

Republic of the Philippines
HOUSE OF REPRESENTATIVES
Quezon City
SEVENTEENTH CONGRESS
First Regular Session
HOUSE BILL NO. 3798



Introduced by Representative Divina Grace C. Yu

EXPLANATORY NOTE

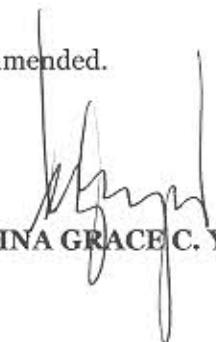
There is a rapid expansion of the use of modern biotechnology not only for scientific research but also for products for commercial releases and purposes. However, concerns were raised over modern biotechnology's potential impacts on the environment, particularly on biological diversity, on human health, and on social and cultural well-being. In order to lessen or to totally prevent these adverse potential impacts, the Cartagena Protocol on Biosafety to the United Nations Convention on Biological Diversity which the Philippines is a signatory, was entered into force on 11 September 2003.

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, Executive Order No. 514, dated 17 March 2006 was issued and established the National Biosafety Framework and strengthened the existing National Committee on Biosafety of the Philippines.

Significantly, the United Nation (UN) General Assembly, during the tenth meeting of the Conference of Parties to the CBD in Nagoya Japan on October of 2010, recommended for the UN to declare 2011-2020 as the Decade on Biodiversity. Consistent with such declaration, former President Benigno C. Aquino III issued Proclamation No. 178 which declared the years 2011-2020 as the National Decade on Biodiversity in the Philippines. The Proclamation *likewise "enjoined all branches and agencies of the government, including government-owned and controlled corporations, local government units, and state universities and colleges to initiate activities to promote biodiversity conservation, in cooperation with the private sector, community organizations and non-government organizations."*

It is therefore imperative to institutionalize the National Biosafety Framework and the National Committee on Biosafety (NCMB) to fully implement and realize the country's role and undertaking under the Cartagena Protocol and the United Nations declaration of Decade on Biodiversity.

In view hereof, approval of this bill is earnestly sought and recommended.


DIVINA GRACE C. YU

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AN ACT
STRENGTHENING THE NATIONAL BIOSAFETY FRAMEWORK AND
INSTITUTIONALIZING THE NATIONAL COMMITTEE ON BIOSAFETY OF THE
PHILIPPINES, APPROPRIATING FUNDS THEREFOR AND FOR OTHER
PURPOSES.

Be it enacted by the Senate and the House of Representatives of the Philippines in Congress assembled:

ARTICLE I

DECLARATION OF POLICY AND FRAMEWORK

SECTION 1. *Title.* This Act shall be known as the “**National Commission on Biosafety of the Philippines Act of 2016**”

SEC. 2. *Declaration of Policy.* It is the policy of the state to protect and promote the right to health of the people and instill health consciousness among them. The protection and advancement of the right of the people to a balanced and healthful ecology in accord with the rhythm and harmony of nature is likewise declared by the State. To fulfill these, the State is mandated 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.

SEC. 3. *National Biosafety Framework (NBF).* There is hereby instituted in this Act a National Biosafety Framework with the following scope and objectives:

3.1. *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.

3.2 *Objectives.* The NBF shall have the following objectives:

3.2.1 Strengthen the 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.

SEC. 4. *Definition of Terms.* For purposes of this Act, the following terms shall mean:

- 4.1 ***“Biosafety”*** - refers to 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 the acceptable and manageable levels;
- 4.2 ***“Biosafety Clearing House”*** – refers to 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;
- 4.3 ***“Biosafety Decisions”*** - refers 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;
- 4.4 ***“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;
- 4.5 ***“Genetically modified organism”*** also refers to “living modified organism” under the Cartagena Protocol on Biosafety refers to any living organism that possesses a novel combination of genetic material obtained through the use of modern technology;
- 4.6 ***“Handling and use”*** – means the process by which regulated articles are moved, carried, transported, delivered, stored or worked with;
- 4.7 ***“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;
- 4.8 ***“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;
- 4.9 ***“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; 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;
- 4.10 ***“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;

- 4.11 **“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;
- 4.12 **“Regulated article”**- refers to a genetically modified organism and its products;
- 4.13 **“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;
- 4.14 **“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;
- 4.15 **“Risk management”**- refers to appropriate mechanisms, measures and strategies to identified in the risk assessment including those conditions imposed by concerned departments or agencies;
- 4.16 **“Transboundary movement”** - means the movement of a regulated article from another country to the Philippines; and
- 4.17 **“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.

ARTICLE II

THE NATIONAL COMMISSION ON BIOSAFETY

SEC. 5. *The National Commission on Biosafety of the Philippines (NCBP).* To support the above stated policy, the National Committee on Biosafety of the Philippines is hereby institutionalized and shall be known as the **“National Commission on Biosafety of the Philippines (NCBP)”** under the Department of Science and Technology. The NCBP shall be the lead body to coordinate and harmonize inter-agency and multi-sector efforts to develop biosafety policies in the country 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.

The operationalization of the NCBP in the implementation of the NBF shall be guided by the following principles:

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. **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;

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 the 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;

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.

5. **Socio-economic, Cultural and Ethical Consideration.** 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 people, women, small and medium enterprises and the domestic scientific community, shall be taken in to account in implementing the NBF;

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 hereby implemented through the decision making system in the NBF;

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;

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;

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;

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 Cooperations.** 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;

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

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 the 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.

SEC. 6. Composition of the NCBP. The NCBP shall be headed by the Secretary of the Department of Science and Technology (DOST) as the permanent Chairperson.

The NCBP members shall be the following:

- a. The Secretary of the Department of Agriculture;
- b. The Secretary of the Department of Health;
- c. The Secretary of the Department of Environment and Natural Resources;
- d. The Secretary of Foreign Affairs
- e. The Secretary of the Department of Trade and Industry
- f. The Secretary of the Interior and Local Government
- g. 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;
- h. 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
- i. 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), The National Research Council of the Philippines (NRCP) 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

SEC. 7. NCBP Executive Committee and Technical Working Groups. The NCBP may create an Executive Committee and Technical Working Groups as it deems necessary and appropriate.

SEC. 8. 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.

SEC. 9. Powers and Functions of the NCBP. As the lead body in implementing the NBF, the NCBP shall have the following powers and functions:

9.1 Biosafety Policy functions:

- 9.1.1 Assist concerned departments and agencies in formulating, reviewing, or amending their respective policies, measures and guidelines on biosafety;
- 9.1.2 Hold public deliberations on proposed national policies, guidelines, and other biosafety issues;
- 9.1.3 Provide assistance in the formulation, amendment of pertinent laws, rules and regulations;
- 9.1.4 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;
- 9.1.5 Issue detailed guidelines on the conduct of socioeconomic impact evaluation of biosafety decisions; and
- 9.1.6 Propose to Congress necessary and appropriate legislation.

9.2 Accountability Functions:

- 9.2.1 Monitor the implementation of the NBF by concerned departments and agencies;
- 9.2.2 Ensure coordination among competent national authorities that have shared mandates;
- 9.2.3 Ensure that NCBP guidelines, and the principles and processes established in this Framework are complied with by concerned departments and agencies; and
- 9.2.4 Review procedures for accountability in biosafety decision-making by competent national authorities, with particular emphasis on ensuring independence and impartiality in such decisions.

9.3 Scientific Functions:

- 9.3.1 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;
- 9.3.2 Identify and evaluate potential hazards involved in modern biotechnological experiments or the introduction of regulated articles and recommend measures to minimize risks;
- 9.3.3 Recommend the development and promotion of research programs to establish risk assessment protocols and assessment of long-term environmental effects of regulated articles;
- 9.3.4 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;
- 9.3.5 Review and develop guidelines in the risk assessment of regulated articles for contained use;
- 9.3.6 Assist other agencies in developing risk assessment guidelines and procedures of regulated articles for field trials and commercial release;
- 9.3.7 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;
- 9.3.8 Publish the results of internal deliberations and agency reviews of the NCBP;
- 9.3.9 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
- 9.3.10 Perform such functions as may be requested by concerned departments and agencies.

9.4 Capacity Building Functions:

- 9.4.1 Assist in the development of technical expertise, facilities, and other resources for quarantine services and risk assessments; and
- 9.4.2 Take the lead in developing and implementing a national capacity-building program for biosafety.

SEC. 10. Public Information. The NCBP shall promote and facilitate public awareness, education and participation, including access to information, and also requires mandatory public consultation and disclosure of results of decisions to the public in the decision-making process.

SEC. 11. Community Participation Agreements. - Agreements may be forged between the communities where these areas of biodiversity can be found and any public or private agency for the conduct of biodiversity prospecting activities within their areas of jurisdiction. Any responsible local government unit, duly-accredited people's organization non-government organization or private corporate entity may take the initiative in

organizing the communities concerned to enable them to participate in biodiversity agreements.

The consent of the communities concerned shall be secured before any biodiversity prospecting activities may be conducted to attain the purposes of this Act.

SEC. 12. *Respect to the Indigenous Cultural Communities.* - The customs, beliefs and practices of the indigenous cultural communities with respect to biodiversity shall be given primary consideration and respect in the conduct of biodiversity prospecting activities in accordance with the provisions of this Act.

The customary use of these biological resources shall be promoted and encouraged in accordance with the cultural practices which are compatible with conservation or sustainable use requirements.

SEC. 13. *Implementing Rules and Regulations.* The DOST, DA, DOH, DENR, DTI, DFA, DILG with the participation of the representatives from the consumer and industry sector and other stakeholders, shall formulate the IRR for the effective implementation of this Act. The DOST Secretary shall chair the drafting committee. The IRR shall be issued within ninety (90) days after the effectivity of this Act. Copies of the IRR shall be submitted to the Committees on Science and Technology of both Houses of Congress within thirty (30) days after its promulgation, as well as to other appropriate agencies as may be required by law.

SEC. 14. *Funding.* The DOST, DENR, DA and DOH shall allocate funds from their present budgets for the initial implementation of this Act. Thereafter, the funding requirements shall be included in the budget of DOST of the year following the enactment of this Act.

SEC. 15. *Separability Clause.* If any provision of this Act shall be held unconstitutional or invalid, the other provisions not otherwise affected shall remain in full force and effect.

SEC. 16. *Effectivity.* This Act shall take effect after fifteen (15) days following the date of its publication in the Official Gazette or in two (2) newspapers of general circulation whichever comes earlier.

Approved.