

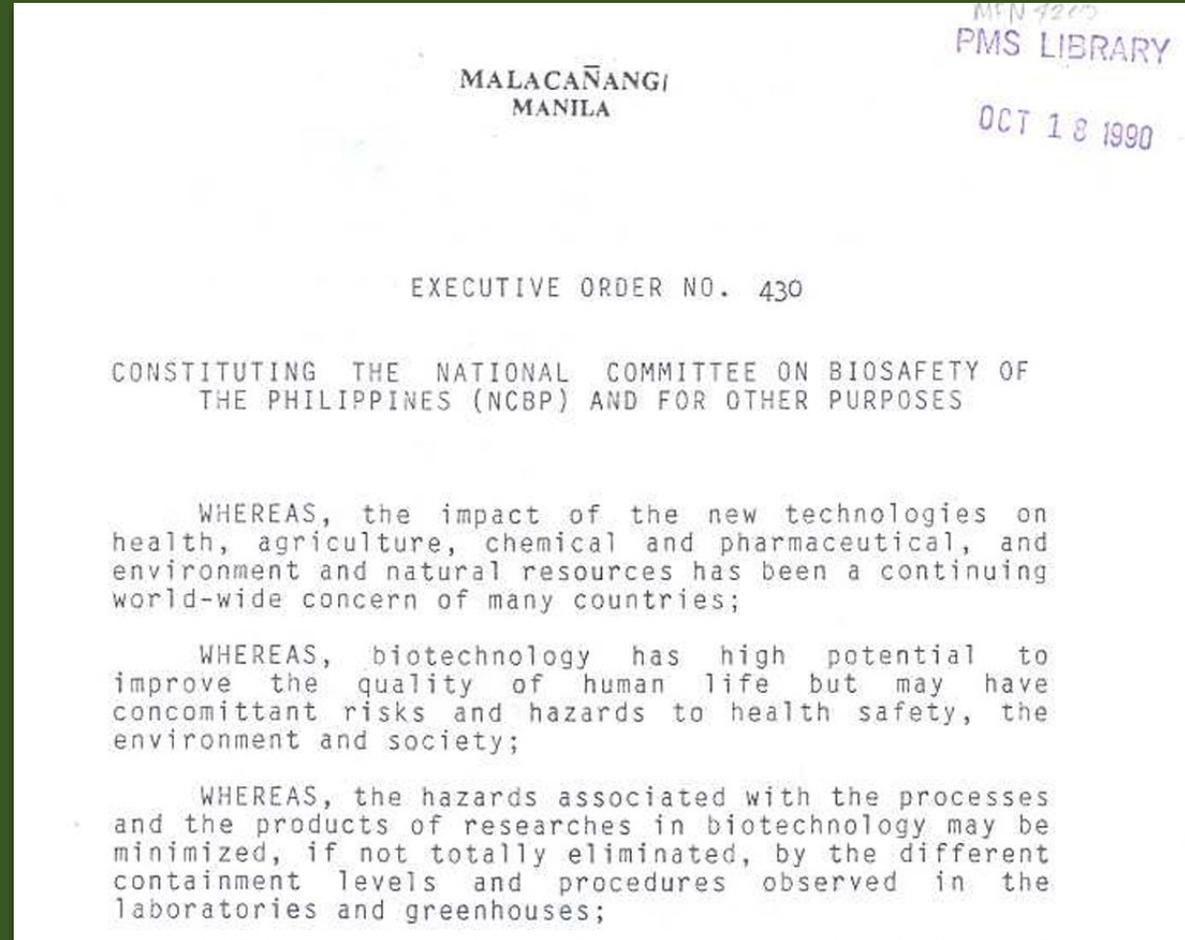


REGULATORY STATUS OF GENETICALLY MODIFIED (GM) ANIMALS IN THE PHILIPPINES

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Overview

1st ASEAN country to initiate a biotechnology regulatory system



Executive Order No. 430, Series of 1990

Overview



Republic of the Philippines
DEPARTMENT OF AGRICULTURE
Office of the Secretary
Elliptical Road, Diliman, Quezon City

April 03, 2002

ADMINISTRATIVE ORDER NO. 8
Series of 2002

SUBJECT: RULES AND REGULATIONS FOR THE IMPORTATION AND RELEASE INTO THE ENVIRONMENT OF PLANTS AND PLANT PRODUCTS DERIVED FROM THE USE OF MODERN BIOTECHNOLOGY

WHEREAS, it is the declared policy of the State to accelerate agricultural development and enhance the production of agricultural crops by optimizing the use of resources and applying modern farming systems and technology to attain food security for domestic use and to expand and diversify agricultural production for export;

WHEREAS, local agriculture can benefit from the safe and responsible use of modern biotechnology by opening the possibility of increasing the yield, improving the product quality, reducing the use of pesticides and other farm inputs, enhancing the integrity of the environment, and reducing the exposure of farmers and consumers to hazardous pesticide residues;

WHEREAS, the Government has recognized, as early as October 15, 1990, with the issuance of Executive Order No. 430, the potentials of modern biotechnology in improving the lives of the people;

WHEREAS, under Republic Act No. 8435, otherwise known as "The Agriculture and Fisheries Modernization Act of 1997", the Government has declared as one of its objectives the modernization of the agriculture sector by transforming it from a resource-based to a technology-based sector;

Official  Gazette

Executive Order No. 514, s. 2006

Signed on [March 17, 2006](#)

MALACAÑANG
MANILA

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;

Overview



**DOST-DA-DENR-DOH-DILG
Joint Department Circular¹
No. 1, series of 2016**

Subject: Rules and Regulations for the Research and Development, Handling and Use, Transboundary Movement, Release into the Environment, and Management of Genetically-Modified Plant and Plant Products Derived from the Use of Modern Biotechnology



**DOST-DA-DENR-DOH-DILG
Joint Department Circular¹
No. 01, series of 2021**

Subject: Rules and Regulations for the Research and Development, Handling and Use, Transboundary Movement, Release into the Environment, and Management of Genetically Modified Plant and Plant Products Derived from the Use of Modern Biotechnology

GM Animals Regulatory Policy



**DOST-DA-DENR-DOH-DILG
Joint Department Circular
No. ____, Series of 2022**

Subject: Rules and Regulations for the Research and Development, Handling and Use, Transboundary Movement, Release into the Environment, and Management of Genetically-Modified Animal and Animal Products Derived from the Use of Modern Biotechnology

GM Animals Regulatory Policy

Applicability

- genetically-modified fisheries and other aquatic resources
- domesticated animals and biological products used for animal husbandry or veterinary purposes
- biological agents used for biocontrol derived from the use of modern biotechnology and containing novel combinations of genetic materials

Products of gene editing that do not contain novel combinations of genetic materials are not covered by this Circular.



GM Animals Regulatory Policy

**Transparency and
Public Participation**

**Standard of
Precaution**

Risk Assessment

**Access to
Information**

Biosafety Decisions

**Environmental and
Health Risk
Assessment**

**Socio-economic,
Ethical and Cultural
Considerations**



GM Animals Regulatory Policy

Based on Classification of Regulated Articles

Research and Development of
a Regulated Article under
Contained Use

Research and Development of
a Regulated Article for Limited
Release into the Environment

Commercial Use of a
Regulated Article Under
Containment

Commercial Use of a
Regulated Article for General
Release

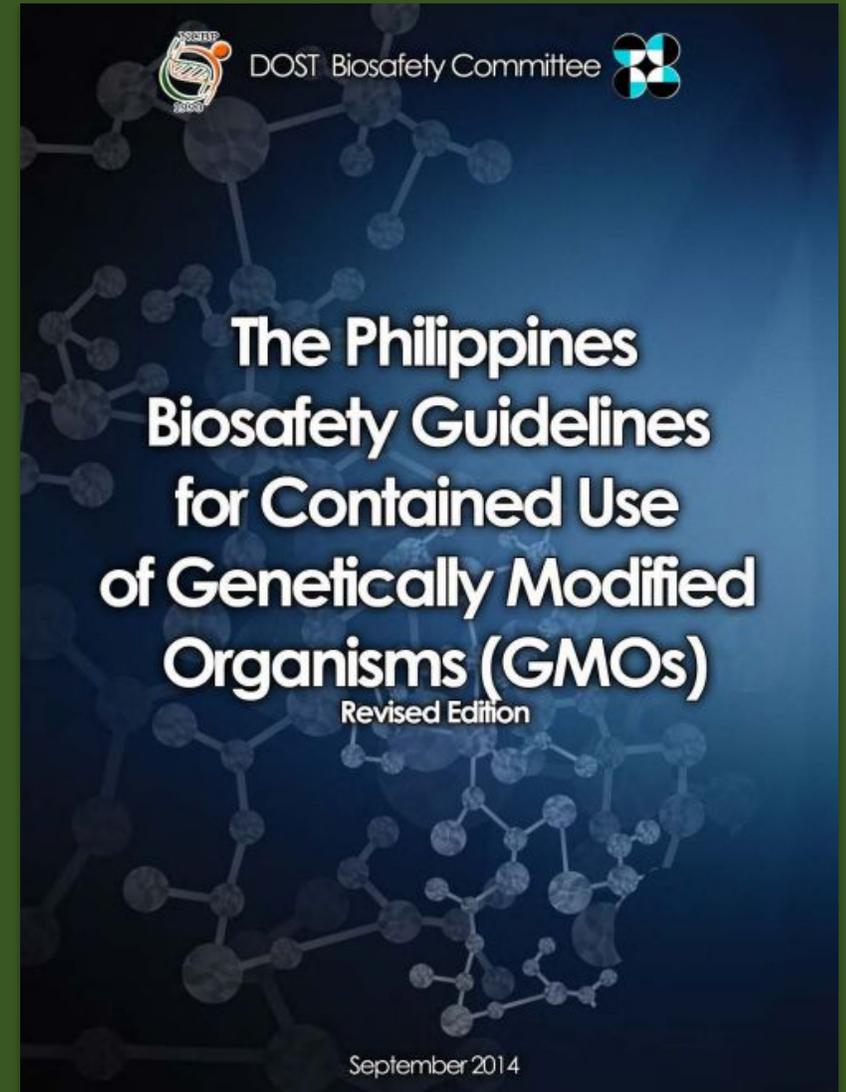


GM Animals Regulatory Policy

Based on Classification of Regulated Articles

Research and Development of
a Regulated Article under
Contained Use

Research and Development of
a Regulated Article for Limited
Release into the Environment



Joint Department Circular on GM Animals *draft*

GM Animals Regulatory Policy

Based on Classification of Regulated Articles

Policy on the Commercial Use of a Regulated Article Under Containment

<ul style="list-style-type: none">• Food, feed, or processing (animals except aquatic species) (BAI)	<ul style="list-style-type: none">• Bioreactor for industrial uses (BAI)
<ul style="list-style-type: none">• Food, feed, or processing (aquatic species)	<ul style="list-style-type: none">• Pets (animals except aquatic species) (BAI)
<ul style="list-style-type: none">• Xenotransplantation (BAI)	<ul style="list-style-type: none">• Ornamental aquatic species (BFAR)
<ul style="list-style-type: none">• Bioreactor for medical/pharmaceutical uses (biopharming) (BAI)	<ul style="list-style-type: none">• Other possible uses (BFAR or BAI)



GM Animals Regulatory Policy

Based on Classification of Regulated Articles

Policy on the Commercial Use of a Regulated Article for General Release into the Environment

<ul style="list-style-type: none">• Food, feed, or processing (animals except aquatic species)	<ul style="list-style-type: none">• Food, feed, or processing (aquatic flora and fauna species)
<ul style="list-style-type: none">• Biocontrol for agricultural purposes	<ul style="list-style-type: none">• Biocontrol for human health, household and industrial purposes
<ul style="list-style-type: none">• Animal disease control	<ul style="list-style-type: none">• Other possible uses



GM Animals Regulatory Policy

General Procedure for Regulated Articles for Commercial Use

BFAR/BAI Biotechnology Office

Joint Assessment Group

BAI or BFAR Director

The application shall be filed at the concerned DA Agency Biotechnology Office (BFAR or BAI).

The Joint Assessment Group shall be chaired by BFAR or BAI and is composed of qualified personnel from the concerned Department's Biosafety Committees based on the particular type of biosafety permit being applied.

The JAG shall make a recommendation to the BAI or BFAR Director.

The BFAR or BAI Director shall grant or deny the application for a biosafety permit based on the technical recommendation from the JAG.



GM Animals Regulatory Policy

Deregulation of Regulated Article

The BFAR or BAI may remove the regulated article from the coverage of this circular if based on the nature of the regulated article, the regulated article **will not pose greater risks to human and animal health and to the biodiversity than its conventional counterpart.**



GM Animals Regulatory Policy

Deregulation of Regulated Article

motu proprio

“on one’s own initiative”

The BFAR or BAI may consider the regulated article for its deregulation with supporting documents equivalent to the contents of a petition.

Through petition

The biosafety permit holder may file with the BAI or BFAR a verified petition to exclude a regulated article





THANK YOU!