



Republic of the Philippines
HOUSE OF REPRESENTATIVES
Quezon City, Metro Manila

EIGHTEENTH CONGRESS
First Regular Session

HOUSE BILL NO. 3372



Introduced by Representative Sharon S. Garin

EXPLANATORY NOTE

This proposed Bill seeks to establish an Act to expedite the regulatory decision-making process in biotechnology 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 development 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 The current regulatory regime, which is based on outdated knowledge and assumptions, must be revised to enable the Philippines to benefit from products of modern biotechnology without delay.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 research and development to further ensure the utility and safety of products of modern biotechnology.

Right now, it 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. This proposed bill will address this concern.

Biotechnology, is also a tool to address poverty, climate change, health issues and competitiveness, thereby helping ensure the well-being of Filipinos. Recent statistics (2015) show that poverty incidence in the Philippines averages about 21.6% of the population; and it is highest among farmers (34.3%). Biotechnology will increase yields and better products, leading to more income for our farmers.

The Philippines is also one of the countries most heavily affected by climate change. Around 20 typhoons visit the Philippines annually. The pattern has been that of increasingly strong typhoons. The damages caused by typhoons Sendong (2011), Pablo (2012) and Yolanda (2013) to property and agriculture have been estimated to be P1.7 billion, P14 billion and P40 billion, respectively. Biotechnology, will provide climate and weather resistant crops that will mitigate the effects of these natural disasters.

The National Economic and Development Authority (NEDA) has already highlighted agricultural biotechnology as a priority sector in agriculture with a direct impact on Ambisyon 2040. Philippine Development Plan 2017-2022 acknowledges

through the Harmonized National R&D Agenda for Agriculture, Aquatic, and Natural Resources 2017-2022 that biotechnology is "a tool to find solutions to agriculture, fisheries, and forestry problems"

Since the 1980s, modern biotechnology has developed many useful products. These include insulin, and corn that is resistant to borers and to a specific herbicide. These GMO corn plants have helped keep livestock and poultry affordable and improved the profitability of 406,000 small resource poor Filipino farmers.

Release to the public of GMO products in the pipeline has been delayed because of cumbersome regulations, which are based on knowledge available during the 1980s. Thus eggplant farmers depend on chemical pesticides (Bt eggplant, a biotech product developed by the University of the Philippines, markedly reduces this dependence), and some people suffer from debilitating Vitamin A deficiency (Golden Rice, a biotech product developed jointly by the International Rice Research Institute and PhilRice, supplies Vitamin A.)

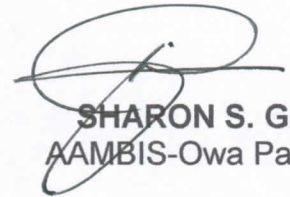
The National Academy of Science and Technology of the Philippines states: "when used properly, GMOs are good for farmers and for the environment. GM foods are safe for animals and humans." The US National Academy for Sciences state: "there is no difference between traditional and biotech crops in terms of risks to human health, not any negative effects on environment from biotech crops." The Food and Drug Administration of the Philippines state that "all food derived from GM crops in the market have met international food safety standards and are as safe as and as nutritious as the food derived from conventional crops" Similarly, the World Health Organization (WHO) declares that "no effects on human health have been shown as a result of the consumption of GM foods."

The University of Wisconsin in a survey covering 900 studies of GMOs found no substantial evidence that foods from biotech crops were less safe than foods from non-biotech crops. The European Commission (Belgium) concludes: "more than 130 research projects, covering a period of more than 23 years of research, and involving more than 500 independent research groups, show that biotechnology, and in particular GMOs, are no more risky than conventional breeding technology." 107 Nobel laureates pointed out to Greenpeace, the United Nations, and Governments around the world that there has never been a single verified case of a negative health outcome of consuming foods improved through biotechnology. In terms of environmental impact, these products have been consistently found to be less detrimental to the environment and beneficial to global biodiversity.

These observations are reinforced by the change of heart of former critics. Among these are Bill Nye, "the Science Guy" who earned a well-deserved reputation as an excellent science communicator. Bill Nye had expressed misgivings about the safety of GMOs. When taken to task for voicing opinions that were not supported by the data he showed that he is truly "the Science Guy" by changing his mind after he evaluated the data more closely. Another is Patrick Moore who was one of the founding member of Greenpeace and served as President of Greenpeace Canada and Director of Greenpeace International. Over time, he came to realize that the facts did not support many of the opposition campaigns to GMOs. He is now a staunch supporter of Golden Rice and agricultural biotechnology. In the late 1990s, Mark Lynas actively opposed GMO crops by participating in vandalism of field trials in the United Kingdom. After realizing that his support for science-based decisions related to climate change were inconsistent with his rejection of the science of modern crop

improvement, he issued a public apology stating, among other things, that: "My conclusion here today is very clear: the GM debate is over. It is finished. Over a decade and a half with three trillion GM meals eaten there has never been a single substantiated case of harm. You are more likely to get hit by an asteroid than to get hurt by GM food. More to the point, people have died from choosing organic, but no one has died from eating GM."

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

A handwritten signature in black ink, consisting of a large, stylized 'S' followed by a horizontal line and a small dot.

SHARON S. GARIN
AAMBIS-Owa Partylist



Republic of the Philippines
HOUSE OF REPRESENTATIVES
Quezon City, Metro Manila

EIGHTEENTH CONGRESS
First Regular Session

HOUSE BILL NO. **3372**

Introduced by Representative Sharon S. Garin

AN ACT

**PROMOTING SAFE AND RESPONSIBLE USE OF MODERN BIOTECHNOLOGY
ESTABLISHING THE BIOTECHNOLOGY AUTHORITY OF THE PHILIPPINES FOR
THIS PURPOSE AND APPROPRIATING FUNDS THEREOF**

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

SECTION 1. Title. – This Act shall be known as the “**Modern Biotechnology
Act of 2018**”.

SEC. 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.

SEC. 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.

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- 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 endproduct 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.

THE BIOTECHNOLOGY AUTHORITY OF THE PHILIPPINES

SEC 5. *Biotechnology Authority of the Philippines (BioAP)* – 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 (DOST).

It shall review existing regulatory bodies & processes with a view to rationalize and integrate the regulatory decision-making process in consultation with competent national government agencies.

The National Committee on Biosafety of the Philippines (NCBP) and other modern biotech regulatory bodies shall henceforth be abolished, and their functions shall be absorbed by the BioAP.

SEC. 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;

- 1 e) Lead public information and education programs to highlight the benefits
2 that can be derived from modern biotechnology;
3 f) Serve as arbiter of all issues relating to biotechnology, particularly those
4 involving biosafety of GMOs;
5 g) Absorb and carry out all functions of the National Committee on Biosafety
6 of the Philippines (NCBP) and other modern biotech regulatory bodies.

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

- 10 a) The DOST Secretary or a designated Undersecretary;
11 b) Four members to be recommended by the National Academy of Science
12 and Technology of the Philippines (NASTPhil);
13 c) Two members to be recommended by the Philippine Chamber of
14 Commerce and Industry (PCCI).

15 **SEC. 8. *Secretariat*** – The BioAP shall have a Secretariat headed by an
16 Executive Director to be appointed by the President of the Philippines upon
17 recommendation by the DOST Secretary. The Executive Director should have at least
18 10 years of professional experience in managing R&D programs.

19 20 CHAPTER III

21 BIOSAFETY ASSESSMENT

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

25 **SEC. 10. *Assessment*** – Biosafety regulations shall have two stages: (1)
26 biosafety assessment covering efficacy and safety to the environment, animal and
27 human health, and (2) commercial competitiveness and related criteria. In all cases,
28 assessment shall be product-based, and not process-based.

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

34 CHAPTER IV

35 IMPORT AND EXPORT OF GMOS

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

39 40 CHAPTER V

41 PROHIBITED ACTS AND PENALTIES

42 **SEC. 13. *Prohibited Acts*** – The following acts shall be prohibited and shall be
43 penalized accordingly:

- 1 a) Unauthorized destruction of biotech crops, whether the crops are used for
2 experimental objectives or for production;
3 b) Sale or distribution of fake GMO seeds;
4 c) Any other acts that are inimical to the safe and responsible use of modern
5 biotechnology and are violative of the regulations set by the BioAP.

6 **SEC. 14. Penalties** – For any violation of the provisions of this Act, and
7 regulations approved by BioAP the following penalties and/or fines shall be imposed:

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

13 Violations of this Act shall not exempt violators from other pertinent laws, rules
14 and regulations that may have also violated by an individual or an organization.
15

16 CHAPTER VI

17 MISCELLANEOUS PROVISIONS

18 **SEC. 15. Exemption From Taxes and Government Procurement System** –
19 Any donation, contribution, bequest, subsidy, or financial aid to the BioAP or any
20 Department, SUC, or research center in support of modern biotechnology shall
21 constitute allowable deductions from taxable income of the donor, and shall be exempt
22 from donor's tax.

23 The provisions of Republic No. 9184, otherwise known as the "Government
24 Procurement Reform Act" shall not apply to the procurement of all items, supplies,
25 materials, and general support services including consulting services, which may be
26 needed by departments, agencies, state universities and colleges, government-owned
27 or controlled corporations, and organizations in the pursuit of any modern
28 biotechnology-related R&D undertaking, project or activity.

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

36 IMPLEMENTING PROVISIONS

37 **SEC. 16. Implementing Rules and Regulations** – Within six (6) months
38 following the effectivity of this Act, the BioAP shall be activated by the DOST Secretary
39 and BioAP Executive Director. All members of the BioAP shall work together to
40 produce the IRR within three months.

41 **SEC. 17. Appropriations** – The amount of Five Hundred Million Pesos
42 (P500,000,000) is hereby allotted to initially implement the provisions of this Act.
43 Thereafter, the funding needed to fully implement the provisions of this Act shall be
44 included in the annual General Appropriations Act.

1 **SEC. 18. *Separability Clause*** – If any provision or part of this Act is declared
2 invalid or unconstitutional, the remaining parts or provisions not affected shall remain
3 in full force and effect.

4 **SEC. 19. *Repealing Clause*** – All laws, decrees, executive orders,
5 proclamations, rules and regulations, and issuances, or parts thereof, which are
6 inconsistent with the provisions of the Act are hereby repealed or amended
7 accordingly.

8 **SEC. 204. *Effectivity*** – This Act shall take effect fifteen (15) days after
9 publication in the Official Gazette or two (2) newspapers of general circulation.

10 *Approved,*