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DENR MEMORANDUM ORDER
No. 2021 - 05

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SUBJECT : **ADOPTION OF THE STANDARD PROTOCOL ON THE CONDUCT OF ENVIRONMENTAL RISK ASSESSMENT OF GENETICALLY MODIFIED PLANT AND PLANT PRODUCTS DERIVED FROM THE USE OF MODERN BIOTECHNOLOGY**

Pursuant to Executive Order (E.O) No. 514 entitled *"Establishing the National Biosafety Framework (NBF), Prescribing Guidelines for its Implementation, Strengthening the National Committee on Biosafety of the Philippines (NCBP) and for other Purposes,"* DOST-DA-DENR-DOH-DILG Joint Department Circular (JDC) No. 1, Series of 2016 and consistent with the substantive requirements of Presidential Decree (P.D.) No. 1586, otherwise known as the Philippine Environmental Impact Statement System, the standard protocol on the conduct of environmental risk and impact assessment of genetically modified plant and plant products derived from the use of modern biotechnology is hereby adopted for the information and guidance of all concerned:

I. MANDATE

The review and evaluation of the submitted Project Description Report (PDR) and Environmental Risk Assessment (ERA) for field trial, commercial propagation and direct use of regulated articles for food and feed, or for processing and review of petition documents for deregulation of regulated articles as well as preparation of technical reports to be submitted to Bureau of Plant Industry (BPI) of the Department of Agriculture will be based on the standard of precaution and environmental risk assessment. Any biosafety decision shall be consistent with policies and standards on risk assessment issued by the NCBP and guided by Annex III of the Cartagena Protocol on Biosafety pursuant to the NBF.

II. PRINCIPLES/GUIDELINES/PROTOCOL

The following principles/guidelines/protocol shall be followed by the DENR-Biosafety Committee (DENR-BC) when performing exposure pathway-based risk assessments and preparing technical reports to be forwarded to the BPI.

A. STANDARD OF PRECAUTION

Lack of scientific certainty or consensus due to insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects of a genetically modified (GM) organism on the environment, particularly on the conservation and sustainable use of biological diversity, and on human health, shall not prevent the DENR from making the appropriate decision to avoid or minimize such potential adverse effects. In such cases, the DENR shall take the necessary action to protect public interest and welfare.

B. RISK ASSESSMENT

The risk assessment shall be mandatory and central in making biosafety decisions, consistent with policies and standards on risk assessment issued by the NCBP; and guided

by the Cartagena Protocol on Biosafety. The form of risk assessment shall be based on the identification of exposure pathways to the GM crop that might result in environmental harm. The formulation of pathways to harm was developed from the capacity-building efforts of the DENR-BC and is consistent with the considerations indicated in Annex III (Risk Assessment) of the Cartagena Protocol on Biosafety. Such risk assessment is based, at a minimum, on information provided and other available scientific evidence to identify and evaluate the possible adverse effect of genetically modified plants and plant products on the environment.

C. PRINCIPLES ON RISK ASSESSMENT

Pursuant to the NBF, the following principles shall be followed when performing a risk assessment to determine whether a regulated article poses significant risks to the environment:

i. The risk assessment shall be carried out in a scientifically sound and transparent manner based on available scientific and technical information. The expert advice of and guidelines developed by relevant international organizations, including intergovernmental bodies and regulatory authorities of countries with significant experience in the regulatory supervision of the regulated article shall be considered. In the conduct of risk assessment, the Cartagena Protocol on Biosafety shall be adopted as well as other internationally accepted consensus documents, such as those issued by the Organization for Economic Co-operation and Development (OECD).

ii. Lack of scientific knowledge or scientific consensus shall not be interpreted as indicating a particular level of risk, an absence of risk, or an acceptable risk.

iii. The identified characteristics of a regulated article and its use which have the potential to pose significant risks to the environment shall be compared to those presented by the non-modified organism from which it is derived and its use under the same conditions.

D. PROTOCOLS

i. The risk assessment shall be carried out case-by-case and on the basis of the transformation event. The required information may vary in nature and level of detail from case to case depending on the regulated article concerned, its intended use, and the receiving environment.

ii. The DENR-BC shall draft a technical report on the evaluation of the application. The report shall then be endorsed and submitted by the DENR-BC Chair to the BPI within 30 days from receipt of the copy of the application.

iii. If new information on the regulated article and its effects on the environment become available, and such information are relevant and significant, the risk assessment shall be readdressed to determine whether the risk has changed or whether there is a need to amend the risk management strategies accordingly.

E. ROLE OF DENR-BC MEMBERS

The DENR-BC is composed of the Environmental Management Bureau (EMB), Biodiversity Management Bureau (BMB), Ecosystems Research and Development

Bureau (ERDB), Forest Management Bureau (FMB), DENR Legal Affairs Service and DENR Policy and Planning Service. The DENR-BC shall ensure that environmental risks and impacts of regulated articles for field trial, commercial propagation and direct use of living modified organisms are evaluated. The following Bureaus will focus on the pertinent provision under their mandate:

i. Environmental Management Bureau (EMB)- substantive requirements of P.D. 1586 or "Establishment of the Philippine Environmental Impact Statement System including other Environmental Management Related Measures and for Other Purposes."
ii. Biodiversity Management Bureau (BMB)- Section 16 of Republic Act 9147 or the Wildlife Resources Conservation and Protection Act."
iii. Ecosystems Research and Development Bureau (ERDB)-formulates and recommends integrated research programs relating to Philippine ecosystems and natural resources such as minerals, lands, forests, as holistic and interdisciplinary fields of inquiry. Generates technologies and promote scientific assistance in the research and development of technologies relevant to the sustainable uses of Philippine ecosystems and natural resources. ERDB will offer support to DENR-BC's review and evaluation focusing on a science-based approach to regulation, through providing the information gained from its research studies on necessary aspects of biosafety such as environmental impact.
iv. Forest Management Bureau FMB - Presidential Decree No. 705 or the Revised Forestry Code of the Philippines and to offer support to the DENR-BC's review and evaluation.

Each Bureau shall adopt their own procedures to ensure that their provisions are followed.

This Order shall take effect immediately.

ROY A. CIMATU
Secretary

REPUBLIC OF THE PHILIPPINES
DEPARTMENT OF ENVIRONMENT AND NATURAL RESOURCES
SENR060376

ANNEX A

Definition of Terms. As used in this Order, the following terms shall mean as:

a) *Biosafety* – the condition in which the probability of harm, injury and damage resulting from the intentional and unintentional introduction and/or use of a regulated article is within acceptable and manageable levels;

b) *Biosafety decision* – the development, adoption and implementation of all biosafety policies, measures and guidelines and in making decisions concerning the research, development, handling and use, transboundary movement, release into the environment and management of regulated articles;

c) *Cartagena Protocol on Biosafety*- an international agreement which aims to ensure the safe handling, transport and use of living modified organisms (LMOs) resulting from modern biotechnology that may have adverse effects on biological biodiversity, taking also into account risks to human health;

d) *Commercial Propagation* – introduction or delivery for introduction into commerce of a regulated article for regeneration into plants or plant products for consumption by humans or animals;

e) *Environment* – surrounding air, water, both ground and surface, land, flora, fauna, humans and their inter-relations;

f) *Environmental Risk Assessment (ERA)* – the conduct of identifying and evaluating the potential adverse effects of regulated articles on the conservation and sustainable use of biological diversity in the likely potential receiving environment using the ERA guidelines;

g) *Field Trial* – any intentional introduction into the environment of a regulated article that passed the contained use and confined test, for purposes of research and development, and for which specific confinement and mitigating measures may be imposed. Field trial may be conducted in a single site or in multiple sites;

h) *Genetically-modified organism (GMO)* – also referred to as "living modified organism" under the Cartagena Protocol on Biosafety and refers to any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology;

i) *Modern biotechnology* – the application of: a) in vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) or direct injection of nucleic acid into cells or organelles; or b) fusion of cells beyond the taxonomic family, that overcome natural physiological reproductive or recombination barriers and that are not techniques used in traditional breeding or selection;

j) Pathway to Harm – is a causal chain of events that need to occur for a harm to be realized. The plausible pathways or conceptual models are constructed to describe how the proposed activity could lead to possible harm to operational protection goals;

k) *Regulated article* – genetically-modified organisms and its products, but limited to genetically-modified plants and plant products under the scope of the JDC;

l) Risk – combination of the likelihood that an adverse consequences of a biohazardous activity or trait that will occur and the magnitude of such a consequence;

m) Transformation – a step in the genetic engineering process where a new gene (transgene) is delivered into the nucleus of a plant cell and inserts into a chromosome where it is passed on to progeny. Transformation means to genetically change a living thing;

n) Transformation event – refers to the instance of entry, stable integration and expression of an introduced gene into a cell, which then develops into a functional organism expressing the introduced gene.