The Philippines' Experience: Drafting the Guidelines on Animal Biotechnology

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Philippines
2024 APEC HLPDAB
August 14, 2024

THE JOINT DEPARTMENT CIRCULAR ON GM ANIMALS AND ANIMAL PRODUCTS

Subject:

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

GM ANIMALS: A REVIEW
Development, Intended Uses and their Regulatory Phases,
Issues and Concerns and Relevant Guidelines
The Regulatory Landscape in Selected Countries and Pertinent Laws and Issuances in the Philippines

Submitted to the Biotechnology Project Office, Department of Agriculture, 2017

Benavidez PJ II, Halos SC, Mingala CN 2017.
GM Animals: A Review for Regulatory Purposes

Republic of the Philippines
Department of Agriculture
OFFICE OF THE SECRETARY
Elliptical Road, Diliman
Quezon City, 1100 Philippines

July 27, 2020

SPECIAL ORDER
No. 582
Series of 2020

Subject: **CREATION OF INTER-AGENCY TECHNICAL WORKING GROUP (IA-TWG) FOR THE FORMULATION OF THE REGULATORY POLICY FOR GENETICALLY MODIFIED ANIMALS (GMA) AND ANIMAL PRODUCTS**

In the interest of service and to ensure effective implementation of the regulatory framework on products of modern biotechnology in accordance with Executive Order No. 514 s. 2006, an Inter-Agency Technical Working Group for the Formulation of the Regulatory Policy for Genetically Modified Animals and Animal Products is hereby created and shall be composed of the following:

Chair	:	Dr. Claro N. Mingala, *BAI / PCC- LBC*
Vice-Chair	:	Dr. Joselito R. Somga, *BFAR*
Members	:	Ms. Ma. Lorelie U. Agbagala, *DOST-NCBP*
		Dr. Fedelino F. Malbas Jr., *DOH-RITM*
		Dr. Faustino C. Icatlo, *PCLAM*
		Dr. Abraham J. Manalo, *BCP*
		Dr. January M. Nones, *NMIS*
		Ms. Mary Ann R. Escoto, *(Alternate) NMIS*
		Dr. Ma. Lourdes Q. Moreno, *DENR-ERDB*
		Dr. Ravelina R. Velasco, *CLSU-College of Fisheries*
		Mr. Andrew D. de los Angeles, *FDA*
		Ms. Amparo C. Ampil, *DA-FAFPD*
		Mr. Joshua Israel V. Sumague, *(Alternate) DA-FAFPD*
		Engr. Jacqueline M. Romualdez, *FPA*
		Dr. Simeona E. Regidor, *BFAR*
		Dr. Rainelda M. dela Peña, *BAI-VLD*

4th International Workshop on Regulatory Approaches for Agricultural Applications of Animal Biotechnologies

12-16 September, 2022 – São Paulo, Brazil

ARTICLES

- Preambulatory Clauses
- Article I. General Provisions
- Article II. Biosafety Decisions
- Article III. Administrative Framework
- Article IV. Policy Guidelines on Biosafety Assessment Based on Classification of Regulated Articles
- Article V. Miscellaneous Provisions

ARTICLE I. GENERAL PROVISIONS

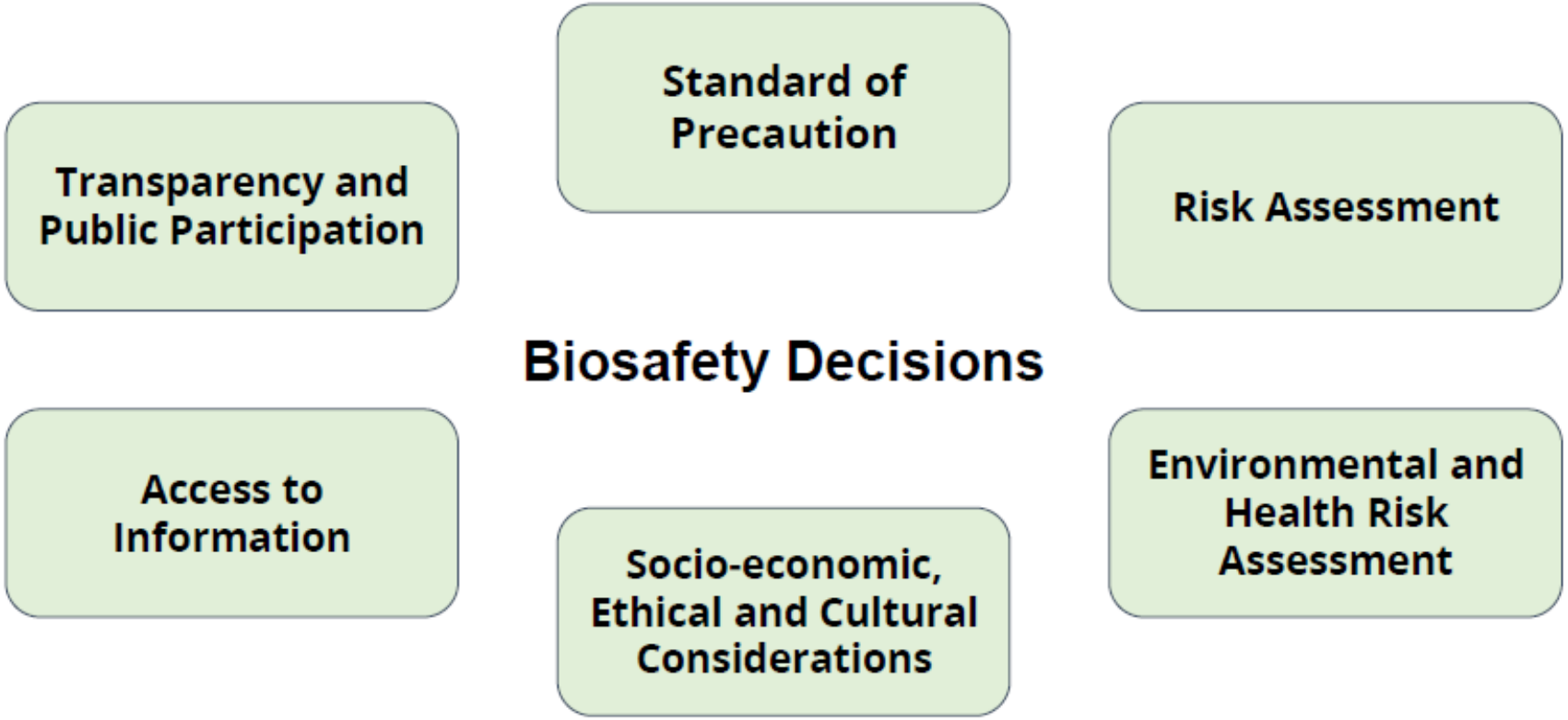
Section 1. Applicability.

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

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

ARTICLE II. BIOSAFETY DECISIONS

Section 3. Guidelines in Making Biosafety Decisions.



ARTICLE III. ADMINISTRATIVE FRAMEWORK

Section 4. Role of Government Agencies (NGAs).

DA

- **Lead in addressing biosafety issues related to the economy's agricultural productivity and food security.**
- **Lead in the evaluation and monitoring of regulated articles.**

DOST

- Lead in ensuring that the best science is utilized and applied in adopting biosafety policies and in making biosafety decisions
- Lead in evaluating and monitoring contained use of regulated articles

DENR

- Ensure that the applicable environmental assessments are undertaken, and potential impacts identified.
- Lead in evaluating and monitoring bioremediation, improvement of genetic resources, and wildlife genetic resources.

DOH

- Formulate guidelines and review results of assessing the health impacts posed by modern biotechnology.
- Lead in evaluating and monitoring processed food derived from or containing GMOs.

DILG

- Formulate guidelines and review results of assessing the health impacts posed by modern biotechnology.
- Lead in evaluating and monitoring processed food derived from or containing GMOs.

ARTICLE III. ADMINISTRATIVE FRAMEWORK

Section 4. Role of Government Agencies (NGAs).

DA	DOH	DENR	DOST	DILG
BAI	FDA	EMB	DOST-BC	LGU
BFAR		BMB		
NMIS				
FPA				
NDA				

ARTICLE III. ADMINISTRATIVE FRAMEWORK

Section 5. Biosafety Committees (BC).

The DOST, DA, DENR, and DOH shall each constitute a Biosafety Committee, or an equivalent body, composed of members possessing scientific or technological knowledge necessary for the evaluation of applications under this Circular, in accordance with their Department's mandate.

ARTICLE III. ADMINISTRATIVE FRAMEWORK

Section 6. Joint Assessment Group (JAG).

- Established and chaired by BAI or BFAR per application of a biosafety permit
- Responsible for the actual conduct of safety evaluation
- Composed of qualified representatives or personnel from the concerned Department's Biosafety Committees

ARTICLE III. ADMINISTRATIVE FRAMEWORK

Section 7 & 8. BAI Biotechnology Office and BFAR Biotechnology Office

Each Bureau shall establish a Biotechnology Office to provide frontline services in accepting, sorting, and processing of application for permits under this Circular. The Biotechnology Office shall also provide technical and administrative assistance to the JAG established by its respective office.

ARTICLE III. ADMINISTRATIVE FRAMEWORK

Section 9. Institutional Biosafety Committee (IBC)

The company or institution applying for a permit shall constitute an IBC composed of at least five members.

The membership of the IBC shall be approved by the DOST-Biosafety Committee for contained use or by the DA-Biosafety Committee for limited release.

ARTICLE III. ADMINISTRATIVE FRAMEWORK

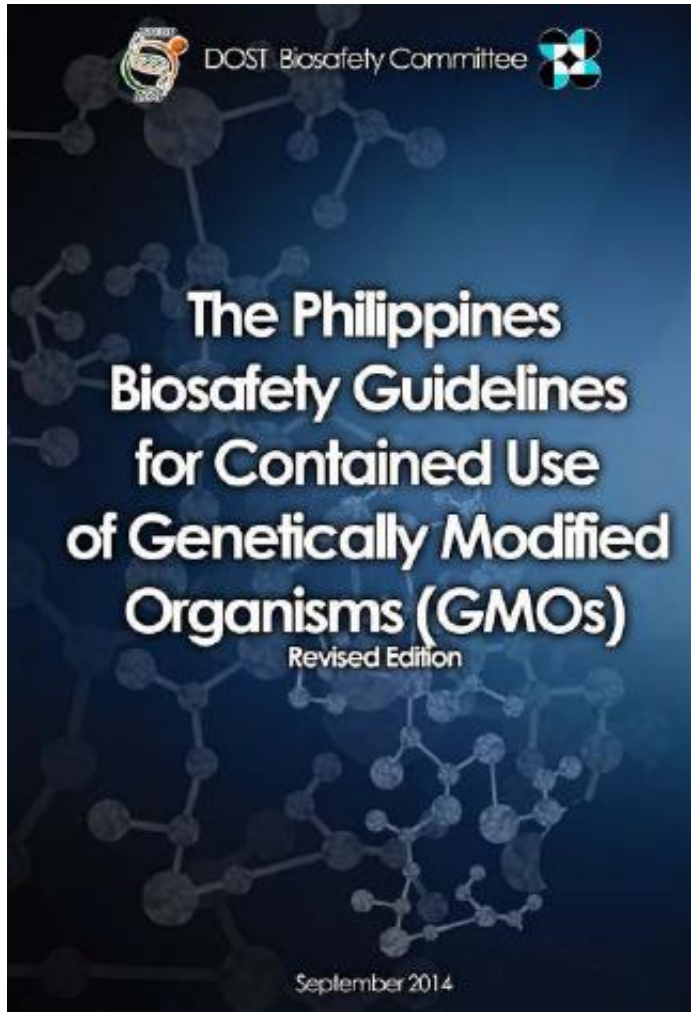
Section 10. External Technical Experts (ETE).

- The DOST, DA, DENR, and DOH may appoint one (1) external expert as their Biosafety Committee consultant to the Joint Assessment Group

ARTICLE IV. POLICY GUIDELINES ON BIOSAFETY ASSESSMENT 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



ARTICLE IV. POLICY GUIDELINES ON BIOSAFETY ASSESSMENT BASED ON CLASSIFICATION OF REGULATED ARTICLES

Policy on the Commercial Use of a Regulated Article Under Containment

• Food, feed, or processing (animals except aquatic species) (BAI)	• Bioreactor for industrial uses (BAI)
• Food, feed, or processing (aquatic species)	• Pets (animals except aquatic species) (BAI)
• Xenotransplantation (BAI)	• Ornamental aquatic species (BFAR)
• Bioreactor for medical/pharmaceutical uses (biopharming) (BAI)	• Other possible uses (BFAR or BAI)

ARTICLE IV. POLICY GUIDELINES ON BIOSAFETY ASSESSMENT BASED ON CLASSIFICATION OF REGULATED ARTICLES

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

• Food, feed, or processing (animals except aquatic species)	• Food, feed, or processing (aquatic flora and fauna species)
• Biocontrol for agricultural purposes	• Other possible uses
• Animal disease control	

ARTICLE IV. POLICY GUIDELINES ON BIOSAFETY ASSESSMENT BASED ON CLASSIFICATION OF REGULATED ARTICLES

		USE		
		Contained	**Limited Release**	**General Release**
PHASE	**R&D**	DOST-BC (Section 11)	BAI or BFAR (Section 12)	
	Commercial	BAI or BFAR (Section 13)		BAI or BFAR (Section 14)

ARTICLE V. MISCELLANEOUS PROVISIONS

Section 25. Appeal.

Applicant, who may be aggrieved by the decision shall have the right to file an appeal to the Secretary of Agriculture within fifteen (15) days.

ARTICLE V. MISCELLANEOUS PROVISIONS

Section 27. Remedies.

In cases of violations of laws, rules and regulations related to biosafety, the following remedies shall apply:

A. Administrative Remedies

B. Criminal Liability

C. Civil Liability

D. International Law

UPDATES:

- Based on the Anti-Red Tape Act's (ARTA) review of the preliminary impact statement, the policy falls under MAJOR regulations; thus, a full regulatory impact assessment (RIA) is required.
- In compliance with RIA, another series of public consultations will be conducted to present other possible policy options, aside from direct regulation, ensuring that the most suitable policy option shall be implemented.

CHALLENGES:

COURT OF APPEALS RULING
April 18, 2024

- to cease and desist from commercially propagating and conducting activities relating to Bt Eggplant and Golden Rice and revoking the Biosafety Permit, until proof of safety and compliance with all legal requirements;
- submitting a concrete mechanisms adopted to monitor all activities conducted, and all measures taken to strengthen the risk assessment procedure
- **enjoining any application for contained use, field testing, direct use as food or feed, or processing, commercial propagation, and importation of genetically modified organisms until compliance is established.**

THANK YOU FOR YOUR ATTENTION!