

Executive Order 514



BY THE PRESIDENT OF THE PHILIPPINES

EXECUTIVE ORDER NO. 514

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 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, it is the policy of the State to 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;

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, the National Committee on Biosafety of the Philippines (NCBP), Department of Science and Technology, Department of Agriculture, Department of Health, and Department of Environment and Natural Resources have played, since 1987, a pioneering and important role in developing and establishing the current biosafety system;

WHEREAS, there is a need to enhance the existing biosafety framework to better respond to the challenges presented by further advances in modern biotechnology and to comply with the administrative requirements of the Cartagena Protocol on Biosafety;

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.

2.2 Objectives. The NBF shall have the following objectives:

2.2.1 Strengthen the existing 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 Enhance the decision-making system on the application of products of modern biotechnology to make it more 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. The mandates, jurisdictions and other powers of all departments and agencies in relation to biosafety and biotechnology shall be guided by the NBF and coordinated with the NCBP and 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. Starting 2006 and thereafter, the funding requirements shall be included in the General Appropriations Bill submitted by each of said departments to Congress.

These concerned departments 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 Executive Order No. 430, s. 1990 until such time that it has completely reorganized under the NBF. The reorganization shall commence immediately after the DOST, DENR, DA, and DOH have entered into an agreement on the sharing of financial and technical resources to support the NCBP and its Secretariat on a sustainable basis, and shall be completed within one year from effective date of such agreement.

All members of the NCBP to be appointed by the President, as required by the NBF, shall assume their positions upon completion of the reorganization.

SECTION 8. Repealing and Amending Clause. All orders, rules and regulations or parts thereto which are inconsistent with any of the provisions of this Order are hereby repealed or amended accordingly. For the avoidance of doubt, the following issuances, unless amended by the respective issuing departments or agencies, shall continue to be in force and effect: Department of Agriculture Administrative Order No. 008, s. 2002; the NCBP Guidelines on the Contained Use of Genetically Modified Organisms, except for provisions on potentially harmful exotic species which are hereby repealed; and all Bureau of Food and Drugs issuances on products of modern biotechnology.

SECTION 9. Effectivity. This Order shall take effect fifteen days after publication in two newspapers of general circulation.

DONE, in the City of Manila, this 17th day of March in the year of our Lord two Thousand and Six.

By the President:

EDUARDO R. ERMITA
Executive Secretary

**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,

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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 shall 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 are hereby 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 responsibly and in accountable manner 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;

<!--[if !vml]--><!--[endif]-->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 of 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 shall 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.

3.2 Objectives. The NBF shall have the following objectives:

3.2.1 Strengthen the existing 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 Enhance the decision-making system on the application of products of modern biotechnology to make it more 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 from the Philippines to another country; 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 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 consumer representative appointed by the President from a list submitted by nationally recognized consumer organizations, 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, each 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 may be called upon to 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. It shall also take the lead in evaluating and monitoring regulated articles intended for contained use.

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. It shall also take the lead in evaluating and monitoring plant and plant products derived from the use of modern biotechnology, as provided in Department of Agriculture Administrative Order No. 008, s. 2002.

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. It shall also take the lead in evaluating and monitoring processed food derived from or containing genetically modified organisms.

4.11 Mandate of Associated 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; the National Commission on Indigenous Peoples in relation to biosafety decisions which have a specific impact on indigenous peoples and communities; and the Department of Interior and Local Government, in relation to biosafety decisions which have an impact on the autonomy of local government units.

4.12 Focal Point and Competent National Authorities.

4.12.1 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:

4.12.1.1 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;

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

4.12.1.3 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,

4.12.1.4 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.

4.12.2 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.

4.13 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.

4.14 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 consistent with internationally accepted standards relating to the conduct of social, economic, ethical, cultural and other assessments, as appropriate, 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

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 guidelines to be issued by the NCBP, which shall include, among others, the following:

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 it is necessary to enable the concerned stakeholders to effectively conduct a scientific risk assessment.

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, meaningful, responsible, and accountable 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 the filing of such application with the NCBP shall be sufficient, unless the NCBP deems that 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 commercial releases, in the national print 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, as appropriate, 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 shall be informed of the final decision promptly, have access to the decision, and shall be provided with the reasons and

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 shall be strengthened;

- (a) Policy makers shall 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 shall 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 shall be supported to enable them to address the safety issues of regulated articles; and,
- (d) The general public shall 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.

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.

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. The NCBP shall initiate and lead such review every five years from effectivity date of this Order, unless in its determination circumstances, such as emergencies or new developments in 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.