	Anticoagulant, antithrombotics, fibrinolytics	1
rMethionyl human granulocyte colony stimulating factor	Haematopoietic agent	1
rSomatotropin	Growth hormone	5
rInsulin	Anti-Insulin Dependent Diabetes	10
rHepatitis B vaccine	Protection from Hepatitis B	5
rHuman interferon â-1a	Therapy for Multiple sclerosis	1
Probable GM products	**Use**	**No of preparations**
Epoetin á [10] Epoetin â	Haematopoietic agent	2
Herceptin	Haematopoietic agent	1
Taxol	Anti-cancer	1
	Breast and ovarian cancer therapy	1
ReoPro Abciximab	Anticoagulant/antithrombotic	1
Interferon á 2b	Fibrinolytic	1
Interferon á 2a	Antiviral	2
Interferon á –n1	Antiviral	1
Peginterferon á 2b	Antiviral	1
Peginterferon á 2a	Antiviral	1
Simulect (Basiliximab)	Haemostatic	1
Human anti-hemophilic factor VIII	Immunosuppressant Anticoagulant/antithrombotic	1
	Fibrinolytic	2
Human anti-thrombin III	Haemostatic	1
Somatostatin	Haemostatic	2
Daclizumab	Immunosuppressant	1

do not segregate transgenic from non-transgenic harvests. Hence, these commodities may or may not contain the GM varieties.

The Philippines imports almost all of its soybean requirements, whether as bulk grain, soybean meal, isolated soy protein, textured vegetable protein, or in other forms. The major country suppliers include Argentina, USA, Canada, and Brazil; all producing glyphosate-tolerant soybean. Other commodity imports include rice, wheat, corn, and cotton. More than 50% of cotton is imported from the USA and Australia where *Bt* cotton is grown. Corn and its products like corn oil, cornstarch, dextrose, and high-fructose corn syrup are sometimes obtained from the USA. Major sources of tomato paste used in various food preparations are the USA and China. Table 13 shows the possible presence or absence of GMOs in Philippine commodity imports.

Animal feeds are also added with enzymes to improve digestibility. Our import of feed enzymes in 2001 is more than 400, 000 t (BAI).

Table 13. Presence of GMOs in Philippine commodity imports in 2001.

Commodity/ Origin	Quantity (Qty)	Value	% Share (Qty)	GM content
Soya Beans	315.16	74.37	100.00	+
USA	226.17	50.65	71.76	+
Argentina	53.55	13.01	16.99	+
Canada	14.07	3.74	4.46	+
Brazil	8.77	3.30	2.78	+
India	2.67	1.47	0.85	_
Others	9.93	2.20	3.15	_
Cotton	46.10	49.77	100.00	+
USA	17.95	18.01	38.94	+
Australia	8.33	10.54	18.07	+
Pakistan	4.82	4.96	10.46	
Argentina	2.95	2.74	6.40	
Ivory Coast	2.53	2.66	5.49	
Others		9.52	10.86	20.65

% of soybeans import with GM soybeans~96%
% of cotton import with GM cotton~57%

Manalo, A. 2003

Food and preparations

There are more than 1, 700 packaged food registered with the DOH-BFAD containing soya, corn, and tomatoes singly or in combination (Table 14). Since not all food manufacturers in the Philippines are registered with BFAD, there are probably more products in the market containing soya, tomatoes, and corn.

Table 14. Food and preparations registered with the BFAD containing soya, corn, and tomato ingredients.

Ingredients	Food preparations
Corn products Corn meal Whole corn kernels Corn oil Corn starch Dextrose Corn syrup, high fructose corn syrup (HFCS) Butter substitutes: margarine cream fat, shortening Soya products Soybean flour Ground beans Lecithin Soya bean Fermented beans Soya oil Textured vegetable protein Isolated soy protein Butter substitutes: margarine cream fat, shortening Tomato Tomato paste Whole tomatoes	Canned salted beans Canned corn kernels, frozen baby corn Popcorn packs, Korniks Breakfast cereals, Tortillas, Taco shells Nacho Corn chips, corn flakes, cookies, cookie bars, Crackers, biscuits, Wafers, Corn muffins, Cheese balls Sandwich spread, Pate, Jams Candies, chocolate bars, cereal bars Instant noodles, quick cooking noodles, Canned soups, soup base powders/cubes Soup mix sachets, etc Soy sauce, Barbecue sauce, Spaghetti sauce, Pizza sauce, Catsup, Worcestershire sauce, Steak sauce, Gravy mix, Pastry wrappers Protein tablets, High protein drinks Carnithine capsules Infant formula, Soya milk Sausages, Longganiza, Hams, Tocino, Tapa Potted meat, luncheon meat, Ham spread, Meat chunks, Hamburger patties/mixes, Corned beef, Pork dash, Frankfurters, Hotdogs, Bologna, Meat loaf, Salami, Bacon, Turkey meat preparations, Chicken meat preparations, Beef stew and similar beef dishes, Pot pies, lasagna, “lechon paksiw”, Afritada, Bistek Tagalog, Meat and beans, Pepperoni, Embotido, Kaldereta, Dinuguan, Adobo, Vege-meats, Vege-burgers, Tofu, tokwa, Vegetarian foods/meals, soya chunks Canned fish: Different preparations of tuna, sardines, mackerel, bangus, etc. Tomato juice Baby foods

Halos, 2003

Crops

Since September 2002, BPI has received and processed applications for biosafety permits for 19 transformation events, 1 for propagation and 18 for import for direct use for food, feed, and processing (Table 15).

The Philippines approved the first commercial planting of *Bt* corn MON 810 in 2002. During the first cropping season after approval, 126 ha of *Bt* corn MON810 have been planted, and during the second season, about 12,000 ha were planted. The area is

Table 15. Transformation events approved for propagation or import for direct use for food, feed, or processing by BPI as of November 2004.

Transformation event	Added trait	Permit applied for	Status
1. Corn event MON810	Protection from corn borer	Propagation	Approved
2. Corn event Bt11	Protection from corn borer	Direct use	Approved
3. Soybean event 40-3-2 glyphosate	Tolerance to herbicide	Direct use	Approved
4. Corn event GA21	Tolerance to herbicide glyphosate	Direct use	Approved Approved
5. Corn event MON863	Protection from corn root worm	Direct use	Approved
6. Corn event NK603	Tolerance to herbicide glyphosate	Direct use	Approved
7. Corn event TC1507	Resistance to lepidopteran pests of corn	Direct use	Approved
8. Canola event RT73	Tolerance to herbicide glyphosate	Direct use	Approved
9. Cotton event 531	Protection from feeding damage by lepidopterans	Direct use	Approved
10. Cotton event 15985	Protection from feeding damage by lepidopterans	Direct use	Approved
11. Cotton event 1445	Tolerance to herbicide glyphosate	Direct use	Approved
12. Sugar beet event 77	Tolerance to herbicide glyphosate	Direct use	Approved
13. Potato event in lines: RBMT-21-129 RBMT21-350 RBMT22-82	Protection from Colorado potato beetle and from potato leaf roll virus (PLRV)	Direct use	Approved
14. Potato event in lines: RBBT02-06 SPBT 02-05	Protection from Colorado potato beetle	Direct use	Approved
15. Potato event in lines: RBT 15-101 SEMT 15-02 SEMT 15-15	Protection from Colorado potato beetle and from PLRV	Direct use	Approved
16. Corn event DBT 418	Protection from corn borer	Direct use	Approved
17. Corn event DLL 25	Tolerance to herbicide phosphinotricin	Direct use	Approved
18. Corn event T25 phosphinotricin	Tolerance to herbicide	Direct use	Approved
19. Corn event Bt176	Protection from corn borer	Direct use	Approved

Halos, 2004

expected to increase as Pioneer Hybrid International has licensed the same transformation event.

2.3.2 Modern Biotechnology R& D in the Philippines

Biotechnology researches are advantageous for the Philippines because of its rich reservoir of genetic resources and biodiversity. Harnessing biodiversity and biotechnology should be positioned as a development challenge and an economic opportunity but at the same time ensuring the safe use of the technology. As early as 1995, the country started its venture on modern biotechnology application to several crops and animals. Progress is on the way in terms of genetic engineering of papaya, banana, sweet potato, coconut, and buffalo for disease resistance and improved quality products.

The Philippines has an active R&D geared towards the application of modern biotechnology, particularly in the field of genetic engineering, genomics, gene cloning, and proteomics. For instance, there are 24 genes being introduced into 11 crops through genetic engineering to solve production, postharvest, and quality problems in rice, corn, mango, coconut, papaya, banana, tomato, squash, cotton, sweetpotato, and eggplant (Table 16). Most of the introduced traits confer pest protection.

The development of biocontrol and bioremediation agents, whether in their native state or genetically manipulated, is also a very active area of research. R&D projects on developing biocontrol agents do raise biosafety concerns (Table 17).

Aside from developing its own capabilities on modern biotechnology, the Philippines is also importing genetically engineered crops for direct use or propagation that are being genetically modified elsewhere as summarized in Table 18.

Most of the plants being developed are agricultural crops. India and Thailand supply rice to the Philippines and are developing recombinant rice varieties. USA also supplies rice to the Philippines and has already approved for propagation of recombinant rice, although this is not yet commercially produced. Wheat, another commodity import of the Philippines, is being genetically engineered in India, China, USA, and Argentina. Some tree species are also being genetically engineered: poplar, teak, pines, falcata, and eucalyptus. Falcata, teak, and eucalypts are introduced forest plantation crops in the Philippines.

Table 16. GMOs being developed and tested by various institutions in the Philippines.

Target product	Institutions involved
Transgenic crops with beneficial agricultural traits	
1. long shelf life papaya	UPLB-IPB, University of Queensland, PCARRD, DOST, PCASTRD
2. long shelf life mango	ISAAA, Seneca,DOST-PCARRD, PCASTRD
3. papaya ring spot virus (PRSV)-resistant papaya	UPLB-IPB, Cornell University, University of Hawaii, MARDI (Malaysian Agricultural Research Development Institute), ISAAA, PCARRD, DOST
4. (BBTV) resistant banana bunchy top virus	UPLB-IPB, DOST-Philippine Nuclear Research Institute (PNRI), PCARRD, BAR, IAEA
5. banana resistant to banana bract mosaic virus	UPLB-BIOTECH
6. long shelf life Ecuador dwarf banana	DOLE Asia
7. Ecuador dwarf banana with antifungal genes	DOLE Asia
8. coconut cultivars with quality oil	DOST, PCARRD, UPLB-IPB, DA-PCA Albay, UPLB-Institute of Biological Sciences (IBS)
9. corn resistant to Asiatic corn borer, downy mildew, and stalk rot complex	UPLB-IPB, International Maize and Wheat Center (CMMYT), Asian Maize Biotechnology Network (AMBIONET), PCARRD, BAR
10. glyphosate-tolerant/Insect protected and glyphosate tolerant corn NK603 x MON810; NK603	CODA, Monsanto
11. Bt (cry1N) corn	Pioneer Hi-Bred Phils., Inc
12. Bt 11 corn	UP Mindanao, Syngenta
13. Bt 3243 corn	UP Mindanao, Syngenta
14. feathery mottle virus- resistant sweetpotato	UPLB-IPB, LSU, ISAAA, PCARRD
15. weevil-resistant sweetpotato	UPLB-IPB, BAR
16. virus-resistant tomato	UPLB-Department of Plant Pathology, BAR
17. virus-resistant squash	UPLB-Department of Plant Pathology, BAR
18. Bt cotton (proposed)	CODA, DA-Biotech Program
19. insect-protected eggplant (proposed)	CLSU, PhilRice, UPLB-IPB, PCARRD
20. (GNA) insect-resistant rice	PhilRice
21. vitamin A-enriched rice	PhilRice
22. tungro-resistant rice	PhilRice
23. bacterial leaf blight-resistant rice	PhilRice
24. improved Gracilaria and Kappaphycus seaweeds	UP Diliman-Marine Science Institute (MSI)
25. DNA hog cholera vaccine	UP Diliman-NIMBB, BAI, BAR
26. banana vaccine against *Salmonella typhi*	UP Manila- IBMB, UPLB-BIOTECH, UP Diliman-National Institute of Molecular Biology and Biotechnology (NIMBB)
27. vaccine against dengue	UP Diliman-NIMBB, St Luke's Medical Center
28. malaria vaccine	UP Manila-IBMB, UP Diliman-NIMBB
29. Schistosomiasis vaccine	UP Manila-IBMB
30. anti-cancer drugs	UP Diliman-NIMBB, MSI, NSRI
31. taq polymerase	UPLB-BIOTECH
32. amylase	UPLB-BIOTECH

Halos, 2003

Table 17. Local biocontrol products in development and biosafety issues.

Biotech product	Application	Biosafety issue
Nuclear polyhydrosis virus	Insecticide against Spodoptera litura, pest of onion, peanuts, asparagus	Effect on non-target organisms Effect on human handlers
Green water technology	Control of pond grow out prawn diseases	Effect on non-target organisms Effect on human handlers
Biocontrol agents	Control of hatchery prawn diseases	Effect on non-target organisms
Trichoderma biocon pellets	Control of plant diseases	Effect on human handlers
Amblyseius longispinosus	Control of various phytophagous mites	Effect on non-target organisms Effect on human handlers
Trichoderma harzianum	Management of *Phytophthora* disease in durian	Effect on non-target organisms Effect on human handlers
Fungal hyperparasites	Control of major crop diseases	Effect on non-target organisms Effect on human handlers
Phytoselid predators organisms	Control of ornamental mite pests	Effect on non-target

Table 18. Crop plants commonly imported for direct use or propagation in the Philippines that are being genetically engineered elsewhere.

Crop plant	Countries actively developing GM varieties
Apple, Banana, Barley, *Brassica sp,* Cabbage, Cacao, Cantaloupe, Carrot, Canola, Cassava, Chickpea, Chili, Chinese cabbage, Citrus, Coconut, Coffee, Cotton, Corn, Eggplant, *Eucalyptus* sp., Garlic, Grape, Green pepper, Lettuce, Melon, Mungbean, Musk melon, Oil palm, Oil seed rape, Orchid, Papaya, *Paraserianthes falcataria,* Peanut, Persimmons, Petunia, Pineapple, Potato, Rice, Rubber, Shallot, Sorghum, Soybean, Squash, Strawberry, Sugar beet, Sugarcane, Sunflower, Sweet pepper, Sweet potato, Teak, Tobacco, Tomato, *Triticale*, Wheat, Winged bean, Zucchini	Argentina, Armenia, Azerbaijan, Bangladesh, Bolivia, Bosnia- Herzegovina, Brazil, Chile, China, Columbia, Costa Rica, Croatia, Cuba, Egypt, India, Indonesia, Kenya, Korea Rep, Malaysia, Mexico, Morocco, Muldova Rep, Pakistan, Peru, Philippines, Serbia and Montenegro, South Africa, Tunisia, Thailand, Venezuela, Vietnam, Uruguay, Zimbabwe, EU, Canada, Japan, USA

Halos, 2003

2.3.3 Institutional and Human Resources

Biotechnology research institutes were formally organized with the establishment of the National Institute for Applied Microbiology and Biotechnology (BIOTECH) at UPLB in 1979. It was followed in 1997 with the formal organization of three other biotechnology research institutes in UP Manila, UP Diliman, and UP Iloilo, promoting various biotechnology-based R&D programs. These institutes brought forth R&D in agriculture, medicine, fisheries, and industry.

Several institutions in the Philippines are equipped with modern biotechnology facilities and equipment. Most of these facilities are located at UPLB, particularly BIOTECH, IPB-UPLB, and IBS-UPLB. Other institutes are UP Diliman, Philippine Rice Research Institute (PhilRice), Leyte State University (LSU), St. Luke's Medical Center, Philippine Sugar Research Institute (PHILSURIN) and Philippine Carabao Center (PCC). Most of our scientists-experts are based in these institutions (Table 19).

Table 19. Institutions on modern biotechnology R&D, research activities, and number of senior researchers.

Institution	Research activities	Number of senior researchers
PhilRice	Transformation, gene cloning DNA profiling of rice varieties Marker-aided selection Greenhouse testing of recombinant rice	7
IPB, UPLB	Transformation, gene cloning DNA profiling of crops and microorganisms Marker-aided selection Greenhouse testing of recombinant crops	7
BIOTECH, UPLB	Transformation, gene cloning Molecular markers	5
IBS, UPLB	Molecular markers	3
NIMBB, UP Diliman	Transformation, gene cloning, Molecular markers	5
MSI-UP Diliman	Transformation, molecular markers	2
NSRI-UP Diliman	Molecular markers	5
NIBMB, UP Manila	Gene cloning, Molecular markers	4
St Luke's Medical Center	Gene cloning, Molecular markers	
PHILSURIN	Molecular markers	4
Total		44

There are also several Institutional Biosafety Committees (IBCs) created by institutions engaged in activities involving genetic engineering and potentially hazardous biological systems. The membership of IBCs is approved by the NCBP. The IBC evaluates and monitors the biosafety aspects of their respective institution's biological research and recommends projects/activities for approval of the NCBP. They ensure that the environment and human health are safeguarded in the conduct of any potentially biohazardous activities by the institution or by any of its employees or researchers. The IBC is also responsible for informing the surrounding communities of plans for planned release, including the concomitant risks thereof, if any. The IBC comprises of a minimum of 5 members: the chairperson, 2 scientists of relevant disciplines, and 2 community representatives.

There are currently 97 IBCs constituted by private and public institutions in the country (Table 20). The private sector comprises about 54 % and the rest by public universities, R&D, and medical centers.

Table 20. IBCs in the Philippines.

Institutions	Private	Public
Seed producers	45	
Monsanto Phils Inc	(41)	
R&D, Medical Centers	6	16
Universities	3	16
Others	9	2 (IRRI, ICLARM)
Total	63	34

Halos, 2003

The Philippines has manpower capabilities and infrastructure complements to address the need to maximize the use of modern biotechnology and ensure its safe use. However, these are modest compared to other countries. There are about 955 experts in the country in various fields of sciences recognized by the NRCP and NAST, who are either currently active or retired from educational and R&D institutions (Table 21). To date, we have a core of 317 scientists-experts who are conducting modern biotechnology and traditional researches.

There is, however, a dearth of legal expertise, specifically in the field of biotechnology and biosafety. We have less than five experts in this field, but there are quite a number of experts in environmental law, health and public safety, trade, etc., from whom we can draw legal assistance.

Table 21. Number of experts in general fields of specialization.

Field of expertise	Number
Agriculture and forestry	259
Biological sciences	164
Chemical sciences	127
Earth sciences	53
Engineering fields	83
Medical sciences	205
Pharmaceutical sciences	23
Physical sciences	41
Total	955

Halos, 2003

2.3.4 Capacity Building

Biosafety is a new concept and capacity needs to be built in offices and areas not yet covered by the NCBP and DA. Capacity building is being undertaken by DA in collaboration with various institutions like ISAAA, United States Department of Agriculture (USDA), United States Agency for International Development (USAID), Monsanto, Syngenta, private suppliers of laboratory reagents, and other agencies. The BCP, with support from the USAID, has also undertaken national capacity-building activities in cooperation with the DA-Biotechnology Program (Table 22).

In addition to continuing with policy consultations, public information campaign targeting policy makers, media practitioners, and the general public; and seminar workshops and study tours for regulators. Future plans for capacity building at DA includes degree programs for personnel in regulatory and in R&D agencies, and collaborative programs between DA R&D agencies and foreign laboratories/outfits.

Since most products of modern biotechnology are agricultural crops, capacity building has mostly focused on the agricultural sector. It is important to expand this focus and include other sectors as well.

Table 22. Capacity building in biotechnology/biosafety supported and/organized by various organizations from 2002-2003.

Participants	Type	Frequency	Sponsoring organization
Multi-sectoral groups/ general public	Policy (DA-Administrative Order [AO] No. 8) consultation	6 regional 2 national	DA
Policy makers (LGU), Congress, DA Policy Staff)	Biotechnology/biosafety lecture	3	DA-Biotech
	Biotechnology/biosafety conference		OECD
Personnel in the regulatory system (includes DA-BAT and STRP members)	Study tour on biotech regulation	2	DA, USDA, Monsanto Co
	Risk assessment workshop	5	DA, ISAAA, ASEAN, ILSI
	Seminar on basic biotechnology	1	DA-Biotech, AGILE
	Laboratory tour	1	DA-Biotech, AGILE
	Orientation to DA-AO No.8	3	AGILE
	Training-workshop on DA-AO No. 8 implementation	4	DA, AGILE, Monsanto,
	IRM seminar-workshop	2	Pioneer Hi-Bred
Regulatory personnel, technology developers, DA field personnel and DA Policy Staff	Seminar on biosafety framework & implementation	1	DA-Biotech, ISAAA, SEARCA-BIC
DA-regulatory agencies (BPI, BAI, National Meat Inspection Council [NMIC])	Upgrading of laboratories	6 labs	DA-Biotech, PL480
Personnel of DA-regulatory agencies and BFAD-DOH	Training courses on basic molecular techniques, DNA extraction, DNA profiling, GM-seed/ingredient detection by polymerase chain reaction (PCR) and enzyme-linked immunosorbent assay (ELISA)	8 courses	DA-Biotech, BFAD, SEAMIC, IMFJ, Monsanto,
	Validation of protocols	7 labs	Syngenta, AGILE
Public information campaign on biotechnology/biosafety Media practitioners and general public	Seminars	15	DA-Biotech, SEARCA-BIC, BAR, NAST, BCP, WASP, LIKAS, PCARRD
	Press releases	Occasional	
	Advertisement	Occasional	
	Radio talk/interview	Occasional	
	TV interview	Occasional	
	Comics	2	
Members of the clergy	Dialogue	8	BCP
Science teachers/ professors	Seminar on biotechnology/biosafety	5	BCP, NIMBB-UP Diliman, PhilAAS

Table 22. (Continued).

Participants	Type	Frequency	Sponsoring organization
Food/Feed industry	Food/Feed safety of GMcrops	5	BCP
STRP members, technology developers in the public sector	Writeshop on biotech issues	1	BCP
Farmers to established GM-crop and experiments	Study tour: seminar and field visits	1	BCP
IBC members	Seminar-workshop	2/year	Monsanto

2.4 GOVERNMENT POLICY ENVIRONMENT

State policies mandated by the 1987 Constitution guide concerned departments and agencies in implementing biotechnology- and biosafety-related activities. The overall policy of the Philippines on sustainable development as laid down in the National Agenda for Sustainable Development for the 21st Century (Philippine Agenda 21 or PA 21) also guides biosafety implementation of the NBF.

The Philippine government has recognized early that biotechnology is a driving force for economic development when President Ferdinand Marcos approved and provided funding for the establishment of BIOTECH in 1979. BIOTECH is mandated to apply biotechnology in research to develop industrial processes and improve food production and food processing. In the early years of the administration of President Corazon Aquino, DOST declared biotechnology as one of the leading-edge technologies and was one of the major research areas supported by the newly established PCASTRD. Majority of R&D projects in BIOTECH and PCASTRD, however, focused on traditional biotechnology. Subsequently, in 1990, President Corazon Aquino signed Executive Order (EO) 430 declaring a national biosafety policy and creating a National Committee on Biosafety of the Philippines (NCBP), a policy initiative of the scientific community. Although EO 430 initiative was triggered by the entry of new strains of rice pathogens for research, the biosafety guidelines soon evolved to cover research activities on GMOs. In 1996, the National Agricultural Biotechnology R&D Program of PCARRD started with focus on GM crop development. In 1997, then President Fidel Ramos signed the Agriculture and Fisheries Modernization Act (AFMA).

AFMA recognizes that biotechnology is a major tool in transforming agriculture from a resource-based to a technology-based sector and specifies minimum amount for funding for biotechnology research.

In January 2000, President Joseph Estrada issued a Memorandum Circular on Institutionalizing the National Policy on Biotechnology. On 16 July 2001, President Gloria Macapagal-Arroyo issued a Policy Statement on Modern Biotechnology, reiterating the government policy of promoting the safe and responsible use of modern biotechnology and its products as one of several means to achieve and sustain food security, equitable access to health services, sustainable and safe environment and industry development.

In the international arena, the Philippines is a member-party to several international agreements, which impacts on the implementation of biosafety practices in the country. As a member of the World Trade Organization (WTO), the Philippines complies with the Agreement on Sanitary and Phytosanitary Measures (SPS) whose work is covered by three standard setting bodies: (1) Codex Alimentarius Commission for food safety; (2) International Office of Epizootics for animal health; and, (3) International Plant Protection Convention for plant health. It is also a member-party to CBD having signed in 1992 and ratified on October 2003. The country also signed the Cartagena Protocol on Biosafety on 24 May 2000 but has yet to ratify it.

President Gloria Macapagal-Arroyo issued a Policy Statement on Modern Biotechnology, reiterating the government policy of promoting the safe and responsible use of modern biotechnology and its products as one of several means to achieve and sustain food security, equitable access to health services, sustainable and safe environment and industry development

The Philippines has a fairly elaborate system of policies, laws, and regulations to cover virtually any threat to the environment as well as to public health and safety. But recent developments have pointed to a need to specifically address the concern for biosafety, arising from the use of modern biotechnology. The discussion of the issue reflects the global debates about the uncertainties posed by the production and release of LMOs[1] used in agriculture and commodities derived from LMOs used as food and medicine.

2.5 LEGAL INSTRUMENTS RELATED TO BIOTECHNOLOGY AND BIOSAFETY

The inventory and analysis of legal instruments provide the legal background in developing the NBF. The scope of the legal review is broadened by the context of regulating biotechnology activities to ensure biosafety, which includes other relevant areas of law for purposes of regulation and administration.

The breadth of the field of analysis is as wide as the reach of the objectives of the regulatory framework, which include: (1) public health and safety — protection against adverse effects of LMO and LMO-derived commodities on humans; (2) food security/poverty alleviation taking advantage of modern food production for safe, abundant, and affordable food; protection of food crops, property rights over seeds, other intangible farm inputs including traditional knowledge; (3) environmental protection/biodiversity conservation — safety against adverse impacts on natural ecosystems, broadly including traditional lifestyles associated with natural resources; and, (4) meeting state obligations under international treaties.

The key terms that bind the regulatory framework are *modern biotechnology* and *biosafety*. The CBD defines biotechnology as "any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use." In the Cartagena Protocol, the relevant term used is *modern biotechnology*, defined as "the application of (a) in vitro nucleic acid techniques, including rDNA and direct injection of nucleic acid into cells or organelles; or, (b) fusion of cells beyond the taxonomic family." Under national regulations (DA-AO No. 8), it is defined more specifically as "(i) recombinant nucleic acid techniques involving the formation of new combinations of genetic material by the insertion of nucleic acid molecules produced by whatever means outside an organism, into any virus, bacterial plasmid, or other vector system and their incorporation into a host organism in which they do not naturally occur but in which they are capable of continued propagation; (ii) techniques involving the direct introduction into an organism of heritable material prepared outside the organism including micro-injection, macro-injection, and micro-encapsulation; and (iii)

cell fusion, including protoplast fusion or hybridization techniques where live cells with new combinations of heritable genetic material are formed through the fusion of two or more cells by means of do not occur naturally."

There is no official definition of *biosafety*. It is commonly understood as, following the language of the Protocol, "protection against potential adverse effects of modern biotechnology on biological diversity, also taking into account risks to human health."

2..5.1 Context of biotechnology and biosafety

Table 23 gives an overview of some legal instruments that may be relevant to biotechnology and biosafety. It provides an extensive list with short descriptions. Some texts of the laws and regulations are provided in the succeeding discussion.

Public health and safety

Under the **Code on Sanitation,** food must be

Table 23. Overview of relevant legal instruments.

Regulatory objective	Overview
Public health and safety	laws regulating purity and safety of ingredients in food and medicines; sanitary preparation of food; promoting alternative medicine
Food security	laws promoting modern and efficient agriculture; developing high yield seeds/ crop varieties; protecting rights of developers of improved seeds, varieties, even GM species
Environmental protection	laws and regulations protecting against adverse impacts of human development activities on natural ecosystems and specific wildlife species
Treaty obligations	rights and obligations of the country under international agreements that we are a party to
Specific biosafety regulations	administrative regulations specific to biotechnology and biosafety issues
Rights and obligations	provisions under the laws and regulations defining the roles of stakeholders of stakeholders and interest groups
Legal remedies/penalties	provisions penalizing violations of the relevant laws; laws and regulations outlining procedures for the exercise and protection of private rights

obtained from sources approved by the local health authority. Sample coverage includes procuring meat under sanitary or veterinary supervision; prescribing that food is free from radioactivity, etc. The law is concerned mostly with clean preparation and proper storage of food and the disposal of by-products of food preparation and processing. It does not cover regulation of the nature of the ingredients in food or whether those ingredients are safe for human consumption per se.

The **Food and Drug Law** establishes standards and quality measures for food, drug, and cosmetics; and adopts measures to insure pure and safe supply of these. It prohibits the manufacture, sale, offering for sale, or transfer of any adulterated or misbranded food, drug, device, or cosmetic; and adulteration or misbranding ofthese.

In 1992, the **Consumer Act of the Philippines** was enacted to provide safety and quality standards for consumer products, including performance- or use-oriented standards, codes of practice, and methods of tests. It aims to protect the public against unreasonable risks of injury associated with consumer products; to ensure safe and good quality of food, drugs, cosmetics and devices; and to regulate their production, sale, distribution, and advertisement to protect the health of the consumer. It prohibits the importation into the country of consumer products that are injurious, unsafe, and dangerous.

Under both Acts, "adulterated food, drug, or cosmetic" is defined as that which, among others, bears or contains any poisonous or deleterious substance, which may render it injurious to health. The Consumer Act likewise mandates compulsory labeling and fair packaging to enable the consumer to obtain accurate information as to the nature, quality, and quantity of the contents of consumer products; and to facilitate his comparison of the value of such products. It may be argued that GM products fall under the coverage for purposes of determining whether it is poisonous or deleterious. Also, if labeling of GM products is false or mislabeling of the same happens, there could be a violation of the said law.

The **Traditional and Alternative Medicine Act** (**TAMA**) encourages the development of traditional and alternative health care and its integration into the national health care delivery system. It establishes the Philippine Institute of Traditional and Alternative Health Care, which is tasked to plan and carry out

R&D activities in the areas of traditional and alternative health care; to formulate a code of ethics and standards for the practice of traditional and alternative health care modalities; to develop a research program on the indigenous Philippine traditional health care practices performed by "traditional healers" using scientific research methodologies; and to promulgate standards and guidelines for the manufacture, quality control, and marketing of different traditional and alternative health care materials and products. Traditional and alternative health care does not contemplate the use modern biotechnology methods. The law is included in this broad survey to the extent that biotechnology products and techniques may draw inspiration from traditional knowledge systems. Competing products from modern biotechnology could eventually threaten traditional practices, among other impacts.

Food security/ poverty alleviation

Under the **Seed Industry Development Act,** the State declares it a policy to promote and accelerate the development of the seed industry and, for this purpose, conserve, preserve, and develop the plant genetic resources of the nation. It creates the National Seed Industry Council, composed of representatives from the government and private sectors. The Council's main function is to formulate policies that will stimulate plant-breeding activities for the development of the genetic resources of the country. It also institutes a National Seed Quality Control Service, which formulates and develops plans and programs on seed quality control services and activities on seed testing, plant/seed material confirmation, and other quality control schemes.

The law is complemented by the **High-Valued Crops Development Act**, which mandates the State to develop high-value crops as export crops that will significantly augment the foreign exchange earnings of the country, through an all-out promotion of the production, processing, marketing, and distribution of high-value crops in suitable areas of the country. It tasks the DA to establish experimental stations and seed farms for the development of varieties suitable to agro-climactic conditions of the area and markets that will provide greatest value added to high-value crops. Both laws do not exclude modern biotechnology techniques as a means for crop development or improving seed quality.

The **AFMA** aims to modernize the agriculture and fisheries sectors by transforming them from a resource-based to a technology-based

industry, by ensuring their equitable access to assets, resources and services, and by promoting higher value crops, value-added processing, agribusiness activities, and agro-industrialization. It also mandates the DA, in consultation with concerned government agencies and NGOs, to formulate and implement a medium- and long-term comprehensive Agriculture and Fisheries Modernization Plan focusing on food security, global competitiveness, sustainability, among others. It establishes the Bureau of Agriculture and Fisheries Product Standards to set and implement standards for agricultural and fishery products to ensure consumer safety and promote product competitiveness. Thus, it also relates to the Food and Drug Law. The law does not have a specific provision dealing directly with biotechnology, but it encourages research, development, and use of technology in agricultural production.

In fisheries, the **Fisheries Code** declares as policy of the State, among others, "to ensure the rational and sustainable development, management, and conservation of the fishery and aquatic resources consistent with the primordial objective of maintaining a sound ecological balance, protecting and enhancing the quality of the environment." The introduction of foreign finfish, mollusk, crustacean, or aquatic plants in Philippine waters without a sound ecological, biological, and environmental justification based on scientific studies shall not be allowed subject to the biosafety standard as provided for by existing laws.[11] However, the DA may approve the introduction of foreign aquatic species for scientific/research purposes. The law also provides for conservation and rehabilitation measures for rare, threatened, and endangered species; and banning of the fishing and/or taking of rare, threatened, and/or endangered species, including their eggs/offspring as identified by existing laws. The fisheries policy puts a premium on aquaculture as a major source of fishery products in the future. Biotechnology offers huge potential benefits in increasing the yield of aquaculture, as well as contributing to the conservation of threatened species.

In the area of protection of economic rights, the **Plant Variety Protection Act** protects and secures the exclusive rights of breeders with respect to their new plant variety by granting them a Certificate of Plant Variety Protection, subject to prescribed requirements, and by defining the rights of holders. It establishes the National Plant Variety Protection Registrar, which has original and exclusive jurisdiction to receive, process, and examine all

applications for Certificate of Plant Variety Protection in accordance with this Act. It also creates the National Plant Variety Protection Board, which has original and exclusive appellate jurisdiction over all acts of the Registrar; and original jurisdiction over petitions for compulsory licensing, nullity, and cancellation of a Certificate of Plant Variety Protection. The law, however, fails to address the correlative issue of farmers' rights.

The **Intellectual Property Code** regulates the more familiar forms of intellectual property rights: 1) copyright and related rights; 2) trademarks and service marks; 3) geographic indications; 4) industrial designs; 5) patents; 6) layout designs [topographies] of integrated circuits; and 7) protection of undisclosed information.

Patents are the most contentious, providing exclusive rights over non-naturally-occurring living organisms. Section 21 of the law provides that "patentable invention" refers to "any technical solution of a problem in any field of human activity which is new, involves an inventive step, and is industrially applicable. It may be, or may relate to, a product, or process, or an improvement of any of the foregoing." However, plant varieties or animal breeds or essentially biological processes for the production of plants or animals, except microorganisms and non-biological and microbiological processes, cannot be the subject of a patent. But are GM crops considered varieties? Transgenic species of plants, animals, and microbes have been the subject of patents in other jurisdictions, which have similar criteria for patentability under our laws. It is argued that transgenics alter the organism's genome more than just creating new varieties or breeds. Any alteration above the taxonomic level of a variety or breed is not excluded from patentable subject matter.

The National Economic Development Authority (NEDA) and DTI set investment priorities for the country. The **1999 Investment Priorities Plan (IPP)** provides for the listing of industries and projects that qualify for fiscal incentives. It encourages and promotes certain environment-friendly industries and the attainment of ISO 9000 and ISO 14000 certification. The encouragement for the private sector, including biotech industries, to embrace the concept of Environmental Management Systems (EMS) aims to achieve a balanced pursuit of productivity and economic growth side by side with environmental standards compliance and ecological integrity of the country.

On the matter of protection against adverse impacts on agriculture, the **Plant Quarantine Law** restricts the importation and/or introduction into the Philippines of plants, plant products, soil, packing materials of plant origin capable of harboring and are a source or medium of infection/infestation of plant pests, subject to quarantine orders, rules, and regulations as may be promulgated. It prohibits the importation of certain species of animals, which are liable to become agricultural crop pests and capable of causing injury to agricultural crops. The law is broad enough to cover LMOs or GM crops, which may pose a threat to locally used species/ varieties. The law is closely related to the impact assessment regulations under the environmental laws.

The Fertilizer and Pesticide Authority (FPA) was created with the objectives of assuring the agricultural sector of adequate supply of fertilizer and pesticide; rationalizing the manufacture and marketing of fertilizers; protecting the public from the risks inherent in the use of pesticides; and educating the agricultural sector on the safe and effective use of these products. It is empowered to prevent importation and regulate exportation of agricultural commodities containing pesticide residues above accepted tolerance levels. The FPA may have a remote relevance to biosafety in that GM crops are often created to give crops added resistance to pests. That could have an impact in changing the demand for fertilizers and pesticides, and perhaps on the issue of resistance of pests to pesticides from constant exposure to the GM crops.

Environmental protection

The **Philippine Environmental Policy** provides that all agencies and instrumentalities of the national government, including government-owned or government-controlled corporations, as well as private corporations, firms, and entities shall prepare, file, and include in every action, project, or undertaking, which significantly affects the quality of the environment a detailed statement on: (a) the environmental impact of the proposed action, project, or undertaking; (b) any adverse environmental effect, which cannot be avoided should the proposal be implemented; (c) an alternative to the proposed action; (d) a determination that the short-term uses of the resources of the environment are consistent with the maintenance and enhancement of the long-term productivity of the same; and (e) whenever a proposal involves the use of depletable or non-renewable resources, a

finding must be made that such use and commitment are warranted.

On the basis of Section 4 of the Philippine Environmental Policy, an **Environmental Impact Statement System** (EIS) was established, requiring every proposed project and undertaking, which significantly affect the quality of the environment to prepare an EIS after conducting an impact assessment study. It provides that the President of the Philippines may, on her own initiative or upon the recommendation of the DENR, by proclamation declare certain projects, undertakings, or areas in the country as environmentally critical. Under said law, no person, partnership, or corporation shall undertake or operate any such declared environmentally critical project or area without first securing an Environmental Compliance Certificate (ECC). All other projects, undertakings, and areas not declared by the President as environmentally critical shall be considered as non-critical and shall not be required to submit an environmental impact statement. Non-critical projects and undertakings may, however, be required to provide additional environmental safeguards. In 1981, environmentally critical areas (ECA) and environmentally critical projects (ECP) were identified under **Presidential Decree No. 2146**. The release of GMOs into the environment is not listed as an ECP, but the area where it will be released may qualify as an ECA. It is also possible that the DENR may require additional environmental safeguards prior to their release.

The Philippine Environment Code provides guidelines concerning the management of the country's air, water, land use, natural resources, and waste. Except for the provisions on Water Quality Management, Land Use Management, and Flood Control and Natural Calamities, the Code has been modified and amplified by the Philippine Clean Air Act of 1999, the Fisheries Code, the Wildlife Act, the Creation of the Department of Energy Act (Republic Act No. 7638), the Philippine Mining Act, the Ecological Solid Waste Act, and the Local Government Code. Under the Code, the disposal of wastes and substances into any water body shall be regulated. It is the responsibility of the polluter to contain, remove, and clean up water pollution incidents at his own expense. Any pollution caused by the production, testing, and release of GM products into the environment shall be subject to the provision of the Code, as amended by the new laws.

The Philippine Agenda 21 provides for the policy framework of the country's strategy for sustainable development. Among the significant features include: (a) the realization of the continuing deterioration of the natural and social environment; (b) a vision of "appropriate (not maximum) productivity" within the limits of the natural environment's carrying capacity; (c) adoption of a policy mix of market-based instruments and command-and-control measures as techniques to induce changes in production and consumption patterns; and (d) adoption of social marketing approaches in the effort to inform, educate, and communicate the imperative of sustainable development to the public-at-large to effect a reorientation of fundamental societal values. The benefits of modern biotechnology in producing revolutionized products that increase productivity and value must not compromise the ability of the future generations to meet their own needs.

The **Wildlife Resources Conservation and Protection Act** regulates the collection, possession, and/or local transport of wildlife, their by-products and derivatives, (including exotic species, which are subject to trade, are cultured, maintained, and/or bred in captivity or propagated in the country) by requiring an authorization from the DENR Secretary (in case of terrestrial plant and animal species, turtles and tortoises, and wetland species, including dugong) or the DA (in case of declared aquatic critical habitats, all aquatic resources, except dugong) upon a showing that the activity is not detrimental to the survival of the species or subspecies involved and/or their habitat. The Act permits breeding or propagation of wildlife for commercial purposes, provided that only progenies of wildlife raised, as well as unproductive parent stock shall be utilized for trade, subject to an environmental impact study whenever appropriate. The law further provides that all activities dealing on genetic engineering and pathogenic organisms in the Philippines, as well as activities requiring the importation, introduction, field release, and breeding of organisms that are potentially harmful to man and the environment shall be reviewed in accordance with the biosafety guidelines (without defining them or making reference to a specific instrument) ensuring public welfare and the protection and conservation of wildlife and their habitats There are specific laws and administrative regulations providing for the protection of certain wildlife species, such as the *Pithecophaga jefferyi*, commonly known as the Philippine Eagle; marine turtles, turtle eggs, and their by-products; dolphins, whales, and porpoises; whale sharks and manta rays;

the *Dugong* or sea cow (*Dugong dugon*); as well as the tindalo, akle, or molave trees, which may or may not be affected by introduction of LMOs to their habitats, or the use of modern biotechnology for conservation of the species.

The Revised Forestry Code reorganized certain related offices into the Bureau of Forest Development with the following mandate: to be responsible for the protection, development, management, regeneration, and reforestation of forest lands; the implementation or multiple use and sustained yield management in forest lands; the protection, development, and preservation of national parks, marine parks, game refuges, and wildlife; the implementation of measures and programs to prevent kaingin and managed occupancy of forest and grazing lands; and the enforcement of forestry, reforestation, parks, game and wildlife laws, rules and regulations, among others. It provides incentives to qualified persons engaged in industrial tree plantation, tree farming, and/or agro-forest farming. However, it reserves the regulation of mining operations in forest lands to mining laws, rules, and regulations, with the only caveat that the protection, development, and utilization of other surface resources be given due regard. The law is relevant in that GM trees may be used for higher timber yields or greater carbon sequestration abilities, the introduction of which may pose risks to natural stands.

The **NIPAS Act** establishes a National Integrated Protected Areas System (NIPAS), which shall encompass outstanding remarkable areas and biologically important public lands that are habitats of rare and endangered species of plants and animals, biogeographic zones, and related ecosystems, whether terrestrial, wetland, or marine, all of which shall be designated as protected areas. It provides for categories of protected areas (PAs): (a) strict nature reserve, (b) Natural park, (c) natural monument, (d) wildlife sanctuary (e) protected landscapes and seascapes, (f) resource reserve (g) natural biotic areas and (h) other categories established by law, conventions, or international agreements to which the Philippine government is a signatory. Activities within Pas are highly regulated, especially in strict nature reserves and natural parks; thus, the release of GM products thereat is most likely prohibited.

Executive Order No. 247 prescribes guidelines and establishes a regulatory framework (the Inter-Agency Committee on Biological and Genetic Resources) for the prospecting, for scientific and commercial

purposes, of biological and genetic resources, their by-products and derivatives. The Committee is tasked, among others, to ensure that no biological and genetic materials are taken from the Philippines and exported abroad except under a valid research agreement; and to study and recommend appropriate laws on the utilization of biological and genetic resources including new laws on intellectual property rights.

Area-specific laws are relevant in relation to the use of LMO or the conduct of modern biotechnology activities within their jurisdictions. The **Strategic Environmental Plan for Palawan** adopts a comprehensive framework for the sustainable development of the Province of Palawan that is compatible with protecting and enhancing its natural resources and endangered environment. The plan is meant to guide the local government of Palawan and the government agencies concerned in the formulation and implementation of plans, programs, and projects affecting the province, including the establishment of a graded system of protection and development control over the province's tribal lands, forests, mines, agricultural areas, small islands, mangroves, coral reefs, seagrass beds, and the surrounding sea, to be known collectively as the Environmentally Critical Areas Network (ECAN).

In the Laguna Lake area, the **Laguna Lake Development Authority** (**LLDA**) has the responsibility of implementing the policy of the state to promote and accelerate the development and balanced growth of the area and the surrounding provinces, cities, and towns within the context of the national and regional plans and policies for social and economic development; and to carry out the development of the Laguna Lake region with due regard and adequate provisions for environmental management and control, preservation of the quality of human life and ecological systems, and the prevention of undue ecological disturbances, deterioration, and pollution. The LLDA regulates and monitors activities in the Lake area, which would include, for example, the field release of GMOs.

The **Indigenous Peoples Rights Act (IPRA)** recognizes and protects the rights of ownership and possession of indigenous cultural communities and indigenous peoples (ICCs/IPs) to their ancestral lands and domains, including the right to manage and conserve natural resources within the territories, and the

right to negotiate the terms and conditions for the exploration of these natural resources for the purpose of ensuring ecological and environmental protection and conservation measures, pursuant to national and customary laws. It affords the ICCs/IPs the right to control, develop, and protect their sciences, technologies, and cultural manifestations, including human and other genetic resources, seeds, and derivatives of these resources, traditional medicines and health practices, vital medicinal plants, animals and minerals, indigenous knowledge systems and practices, as well as knowledge of the properties of fauna and flora. The law also affords the ICCs/IPs priority rights in the harvesting, extraction, development, or exploitation of any natural resources within the ancestral domains.

The **Animal Welfare Act** provides for the regulation of the establishment and operations of all facilities utilized for breeding, maintaining, keeping, treating, or training of all animals either as objects of trade or as household pets. It provides that only adequate, clean, and sanitary establishments of animals that will not be used for, nor cause pain and/or suffering to the animals shall be issued certificate of registration and allowed to operate. It prohibits the killing of any animal other than cattle, pigs, goats, sheep, poultry, rabbits, carabaos, horses, deer, and crocodile, except when, among others, the animal is killed after it has been used in authorized research or experiments. It declares that every person has the duty to protect the natural habitat of wildlife. The destruction of said habitat is considered a form of cruelty to animals and its preservation is a way of protecting the animals. The application of modern technology to modify animals must take into account the provisions of this act.

In the area of administration, the national government is primarily responsible for the conservation, management, development, and proper use of the country's environment and natural resources, as well as the licensing and regulation of all natural resources as may be provided for by law in order to ensure equitable sharing of the benefits derived therefrom for the welfare of the Filipinos as provided in the **Administrative Code.** The staff sectoral bureaus under the DENR consist of the following: Forest Management Bureau (FMB) (forest development and conservation), Lands Management Bureau (LMB) (rational land classification management and disposition), Mines and Geosciences Bureau (MGB) (geology and mineral resources

exploration, development and conservation), Environmental Management Bureau (EMB) (environmental management, conservation and pollution control), ERDB (integrated research programs relating to Philippine ecosystems and natural resources such as minerals, lands, forests, as holistic and interdisciplinary fields of inquiry), and PAWB (management of integrated protected areas system; preservation of biological diversity, genetic resources, and endangered flora and fauna).

Under the **Local Government Code,** LGUs share with the national government the responsibility in the management and maintenance of ecological balance within their territorial jurisdiction. It requires the LGUs to exercise such other powers and discharge such other functions and responsibilities as necessary, appropriate, or incidental to the efficient and effective provision of basic services and facilities, as well as the protection of public welfare.

Treaty obligations

The **CBD** contains three provisions directly related to LMOs. Article 19(3) has generated the negotiations leading to the Cartagena Protocol, while Article 8(g) and 19(4) contain obligations applicable to all Parties to the CBD independently of their becoming parties to the Protocol. Article 8(g) requires parties to regulate, manage, or control risks associated with LMOs, resulting from biotechnology, which are likely to have impacts on the conservation and sustainable use of biological diversity, taking also into account the risks to human health. Article 19(4) requires each party to provide information on domestic regulations concerning use and safety to any other party to which a LMO is provided, as well as any available information on the adverse effects which the introduction may have for this party. While the CBD is comprehensive, it also provides the possibility for the Conference of the Parties (COP) to the CBD to negotiate additional annexes and protocols, to better implement its objectives.

In January 29, 2000, the Conference of the Parties to the CBD adopted a supplementary agreement to the Convention known as the **Cartagena Protocol on Biosafety.** The Protocol seeks to protect biological diversity from the potential risks posed by LMOs resulting from modern biotechnology. It establishes an advanced informed agreement (AIA) procedure for ensuring that countries are provided with the information necessary to make informed decisions before agreeing to the import of such organisms into their territory. The Protocol contains reference to a

The Cartagena Protocol aims to "ensure an adequate level of protection in the field of the safe transfer, handling, and use of living modified organisms resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, and specifically focusing on transboundary movements."

precautionary approach and reaffirms the precaution language in Principle 15 of the Rio Declaration on Environment and Development. The Protocol also establishes a BCH to facilitate the exchange of information on LMOs and to assist countries in the implementation of the Protocol.

The Protocol and the **General Agreement on Tariffs and Trade (GATT)-WTO Agreements** overlap because both contain rules that govern the international trade of LMOs. With the entry into force of the Protocol, two international agreements will address the ability of countries to restrict the importation of LMO products in order to protect the environment from possible adverse effects. The WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) governs all measures that may directly or indirectly affect international trade in any products, and with the policy objective of protecting animal or plant life or health from risk arising from pests, diseases, or contaminants within the territory of the member. Both the Protocol and the SPS Agreement require the use of scientific risk assessments and call for transparent measures. They both incorporate the precautionary principle, although put differing emphases on it. Also, the application of the precautionary principle in the SPS Agreement is explicitly provisional, while the Protocol's precautionary approach has no provisional language. The potential sources of tension between the two treaty regimes are centered on two principal issues: (1) whether decisions by a country to prohibit or restrict the import of an LMO should be based on science, and (2) whether a country could use the Protocol either to discriminate between LMO imports from different countries or to favor its domestic industries.

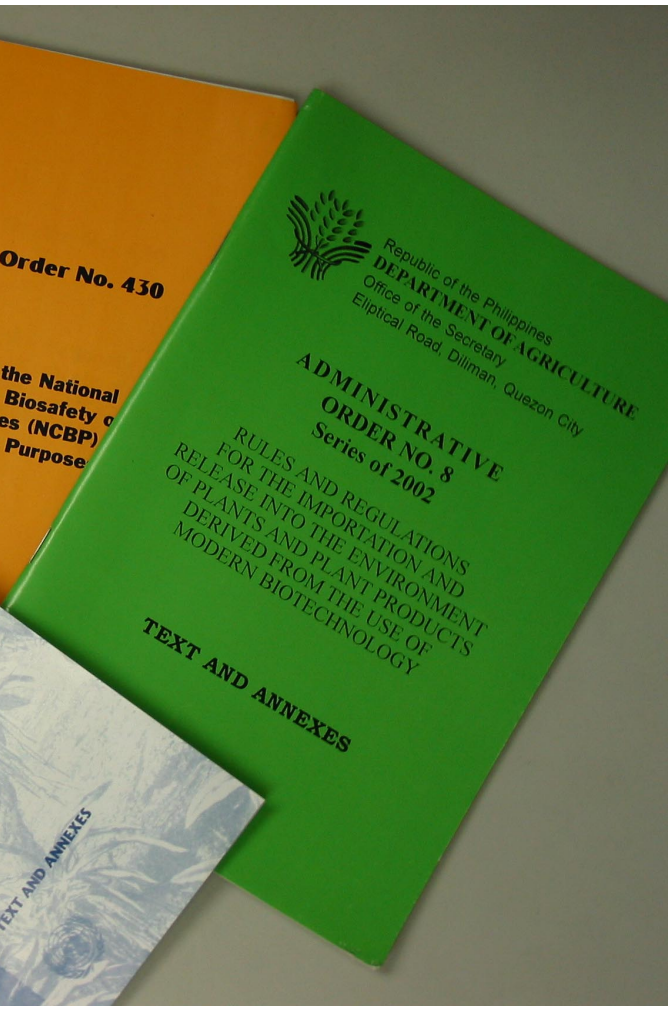
2.5.2 Biotechnology and biosafety regulations

Executive Order No. 430 and the Philippine Biosafety Guidelines

The first biotechnology regulatory system in the ASEAN region was established in the Philippines as an offshoot of the recommendations from the scientists asking the national government to formulate a national policy on biosafety and create a technical body to draft guidelines to ensure that experiments using GMOs do not pose unacceptable risks to human health and the environment.

Thus, on 15 October 1990, then President Corazon C. Aquino issued EO No. 430 constituting the NCBP, a multi-disciplinary, inter-agency technical advisory body tasked to "undertake the study and evaluation of existing laws, policies, and guidelines on bio-technology; and recommend measures for its effective utilization and prevention of possible pernicious effects on the environment."

The NCBP is composed of ten members, including the DOST Undersecretary for R&D DOST who acts as its Chairman. It has four practicing scientists representing the biological, physical, social, and environmental sciences and two community representatives. Four regulatory agencies are likewise represented, namely, DA, DENR and DOH. The President appoints all members except for representatives of the regulatory agencies. The NCBP issued two guidelines for work on GMOs in 1991 and 1998, respectively. The first guideline covers work on genetic engineering as well as activities requiring importation, transport, and contained use of GMOs. It describes national and IBCs, criteria for evaluating work under containment, the required physical and biological containment,



as well as disposal procedures of materials used in the experiment.

Rapid advances in other countries in field trials of selected GMOs have compelled the NCBP to look into the adequacy and relevance of the 1991 Guidelines. In 1998, the Guidelines for Planned Release of Genetically Manipulated Organisms and Potentially Harmful Exotic Species (PHES) was issued by the NCBP.

The Guidelines apply to the deliberate release of GMOs and PHES into the Philippine environment, except: (a) work performed under contained conditions; (b) accidental releases from contained facilities; (c) use of pharmaceutical, processed food, animal feed, industrial, and other products that are already being regulated; (d) work involving organisms, which result from natural reproduction or the use of traditional breeding practices; and (e) such other activities as the NCBP may in the future declare to be excluded.

The NCBP is the highest regulatory body in the Philippines with respect to the introduction, use, and transfer of GMOs and PHES. No person or institution shall release into the environment any GMO or PHES without the prior approval of the NCBP subject to compliance with any rules, regulations, or requirements of other government regulatory authorities. While the NCBP has broad responsibilities, it has no regulatory function and actually relies on the individual mandates of its regulatory agency members. Thus, its decisions are recommendatory and rely on its member Departments (DA, DENR, and DOH) to approve the recommendation of the Committee.

The DA is responsible for monitoring the movement and effects of GMOs or PHES

approved for release; the DENR monitors the environmental effects of the planned release; while the DOH monitors the effects of such release to human health.

The NCBP is also assisted by IBCs created by institutions who evaluate and monitor the biosafety aspects of their respective institution's biological research and recommends projects/ activities for approval of the NCBP.

DA-AO No. 8, Series of 2002

In April 2002, the DA issued **A0 No. 8, Series of 2002,** prescribing regulations for the importation and release into the environment of plants and plant products derived from the use of modern biotechnology. It was issued to supplement the existing guidelines on the importation and release into the environment of products of modern biotechnology by institutionalizing existing operational arrangements between BPI and the NCBP; and by providing regulations to govern the release of such products for propagation or for direct use as food or feed, or for processing.

AO No. 8 covers the importation or release into the environment of: (1) any plant which has been altered or produced through the use of modern biotechnology if the donor organism, host organism, or vector or vector agent belongs to any of the genera or taxa classified by BPI as meeting the definition of plant pest or is a medium for the introduction of noxious weeds; or (2) any plant or plant product altered or produced through the use of modern biotechnology which may pose significant risks to human health and the environment based on available scientific and technical information. It does not apply to the contained use of a regulated article, which is within the regulatory supervision of the NCBP. Prior to importation or release into the environment of regulated articles, the AO requires mandatory risk assessment of recombinant plants and plant products and for products intended for propagation, introduction must be made step by step. First, experiments must be conducted under contained conditions. Then the products tested in field trials. Finally, when all safety and bioefficacy data are obtained, the product is reviewed for commercial release. Risk assessment is done according to the principles provided for by the Cartagena Protocol on Biosafety. Risk assessment (RA) is science-based, carried out on a case by case manner, targets a specific crop and its transformation event, adopts the concept of substantial equivalence in identifying risk, allows review,

and provides that the absence of scientific information or consensus should not be interpreted to indicate the absence or presence and level of risk.

The AO also provides that no regulated article intended for contained use shall be allowed importation or be removed from the port of entry unless duly authorized by BPI upon the endorsement of NCBP. It prescribes requirements for the importation of regulated articles for contained use. Also, it prescribes the approval process and the requirements for field testing, propagation, release and delisting of regulated articles, and the requirements for the importation of regulated articles for direct use as food or feed or for processing. It provides that during the transition period until June 30, 2003, *Applications to Field Test* shall be filed with and processed by the NCBP in accordance with its Guidelines on Planned Release of Genetically Manipulated Organisms and Potentially Harmful Exotic Species. No permit shall be required to import for direct use as food or feed, or for processing, a regulated article that has been approved for commercial distribution as food or feed by the regulatory authorities in the country of origin; provided that in case the regulated article is intended for use as feed or for processing into feed, importation shall be allowed only if the regulatory authorities in the country of origin have likewise determined that the regulated article poses no significant risks to human health.

DA Memorandum Circular (DAMC) Nos. 7 and 8, Series of 2003

These were promulgated pursuant to Section 3 of AO 8, respectively establish Guidelines for Conduct of Risk Assessment for Applications Using an Approved Transformation Event and for the Phytosanitary Inspection of Regulated Articles for Food, Feeds, and Processing. DAMC No. 8 prescribes the requirements for the issuance of permits, on or after July 1, 2003, for the importation of plants and plant products derived from the use of modern biotechnology and which are intended for direct use as food and feed, or for processing. (Importations covered by permits issued before July 1, 2003 shall be subject only to the conditions laid down at the time of their issuance.) It requires that plant and plant products of GM origin intended for direct use as food or feed, or for processing must carry a certificate of GMO content issued by an authorized body from the country of origin or by an accredited laboratory. It prohibits the entry into the country of plant and plant

products intended for direct use as food or feed, or for processing, with one or more transformation events not listed in the approval registry, unless accompanied by a biosafety permit.

2.5.3 Rights and obligations of stakeholders

How are decisions made at the first instance ? The prior approval of the NCBP is required before any person or institution could release into the environment any GMO or PHES. However, approval by the NCBP does not in any way exempt the project proponent from complying with rules, regulations, or requirements of other government regulatory authorities. The project proponent has the sole responsibility to determine if the proposed planned release requires any permit, license, or approval of such regulatory authorities, and to obtain the same if required.

The adoption of resolutions, guidelines, or policies in the NCBP requires the affirmative vote of at least six of its members. Member agencies defer to the NCBP in making their agency decisions [e.g., grant of permits], but in theory the member agencies are not bound by the NCBP decision. This interpretation is a radical departure from what may appear as a clear mandate from EO 430 and merits more explanation or further study.

In cases of appeals, **The Guidelines for the Appeal Process Pursuant To Section 18 of A.O. No. 8 (Series of 2002)** authorizes the Biotechnology Advisory Team, created under Special Order No. 533 (Series of 2002), to study appeals submitted to the Secretary of Agriculture upon its referral and to recommend the appropriate courses of action.

How may stakeholders intervene in the process? The Local Government Code provides that every national agency or government-owned or government-controlled corporation authorizing or involved in the planning and implementation of any project or program that may cause pollution, climatic change, depletion of non-renewable resources, loss of crop land, rangeland, or forest cover, and extinction of animal or plant species must consult with the LGUs, NGOs, and other sectors concerned and explain the goals and objectives of the project or program, its impact upon the people and the community in terms of environmental or ecological balance, and the measures that will be undertaken to prevent or minimize the adverse effects thereof. It requires that prior to project

or program implementation by government authorities, there must be consultations, and prior approval by the "sanggunian" concerned.

The right of the people to information on matters of public concern is guaranteed in the 1987 Philippine Constitution. The Philippine Supreme Court has declared that this right is not a private right but a public right, which may be asserted by any citizen. It also held that the constitutional provisions on the right to information are self-executing (i.e., the Constitution grants the right and supplies the rules by which it may be exercised). The right can embrace a broad spectrum of subjects, which the public may want to know, either because these directly affect their lives, or simply because such matters naturally arouse the interest of an ordinary citizen. The Supreme Court outlined the restrictions to this right, which include: (a) national security matters; (b) trade secrets and banking transactions; (c) classified law enforcement matters; and (d) other confidential information, such as those provided by statutes and all other acknowledged limitations.

2.5.4 Legal remedies

Remedies under specific laws/regulations

The **Plant Quarantine Law** restricts the importation and/or introduction of plants, plant products, soil, packing materials of plant origin capable of harboring and are a source or medium of infection/infestation of plant pests It prohibits the importation of certain species of animals, which are liable to become agricultural crop pests and capable of causing injury to agricultural crops. Any person, company, or corporation who violates the provisions of this law, or forges, counterfeits, alters, defaces, and destroys any document issued by virtue of this law shall be fined not more than P20,000.00 or by imprisonment from prison correctional to prison mayor, or both, at the discretion of the Court.

The **Wildlife Resources Protection Act** provides that no exotic species shall be introduced into the country, unless a clearance from the Secretary or the authorized representative is first obtained. In no case shall exotic species be introduced into protected areas covered by NIPAS and to critical habitats under Section 25 of the Wildlife Act.

The **Seed Industry Development Act** prohibits the importation in commercial quantities of species of seeds that are being produced locally, except seeds that are difficult to grow under ordinary conditions or when allowed by the Seed Industry Council; and the exportation of rare species, varieties, lines, and strains of plants from the country, except for scientific or international exchange purposes, which shall be determined the Council.

Under the **Philippine Plant Variety Protection Act,** any person who believes that the applicant for breeder's right is not entitled to the grant of the Certificate of Plant Variety Protection may file an opposition thereto within the period prescribed by the National Plant Variety Protection Board. Infringement covers the following acts by a person who is not entitled to do so: selling or importing the novel variety, or offering it for sale; sexually multiplying the novel variety as a step to marketing it; and using the novel variety in producing (as distinguished from developing) a hybrid or different variety thereof.

The **Pollution Control Law** prohibits the throwing, running, draining, or disposing into any of the water, air, and/or land resources; or causing, permitting, suffering to be thrown, running, draining, allowing to seep or disposing any organic or inorganic matter or any substance in gaseous or liquid form that shall cause pollution. It requires any person to secure a permit for the following activities: (a) construction, installation, modification, or operation of sewage works; (b) increase in volume or strength of any wastes in excess of permissive discharge; (c) construction, installation, or operation of an establishment which would cause an increase in the discharge of waste or would alter the physical, chemical, or biological properties.

Any pollution caused by the release of GM products in water bodies shall be covered under the provisions of this Act. Emission discharges caused by the release of GM products beyond the allowable limits is punishable under the **Philippine Clean Air Act of 1999.**

Any person, natural or juridical, who violates the provision of the **EIS System** or the terms and conditions in the issuance of the ECC, or of the standards, rules, and regulations issued by the DENR shall be punished by the suspension or cancellation of his/her ECC and/or a fine in an amount not to exceed P50, 000 for every violation at the discretion of the Pollution Adjudication Board.

Remedies under the general laws

The relevant provisions of the **New Civil Code of the Philippines** (on Human Relations) are as follows: (1) Art. 19. Every person must, in the exercise of his rights and in the performance of his duties, act with justice, give everyone his due, and observe honesty and good faith; (2) Art. 20. Every person who, contrary to law, willfully or negligently causes damage to another, shall indemnify the latter for the same; (3) Art. 21. Any person who willfully causes loss or injury to another in a manner that is contrary to morals, good customs or public policy shall compensate the latter for the damage; (4) Art. 23. Even when an act or event causing damage to another's property was not due to the fault or negligence of the defendant, the latter shall be liable for indemnity if through the act or event he was benefited; (5) Art. 27. Any person suffering material or moral loss because a public servant or employee refuses or neglects, without just cause, to perform his official duty may file an action for damages and other relief against the latter, without prejudice to any disciplinary administrative action that may be taken: and, (6) Art. 28. Unfair competition in agricultural, commercial or industrial enterprises or in labor through the use of force, intimidation, deceit, machination or any other unjust, oppressive or highhanded method shall give rise to a right of action by the person who thereby suffers damage.

The Civil Code also regulates nuisance, which is defined as any act, omission, establishment, business, condition of property, or anything else, which injures or endangers the health or safety of others; annoys or offends the senses; or hinders or impairs the use of property (Art. 694). Under Art. 699, the remedies against a public nuisance are: prosecution under the Penal Code or any local ordinance: civil action; or abatement without judicial proceedings. The Code, in another part, provides for compensation for different kinds of damages resulting from intentional or negligent acts.

The Revised Penal Code provides that any person who, by reckless imprudence, shall commit any act which, had it been intentional, or by simple imprudence or negligence, would constitute a felony. Reckless imprudence consists in the voluntary, but without malice, doing or failing to do an act from which material damage results by reason of inexcusable lack of precaution on the part of the person performing or failing to perform such act, taking into consideration his employment or occupation, degree of intelligence, physical condition, and other circumstances regarding persons, time, and

place. Simple imprudence consists in the lack of precaution displayed in those cases in which the damage impending to be caused is not immediate nor the danger clearly manifest.

However, since we need a more comprehensive framework for coordinating responses not only for GMOs but also for other similar threats to biodiversity, there is a need to be more expansive than the scope of the Protocol.

Specifically, the proposed law should strengthen the NCBP so that it has oversight functions over regulations issued by member agencies, which are related to the Committee's mandate. A provision in the law should make the DENR, DOH, and DA adhere to the policy set by the Committee.

As the governance arrangements evolve, it is important that a biosafety framework allows for flexibility. The framework should have a strong focus on procedures for stakeholder participation, setting forth the rights of interested parties to information not otherwise classified as confidential (trade secrets, etc), which will allow these parties to genuinely comment, criticize, or support the Committee's actions. These procedures should also be adopted by member agencies in their own rulemaking processes.

The current biosafety regulations are measures extrapolated or adapted from existing laws. They are effective in coordinating government action [a clear must, since so many laws, procedures, and agencies are involved], but have limited effect in enforcement because of the transitory nature of the administrative mechanisms, absent a legislative act that gives the agency original powers and means to exercise these powers.

There is a lesson to be learned from the development, implementation and eventual modification of EO 247. The implementation of the regulation suffered under the difficulty of having no real teeth, no budget, and being ad hoc — with members and staff merely pulled out from their other regular duties. When the Wildlife Act was passed, some permanence was achieved, and a clear mandate was provided — although procedures established under the EO were significantly changed.

It is inevitable that the regulatory regime for biosafety will undergo the same process. The challenge is to learn from the limited transitory phase under the administrative regulations, and make sure that the legislative act will benefit fully from the experience – to be evidenced by legal and technical inputs as well as general inputs from public participation and agency decisions.

There is still a reasonable wait for Presidential ratification of, and Senate concurrence in, the Cartagena Protocol. In the meantime, we should gain experience from the existing regulatory setup, which is really an interim framework that has to be continually revised and enhanced. Thereafter, we can push for the new comprehensive legislation that incorporates lessons learned from experience.

III. Situational Analysis

This section analyzes the technical and legal data gathered from the inventories and identifies the gaps and needs for an NBF.

3.1 SCOPE OF REGULATION

Existing laws do not directly take into account LMOs, although they are not necessarily excluded. For example, EIA regulations do not list introduction of LMOs as an "ECP" and the Wildlife Act only prohibits the introduction of "exotic species." It is quite obvious though that the introduction or field release of GMOs poses an environmental risk and their impact may be similar to that of exotic species. Modifying these regulations to take GMOs into account is not as simple as amending them by imposing new procedures for GMOs. To illustrate, the definition of "exotic species" under the Wildlife Act is "species or subspecies which do not naturally occur in the country." It is debatable whether

GMOs are species that are new or separate from the naturally occurring ones. Scientists are likely to say they are not; *Bt* corn is still corn. Since corn exists in the country, then *Bt* corn is technically not an exotic species and the regulatory scheme under the Wildlife Act will not apply[12].

The creation of the NCBP does not solve the above problems because the Committee does not have the power to amend or re-interpret the laws (such as the Wildlife Act) to account for GMOs. It has to sift through the various existing laws and find provisions that are more general so as to accommodate inclusion of GMOs. The Plant Quarantine Law is more generally worded but it has a very limited scope — it applies only to the importation of plants; to the importation of animals only if they are potential pests; and it is primarily for the protection of agriculture[13]. GM-cows, sheep, etc., would not be covered because they are animals but not pests and they do not pose dangers to agricultural crops though they may eventually pose risks for humans when their milk or meat is consumed.

Should a biosafety framework be broad enough to cover related issues such as IAS, which also pose similar threats to biodiversity? Should it be limited to the coverage of the Cartagena Protocol or go beyond it? Even if we design from scratch and disregard existing legal limitations, this still poses an administrative problem because GMOs and commodities derived from them are in a sense a subset of products that have been traditionally regulated separately by different agencies - whether as plants or animals subject to quarantine, as ingredients in food, or as drugs. From a scientific standpoint, they are a separate class because they share the characteristic of having been produced/ modified through modern genetic manipulation techniques.

One option in designing the appropriate institution is to centralize regulation in a super agency with original regulatory powers over GMOs and derived commodities. However, from an administrative standpoint, regulating GMOs and derived commodities together does not make sense and is not necessarily more efficient, because the pathways for their production, distribution, and use are different, although they may pose similar risks owing to their common attribute. Besides, it will not fly politically because this option is most disruptive of regulatory status quo.

The other option to consider is to retain GMOs and derived commodities as a sub-

category of traditionally regulated materials — plant/animals subject to quarantine; activities/ materials subject to EIA, RA; food or drug subject to sanitary/ safety regulations — and leave their regulation to the agencies already managing these activities. But there is a need to retain NCBP as a coordinating body strengthened with powers to compel conformity from the regulatory agencies.[13]

A law or regulation that is limited to national compliance with obligations under the Protocol seems very narrow, unless it is nested in a more comprehensive framework that rationally looks at the various threats to biodiversity, and taking into account risks to human health.

We do not have such an umbrella framework since responsibility for environmental protection and biodiversity is lodged with the DENR, while crop protection is with the DA, and human health and safety is with the DOH. A biosafety framework, while dealing mainly and in great detail on GMOs, must provide an opportunity to link up and rationalize the related responsibilities under the different agencies. The NCBP is a good start, not counting its inherent lack of original powers, as discussed further below.

3.2 BASIC PRINCIPLES TO BE EMBODIED IN A BIOSAFETY FRAMEWORK

We list below some of the more basic principles that should be incorporated in the framework.

3.2.1 Precautionary principle

The Cartagena Protocol adheres to the precautionary principle, which was laid down categorically in the CBD. This fundamental underpinning of the Protocol has been criticized as too stringent. Katz[14], for example, presents the common argument that "the Biosafety Protocol attempts to address many concerns, but has resorted too readily to an overly stringent version of the precautionary principle. The result may be unnecessary restraints on trade, either because of unfounded fears of biotechnology or veiled attempts at protectionism. Unwarranted restraints of the further development of safer versions and uses of transgenic plants may deprive the environment of the beneficial effects of genetic engineering." The precautionary principle puts the burden of proof of safety on the proponent of GM organisms or derived commodities[15]. But then "such proof — proof that no adverse effects are possible — is beyond even the most able

scientist's grasp, as one cannot prove a negative proposition. As a result, the precautionary principle is an excuse for interminable delays in the introduction of new technologies, and those delays can have negative consequences of their own[16].

Some scholars propose a deeper examination of the precautionary principle to move away from its invocation to stop particular technologies[17]. It has been suggested that risk, uncertainty, and ignorance are different concepts that get lumped together, the last two being incompatible with the probabilistic models of traditional risk assessment[18]. In the end, how people understand, accept, and respond to the principle depends on the societal and institutional context in which it operates[19].

What is our interpretation of the principle? Do we know the risks and is the issue simply one of probability? Or do we not even know what the risks are? How do we verify applicant-provided information? The regulations provide that "lack of scientific knowledge or scientific consensus should not necessarily be interpreted as indicating a particular level of risk, an absence of risk, or an acceptable risk," following the language of the Protocol. While the statement may be true, it is hardly helpful as basis for action or inaction. Proponents of stringent precautionary rules would say that in the absence of positive proof of safety, there should be no action [i.e., not to allow importation, field testing etc.]. DA-AO8 interprets the concept of precautionary approach as provided in the Protocol to mean that regulatory agencies can make a decision on available scientific evidence and that the absence of scientific evidence or consensus should not be interpreted in relation to the presence and level or absence of risk.

3.2.2 Socioeconomic considerations

In evaluating whether to allow field release or commercial production of GM crops, perhaps it will be useful to look outside of the issue of risks alone but evaluate whether there is an urgency to make a decision at all. If the issue is improving yield/ production, perhaps we should ask the question — have we exhausted other means of increasing production, such as irrigation, integrated pest management, etc., without resorting to the use of GM crops? Have our traditional crop varieties been threatened enough by pests that we need to use pest-resistant GM strains? This is in effect, skirting the issue, but that is a precaution, too, without being remiss in finding alternatives to the potential "losses" in not adopting GM technologies.

We should bear in mind that GMO policy is not only a biosafety issue that may be resolved through simple risk analysis. Science provides only half of the decision criterion in the larger question of whether the policy is *in our best interest overall*. It may be safe, but will it really increase productivity and improve the plight of farmers?

The debates in Cartagena included reference to socioeconomic considerations in making decisions on whether to allow the import and release of GMOs, although the final text of the Protocol succumbed to the pressure of conforming with obligations under international trade agreements. Nevertheless, it recognizes that a State may consider the socioeconomic impact on traditional uses by IPs and local communities as a basis for decision.

Member-countries, while bound as a party to the Protocol, are not restricted from going beyond the minimum standard set by the Protocol regarding the consideration of socioeconomic impacts in pursuit of our national interest. We need to further study how we can include these impacts in GMO policy decision making without inviting the attack of being protectionist under our trade obligations.

3.2.3 Stakeholder participation

The Philippines is well regarded for having an aggressive civil society that actively participates in government decision making. Our laws, especially post-EDSA, specifically provide avenues for stakeholder participation. In relation to biotechnology and biosafety, there is even a greater need to provide for such involvement. The issues are very fluid considering that we are still building knowledge and experience in regulation. For the moment, decision criteria under the regulations are intentionally broad because we do not want to be boxed in and limited in our options. But leaving the regulators with a very wide discretion is a temptation for arbitrary action. Arbitrariness can be checked if all interested sectors are represented in the decision-making process.

We propose that, in the absence of detailed rules of procedure regarding the technical aspect of the issue, the regulation should focus on a transparent and credible decision-making process at this time as it ensures that future changes (including the adoption of detailed technical procedures) are arrived at in a consultative, rational, open, and deeply considered manner.

3.2.4 Best available technology/scientific information

Biotechnology has advanced so rapidly over the last decade. Scientists have not only come up with GMOs that have tremendous potential benefits but have also developed the complementary science of evaluating and monitoring their impact on natural ecosystems and human health. There are still a lot of debate, scientific uncertainties, and unknown factors to be sure. But what is even more relevant to us is the question — how much of this knowledge is available to us for making informed decisions on GMO policy?

We should also consider that there is a minimum or threshold scientific knowledge and experience that is required to make responsible and informed decisions. What is this threshold and do we have it in the country? If it is available locally, is it accessible to the government agencies that make the decisions, or is the knowledge in the hands of the private sector, academe, or other inaccessible institutions?

The principle of accessing the best available scientific information largely rests on the financial and technical reservoir of the decision-making body. Our government has limited resources, which are already spread too thinly over equally demanding programs. Is the amount allocated for this issue sufficient? Will additional amounts (taken elsewhere) be justified considering that GMOs have a very limited "constituency?" Can we pass on the costs?

Under the Protocol, the exporter has the responsibility to provide the necessary information needed by the importing state in order to make a decision. Even so, we need to independently verify the accuracy of that information.

3.2.5 Integration/coordination/ effectiveness of administration

We strive to have an efficient system of regulation that avoids duplication and too many layers of bureaucracy. Currently, there are several points of overlap that can be remedied by integrating requirements, evaluation, and grant of permits by several agencies.

One example would be the requirements for RA and EIA, which are at present required by the DA and the DENR, respectively. The two regulatory measures are complementary and may be tied together procedurally, and their permit requirements coordinated.

Is risk assessment properly an EIA matter, or an agricultural crop protection matter? In the end, it does not really matter as long as both regulations have the same purpose of protecting against adverse impacts. But there can be potential duplication and conflict in implementation strategies, as well as points of intervention by stakeholders. For example, the EIS system has an elaborate procedure for public participation and social acceptability, which is absent in quarantine procedures. Both government agencies may require from proponents substantively similar actions but at different times, using different procedures and involving different government processing, all causing undue delays.

3.2.6 Subsidiarity: decision at the appropriate level

Subsidiarity tends to balance the tendency of integration to centralize control of regulation. The principle of subsidiarity provides that decisions should be made at the lowest level where competence exists. This rests on the theory that decentralized management is more responsive, and for as long as the lower level of

government has competence and jurisdiction, then it should be left to decide on its own.

In the case of GMOs, the impact of field release, for example, may have a very limited geographical extent. While it may not be reasonable to expect that local institutions have the technical capacity to evaluate RAs in order to grant permits, the local institutions should have a substantial influence on the final decision because they have a better knowledge of the total picture locally (including socioeconomic considerations).

3.2.7 Compensation/liability rules

Our laws and regulations rely heavily on direct criminal and administrative sanctions to compel compliance. While this system of deterrence is quite effective and simple to administer, it also depends on the capacity of the government to monitor and enforce the rules. We have a perpetual lack of investment in effective law enforcement and this is not going to change anytime soon.

An alternative to direct government sanctions is to enable private suits where private interests are affected[20]. The theory is that private persons are more vigilant in protecting their rights. A biosafety framework should also provide for mechanisms for appropriate tort suits that will achieve the same level of deterrence as criminal or administrative sanctions. This can include compensation/liability for intentional and negligent acts; development of strict liability regimes or negligence rules appropriate to the level of risks; and the amendment of evidentiary rules to shift the burden of proof or to create presumptions.

The development of a local tort mechanism, which would also include private international tort, should be made in coordination with the process of coming up with an international regime on liability and redress under the Protocol.

3.3 PROBLEM AREAS IN A REGULATORY MECHANISM

3.3.1 Limitations of existing regulations

The increasing scope and complexity of genetic engineering and its applications warrant a closer look at the structure and composition of the NCBP. While the NCBP is clothed with broad responsibilities, its powers actually derived from the individual mandates of member-institutions and the residual powers of the President in safeguarding the general welfare. It may be argued that its decisions are actually only recommendatory, and only have

force because the member-agencies (who possess the real power under their legislative mandates) acquiesce or choose to respect the decision of the Committee.

This is evident in the manner in which the NCBP Guidelines and the DA regulations tend to overlap (e.g. risk assessment and field release regulations). Under DA-AO No. 8, the BPI authorizes importation of regulated articles, while the NCBP merely endorses its evaluation to BPI[21]. It is to the credit of both agencies that efforts are being made to ensure harmonization of their respective issuances. The NCBP has no control over EIA regulations, as it is the DENR that possesses the mandate. Neither does the NCBP have regulatory power over crop protection, seed/ variety improvement, quarantine, etc., as these are lodged in the DA.

Even within Departments, coordination and harmonization need to be addressed. The DA representative in the NCBP is the Chief Quarantine Officer, the BPI Director who is officially represented by the Chief of the Plant Quarantine Division. The DOH representative is the BFAD Director, and the DENR representative is the ERDB Director. These representatives come from the concerned regulatory agencies of their Departments, except for DENR who is represented by its research sector. The DA representative covers only plants but not animals and fishes, which are regulated by the BAI and the BFAR, respectively. The DENR representative does not have any regulatory authority as the relevant regulatory functions rest with the FMB for forest species, the PAWB for terrestrial wildlife species, and the EMB for EIA. Moreover, the process by which community representatives are selected is vague begging the question as to "What community is being represented?" The chairmanship of the committee being lodged with DOST inadvertently gives more emphasis on regulation of research and the NCBP has left out regulation on the commercial use of genetically engineered organisms and newly introduced species.

The NCBP is attached to the DOST, understandably because the subject matter involves high technology and scientific expertise. But DOST does not have regulatory powers that may be used to regulate activities that pose potential threats. These powers are with DA, DENR, and DOH. Neither does DOST has powers to grant incentives to promote the safe use and optimal exploitation of new technology and its products. The NCBP, however, has the

advantage of a well-informed and balanced/ objective decision-making process, because of its diverse membership. Notably, it is dominated by non-government members of proven competence in various fields.

The other biosafety guideline currently operating is DA-AO 8, which regulates the importation, release into the environment, and propagation and commercialization, specifically of plants and plant products derived from the use of modern biotechnology. On the import of products for direct use, the DA has realized Filipino importers of biotech commodities cannot possibly apply for the permits because they would not have access to the data required to show the safety and bioefficacy of these products. Neither would commodity exporters but rather the technology developers would have the necessary data. Furthermore, requiring individual importers to seek approval for the same transformation event would place unnecessary burden to the regulatory system. Hence, it was decided early on that technology providers should file for the applications for biosafety permit since they own the technology and possess the required information. However, there would still be problems in compliance since some transformation events are owned by companies that are not represented in the Philippines. For example, there are four transformation events in tomato owned by DNA Plant Technology Corporation, Agritope Inc, Zeneca Seeds, Calgene Inc., and Monsanto Company, of which only Monsanto has a Philippine representative.

DA-AO 8 is derived from the Plant Quarantine Law and thus the entry of plant products that are considered not to become plant pest or not to carry plant pest such as soya/corn oil, corn syrup, tomato paste, isolated soy protein, and textured vegetable protein are not regulated. The detection of whether products like these are derived from recombinant organisms is not technically feasible in vegetable oils and in similar products because processing could destroy the tell-tale substances like new protein and introduced DNA. No agency is responsible for issuing import permits for these commodities but manufacture of products using these ingredients is regulated by BFAD.

The DA has difficulties in requiring countries to declare the presence of specific transformation events in each shipment as required in DA-AO No. 8. The USA submitted a list of transformation events present in commercially grown crops,

however, it will not issue certification on the presence of transformation events for each shipment delivered to the Philippines. China declared that it grows recombinant tomato and sweet pepper but claims that they do not export these to the Philippines. As it turns out, some tomato paste imported into the Philippines comes from China.

The safety assessment of pharmaceuticals, whether these are genetically modified or not, is already a very rigid and expensive process. Drug development from discovery to the market costs about US$500 million, much of this spent on clinical trials that assess efficacy and safety. Our problems with medical preparations are with fakes, with herbals that have not undergone such scientific bioefficacy and biosafety assessments, and the high cost of prescription drugs. These problems are beyond the scope of a biosafety protocol. There is, however, research on pharmaceutical plants, which may be grown in the Philippines and which should be addressed by regulation. Another issue that can be addressed is the import, handling, and transport of human-infectious agents, whether transgenic or not used in research.

We lack biosafety guidelines on the handling of recombinant microorganisms, fish, and farm animals for their release into an open environment. Furthermore, while we have guidelines on the R&D of PHES, we lack safety guidelines on their large-scale release to the environment. There is also a need to provide safety guidelines on the release of biocontrol agents and bioremediation agents, which are by their inherent trait and intended use may cause an impact on biodiversity and on human health.

The administrative mechanism for biosafety regulation has to be flexible and adaptable, considering that even the global governance regime is evolving. In responding to the emergent technology regulated, a better institutional design is needed which retains regulatory flexibility while a technology's contours become clear—without creating binding precedents or a dedicated bureaucracy. In our case, the transitory nature of the administrative mechanism is a weakness. We have an institution such as the NCBP setting policy and evaluating proposals, but the agency is hampered by lack of permanence (since it is only an executive creation) and budget.

3.3.2 Over-regulation — a word of caution

Over-regulation could lead to a burdening of the regulatory system with limited returns on

investments and missed opportunities. The cost of regulation should be considered in the crafting of appropriate biosafety policies. The existing system of regulating GM crops in various countries following the consensus documents of the OECD appears adequate as attested by a number of reviews of international bodies. It will not help the Philippines to implement a more rigid structure considering our limited technical capacity and financial resources. Regulation of GM crops needs collaboration between the technology developer and regulatory system, information about the transformation and its detection must be provided to effect regulation. Regulation requires the establishment of secured facilities, which are more expensive than the regular research facility. Hence, this increases the cost of technology development and could limit our ability to develop technologies for problems unique to the Philippines.

3.3.3 Capacity building

The cost of evaluating and verifying claims in applications is enormous. While the duty lies with the applicant to provide the information regarding impacts and risks, the government has to independently verify the claims. In theory you can charge the applicant for the cost of independent evaluation but that effectively doubles their costs (besides from being an unreasonably high regulatory fee). Should there be an international regime of certification similar to ISO or to forestry?

We do not have enough technical expertise to conduct independent studies; "best available scientific information" (considering also the cost) may not be adequate and may become the stumbling block in making informed decisions. Yet, our existing regulatory regime is largely 'scientific' in orientation. We need to explore 'socioeconomic considerations' in decision making, if this can be extended beyond the limited scope under the Protocol without being open to attack of protectionism under the trade agreements.

The capacity for modern biotechnology and biosafety programs is modest compared with other countries. There are about 955 experts in the various fields of sciences recognized by the NRCP and NAST working in or retired from educational and R&D institutions in the country. Although this appears to be a sufficient pool of experts from which various regulatory agencies can draw upon to assist them in setting up and implementing their biosafety regimes, experience at the DA-BPI shows that biotechnology and biosafety are new concepts and many scientists need some

introduction to modern biotechnology principles and biosafety concepts and be trained in the conduct of reviews of RA.

In the RA review of recombinant organisms, there is always a need for experts in molecular biology principles and techniques. In addition to having capacity to develop RA procedures and conduct their reviews, there is also a need for capacity to monitor the implementation of field trials and compliance to approval conditions and the import of regulated materials. There is a need to train personnel from the DA Regional Field Units to monitor the implementation of field trials and compliance to approval conditions and the import of regulated materials. Laboratory services must be developed to enable regulatory agencies to monitor the entry of regulated articles.

Biosafety is a relatively new concept thus awareness must be increased and capacities strengthened. The concept of biosafety has to be well articulated. Capacity-building programs in relation to the implementation of DA AO No. 8 has been designed by the DA Office of Policy and Planning and implemented by the DA-Biotechnology Program in collaboration with various institutions. However, there is a need to expand this program beyond DA. There are other government regulators (e.g., DENR, DOH) whose capacity also needs to be strengthened. There are other government agencies, including LGUs, whose capacity also needs to be strengthened so that they can respond intelligently to the issues raised. A national capability-building program on biosafety should target policy makers, regulators, the R&D sector, and the general public.

One fall-out of the general attack on GMOs is to draw scarce resources away from public research organizations whose mandate is to create technology for the poor. "The cost, scientific attractiveness, and intellectual property aspects of GMOs are apt. This likelihood is exacerbated by the vulnerability of public sector and international funding to political attacks by the anti-GMO movement. The unfortunate consequence is that the poor farmers of less developed countries have an ever-shrinking scientific establishment to serve them. If technology is a driving force behind farm restructuring, GMOs seem to be devilishly suited to help large farms, indirectly hurting small farms by depriving them of new technology. An ironic solution to this is

actively to promote the public sector research and development of GMOs for poor farms."

3.4 GAPS IN SUBSTANTIVE REGULATIONS IN LIGHT OF OBLIGATIONS UNDER THE CARTAGENA PROTOCOL

We have not ratified the Cartagena Protocol and it may take awhile before Senate concurrence can be obtained. Because we have not yet officially adhered to the Protocol, there is as yet no designated focal point or competent authority to coordinate with the international implementation of the Protocol. This will later pose a problem, because GMO regulation is lodged in different agencies, depending on whether the organisms or products are crop or environmental threats, or pose risks to humans who use the products as food or drugs. In the absence of a permanent administrative agency with original legislative charter, budget, regulatory and enforcement powers, can NCBP serve these functions?

The Protocol establishes a two-pronged approach regarding the international trade of genetically modified agricultural products — the AIA regime for products that are released into the environment, and the labeling required for GMOs intended as food products. In both strategies, there is a heavy need for science-based management information. Although the burden of providing the information is on the exporter of the GMOs or derived commodities, the national administrative agency must possess the capacity to evaluate and verify the information provided. Would the NCBP serve as coordinator for such capacity building?

3.5 ROLE OF STAKEHOLDERS AND INTEREST GROUPS

3.5.1 Scope of decision making

The impact of GMOs on the environment or people's health is very localized, but the discourse on GMOs has been internationalized by linking the issue to globalization. Activists and political groups can exploit the contradictions to rescale and redefine biotechnology regulation, as in the case of Brazil[22]

Six of the 10 members of the NCBP come from the private sector (at least 4 are scientific experts; 2 respected members of society). Six votes are needed to make a decision. While it is expected that the body as a group deliberates on each decision, there is a distinct possibility

of non-government members carrying any decision. This opens the institution to attack - what is the accountability of non-government members? Are they public officers exercising governmental functions? Admittedly, the strength of the NCBP as an institution lies in the significant participation of non-government members in the Committee, especially if they offer diverse perspectives that can encompass the wide range of interests of stakeholders who are not directly represented.

3.5.2 Public hearings

Public consultation is a staple method employed by government agencies to get feedback on rulemaking. There is no standard by which genuine public consultation can be gauged, since it does not follow that there is a failure of consultation when the agency adopts a rule or decision that is different from the one advocated by interest groups. To what extent are the positions/interests of stakeholders 'heard'? Are the procedures for participation clear and facilitative, or can they be perceived as restrictive/selective? Is the right of stakeholders to be heard guaranteed; that is, legally demandable?

Perhaps the strongest form of public consultation is the "social acceptability" criterion under the EIS system. Under the rules, community decisions can conceivably allow or block a project. If we grant that RA is subsumed under EIA, then the rules on social acceptability will apply.

The guidelines of the NCBP and DA-AO No. 8 have been presented for public consultations prior to their adoption. In fact, DA-AO No. 8 has undergone two rounds of countrywide consultation within a two-year period prior to adoption. Existing guidelines on public sector participation in the implementation of these guidelines include the inclusion of community representatives in the IBCs and in the NCBP, requiring applicants to post project information in public places and invite comments in field trial sites and requiring applicants to publish invitations for comments about their applications. However, based on current application process with the BPI, there may be a need to publicly campaign and arouse public interest for the agency to obtain critical and helpful comments. Apparently, most of the letters of support for *Bt* corn were obtained after seminars explaining its composition and use. The current practice of requiring applicants to publish information sheets in major dailies should be revised to include one written in the national language. Only a well-informed public can make critical and helpful comments, hence efforts to

increase public awareness and education should also be made.

3.5.3 Role of NGOs

NGOs have been instrumental in posing the difficult questions to decision makers and demanding a response. Whether NGO answers to these questions ultimately are backed by science or determined to be unfounded, governments and the agricultural biotechnology industry cannot ignore the concerns voiced by NGOs if their goals are to increase public acceptance of GMOs and confidence in the regulatory systems governing their development and marketing. There are questions as to the accountability of NGOs with respect to their claims. Somehow NGOs and conservation activities are privileged and exempt from responsibility for the consequences of their actions, yet they too often receive the uncritical adulation of the media.

The impact of NGOs is undeniable. In a study on the role of NGOs during the negotiations for the Biosafety Protocol, the following insights were made:

"First, environmental NGOs, such as Greenpeace, Friends of the Earth, Third World Network, RAFI and others, employed a number of strategies in order to influence the contents of the Biosafety Protocol during its negotiation process and its adoption in the period between 1992 and 2000: lobbying, advocating, promoting, and exerting public pressure. Of these strategies, lobbying turned out to be the most effective. Second, by employing these strategies, the NGOs were able to some extent -– together with other actors – to influence the contents of the Protocol, notably the inclusion of the precautionary principle, the broadening of the Protocol's scope, the inclusion of socioeconomic considerations and the liability issue as well. Furthermore, without the pressure of NGOs, the formal mandate to negotiate the Protocol might not have been adopted by governments in 1995 in the first place. Third, NGOs indirectly influenced negotiations and decision making, primarily outside the formal process. This was due to the rules of procedure of the biosafety negotiations on the one hand and the NGOs' position within the international system on the other. These procedures and position constrain NGOs in employing formal negotiation roles. Fourth, environmental NGOs particularly influenced policy outcomes by lobbying government delegates, by co-operating with developing countries and by mobilizing public pressure. Finally,

environmental NGOs exercised the most influence in the so-called 'pre-negotiation' phase, because the participation procedures were more lenient during this initial phase."

In the end, a regulatory system that enjoys the confidence of the public, as well as that of the business and farming communities, is essential to the success of biotechnology. Not only are the environmental risks too great to permit any other course; the consequences of public doubt and distrust are also too significant and too corrosive of the faith in regulatory credibility necessary for a viable administrative system.

3.6 LEGAL REMEDIES AND LIABILITY FOR HARM

There is little mention in the existing regulatory regime of remedying accidental or intentional releases that in fact results in harm or increases the risks for harm.

There is no law providing penalties for violations of NCBP and DA regulations, except indirectly through existing laws on EIA, wildlife protection, quarantine, etc., which are not sufficient. We have regulations on import control and quarantine, and guidelines for contained use and field release. But the guidelines are just that — guidelines that cannot be imposed on practitioners under pain of punishment for violation. Our tort system is quite primitive. It is inadequate to achieve optimal deterrence of negligent or intentional harmful acts, especially of this magnitude and complexity.

Criminal and administrative penalties are the usual sanctions, but a purely administrative scheme cannot adequately protect the public safety and the environment. Tort law may be used, but should be modified to include a system of rebuttable presumptions designed to ease the plaintiffs' burden in proving causation, financial responsibility requirements such as mandatory insurance, and a standard of joint and several strict liability. This proposal for regulating rDNA releases could serve as an important model for future regulation of emerging technologies by harnessing the knowledge and expertise of entrepreneurs to serve the public interest. A similar rebuttable presumption of defect in case of GMO-caused damage has been proposed at the international level.

Under U.S. product liability law, claims for "failure to warn" are likely to prosper because, due to the extremely high cost of developing the products, extensive testing is sometimes not financially feasible. It may be worth

exploring the possibility of adapting similar liability rules into our tort system.

Apart from the liability of introducers of GMOs, should there be liability rules for government decision makers? On the other extreme, should there be rules to protect them when unforeseen consequences actually happen despite the wide safety margins?

3.7 RECOMMENDATIONS

Based on the analysis above, some recommendations have been arrived at. There is no single course of action recommended; instead, the suggestions are presented as alternatives.

3.7.1 Working under the existing administrative regulations

There are remedial measures that can be adopted quickly by amending existing regulations. These relate mostly to procedural matters.

a) ***Strengthen NCBP.*** Taking off from the policy statement made by President Arroyo promoting biotechnology, the NCBP, relying on its powers under its enabling Executive Order, can require member agencies to see to it that the rules they set under their individual jurisdictions be compatible with the policies set by the Committee in pursuance of the common goals set by the President. The NCBP still will not exact compliance from agencies because the latter are implementing specific laws that came prior to the Committee's establishment. But then the President, as head of the Executive Department, can exercise her supervisory powers over cabinet offices and make them conform to the state policies;

b) ***Coordinate and harmonize procedures from different agencies.*** Member-agencies can take measures to harmonize procedural requirements relating to GMOs with the goal of creating a 'one-stop shop' for information, process permits, etc. Agencies can then amend their rules to implement the simplified procedure in dealing with GMOs.

A set of harmonized RA guidelines to ensure that objectives of the biosafety policy be attained for all - safety to people, animals, and environment- should be adopted by the implementing agencies.

For GMOs not covered under NCBP or DA-AO No. 8, measures must be taken to ensure that regulations formulated for these GMOs are harmonized. NCBP can take the lead in ensuring that all these proposed guidelines are compatible or are harmonized with each other. The current practice of requiring NCBP clearance for the import of exotic and recombinant organisms for R&D purposes by the BPI should extend to imports of fish; animals; and biocontrol, biocomposting, and bioremediation agents for research purposes.

c) ***Streamline information gathering and processing, in anticipation of the information sharing requirements under the Protocol***; and,

d) ***Tap resources for capacity building, tie up with the academe, civil society, and the private industry.***

There are two options to achieve the above under the present limitation of having no existing enabling law specific to GMOs. One is to push for an Executive Order amending the NCBP charter and providing more powers and substantive regulations. The other option, which incidentally will achieve the same effect, is to push for a joint AO, or at least complementary AOs from the relevant cabinet offices, incorporating the substantive regulations in their own rules. Either course of action will still suffer the inherent limitation of being mere executive issuances limited by existing laws. The more permanent fix is to push for a new law specifically tackling GMOs and biosafety.

3.7.2 Formulating new enabling legislation

The Model Act developed by Abramson and Reifschneider (2002) for national implementation of the Cartagena Protocol contains the minimum requirements for complying with state obligations under the agreement. The authors intend for this Model Act to provide a structure that could:

- Assist regulators, scientists, and other stakeholders with initial efforts to prepare new national biosafety frameworks or to consider amendments to existing laws and regulations that might be required;

- Help governments review and test concepts and provisions in existing national legislative proposals under consideration; and

- Be readily adapted to suit local needs and adopted, in whole or in part, to meet national objectives.

The Model Act provides a regulatory framework that defines what is regulated and the key mechanisms for implementation. It is envisioned that secondary legislation, including regulations, guidance documents, handbooks, etc. would be created to provide additional details. This structure has been selected because it provides a good balance between certainty for the regulated community and flexibility for the regulators to make adjustments to the details as experience is gained and scientific understanding advances.

However, since we need a more comprehensive framework for coordinating responses not only for GMOs but also for other similar threats to biodiversity, there is a need to be more expansive than the scope of the Protocol.

Specifically, the proposed law should strengthen the NCBP so that it has oversight functions over regulations issued by member-agencies, which are related to the Committee's mandate. A provision in the law should make the DENR, DOH, and DA adhere to the policy set by the Committee.

As the governance arrangements evolve, it is important that a biosafety framework allows for flexibility. The framework should have a strong focus on procedures for stakeholder participation, setting forth the rights of interested parties to information not otherwise classified as confidential (trade secrets, etc), which will allow these parties to genuinely comment, criticize, or support the Committee's actions. These procedures should also be adopted by member-agencies in their own rulemaking processes.

The current biosafety regulations are measures extrapolated or adapted from existing laws. They are effective in coordinating government action (a must, since so many laws, procedures, and agencies are involved), but have limited effect in enforcement because of the transitory nature of the administrative mechanisms, absent a legislative act that gives the agency original powers and means to exercise these powers.

There is a lesson to be learned from the development, implementation, and eventual modification of EO 247. The implementation of the regulation suffered under the difficulty of having no real teeth, no budget, and being ad hoc — with members and staff merely

pulled out from their other regular duties. When the Wildlife Act was passed, some permanence was achieved, and a clear mandate was provided — although procedures established under the EO were significantly changed.

It is inevitable that the regulatory regime for biosafety will undergo the same process. The challenge is to learn from the limited transitory phase under the administrative regulations, and make sure that the legislative act will benefit fully from the experience – to be evidenced by legal and technical inputs as well as general inputs from public participation and agency decisions.

There is still a reasonable wait for Presidential ratification of, and Senate concurrence in, the Cartagena Protocol. In the meantime, we should gain experience from the existing regulatory setup, which is really an interim framework that has to be continually revised and enhanced. Thereafter, we can push for the new comprehensive legislation that incorporates lessons learned from experience.

IV. Crafting the National Biosafety Framework

An NBF is a combination of policy, legal, administrative, and technical instruments developed to ensure an adequate level of protection in the field of the safe transfer, handling, and use of LMOs resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health.

NBFs vary from country to country, but they often contain a number of common components: (a) a government policy on biosafety; (b) a regulatory regime for biosafety; (c) a system to handle notifications or requests for authorizations; (d) a system for "follow up" such as enforcement and monitoring for environmental effects; and (e) mechanisms for public awareness, education, and participation.

The proposed NBF for the Philippines did not emerge from a vacuum. Biosafety regulations have been in the country since 1990 with the issuance of Executive Order No. 430, creating the NCBP. The NCBP has had a wealth of experience regulating biosafety in the Philippines. So does the DA with its DA-A0 No. 8, Series of 2002. These regulations have been taken into account in drafting the NBF.

Although many believe that the current system is functional and working well, there is consensus that such system must be strengthened, including the capabilities of the different regulatory and implementing agencies, the research institutions, and civil society organizations. The adoption of the framework will further increase the need for such strengthening. This is the reason why a capacity-building need is integrated into the framework.

The proposed NBF, to the extent allowed by law, provides solutions to identified gaps under the current system. However, it is not a substitute for legislation that must eventually be enacted to deal with the challenge of maximizing benefits provided and managing risks posed by modern biotechnology. Such legislation is necessary to provide more permanent rules, institutions, and funding to adequately deal with this challenge. The framework is limited and cannot go beyond existing policies, laws, and administrative issuances related to modern biotechnology and biosafety. These policies, laws, and issuances are, however, consolidated into one integrated framework so as to provide clarity, transparency, and predictability to biosafety decision making in the Philippines. Avoiding jurisdictional conflicts and facilitating public consensus are additional reasons for such a framework.

The proposed framework does not substitute for rules and regulations that relevant government agencies must issue in the exercise of their current powers and jurisdiction. For this reason, it is not as detailed as some, including a few expert reviewers, expect. The framework is intended to guide such exercise by the concerned agencies and, in particular, mandates coordination among them where appropriate and applicable. The framework does contain general principles and minimum guidelines that the relevant agencies are expected to follow and which their respective rules and regulations must conform with.

The proposed framework also goes beyond the Cartagena Protocol on Biosafety. As Article 2

of the Protocol itself provides, *"Nothing in this Protocol shall be interpreted as restricting the right of a Party to take action that is more protective of the conservation and sustainable use of biological diversity than that called for in this Protocol, provided that such action is consistent with the objective and the provisions of this Protocol and is in accordance with that Party's other obligations under international law."* In addition, the framework is intended to apply to all biosafety decisions in the Philippines and not just to those decisions with transboundary elements, which the Protocol covers. To have separate frameworks for domestic and transboundary biosafety decisions would be confusing and inefficient. The proposed framework, however, contains the minimum requirements for implementing the Cartagena Protocol and can serve as an interim legal regime for its domestic enforcement and for compliance with its obligations.

It should, therefore, be understood that the proposed NBF is an interim step towards a more permanent legislative framework. Because of this, it will continue to have many of the gaps and inadequacies of the existing system. In particular, critical issues related to creation of new agencies, funding and legal remedies for liability and compensation are not addressed adequately as new legislation is required to deal with these issues. In the meantime, however, having an interim biosafety framework brings many advantages, particularly its flexibility. The framework should be revisited, reviewed, and revised periodically to ensure that it is effective in meeting its stated objectives. The interim period should also be utilized to gain experience and to learn implementation lessons that should subsequently be incorporated into new legislation. The proposed NBF is attached as Annex A.

4.1 COMPONENTS OF THE NBF

The draft EO establishing the NBF, prescribing guidelines for its implementation, strengthening the NCBP, and for other purposes contains the following components, is summarized below:

Preamble

The Preamble recognizes the following: (1) the rapid expansion of the use of modern biotechnology not only for scientific research but also for commercial purposes, and its potential for human well-being if safety measures are in place; (2) the growing concern over its potential impacts on the environment, particularly on biological diversity, on human health, and on social and cultural well-being; (3) the entry into force of the Cartagena

Protocol on Biosafety on 11 September 2003 which the Philippines signed on 24 May 2000; (4) the need for an NBF responsive to the challenges presented by modern biotechnology; and, (5) the need to strengthen the NCBP to better respond to these challenges.

Section 1. State Policies

The following state policies mandated by the 1987 Constitution shall guide the concerned government department and agencies: (1) *Right to Health; (2) Right to a Healthful Ecology* (Article II, Section 16); (3) *Priority to Science* (Article II, Section 17); (4) *Role of the Private Sector* (Article II, Section 20); (5) *Rural Development* c (Article II, Section 21; Article XIII, Section 5); (6) *Right of Indigenous Peoples and Communities* (Article XIII, Section 5); (7) *Right to Information* (Article II, Section 28); (8) *Local Autonomy* (Article 10, Section 2); (9) *Right to Participation* (Article XIII, Section 16); (10) *Science and Technology* (Article XIV, Sections 10 and 12); and, (11) *Consumer Protection* (Article. XVI, Section 9).

Section 2. Principles

The following principles, based on national and international law, shall apply in a mutually supportive manner to the implementation of the NBF: (1) *Policy on Modern Biotechnology* - The State shall promote the safe and responsible use of modern biotechnology and its products as one of the several means to achieve and sustain food security, equitable access to health services, sustainable and safe environment and industry development; (2) *Policy on Sustainable Development* - The overall policy of the Philippines on sustainable development, as laid down in PA 21, shall equally guide the implementation of the NBF; (3) *A Balanced Approach* - The NBF recognizes both the potential benefits and risks of modern biotechnology; (4) *A Scientific Approach* - The implementation of the NBF shall be based on the best available science and knowledge that are of highest quality, multi-disciplinary, peer-reviewed, and consistent with international standards; (5) *Socioeconomic, Cultural, and Ethical Considerations* - These considerations shall be taken into account in developing biosafety policies, measures, and guidelines; (6) *Using Precaution* - In accordance with Principle 15 of the Rio Declaration of 1992 and the relevant provisions of the Cartagena Protocol on Biosafety, in particular Articles 1, 10 (paragraph 6) and 11 (paragraph 8), the precautionary approach shall guide biosafety decisions; (7) *Transparency and Public Participation* - Stakeholders should be provided access to information and the

opportunity to participate in biosafety decision -making processes; (8) C*onsensus Building* -. In making biosafety decisions, all concerned government departments and agencies shall exert all efforts to find consensus among all relevant stakeholders to be achieved in a transparent and participatory manner, and based on the best available science and knowledge; (9) *Principle of Subsidiarity* - As provided by law and where competence exists, all levels of government, includingLGUs, shall participate in implementing the NBF; (10) *Availability of Remedies* - Effective access to judicial and administrative proceedings, including redress and remedy, shall be available in accordance with Philippine law; (11) *International Obligations and Cooperation* - The NBF shall be implemented in a manner consistent with and mutually supportive to the international obligations of the Philippines; (12) *Efficient Administration and Timely Decision Making* - The NBF decision-making process must be conducted in an efficient, coordinated, effective, predictable, cost-effective, and timely manner; (13) *Public interest and welfare* - In cases of conflict in applying these principles, the principle of protecting public interest and welfare shall always prevail.

Section 3. Scope, Objectives, and Definitions.

The NBF covers products of modern biotechnology, exotic species, and IAS. It covers all activities related to the development, adoption, and implementation of all biosafety policies, measures, and guidelines, and in making decisions concerning R&D, handling and use, transboundary movement, release into the environment, and management of regulated articles. The NCBP and concerned departments and agencies may apply, when allowed by law, the principles, mechanisms, and processes developed and implemented under the NBF to similar problems such as addressing the issue of exotic species and IAS. Where appropriate, they may adopt the administrative and decision-making systems established in this framework. Its objectives are: (1) to establish a science-based determination of biosafety; (2) to establish a decision-making system that is efficient, predictable, effective, balanced, culturally appropriate, ethical, transparent, and participatory; and (3) to serve as guidelines for implementing international obligations on biosafety. Definitions provide context to the terms used.

Section 4. Administrative Framework

The administrative framework focuses on the need to address the issue of inter-departmental roles in biosafety and the need for a manageable system for decision making. It recognizes the mandates of various agencies such as the NCBP, key departments (DOST, DA, DENR, DOH), and local governments as provided by law. It also defines the role of the Focal Point, competent national authorities, the BCH Focal Point, and other stakeholders.

Section 5. Decision-making Processes

Biosafety decisions shall be made in accordance with existing laws and the following guidelines: *(1) Standard of Precaution*. – The lack of scientific certainty or consensus shall not prevent concerned government departments and agencies from taking the appropriate decision to avoid or minimize such potential adverse effects, as provided for under Article 10 (paragraph 6) and Article 11 (paragraph 8) of the Cartagena Protocol on Biosafety; *(2) RA*. - RA shall be mandatory and central in making biosafety decisions. It shall identify and evaluate the risks to human health and the environment, and if applicable, to animal health. The conduct of RA by concerned departments and agencies shall be in accordance with the policies and standards on RA issued by the NCBP, and shall likewise be guided by Annex III of the Cartagena Protocol. As appropriate, such departments and agencies may issue their own respective administrative issuances establishing the appropriate RA under their particular jurisdictions; *(3) Role of EIA*.- The application of the EIA system to biosafety decisions shall be determined by concerned departments and agencies subject to the requirements of law and the standards set by the NCBP. Where applicable and under the coordination of the NCBP, concerned departments and agencies shall issue joint guidelines on the matter; *(4) Socioeconomic, Ethical, Cultural, and other considerations.* - Consistent with Article 26 of the Cartagena Protocol on Biosafety, concerned government departments and agencies may take into account socioeconomic considerations arising from the impact of regulated articles on the conservation and sustainable use of biological diversity, especially with regard to the value of biological diversity to indigenous and local communities. Socioeconomic, ethical, cultural, and other assessments, as appropriate, shall be conducted particularly prior to decisions to commercialize products of modern biotechnology. The NCBP shall issue guidelines relating to the conduct of these assessments. These assessments shall be conducted separately from RA and in a transparent, participatory, and

rigorous manner; *(5) Decisions under the Cartagena Protocol.-* Competent national authorities (DA, DENR, DOST, DOH) may adopt the procedures provided in Articles 7–13 of the Protocol or issue their own respective rules and regulations consistent with the Protocol. In all cases, the time frames for decisions required under the protocol shall be followed; (*6) Monitoring and Enforcement. -* The conditions attached to approvals, particularly those intended for purposes of risk management, shall be strictly monitored. Monitoring shall be done transparently, in coordination with other Department and agencies, and shall involve relevant stakeholders.

Section 6. Access to Information

The right of the public and the relevant stakeholders to information related to biosafety decisions is recognized and respected. Concerned departments and agencies shall disclose all information on such applications in a prompt and timely manner; the protection of confidential information is mandated, subject to certain requirements. Information on biosafety decisions shall include a summary of the application, the results of the RA and other relevant assessments done, the public participation process followed, and the basis for approval or denial of the application.

Section 7. Public Participation

Concerned departments and agencies shall promote; facilitate; and conduct public awareness, education, and meaningful participation. Public participation shall apply to all stages of the biosafety decision-making process. In conducting this process, the following minimum requirements shall be followed: (a) notice to all concerned stakeholders; (b) adequate and reasonable time frames; (c) public consultations or formal hearings where there is public controversy, and dialogue and consensus building among all stakeholders; and (d) written submissions.

Section 8. Capacity Building and Financial Resources

Implementing the NBF requires the design, adoption, and implementation of a capacity-building program supported by adequate financial resources.

Section 9. Remedies

In cases of violation of laws, rules, and regulations related to biosafety, the following remedies shall apply: administrative remedies, criminal liability, civil liability, and international legal norms on liability and compensation, including those that may be developed and adopted under the Cartagena Protocol. Recognizing the current gaps in the

law on remedies related to biosafety, appropriate legislation shall be recommended to Congress to address this gap, among others.

Section 10. Review

The NBF shall be reviewed periodically to identify gaps and lessons learned from its implementation. Lessons learned from implementing the NBF shall be documented and, at an appropriate time, conveyed to Congress for purposes of developing, drafting, and adopting legislation on biosafety.

4.2 NBF DEVELOPMENT PROCESS

The proposed NBF for the Philippines went through a series of drafts, each draft being revised based on inputs from multi-stakeholder consultations beginning with an Expert's Group Workshop (EGW), followed by three regional workshops in Mindanao, Luzon, and Visayas, a national workshop in Tagaytay City, and an NCC review. Thus, the NBF had four drafts: (1) working draft of the NBF; (2) regional draft of the NBF; (3) national draft of the NBF; and, (4) NCC draft of the NBF. The present draft, herein annexed, is the NCC draft of the NBF.

Figure 2 shows the process followed in the development of the proposed NBF.

4.3 PUBLIC PARTICIPATION IN DEVELOPING THE NBF

4.3.1 Identifying the stakeholders

The DENR-PAWB/NEA engaged the Development Academy of the Philippines (DAP) to conduct a stakeholder analysis and provide the workshop consultancy services for the NBFP to ensure neutrality and transparency in the public participation process. Specifically, DAP was tasked to develop a detailed design of the workshops (three regional workshops and one national workshop) and handle the workshop process. The DAP staff also served as facilitators for these workshops.

The stakeholder analysis was conducted to identify the key players in biosafety-related concerns in the Philippines; and assess their interests, including the ways in which such interests will affect the NBF workshops. An analysis of the various interests was done to draw out the main and needed assumptions that will help in ensuring the viability of the workshops. The analysis also helped in predicting the potential problem areas, as well as in conceiving possible measures to manage these problem areas. The results of the stakeholder analysis provided valuable inputs

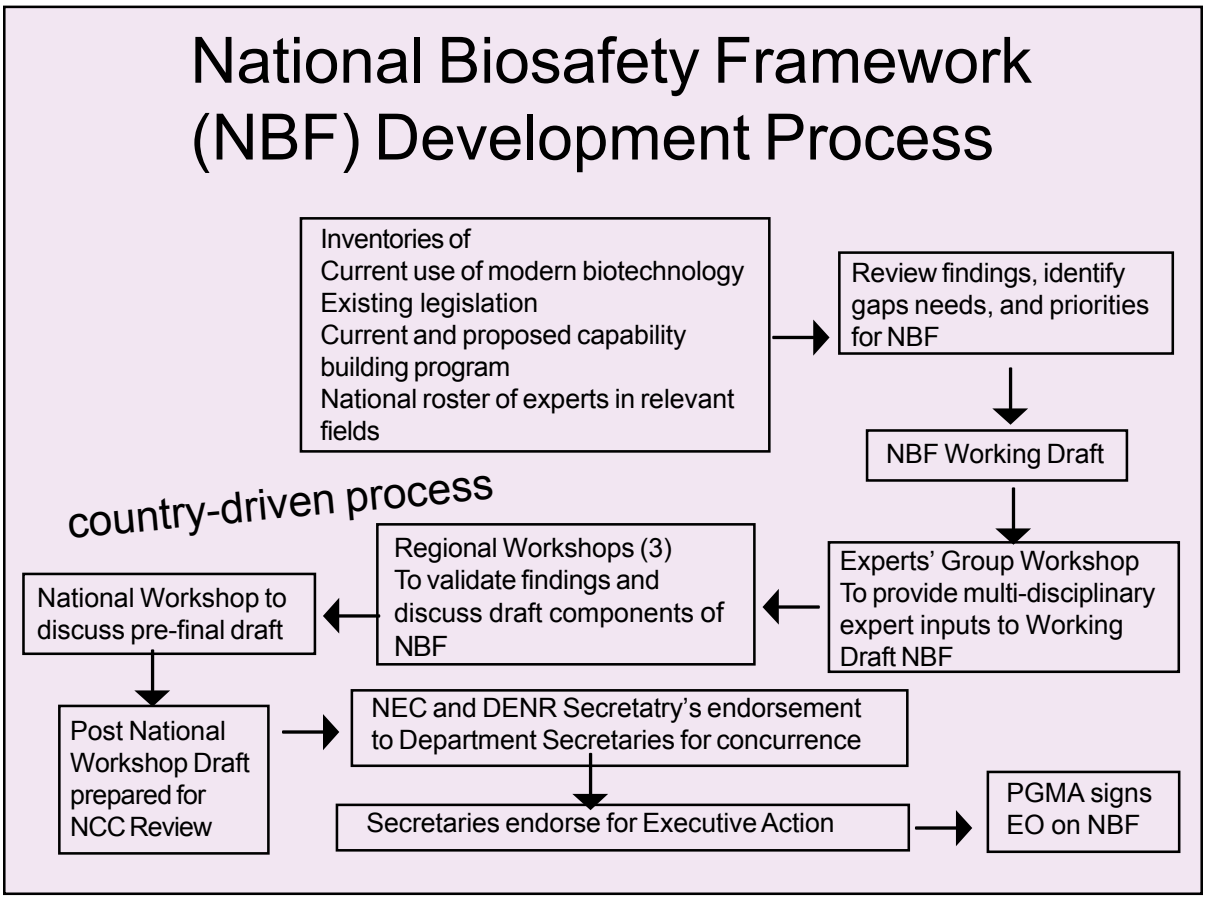


Figure 2. NBF development process.

in the designing of the workshops and in selecting the appropriate forms for stakeholder participation.

Stakeholders were selected based on representation of the following: (1) areas with existing research and development, release, and commercialization of GMOs; (2) areas where biotechnology and biosafety is a critical issue, and where there is strong promotion and opposition to GMOs; (3) areas considered as biodiversity hotspots; and (4) areas of operation or geographic representation.

4.3.2 Norms for public participation

Biosafety issues are best handled with the participation of all relevant stakeholders. The principles of transparency, participatory consultation, and consensus building were adopted in the formulation of the NBF. In the conduct of the various workshops, workshop norms were set by the DAP. These norms include emphasizing that the workshop is not a venue for debate, although the participants may present opinions or provide alternatives and respect for each other's views. It was also emphasized that while consensus is desired, it

may not be possible to reach full consensus on the contents of the NBF due to the highly polarized views of the stakeholders. Disagreements and contrary opinions, however, can be registered and bracketed and later decided on by the decision makers in government.

The principles adopted in the process helped elicit trust and confidence of the stakeholders. It also helped that the NCC had representatives from the NGO and industry sectors who have opposing views on the issues and were given the chance to voice out their opinions and register their disagreements on certain issues.

4.3.3 Public participation through multi-stakeholder process

The NBF underwent a total of five multi-stakeholder, multi-disciplinary, and geographic consultations.

EGW

An EGW was held on October 8, 2003 at the SEAMEO-INNOTECH, Quezon City participated in by 37 multi-disciplinary experts from academic and research institutions, industry, government, and civil society organizations. The EGW was conducted to review the first working draft of the NBF and generate feedbacks and comments from these experts. A peer review of the draft was also

conducted electronically. From this exercise and from written comments received both locally and internationally, a regional draft of the NBF was prepared for consultation at the regional level.

Regional Workshops

For the regional workshops, DAP identified and generated a long list of possible participants from national and line government agencies, LGUs, academic and research institutions, civil society organizations, and the private sector.

These regional workshops were conducted in Davao City from January 5 to 6, 2004 (for Mindanao); in Quezon City from January 8 to 9, 2004 (for Luzon); and in Cebu City from January 12 to 13, 2004 (for Visayas). Inputs from the regional workshops were incorporated into a national draft of the NBF, which was then subjected to consultation at the national level.

Mindanao Regional Workshop

Forty-eight participants, representing national and local government agencies, academe and research institutions, civil society organizations, and the private sector, attended the regional workshop for Mindanao held at the Grand Men Seng Hotel in Davao City.

The objectives of the workshop were: (1) to validate the data and information gathered by the technical and legal consultants on the current uses of modern biotechnology, existing legislation or legal instruments related to biotechnology/biosafety, existing or planned capacity-building programs or projects related to the safe use of biotechnology, and expertise in the country; and (2) to solicit feedbacks, comments, suggestions, and other inputs to the regional draft of the NBF.

Participants were divided into four small groups to discuss specific sections of the regional draft of the NBF (Table 23).

Luzon Regional Workshop

The regional workshop for Luzon was held at the SEAMEO-INNOTECH in Quezon City and attended by 56 participants, representing national and local government agencies,

Table 23. Workshop groups and topics discussed.

Group	Topic
Group 1	Definitions, Objectives, and Scope State Polices Decision-making Process Review
Group 2	Definitions, Objectives, and Scope Principles Administrative Framework
Group 3	Definitions, Objectives, and Scope Access to information Public Participation Remedies
Group 4	Definitions, Objectives, and Scope Capacity building and Financial Resources

academe and research institutions, civil society organizations, and private sector. The same objectives and process were followed as in the Mindanao workshop.

Visayas Regional Workshop

The regional workshop for Visayas was held at the Sarrosa International Hotel in Cebu City and attended by 31 participants, representing national and local government agencies, academe and research institutions, civil society organizations, and private sector. The same objectives and process were followed as in the Mindanao and Luzon workshops.

National Workshop

The national workshop was held at the DAP Conference Center in Tagaytay City and attended by 78 participants, representing national and local government agencies, academe and research institutions, civil society organizations, and private sector, members of the NCC, and observers from UNEP-GEF and USDA. Selection of participants was based on extent of participation and substantive inputs in the regional consultations, and geographic and sectoral representation.

The welcome address was given by Dr. Theresa Mundita S. Lim, Director of the DENR-PAWB and NEA of the UNEP-GEF NBF Project in the Philippines. The then DENR Secretary Elisea G. Gozun delivered the keynote message. In her message, she underscored the importance of ensuring human and environmental safety and expressed support for the safe and responsible use of modern biotechnology and its products as one of the several means to achieve sustainable development. Other messages were given by

Dr. Nizar Mohamed, UNEP Regional Coordinator on NBF Projects for Asia-Pacific; Mr. Demetrio Ignacio, Jr., DENR Undersecretary for Policy and Planning and Chairperson of the NCC; Dr. Segfredo Serrano, DA Assistant Secretary for Policy and Planning and NCC Co-chair; and Dr. Rogelio A. Panlasigui, DOST Undersecretary for R&D and NCBP Chair.

Mr. Ignacio expressed appreciation of the valuable inputs provided by the stakeholders and stressed that government must show political will and come to a decision on the NBF. He also acknowledged the many challenges and the difficult responsibility faced in addressing the many diverse views. He emphasized that at the end of the day, what matters is not only business, or science, or the environment, or the Cartagena Protocol, or even biological diversity, but finding the formula that will provide the greatest good for the greatest number of people.

Dr. Serrano challenged the participants to be virulently parochial to the interest of the sector they represent; since it is only by shedding blood in the field of logical debate, while keeping in mind the national interest and patrimony that people begin to cultivate the fertile soil with which to reap policies, programs, and policy decisions that are very robust and consistent with the nation's goals and objectives.

Dr. Panlasigui highlighted three points: (1) harmonization and balance – harmonizing the provisions of the NBF with existing policies, laws, rules, and regulations dealing with biosafety issues, biotechnology activities, and concerns and the provisions of the Cartagena Protocol; (2) the essential role of the NCBP, which has been recognized as a repository of wealth and experience in regulating biosafety in the country and NBCP's acceptance of the challenge and commitment to serve as the lead agency in implementing the NBF; and (3) the need for a clear source of funds so that the NBF can be implemented.

The workshop and discussion during the national workshop focused on three sections of the national workshop draft of the NBF (now in the form of an EO), namely: (a) scope, objectives, and definitions; (b) administrative framework; and (c) decision-making process. Other sections of the draft NBF have already been acceptable to most stakeholders as early as the regional consultations and these are the sections that still contain contentious provisions, which need further discussion.

There was recognition that there are certain provisions that everybody wants to see in the NBF and that there are some provisions that will remain as issues or challenges and will remain unresolved for some. There was general consensus, however, that the NBF should move on.

4.3.4 Public participation in the NCC

Following the national workshop held in Tagaytay City, a revised draft of the NBF was prepared by the consultants based on the results of that workshop. The NCC draft of the NBF was deliberated on by the NCC in six meetings from March to August 2004. Thereafter, the NCC, through then DENR Secretary Elisea Gozun, endorsed a final draft to the secretaries of the various Departments (DA, DOST, DOH, DFA, DILG, DTI) and the NCBP for concurrence and/or endorsement for approval by the Office of the President, and further comments, if any.

Public participation continued through the presence of representatives of relevant stakeholders in these meetings. Indeed, one of the critical decisions made in the early stages (resulting from feedback in the EGW) was to allow stakeholders such as NGOs and industry to sit and participate actively in NCC meetings.

4.4 STAKEHOLDER ISSUES AND CONCERNS

The main issues and concerns raised by stakeholders in the series of consultations workshops are summarized below.

4.4.1 Scope of the NBF

The working draft of the NBF limited the scope of the NBF to products of modern biotechnology, exotic species, and IAS. Several differing views, however, were raised on the scope of the NBF. Some opined that the scope should be broadened to include all newly bred organisms, whether products of conventional biotechnology, traditional biotechnology, or organic methods, particularly because a lot of new and natural products that are being discovered or prospected have risks to human health, and must satisfy the biosafety principle. Others felt that the NBF should be viewed in the perspective of national interest - for biosecurity, trade, and commerce.

Other participants suggested limiting the scope of the NBF to GMOs and genetic engineering only; since this is what is being debated on and is highly contentious. Moreover, the Cartagena Protocol clearly covers GMOs only. Others argued that the biotechnology regulatory system needed to address GMOs and exotic species, and IAS are not exact overlays and one cannot simply be used for the other. For example, RA for exotic species and IAS requires a different set of scientists (e.g., ecologists, etc.) than RA for GMOs (e.g., molecular biologist).

By putting these two very different organisms into one framework, one runs the risk of confusing the public by suggesting some comparability between the two. In fact, as the draft NBF recognizes, while GMOs offer significant potential benefits for the Philippines, IAS are, by definition, destructive and present substantial and known threats to the environment.

The same concern for the inclusion of products of modern biotechnology, exotic species and IAS in the regional and national drafts of the NBF were reechoed in the regional and national workshops. Participants reasoned that their release into the environment is a biosafety concern.

The NCC further discussed the merits of including exotic species and IAS in the scope of the NBF; considering that the processes provided for under the NBF primarily address GMOs and there might be potential difficulty in applying the same to the issue of exotic species and IAS. However, towards the end of

the NCC review, it was decided to retain the inclusion of exotic species and IAS with a caveat that the principles, mechanisms, and processes developed and implemented under the NBF may apply, when allowed by law, in addressing the issue of exotic species and IAS. Where appropriate, the administrative and decision-making systems under the NBF may also be adopted in addressing this issue.

4.4.2 Principle of subsidiarity

In the EGW and in written comments on the working draft of the NBF, there was much discussion on the principle of subsidiarity.

Subsidiarity under Article 25 of the CBD specifically refers to the establishment of a subsidiary body on scientific, technical, and technological advice. The nature of this body is scientific rather than political. The concept of subsidiarity in the NBF, however, treats LGUs as decision-making subsidiary bodies. It recognizes the substantial influence of local governments on the final decision making on biosafety because they have a better knowledge of the total picture locally, particularly on the socioeconomic implications of a biosafety decision.

This is viewed by some as a derogation of the subsidiarity provision under the CBD, while providing it a semblance of being technical by limiting this delegation of decision making at the lowest level "where competence exists." Not only was scientific body replaced by a political entity, worse, non-biosafety considerations such as socioeconomic implications were inserted as well. It was recommended that the principle on subsidiarity be amended to reflect the language and intent of the similar provision found in the CBD.

Others suggested that the principle of subsidiarity should be rethought and that a venue for review by a higher body be considered in case of conflicts in decisions or in the resolution of science-and technology-related policy issues. Others opined that the principle of subsidiarity, as it is stated, will be subject to political influences. LGUs should, therefore, only participate in the development of the standards and information requirements that are used to inform a decision but should not become directly involved in case-by-case approvals, other than as a source of information and expertise that decision makers can call on.

The same issues, concerns, and arguments on the principle of subsidiarity were again raised in the regional and national workshops. Some

participants contended that while this principle may be ideal, it would work only if there was sufficient technical expertise at the local level. However, others pressed that the lack or insufficiency of competence at the lowest level should not undermine the role of LGUs as laid down in the Local Government Code.

Instead, the government should take responsibility in raising the capacity of local governments and local units of relevant agencies in biosafety. Without recognizing the need for capacity building, the principle of subsidiarity means nothing since it will always be undermined by the issue of lack of competence, which is the current state of LGUs.

Other participants opined that decisions can be made locally provided there is local participation by the agencies of the DA, DENR, DOH, and DOST; and experts from local and national research institutions and academe in assisting the LGU arrive at well-informed decisions. The other position is that decisions should not be done at the local level, but the views of LGUs should be considered in biosafety decision making.

The NCC finally decided for a reformulation of the principle to indicate that "as provided by law and where competence exists, all levels of government, including LGUs, shall participate in implementing the NBF."

4.4.3 Socioeconomic, ethical, and cultural considerations

From the start of the consultations, stakeholders have had opposing views on the inclusion of socioeconomic, ethical, and cultural considerations in biosafety decision making. It was acceptable to some who felt that it was very important to assess the socioeconomic dimensions of the technology. It was, however, unacceptable to others who felt that socioeconomic, ethical, and cultural considerations have no relevance to biosafety principles.

In particular, three options were proposed: (a) exclude completely, except those socioeconomic considerations explicitly allowed under the Cartagena Protocol; (b) include comprehensively; and, (c) limited and qualified inclusion.

Article 26 of the Cartagena Protocol provides that Parties, in reaching a decision, may take into account, consistent with their international obligations, socioeconomic considerations arising from the impact of LMOs (or GMOs) on the conservation and

sustainable use of biodiversity, especially with regard to the value of biological diversity to indigenous and local communities. This properly limits the socioeconomic considerations that may be taken into account and only to the extent that it is consistent with international obligations.

Some scientists argued that biosafety is primarily a scientific procedure. It specifically addresses health and environment safety, and the only objective way this can be evaluated is through a proper, science-based risk-assessment and risk-management process.

Therefore, all provisions that are not germane to science-based biosafety assessment, in particular the so-called "socioeconomic considerations," "social impact assessment," and "parallel and simultaneous process of socioeconomic risk evaluation" should be deleted. There should be no such reference in a biosafety framework as there are other existing frameworks where it will apply.

Industry representatives opine that it is important to define the parameters, standards, and mechanisms for socioeconomic, ethical, and cultural assessments, including when it is appropriate or applicable.

The type of ethical, religious, and cultural requirements set forth in the NBF are highly unusual for biosafety regulation, or indeed for the regulation of any technology or product and are *per se* not science-based. These considerations may be included, as provided for in the Cartagena Protocol, but should not be made mandatory, the point being that socioeconomic issues are normally addressed by the technology generators themselves before any marketing decisions are made. It is they who ultimately take the risks for commercial failure and not the farmers because the latter are given the choice whether to adopt the technology or not.

The move for socioeconomic, ethical, and cultural assessments parallel to and simultaneous with RA is nearly impossible to implement and would unnecessarily delay the regulatory decision-making process. Conducting separate socioeconomic, ethical, and cultural assessments adds a layer to the bureaucracy, spiral the cost for the applicant which can impact on the final price of the product once commercialized. It is important to recognize that protecting the interest of the community and the consumers includes giving due concern to the business sector.

Some government representatives also expressed that socioeconomic considerations are outside the coverage of biosafety assessment but are an inherent function of relevant departments and should be properly placed within its policy or planning units. In addition, socioeconomic studies are done only on the assumption that the safety of the technology to humans and the environment has been determined under biosafety rules.

It is also important to assess the extent to which the treatment of socioeconomic considerations in the NBF is consistent with existing international obligations of the Philippines, particularly that of WTO obligations. The Cartagena Protocol explicitly allows Parties to take into account these considerations in making biosafety decisions and the WTO agreements also allow this so long as these considerations are not used principally as trade restraints (in other words, we are not allowed to invent such issues but if they are legitimate concerns, the WTO agreements allow us to take them into account).

In particular, such assessments should be implemented in a manner consistent with Article 26 of the Cartagena Protocol on Biosafety and GATT 1994's Article XX (b) and (g), which allow countries to adopt or enforce measures that would otherwise be inconsistent with the basic trade obligations but which nevertheless are, inter alia, necessary to protect human, animal or plant life or health, or relating to the conservation of exhaustible natural resources if such measures are made effective in conjunction with restrictions on domestic production or consumption, provided that such measures must not be applied "in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail, or a disguised restriction on international trade."

Participants supporting the inclusion of these considerations in the NBF recommended that considerations should be taken into account at all times in coming up with biosafety decisions (i.e., from contained use to open field release to commercialization). These considerations have a rightful place in the NBF since science and technology has a very strong potential impact on society. Thus, biosafety as a related concern is appropriately considered within a socio-cultural context. Even ethical guidelines are culturally influenced.

In the regional and national workshops, there was still much discussion on whether

socioeconomic considerations should be explicit in the NBF when it is not so in the Cartagena Protocol and whether these considerations prevail over science. It was beginning to be clear to the participants that socioeconomic, ethical, and cultural assessments are separate and distinct from RA and that biosafety determination was strictly science-based. Generally, however, the use of socioeconomic considerations in decision making was accepted; but there should be a careful balance in looking at the various considerations, parameters, and mechanisms for decision making, including when it is applied in the decision-making process.

At the NCC review, discussions on the use of "may" (voluntary) and "shall" (mandatory) in taking into account socioeconomic considerations in biosafety decision making continued to prevail. Finally, after its review following the results of the consultations and positions of the key departments, the NCC agreed that RA (or biosafety assessment) is strictly science-based. RA is separate and distinct from socioeconomic, ethical, cultural, and other assessments; and conducted separately from these assessments. The conduct of socioeconomic, ethical, cultural, and other assessments in biosafety decision making should be considered prior to commercialization and only after a biosafety (science-based RA) determination has been made. The following reformulation in Section 5.4 of the NBF was agreed on: "Consistent with Article 26 of the Cartagena Protocol, concerned government departments and agencies may take into account socioeconomic considerations arising from the impact of regulated articles on the conservation and sustainable use of biological diversity, especially with regard to the value of biological diversity to indigenous and local communities.

The 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 RA and in a transparent, participatory, and rigorous manner."

4.4.4 EIA

The role of EIA in biosafety decision making was another major point of contention, with a range of positions raised. On the one hand, EIA was said to have no relevance to biosafety principles. On the other hand, all biosafety decisions must be subjected to the Philippine EIS Sytem. The middle view is that several biotechnology research activities will not

require EIA but most field releases, whether general or depending on extent of release, could fall under the EIS System.

The Philippine EIS System requires every proposed project and undertaking, which significantly affects the quality of the environment to prepare an EIS after conducting an impact assessment study. Under the said law, no person, partnership, or corporation shall undertake or operate any such declared ECP or ECA without first securing an ECC. The release of GMOs into the environment is not listed as an ECP, but the area where it will be released may qualify as an ECA. It is also possible that the DENR may require additional environmental safeguards prior to their release.

Initial position of the DA indicated that modern agriculture biotechnology is a novel process or technology applied to the same farming activity. It does not involve a change in the traditional use of the prime agriculture land as in the case of the conversion of agriculture land to non-agriculture use, which would require an EIA. Hence, EIA is not relevant to biosafety assessment of biotech agriculture plants.

This is contrary to the argument that the release of GMOs into the environment poses risks to the environment, and for which EIA should be applied. DA acknowledged this mandate of the DENR and proposed that the EIA process be integrated into or harmonized with the DA approval process, particularly its RA protocol, rather than have two parallel processes. It was further suggested that DENR take the lead in undertaking the EIA of products of modern biotechnology intended for bioremediation, improvement of forest genetic resources and terrestrial wildlife species, which fall under its mandate; and review and monitor environmental RAs of other uses, in coordination with other departments and agencies and the DA continues to regulate plants and plant products aided by an environmental RA as per approval process under DA-AO No. 8, with the participation of the DENR. There was a general understanding that DENR and DA need to harmonize the EIS system and DA-AO No. 8 as they relate to biosafety.

Other participants stated that the inclusion of a full EIA into the process is yet another potentially complicating factor, raising similar concerns as socioeconomic considerations.

While a body of knowledge exists nowadays on RA of GMOs, experience is very limited with regard to socioeconomic considerations and EIA as applied to GMOs. Several countries have established separate programs and mechanisms to generate more detailed environmental and socioeconomic impact data and advice, which feed into the ultimate decision-making process, but are not an integral and mandatory component of a case-by-case evaluation. Some participants further opined that while a full EIA may not be warranted, the application of other provisions under the EIS system should be considered. This includes the posting of an environmental bond by proponents to answer for any untoward incident related to release and commercialization, and the establishment of an environmental rehabilitation fund to be sourced from the application fees.

The NCC review also concluded that the application of the EIA system to biosafety decisions shall be determined by concerned departments and agencies subject to the requirements of law and the standards set by the NCBP. Where applicable and under the coordination of the NCBP, concerned departments and agencies shall issue joint guidelines on the matter.

4.4.5 Expanded composition and functions of the NCBP

Another major concern raised was on administrative and implementing structures and the need to clearly identify roles and responsibilities, as well as authorities, liabilities, and accountabilities.

The NBF should review the roles and functions of the NCBP and provide an alternative to this institutional structure and not be limited by the existing EO that created the mandate of NCBP. The existing NCBP should be further strengthened in two areas: first, additional resources for its main tasks of formulating policy, setting biosafety standards and commissioning expert panels; and second, explicit recognition by the duly constituted regulatory bodies in the executive departments of the NCBP's scientific competence and authority on matters related to biosafety.

The mandates of the various departments are fairly clear, however, the actual process for decision making and how decisions would be taken (and by whom) in light of the input of the many different agencies involved is not clear. Typically, a national committee might be established for decision making with representation from relevant departments and

institutions, but the decision would be based on the scientific RA conducted by independent scientific experts. The present draft appears to create a large bureaucracy for decision making that requires multiple individual department or agency approvals that are not based upon and have little to do with the scientific RA. While many of the factors listed can and should be taken into account, a streamlined administrative process for receiving, handling, and responding to requests for authorizations, with appropriate mechanisms for inter-agency input or consultations, needs to be created, with decisions based on the scientific RA, as described in the Biosafety Protocol.

The difficulty of having many different government agencies addressing the concerns on biotechnology and biosafety considering the amount of red tape in most developing countries was noted. The need for a single window or desk in the government that will address all concerns on biotechnology and biosafety-related issues was suggested and supported by several stakeholders.

At the regional workshops, various structures were suggested, namely: (1) create a single independent, higher, oversight agency or council that will oversee all biotechnology efforts from research to release stages; (2) create new body under the Office of the President; (3) create a coordinating body and leave implementation to different agencies; and, (4) strengthen the NCBP by amending membership and functions, and ensuring funds for its operation.

The national draft of the NBF (compared to the regional draft) proposed the creation of a National Biosafety Board or NBB whose main task is policy making. The NBB would serve as the highest policy-making body for biosafety and monitor the implementation of the NBF to the end that an effective, coordinated and systematic research, projects, and programs are achieved. Under this board is the NCBP.

There were various reactions to this proposal. Some wanted a clarification of the role of NCBP in relation to the NBB. Some suggested creating a commission rather than a board (a commission is more permanent than a board) that is co-terminous with the term of the President. Some emphasized that there is no need to establish a super body, rather there should be harmonization to address overlapping issues across departments. What needs to be seen is the organizational

infrastructure and consequent relationships required to implement the NBF.

Others suggested that there should be only one body (whether it is NBB or NCBP), strengthen it, give it all the functions of both NBB and NCBP, and put it either under DOST or under the Office of the President.

Based on the results of the national consultation and using the best judgment of the NBFP consultants, the NCC draft of the NBF pushed for the strengthening of the NCBP instead of creating another layer of bureaucracy. In the NCC review, it was agreed to expand the powers of the NCBP by giving it policy-coordinating and standard-setting functions, with concerned departments exercising their mandates as provided by law. There was much discussion on the composition and number of NCBP membership and funding. In particular, it was suggested to raise the level of membership to secretaries or designated representatives in order to strengthen the commitment of each department in terms of decision making and funding support for all NCBP and its related activities. The proposed number of 15 members, composed of representatives from science and technology (as permanent Chair), agriculture, health, environment and natural resources, foreign affairs, trade and industry, and interior and local governments; representative of civil society, community representative from the farmers, fisherfolk, and indigenous sector; representative from industry; a biological scientist; a physical scientist; an environmental scientists; a health scientist; and a social scientist was considered too big and may be unwieldy. The creation of an executive committee and technical working group was proposed. A transition period of one year allowing the NCBP and its to continue to exercise its present functions under EO 430 until such time that it has completely reorganized under the NBF was also proposed. Funding shall be provided from the allocations of the DENR, DA, DOST, and DOH arethereafter included in the General Appropriations Act.

4.4.6 Other issues and concerns

Other issues and concerns and the spectrum of opinions raised during the consultations, which need mention include the following:

- ***Use of the term Precautionary Approach***
  Several comments were raised on the use of the precautionary principle in the NBF given that the internationally accepted definition of the term is still unclear. It was strongly recommended to use the

precise terminology used in the Cartagena Protocol (Article 1, Objective), which is "precautionary approach." This term is clearly defined by Principle 15 of the Rio Declaration, enjoys international consensus ,and is referred to as a guiding principle of the Cartagena Protocol.

- ***Role of LGUs in biosafety decision making***

  Comments raised on the role of LGUs in biosafety decision making were similar to those raised on the issue of subsidiarity. Biosafety assessment is a highly scientific exercise for which LGUs do not as yet have the competence. Scientists argue that like plant and animal quarantine, it is national in character and cuts across local government jurisdictions and should therefore be reserved for NCBP and national regulatory bodies. Concerns were also raised that LGUs are political in nature, may be influenced by lobby groups, and therefore may stymie the decision-making process.

  A needs-based capacity-building and awareness-raising program is important to raise the level of understanding and appreciation of this science by the LGUs.

- ***Funds***

  Other stakeholders felt that the NBF still falls short with respect to issues relating to implementability, mainly on account of its undefined and unclear funding commitment. Several proposals were put forth to ensure funding for implementation. Among them: (1) specific budgetary allocations should be provided for in the General Appropriations Act of the respective departments involved, in a committed and sustainable basis for its implementation; (2) regulatory agencies should explore the possibility of charging administrative/ regulatory fees that at least covers full cost of services being rendered; (3) tap Agricultural Competitiveness Enhancement Fund (ACEF) specifically from the importation of GM products; (4) consider establishing a biosafety trust fund to be managed by an inter-agency body; (5) enter into a joint Memorandum of Agreement among key departments for sharing of funds; and, (6) a statutory legislation with specific budgetary commitments should be put forth in the form of a Republic Act (RA).

Others expressed the opinion that congressional action or a law is not a guarantee that funds will be made available for NBF implementation. A case in point is the AFMA, which despite specific provisions of budget, cannot fully take off. There is a need to look at creative ways to finance and sustain the implementation of the NBF because no matter how good the intent, the NBF will be difficult to implement without funding.

- *Capacity building*

  There was consensus on the need to consider key elements in capacity building such as needs assessment. Others felt the need for more rigorous and cost-effective capacity-building modalities than just exposure to seminars, study tours, etc. Areas for training should not only focus on technical aspects but should also include participatory processes, socioeconomic aspects, resource mobilization, standard modules/curricula/ tools, knowledge management mechanisms, etc. Others saw the need to train PhDs and experts who can provide very well considered and well thought out biosafety analysis for the decision makers to implement.

- *Monitoring*

  The importance of post-approval monitoring of biotechnology products was emphasized. Some noted the need for an impact monitoring framework or process to determine, even in the absence of new relevant information, the correctness of a biosafety decision through time. What happens after a biosafety decision may not be the same as the situation before such decision was made.

- *Liability and compensation*

  There should be a provision for accountability and compensation of unforeseen long-term negative effects to the environment and damages caused to users.

- *Labeling*

  Some stakeholders view labeling as a biosafety issue because there can be no effective monitoring of health and environmental impacts if the product itself is not labeled. Labeling, to some, is a necessary feature of product identification and is a means for information and public awareness raising. Appropriate labels are consumer rights, consistent with the Consumers Act of the Philippines and the

constitutional provision on consumer protection. It is also a safety measure. Others, however, do not see labeling as a biosafety issue.

- ***Legislation***

  It should be noted that throughout the consultations, the need for a law on biosafety was raised to address issues that require congressional action (i.e., creating new offices, budget, penal sanctions and civil remedies, including liability and redress). However, also throughout the consultations, there was consensus that due to the rapid development of the technology, it would be more prudent to come up with an executive order or an administrative regulation and based on the lessons learned, formulate a law at a later in time. An executive order or an administrative regulation will provide more flexibility in case there is a need to amend provisions that are unclear or are difficult to implement or are not attune to current developments. It also takes a shorter time to amend compared to a law. A periodic review of the NBF and lessons learned from its implementation shall be documented, and at an appropriate time, conveyed to Congress for purposes of developing, drafting, and adopting legislation on biosafety.

4.5 LESSONS LEARNED AND BEST PRACTICES

There are lessons that can be learned from the experience of the Philippines in developing its NBF. These are:

4.5.1 Public participation and legitimacy

Public participation, when done right, increases the legitimacy of a process of developing a biosafety framework. Such a process can be extremely controversial, and when led by the government, can be perceived by some stakeholders as inherently biased. The Philippines is no exception to this, given the stated policy on modern biotechnology issued earlier by President Gloria Macapagal Arroyo. The extent and the manner through which the relevant stakeholders were able to participate in developing the draft framework have gone a long way to legitimizing the process – and ultimately its result.

4.5.2 Uunintended benefits of a good process

In developing a biosafety framework, the process can result in significant unintended benefits, making such process perhaps more

significant than its result. Clearly, the process of developing the NBF has had important consequences for biosafety decision making in the country. For one, it has emphasized to the major governments and department agencies the importance of coordinating their respective jurisdictions and harmonizing overlapping policies, rules, and regulations.

4.5.3 Dialogue among stakeholders

Another unintended consequence resulting from a good process is that public participation can engender or facilitate a dialogue, over a sustained period of time among stakeholders with diverse and even opposing viewpoints. This happened in the Philippines where the public participation processes (the regional and national workshops in particular) became a "safe haven" for discussion and disagreement. As the results of the workshops illustrate, the stakeholders did not necessary resolve their differences but certainly the processes were quite successful in clarifying positions.

4.5.4 Innovation and imagination through public participation

Public participation also contributes to the quality of the biosafety framework by identifying innovative and imaginative solutions to complex issues. Through sustained discussion, stakeholders were able to clarify issues and more importantly brainstorm for solutions in some of the most critical issues. These include issues like:
(a) incorporating environmental assessment into the biosafety decision-making process; (b) dealing with socioeconomic, cultural, and ethical considerations in making biosafety decisions; and, (c) dealing with the challenge of strengthening the NCBP.

4.5.5. Best practices in public participation

Public participation, to work, must be conducted and implemented well. It should not be resorted to for show or as a token gesture but as a serious attempt to identify and include in the policy process the viewpoints of relevant stakeholders. An understanding of stakeholder views is not however a guarantee for success. The public participation process must also be transparent, facilitated in an excellent manner, fair and consistent, inclusive, and aimed at problem solving.

Transparency

Public participation processes must be always conducted in a transparent manner. In the NBF process, for example, stakeholders were provided with public notice of processes and availability of documents within a reasonable time frame. This enabled them to prepare for

meetings and workshops and to provide written comment on documents that were distributed.

Facilitation

Good facilitation is an essential condition for success in any public participation process. This is even more crucial for a topic like modern biotechnology and GMOs where stakeholders have strong and opposing views. The facilitation must be independent and neutral and must be directed at identifying solutions rather than rehashing old arguments. In this respect, the DAP facilitators in the NBF process met these characteristics of good facilitation.

Fairness and Consistency

Related to the need to have excellent facilitation is the absolute imperative for the organizers of a public participation process to be fair and consistent with all stakeholders. These characteristics were clearly evident in the NBF process from the selection of participants in all the workshops to consistently reflecting the results of discussion in subsequent drafts of the framework.

Inclusive participation

A critical element for the success of the public participation process followed in developing the NBF was the inclusion of relevant stakeholders throughout the regions of the country and from all affected sectors. This inclusive participation meant the process (and its result) benefited from the diversity of views and the brainstorming that results from engaged discussion.

Problem solving

The final best practice of public participation that can be identified in the Philippine experience of developing the NBF is the manner in which the public processes became a venue for problem solving and identification of solutions. As noted above, this is clear in how the process helped identify solutions to such complex issues as the role of environmental assessment in biosafety decision making; in incorporating socioeconomic, cultural, and ethical considerations in making biosafety decisions; and in strengthening the NCBP.

4.6 CONCLUSION

The EO establishing the NBF, prescribing guidelines for its implementation, strengthening the NCBP, and for other purposes has not yet been officially adopted. The DFA and DOH have given their full concurrence on the NBF. The concerns of the DTI, DILG, and DA have been adequately

addressed. What remains to be addressed are the concerns raised by the DOST and NCBP as regards the NCBP expanded structure and functions; the change of the name NCBP in the NBF to NBB of the Philippines so that there is a clear distinction between the current NCBP and the strengthened NCBP; and. the provision of specific budgetary allocations in the General Appropriations Act of the respective departments involved, in a committed and sustainable basis for its implementation, and more importantly in the form of a republic act instead of an executive order. How the decision makers conclude the final stages of this process matters in the final evaluation of this experience.

Endnotes

1 Unless otherwise indicated information was obtained from the Encyclopedia Americana

2 BAS 2002 agricultural statistics

3 Management options for the Golden Apple Snail www.philrice.gov.ph

4 PROSEA, Plant Resources of Southeast Asia Vol 11

5 Major weeds of the Philippines 1984 Moody K, Munroe CE, Lubigan RT, Paller Jr EC Weed Science Society of the Philippines UPLB

6 Philippine Daily Inquirer, Aug 8, 2003

7 GM Science Review First Report pp33 www.gmsciencedebate.org/report/

8 http://www.flair-flow.com/industry-docs/ffe52002.html

9 MIMS, Vo. 32 No.2 2003

10 www.amgen.com/product/AboutEpogen.html accessed Aug 19, 2003

11 Fisheries Code, sec. 10.

12 R.A. No. 9147, Sec. 5(j). This is complicated further under Sec. 13, which prohibits the introduction of exotic *wildlife,* and corn is not a wild [but domesticated/ cultivated] species.[1]

13 In practice, for example, the NCBP can issue a regulation [effectively a joint AO] that will automatically supersede general regulations in the DA, DENR and DOH, but limited only to the subcategory of regulated materials or activities involving GMOs.

14 Katz 2001.

15 Kolehmainen 2001. She calls for a moratorium on the sale of genetically modified food and crops until adequate safety testing answers the questions the technology raises.

16 Adler 2000. He adds: “One can readily see the failings of the precautionary principle if one considers the consequences of foregoing technologies that the world now takes for granted. ‘If our technologies had remained stuck in the past and if somehow the world’s population had nevertheless been able to grow to its current level, the impact of humanity on the natural environment would have been calamitous.’ Had agricultural productivity in 1993 remained what it had been in 1961, existing levels of food production would have required increasing agricultural land by 80% or more over 1961 levels. In other words, an additional 3,550 million hectares—over one-quarter of the earth’s land area excluding Antarctica—would have had to be converted to agricultural uses.”

"Habitat loss around the world poses a real threat to biodiversity. Absent advances in agricultural production, the world's burgeoning population, and the consequent increased demand for food production, will accelerate this trend. If the parties to the Convention on Biological Diversity want to arrest this trend, their efforts would be better spent building institutional capacities for habitat conservation. A global regulatory regime for biotechnology will not do much to stem the loss of biological diversity. If anything it could make this real problem worse." (citing others).

[17] Löfstedt, et al. 2002. "Research might help to prevent such excesses, by partitioning technologies into analytically distinct categories, suited to common rules. For example, is there a reasoned basis for treating agricultural biotechnology based on genetic modification differently than that based on genomics, for identifying alleles that could then be selected through conventional breeding? Are there general rules for categorizing the objects of regulation, assuming no institutional constraints?" (citing others).

[18] Giampietro 2002.

[19] Dratwa 2002.

[20] Current developments in tort, environmental torts specifically, even allow suits in instances where the private interests are minimal and the public interest [e.g. damage to ecosystem] is more prominent. Yet, these are still private suits.

[21] DAAO No. 8, series of 2002. Sec. 5, Sec. 6(A)(2), Sec. 8(A)(2).

[22] Jepson 2002. "GMOs' ontological ambiguity encourages rescaling of governance and the creation of new spaces of political engagement. State-level politicians and activists, who may draw upon the regional linkages to global markets and international support, can negotiate the limits and rules for releasing GMOs. They challenge the supremacy and concentration of bio-knowledge in the hands of the state or transnational corporation. IDEC and Greenpeace have further changed the politics by drawing from globalized anti-GM discourses and international consumer advocacy groups to help redefine how this new biotechnology is to be integrated in the country's production and food systems. Moreover, the two groups exploit the very nature of transgenic crops to pry open the narrow regulatory scope that CTNBio has defined for GM release into the environment. They have actively attacked CTNBio's authority to broaden the scope of GM policy debate to incorporate the murky health, environment and social questions."

"The Brazilian biosafety case is relevant because one can see how various actors — from federal technocrats, state-level opposition governments, and internationalized NGOs — use nature itself, or in this case the 'quasi-nature' to challenge biotechno logy power geometries. GMOs become political subjects in the politics of scale. What this case illustrates, perhaps to an extreme, is that any study of the politics of scale in relation to the environment, resource use, or 'nature' must consider seriously how resources—be they forests, water, climate, or genetic resources — shape and are intrinsic to how scale is contested and constructed in the broader context."

"Finally any study of globalization should not privilege the 'global' or the 'local'; rather, the challenge is to identify how new global relationships change political and economic geometries at all scales. As the Brazilian biosafety debate suggests, the globalization–environment question must be answered by exploring how political activism struggles over spatial geometries of power. Moreover, studies linking globalization and the environment should highlight how the struggle to upscale and downscale governance consequently redefines discourses, resources and power."

"Finally, my argument warns not to conflate the globalized political discourses, symbols, and tactics with actual environmental concerns. In this case, closer inspection revealed that GM crop experimentation and production are not artifacts of globalization, but that the political reactions to them are global in scope and strategy. Without careful analysis of the particular connections between global processes and environmental outcomes, analyses are doomed to reproduce the flawed 'juggernaut' globalization model."

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ANNEX A
(Draft Version 8.11.04)

MALACAÑANG
MANILA

BY THE PRESIDENT OF THE PHILIPPINES

EXECUTIVE ORDER NO.___

ESTABLISHING THE NATIONAL BIOSAFETY FRAMEWORK, PRESCRIBING GUIDELINES FOR ITS IMPLEMENTATION, STRENGTHENING THE NATIONAL COMMITTEE ON BIOSAFETY OF THE PHILIPPINES, AND FOR OTHER PURPOSES

WHEREAS, there is rapid expansion of the use of modern biotechnology not only for scientific research but also for products for commercial releases and purposes;

WHEREAS, there is a growing concern over modern biotechnology's potential impacts on the environment, particularly on biological diversity, on human health, and on social and cultural well-being;

WHEREAS, the Cartagena Protocol on Biosafety to the United Nations Convention on Biological Diversity which the Philippines signed on 24 May 2000 entered into force on 11 September 2003;

WHEREAS, there is a need to establish and implement a National Biosafety Framework that would respond to the challenges presented by modern biotechnology;

WHEREAS, the National Committee on Biosafety of the Philippines (NCBP) has played, since 1987, a pioneering and important role in developing and establishing the current biosafety system, and that it needs to be strengthened so that it can better respond to these challenges.

NOW, THEREFORE, I, **GLORIA MACAPAGAL-ARROYO,** President of the Philippines, by virtue of the powers vested in me by law, do hereby order:

SECTION 1. Adoption and Operationalization of the National Biosafety Framework. The National Biosafety Framework (NBF) for the Philippines, attached hereto as Annex A, is hereby adopted.

SECTION 2. Scope and Objectives. The NBF shall have the following scope and objectives:

2.1 Scope. The NBF shall apply to the development, adoption and implementation of all biosafety policies, measures and guidelines and in making biosafety decisions concerning the research, development, handling and use, transboundary movement, release into the environment and management of regulated articles.

The NCBP and concerned departments and agencies may apply, when allowed by law, the principles, mechanisms and processes developed and implemented under the NBF to similar problems such as addressing the issue of exotic species and invasive alien species. Where appropriate, they may adopt the administrative and decision-making systems established in this Order.

2.2 Objectives. The NBF shall have the following objectives:

2.2.1 Establish a science-based determination of biosafety to ensure the safe and responsible use of modern biotechnology so that the Philippines and its citizens can benefit from its application while avoiding or minimizing the risks associated with it;

2.2.2 Establish a decision-making system on the application of products of modern biotechnology that is efficient, predictable, effective, balanced, culturally appropriate, ethical, transparent and participatory; and,

2.2.3 Serve as guidelines for implementing international obligations on biosafety.

SECTION 3. Administrative Framework and Decision-Making processes. In making biosafety decisions, the administrative system and decision-making processes established in the NBF shall be complied with.

SECTION 4. Strengthening the National Committee on Biosafety of the Philippines (NCBP). The NCBP is hereby strengthened. Its mandate, functions, composition and organization are set forth in the NBF

SECTION 5. General Mandate on Departments, Offices and Agencies. All departments and agencies shall exercise jurisdiction and all other powers that they have been conferred with under existing laws. They shall be guided by the NBF and coordinate with each other in exercising such powers.

SECTION 6. Funding. The DOST, DENR, DA, and DOH shall allocate funds from their present budgets to implement the NBF, including to support the operations of the NCBP and its Secretariat for 2004 and 2005. Starting 2006 and thereafter, the funding requirements shall be included in the General Appropriations Bill submitted to Congress.

These concerned departments, on an annual or other periodic basis, shall enter into agreement on the sharing of financial and technical resource to support the NCBP and its Secretariat.

SECTION 7. Transition. The NCBP and its present members shall continue to exercise their present functions under EO 430 until such time that it has completely reorganized under the NBF, which reorganization shall be completed within one year of its effectivity.

All members of the NCBP to be appointed by the President, as required by the NBF, shall assume their positions within the same period of time.

SECTION 8. Repealing and Amending Clause. All orders, rules and regulations or parts thereof which are inconsistent with any of the provisions of this Order are hereby repealed or amended accordingly.

SECTION 9. Effectivity. This Order shall take effect immediately.

DONE, in the City of Manila, this ____ day of _____ in the year of our Lord two thousand and four.

GLORIA MACAPAGAL-ARROYO

By the President:

Executive Secretary

The National Biosafety Framework for the Philippines

SECTION 1. CONSTITUTIONAL POLICIES

In implementing the National Biosafety Framework (NBF), the following state policies mandated by the 1987 Constitution shall guide the concerned government department and agencies:

1.1 ***Right to Health.*** The State shall protect and promote the right to health of the people and instill health consciousness among them (Article II, Section 15);

1.2 ***Right to a Healthy Environment.*** The State shall protect and advance the right of the people to a balanced and healthful ecology in accord with the rhythm and harmony of nature (Article II, Section 16);

1.3 ***Priority to Science.*** The State shall give priority to education, science and technology, arts, culture, and sports to foster patriotism and nationalism, accelerate social progress, and promote total human liberation and development (Article II, Section 17);

1.4 ***Role of the Private Sector.*** The State recognizes the indispensable role of the private sector, encourages private enterprise, and provides incentives to needed investments (Article II, Section 20);

1.5 ***Rural Development.*** The State shall promote comprehensive rural development and agrarian reform (Article II, Section 21) and shall provide support to agriculture through appropriate technology and research, and adequate financial, production, marketing, and other support services (Article XIII, Section 5);

1.6 ***Right of Indigenous Peoples and Communities.*** The State recognizes and promotes the rights of indigenous cultural communities within the framework of national unity and development (Article II, Section 22). The State, subject to the provisions of this Constitution and national development policies and programs, shall protect the rights of indigenous cultural communities to their ancestral lands to ensure their economic, social, and cultural well-being (Article XIII, Section 5);

1.7 ***Right to Information.*** Subject to reasonable conditions prescribed by law, the State adopts and implements a policy of full public disclosure of all its transactions involving public interest (Article II, Section 28);

1.8 ***Local Autonomy.*** The territorial and political subdivisions shall enjoy local autonomy (Article 10, Section 2);

1.9 Right to Participation. The right of the people and their organizations to effective and reasonable participation at all levels of social, political, and economic decision-making shall not be abridged. The State shall, by law, facilitate the establishment of adequate consultation mechanisms (Article XIII, Section 16);

1.10 Science and Technology. Science and technology are essential for national development and progress. The State shall give priority to research and development, invention, innovation, and their utilization; and to science and technology education, training, and services. It shall support indigenous, appropriate, and self-reliant scientific and technological capabilities, and their application to the country's productive systems and national life. The State shall regulate the transfer and promote the adaptation of technology from all sources for the national benefit. It shall encourage the widest participation of private groups, local governments, and community-based organizations in the generation and utilization of science and technology (Article XIV, Sections 10 and 12); and,

1.11 Consumer Protection. The State shall protect consumers from trade malpractice and substandard and hazardous products (Article. XVI, Section. 9).

SECTION 2. PRINCIPLES

The following principles, based on national and international law, shall apply in a mutually supportive manner to the implementation of the NBF:

2.1 Policy on Modern Biotechnology. The NBF shall be implemented in the context of the overall policy of the Philippines on modern biotechnology, to wit: The State shall promote the safe and responsible use of modern biotechnology and its products as one of the several means to achieve and sustain food security, equitable access to health services, sustainable and safe environment and industry development;

2.2 Policy on Sustainable Development. The overall policy of the Philippines on sustainable development, as laid down in Philippine Agenda 21, shall equally guide the implementation of the NBF;

2.3 A Balanced Approach. A balanced approach, which recognizes both the potential benefits and risks, shall guide the implementation of the NBF. This shall be based on recognition that modern biotechnology has significant potential for human well-being if developed and used with adequate safety measures for the environment and human health. Such approach recognizes both the potential benefits and risks of modern biotechnology to human health, agricultural productivity, food security, the livelihoods of the poor, biological diversity and the environment;

2.4 A Scientific Approach. The implementation of the NBF shall be based on the best available science and knowledge. Such science and knowledge must be of the highest quality, multi-disciplinary, peer-reviewed, and consistent with international standards as they evolve;

2.5 Socio-economic, Cultural, and Ethical Considerations. The socio-economic, ethical and cultural benefits and risks, of modern biotechnology to the Philippines and its citizens, and in particular on small farmers, indigenous peoples, women, small and medium enterprises and the domestic scientific community, shall be taken into account in implementing the NBF;

2.6 Using Precaution. In accordance with Principle 15 of the Rio Declaration of 1992 and the relevant provisions of the Cartagena Protocol on Biosafety, in particular Articles 1, 10 (par. 6) and 11 (par. 8), the precautionary approach shall guide biosafety decisions. The principles and elements of this approach shall be implemented through the decision-making system in the NBF;

2.7 Transparency and Public Participation. Decision taken under the NBF shall be arrived at in a transparent and participatory manner. Biosafety issues are best handled with the participation of all relevant stakeholders and organizations. They shall have appropriate access to information and the opportunity to participate in biosafety decision-making processes;

2.8 Consensus Building. In making biosafety decisions, all concerned government departments and agencies shall exert all efforts to find consensus among all relevant stakeholders using well-accepted methods such as negotiation, mediation, and other appropriate dispute resolution processes. Such consensus, to be achieved in a transparent and participatory manner, shall be based on the best available science and knowledge and shall not compromise public safety and welfare;

2.9 Principle of Subsidiarity. As provided by law and where competence exists, all levels of government, including local government units, shall participate in implementing the NBF;

2.10 Availability of Remedies. Effective access to judicial and administrative proceedings, including redress and remedy, shall be available in accordance with Philippine law;

2.11 International Obligations and Cooperation. In accordance with international law, the NBF shall be implemented in a manner consistent with and mutually supportive to the international obligations of the Philippines, in particular its obligations under international trade and environmental law. Multilateral, regional and bilateral cooperation in implementing the NBF, in particular its sections on capacity building and financial resources, shall be encouraged;

2.12 Efficient Administration and Timely Decision Making. The NBF decision making process must be conducted in an efficient, coordinated, effective, predictable, cost-effective and timely manner. Undue delay shall be avoided without compromising transparency, public participation, public safety, and public welfare; and,

2.13 Public interest and welfare. In cases of conflict in applying these principles, the principle of protecting public interest and welfare shall always prevail. No section or provision in this Framework shall be construed as to limit the legal authority and mandate of heads of departments and agencies to consider the national interest and public welfare in making biosafety decisions.

SECTION 3. SCOPE, OBJECTIVES AND DEFINITIONS

3.1 Scope. The NBF shall apply to the development, adoption and implementation of all biosafety policies, measures and guidelines and in making decisions concerning the research, development, handling and use, transboundary movement, release into the environment and management of regulated articles.

The NCBP and concerned departments and agencies may apply, when allowed by law, the principles, mechanisms and processes developed and implemented under the NBF to similar problems such as addressing the issue of exotic species and invasive alien species. Where appropriate, they may adopt the administrative and decision-making systems established in this Framework.

3.2 Objectives. The NBF shall have the following objectives:

3.2.1 Establish a science-based determination of biosafety to ensure the safe and responsible use of modern biotechnology so that the Philippines and its citizens can benefit from its application while avoiding or minimizing the risks associated with it;

3.2.2 Establish a decision-making system on the application of products of modern biotechnology that is efficient, predictable, effective, balanced, culturally-appropriate, ethical, transparent and participatory; and,

3.2.3 Serve as guidelines for implementing international obligations on biosafety.

3.3 Definitions. For purposes of this framework, the following terms shall mean:

3.3.1 "Biosafety" is a condition in which the probability of harm, injury and damage resulting from the intentional and unintentional introduction and/or use of a regulated article is within acceptable and manageable levels;

3.3.2 "Biosafety Clearing house" is an information exchange

mechanism established by the Cartagena Protocol on Biosafety to assist parties in the implementation of its provisions and to facilitate sharing and exchange of scientific, technical, environmental and legal information on, and experience with, regulated articles;

3.3.3 "Biosafety decisions" apply to the development, adoption and implementation of all biosafety policies, measures and guidelines and in making decisions concerning the research, development, handling and use, transboundary movement, release into the environment and management of regulated articles;

3.3.4 "Contained use" means any operation, undertaken within a facility, installation or other physical structure, which involves genetically modified organisms that are controlled by specific measures that effectively limit their contact with, and their impact on, the external environment;

3.3.5 "Genetically modified organism" also refers to "living modified organism" under the Cartagena Protocol on Biosafety and refers to any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology;

3.3.6 "Handling and Use" means the process by which regulated articles are moved, carried, transported, delivered, stored or worked with;

3.3.7 "Hazard" refers to traits inherent to or activities of a regulated article that may cause harm to human or animal health or to the environment;

3.3.8 "Management" means measures adopted after the release of regulated articles to ensure their safe use and, in cases of commercial release, shall also include product monitoring and product identification;

3.3.9 "Modern biotechnology" means the application of: a) in vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) or direct injection of nucleic acid into cells or organelles; or b) fusion of cells beyond the taxonomic family, that overcome natural physiological reproductive or recombination barriers and that are not techniques used in traditional breeding or selection;

3.3.10 "Product identification" refers to information on the presence of a regulated article in a particular product, as implemented by concerned departments and agencies through import and export documents, unique identification system, or similar applicable approaches such as product labeling;

3.3.11 "Product Monitoring" refers to any post-commercialization

measure that provides data on the fate and effects of the regulated article, in order to confirm compliance with regulatory requirements, collect information necessary for controlling and managing potentially adverse public health or environmental situations, assess environmental quality and detect unexpected or potentially damaging effects on human and animal health and the environment. Product monitoring helps reduce uncertainty remaining from risk assessment, confirm conclusions with additional data and provide informational feedback on system status or conditions;

3.3.12 "Regulated article" refers to a genetically modified organism and its products;

3.3.13 "Risk" refers to the combination of the likelihood that an adverse consequence of a biohazardous activity or trait will occur and the magnitude of such a consequence;

3.3.14 "Risk assessment" refers to the procedure that identifies, evaluates and predicts the occurrence of possible hazards to human and animal health and the environment and designs mitigating measures to avert or minimize these hazards;

3.3.15 "Risk management" refers to appropriate mechanisms, measures and strategies to regulate, manage and control risks identified in the risk assessment including those conditions imposed by concerned departments or agencies;

3.3.16"Transboundary movement" means the movement of a regulated article from another country to the Philippines; and,

3.3.17 "Transformation event" means one instance of entry, stable integration and expression of an introduced gene into a cell which then develops into a functional organism expressing the introduced gene.

SECTION 4. ADMINISTRATIVE FRAMEWORK

The administrative mechanism for biosafety decisions shall be as follows:

(a) National scientific and technical biosafety standards and standards on methods and procedures for ensuring biosafety in the country, shall be set by the NCBP consistent with existing laws;

(b) Basic policies on addressing public interests on biosafety shall be developed by the NCBP, provided the same are consistent with law and/or if such policies are found insufficiently addressed in existing mandates and regulations of pertinent agencies;

(c) Member-agencies of the NCBP shall continue to perform their regulatory functions in accordance with their legal mandates, provided that their

policies and programs relating to biosafety shall be discussed in the NCBP for purposes of harmonization with other agencies' functions;

(d) Other concerned agencies shall coordinate with NCBP on matters that may affect biosafety decisions as provided in Sections 4.7 to 4.14;

(e) Administrative functions required under the Cartagena Protocol on Biosafety shall be performed by agencies as provided in Section 4.14 and 4.15; and,

(f) The role of stakeholders and the general public shall be recognized and taken into account as provided in Sections 6 and 7.

4.1 ***Mandate of the National Committee on Biosafety of the Philippines (NCBP).*** The NCBP shall be the lead body to coordinate and harmonize inter-agency and multi-sector efforts to develop biosafety policies in the country (where such are not already stipulated by law) and set scientific, technical and procedural standards on actions by agencies and other sectors to promote biosafety in the Philippines; oversee the implementation of the NBF; act as a clearing house for biosafety matters; and coordinate and harmonize the efforts of all concerned agencies and departments in this regard.

4.2 ***Composition of the NCBP***. The NCBP shall be composed of the following:

4.2.1 The Secretaries of the Departments of Science and Technology, Agriculture, Health, Environment and Natural Resources, Foreign Affairs, Trade and Industry, and Interior and Local Governments or their designated representatives. The DOST Secretary shall be the permanent Chair;

4.2.2 A representative of civil society to be recommended by the Civil Society Counterpart of the Philippine Council on Sustainable Development (PCSD) to the NCBP and appointed by the President, serving for a term of three (3) years, renewable for another term;

4.2.3 A community representative from the farmers, fisherfolk and indigenous sector appointed by the President from a list submitted by nationally recognized sectoral organizations, serving for a term of three (3) years, renewable for another term;

4.2.4 A representative from industry appointed by the President from a list submitted by the Secretary of Trade and Industry, serving for a term of three (3) years, renewable for another term; and,

4.2.5 A biological scientist, physical scientist, environmental scientist, health scientist, and social scientist to be endorsed by the DOST Secretary upon the

recommendation of recognized professional and collegial bodies such as the National Academy of Science and Technology (NAST) and the Philippine Social Science Council (PSSC), and appointed by the President, serving for a term of three (3) years, renewable for another term.

4.3 ***NCBP Executive Committee and Technical Working Groups.*** The NCBP may create an Executive Committee and Technical Working Groups as it deems necessary and appropriate.

4.4 ***Meetings of the NCBP.*** The NCBP shall meet regularly as it deems fit and shall formulate its standards for making decisions.

4.5 ***NCBP Secretariat.*** The NCBP shall create a Secretariat that shall be based in the DOST. All other concerned agencies shall participate in the functions of the Secretariat.

4.6 ***Powers and Functions of the NCBP.*** As the lead body in implementing the NBF, the NCBP shall have the following powers and functions:

4.6.1 Biosafety Policy Functions

4.6.1.1 Assist concerned departments and agencies in formulating, reviewing, or amending their respective policies, measures and guidelines on biosafety;

4.6.1.2 Hold public deliberations on proposed national policies, guidelines, and other biosafety issues;

4.6.1.3 Provide assistance in the formulation, amendment of pertinent laws, rules and regulations;

4.6.1.4 In coordination with concerned departments and agencies and consistent with the requirements of transparency and public participation as provided in Sections 6 and 7 of the NBF, shall take the lead in periodically reviewing the NBF;

4.6.1.5 Issue detailed guidelines on the conduct of socio-economic impact evaluation of biosafety decisions; and,

4.6.1.6 Propose to Congress necessary and appropriate legislation.

4.6.2 Accountability Functions

4.6.2.1 Monitor the implementation of the NBF by concerned departments and agencies;

4.6.2.2 Ensure coordination among competent national authorities that have shared mandates;

4.6.2.3 Ensure that NCBP guidelines, and the principles and processes established

in this Framework are complied with by concerned departments and agencies; and,

4.6.2.4 Review procedures for accountability in biosafety decision-making by competent national authorities, with particular emphasis on ensuring independence and impartiality in such decisions.

4.6.3 Scientific Functions

4.6.3.1 Facilitate the study and evaluation of biosafety research and control and minimize the concomitant risks and hazards associated with the deliberate release of regulated articles in the environment;

4.6.3.2 Identify and evaluate potential hazards involved in modern biotechnological experiments or the introduction of regulated articles and recommend measures to minimize risks;

4.6.3.3 Recommend the development and promotion of research programs to establish risk assessment protocols and assessment of long-term environmental effects of regulated articles;

4.6.3.4 Develop working arrangements with the government quarantine services and institutions in the evaluation, monitoring, and review of projects vis-à-vis adherence to national policies and guidelines on biosafety;

4.6.3.5 Review and develop guidelines in the risk assessment of regulated articles for contained use;

4.6.3.6 Assist other agencies in developing risk assessment guidelines and procedures of regulated articles for field trials and commercial release;

4.6.3.7 Review the appointment of the members of the Institutional Biosafety Committees created by institutions engaged in activities involving regulated articles, upon recommendation by their respective heads of institutions;

4.6.3.8 Publish the results of internal deliberations and agency reviews of the NCBP;

4.6.3.9 Hold discussions on the comparative ecological, economic and social impacts of alternative approaches to attain the

purposes/objectives of the proposed genetic modification products and/or services; and,

4.6.3.10 Perform such functions as may be requested by concerned departments and agencies.

4.6.4 Capacity Building Functions

4.6.4.1 Assist in the development of technical expertise, facilities, and other resources for quarantine services and risk assessments; and,

4.6.4.2 Take the lead in developing and implementing a national capacity-building program for biosafety.

4.7 ***Mandate of the Department of Science and Technology***. The Department of Science and Technology (DOST), as the premiere science and technology body in the country, shall take the lead in ensuring that the best available science is utilized and applied in adopting biosafety policies, measures and guidelines, and in making biosafety decisions. The DOST shall ensure that such policies, measures, guidelines and decisions are made on the basis of scientific information that is of the highest quality, multi-disciplinary, peer-reviewed, and consistent with international standards as they evolve. In coordination with other concerned departments and agencies, and consistent with the requirements of transparency and public participation as provided in Sections 6 and 7 of the NBF, it shall exercise such jurisdiction and other powers that it has been conferred with under existing laws.

4.8 ***Mandate of the Department of Agriculture***. As the principal agency of the Philippine government responsible for the promotion of agricultural development growth, rural development so as to ensure food security and contribute to poverty alleviation, the Department of Agriculture shall take the lead in addressing biosafety issues related to the country's agricultural productivity and food security. In coordination with other concerned departments and agencies, and consistent with the requirements of transparency and public participation as provided in Sections 6 and 7 of the NBF, it shall exercise such jurisdiction and other powers that it has been conferred with under existing laws.

4.9 ***Mandate of the Department of Environment and Natural Resources***. As the primary government agency responsible for the conservation, management, development and proper use of the country's environment and natural resources, the Department of Environment and Natural Resources (DENR) shall ensure that environmental assessments are done and impacts identified in biosafety decisions. It shall also take the lead in evaluating and monitoring regulated

articles intended for bioremediation, the improvement of forest genetic resources, and wildlife genetic resources.

4.10 Mandate of the Department of Health. The Department of Health (DOH), as the principal authority on health, shall formulate guidelines in assessing the health impacts posed by modern biotechnology and its applications. The DOH shall also require, review and evaluate results of environmental health impact assessments related to modern biotechnology and its applications. In coordination with other concerned departments and agencies, it shall exercise such jurisdiction and other powers that it has been conferred with under existing laws.

4.11 *Mandate of the National Commission on Indigenous Peoples*. The National Commission on Indigenous Peoples (NCIP) shall take the lead in ensuring that the rights of indigenous peoples and communities are recognized and protected in all biosafety decisions made which affect them. In coordination with other concerned departments and agencies, and consistent with the requirements of transparency and public participation as provided in Sections 6 and 7 of the NBF, the NCIP shall exercise such jurisdiction and other powers that it has been conferred with under existing laws. In particular, the NCIP shall ensure that free and prior informed consent by indigenous peoples and communities has been given to the introduction and/or use of regulated articles within the ancestral lands and domains of indigenous peoples and communities.

4.12 Local Government Units. The autonomy of local government units (LGUs) is recognized under existing laws and regulations. In this regard, the DILG, in coordination with appropriate agencies, shall encourage and support the active participation of LGUs in capacity building, decision making, program planning, and implementation related to biosafety.

4.13 Mandate of Other Departments and Agencies. In coordination with other concerned departments and agencies, and consistent with the requirements of transparency and public participation as provided in Sections 6 and 7 of the NBF, all other departments and agencies shall exercise such jurisdiction and other powers that it has been conferred with under existing laws. In particular, the following departments and agencies shall participate in biosafety decision making, where appropriate: the Department of Foreign Affairs in promoting and protecting Philippine interests on biosafety in bilateral, regional and multilateral forums; the Department of Trade and Industry in relation to biosafety decisions which have an impact on trade, intellectual property rights, investments and consumer welfare and protection.

4.14 Focal Point and Competent National Authorities.

4.14.1 For purposes of Article 19 of the Cartagena Protocol on Biosafety, the national focal point responsible for liaison with the Secretariat shall be the Department of Foreign Affairs. The competent national authorities, responsible for performing the administrative functions required by the Protocol, shall be, depending on the particular genetically modified organisms in question, the following:

4.14.1.1 The Department of Agriculture, for biosafety decisions, when covered by the Protocol, concerning plants and plant products derived from modern biotechnology, fisheries and other aquatic resources, domesticated animals and biological products used for animal husbandry or veterinary purposes and biological agents used for biocontrol;

4.14.1.2 The Department of Science and Technology, for biosafety decisions concerning research and development, when covered by the Protocol;

4.14.1.3 The Department of Health, for biosafety decisions concerning pharmaceuticals for humans that are not explicitly excluded under Article 5 of the Protocol, i.e. pharmaceuticals which are not addressed by other relevant international agreements or organizations; and,

4.14.1.4 The Department of Environment and Natural Resources, for biosafety decisions covered by the Protocol that concern regulated organisms intended for bioremediation, the improvement of forest genetic resources, and wildlife genetic resources, and applications of modern biotechnology with potential impact on the conservation and sustainable use of biodiversity.

4.14.2 The national focal point and the competent authorities listed above shall, as appropriate, coordinate with the NCBP in accordance with its mandate under Section 4.1. For genetically modified organisms not falling under the jurisdiction of the competent authorities enumerated above, the NCBP shall designate the appropriate agency that shall act as such authority.

4.15 Biosafety Clearing House. Concerned government departments and agencies shall utilize the Biosafety Clearing House (BCH) of the Cartagena

Protocol on Biosafety in developing and adopting biosafety policies, guidelines, and measures and in making biosafety decisions. The NCBP Secretariat shall serve as the focal point for the BCH in coordination with the DENR-PAWB serving as the focal point for the Clearing House Mechanism (CHM) of the Convention on Biological Diversity.

4.16 Role of Stakeholders and the Public. The role of relevant stakeholders and the public in biosafety decisions is provided for in Sections 6 and 7 of this Framework.

SECTION 5. DECISION-MAKING PROCESSES

Biosafety decisions shall be made in accordance with existing laws and the following guidelines:

5.1 Standard of Precaution. In accordance with Article 10 (par. 6) and Article 11 (par. 8) of the Cartagena Protocol on Biosafety, lack of scientific certainty or consensus due to insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects of a genetically modified organism on the environment, particularly on the conservation and sustainable use of biological diversity, and on human health, shall not prevent concerned government departments and agencies from taking the appropriate decision to avoid or minimize such potential adverse effects. In such cases, concerned government department and agencies shall take the necessary action to protect public interest and welfare.

5.2 Risk Assessment. Risk assessment (RA) shall be mandatory and central in making biosafety decisions. It shall identify and evaluate the risks to human health and the environment, and if applicable, to animal health.

5.2.1 Principles of Risk Assessment. The following principles shall be followed when performing a RA to determine whether a regulated article poses significant risks to human health and the environment:

5.2.1.1 The RA shall be carried out in a scientifically sound and transparent manner based on available scientific and technical information. The expert advice of and guidelines developed by, relevant international organizations, including intergovernmental bodies, and regulatory authorities of countries with significant experience in the regulatory supervision of the regulated article shall be taken into account in the conduct of risk assessment;

5.2.1.2 Lack of scientific knowledge or scientific consensus shall

not be interpreted as indicating a particular level of risk, an absence of risk, or an acceptable risk;

5.2.1.3 The identified characteristics of a regulated article and its use which have the potential to pose significant risks to human health and the environment shall be compared to those presented by the non-modified organism from which it is derived and its use under the same conditions;

5.2.1.4 The RA shall be carried out case-by-case and on the basis of transformation event. The required information may vary in nature and level of detail from case to case depending on the regulated article concerned, its intended use and the receiving environment; and,

5.2.1.5 If new information on the regulated article and its effects on human health and the environment becomes available, and such information is relevant and significant, the RA shall be readdressed to determine whether the risk has changed or whether there is a need to amend the risk management strategies accordingly.

5.2.2 ***Risk Assessment Guidelines.*** The conduct of RA by concerned departments and agencies shall be in accordance with the policies and standards on RA issued by the NCBP. Annex III of the Cartagena Protocol shall also guide RA. As appropriate, such department and agencies may issue their own respective administrative issuances establishing the appropriate RA under their particular jurisdictions.

5.3 Role of Environmental Impact Assessment. The application of the EIA System to biosafety decisions shall be determined by concerned departments and agencies subject to the requirements of law and the standards set by the NCBP. Where applicable and under the coordination of the NCBP, concerned departments and agencies shall issue joint guidelines on the matter.

5.4 *Socio-economic, Ethical, Cultural and Other Considerations.* Consistent with Article 26 of the Cartagena Protocol, concerned government departments and agencies may take into account socio-economic considerations arising from the impact of regulated articles on the conservation and sustainable use of biological diversity, especially with regard to the value of biological diversity to indigenous and local communities.

The 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.

5.5 ***Decisions under the Cartagena Protocol***. For decisions required under the Cartagena Protocol on Biosafety, the competent national authorities identified may choose to adopt the procedures of the Advance Informed Agreement as provided in Articles 7, 8, 9, 10, 11, 12 and 13 of the Protocol or issue their own respective rules and regulations provided that such rules and regulations are consistent with the Protocol. In all cases, decisions under this Framework shall fall within those timeframes required under the Cartagena Protocol. As provided however in the Protocol, failure to comply with such timeframes shall not imply consent to an intentional transboundary movement of genetically modified organisms covered under the Protocol.

5.6 Monitoring and Enforcement. All concerned departments and agencies shall monitor compliance to the conditions attached to approvals and authorizations, especially on risk management, in a manner that is transparent, and in coordination with other agencies, including LGUs, and other stakeholders.

It shall also include monitoring for impacts, whether anticipated or not, of the introduced product on environment and health.

SECTION 6. ACCESS TO INFORMATION

The right of the public and the relevant stakeholders to information related to biosafety decisions is recognized and shall always be respected in accordance with the following guidelines.

6.1 ***Information on Applications***. Concerned departments and agencies shall, subject to reasonable limitations to protect confidential information as provided below, disclose all information on such applications in a prompt and timely manner. Such departments and agencies may require applicants to provide the information directly to concerned stakeholders.

6.2 ***Confidential Information.*** In all applications for approvals, whether domestic or foreign, concerned departments and agencies shall ensure that it has procedures and regulations to determine and protect confidential information; Provided, however, that the concerned agencies may refuse declaring the confidentiality of such information if the public interest in disclosure outweighs the prejudice that the disclosure would cause to any entity.

6.3 Information on Biosafety Decisions. The public and stakeholders shall have access to all biosafety decisions and the information on which they are based, subject to limitations set in Section 6.2 of this Framework. Such decisions shall summarize the application, the results of the risk assessment, and other relevant assessments done, the public participation process followed, and the basis for approval or denial of the application.

6.4 Information on Risk Management, Product Monitoring, and Product Identification. All relevant stakeholders shall have access to information related to risk management and product monitoring. Information on product identification shall be provided to the general public.

SECTION 7. PUBLIC PARTICIPATION

The concerned government departments and agencies, in developing and adopting biosafety policies, guidelines and measures and in making biosafety decisions, shall promote, facilitate, and conduct public awareness, education, and meaningful participation. They shall incorporate into their respective administrative issuances and processes best practices and mechanisms on public participation in accordance with the following guidelines:

7.1 ***Scope of Public Participation.*** Public participation shall apply to all stages of the biosafety decision-making process from the time the application is received. For applications on biotechnology activities related to research and development, limited primarily for contained use, notice of such application through the NCBP shall be sufficient unless public interest and welfare requires otherwise.

7.2 ***Minimum Requirements of Public Participation.*** In conducting public participation processes, the following minimum requirements shall be followed:

7.2.1 Notice to all concerned stakeholders, in a language understood by them and through media to which they have access. Such notice must be adequate, timely, and effective and posted prominently in public places in the areas affected, and in the case of field trials and commercial releases, in both national and local print and broadcast media. In all cases, such notices must be posted electronically in the internet;

7.2.2 Adequate and reasonable time frames for public participation procedures. Such procedures should allow relevant stakeholders to understand and analyze the benefits and risks, consult with independent experts, and make timely interventions. Concerned departments and agencies shall include in their appropriate rules and regulations specific time frames for their respective public

participation processes, including setting a minimum time frame as may be appropriate;

7.2.3 Public consultations, as a way to secure wide input into the decisions that are to be made. These could include formal hearings in certain cases, or solicitation of public comments, particularly where there is public controversy about the proposed activities. Public consultations shall encourage exchanges of information between applicants and the public before the application is acted upon. Dialogue and consensus-building among all stakeholders shall be encouraged. Concerned departments and agencies shall specify in their appropriate rules and regulations the stages when public consultations are appropriate, the specific time frames for such consultations, and the circumstances when formal hearings will be required, including guidelines to ensure orderly proceedings. The networks of agricultural and fisheries councils, indigenous peoples and community-based organizations in affected areas shall be utilized;

7.2.4 Written submissions. Procedures for public participation shall include mechanisms that allow public participation in writing or through public hearings, and which allow the submission of any positions, comments, information, analyses or opinions. Concerned departments and agencies shall include in their appropriate rules and regulations the stages when and the process to be followed for submitting written comments; and,

7.2.5 Consideration of public concerns in the decision-making phase following consultation and submission of written comments. Public concerns as reflected through the procedures for public participation shall be considered in making the decision. The public must be informed of the final decision promptly, have access to the decision, and shall be provided with the reasons and considerations resulting in the decision, upon request.

SECTION 8. CAPACITY BUILDING AND FINANCIAL RESOURCES

Implementing the NBF requires the design, adoption and implementation of a capacity-building program supported by adequate financial resources. The following considerations shall be taken into account in developing such a program:

8.1 Need for Capacity Building. To ensure the proper implementation of the NBF, the capacities of various sectors: policy-makers, regulatory agencies, local government units, research community and the general public involved in performing various tasks must be strengthened;

(a) Policy makers must be made aware of issues and provided with sufficient and most current information on biosafety for the enactment of appropriate policies, regulations and programs;

(b) Expertise and appropriate facilities in regulatory agencies must be developed for the safety assessment of regulated articles, harmonization of regulatory policies and procedures and monitoring compliance and outcomes to biosafety regulations;

(c) The research community must be supported to enable them to address the safety issues of regulated articles; and,

(d) The general public must be made aware of issues, provided with the correct information and enabled to participate in the biosafety decision-making process. The capacity of environmental and developmental non-government organizations, people's organizations, professional organizations, including industry and other concerned entities to assist in this capacity-building program shall be enhanced. Agencies involved in implementing the NBF should undertake programs to achieve the above objectives.

8.2 Areas for Capacity Building. Capacity building in all areas relevant to biosafety and biosafety-decision making is necessary, and particularly in the following: in conducting risk assessment; in undertaking social, economic, cultural, ethical and other assessments; and, in implementing transparent and effective public participation procedures.

8.3 Designing and Implementing a Capacity-Building Program. In coordination with other concerned government department and agencies, and with the participation of all relevant stakeholders, the NCBP shall take the lead in developing and implementing multi-agency and multi-sector capacity-building programs that are needed for the effective implementation of the NBF. The basis of such programs shall be a capability needs assessment undertaken by each concerned department and agency and by the relevant stakeholders.

8.4 Financial Resources. The DOST, DENR, DA, and DOH shall allocate from their present budgets such amount as may be necessary to implement the NBF, including to support the operations of the NCBP and its Secretariat. Thereafter, the funding requirements shall be included in the General Appropriations Bill submitted to Congress.

These concerned departments, on an annual or other periodic basis, shall enter into agreement on the sharing of financial and technical resource to support the NCBP and its Secretariat.

SECTION 9. REMEDIES

In cases of violations of laws, rules, and regulations related to biosafety, the following remedies shall apply:

9.1 ***Administrative Remedies.*** The concerned departments and agencies shall ensure, in accordance with law, that the right of appeal and other administrative remedies are available to applicants and relevant stakeholders in biosafety decisions.

9.2 ***Criminal Liability.*** Natural or juridical persons committing offenses in violation of existing laws shall be prosecuted and penalized in accordance with such laws.

9.3 ***Civil Liability***. Philippine laws on liability and compensation for damages resulting injuries committed on persons shall apply in accordance with such laws. Concerned departments or agencies shall study the feasibility of requiring such instruments as indemnification bonds.

9.4 ***International Law.*** International legal norms on liability and compensation, including those developed and adopted under the Cartagena Protocol on Biosafety, shall likewise apply.

9.5 ***Review of Remedies.*** Recognizing the current gaps in the law on remedies related to biosafety, the NCBP shall, as a matter of priority, review the existing laws and recommend to Congress the appropriate legislation.

SECTION 10. REVIEW

The NBF shall be reviewed periodically to identify gaps and lessons learned from its implementation and to incorporate new information that may lead to its improvement. Such review shall be conducted in five year intervals unless circumstances, such as emergencies or new developments in the science and technology, require an earlier review.

10.1 ***Review Process.*** The review shall be initiated by the NCBP and shall involve concerned departments and agencies. Public consultations, in accordance with Section 6, shall be undertaken whenever substantive changes are proposed to the Framework.

10.2 ***Process of Delisting***. Delisting of regulated articles shall rest on the regulatory agencies, subject to guidelines set under the NCBP process. The NCBP shall initiate a study on the feasibility of a delisting procedure for regulated articles.

10.3 ***Legislation***. Lessons learned from implementing the Framework shall be documented and, at an appropriate time, conveyed to Congress for purposes of developing, drafting and adopting legislation on biosafety.

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DEPARTMENT OF ENVIRONMENT AND NATURAL RESOURCES-
PROTECTED AREAS AND WILDLIFE BUREAU
Ninoy Aquino Park and Wildlife Center
Quezon Avenue, Diliman 1101, Quezon City, Philippines
Tel. No. (632) 9246031-35, Fax No. (632) 9240109
Website: www.pawb.gov.ph