

Republic of the Philippines
HOUSE OF REPRESENTATIVES
Quezon City

SEVENTEENTH CONGRESS
Second Regular Session

House Bill No. **7705**



Introduced by Representative GLORIA MACAPAGAL ARROYO

**AN ACT SUPPORTING MODERN BIOTECHNOLOGY FOR SUSTAINABLE
RURAL DEVELOPMENT IN THE PHILIPPINES AND APPROPRIATING
FUNDS THEREOF**

EXPLANATORY NOTE

This bill seeks to establish an Act to expedite the regulatory decision-making process to help ensure the health and well-being of Filipinos, promote competitiveness, help reduce hunger and poverty and help mitigate the effects of climate change. It is time that safe and responsible use of biotechnology is included in the Philippine tool kit to meet national developmental goals. The current regulatory regime, which is based on outdated knowledge and assumptions, must be revised to enable the Philippines to benefit from products of modern biotechnology without delay. Support is also needed to accelerate R&D to further ensure the utility and safety of products of modern biotechnology.

It now takes 65 months or more to complete all requirements for the commercial release of modern biotechnology products.

The cumbersome regulations can no longer be justified for they effectively discriminate against local public biotech research institutions which have limited resources to comply with the existing regulations.

In view of the foregoing, approval of this bill is earnestly sought.


GLORIA MACAPAGAL ARROYO
2nd District, Pampanga

Republic of the Philippines
HOUSE OF REPRESENTATIVES
Quezon City

SEVENTEENTH CONGRESS
Second Regular Session

House Bill No. **7705**

Introduced by Representative GLORIA MACAPAGAL ARROYO

**AN ACT SUPPORTING MODERN BIOTECHNOLOGY FOR SUSTAINABLE
RURAL DEVELOPMENT IN THE PHILIPPINES AND APPROPRIATING
FUNDS THEREOF**

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

**CHAPTER 1
GENERAL PROVISIONS**

SECTION 1. *Short Title.* - This Act shall be known as the "Modern Biotechnology Act of 2018".

SECTION 2. *Declaration of Policy.* - It shall be the policy of the State to support safe and responsible use of modern biotechnology for the development of bio-based industries in agriculture, agroforestry, food processing, human health and medicine, and processing of high value commercial products.

SECTION 3. *Objectives.* - In pursuit of this policy, this Act shall have the following objectives:

- a) Establish a Biotechnology Authority of the Philippines (BioAP) to provide leadership in biotechnology industry development and rationalize the regulation of modern biotechnology.
- b) Support strong new & existing programs to develop scientific human resources in educational and research institutions that are dedicated to modern biotechnology.
- c) Establish state-of-the-art facilities for the development of modern biotechnology, as well as facilities for processing high value products and medical (pharmaceutical) preparations with modern biotechnology components; and
- d) Provide sustained funding for modern biotechnology programs in agriculture, agroforestry, food processing, health, and manufacturing high value products for local and international markets.

SECTION 4. *Definition of Terms.* - As used in this Act:

- a) Genetically modified organism (GMO) refers to an organism whose genetic material has been altered through genetic engineering;

- b) Modern biotechnology refers to techniques for modifying genomes for the production of new bio-based products;
- c) Genome is the genetic material containing all the information needed to build and maintain an organism;
- d) Product-based regulatory approach refers to the assessment of the merits of the end-product rather than the process used to produce it.
- e) Science-based regulatory approach refers to the application of knowledge and criteria derived from consensus of independent academies of science and similar scientific bodies, as opposed to opinions of individuals.

CHAPTER II

THE BIOTECHNOLOGY AUTHORITY OF THE PHILIPPINES

SECTION 5. *Implementing Arm.* – To implement the provisions of this Act, the Biotechnology Authority of the Philippines (BioAp) is hereby established. It shall be attached to function as an agency of the Department of Science and Technology. The BioAP shall absorb the functions of the National Committee on Biosafety of the Philippines (NCBP) and other modern biotech regulatory bodies which shall be henceforth abolished. It shall review existing regulatory bodies & processes with a view to rationalize & integrate the regulatory decision-making process in consultation with competent national government agencies.

SECTION 6. *Functions of the BioAP.* – The BioAP shall perform the following functions:

- a) Formulate strategies, policies and guidelines for modern biotechnology programs and projects in the Philippines with priority on agriculture, agroforestry, health and medicine, and processing high value food and health products for the local and international markets.
- b) Review, improve and implement biosafety regulations for products of modern biotechnology and ensure that they are science-based and simplified with a product-based and not a process-based regulatory approach.
- c) Promote capacity building in modern biotechnology in line with international policies followed by developed countries in educational and R&D institutions by strengthening biotechnology taking into account the attainment of national development goals.
- d) Support government educational and R&D institutions to develop long-term programs in modern biotechnology which will serve as basis for sustainable funding.
- e) Lead public information and education programs to highlight the benefits that can be derived from modern biotechnology.
- f) Serve as arbiter of all issues relating to biotechnology, particularly those involving biosafety of GMOs.

SECTION 7. *Members.* – The BioAP shall consist of the following members to be appointed upon the recommendation of the Secretary of DOST, by the President of the Philippines for a five-year term, renewable for another term or more in exceptional cases:

- a) The DOST Secretary or a designated Undersecretary;
- b) Four members to be recommended by the National Academy of Science and Technology of the Philippines (NASTPhil);

- c) Two members to be recommended by the Philippine Chamber of Commerce and Industry (PCCI).

SECTION 8. *Secretariat.* – The BioAP shall have a Secretariat headed by an Executive Director to be appointed by the President of the Philippines upon recommendation by the DOST Secretary. The Executive Director should have at least 10 years professional experience in managing R&D programs.

CHAPTER III

BIOSAFETY ASSESSMENT

SECTION 9. *Science-based Biosafety Guidelines.* – The Authority shall ensure that the government formulates and strictly implements science-based biosafety guidelines and regulations.

SECTION 10. *Assessment.* – Biosafety regulations shall have two stages: 1) biosafety assessment covering efficacy and safety to the environment, animal and human health, and 2) commercial competitiveness and related criteria.

In all cases, assessment shall be product-based, and not process-based.

SECTION 11. *Product Safety Committees.* – Each and every public and private R&D organization shall have a product safety committee. Every one of these committees shall perform biosafety assessment of all biotechnology and certify that these products to be submitted for the BioAP's approval shall have passed biosafety assessment in accordance with its guidelines.

CHAPTER IV

IMPORT-EXPORT OF GMOs

SECTION 12. *International Commitments.* – In case of conflict between international commitments and the science-based, product-oriented approach, the latter shall prevail.

CHAPTER V

MISCELLANEOUS PROVISIONS

SECTION 13. *Penalties.* – For any violation of the provisions of this Act, and regulations approved by BioAP, or unauthorized destruction of modern biotechnology experiments, the following penalties and/or fines shall be imposed:

- a) Imprisonment for two (2) years and/or fine of five hundred thousand pesos (Php500,000) if violation if made by an individual.
- b) Fine of ten (10) million pesos (Php 10,000,000) if violation is made by an institution or organization and/or suspension of privilege to operate within the Philippines

Violation of this Act shall not exempt violators from other pertinent laws, rules and regulations that may have also violated by an individual or an organization.

SECTION 14. *Exemption from Taxes and Government Procurement System.* – Any donation, contribution, bequest, subsidy, or financial aid to the BioAP or any Department, SUC, or research center in support of modern biotechnology shall constitute allowable deductions from taxable income of the donor, and shall be exempt from donor's tax.

The provisions of Republic Act 9184, otherwise known as the "Government Procurement Reform Act" shall not apply to the procurement of all items, supplies, materials, and general support services including consulting services, which may be needed by departments, agencies, state universities and colleges, government-owned or controlled corporations, and organizations in the pursuit of any modern biotechnology-related R&D undertaking, project or activity.

For this purpose, the DOST Secretary shall certify such procurement whether in the nature of equipment, furniture, as well as trucking, hauling and related or analogous services. The Office of the DOST Secretary, through BioAP, shall create the guidelines for such procurements, subject to existing rules and regulations of the Commission on Audit.

CHAPTER VI

IMPLEMENTING PROVISIONS

SECTION 15. *Implementing Rules and Regulations.* – Within six (6) months following the effectivity of this Act, the BioAP shall be activated by the DOST Secretary and BioAP Executive Director. All members of the BioAP shall work together to produce the IRR within three months.

SECTION 16. *Appropriations.* – The amount of Five Hundred Million Pesos (P500,000,000) is hereby allotted to initially implement the provisions of this Act. Thereafter, the funding needed to fully implement the provisions of this Act shall be included in the annual General Appropriations Act.

SECTION 17. *Separability Clause.* - If any provisions or part hereof, is held invalid or unconstitutional, the remainder of the law or the provision not otherwise affected shall remain valid and subsisting.

SECTION 18. *Repealing Clause.* - Any law, presidential decree or issuance, executive order, letter of instruction, administrative order, rule or regulation contrary to or inconsistent with the provision of this Act is hereby repealed, modified or amended accordingly.

SECTION 19. *Effectivity Clause.* - This Act shall take effect fifteen (15) days after its publication in at least two (2) newspapers of general circulation with its Implementing Rules and Regulations promulgated by the MPPPC within sixty (60) days from the formal organization of the Council.

Approved,