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DOST-DA-DENR-DOH-DILG
Joint Department Circular[1]
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

WHEREAS, the Constitution protects the rights of the people to life, to health and to a balanced and healthful environment;

WHEREAS, the Philippines is a party to the United Nations Convention on Biological Diversity and its Cartagena Protocol on Biosafety;

WHEREAS, Executive Order (E.O.) No. 514, series of 2006, "*Establishing the National Biosafety Framework, Prescribing Guidelines for Its Implementation, Strengthening the National Committee on Biosafety of the Philippines, and for other Purposes,*" was issued to guide 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;

WHEREAS, under E.O. No. 514, series of 2006, the National Committee on Biosafety of the Philippines (NCBP) shall be the lead body to coordinate and harmonize inter-agency and multi-sector efforts to develop biosafety policies in the country and set scientific, technical and procedural standards on actions by agencies and other sectors to (a) promote biosafety in the Philippines; (b) oversee the implementation of the National Biosafety Framework (NBF); (c) act as a clearing house for biosafety matters; and (d) coordinate and harmonize the efforts of all concerned agencies and departments in this regard;

WHEREAS, the Department of Science and Technology (DOST), under E.O. No. 292, series of 1987, "*Instituting the Administrative Code of 1987,*" is mandated to provide central direction, leadership and coordination of scientific and technological efforts and ensure that the results therefrom are geared and utilized in areas of maximum economic and social benefits for the people;

[1] Circulars shall refer to issuances prescribing policies, rules and regulations, and procedures promulgated pursuant to law, applicable to individuals and organizations outside the Government and designed to supplement provisions of the law or to provide means for carrying them out, including information relating thereto xxx (E.O. 292, Bk IV, Ch 11, Sec 50 (1)).

WHEREAS, under the NBF, the DOST shall take the lead in evaluating and monitoring regulated articles intended for contained use;

WHEREAS, the Department of Agriculture (DA), through the Bureau of Plant Industry (BPI), is responsible for the prevention of introduction, incursion, establishment and subsequent spread of plant pests by regulating the international and domestic movements of plants and plant products, under Presidential Decree (P.D.) No. 1433, as amended, *"Promulgating the Plant Quarantine Law of 1978, thereby Revising and Consolidating Existing Plant Quarantine Laws to Further Improve the Plant Quarantine Service of the Bureau of Plant Industry"*;

WHEREAS, the DA, under E.O. No. 292, series of 1987, is responsible for promoting the well-being of farmers and other rural workers, by providing an environment in which they can increase their income, improve their living conditions, and maximize their contributions to the national economy;

WHEREAS, the Department of Environment and Natural Resources (DENR), under E.O. No. 192, series of 1987, *"Reorganization Act of the Department of Environment and Natural Resources,"* is the primary agency responsible for the conservation, management, development and proper use of the country's environment and natural resources, and the regulation of projects and activities that may significantly affect the environment;

WHEREAS, the Department of Health (DOH), under E.O. No. 292, series of 1987, is primarily responsible for the formulation, planning, implementation, and coordination of policies and programs in the field of health, with the primary function of promoting, protecting, preserving or restoring the health of the people through the provision and delivery of health services and through the regulation and encouragement of providers of health goods and services;

WHEREAS, pursuant to Republic Act (R.A.) No. 7160, otherwise known as the *"Local Government Code of 1991,"* the Department of the Interior and Local Government (DILG) has the power and function to establish a system of coordination and cooperation among the citizenry, local executives and other departments, to ensure effective and efficient delivery of basic services to the public, specifically, agricultural extension and on-site research services and facilities, which include prevention and control of plant and animal pests and diseases;

WHEREAS, Sections 2(c), 26, and 27 of R.A. No. 7160 require prior consultation with local government units (LGUs) and relevant stakeholders to explain the goals and objectives of a project or program, its impact upon the people and the community in terms of environmental or ecological balance, and the measures that will be undertaken to prevent or minimize the adverse effects thereof;

WHEREAS, the Departments of Agriculture, Health, and Interior and Local Government, are responsible for the enforcement of food safety and sanitary rules and regulations, including inspection and compliance, under Republic Act No. 10611, otherwise known as the *"Food Safety Act of 2013"*;

WHEREAS, under Republic Act No. 7394, "*Consumer Act of the Philippines,*" it is the policy of the State to protect the interests of consumers, promote their general welfare, and to establish standards of conduct for business and industry including the protection against hazards to health and safety;

WHEREAS, under Republic Act No. 11032, *"Ease of Doing Business and Efficient Government Service Delivery Act of 2018," the* State shall take appropriate measures to promote transparency in each agency with regard to the manner of transacting with the public, which shall encompass a program for the adoption of simplified requirements and procedures that will reduce the red tape and expedite business and nonbusiness related transactions in government;

NOW, THEREFORE, the Departments of Science and Technology, Agriculture, Environment and Natural Resources, Health, and Interior and Local Government issue this Joint Department Circular governing 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.

ARTICLE I. GENERAL PROVISIONS

Section 1. **Applicability.** This Joint Department Circular shall apply to the research, development, handling and use, transboundary movement, release into the environment, and management of plants and plant products derived from the use of modern biotechnology. Consistent with the National Committee on Biosafety of the Philippines Resolution No. 001, series of 2020, "*The Regulation of Plant and Plant Products Derived from the Use of Plant Breeding Innovations (PBIs) or New Plant Breeding Techniques (NBTs),*" products of PBIs or NBTs that do not contain novel combinations of genetic materials obtained through the use of modern biotechnology are not covered by this Circular.

Section 2. **Definition of Terms.** For purposes of this Circular, the following terms shall mean:

a) "*Applicant*" – refers to the juridical person who, for the duration of the proposed activity, has control over the importation or release into the environment of a regulated article and shall ensure compliance with all the requirements in this Circular and the conditions specified in the relevant permit. An applicant may be: (1) any of the departments or agencies of the Philippine Government; (2) a university-based research institution in the Philippines; (3) an international research organization duly recognized by the Philippine Government and based in the Philippines, subject to terms and conditions agreed between the organization and the government of the Philippines; (4) a corporation registered with the Securities and Exchange Commission of the Philippines; or (5) a cooperative registered with the Cooperative Development Authority of the Philippines;

b) *"Biosafety"* – refers to 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;

c) *"Biosafety decision"* – applies to 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;

d) *"Biological diversity" or "biodiversity"* – refers to the variability among living organisms from all sources including, among others, terrestrial, marine and other aquatic ecosystems and the ecological complexes of which they are part; this includes diversity within species, between species and of ecosystems;

e) *"Commercial propagation"* – refers to the introduction or delivery for introduction into commerce of a regulated article for regeneration into plants or plant products for consumption by humans or animals;

f) *"Contained use"* – refers to any operation, undertaken within a facility, installation or other structures, which involves genetically modified organisms (GMOs) that are controlled by specific measures that effectively limit their contact with, and their impact on, the external environment. Containment may be achieved by physical, biological, chemical, or temporal measures, or a combination of these;

g) *"Country of origin"* – refers to the country where the genetically modified plants or plant products were developed or produced;

h) "Ecosystem" – refers to a dynamic complex of plant, animal and micro-organism communities and their non-living environment interacting as a functional unit;

i) "*Environment*" – refers to any ecosystem that is likely to come into contact with a regulated article;

j) *"Environmental risk assessment (ERA)"* – refers to the evaluation of the likelihood that adverse effects on the conservation and sustainable use of biological diversity may occur as a result of exposure to a regulated article;

k) *"Field trial "* – refers to any intentional introduction of a regulated article into the environment, as authorized by the Bureau of Plant Industry, wherein specific isolation and mitigating measures are imposed to restrict movement outside an approved site;

l) *"Genetically modified organism (GMO)"* – also refers to "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;

m) *"Handling and use"* – refers to the process by which regulated articles are moved, carried, transported, delivered, stored or worked with;

n) "Hazard" – refers to any source of potential damage, harm or adverse effects;

o) *"Modern biotechnology"* – refers to the application of: (1) in vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) or direct injection of nucleic acid into cells or organelles; or (2) 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;

p) "*Plant*" – refers to any living stage or form of any member of the plant kingdom and parts thereof, including seeds, rhizomes, bulbs and corms, grafts, leaves, roots, scions and others that may be used for propagation;

q) "*Plant product*" – refers to any material derived from plants in their natural state or in processed form;

r) "*Person*" – refers to any natural person or juridical entity, such as an organization, corporation, or cooperative;

s) "*Pest-protected plant*" – refers to any plant that is made pest-resistant through the use of any of the techniques of modern biotechnology;

t) *"Plant-incorporated protectant (PIP)"* – refers to pesticidal substance produced by plants and the genetic material necessary for the plant to produce the substance;

u) "*Public hearing"* – refers to the face-to-face or virtual meeting with stakeholders to provide information and opportunity for them to submit comments on any application for field trial of a regulated article;

v) *"Public participation"* – refers to the promotion, facilitation and conduct of public awareness, education, and meaningful, responsible and accountable participation in the development and adoption of biosafety policies, guidelines and measures, and applies to all stages of the biosafety decision-making process from the time the application is received. Public participation shall include: (1) notice to all concerned stakeholders, in a language understood by them and through media to which they have access; (2) adequate and reasonable timeframes for public participation procedures; (3) public consultations, as a way to secure wide input into decisions to be made; (4) written submissions; and (5) consideration of public concerns in the decision-making phase following consultation and submission of written comments;

w) *"Regulated article"* – refers to genetically modified plants and plant products under the scope of this JDC;

x) *"Release into the environment"* – refers to the field trial or commercial propagation of a regulated article;

y) *"Responsible officer"* – refers to an officer appointed by the applicant for the

importation or release into the environment of a regulated article who shall ensure that all appropriate measures are taken to prevent significant risks to human health and the environment. The responsible officer shall be a resident of the Philippines and the highest-ranking officer of the applicant;

z) "Risk" – refers to the likelihood of the occurrence of damage, harm or an adverse effect;

aa) "*Risk assessment*" – refers to the scientifically based process of hazard identification and estimation of risk;

bb) "*Risk management*" – refers to the appropriate mechanisms, measures and strategies to regulate, mitigate, and control risks identified in the risk assessment;

cc) *"Sanitary and Phytosanitary Import Clearance (SPSIC)"* – refers to the document issued prior to importation by the concerned bureau or agency to ensure that the products being imported meet standards to protect human, animal or plant life or health, ensuring that the agricultural and fishery products are safe for consumers and to prevent the spread of pests or diseases among animals or plants. Such document also prescribes the conditions to be complied with by the importer for the maintenance of quality and suitability of the product for intended purpose;

dd) *"Stacked events"* – refer to genetically modified plants and their products that have been developed using multiple transformation events encoding several proteins that confer specific traits;

ee) *"Transboundary movement"* – refers to the movement of living modified organisms from one country to another; and

ff) *"Transformation event"* – refers to the uptake and integration of specific sequences of DNA in the genome of the host organism in which the introduced DNA is intended to change the phenotype of the recipient organism in a predictable manner.

ARTICLE II. BIOSAFETY DECISIONS

Section 3. **Guidelines in Making Biosafety Decisions.** The principles under the NBF shall guide concerned agencies in making biosafety decisions to determine whether a regulated article does not pose greater risks to human health and the environment compared to its conventional counterpart. In making biosafety decisions, the concerned agencies shall take into account the following:

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 organism on the environment, particularly on the conservation and sustainable use of biological diversity, and on human health, shall not prevent concerned government departments and agencies from making the appropriate decision to avoid or minimize such potential adverse

effects. In such cases, concerned government departments and agencies shall take the necessary action to protect public interest and welfare.

B. *Risk Assessment.* 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 Annex III of the Cartagena Protocol on Biosafety. 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 human health and the environment:

1. 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 taken into account. In the conduct of risk assessment, the principles articulated by the Codex Alimentarius Commission Guidelines 44-2003: *Principles for the Risk Analysis of Foods Derived from Modern Biotechnology* and 45-2003: *Guideline for the Conduct of Food Safety Assessment of Foods Derived from the Recombinant-DNA Plants*, including subsequent amendments thereto, shall be adopted;
2. 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;
3. The identified characteristics of a regulated article and its use which have the potential to pose significant risks to human health and 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;
4. The risk assessment shall be carried out case-by-case and on the basis of 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; and
5. If new information on the regulated article and its effects on human health and the environment becomes available, and such information is 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.

C. *Environmental and Health Risk Assessment.* In making biosafety decisions under this Circular, government departments and agencies shall consider the environmental and health risks of the proposed activity. For this purpose, the evaluation of the applicable environmental and health risks is integrated into this Joint Department Circular.

D. *Social, Economic, Ethical, and Cultural Considerations.* In reaching a decision for the direct use as food and feed, or for processing, or the commercial propagation of a regulated article, social, economic, ethical, and cultural consideration arising from the impact of regulated articles on the conservation and sustainable use of biological diversity may be taken into account, especially with regard to the value of the affected biological diversity to local and indigenous cultural communities.

E. *Access to Information.* Government departments and agencies shall respect the right of the public and stakeholders to information relevant to biosafety decisions including information on applications, results of risk assessments, environmental, health and food safety assessments, public participation processes, and other information on which biosafety decisions are made, subject to the protection of confidential business information that does not impair the ability of stakeholders to effectively conduct a scientific risk assessment.

F. *Transparency and Public Participation.* Decision taken under this Circular shall be arrived at in a transparent and participatory manner. Stakeholders and the public shall have appropriate access to information and the opportunity to participate in a responsible and accountable manner in biosafety decision-making processes. To ensure public participation, the following requirements shall be complied with:

1. *Notice to all concerned stakeholders, in a language understood by them and through media to which they have access.* Such notice must be adequate, timely, and effective and posted prominently in public places in the areas affected, and in the case of commercial releases, in the national print media. In all cases, such notices must be posted electronically on the internet;
2. *Adequate and reasonable time frames for public participation procedures.* Such procedures should allow stakeholders to understand and analyze the benefits and risks, consult with independent experts, and make timely interventions. Concerned departments and agencies shall include in their appropriate rules and regulations specific time frames for their respective public participation processes, including setting minimum and maximum time frames as prescribed by law;
3. *Public consultation, as a way to secure wide input into decisions to be made.* This may entail the conduct of formal hearings in certain cases, or solicitation of public comments, particularly where there is public controversy surrounding the proposed activities. Public consultations, including public hearings, may be conducted through the use of electronic media to promote public safety when warranted by the occasion, and to allow wider participation from stakeholders. These consultations shall encourage exchanges of information between applicants and the public before the application is acted upon. Dialogue and consensus-building among all stakeholders shall be encouraged. Concerned departments and agencies shall specify in their appropriate rules and regulations the stages when public consultations are appropriate, the specific time frames for such consultations, and the circumstances when formal hearings will be required, including guidelines to ensure orderly proceedings. The networks of agricultural and fisheries councils, indigenous peoples and community-based organizations in affected areas may be utilized;
4. *Written submissions.* Procedures for public participation shall include mechanisms that allow public participation in writing or through public consultations as appropriate, and which allow the submission of any positions, comments, information, analyses or opinions; and
5. *Consideration of public concerns in the decision-making phase following consultation and submission of written comments.* Public concerns as reflected through the procedures for public participation shall be considered in making the decision. The public shall be informed of the final decision promptly, and shall be provided with the reasons and considerations resulting in the

decision, upon request.

G. *Prompt and Efficient Action.* Each agency involved in the implementation of this Circular shall include in its Citizen's Charter provisions to ensure compliance with the periods prescribed herein.

ARTICLE III. ADMINISTRATIVE FRAMEWORK

Section 4. **Role of National Government Agencies.** Consistent with the NBF and the laws granting their powers and functions, these national government agencies shall have the following roles:

A. *Department of Agriculture (DA).* As the principal agency of the Philippine Government responsible for the promotion of agricultural and rural growth and development so as to ensure food security and contribute to poverty alleviation, the DA shall take the lead in addressing biosafety issues related to the country's agricultural productivity and food security. In coordination with other concerned departments and agencies, and consistent with the requirements of transparency and public participation, it shall exercise such jurisdiction and other powers that it has been conferred with under existing laws. It shall also take the lead in the evaluation and monitoring of regulated articles.

B. *Department of Science and Technology (DOST).* As the premiere science and technology body in the country, the DOST shall take the lead in ensuring that the best available science is utilized and applied in adopting biosafety policies, measures and guidelines, and in making biosafety decisions. The DOST shall ensure that such policies, measures, guidelines and decisions are made on the basis of scientific information that is of highest quality, multi-disciplinary, peer-reviewed, and consistent with international standards as they evolve. In coordination with other concerned departments and agencies, and consistent with the requirements of transparency and public participation, it shall exercise such jurisdiction and other powers that it has been conferred with under existing laws. It shall also take the lead in evaluating and monitoring regulated articles intended for contained use.

C. *Department of Environment and Natural Resources (DENR).* As the primary government agency responsible for the conservation, management, development and proper use of the country's environment and natural resources, the DENR shall ensure that the applicable environmental assessments are undertaken and potential impacts identified. It shall also take the lead in evaluating and monitoring regulated articles intended for bioremediation, the improvement of forest genetic resources and wildlife genetic resources.

D. *Department of Health (DOH).* The DOH, as the principal authority on health, shall formulate guidelines in assessing the health impacts posed by modern biotechnology and its applications. The DOH shall also require, review and evaluate results of the applicable health impact assessments related to modern biotechnology and its applications. In coordination with other concerned

departments and agencies, it shall exercise such jurisdiction and other powers that it has been conferred with under existing laws. It shall also take the lead in evaluating and monitoring processed food derived from or containing genetically modified organisms.

E. *Department of the Interior and Local Government (DILG).* The DILG shall coordinate with the DA, DOST, DENR, and DOH in overseeing the implementation of this Circular in relation to activities that are to be undertaken in specific LGUs, particularly in relation to the conduct of public consultations as required under the Local Government Code. The DILG shall exercise jurisdiction and other powers that it has been conferred with, in relation to biosafety decisions which have an impact on the autonomy of local government units, while taking into account the national application of quarantine functions, including biosafety assessments and evaluations.

Section 5. **Biosafety Committees.** 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. Any member of the Biosafety Committee may be assigned by the concerned Department to the Joint Assessment Group.

Section 6. **Bureau of Plant Industry (BPI).** The Department of Agriculture-Bureau of Plant Industry shall provide frontline services for the processing of applications for field trial, commercial propagation, and direct use permits. The BPI shall open an application file for all biosafety permit applications and keep updated its Approval Registries. During the processing of an application, the BPI shall provide technical and administrative assistance to the Joint Assessment Group. The BPI shall also prepare the consolidated report on the Public Information Sheet and announce at its website all applications and biosafety permits issued.

Section 7. **Joint Assessment Group (JAG).** A Joint Assessment Group shall be established composed of qualified representatives or personnel from the concerned Departments' Biosafety Committees and external technical experts. The JAG shall evaluate applications for field trial, commercial propagation, and direct use to determine whether a regulated article does not pose greater risks to human health and the environment compared to its conventional counterpart, and make its recommendations to the BPI Director.

Section 8. **Institutional Biosafety Committee (IBC).** The company or institution applying for permits for contained use or field trial of a regulated article shall constitute an IBC. The membership of the IBC shall be approved by the DOST-BC for contained use or by the DA-BC for field trial.

The IBC shall be composed of at least five (5) members, three (3) of whom shall be designated as scientist-members and the other two (2) shall be community representatives. All scientist-members must possess scientific or technological knowledge and expertise sufficient to enable them to properly evaluate and monitor any work involving regulated articles conducted by the applicant. The community

representatives must not be affiliated with the applicant and must be actively engaged in community affairs in the locality where the activities are to be conducted.

The IBC approved by the DA-BC shall have joint responsibility with the applicant for the conduct of the initial risk assessment and preparation of proposals for risk management of the proposal for field trial. It shall also have joint responsibility with the applicant for ensuring compliance with any permit conditions that may be imposed on the field trial.

Section 9. **External Technical Experts.** The DOST, DA, DENR, and DOH may appoint one (1) external expert each to act as their Biosafety Committee's consultant to the Joint Assessment Group. The external expert shall complement the existing technical expertise of the Departments represented in the JAG. Such technical experts must be well-respected in the scientific community as evidenced by positions held in science-based organizations, awards and recognitions, or publications in local and international peer-reviewed scientific journals.

ARTICLE IV. CONTAINED USE OF REGULATED ARTICLES

Section 10. **Policy on Contained Use of Regulated Articles.** The contained use of regulated articles shall be governed by the DOST Biosafety Committee (DOST-BC) in accordance with the *Biosafety Guidelines for Contained Use of Genetically Modified Organisms* approved by the National Committee on Biosafety of the Philippines. The risk assessment shall also be governed by the *Biosafety Guidelines for Contained Use of Genetically Modified Organisms.*

The DOST-BC shall make public a summary of each application for contained use through the DOST website and shall include the action/decision taken on such application.

ARTICLE V. FIELD TRIAL OF REGULATED ARTICLES

Section 11. **Policy on Field Trial of Regulated Articles.** No regulated article shall be released into the environment for field trial unless a Biosafety Permit for Field Trial has been secured in accordance with this Circular. Applications for such permits for regulated articles developed in the Philippines may be filed with the BPI provided that their contained use has satisfactorily been completed. Applications for permits for regulated articles developed in other countries may be filed directly for a Biosafety Permit for Field Trial if the BPI determines that the data set generated in other countries is applicable to the local setting.[2]

Section 12. **Procedural Requirements for Securing a Biosafety Permit for Field Trial.** Any applicant who desires to conduct field trial of regulated articles shall submit an application to the BPI. An application for field trial of a regulated article may cover single or multiple field trial sites, the size and duration of which will be specified by the applicant. The suitability of each field trial site shall be assessed separately by the Joint

[2] Consistent with the decision by the National Committee on Biosafety in the Philippines reached during its 21st meeting held on 26 March 2021.

Assessment Group for purposes of determining any potential risks to the environment or health.

For pest-protected plants, the applicant may apply for a field trial to meet the data requirements for biosafety evaluation under this Circular and PIP registration following FPA guidelines on the registration of biorational pesticides.

A. **Filing of Application Form and Supporting Documents for Field Trial.**
   1. Application Form. – A printed copy and an electronic copy of the Application for Field Trial;
   2. When applicable, certification from the DOST-BC that the regulated article has completed contained use, including recommendations of the DOST-BC on conditions or issues to be addressed during field trial;
   3. Copy of the initial risk assessment and proposed management procedures prepared by the IBC, which may be supplemented by a technical dossier consisting of relevant scientific information available at the time the application was filed. The proposed field trial management procedures must provide details on how to ensure reproductive isolation of the regulated article and prevent its accidental release or movement beyond the confines of the trial site;
   4. Details of a contingency plan in case of *force majeure* or intrusions in the field trial site;
   5. Copy of the proposed Public Information Sheet (PIS) for Field Trial;
   6. National Commission on Indigenous People (NCIP) Certification Precondition (if applicable);
   7. If the site is within an ancestral domain or ancestral land, the applicant shall secure the Free and Prior Informed Consent (FPIC) of the concerned Indigenous People/Indigenous Cultural Community in accordance with the Indigenous People's Rights Act. If the site is within a protected area under the National Integrated Protected Area System, the applicant shall secure an endorsement from the Protected Area Management Board of the protected area; and
   8. Proof of payment of application fees.

B. **Acceptance of Application.** Upon receipt of the application, the BPI shall determine if all the required documents are submitted. No application shall be formally accepted unless documentation is complete. An accepted application shall be posted on the websites of the (1) NCBP and BPI, and (2) DA offices in the province, city or municipality where the field trial will be conducted. The public may submit their comments on the uploaded information within fifteen (15) working days from the first day of posting.

C. **Processing of Application.**
   1. Within three (3) working days upon receipt of the application, the BPI shall forward the application, together with the supporting documents to the DOST, DA, DENR, and DOH Biosafety Committees. At the same time, the BPI shall review the PIS for Field Trial and, if found sufficient, shall advise the applicant to post the approved PIS within three (3) working days based on Section 13 (Public Participation for Field Trial) below.

2. The public comments on the PIS shall be addressed to the Office of the BPI Director, which shall forward the comments to the applicant for response. The public comment period shall commence from the first day of posting of the PIS and shall have a duration of fifteen (15) working days. Within two (2) working days after the termination of public comment period, the BPI shall compile all comments received and transmit this to the applicant. Within five (5) working days upon receipt, the applicant shall submit to the BPI its response, addressing the concerns raised by interested parties. Within two (2) working days after receipt of the applicant's response, the consolidated report reflecting the comments from the public and the response of the applicant to such comments shall be submitted to the BPI Director.
3. Within ten (10) working days upon receipt of the application, the DOST, DA, DENR, and DOH Biosafety Committees shall review the application and designate two (2) representatives to the Joint Assessment Group (JAG). The DOH-BC may make a determination of non-coverage for the specific application for field trial. Such determination must be officially communicated to the Chair of the JAG. Should a Biosafety Committee decide to engage outside expertise, the committee shall advise the Chair of the JAG of the participation of one (1) external technical expert in the meeting(s) to address specific issues in the application.
4. The JAG shall be chaired by the Department of Agriculture Biosafety Committee Chair or his designee who must also be a member of the DA-BC. The Chair shall be an additional member to the JAG aside from the two representatives from the DA.
5. Within ten (10) working days after receipt of the application, the Chair of the JAG through the BPI shall schedule and convene the first meeting of the JAG. The Chair of the JAG may invite the applicant to address concerns that may be raised during the meeting.
6. During the first meeting, the JAG and the external expert(s), if any, shall discuss and review the Risk Assessment Report and other supporting documents. The applicant shall ensure that its authorized representative is available to join the meeting through tele- or video-conferencing in case the JAG has questions for the applicant. The JAG may set a second meeting if there are additional concerns that require further discussion. The JAG shall immediately communicate to the applicant the need for additional information. This information must be provided by the applicant within five (5) working days from receipt of the request. If no additional concerns or clarifications are raised, the JAG shall draft a recommendation document for the BPI Director.
7. Should a second and final meeting be required, this should be scheduled within five (5) working days from receipt of the additional information. The JAG shall draft a recommendation document for the BPI Director at the end of this meeting.
8. Should any implementing agency be unable to send representatives to the JAG or perform any of functions within the periods prescribed in this Circular, the evaluation of the remaining members of the JAG shall proceed, and the application shall be processed on the presumption that the said agency poses no objection to the conclusions reached and recommendations made by the JAG.
9. The BPI shall document the discussions of the JAG during its meetings and

assist in the preparation of the recommendation document for the BPI Director. The Chair of the JAG shall facilitate the finalization of the draft recommendation document after circulating it to the members of the JAG for any comments and their signature. The final recommendation document shall be submitted to the BPI Director within seven (7) working days after the conclusion of the meeting(s), resolving all requests for additional information and other outstanding issues.

D. **Action on the Application.** The Director of the Bureau of Plant Industry shall issue a decision to approve or disapprove the application within five (5) working days upon receipt of the recommendation document from the JAG, based on the following considerations:
   1. Compliance with administrative procedure and requirements;
   2. Recommendation of the Joint Assessment Group;
   3. Issues and concerns raised during the public participation period; and
   4. Applicant's response to the issues and concerns raised for the applied regulated article.

E. If the application is approved, a Biosafety Permit for Field Trial shall be issued. The original copy of the biosafety permit shall be transmitted to the applicant. Certified true copies shall be provided to the DA, DOST, DENR, DOH, NCBP, and the DA Regional Executive Director concerned. The BPI Director shall keep a duplicate copy for documentation and to maintain the application file.

F. Issuance of the permit shall be announced via the DA-BPI website within 24 hours from receipt thereof by the applicant.

G. A Biosafety Permit for Field Trial shall be issued for every approved field trial site. The applicant must commence with the activity within two (2) years from date of issuance of the permit, unless it is sooner revoked for any of the reasons set forth in Section 12.K. *Revocation of Biosafety Permit for Field Trial.*

H. **Permit Conditions.** The permit holder shall comply with the following conditions and such other conditions which the BPI shall state in the Biosafety Permit for Field Trial:
   1. The permit holder shall submit to the BPI monitoring reports on the performance characteristics of the regulated article in accordance with the monitoring and reporting requirements specified in the biosafety permit;
   2. The permit holder shall immediately notify the Director of BPI, in writing, should any of the following cases occur:
      a. In the event that new information becomes available, indicating that the regulated article would pose greater risks to human health and the environment as compared to its conventional counterpart;
      b. In cases wherein risk mitigation measures implemented were found to be insufficient; and
      c. In cases wherein contingency measures had to be implemented.

I. **Compliance with Other Agency Regulations.** The Biosafety Permit for Field Trial shall not excuse the applicant from complying with relevant regulations of

other government agencies.

J. **Submission of Report.** Within ninety (90) working days from the completion of the field trial, the applicant shall submit to the BPI two (2) hard copies and a soft copy of the terminal report on the results of the field trial. The report shall be in the format prescribed by the BPI and state, among others, whether the objectives of the field trial were achieved; a description of any unforeseen risks to human health and environment observed during the conduct of the field trial; the steps taken by the applicant to mitigate them; and the final disposition of the regulated article. Such report must be endorsed by the IBC. The first copy shall be retained by the BPI and the second copy shall be transmitted to NCBP for its reference and file.

K. **Revocation of Biosafety Permit for Field Trial.** A Biosafety Permit for Field Trial may be revoked for any of the following grounds:
   1. Provision of misleading information in the Application;
   2. Discovery of new, relevant and significant information that the regulated article poses greater risks to human health and the environment compared to its conventional counterpart;
   3. Non-compliance with the conditions of the permit;
   4. Failure to allow monitoring of activities within the field trial site; and
   5. Other grounds the relevant regulatory agencies may deem necessary to protect human health and the environment.

Section 13. **Public Participation for Field Trial.**

A. The BPI shall make public all applications and Biosafety Permits for Field Trial through posting on the websites of the (1) NCBP and BPI, and (2) DA offices in the province, city or municipality, and barangay where the field trial will be conducted.

B. The applicant, in consultation with the City/Municipal Local Government Operations Officer (C/MLGOO), shall inform the local chief executive, through written correspondence, of the proposed field trial(s) to be conducted in the LGU, together with a request to conduct a public hearing. The letter shall include a copy of the PIS for Field Trial approved by the BPI and the risk assessment documents submitted to BPI.

C. In consultation with the LGU(s), the applicant shall post the PIS in at least two (2) conspicuous places within the vicinity of the city/municipality and at least two (2) conspicuous places within the vicinity of the barangay where the proposed field trials will be conducted. Posting shall be done at least five (5) working days prior to the public hearing. The PIS shall be written in a language understood by the community and shall include, among others the following:
   1. Name of the applicant and contact details;
   2. Name and contact details of the responsible officer/authorized representative;
   3. Description of the regulated article for field trial;
   4. Description, size, duration, and purpose of the proposed field test;
   5. Potential benefits and risks of the regulated article; and

6. An invitation for interested parties to (a) send their comments on the proposed field trial to the BPI Director within the fifteen (15)-working-day posting period, and (b) attend the public hearing.

D. Comments may be sent by personal delivery, registered or ordinary mail, courier service, or electronic mail, but must be received by the Office of the BPI Director within the fifteen (15)-working-day posting period. The BPI shall forward to the applicant comments that must be addressed. The applicant's responses will be submitted to the Office of the BPI Director and will be part of the considerations for his decision to approve or disapprove the application.

E. At least five (5) working days after the posting of the PIS, the applicant, in consultation with the C/MLGOO, shall inform the local chief executive of the proposed field trial(s) to be conducted in the LGU, together with a written request to conduct a public hearing. The public hearing shall be conducted within twenty (20) working days after receipt of the request, after which the City/Municipal Sanggunian shall issue its resolution.

F. Within two (2) working after the issuance of the Sanggunian resolution, the applicant shall submit to the BPI a written report on the public consultation containing the following: (1) summary of issues and comments raised during the posting period and public hearing, and how these concerns were addressed; and (2) the resolution of the City/Municipal Sanggunian concerned pursuant to Section 27 of the Local Government Code. If, within the required period, the applicant fails to secure the city/municipal resolution endorsing the conduct of the field trial, the applicant may request the BPI Director for extension of time to comply with this requirement.

ARTICLE VI. COMMERCIAL PROPAGATION OF REGULATED ARTICLES

Section 14. **Policy on Commercial Propagation of Regulated Articles.** No regulated article shall be released for commercial propagation unless: (a) a Biosafety Permit for Commercial Propagation has been secured in accordance with this Circular; (b) the field trial conducted in the Philippines shows that the regulated article does not pose greater risks to human health and the environment as compared to its conventional counterpart; (c) food and feed safety studies show that the regulated article does not pose greater risks to human health as compared to its conventional counterpart, consistent with the Codex Alimentarius Commission Guidelines 44-2003: *Principles for the Risk Analysis of Foods Derived from Modern Biotechnology* and 45-2003: *Guideline for the Conduct of Food Safety Assessment of Foods Derived from the Recombinant-DNA Plants*; and, (d) if the regulated article is a pest-protected plant, its transformation event producing the active ingredient that serves as plant-incorporated protectant (PIP) has been duly registered with the Fertilizer and Pesticide Authority (FPA).

Section 15. **Procedural Requirements for Securing a Biosafety Permit for Commercial Propagation.** Any applicant who desires to register a regulated article in the Approval Registry for Commercial Propagation shall submit an application to the BPI.

A. **Filing of Application Form and Supporting Documents for Commercial Propagation.**
   1. Application Form. – A printed copy and an electronic copy of the Application for Commercial Propagation;
   2. Technical dossier consisting of scientific literature, unpublished studies or test data, or such other scientific materials relied upon by the applicant to show that, for the use it is intended, the regulated article does not pose greater risk to human health and the environment as compared to its conventional counterpart;
   3. Applicant's Risk Assessment Report for Commercial Propagation;
   4. Copy of the proposed Public Information Sheet (PIS) for Commercial Propagation; and
   5. Proof of payment of application fee.

B. **Acceptance of Application.** Upon receipt of the application, the BPI shall determine if all the required documents are submitted. No application shall be formally accepted unless documentation is complete. An accepted application shall be posted on the DA-BPI website and the public may submit their comments on the uploaded information within fifteen (15) working days.

C. **Processing of Application.**
   1. Within three (3) working days upon acceptance of the application, the BPI shall forward the application, together with the supporting documents, to the DOST, DA, DENR, and DOH Biosafety Committees. At the same time, the BPI shall review the PIS for Commercial Propagation and, if found sufficient, shall advise the applicant to publish the approved PIS in one (1) newspaper of general circulation within three (3) working days. The approved PIS shall also be published in the official website of the applicant and the official website of the BPI.
   2. The public comments on the PIS shall be addressed to the Office of the BPI Director, which shall forward the comments to the applicant for response. The posting and publication of the PIS should be consistent with Section 16 (Public Participation for Commercial Propagation). Within two (2) working days after the termination of public comment period, the BPI shall compile all comments received and transmit this to the applicant. Within five (5) working days upon receipt, the applicant shall submit its response to the BPI, addressing the concerns raised by interested parties. Within two (2) working days after receipt of the applicant's response, the consolidated report reflecting the comments from the public and the response of the applicant to such comments shall be submitted to the BPI Director.
   3. Within ten (10) working days upon acceptance of the application, the DOST, DA, DENR, and DOH Biosafety Committees shall review the application and designate two (2) representatives to the Joint Assessment Group (JAG). Should a Biosafety Committee decide to engage outside expertise, the committee shall advise the Chair of the JAG of the participation of one (1) external technical expert in the meeting(s) to address specific issues in the application.
   4. The JAG shall be chaired by the Department of Agriculture Biosafety Committee Chair or his designee who must also be a member of the DA-BC. The Chair shall be an additional member to the JAG aside from the two

representatives from the DA.

5. Within ten (10) working days after receipt of the application, the Chair of the JAG through the BPI shall schedule and convene the first meeting of the JAG. The Chair of the JAG may invite the applicant to address concerns that may be raised during the meeting.
6. During the first meeting, the JAG and the external expert(s), if any, shall discuss and review the Risk Assessment Report and other supporting documents. The applicant shall ensure that its authorized representative is available to join the meeting through tele- or video-conferencing in case the JAG has questions for the applicant. The JAG may set a second meeting if there are additional concerns that require further discussion. The JAG shall immediately communicate to the applicant the need for additional information. This information must be provided by the applicant within five (5) working days from receipt of the request. If no additional concerns or clarifications are raised, the JAG shall draft a recommendation document for the BPI Director.
7. Should a second and final meeting be required, this should be scheduled within five (5) working days from receipt of the additional information. The JAG shall draft a recommendation document for the BPI Director at the end of this meeting.
8. Should any implementing agency be unable to send representatives to the JAG or perform any of functions within the periods prescribed in this Circular, the evaluation of the remaining members of the JAG shall proceed, and the application shall be processed on the presumption that the said agency poses no objection to the conclusions reached and recommendations made by the JAG.
9. The BPI shall document the discussions of the JAG during its meetings and assist in the preparation of the recommendation document for the BPI Director. The Chair of the JAG shall facilitate the finalization of the draft recommendation document after circulating it to the members of the JAG for any comments and their signature. The final recommendation document shall be submitted to the BPI Director within seven (7) working days after the conclusion of the meeting(s), resolving all requests for additional information and other outstanding issues.

D. **Action on the Application.** The Director of the Bureau of Plant Industry shall make a decision to approve or disapprove the application within five (5) working days upon receipt of the recommendation document from the JAG, based on the following considerations:
   1. Compliance with administrative procedure and requirements;
   2. Recommendation of the Joint Assessment Group;
   3. Issues and concerns raised during the public participation period; and
   4. Applicant's response to the issues and concerns raised for the applied regulated article.

E. If the application is approved, a Biosafety Permit for Commercial Propagation shall be issued. The original copy of the biosafety permit shall be transmitted to the applicant. Certified true copies shall be provided to the DA, DOST, DENR, DOH, and NCBP. The BPI Director shall keep a duplicate copy for documentation and to maintain the application file.

F. Issuance of the permit shall be announced via the DA-BPI website within 24 hours upon its receipt by the applicant.

G. The Biosafety Permit for Commercial Propagation shall remain valid unless revoked for any reasons set forth under Section 15.J. *Revocation of Biosafety Permit for Commercial Propagation.*

H. **Permit Conditions.** The permit holder shall comply with the following conditions and such other conditions which the BPI shall state in the Biosafety Permit for Commercial Propagation:
   1. The permit holder shall immediately notify the Director of BPI, in writing, in the event that new information becomes available, indicating that the regulated article would pose greater risks to human health and the environment as compared to its conventional counterpart;
   2. In the event new information becomes available indicating that the regulated article could pose greater risks to human health and the environment as compared to its conventional counterpart, the applicant shall, on its own, immediately take measures necessary to protect human health and the environment;
   3. The permit holder shall not cause the commercial propagation in areas where the local government unit has a known policy or ordinance prohibiting the propagation or entry of regulated articles. For this purpose, it shall include in the labeling of products that these are not intended for propagation in prohibited areas.

I. **Compliance with Other Agency Regulations.** The Biosafety Permit for Commercial Propagation shall not excuse the applicant from complying with relevant regulations of other government agencies.

J. **Revocation of Biosafety Permit for Commercial Propagation.** A Biosafety Permit for Commercial Propagation may be revoked for any of the following grounds:
   1. Provision of misleading information in the Application;
   2. Discovery of new, relevant and significant information that the regulated article poses greater risks to human health and the environment compared to its conventional counterpart;
   3. Non-compliance with the conditions of the permit; and
   4. Other grounds the relevant regulatory agencies may deem necessary to protect human health and the environment.

Section 16. **Public Participation for Commercial Propagation.**

A. The BPI shall make public all applications and Biosafety Permits for Commercial Propagation through posting on the NCBP and BPI websites.

B. The applicant shall prepare the PIS which shall include, among others, the following:
   1. Name of the applicant and contact details;

2. Name and contact details of the responsible officer/authorized representative;
3. Description of the regulated article for Commercial Propagation;
4. Potential benefits and risks of the regulated article;
5. Countries where approvals have been granted; and
6. An invitation for interested parties to send their comments on the proposed commercial propagation to the Office of the BPI Director within a period of fifteen (15) working days from the date of publication.

C. Within three (3) working days upon approval by the BPI, the applicant shall publish a copy of the approved PIS for Commercial Propagation in one (1) newspaper of general circulation. The approved PIS shall also be published in the official website of the applicant and the official website of the BPI.

D. During the comment period, any interested person may submit to the BPI written comments regarding the application, which may include issues related to social, economic, ethical, and cultural considerations arising from the impact of regulated articles on the conservation and sustainable use of biological diversity. Comments may be sent by personal delivery, registered or ordinary mail, courier service, or electronic mail, but must be received by the Office of the BPI Director within the prescribed period of fifteen (15) working days from the date of publication.

E. The BPI shall forward to the applicant comments that must be addressed. The applicant's responses will be submitted to the Office of the BPI Director and will be part of the considerations for his decision to approve or disapprove the application.

ARTICLE VII. DIRECT USE OF REGULATED ARTICLES FOR FOOD AND FEED, OR FOR PROCESSING

Section 17. **Policy on Direct Use of Regulated Articles for Food and Feed, or for Processing.** No regulated article, whether imported or developed domestically, shall be permitted for direct use as food and feed, or for processing, unless: (a) a Biosafety Permit for Direct Use has been issued by the BPI; (b) in the case of an imported regulated article, the regulated article has been authorized for commercial distribution as food and feed in the country of origin; and (c) regardless of the intended use, the regulated article does not pose greater risks to human health as compared to its conventional counterpart, consistent with the Codex Alimentarius Commission Guidelines 44-2003: *Principles for the Risk Analysis of Foods Derived from Modern Biotechnology* and 45-2003: *Guideline for the Conduct of Food Safety Assessment of Foods Derived from the Recombinant-DNA Plants.*

Section 18. **Procedural Requirements for Securing a Biosafety Permit for Direct Use for Food and Feed, or for Processing.** Any applicant who desires to register a regulated article in the Approval Registry for Direct Use shall submit an application to the BPI.

A. **Filing of Application Form and Supporting Documents for Direct Use.**
   1. Application Form. – A printed copy and an electronic copy of the Application for Direct Use;

2. Technical dossier consisting of scientific literature, unpublished studies or test data, or such other scientific materials relied upon by the applicant to show that, for the use it is intended, the regulated article does not pose greater risk to human health and the environment as compared to its conventional counterpart;
3. Applicant's Risk Assessment Report for Direct Use;
4. Copy of the proposed Public Information Sheet (PIS) for Direct Use; and
5. Proof of payment of application fee.

B. **Acceptance of Application.** Upon receipt of the application, the BPI shall determine if all the required documents are submitted. No application shall be formally accepted unless documentation is complete. An accepted application shall be posted on the DA-BPI website and the public may submit their comments on the uploaded information within fifteen (15) working days.

C. **Processing of Application.**
1. Within three (3) working days upon acceptance of the application, the BPI shall forward the application, together with the supporting documents, to the DOST, DA, DENR, and DOH Biosafety Committees. At the same time, the BPI shall review the PIS for Direct Use and, if found sufficient, shall advise the applicant to publish the approved PIS in one (1) newspaper of general circulation within three (3) working days. The approved PIS shall also be published in the official website of the applicant and the official website of the BPI.
2. The public comments on the PIS shall be addressed to the Office of the BPI Director, which shall forward the comments to the applicant for response. The posting and publication of the PIS should be consistent with Section 19 (Public Participation for Direct Use). Within two (2) working days after the termination of public comment period, the BPI shall compile all comments received and transmit this to the applicant. Within five (5) working days upon receipt, the applicant shall submit its response to the BPI, addressing all the concerns raised by interested parties. Within two (2) working days after receipt of the applicant's response, the consolidated report reflecting the comments from the public and the response of the applicant to such comments shall be submitted to the BPI Director.
3. Within ten (10) working days upon acceptance of the application, the DOST, DA, DENR, and DOH Biosafety Committees shall review the application and designate two (2) representatives to the Joint Assessment Group (JAG). The DENR-BC may make a determination of non-coverage for the specific application for direct use. Such determination must officially be communicated to the Chair of the JAG. Should a Biosafety Committee decide to engage outside expertise, the committee shall advise the Chair of the JAG of the participation of one (1) external technical expert in the meeting(s) to address specific issues in the application.
4. The JAG shall be chaired by the Department of Agriculture Biosafety Committee Chair or his designee who must also be a member of the DA-BC. The Chair shall be an additional member to the JAG aside from the two representatives from the DA.
5. Within ten (10) working days after receipt of the application, the Chair of the JAG through the BPI shall schedule and convene the first meeting of the JAG.

The Chair of the JAG may invite the applicant to address concerns that may be raised during the meeting.

6. During the first meeting, the JAG and the external expert(s), if any, shall discuss and review the Risk Assessment Report and other supporting documents. The applicant shall ensure that its authorized representative is available to join the meeting through tele- or video-conferencing in case the JAG has questions for the applicant. The JAG may set a second meeting if there are additional concerns that require further discussion. The JAG shall immediately communicate to the applicant the need for additional information. This information must be provided by the applicant within five (5) working days from receipt of the request. If no additional concerns or clarifications are raised, the JAG shall draft a recommendation document for the BPI Director.
7. Should a second and final meeting be required, this should be scheduled within five (5) working days from receipt of the additional information. The JAG shall draft a recommendation document for the BPI Director at the end of this meeting.
8. Should any implementing agency be unable to send representatives to the JAG or perform any of functions within the periods prescribed in this Circular, the evaluation of the remaining members of the JAG shall proceed, and the application shall be processed on the presumption that the said agency poses no objection to the conclusions reached and recommendations made by the JAG.
9. The BPI shall document the discussions of the JAG during its meetings and assist in the preparation of the recommendation document for the BPI Director. The Chair of the JAG shall facilitate the finalization of the draft recommendation document after circulating it to the members of the JAG for any comments and their signature. The final recommendation document shall be submitted to the BPI Director within seven (7) working days after the conclusion of the meeting(s), resolving all requests for additional information and other outstanding issues.

D. **Action on the Application.** The Director of the Bureau of Plant Industry shall make a decision to approve or disapprove the application within five (5) working days upon receipt of the recommendation document from the JAG, based on the following considerations:
   1. Compliance with administrative procedure and requirements;
   2. Recommendation of the Joint Assessment Group;
   3. Issues and concerns raised during the public participation period; and
   4. Applicant's response to the issues and concerns raised for the applied regulated article.

E. If the application is approved, a Biosafety Permit for Direct Use shall be issued. The original copy of the biosafety permit shall be transmitted to the applicant. Certified true copies shall be provided to the DA, DOST, DENR, DOH, and NCBP. The BPI Director shall keep a duplicate copy for documentation and to maintain the application file.

F. Issuance of the permit shall be announced via the DA-BPI website within 24 hours from receipt thereof by the applicant.

G. The Biosafety Permit for Direct Use shall remain valid unless revoked for any reasons set forth under Section 18.J. *Revocation of Biosafety Permit for Direct Use.*

H. **Permit Conditions.** The permit holder shall comply with the conditions set by the BPI as stated in the Biosafety Permit for Direct Use.

I. **Compliance with Other Agency Regulations.** The Biosafety Permit for Direct Use shall not excuse the applicant from complying with relevant regulations of other government agencies.

J. **Revocation of Biosafety Permit for Direct Use.** A Biosafety Permit for Direct Use may be revoked for any of the following grounds:
   1. Provision of misleading information in the Application;
   2. Discovery of new, relevant and significant information that the regulated article poses greater risks to human health and the environment compared to its conventional counterpart;
   3. Non-compliance with the conditions of the permit; and
   4. Other grounds the relevant regulatory agencies may deem necessary to protect human health and the environment.

Section 19. **Public Participation for the Direct Use for Food and Feed, or for Processing.**

A. The BPI shall make public all applications and Biosafety Permits for Direct Use through posting on the NCBP and BPI websites.

B. The applicant shall prepare the PIS which shall include, among others, the following:
   1. Name of the applicant and contact details;
   2. Name and contact details of the responsible officer/authorized representative;
   3. Description of the regulated article for Direct Use;
   4. Potential benefits and risks of the regulated article;
   5. Countries where approvals have been granted; and
   6. An invitation for interested parties to send their comments on the proposed direct use to the Office of the BPI Director within a period of fifteen (15) working days from the date of publication.

C. Within three (3) working days upon approval by the BPI, the applicant shall publish a copy of the approved PIS for Direct Use in one (1) newspaper of general circulation. The approved PIS shall also be published in the official website of the applicant and the official website of the BPI.

D. During the comment period, any interested person may submit to the BPI written comments regarding the application, which may include issues related to social, economic, ethical, and cultural considerations arising from the impact of regulated articles on the conservation and sustainable use of biological diversity. Comments may be sent by personal delivery, registered or ordinary mail, courier service, or electronic mail, but must be received by the Office of the BPI Director within the

prescribed period of fifteen (15) working days from the date of publication.

E. The BPI shall forward to the applicant comments that must be addressed. The applicant's responses will be submitted to the Office of the BPI Director and will be part of the considerations for his decision to approve or disapprove the application.

ARTICLE VIII. GENETICALLY MODIFIED PLANTS AND PLANT PRODUCTS WITH STACKED EVENTS PRODUCED THROUGH CONVENTIONAL BREEDING

Section 20. **Regulation of Stacked Events.** Plants produced through conventional breeding of genetically modified parental lines with approved individual events are not considered novel. The permit holder or an authorized licensee of registered events may request for the listing of their stacked events in the BPI Approval Registry for Commercial Propagation or BPI Approval Registry for Direct Use, as the case may be.

Section 21. **Listing in the BPI Approval Registry for Propagation.** Stacked events may be listed in the BPI Approval Registry for Propagation only if each parental event has a Biosafety Permit for Commercial Propagation. The permit holder or an authorized licensee of registered events may also request the BPI for the listing of any sub-stacks or intermediate stacks.

Section 22. **Listing in the BPI Approval Registry for Direct Use.** Stacked events may be listed in the BPI Approval Registry for Direct Use only if each parental event has a Biosafety Permit for Direct Use. The permit holder or an authorized licensee of registered events may also request the BPI for the listing of any sub-stacks or intermediate stacks.

Section 23. **Registration under the Fertilizer and Pesticide Authority.** For the commercial propagation of plants with stacked events involving multiple plant-incorporated protectants (PIP), aside from the requirement that the component single PIPs must have been previously registered under the Fertilizer and Pesticide Authority, the stacked PIP x PIP must also be registered as a new product under the FPA based on its own guidelines on the registration of biorational products. The FPA registration of stacked PIP x PIP will involve desktop evaluation of interaction effects, particularly the potential synergy between the registered component PIPs to determine non-negligible risk to non-target organisms allowing for data transportability where these are deemed acceptable.

ARTICLE IX. IMPORTATION OF REGULATED ARTICLES

Section 24. **Policy on the Importation of Regulated Articles.** All importations of regulated articles shall be covered by the Department of Agriculture general guidelines on the importation of plants, planting materials, and plant products, which is being implemented by the BPI-National Plant Quarantine Services Division (BPI-NPQSD). Only single events listed in the Approval Registry for Field Trial, Commercial Propagation, or Direct Use and their stack combinations shall be allowed to be imported into the country for the use specified in the particular registry.

Section 25. **Additional Documentary Requirements.** Aside from the requirements of the BPI-NPQSD, any person who desires to import a regulated article shall also be required to submit the following documents:

A. **Importation for Contained Use.**
   1. DOST-BC Letter of Endorsement stating that:
      a. A scientific and technical review of the proposed use has been conducted;
      b. The physical containment facility to be used for the activity is suitable for the proposed use; and
      c. The importation is being endorsed with conditions imposed on movement, storage, and use of the regulated article.
   2. Letter from the applicant specifying the actions and procedures that will be undertaken to comply with the conditions of the DOST-BC on the importation, movement, storage, and use of the regulated article, if any, and plant quarantine import conditions.

B. **Importation for Field Trial, or Commercial Propagation, or Direct Use.**
   1. A GMO Declaration that shall indicate that the importation does contain or may contain a genetically modified organism. The declaration may be issued by the responsible officer from the country of origin, accredited laboratories, the shipper, or importer.
      a. For importation for field trial or commercial propagation, a GMO Declaration clearly identifying the specific transformation event(s) present in the shipment.
      b. For importation for direct use, a GMO Declaration specifying the transformation event(s) that are or may be present in the shipment.

ARTICLE X. MISCELLANEOUS PROVISIONS

Section 26. **Monitoring for Compliance with Permit Conditions.** Compliance with the conditions of the biosafety permit for field trial, commercial propagation, or direct use shall be monitored by the BPI, with the assistance of other agencies.

Section 27. **Approval Registry for Regulated Articles.** The BPI shall keep and regularly update an Approval Registry for Regulated Articles of the following:
A. Direct use as Food and Feed, or for Processing;
B. Commercial Propagation; and
C. Field Trial.

The Approval Registry shall incorporate the decision document that summarizes the risk assessment for the approved regulated article.

Except for the SPSIC, no permit shall be required for the importation of regulated articles that are listed in the Approval Registry. All registries shall be accessible to the public and posted on the BPI website.

Section 28. **Application File.** The BPI shall open an application file for every accepted application in accordance with this Circular. The application for a biosafety permit, its supporting documents, JAG recommendation report, written comments submitted by other government agencies and the public, and any and all documents relating to the application shall form part of the application file. Each application file shall be assigned an identification number for reference purposes.

Section 29. **Reportorial Requirements.** Aside from those required by law and regulations, the BPI may impose reportorial requirements on the regulated article approved for field trial, commercial propagation, or direct use. The details of the required reports shall be specified in the biosafety permit to be issued to the applicant.

Section 30. **Management of Regulated Article.** The Biosafety Committees of the DOST, DA, DENR, and DOH shall conduct regular review of management measures of regulated articles by biosafety permit holders. They shall also monitor compliance with permit conditions and may recommend improvements in the conduct of activities detailed in this Circular.

Section 31. **Confidential Information.**

A. If there are portions of the applications mentioned in this Circular that contain trade secrets or confidential business information, each page of the application containing such information shall be marked "Commercial-in-Confidence" (CIC) by the applicant. In addition, portions of the application which are deemed "CIC" shall be so designated. The applicant shall also submit one (1) copy of the application with all the CIC deleted, marked with "CIC deleted" on each page where the CIC was deleted. If an application does not contain any CIC, then the first page of all copies submitted to the BPI shall be marked "No CIC".

B. In no case, however, shall the following information be considered CIC:
   1. Name and address of the applicant;
   2. Description of the regulated article;
   3. Description of the intended destination (including all intermediate and final destinations), uses, and distribution of the regulated article;
   4. Summary of the risk assessment of the effects of the regulated article on human health and the environment;
   5. Description of the proposed procedures, processes and safeguards, which will be used by the applicant to prevent escape and dissemination of the regulated article at each of the intended destinations, where appropriate;
   6. Description of the methods and plans for emergency response in case of accidental release of the regulated article into the environment; and
   7. Description of the proposed method of final disposition of the regulated article.

C. The BPI shall inform the applicant if the information the latter identified as CIC does not qualify for such treatment and shall provide the applicant an opportunity for consultation and review of its decision prior to disclosure to any third party.

D. An applicant may refer to data or results from applications previously submitted by other applicants: Provided, that (1) the information, data or results are not CIC, or (2) if the otherwise, the previous applicants have given their consent in writing

to the use of their confidential information, data or results.

E. Documents that are made available to stakeholders and the public shall exclude portions that are marked as "CIC"; however, the documents shall clearly indicate with "CIC deleted" the part where the confidential information was removed.

Section 32. **Outside Experts and Accredited Laboratories.** In the implementation of this Circular, the concerned department or agency may coordinate, seek the services of, and consult with international or governmental agencies and public or private research institutes or accredited laboratories, educational establishments, and individuals or entities with expertise relevant to biosafety. In cases of conflicting scientific findings among experts, the National Academy of Science and Technology (NAST) shall act as the final authority in the resolution thereof.

Section 33. **Fees.** As may be authorized by law, fees may be imposed by the concerned department or agency in such amount as may be necessary to cover the costs of evaluating applications and petitions and monitoring compliance with permit conditions.

Section 34. **Petition for Reconsideration.** In case of the applications for field trial, commercial propagation, and direct use, an aggrieved party may file a request for the reconsideration of the decision with the DA Secretary within fifteen (15) working days from the announcement of the decision.

The petition for reconsideration may involve payment of fees to cover the cost of re-evaluation of the decision made.

Section 35. **Funding.** The DOST, DA, DENR, 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 Committees.

Section 36. **Remedies.** In cases of violations of laws, rules and regulations related to biosafety, the following remedies shall apply:

A. *Administrative Remedies.* The concerned departments and agencies shall ensure, in accordance with law, that administrative remedies, including the right to appeal, are available to applicants and stakeholders in biosafety decisions.

B. *Criminal Liability.* Natural or juridical persons committing offenses in violation of existing laws shall be prosecuted and penalized in accordance with such laws.

C. *Civil Liability.* Philippine laws on liability and compensation shall apply to all damages and injuries arising from any violation of this Circular.

D. *International Law.* International legal norms on liability and compensation, including those developed and adopted under the Cartagena Protocol on Biosafety, shall likewise apply.

Section 37. **Issuance of Implementing Orders.** The concerned national government agencies may issue subsequent implementing orders pursuant to their respective

functions in this Circular, subject to prior notice with the other national government agencies.

Section 38. **Transitory Provisions.**

A. Regulated articles with Biosafety Permits issued under the DOST-DA-DENR-DOH-DILG Joint Department Circular no. 1, series of 2016, for commercial propagation and direct use have undergone the required safety assessment involving all concerned regulatory agencies. All existing original and renewed Biosafety Permits for commercial propagation and direct use issued therein shall remain valid unless otherwise revoked under conditions set in Section 15.J. for Commercial Propagation and Section 18.J. for Direct Use of this new Joint Department Circular.

B. All new applications for Biosafety Permit for contained use, field trial, commercial propagation and direct use shall be processed in accordance with this new Circular.

C. All pending applications for Biosafety Permit, both original and for renewal, filed under the DOST-DA-DENR-DOH-DILG Joint Department Circular no. 1, series of 2016, shall be processed in accordance with the provisions thereof within eighty-five (85) working days from the acceptance of the application for biosafety permit under the said Joint Department Circular no. 1, series of 2016.

D. All pending petitions for deregulation filed pursuant to Article IX of the DOST-DA-DENR-DOH-DILG Joint Department Circular no. 1, series of 2016, shall be resolved in accordance with the provisions thereof within twenty (20) working days from the effectivity of this Circular.

Section 39. **Repealing Clause.** Unless otherwise repealed or amended expressly, all DA administrative orders and memorandum circulars consistent with this Joint Department Circular relating to the technical evaluation and monitoring of regulated articles are deemed adopted and issued under this Circular. All existing rules and regulations inconsistent with this Circular are hereby modified, revoked, or repealed accordingly.

Section 40. **Separability.** The provisions of this Circular are hereby declared to be separable. If any part or provision of this Circular shall be declared invalid, the remaining portions or provisions shall not be affected thereby and shall be construed as if it did not contain the invalid term or provision.

Section 41. **Effectivity**. This Joint Department Circular shall take effect fifteen (15) days after its publication in two (2) newspapers of general circulation. A copy of this issuance shall also be submitted to the University of the Philippines Law Center.

CERTIFIED COPY

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