DEPARTMENT OF AGRICULTURE

POLICIES ON BIOTECH (GE/GnEd) ANIMALS IN THE PHILIPPINES

Joint Department Circular GM Animals and Animal Products Rules and Regulations

Claro N. Mingala, DVSM, PhD
Chair
Inter-Agency for the Formulation of the Regulatory Policy for Genetically Modified Animals (GMA) and Animal Products

DOST-DA-DENR-DOH-DILG
Joint Department Circular
No. ___, 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 Animal and Animal Products Derived from the Use of Modern Biotechnology

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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 Deregulation of Regulated Article
- ❑ Article VI Miscellaneous Provisions

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Article I. General Provisions
Section 1.

Applicability

This Joint Department Circular (JDC) shall apply to the research, 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 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.**

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Article I. Section 2. Definition of Terms

aa. **New/Novel Combination of Genetic Material**

a stable insertion in the genome of one or more genes or DNA sequences that encode proteins that could **not occur through conventional breeding or are found in nature, or are the result of spontaneous or induced mutagenesis**

Article II.
Biosafety Decisions

Section 3. Guidelines in Making Biosafety Decisions

A. Standard of Precaution
B. Risk Assessment
C. Environmental and Health Risk Assessment
D. Socio-economic, Ethical and Cultural Considerations
E. Access to Information
F. Transparency and Public Participation

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Article III.
Administrative Framework
Section 4. Role of National Government Agencies

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

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Article III.
Administrative Framework

Section 5. **Biosafety Core Team (BCT)**

The DOST, DA, DENR, and DOH shall constitute their respective Biosafety Core Team, or an equivalent body, composed of personnel **based within the agency** possessing scientific or technological knowledge sufficient in the evaluation of applications under this Circular with respect to the Department's mandate.

At least two members of the relevant BCT shall be designated as representative-member to the JAG.

Article III.
Administrative Framework

Section 6. **Joint Assessment Group (JAG)**
The BAI or BFAR, as the case may be, shall establish a JAG per application of a biosafety permit. The JAG shall be **responsible for the actual conduct of safety evaluation** under this Circular...

...The JAG **shall facilitate the drafting and finalization of its recommendation documents for submission** to the BAI or BFAR Director who will approve or deny the issuance of the biosafety permit.

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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 Biotech 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

Section 10.

Scientific and Technical Review Panel

Section 11.

External Technical Experts

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Article IV

Policy Guidelines on Biosafety Assessment Based on Classification of Regulated Articles

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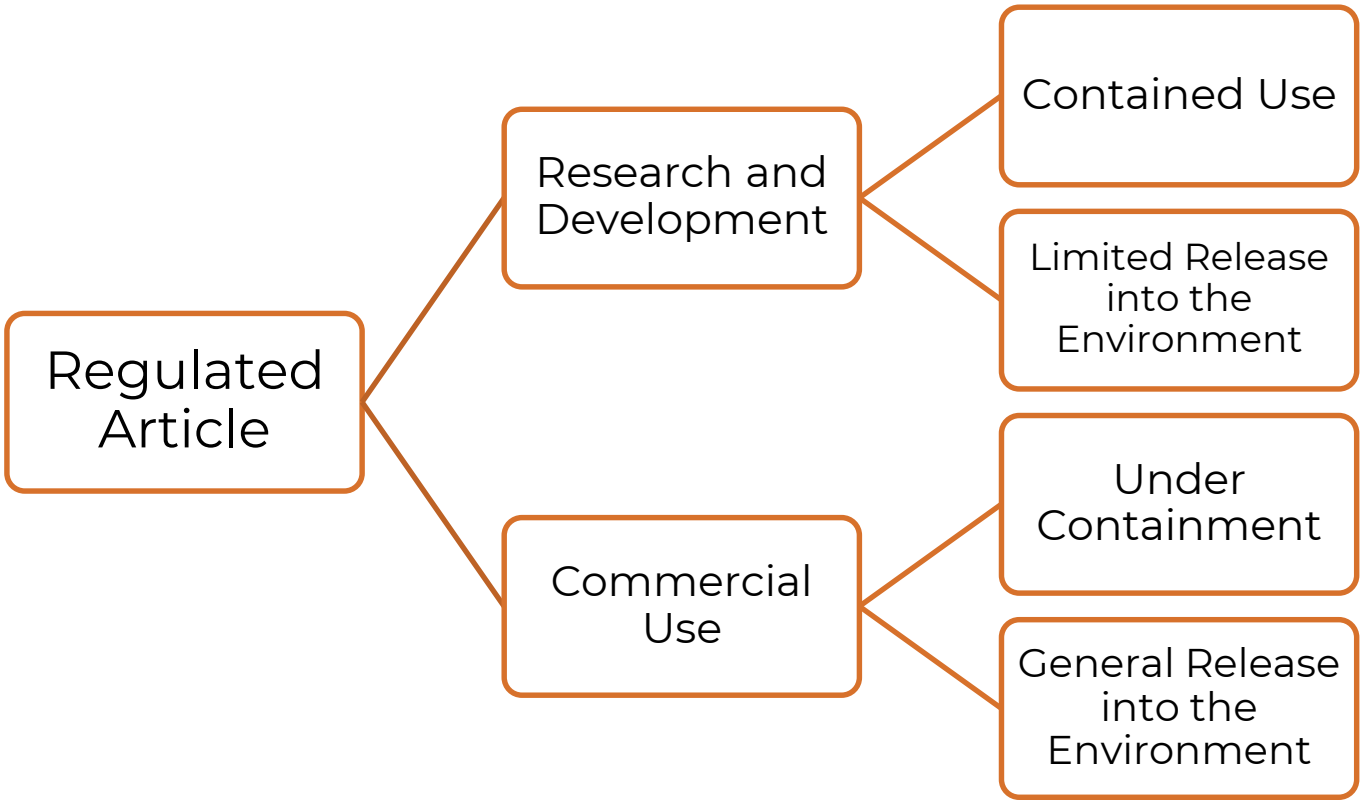
Classification of Regulated Articles

Article IV



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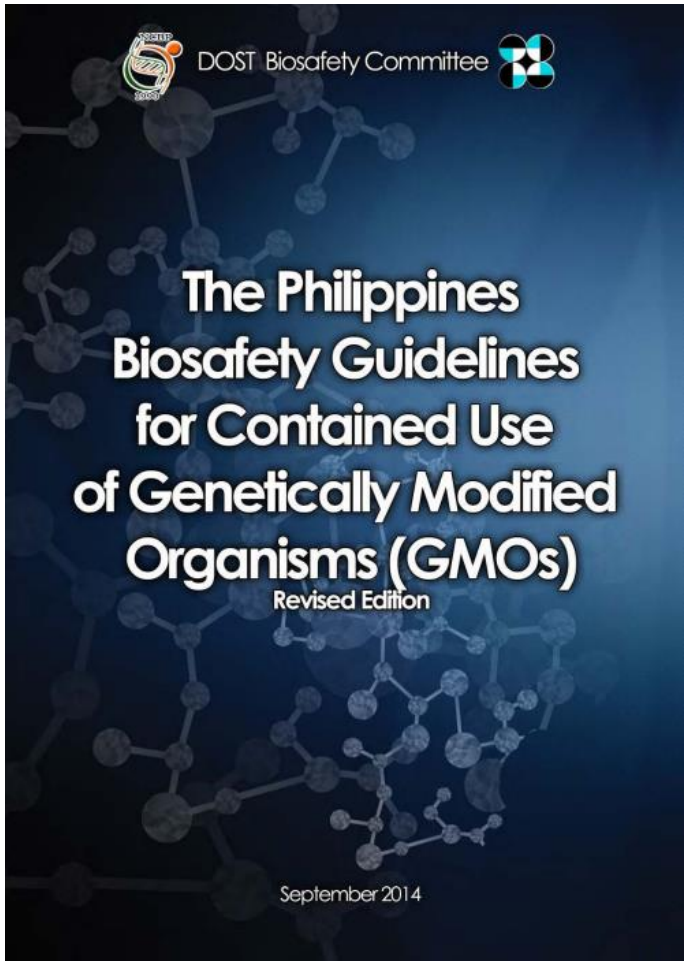
Article IV. Section 11.

R&D of a Regulated Article under Contained Use



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Article IV. Section 12.

R&D of a Regulated Article for Limited Release into the Environment

The limited release of a regulated article for the purpose of research and development shall be governed by the **DOST-Biosafety Committee in coordination with other concerned regulatory agencies, such as the BAI, BFAR, FPA, EMB, and BMB.**

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Article IV. Section 13.

Formulation and Issuance of Joint Guidelines based on Particular Commercial Use of a Regulated Article

The concerned government regulatory agencies **shall jointly formulate and issue corresponding guidelines** on the decision-making procedure for the safety evaluation of a regulated article.

Article IV. Section 13.

Purpose-specific Guidelines for Commercial Use of a Regulated Article shall determine, among others

a) Definition of terms
b) Permitted commercial uses or applications
c) Specific functions of government regulatory agencies involved
d) Procedure for the application and issuance of a biosafety permit for a particular use, including the decision-making process involved

Concerned Regulatory Agencies on the Commercial Use of a Regulated Article under Containment

Article IV, Section 14

Food, Feed, or Processing (Animals Except Aquatic)	• BAI • FDA, NMIS, NDA, EMB, BFAR (Aquatic Feeds)
Food or Processing (Aquatic species)	• BFAR • FDA, EMB
Xenotransplantation	• BAI • FDA, EMB
Bioreactor (Medical/Pharmaceutical)	• BAI • FDA, EMB
Bioreactor (Industrial)	• BAI • EMB
Pets (Terrestrial)	• BAI • EMB
Ornamental Aquatic Species	• BFAR • EMB
Others	• BAI and/or BFAR • Other concerned agencies

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Concerned Regulatory Agencies on the Commercial Use of a Regulated Article for General Release into the Environment

Article IV, Section 15

Food, Feed, or Processing (Animals Except Aquatic)	• BAI • FDA, NMIS, NDA, EMB, BFAR (for aquatic feeds)
Food or Processing (Aquatic Species)	• BFAR • FDA, EMB
Biocontrol (Agricultural purposes)	• BAI • FPA, EMB
Biocontrol (For Human Health, Household, and Industrial Uses)	• BAI • DOH, FDA, EMB, BMB
Animal Disease Control	• BAI for terrestrial / BFAR for aquatic animal, fauna • EMB
Others	• BAI or BFAR • Other concerned agencies

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Policy on the Commercial Use of a Regulated Article

Article IV, Section 13

Filing

- The developer shall **file an application** for biosafety permit for commercial use, whether under containment or for general release into the environment **at the BAI or BFAR Biotechnology Office** as the case may be.

Evaluating

- BAI or BFAR shall form a **JAG** with the **concerned regulatory agencies** specified in the Circular. The **JAG shall evaluate** and make a **technical recommendation** to the BAI or BFAR Director.

Granting of the Biosafety Permit

- **The BAI or BFAR Director shall grant or deny** the application for a biosafety permit as per recommendation of the JAG.

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Deregulation of Regulated Article

Proposals for further discussion

- Validity of the biosafety permit shall be the same with the existing permits provided by the agency.
- To anchor the biosafety permit for GM Animals and Animal Products to that of GM Plant and Plant Products regulations.
- A firm scientific justification as to deciding the validity of biosafety permit for GM Animals and Animal Products.

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Funding

Section 40, Article VII – Miscellaneous Provision

The DOST, DENR, DA, DOH, and DILG **shall allocate from their present budgets such amount as may be necessary to implement this Circular**, including support to operations of their respective Biosafety Core Team and Biotechnology Office, as applicable. The **Department of Agriculture shall allocate funds for the creation of the BAI Biotechnology Office and the BFAR Biotechnology Office**, including the creation of plantilla positions or assignment of necessary personnel for the setting up and maintenance of a physical office. Thereafter, the funding requirements shall be included in the annual General Appropriations Act submitted to Congress.

Thank you.

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