



IN THE PIPELINE:

Status of Policy Initiatives on Genetically Modified and Gene-Edited Animals

CLARO N. MINGALA, DVM, PhD

Scientist IV, Technical Adviser to the DA
Undersecretary for Livestock and Director of the
DA National Livestock Program

Status of the GM Animal Policy

- 2020: Creation of an Inter-Agency Technical Working Group (IA-TWG) for the formulation of GM animal policy

- Completion of Preliminary Impact Assessment in compliance with ARTA Memorandum Circular No. 2022-06



2017

2020

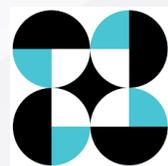
2023

2024



- 2017: DA Studies on GM Animals and New Breeding Techniques conducted by Benavidez, PJ II, Halos, SC & Mingala, CN
- 2019: Endorsement of the studies to NCBP

- 2023: Conduct of public consultations and further refinements based on the recommendations and comments gathered
- Implementation of ARTA Memorandum Circular No. 2022-06, which requires the conduct of Regulatory Impact Assessment for new policy proposals



Proposed DOST-DA-DENR-DOH-DILG 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

Applicability

- ✓ **GM fisheries and other aquatic resources**
- ✓ **GM domesticated animals**
- ✓ **Biological agents for agriculture and fisheries used for biocontrol derived from the use of modern biotechnology**

Products of gene editing are NOT covered under this Circular.

Guidelines in Making Biosafety Decisions

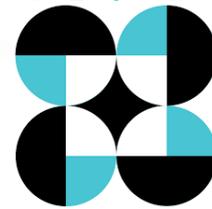


- ✓ **Risk Assessment**
- ✓ **Standard of Precaution**
- ✓ **Environmental and Health Risk Assessment**
- ✓ **Social, Economic, Ethical, and Cultural Considerations**
- ✓ **Access to Information**
- ✓ **Transparency and Public Participation**
- ✓ **Prompt and Efficient Action**

Role of National Government Agencies



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



- 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



- 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.



- 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.



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Policy Guidelines

		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)

* Please send an email to teambiotech@bai.gov.ph to get a copy of the draft policy.

Current Status

- Ongoing conduct of **full Regulatory Impact Assessment (RIA)** on the proposed regulation, providing relevant quantitative and qualitative data on its impacts (expected to be completed by 2nd quarter of 2025)

- **Next step:**
Public consultations, particularly on the results of the RIA

PRELIMINARY IMPACT ASSESSMENT

ARTA
ANTIHERBICIDE AUTHORITY
OFFICE OF THE PRESIDENT

[ADVANCED COPY ONLY]

ANNEX A. ARTA FINDINGS, COMMENTS AND RECOMMENDATIONS

PROPOSAL DETAILS	
Title of the regulatory proposal	DA-DENR-DOH-DILG JOINT DEPARTMENT CIRCULAR SERIES OF 2024 OR THE 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
Agency	Department of Agriculture (DA) – Bureau of Animal Industry (BAI)
Tracking Number	2024-02-PIS

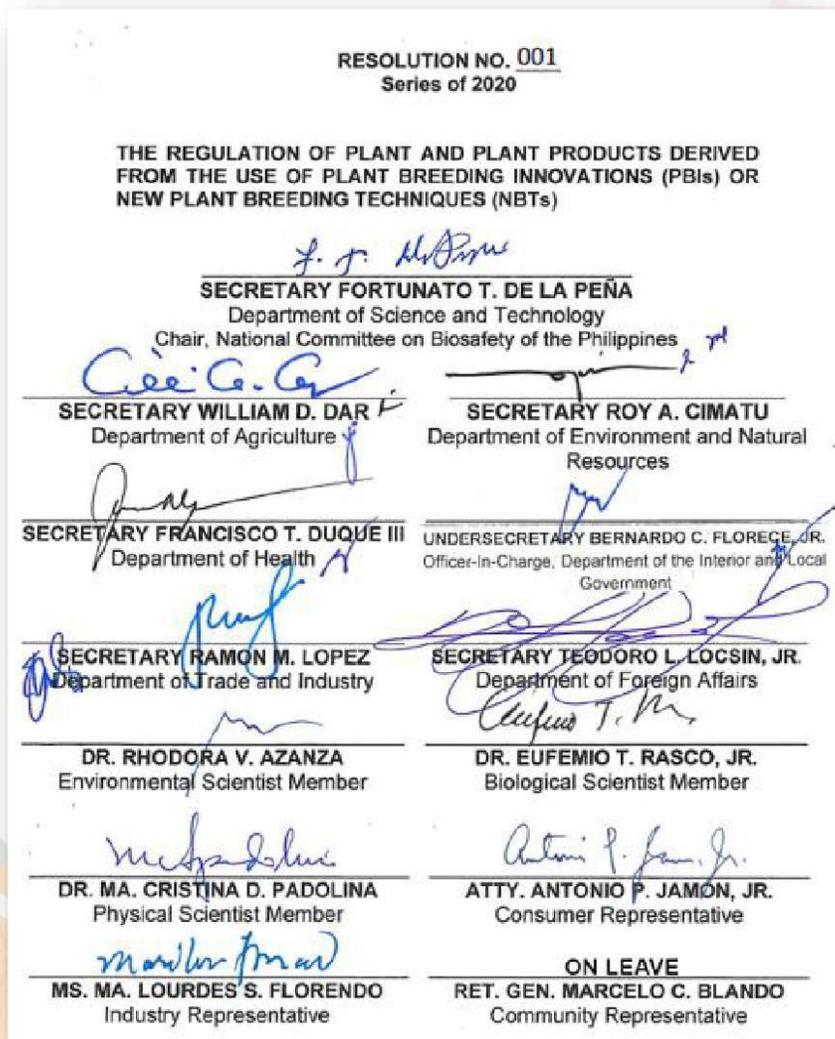
ASSESSMENT DETAILS		
Assessed by:	Reviewed by:	Recommending Approver by:
BETTER REGULATIONS OFFICE – SECTORAL DIVISION A	OMER CALIPH M. ... Division Chief, Better Regulations Office – Sectoral Divisions A	MARIEA L. M. RB ... Director, Better Reg. Office
Approved by:		
... Secretary General, DIVINAGRA ... Approval: MM/DD		

ONGOING

4. SUMMARY OF THE PRELIMINARY IMPACT ASSESSMENT (PIS)

1. The proposed regulation aims to establish a robust, science-based regulatory framework to ensure the safe application of modern biotechnology in genetically modified (GM) animals and animal products. The objective is to ensure the safety of the development, adoption, and use of GM animals and animal products in the country through the conduct of science-based assessments. It also seeks to address the lack of comprehensive regulations governing the safe handling, use, and management of GM animals and animal products derived from modern biotechnology in the Philippines which prevents the benefits of using such technology.
2. The preferred policy option is the creation of a comprehensive regulatory framework in the form of DA-DENR-DOH-DILG Joint Department Circular (JDC), Series of 2024 or the 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 as it claimed to provide a balanced approach that safeguards human and animal health and environmental safety while promoting scientific innovation and industry growth in modern biotechnology applications in animals.
3. BAI also anchored its proposal to Executive Order (EO) No. 514, s. 2006 or the issuance Establishing the National Biosafety Framework Prescribing Guidelines for Its Implementation, Strengthening the National Committee on Biosafety of the Philippines, and For Other Purposes

Policy on New Breeding Techniques



- NCBP Resolution No. 1, s2020 states that products of Plant Breeding Innovations (also generally referred as New Breeding Techniques) may be a GMO if they contain a **novel combination of genetic material obtained using modern biotechnology.**
- Non-GMO or conventional products if they do not contain a novel combination of genetic material.

→ **Will the same principle be applied for NBTs in animals?**

Current Status

A benchmarking study to look into the various aspects in the adoption and use of NBTs in livestock and fisheries is set to be conducted in support of policy development—expected to be completed by 3rd quarter of the year.



PRRS-resistant Pigs (GEd)

Resistance was achieved by deleting the CD163 gene, which serves as a virus-binding site. Considered conventional in Brazil and Colombia.

Gene-edited animals approved in the global market



GEd “Madai” Red Sea Bream

Achieved through knock-out of myostatin, which suppresses muscle growth, increasing the edible part 1.2-1.6 times than the conventional fish, with an improved feed utilization efficiency by about 14%. Approved for commercial sale in Japan.

References:

Van Eenennaam, AL. 2023. *New Genomic Techniques (NGT) in animals and their agri/food/feed products*. ESFA Supporting Publications, Vol. 20 (Issue 9). <https://doi.org/10.2903/sp.efs.2023.EN-8311>
ISAAA's GEd Animal Database: <https://www.isaaa.org/animalbiotechdatabase/default.asp?RegProcess=1>



Thank you for your attention.

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