



**DOST-DA-DENR-DOH-DILG
Joint Department Circular¹
No. 1, series of 2016**

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, the President issued 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*," 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 articles²;

WHEREAS, the Department of Science and Technology (DOST) is mandated to provide central direction, leadership and coordination of scientific and technological efforts, including modern biotechnology as one of its priority research areas, that are geared and utilized in areas of maximum economic and social benefits for the people;

WHEREAS, under the National Biosafety Framework (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,

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 (R.O. 292, Bk IV, Ch 11, Sec 50 [1]).

² "Regulated article" refers to a genetically modified organism and its products (NBF, Sec. 3.3.12).

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 amended³, "*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, "*Instituting the Administrative Code 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, 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 significantly affect the environment under P.D. No. 1586, as amended, "*Establishing an Environmental Impact Statement System Including other Environmental Management-Related Measures and for other purposes*"⁴;

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), nongovernmental organizations, and other sectors concerned, 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

³EO No. 292, Administrative Code.

⁴Under Executive Order No. 192 (1987), the functions of the National Environmental Protection Council have been transferred to the Environmental Management Bureau of the Department of Environment and Natural Resources.

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;

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 genetically-modified plant and plant products derived from the use of modern biotechnology, included under "regulated articles."

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 inter alia, 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) *"Confined Test"* – refers to a field test of genetically modified plants not approved for general release, in which measures for approved isolation and materials confinement are enforced in order to confine the experimented plant material and genes to the test site;
- g) *"Contained use"* – refers to any operation, undertaken within a facility, installation or other physical 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;
- h) *"Country of origin"* – refers to the country where the goods or service was produced;
- i) *"Deregulation"* – refers to the state wherein the regulated article ceases to be governed by this Circular but remains subject to applicable laws, rules and regulations, including sanitary and phytosanitary (SPS) measures;
- j) *"Environment"* – refers to surrounding air, water, both ground and surface, land, flora, fauna, humans and their inter-relations;
- k) *"Environmental Impact Assessment (EIA)"* – is a "process that involves predicting and evaluating the likely impacts of a project (including cumulative impacts) on the environment during construction, commissioning, operation and abandonment. It also includes designing appropriate preventive, mitigating and enhancement measures addressing these consequences to protect the environment and the community's welfare";
- l) *"Environmental Risk Assessment (ERA)"* – refers 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;
- m) *"Field Trial"* – refers to 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;

- n) "*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;
- o) "*Handling and use*" – refers to the process by which regulated articles are moved, carried, transported, delivered, stored or worked with;
- p) "*Health Impact*" – refers to a situation or condition that leads to either a positive or a negative health result on people and on population;
- q) "*Health Impact Assessment*" – refers to the combination of procedures, methods and/or tools by which a policy, program or project (i.e. intervention) may be assessed on its potential effects on health of population and the distribution of those effects within the population;
- r) "*Health Risk Assessment*" – refers to a process intended to estimate the risk to a given target organism, system or (sub)population, including the identification of attendant uncertainties, following exposure to a particular agent, taking into account the inherent characteristics of the agent of concern as well as the characteristics of the specific target system;
- s) "*Modern biotechnology*" – refers to 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;
- t) "*National Committee on Biosafety of the Philippines (NCBP)*" – refers to the lead body tasked to coordinate and harmonize inter-agency and multi-sectoral efforts to develop biosafety policies and set scientific, technical and procedural standards on actions by agencies and other sectors to: (1) promote biosafety in the Philippines; (2) oversee the implementation of the NBF; (3) act as a clearing house for biosafety matters; and (4) coordinate and harmonize the efforts of all concerned agencies and departments in this regard;
- u) "*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;

- v) "*Plant pest*" – refers to any form of plant or animal life, or any pathogenic agent, injurious or potentially injurious to plants or plant products;
- w) "*Plant product*" – refers to any product derived from plants in their natural state or in processed form and are capable of harboring plant pests;
- x) "*Plant quarantine officer*" – refers to any person deputized by the BPI Director to conduct quarantine related activities;
- y) "*Person*" – refers to any natural person or juridical entity such as a corporation or cooperative;
- z) "*Plant-incorporated protectant (PIP)*" – refers to pesticidal substance produced by plants and the genetic material necessary for the plant to produce the substance;
- aa) "*Pest-protected plant*" – refers to any plant that is made pest resistant through the use of any of the techniques of modern biotechnology;
- bb) "*Port of entry*" – refers to a port open to both foreign and domestic trade, which includes principal ports and sub-ports of entry;
- cc) "*Product identification*" – refers to information on the presence of a regulated article in a particular product, as implemented by concerned departments and agencies through import and export documents, unique identification system, or similar applicable approaches such as product labeling;
- dd) "*Product monitoring*" – refers to any post-commercialization measure that provides data on the fate and effects of the regulated article, in order to confirm compliance with regulatory requirements, collect information necessary for controlling and managing potentially adverse public health or environmental situations, assess environmental quality and detect unexpected or potentially damaging effects on human and animal health and the environment. Product monitoring helps reduce uncertainty remaining from risk assessment, confirm conclusions with additional data and provide informational feedback on system status or conditions;
- ee) "*Proponent*" – refers to any person or group of persons who submits a project proposal to the competent national authority through the institutional biosafety committee of the applicant for the purpose of conducting experiments on GMOs;
- ff) "*Public hearing*" – refers to the face-to-face meeting with stakeholders to inform the latter of, and provide opportunity to submit comments on, any application for field trial of a regulated article which may pose no greater risks to biodiversity and human health than its conventional counterpart;

- gg) *"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;
- hh) *"Regulated article"* - refers to a genetically-modified organisms and its products, but limited to genetically-modified plants and plant products under the scope of this JDC;
- ii) *"Release into the environment"* - refers to the field testing, propagation, or direct use as food and feed, or for processing, of a regulated article;
- jj) *"Responsible Officer"* - refers to an officer appointed by the applicant for the importation or release into the environment of a regulated article who ensures that all appropriate measures are taken to prevent significant risks to biodiversity, human and animal health arising from the importation or release into the environment of the regulated article. The responsible officer shall be a resident of the Philippines and the highest-ranking officer of the applicant;
- kk) *"Risk"* - refers to the combination of the likelihood that an adverse consequence of a biohazardous activity or trait will occur and the magnitude of such a consequence;
- ll) *"Risk assessment"* - refers to the procedure that identifies, evaluates and predicts the occurrence of possible hazards to human and animal health and the environment;
- mm) *"Risk management"* - refers to appropriate mechanisms, measures and strategies to regulate, manage and control risks identified in the risk assessment including those conditions imposed by concerned departments or agencies;
- nn) *"Sanitary and Phytosanitary Measures (SPS)"* - refers to sanitary and phytosanitary measures, or such measures established to protect human, animal and plant life or health within the country's territory from risks from: (i) entry, establishment or spread of pests, diseases, organisms, animals, products or products thereof; and (ii) additives, contaminants, toxins or disease-causing organisms in foods, beverages or feed stuffs;

- oo) *"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;
- pp) *"Transboundary movement"* - refers to the movement of living modified organisms from party to another party/non-party to the Cartagena Protocol; and
- qq) *"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.

ARTICLE II. BIOSAFETY DECISIONS

Section 3. **Guidelines in Making Biosafety Decisions.** The principles under the NBF shall guide concerned agencies in making biosafety decisions, including:

- 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, CODEX Alimentarius Guidelines on the Food Safety Assessment of Foods Derived from the Recombinant-DNA Plants shall be adopted as well as other internationally accepted consensus documents;

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 Impact Assessment.* In making biosafety decisions under this Circular, government departments and agencies shall consider the environmental and health impact of the proposed activity. For this purpose, the evaluation of environmental and health risks and impacts are integrated into this Joint Department Circular, consistent with the substantive requirements of the EIS System pursuant to P.D. No. 1586, the NBF and R.A. No. 10611. Specifically, the public consultation requirements shall be integrated in the various public participation components under this Circular. The DENR and DOH, through their respective Biosafety Committees, shall conduct the evaluations and submit their findings on compliance with environmental and health impact assessment to the BPI for consideration in the processing of the biosafety permits. DOH evaluation shall be based on the Philippine National Framework and Guidelines for Environmental Health Impact Assessment.

D. *Socio-economic, Ethical and Cultural Considerations.* In making biosafety decisions for the commercialization of a regulated article, concerned departments shall take into account socio-economic, ethical and cultural considerations arising from the impact of regulated articles on the conservation and sustainable use of biological diversity, especially with regard to the value of biological diversity to indigenous and local 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 the Joint Department Circular shall be arrived at in a transparent and participatory manner. Biosafety issues are best handled with the participation of all stakeholders and organizations. They shall have appropriate access to information and the opportunity to participate in a responsible and accountable manner in biosafety decision-making processes. In the conduct of public participation, the following minimum requirements shall apply.
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 a minimum time frame as may be appropriate;
 3. *Public consultations, as a way to secure wide input into decisions to be made.* These could include formal hearings in certain cases, or solicitation of public comments, particularly where there is public controversy about the proposed activities. Public 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 shall be utilized;
 4. *Written submissions.* Procedures for public participation shall include mechanisms that allow public participation in writing or through public hearings, as appropriate, and which allow the submission of any positions, comments, information, analyses or opinions. Concerned departments and agencies shall include in their appropriate rules and regulations the stages when and the process to be followed for submitting written comments; 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, have access to the decision, and shall be provided with the reasons and the decision promptly, have access to the decision, and shall be provided with the reasons and considerations resulting in the decision, upon request.

ARTICLE III. ADMINISTRATIVE FRAMEWORK

Section 4. **Role of National Government Agencies.** Consistent with the NBF and the laws granting their powers and functions, 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 evaluating 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 environmental assessments are done and impacts identified in biosafety decisions. 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 environmental 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 implemented 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 Departments concerned shall constitute the following Biosafety Committees:

- A. *DOST-Biosafety Committee (DOST-BC)*. The DOST-BC shall evaluate applications for contained use and confined test of regulated articles.
- B. *DA-Biosafety Committee (DA-BC)*. The DA-BC shall evaluate applications for field trial, commercial propagation and transboundary movement of regulated articles in accordance with this Circular. It shall also evaluate the independent reports as well as socio-economic, ethical and cultural considerations.
- C. *DENR-Biosafety Committee (DENR-BC)*. The DENR-BC shall lead in evaluating environmental risks and impacts of regulated articles for field trial, commercial propagation, and direct use of living modified organisms in accordance with this Circular.
- D. *DOH-Biosafety Committee (DOH-BC)*. The DOH-BC shall lead in the evaluation of health impacts of regulated articles for field trial, commercial propagation, and direct use of living modified organisms in accordance with this Circular.

Section 6. Institutional Biosafety Committee (IBC). The company or institution applying for and granted permits under this Circular shall constitute an IBC prior to the contained use, confined test, or field trial of a regulated article. The membership of the IBC shall be approved by the DOST-BC for contained use or confined test, or by the DA-BC for field trial. The IBC is responsible for the conduct of the risk assessment and preparation of risk management strategies of the applicant for contained use, confined test, or field trial. It shall make sure that the environment and human health are safeguarded in the conduct of any activity involving regulated articles.

The IBC shall be composed of at least five (5) members, three (3) of whom shall be designated as scientist-members and two (2) members 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 in a position to represent the interests of the communities where the activities are to be conducted. One of the community representatives shall be an elected official in the LGU. The other community representative shall be selected from residents who are members of the Civil Society Organizations represented in the Local Poverty Reduction Action Team, pursuant to DILG Memorandum Circular No. 2015-45. For multi-location trials, community representatives of the IBC shall be designated per site. If the activity may affect ancestral domain or ancestral land, or protected area, the second community representative should represent the indigenous people or protected area management board, as applicable.

Section 7. Scientific and Technical Review Panel (STRP). The DA shall create a Scientific and Technical Review Panel composed of a pool of non-DA scientists with expertise in the evaluation of the potential risks of regulated articles to the environment and human health. The functions of the STRP are as follows:

- A. Evaluate risk assessment submitted by the applicant for field trial, commercial propagation, or direct use of regulated articles;
- B. At the request of the BPI, analyze the comments and issues raised by stakeholders and the public, and make recommendations on how to address these issues; and
- C. Evaluate petitions for deregulation of a regulated article, taking into account the nature and use of the regulated article, and scientific consensus, if any, on the effect of its release on human health and the environment.

The DA shall select scientists/experts in the STRP, who shall meet the following qualifications:

- A. Must not be an official, staff or employee of the DA or any of its attached agencies;
- B. Must not be directly or indirectly employed or engaged by a company or institution with pending applications for permits covered by this Circular;
- C. Possesses technical expertise in at least one of the following fields: food and nutrition, toxicology, ecology, crop protection, environmental science, molecular biology and biotechnology, genetics, plant breeding, animal nutrition; and
- D. Well-respected in the scientific community as evidenced by positions held in science-based organizations, awards and recognitions, publications in local and international peer-reviewed scientific journals.

The number of experts and fields of expertise needed for the STRP review of the application shall be determined by the BPI based on the nature of the regulated article, the details and scope of the field trial, the availability of expertise in the pool and whether or not the regulated article is intended for commercial propagation or direct use.

Each member shall submit an independent report to the BPI. The BPI shall then prepare a consolidated report summarizing the findings of the STRP members involved.

A member of the STRP is entitled to a modest honorarium and reimbursement of costs incurred in the performance of his/her functions. The expenses incurred shall be charged against the funds of the BPI from fees collected.

ARTICLE IV. CONTAINED USE AND CONFINED TEST OF REGULATED ARTICLES

Section 8. Policy on Contained Use and Confined Test of Regulated Articles. The contained use, including experiments inside laboratory, screenhouse, greenhouse, and glasshouse, and confined test of regulated articles shall be governed by the DOST-BC in accordance with the Biosafety Guidelines for Contained Use of Genetically Modified Organisms⁵ approved by the National Committee on Biosafety of the Philippines, unless otherwise provided herein.

The risk assessment, environmental and health impact assessment shall be governed by the Biosafety Guidelines for Contained Use of Genetically Modified Organisms.

Section 9. Public participation for Contained Use and Confined Test. The DOST-BC and the BPI shall make public a summary of each application for contained use and confined test. It should also include the action/decision taken by the DOST-BC on such application through the DOST website. Consistent with the NBF, the applicant shall give notice to the NCBP of such application for contained use or confined test of a regulated article.

ARTICLE V. FIELD TRIAL OF REGULATED ARTICLES

Section 10. 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. Only regulated articles that satisfactorily passed the process on contained use or confined test supervised and officially endorsed by DOST-BC may be subject of application for a Biosafety Permit for Field Trial.

⁵Department of Science and Technology Biosafety Committee under the National Biosafety Committee of the Philippines. 2014. *The Philippines Biosafety Guidelines for the Contained Use of Genetically Modified Organisms (GMOs), Revised Edition*. Published by the DOST-BC, DOST, Taguig City, September 2014.

Section 11. Procedural Requirements for Securing a Biosafety Permit for Field Trial.

- A. Application for Field Trial. - Any applicant who desires to conduct field trial of a regulated article shall submit the following to the BPI Director:
1. Application Form. - Three (3) copies of the Application for Field Trial (Annex "A")
 2. Supporting Documents. - The application shall be accompanied by the following documents:
 - a. Certification from the DOST-BC that the regulated article has completed the experiment for contained use or confined test, including recommendations of the DOST-BC on conditions or issues to be addressed during field trial;
 - b. A 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 biodiversity, human and animal health than its conventional counterpart;
 - c. Information on socio-economic, cultural and ethical consideration
 - d. Copy of the proposed Public Information (PIS) Sheet for field trial (Annex "B") including information required for evaluation of environmental and health impacts;
 - e. Endorsement by the IBC after the conduct of a risk assessment;
 - f. Project Description as prescribed by DENR-BC;
 - g. Project Description as prescribed by DOH-BC;
 - h. National Commission on Indigenous People (NCIP) Clearance(when applicable);
 - i. Import permit(when applicable); and
 - j. Proof of payment of fees.
- B. Multiple Field Trial Sites. - An application for field trial of a regulated article may cover multiple field trial sites, provided that, each field trial site shall be evaluated separately for purposes of determining the risks and impact on the environment and health as well as other considerations.
- C. If the site is within an ancestral domain or ancestral land, or if the field trial may affect the ancestral domain or ancestral land, or the cultural practices of the indigenous people therein, 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, or if the field trial may affect the protected area and biodiversity therein, the applicant shall secure an endorsement from the Protected Area Management Board of the protected area.
- D. Acceptance of Application. - Within five (5) days from receipt of the application, the BPI shall determine if it is sufficient in form and substance.

No application shall be accepted by the BPI without the evaluation and due endorsement of the risk assessment report by the IBC. If the application is sufficient, the BPI shall inform the applicant, forward the application, together with the supporting documents to the DENR-BC and DOH-BC for evaluation of environmental and health impact assessments, and refer the application to the STRP for evaluation of the risk assessment conducted by the IBC. Otherwise, the applicant shall be given a grace period of sixty (60) days within which to correct the defect or insufficiency in the application. If the applicant fails to do so within the grace period, the application shall be deemed denied, but without prejudice to the right of the applicant to submit the same as a new application.

- E. The STRP shall evaluate the application, particularly the risk assessment and risk management strategies based on the risk assessment conducted by the IBC. Based on the information submitted by the applicant, the BPI may require expert evaluation of any socio-economic, ethical or cultural considerations. The DENR-BC and DOH-BC shall evaluate the environmental and health impact of the activity, respectively. The STRP, DENR-BC and DOH-BC shall submit their independent reports to the BPI within thirty (30) days from its receipt of the copy of the application. The BPI shall prepare a consolidated summary of the technical reports and post it on the NCBP and BPI websites. The consolidated report containing the recommendations of the STRP, DENR-BC and DOH-BC shall be available to stakeholders and the public upon request, subject to reasonable limits on non-disclosure of confidential information under Section 40.
- F. Within five (5) days from the submission of the technical reports of the STRP, DOH-BC and DENR-BC, and preparation of the consolidated report, the BPI shall inform the applicant that it can schedule a public consultation following the procedure under Section 12. The applicant shall prepare and submit a report on the public consultation, including the status of endorsement of the *Sungguniang Panlungsod/Bayan*, within a period of thirty (30) days from the conduct of the public consultation.
- G. Within ten (10) days from the submission by the applicant of the report on the public consultation and LGU endorsement, the BPI shall forward the application and all related documents to the DA-BC for evaluation. The DA-BC shall review the application and make its recommendation to the BPI director within ten (10) days. Within five (5) days from receipt of the DA-BC recommendation, the BPI Director shall approve the application if s/he finds that based on the evaluation reports and the safeguards that the proponent adopted to address issues raised by government agencies and stakeholders, the field trial of the regulated article does not pose greater risks to biodiversity, human and animal health than its conventional counterpart; otherwise, the BPI Director shall deny the application.
- H. Upon approval of the application, a Biosafety Permit for Field Trial shall be

issued. The original copy shall be given to the applicant. Other copies shall be provided to the NCBP, DENR-BC and DOI-BC, the DA Regional Executive Director concerned, and DA to maintain the application file.

- I. A Biosafety Permit for Field Trial shall be issued for every approved field trial site. It shall be valid for a period of two (2) years from date of issuance, unless sooner revoked for any of the reasons set forth in (L) below. It may be extended for such period as may be necessary to complete the field trial begun during the two-year period.
- J. Submission of Report. - Within ninety (90) days from the completion of the field trial, the applicant shall submit two (2) copies of the detailed terminal report on the results of the field trial to the BPI. 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 detailed description of potential risks to biodiversity, human and animal health observed during the conduct of the field trial; the steps taken by the proponent to mitigate them; and the final disposition of the regulated article. The duplicate copy shall be transmitted by the BPI to NCBP for its reference and file.
- K. 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 notify the Director of BPI, within the time periods and in the manner specified below, in case of any of the following occurrences:
 - a. Immediately upon discovery, not exceeding twenty four (24) hours, through verifiable means of communication (email, text message, etc.), in the event that new information becomes available indicating that the regulated article could pose greater risks to biodiversity, human and animal health than its conventional counterpart; and
 - b. In writing, as soon as possible, but not to exceed three (3) working days, if the regulated article or associated host organism is found to have characteristics substantially different from those listed in the application, or suffers from any unusual occurrence (e.g., excessive mortality or morbidity, unanticipated effect on non-target organisms).
- L. 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 false information in the Application;
 - 2. Violation of biosafety rules and regulations or of any conditions specified in the permit;
 - 3. Failure to allow the inspection of the field trial site;

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4. Receipt by the BPI of new information that the field trial of the regulated article could pose greater risks to biodiversity, human and animal health than its conventional counterpart; or
5. Such other grounds as the BPI may deem reasonable to prevent greater risks to biodiversity, human and animal health than its conventional counterpart.

Section 12. Public Participation for Field Trial.

- A. The BPI shall make public all applications and Biosafety Permits for Field Trial through posting on the NCBP and BPI websites, and in the offices of the DA and DOST in the province, city or municipality where the field trial will be conducted.
- B. Upon completion of the STRP, DOH-BC and DENR-BC evaluation, the IBC, 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 trials 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 consolidated risk assessment reports.
- C. With the consent of the LGU(s), the IBC, in consultation with the C/MLGOO, shall post notices, in the language understood by the local community, and containing copies of the PIS for field trial approved by the BPI and the consolidated risk assessment report, in at least three (3) conspicuous places within the vicinity of the city/municipality and barangay where the proposed field trials will be conducted at least two (2) weeks prior to the public hearing. The notices shall, among others, invite interested parties to send their comments on the proposed field trial to the BPI within the posting period, and to attend the public hearing. During the comment period, any interested person may submit to the BPI written comments regarding the application.
- D. The applicant, thru their IBC, in consultation with the DA-BC and the C/MLGOO, shall convene the public hearing for purposes of consulting stakeholders, particularly local government officials and functionaries, local communities, indigenous peoples, the Agricultural and Fisheries Council and the Protected Area Management Board, where applicable, in the area where the field trials are to be conducted.
- E. 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 addressing them point-by-point; and (2) the approval of the *Sanggunian* concerned pursuant to Sec. 27 of the Local Government Code. If the applicant fails to secure the LGU endorsement within the required period of submitting the report, the applicant may request for extension of time to secure the LGU endorsement.

Section 13. Risk Assessment. The IBC, prior to the submission of the application, shall (1) evaluate the field trial proposal using the policies and guidelines on risk assessment formulated by the NCBP, DENR, DOH and DA consistent with this

Circular; (2) determine if the data obtained under contained use and confined test conditions provide sufficient basis to authorize the field trial of the regulated article; (3) ensure that field trial of the regulated article does not pose greater risks to biodiversity, human and animal health than its conventional counterpart; (4) require the proponent to perform additional experiments under contained conditions before acting on the field trial proposal; and (5) endorse the field trial proposal to the BPI or reject it for failing the scientific risk assessment. The STRP shall review the risk assessment conducted by the IBC and make its report and recommendation to the BPI.

The risk assessment conducted by the IBC, shall be reviewed by the DENR-BC and the DOH-BC. Upon completion of the review of the risk assessment, the DENR-BC and DOH-BC shall submit their reports to the BPI.

Section 14. Environmental and Health Impact Assessment. On the basis of the Project Description and risk assessment conducted by the IBC, the DENR-BC shall assess the environmental impact of the project and make its recommendations in its report to the BPI. The DOH-BC shall likewise evaluate the application for its health impacts and make its recommendations in its report to the BPI.

ARTICLE VI. COMMERCIAL PROPAGATION OF REGULATED ARTICLES

Section 15. Policy on Commercial Propagation of Regulated Articles. No regulated article shall be released for commercial propagation unless: (1) a Biosafety Permit for Commercial Propagation has been secured in accordance with this Circular; (2) it can be shown that based on field trial conducted in the Philippines, the regulated article does not pose greater risks to biodiversity, human and animal health than its conventional counterpart; (3) food and feed safety studies show that the regulated article does not pose greater risks to biodiversity, human and animal health than its conventional counterpart, consistent with CODEX Alimentarius Guidelines on the Food Safety Assessment of Foods Derived from the Recombinant-DNA Plants and protocols of the DOH and BAI on feeding trials; and (4) if the regulated article is a pest-protected plant, its transformation event that serves as plant-incorporated protectant (PIP) has been duly registered with the Fertilizer and Pesticide Authority (FPA).

Section 16. Procedural Requirement for Securing Biosafety Permit for Commercial Propagation of Regulated Articles.

- A. Application for Commercial Propagation. – Any applicant who desires to release, for commercial propagation, a regulated article which is not listed in the Approval Registry for Commercial Propagation shall submit the following to the Director of BPI:
 1. Application Form. - Five (5) copies of the Application for Commercial Propagation. (Annex "C").
 2. Supporting Documents. - The application shall be accompanied by the

following:

- a. Certification from the BPI: (i) for new application, that the regulated article has undergone satisfactory field trial in the Philippines; (ii) in cases of renewal, a certified true copy of the expired Biosafety Permit for Commercial Propagation;
 - b. A technical dossier consisting of scientific literature, unpublished studies or data from tests performed, or such other scientific materials relied upon by the applicant to show that the release for commercial propagation of the regulated article does not pose greater risks to biodiversity, human and animal health than its conventional counterpart;
 - c. Information on socio-economic, cultural and ethical consideration;
 - d. Copy of the proposed Public Information Sheet for Commercial Propagation (Annex "D") including information required for evaluation of environmental and health impacts;
 - e. Field trial report;
 - f. Project Description as prescribed by DENR-BC;
 - g. Project Description as prescribed by DOH-BC;
 - h. Applicant's Risk Assessment Report;
 - i. Import Permit (when applicable); and
 - j. Proof of payment of fees.
- B. Acceptance of Application. – Within five (5) days from receipt of the application, the BPI shall determine if it is sufficient in form and substance. If the application is sufficient, the BPI shall inform the applicant, forward the application and the supporting documents to the DENR-BC and DOH-BC for evaluation of environmental and health impact assessments, and refer the application to the FPA, BPI-PSSD, BAI and STRP for evaluation of the risk assessment.

Otherwise, the applicant shall be given a grace period of sixty (60) days within which to correct the defect or insufficiency in the application. If the applicant fails to do so within the grace period, the application shall be deemed denied, without prejudice to the right of the applicant to submit the same as a new application.

- C. Evaluation by the STRP and other Agencies. –The BPI shall furnish the following agencies with a copy of the application, and each shall have thirty (30) days from receipt thereof to submit the following:
1. Evaluation of environmental and health impact by DENR-BC and DOH-BC, respectively;
 2. Determination of compliance with food safety standards by BPI-Plant Product Safety Services Division (BPI-PPSSD), in all instances;
 3. Determination if applicant is duly licensed as a pesticide handler in accordance with Presidential Decree No. 1144 and if tolerance levels and good agricultural practices have been established for registration of the transformation event by FPA (if the regulated article is a pest-protected

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- plant);
4. Determination of compliance with feed safety standards by BAI;
 5. Evaluation of the Applicant's risk assessment report by STRP; and
 6. Expert evaluation of any socio-economic, ethical or cultural considerations, as may be required by the BPI.
- D. Within five (5) days from the submission of technical reports of the STRP and other agencies, the BPI shall prepare a consolidated summary of the technical reports and post it on the NCBP and BPI websites. The consolidated report containing the recommendations of the STRP and other agencies shall be made available to stakeholders and the public upon request, subject to reasonable limits on non-disclosure of confidential information under Section 40.
- E. Consistent with Section 17, the applicant shall prepare a report on the public comment. Within five (5) days from the submission by the applicant of the report of the public comment, the BPI shall forward the application and all related documents to the DA-BC for evaluation. The DA-BC shall review the application and make its recommendation to the BPI director within ten (10) days. Within five (5) days of receipt of the DA-BC recommendation, the BPI Director shall approve the application if based on the evaluation reports and the safeguards that the proponent adopted to address issues raised by government agencies and stakeholders, the commercial propagation of the regulated article does not pose greater risks to biodiversity, human and animal health than its conventional counterpart; otherwise, the BPI Director shall deny the application.
- F. Upon approval of the application, a Biosafety Permit for Commercial Propagation shall be issued. The original copy shall be given to the applicant. Other copies shall be provided to the NCBP, all agencies that conducted technical evaluations, and the DA, to maintain the application file.
- G. The Biosafety Permit for Commercial Propagation shall be valid for a period of not more than five (5) years, unless sooner revoked for any of the reasons set forth in (J) below, or deregulated in accordance with Article IX herein.
- 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 notify the Director of BPI, within the time periods and in the manner specified below, in case of any of the following occurrences:
 - a. Immediately upon discovery, not exceeding twenty four (24) hours, through verifiable means of communication (email, text message, etc.), in the event that new information becomes available indicating that the regulated article could pose greater risks to biodiversity, human and animal health than its conventional counterpart; and

- b. In writing, as soon as possible, but not to exceed three (3) working days, if the regulated article or associated host organism is found to have characteristics substantially different from those listed in the application, or suffers from any unusual occurrence (excessive mortality or morbidity, unanticipated effect on non-target organisms).
 - 2. In the event new information becomes available indicating that the regulated article could pose greater risks to biodiversity, human and animal health than 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 false information in the Application;
 - 2. Violation of biosafety rules and regulations or of any conditions imposed in the permit;
 - 3. Availability of new technical information indicating that the commercial propagation of the regulated article could pose greater risks to biodiversity, human and animal health than its conventional counterpart; or
 - 4. Such other grounds as the BPI may deem reasonable to protect human health and the environment.

Section 17. 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, and in the offices of the DA and DOST nationwide.
- B. The applicant shall, within five (5) days of filing the application, publish in two (2) newspapers of general circulation a copy of the approved PIS for Commercial Propagation. The notification shall invite interested parties to send their comments on the proposed release for commercial propagation to the BPI within a period of sixty (60) days from the date of publication.
- C. During the comment period, any interested person may submit to the BPI written comments regarding the application, which shall become part of the application file, including all technical reports from the STRP and other agencies.
- D. The applicant shall submit to the BPI a written report on the public

comments, summarizing the issues raised and addressing them point-by-point.

Section 18. Risk Assessment for Commercial Propagation. The STRP and concerned agencies shall evaluate the proposal for commercial propagation using the policies and guidelines on risk assessment formulated by the NCBP, DENR, DOH, DA, and consistent with the provisions of this Circular. The STRP and concerned agencies shall determine if the data obtained under field trial conditions provide sufficient basis to authorize the commercial propagation of the regulated article. In making the determination, the STRP and concerned agencies shall ensure that the commercial propagation does not pose greater risks to biodiversity, human and animal health than its conventional counterpart. The STRP and concerned agencies may, in their discretion, require the applicant to perform additional experiments under field trial conditions before acting on the commercial propagation proposal. The STRP and concerned agencies shall submit their individual reports and make their recommendations to the BPI.

Section 19. Environmental and Health Impact Assessment. On the basis of the project description and the risk assessment conducted by applicant, the DENR-BC shall evaluate the environmental impact assessment of the project and make its recommendations in its report to the BPI. The DOH-BC shall likewise evaluate the application for its health impacts and make its recommendations in its report to BPI.

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

Section 20. Policy for the 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: (1) the Biosafety Permit for Direct Use has been issued by the BPI; (2) in the case of imported regulated article, the regulated article has been authorized for commercial distribution as food and feed in the country of origin; and (3) regardless of the intended use, the regulated article does not pose greater risks to biodiversity, human and animal health than its conventional counterpart.

Section 21. Procedural Requirements for Securing a Biosafety Permit for the Direct Use of Regulated Articles for Food and Feed, or for Processing.

A. **Application for Direct Use.** - Any applicant who desires to register a regulated article for direct use as food and feed, or for processing in the Approval Registry for Direct Use shall submit the following to the Director of BPI:

1. **Application Form.** - Three (3) copies of the Application for Direct Use (Annex "E")
2. **Supporting Documents.** - The application shall be accompanied by the following:

- a. In the case of imported regulated article, notification from the exporter or country of origin in accordance with existing international agreements on the transboundary movement of genetically modified organisms;
- b. Information on socio-economic, cultural and ethical consideration;
- c. Copy of the proposed PIS for Direct Use, (Annex "F") including information required for evaluation of environmental and health impacts;
- d. in cases of renewal, certified true copy of expired Biosafety Permit for Direct Use issued by BPI; and
- e. Proof of payment of fees.

To facilitate review of the application, the applicant may submit documents to show that the regulated article is allowed for commercial distribution as food and feed, or processing by the regulatory authorities in the country of origin, and does not pose greater risks to biodiversity, human and animal health than its conventional counterpart.

- B. Acceptance of Application. - Within five (5) days from receipt of the application, the BPI shall determine if it is sufficient in form and substance. If the application is sufficient, the BPI shall inform the applicant, forward the application, together with the supporting documents to the DENR-BC and DOH-BC for evaluation of environmental and health impact assessments, and refer the application to the BPI-PPSSD, BAI and STRP for evaluation of the risk assessment.

Otherwise, the applicant shall be given a grace period of sixty (60) days within which to correct the defect or insufficiency in the application. If the applicant fails to do so within the grace period, the application shall be deemed denied, but without prejudice to the right of the applicant to submit the same as a new application.

- C. Referral to the STRP and Other Agencies. - The BPI shall furnish the following agencies with a copy of the application, and each shall have thirty (30) days from receipt of the application from BPI to submit their respective evaluation:
1. Evaluation of environmental and health impact by DENR-BC and DOH-BC, respectively;
 2. Determination of compliance with food safety standards by BPI-Plant Product Safety Services Division (BPI-PPSSD), in all instances;
 3. Determination of compliance with feed safety standards by BAI;
 4. Evaluation of the Applicant's risk assessment report by STRP; and
 5. Expert evaluation of any socio-economic, ethical or cultural considerations, as may be required by the BPI.
- D. Within five (5) days from the submission of technical reports of the STRP and other agencies, the BPI shall prepare a consolidated summary of the technical

reports and post it on the NCBP and BPI websites. The consolidated report containing the recommendations of the STRP and other agencies shall be made available to stakeholders and the public upon request, subject to reasonable limits on non-disclosure of confidential information under Section 40.

- E. Consistent with Section 22, the applicant shall submit a report on the public comment. Within 5 days from the submission by the applicant of the report of the public comment, the BPI shall forward the application and all related documents to the DA-BC for evaluation. The DA-BC shall review the application and make its recommendation to the BPI Director within ten (10) days. Within five (5) days from receipt of the DA-BC recommendation, the BPI Director shall approve the application if based on the evaluation reports and the safeguards that the proponent adopted to address issues raised by government agencies and stakeholders, the regulated article does not pose greater risks to biodiversity, human and animal health than its conventional counterpart; otherwise, the BPI Director shall deny the application.
- F. Upon approval of the application, a Biosafety Permit for Direct Use shall be issued. The original copy shall be given to the applicant. Other copies shall be provided to the NCBP, all agencies that conducted technical evaluations, and the DA, to maintain the application file.
- G. The Biosafety Permit for Direct Use shall be valid for a period of not more than five (5) years, unless sooner revoked for any of the reasons set forth in (J) below.
- 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 false information in the Application;
 - 2. Violation of biosafety rules and regulations or of any conditions imposed in the permit;
 - 3. Availability of new technical information indicating that the direct use of the regulated article could pose greater risks to biodiversity, human and animal health than its conventional counterpart; or
 - 4. Such other grounds as the BPI may deem reasonable to protect human health and the environment.

Section 22. **Public Participation for Direct Use.**

- A. The BPI shall make public all applications for direct use through posting on

the NCBP and BPI websites, and in the offices of the DA and DOST nationwide;

- B. The applicant shall, within five (5) days of filing the application, publish in two (2) newspapers of general circulation a copy of the approved PIS for Direct Use. The notification shall invite interested parties to send their comments on the proposed application for direct use to the BPI within a period of sixty (60) days from the date of publication;
- C. During the comment period, any interested person may submit to the BPI written comments regarding the application and these shall become part of the application file, including all technical reports from the STRP and other agencies; and
- D. The applicant shall submit to the BPI a written report on the public comments, summarizing the issues raised and addressing them point-by-point.

Section 23. Risk Assessment, Environmental and Health Impact Assessment. The assessment of risks of regulated articles for direct use as food and feed, or for processing shall be guided by the best practices of OECD, CODEX Alimentarius Principles for the Risk Analysis of Foods Derived from Modern Biotechnology and the CODEX Alimentarius Guidelines for the Conduct of Food Safety Assessment of Foods Derived from Recombinant DNA Plants, and other relevant internationally accepted best practices.

The BPI shall forward the application to the DENR-BC and DOH-BC for evaluation of environmental and health impact. DOH evaluation shall be based on the Philippine National Framework and Guidelines for Environmental Health Impact Assessment. No living modified organism imported for direct use as food and feed, or for processing as food and feed shall be propagated without compliance with the requirements of contained use, confined test, field trial and commercial propagation regulations.

ARTICLE VIII. IMPORTATION OF REGULATED ARTICLES

Section 24. Identification of Regulated Articles for Importation. The documentation accompanying the regulated article shall indicate that it is or may contain a genetically modified organism.

Section 25. Policy on the Importation of Regulated Articles. All importation of regulated articles for the purpose of contained use, confined test, field trial, commercial propagation, or direct use for food and feed or for processing shall be covered by the Sanitary and Phytosanitary Import Clearance (SPSIC) issued by the BPI based on a valid biosafety permit secured in accordance with this Circular. Provided, that only regulated articles listed in the approval registry referred to in Section 36 hereof shall be issued an SPSIC. No shipment of regulated articles shall be allowed entry into the country without an SPSIC.

Section 26. Documentary Requirements. Any applicant who desires to import a regulated article shall submit the following to the BPI Director:

A. Importation for Contained Use/Confined Test

1. Three (3) copies of the Application Form for Importation for Contained Use/Confined Test;
2. DOST-BC Letter of Endorsement. The Application to Import shall include a letter of endorsement from the DOST-BC stating the following:
 - a. It has conducted a scientific and technical review of the proposal for contained use/confined test and finds that the proposed activity does not pose greater risks to human and animal health and biodiversity than its conventional counterpart;
 - b. The physical containment facility where the proposed activity will be performed has been found to be suitable for the purpose;
 - c. It endorses the importation of the regulated article for contained use/confined test; and
 - d. The conditions imposed upon the importation, movement, storage and use of the regulated article, if any;
3. Letter from the applicant stating the actions and procedures it has or will undertake to comply with the conditions of the CNA on the importation, movement, storage and use of the regulated article, if any, and the permit conditions provided in Section 27 (B) below; and
4. Payment of SPSIC processing fees to BPI.

B. Importation for Field Trial, or Commercial Propagation, or Direct Use

1. Three (3) copies of the Application Form for Importation for Field Trial, and Online application for Commercial Propagation and Direct Use;
2. *Proforma* Invoice coming from the supplier;
3. For field trial and commercial propagation, the GMO declaration shall clearly identify the specific Transformation Event(s) present in the regulated article. For direct use, the GM declaration should specify that only approved transformation events are present in the shipment. The declaration may be issued by the responsible officer from the country of origin, accredited laboratories, shipper or importer;
4. Location from port of entry to final destination (for plants and planting materials); and
5. Payment of SPSIC processing fees to DA Trade System and/or the BPI.

In addition to the documents required in Section 26 (A) and (B), the following additional information and documents for importation of regulated article are required:

1. Country of origin;
2. Quantity of the regulated article to be imported and the proposed schedule and number of importation;
3. A detailed description of all intermediate destinations, where applicable;
4. In cases of commercial propagation, a detailed description of the terms and conditions, if any, under which the regulated article has been allowed for propagation by the regulatory authorities in the country of origin; and

5. Further, in cases of commercial propagation, (1) a certification from the country of origin that the regulated article to be imported is of the same transformation event as that which has undergone satisfactory field trial in the Philippines; and (2) a notification from the exporter or country of origin in accordance with existing international agreements on the transboundary movement of genetically modified organisms shall be necessary.

Section 27. Procedural Requirements for Securing an SPSIC for Contained Use/Confined Test or Field Trial.

- A. Processing of the Application. - Within fifteen (15) days from acceptance of the application, the BPI Director shall approve the application if the importation of the regulated article does not pose greater risks to biodiversity and human health than its conventional counterpart; otherwise, the application shall be denied.

Upon approval of the application, an SPSIC shall be issued in duplicate copies. The original shall be given to the applicant for presentation to the National Plant Protection Organization (NPPO) of the country of origin. The duplicate shall be furnished to the BPI to be filed with the application. No regulated article shall be allowed to be imported into the country or be removed from the port of entry without compliance with Sanitary and Phytosanitary (SPS) regulations.

- B. SPSIC Conditions for Contained Use, Confined Test and Field Trial. - The importer shall comply with the following conditions:
 1. The regulated article shall be imported solely and exclusively for the activity applied for;
 2. The regulated article shall only be imported at the port of entry designated in the permit;
 3. The regulated article shall be maintained only in the physical containment facility or intermediate destinations specified in the permit;
 4. The regulated article shall be maintained and disposed of in a manner as to prevent greater risks to biodiversity, human and animal health than its conventional counterpart;
 5. All packing materials, shipping containers, and any other materials accompanying the regulated article shall be treated or disposed of in such a manner as to prevent greater risks to biodiversity, human and animal health than its conventional counterpart;
 6. A Plant Quarantine Officer shall be allowed access during regular business hours to the physical containment facility or intermediate destinations where the regulated article is located and to any records relating to the importation of the regulated article;
 7. The regulated article shall be subject to the application of measures, including final disposal, which the BPI Director determines to be necessary or desirable, to prevent the accidental or unauthorized release of the regulated article;

8. Whenever possible, the regulated article shall be identified with a label showing the permit number, the name of the regulated article and the date of importation;
 9. The importer shall notify the BPI Director immediately in case of the following occurrences:
 - a. Within twenty four (24) hours upon discovery, through verifiable means of communication (email, text message, etc.), new information becomes available that the regulated article could pose greater risks to biodiversity, human and animal health than its conventional counterpart; and
 - b. Within three (3) days upon discovery, through written correspondence, the regulated article or associated host organism is found to have characteristics substantially different from those listed in the application, or suffers from any unusual occurrence (excessive mortality or morbidity, unanticipated effect on non-target organisms);
 10. The importer, shall on its own, immediately take measures necessary to protect human health and the environment whenever new information becomes available indicating that the regulated article could pose greater risks to biodiversity, human and animal health than its conventional counterpart; and
 11. Such other SPS measures that the BPI may deem necessary or desirable to impose to protect human health and the environment.
- C. Notice of Arrival of Shipment. – Within fifteen (15) days from arrival of every shipment of the regulated article, the applicant shall notify the BPI and present the SPSIC together with the name of carrier, name of shipper and date of arrival.
- D. Refusal of Issuance or Revocation of SPSIC. –The issuance of the SPSIC shall be refused or the SPSIC shall be revoked for any of the following grounds:
1. Revocation by the DOST-BC of its Letter of Endorsement, for cases of contained/confined test;
 2. Provision of false information in the Application to Import;
 3. Misdeclaration of shipment;
 4. Violation of relevant SPS or biosafety rules and regulations or of any conditions imposed in the SPSIC;
 5. Refusal to allow the inspection of the physical containment facility or intermediate destination of the regulated article; or
 6. Availability of new technical information to the BPI indicating that the regulated article, if allowed for its intended use, will pose greater risks to human and animal health and to the biodiversity than its conventional counterpart.

Section 28. Procedural Requirements for Securing an SPSIC for Commercial Propagation or Direct Use. The application and issuance of an SPSIC for Commercial Propagation or for Direct Use shall be done online in accordance with

the process in BPI Plant Quarantine Order No. 1, s. 2014, and shall comply with DA A.O. No. 9, s. 2010 and other applicable orders and circulars of the DA.

Section 29. Application Process for the Issuance of SPSIC for Commercial Propagation and Direct Use. The following are the steps for the issuance of SPSIC for commercial propagation and direct use:

- A. The importer shall apply online in the DA Trade System (DTS) website.
- B. Upon receipt thereof, the technical staff from the BPI - National Plant Quarantine Services Division (BPI-NPQSD) shall evaluate the online application.
- C. The Chief of the BPI-NPQSD shall endorse the evaluated application to the BPI Director.
- D. Upon endorsement of the application and in accordance with the criteria set by this issuance, the BPI Director shall approve/disapprove the application.
- E. If approved, the importer shall print the approved SPSIC and proceed with their importation.

Section 30. Registration for SPSIC Application. Prior to the application of SPSIC under this Circular, all BPI-registered importers are required to register with DTS.

Section 31. Procedures for Inspection at the Port of Entry for Commercial Propagation and Direct Use. The commodity shall be subject to the existing procedures for inspection at the port of entry:

- A. The importer shall file an Electronic Request for Inspection (eRFI) with the DTS at least twenty-four (24) hours prior to the arrival of the shipment.
- B. The following documents shall be submitted at the port of entry:
 1. Hard copy of the eRFI;
 2. Valid Phytosanitary Certificate (original) issued by the Plant Quarantine of the country of origin with the compliance of conditions, if any, stated in the SPSIC or equivalent certificate;
 3. Valid SPSIC issued by the BPI-NPQSD;
 4. Bill of Lading/Airway Bill;
 5. BOC Import Entry Internal Revenue Declaration;
 6. Packing List/Commercial Invoice;
 7. GMO Certification, if applicable;
 8. Photocopy of the Broker Clearance Certificate(BCC)/Special Power of Attorney (SPA), in the absence of the importer; and
 9. Fumigation Certificate or any other required treatment, if applicable.

Section 32. General Inspection Procedure for Commercial Propagation and Direct Use.

- A. In the initial inspection conducted at the Bureau of Customs (BOC) Designated Examination Area (DEA), the BPI-NPQSD shall be allowed to check on the quality and quantity of the shipment based on the submitted documents of the importation.

1-

- B. Upon arrival of the imported commodities, the BPI-NPQSD shall conduct a *thorough check and inspection*. If the shipment contains commodities/varieties other than that stated in the accompanying SPSIC, the excess shipment of other similar variety shall be segregated and recommended to the BOC for disposal, in accordance with Section 27 (B) (7) hereof, without prejudice to the filing and imposition of appropriate sanctions and penalties.
- C. If during the checking by the PQS inspectors, it is found that the volume/quantity has exceeded the allotted quantity covered by SPSIC, the excess shipment shall be recommended to the BOC for disposal, in accordance with Section 27 (B) (7) hereof.
- D. The Plant Quarantine Officer/Inspector at the port of entry shall undertake the following procedures:
 - 1. Collect representative samples necessary for laboratory analysis, and;
 - 2. Examine the submitted samples to determine the presence of insects, diseases, nematodes and other pests, including analysis for pesticide residue level, heavy metals, other contaminants and/or toxins produced by microorganisms; and
 - 3. Authorize the delivery under guard by the Plant Quarantine Officer and follow-up inspection/examination at the importer's cold storage/warehouse.
- E. Based on the results of inspection and examination, any of the following may be applied:
 - 1. Applicable plant quarantine treatment (if necessary);
 - 2. Return to the country of origin;
 - 3. Re-export to other accepting countries; or
 - 4. Destruction.
- F. In all cases, all expenses shall be borne by the importer.

ARTICLE IX. DEREGULATION OF REGULATED ARTICLE

Section 33. Ground for Deregulation. Before the expiration of the Biosafety Permit for Commercial Propagation and/or Direct Use, the BPI may, *motu proprio*, or through a petition thereto, remove the regulated article from the coverage of this circular if based on the nature of a regulated article and its use, the regulated article will not pose greater risks to human and animal health, and to the biodiversity than its conventional counterpart.

Section 34. Requirements for Deregulation.

- A. **Petition for Deregulation.** – Any person may file with the BPI a verified petition to exclude a regulated article from the coverage of this Circular. The petition, which shall be in two (2) copies, shall contain the following:
 - 1. Name and address of the petitioner;
 - 2. Name of regulated article subject of the petition;
 - 3. Factual ground why this Circular should not apply to the regulated article; and

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4. Published scientific literature relied upon by the petitioner.

Should BPI, *motu proprio*, consider the regulated article for its deregulation, the BPI shall declare such intention with supporting documents equivalent to the contents of a petition.

- B. Publication. – Within five from receipt, the BPI shall inform the petitioner if the petition satisfies the requirements of Section 34 and order the petitioner to have the petition published in two (2) newspapers of general circulation with a notice soliciting comments thereon. Should the BPI declare intention for deregulation, the same shall be published in two (2) newspapers of general circulation with a notice soliciting comments thereon.

The notice shall invite interested parties to send their comments on the petition for deregulation to the BPI within a period of sixty (60) days from the date of publication. During the comment period, any interested person may submit to the BPI written comments regarding the petition which shall become part of the petition file. Proof of publication must be submitted within fifteen (15) days from the date of publication.

- C. STRP Report. – Upon granting due course to the petition or BPI declaration of intention to deregulate, the BPI Director, shall furnish a copy to the STRP. The STRP shall evaluate the petition taking into account the nature and use of the regulated article and the scientific consensus, if any, on the effect of its release on human health and the environment, and submit its report to the BPI within thirty (30) days from receipt of a copy of the application.
- D. Referral to DENR-BC and DOH-BC. –The BPI shall furnish the DENR-BC and DOH-BC with a copy of the petition, and each shall have thirty (30) days from receipt of the application from the BPI to submit their respective evaluation on the environmental and health impacts of the proposed deregulation.
- E. Decision. – Within one hundred twenty (120) days from receipt of the certificate evidencing publication of the petition in accordance with Item B of this Section and taking into account the reports of the STRP, DENR-BC and DOH-BC, the DA-BC shall be convened to determine whether or not the application shall be endorsed to the BPI Director for approval. Within fifteen (15) days from endorsement by the DA-BC of the petition, the BPI Director shall resolve the petition and inform the petitioner in writing of his decision. The BPI Director shall decide based on the petition file, to: (1) approve the petition, in which case the BPI Director shall declare the regulated article as no longer covered by this Circular; or (2) deny the petition, in which case the petitioner may apply for renewal of the Biosafety Permit; or (3) require the petitioner to submit additional scientific literature or experimental data.

In case of BPI's own consideration for deregulation, and within one hundred twenty (120) days from receipt of the certificate evidencing publication, and

taking into account the reports of the STRP, DENR-BC and DOH-BC, the DA-BC shall be convened to determine whether or not deregulation may be considered. Within fifteen (15) days from positive endorsement by the DA-BC, the BPI Director may declare the regulated article as no longer covered by this Circular or require the permit holder to apply for renewal of the Biosafety Permit.

Should new technical information become available indicating that the deregulated article could pose greater risks to biodiversity, human and animal health, the deregulated article shall again be subject to this Circular for purposes of ensuring environmental and health safety.

ARTICLE X. MISCELLANEOUS PROVISIONS

Section 35. Monitoring. The field trial and commercial propagation of the regulated article shall be monitored by the BPI, DENR, DOH and other appropriate government authorities (including the IBC, in the case of field trials), and submit to the DA-BC the results of monitoring activities at intervals specified in the approved monitoring schedule. The BPI shall prepare a consolidated monitoring report and post it in the NCBP and BPI website.

Section 36. 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;
- C. Field trial; and
- D. Deregulated articles.

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.

The Biosafety Permit of regulated articles that are listed in Annex "G" of this Circular shall remain valid until their expiration.

Section 37. Application File. The BPI shall open an application file for every application given due course in accordance with this Circular. The application for permit, supporting documents, evaluation reports, 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. A summary of the application file (Decision Document) shall be posted on the website of the BPI.

Section 38. Reportorial Requirements. The following reports shall be submitted to the BPI:

- A. Reports from the IBC.

1. *Annual report of projects under supervision during the year.* The IBC shall submit a report to the BPI not later than the 15th day of March of each year.
2. *Completion report.* The IBC shall submit a report upon completion of a field trial not later than one hundred twenty (120) days from completion date.
3. *Incident report.* In case of any accident or untoward incident that may put human health or the environment at risk, the applicant shall immediately report the same to the IBC and the BPI. The report shall describe the accident or untoward incident, the actions taken to mitigate it, and the persons and government authorities notified. In no case shall reporting the accident or untoward incident to the BPI relieve the applicant and the institution of their obligations under the law. The BPI may require the IBC to submit follow-up reports on the long term effects of the field trial.

B. Reports from the Applicant

1. *Progress report.* The applicant shall submit progress report/s of all ongoing projects to the IBC every end of February, for inclusion in the annual report of the IBC.
2. *Incident report.* The applicant shall report immediately to the IBC and the BPI any unexpected observations, untoward incidents, results or accidents and unexplained illnesses or absences of personnel which may be attributed to the activities involving the regulated article.
3. *Completion report.* The applicant shall submit a completion report of the field trial to the IBC ninety (90) days after its completion.

C. Monitoring Reports. Concerned agencies shall submit the monitoring reports to the BPI.

Section 39. Management of Regulated Article. The Biosafety Committees of the DOST, DA, DENR and DOH shall conduct regular review of, recommend, and monitor compliance to, management strategies/measures of regulated articles by Biosafety Permit holders.

Section 40. 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 the environment and human health;
 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 it 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 (i) the information, data or results are not CIC, or (ii) 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 41. Outside Experts and Accreditation of Laboratories. In the implementation of this Circular, including without limitation the evaluation of risk assessment studies and risk management measures, 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 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 42. Fees. 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 43. Appeal. In case of the applications for field trial, commercial propagation and direct use, any stakeholder aggrieved by the decision of the BPI shall have the right to appeal the decision of the BPI Director to the Secretary of Agriculture within fifteen (15) days from the receipt of the decision.

Section 44. Funding. The DOST, DENR, DA, DOH and DILG shall allocate from their present budgets such amount as may be necessary to implement this Circular, including support to operations of their respective Biosafety Committees and its secretariat, as applicable. Thereafter, the funding requirements shall be included in the General Appropriations Bill submitted to Congress.

Section 45. 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 the right of appeal and other administrative remedies 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 for damages resulting injuries committed on persons shall apply in accordance with such laws.
- 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 46. Issuance of Implementing Orders. The concerned national government agency may issue subsequent implementing orders pursuant to their respective functions in this Circular, subject to prior notice with the other national government agencies.

Section 47. Transitory Provision. All new applications for Biosafety Permit for contained use, confined test, field trial, commercial propagation and direct use for food and feed, or processing shall be processed in accordance with this Circular. All renewals of Biosafety Permits for commercial propagation and direct use issued under DA A.O. No. 8, series of 2002, shall be processed in accordance with this Joint Department Circular.

Section 48. 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 49. 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 particular invalid term or provision.

Section 50. **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 UP Law Center.


MARIO G. MONTEJO
Secretary

Department of Science and Technology
DSEC-16-0039.3


PROCESO J. ALCALA
Secretary

Department of Agriculture


DEPARTMENT OF AGRICULTURE
For Signature: S-01-16-0287
Received: 01/16/2016 09:22 AM


RAMON J.P. PAJE
Secretary

Department of Environment and
Natural Resources


JANETTE L. GARIN
Secretary

Department of Health


MEL SENEN S. SARMIENTO
Secretary

Department of the Interior and
Local Government



DILG-TRAC OUTGOING 05282016 1341



ANNEX A

Republic of the Philippines
 Department of Agriculture
BUREAU OF PLANT INDUSTRY
 PLANT QUARANTINE SERVICE
 Manila

**Application for Biosafety Permit
 for Field Trial**

_____ (Date)

The Director
 Bureau of Plant Industry

Sir/Madame:

We –

Information	Applicant	Responsible Officer (RO)	Representative of RO (if applicable)
Name			
Address			
Tel. No.			
Fax No.			
Email Address			

based upon the endorsement of the following members of the Institutional Biosafety Committee (IBC) –

Information	Member No. 1	Member No. 2	Member No. 3	Member No. 4	Member No. 5
Name					
Designation					
Address					
Tel. No.					
Fax No.					
Email Address					
Vote					
Signature					
If no signature, reason for such					

hereby request for issuance of Biosafety Permit for Field Trial for the genetically modified (GM) plant/plant product described below:

Designation	Regulated Article	Donor Organism	Host Organism	Vector or Vector Agent	Constituents of the Regulated Article
Common Name					
Scientific Name					
Trade Name					
Other Designations					

Means of Movement	
By Whom	

Entity(ies) Who Developed/ Supplied Regulated Article	Entity # 1	Entity # 2	Entity # 3 (Use another sheet as necessary)
Name			
Address			
Tel. No.			
Fax No.			
Email Address			

* The following supporting documents are attached:

1. DOST-BC certification, if the Regulated Article to be used for field trial was developed in the Philippines.
2. Proposed Public Information Sheet for Field Trial (Annex "B")
3. Technical dossier, which must include the following:
 - a. Molecular biology of systems used/to be used to produce Regulated Article
 - b. Anticipated/actual expression of altered genetic material in the Regulated Article, and how this expression differs from that of non-GM parental organisms
 - c. Data/other information on genetic stability of the introduced gene material
 - d. Biological materials accompanying the Regulated Article during movement (where appropriate)
 - e. Proposed experimental or production design
 - f. Description of field testing site/s
 - g. Proposed procedures, processes & safeguards to prevent escape & dissemination of Regulated Article from intended field testing site/s
 - h. Proposed method of final disposition
 - i. Any information known to applicant that Regulated Article may pose greater risk to human health and environment than unmodified host organism
4. Information on socio-economic, cultural and ethical consideration
5. Project Description as prescribed by DENR-BC;
6. Project Description as prescribed by DOH-BC;
7. NCIP Clearance (when applicable)
8. Import permit (when applicable);
9. IBC Endorsement and the Risk Assessment Report; and
10. Proof of payment of fees.

The undersigned certifies that based on his/her personal knowledge and/or authentic documents: (i) all the information in this application are true and correct; and (ii) this application contains all information and views on which to base a decision and includes relevant data and information known to the applicant which are unfavorable to the application. The undersigned likewise warrants that the regulated article is to be imported solely and exclusively for use in field testing.

(Printed Name and Signature of Responsible Officer/Authorized Representative)

Republic of the Philippines)
_____)

SUBSCRIBED AND SWORN TO before me this ____ day of _____, 200__,
affiant exhibiting to me his/her Community Tax Certificate No. _____ issued on
_____ at _____.

Doc. No. _____;
Page No. _____;
Book No. _____;
Series of 200__.

NOTARY PUBLIC

ANNEX B

PUBLIC INFORMATION SHEET FOR FIELD TRIAL

(To be accomplished by the Applicant in a language/dialect known to the community where the field trial is to be conducted and notarized)

**PROPOSAL FOR THE FIELD TRIAL OF
(Insert name of the Regulated Article).**

1. Name of the Applicant
 2. Address of the Applicant
 3. Telephone Number/ Facsimile Number and E-Mail Address of the Applicant
 4. Name of Project Leader
 5. Name of Responsible Officer/Authorized Representative
 6. Description of the Regulated Article for Field Trial (mention the crop, transformation event, new trait conferred, name of the gene transferred, method of transformation, and advantages of the trait conferred)
 7. Purpose (s) of the Field Trial (state the objectives of the proposed project)
 8. Potential Benefits and Risks of the Regulated Article Relative to the Non-Modified Host Organism
 - a) Potential Benefits (describe how the new trait will benefit farming, the farmer, the environment, and society as a whole)
 - b) Potential Risks (summarize human and animal health, and environmental assessments done and studies implemented indicating potential effects on human and animal health, and the environment)
 9. Brief Summary of the Effects of the Regulated Article on the Target Organism, If It is a Pest Protected Plant (add any information known on its effects on non-target organism)
 10. Location (with GPS coordinates) and Size of the Proposed Field Trial Site
 11. Duration of the Field Trial
 12. Method of Disposal of Regulated Article after Field Trial
 13. Government Agencies Consulted Before Field Trial
- For Additional Information on the proposed field trial, please contact:
(Name of Responsible Officer/Authorized Representative)
(Address)
(Telephone/Facsimile Nos & E-mail Address)

The public is hereby invited to submit their comments on the proposed field trial from the date of posting until the public hearing, to:

Director
Bureau of Plant Industry
San Andres, Malate, Manila
Telephone Number 521-1080
Fax Number 521-1080
E-Mail bpibiotechsecretariat@yahoo.com

Approved for Posting:

Director
Bureau of Plant Industry
Date: _____

ANNEX C

Republic of the Philippines
Department of Agriculture
BUREAU OF PLANT INDUSTRY

PLANT QUARANTINE SERVICE
Manila

**Application for Biosafety
Permit for Commercial
Propagation**

(Date)

The Director
Bureau of Plant Industry

Sir:

We –

Information	Applicant	Responsible Officer (RO)	Representative of RO (if applicable)
Name			
Address			
Tel. No.			
Fax No.			
Email Address			

hereby request for issuance of Biosafety Permit for Commercial Propagation for the genetically modified (GM) plant/plant products describe below

Designation	Regulated Article	Donor Organism	Host Organism	Vector or Vector Agent	Constituents of the Regulated Article
Common Name					
Scientific Name					
Trade Name					
Other Designations					

Identification No. of the Field Testing Application File	
---	--

* The following supporting documents are attached:

1. Certification from the BPI 1) for new application, that the regulated article has undergone satisfactory field trial in the Philippines, 2) in cases of renewal, a certified true copy of the expired Biosafety Permit for Commercial Propagation
2. A technical dossier consisting of scientific literature, unpublished studies or data from tests performed, or such other scientific materials relied upon by the applicant to show that the release for commercial propagation of the regulated article does not pose greater risks to biodiversity, human and animal health than its conventional counterpart;
3. Copy of the proposed Public Information Sheet for Commercial Propagation (Annex "D") including information required for evaluation of environmental and health impacts;
4. Information on socio-economic, cultural and ethical considerations;

5. Field trial report;
6. Project Description as prescribed by DENR-BC;
7. Project Description as prescribed by DOH-BC;
8. Applicant's Risk Assessment Report;
9. Import Permit (when applicable); and
10. Proof of payment of fees.

The undersigned certifies that based on his/her personal knowledge and/or authentic documents: (i) all the information in this application are true and correct; (ii) this application contains all information and views on which to base a decision and includes relevant data and information known to the applicant which are unfavorable to the application. The undersigned likewise warrants that the Regulated Article is to be imported solely and exclusively for commercial propagation.

 (Printed Name and Signature of Responsible Officer/Authorized Representative)

Republic of the Philippines)

SUBSCRIBED AND SWORN TO before me this ____ day of _____, 200__,
 affiant exhibiting to me his/her Community Tax Certificate No. _____ issued on
 _____ at _____.

Doc. No. _____;
 Page No. _____;
 Book No. _____;
 Series of 200__.

NOTARY PUBLIC

ANNEX D

**PUBLIC INFORMATION SHEET FOR
COMMERCIAL PROPAGATION**
(to be accomplished by the Applicant and notarized)

PROPOSAL FOR THE COMMERCIAL PROPAGATION OF
(Insert Name of the Regulated Article)

1. Applicant's Name
2. Applicant's Address
3. Telephone Number/ Facsimile Number, E-Mail Address of the Applicant
4. Name of Responsible Officer/Authorized Representative
5. Description of the Regulated Article for Commercial Propagation (mention the crop, transformation event, new trait conferred, name of the gene transferred, method of transformation, and advantages of the trait conferred)
6. If to be imported, Country (ies) of Origin of the Regulated Article
7. Brief Summary of Potential Effects on Human and Animal Health and the Environment (summarize human and animal health and environmental assessments done and studies implemented indicating potential effects on human and animal health and the environment)
8. Brief Summary of Potential Benefits (Describe how the new trait will benefit farming, the farmer, the environment, and society as a whole)
9. Countries Where Approvals Have Been Granted (for FFP; for Commercial Propagation)

The public is hereby invited to submit their comments to the BPI Director (within 60 days from the date of publication) on the Proposed Commercial Propagation of Name Transformation Event.

Director
Bureau of Plant Industry
San Andres, Malate, Manila
Telephone Number 521-1080
Fax Number 521-1080
E-Mail bpibiotechsecretariat@yahoo.com

Approved for Publication: _____
Director
Bureau of Plant Industry
Date:

ANNEX E

Republic of the Philippines
Department of Agriculture
BUREAU OF PLANT INDUSTRY

PLANT QUARANTINE SERVICE
Manila

**Application for Biosafety
Permit for Direct Use as
Food and Feed, or for
Processing**

(Date)

The Director
Bureau of Plant Industry

Sir: We

Information	Applicant	Responsible Officer (RO)	Representative of RO (if applicable)
Name			
Address			
Tel. No.			
Fax No.			
Email Address			

hereby request for issuance of Biosafety Permit for Direct Use for the genetically modified (GM) plant/plant product described below.

Designation	Regulated Article	Donor Organism	Host Organism	Vector or Vector Agent	Constituents of the Regulated Article
Common Name					
Scientific Name					
Trade Name					
Other Designations					

Country of Origin	
Quantity	
Flight/Voyage No	
Port of Entry	
Proposed Schedule	

***The following supporting documents are attached**

1. In the case of imported regulated article, notification from the exporter or country of origin in accordance with existing international agreements on the transboundary movement of genetically modified organisms;
2. Information on socio-economic, cultural and ethical considerations;
3. Copy of the proposed PIS for Direct Use, (Annex "F") including information required for evaluation of environmental and health impacts;
4. In cases of renewal, certified true copy of expired Biosafety Permit for Direct Use issued by BPI; and
5. Proof of payment of fees
6. To facilitate review of the application, the applicant may submit documents to show that the regulated article is allowed for commercial distribution as food and feed by the regulatory authorities in the country of origin; and poses no greater risks to biodiversity, and human and animal health than its conventional counterpart. If the regulated article is intended for use as feed or for processing into feeds, the applicant may submit documents to show that the regulatory authorities in the country of origin have likewise determined that the regulated article poses no greater risks to biodiversity, and human and animal health than its conventional counterpart.

The undersigned certifies that based on his/her personal knowledge and/or authentic documents: (i) all the information in this application are true and correct; and (ii) this application contains all information and views on which to base a decision and includes relevant data and information known to the applicant which are unfavorable to the application. The undersigned likewise warrants that the Regulated Article is to be imported solely and exclusively for direct use as food and feed or for processing.

(Printed name and Signature of Responsible Officer/Authorized Representative)

Republic of the Philippines)

SUBSCRIBED AND SWORN TO before me this _____ day of _____, 200____, affiant exhibiting to me his/her Community Tax Certificate No. _____ issued on _____ at _____.

Doc. No. _____;
Page No. _____;
Book No. _____;
Series of 200____.

NOTARY PUBLIC

ANNEX F

**PUBLIC INFORMATION SHEET FOR
DIRECT USE AS FOOD AND FEED, OR FOR PROCESSING**
(to be accomplished by the Applicant and notarized)

**PROPOSAL FOR DIRECT USE AS FOOD
AND FEED, OR FOR PROCESSING**
[Insert Name of the Regulated Article]

1. Applicant's Name
2. Applicant's Address
3. Telephone Number/ Facsimile Number, E-Mail Address of the Applicant
4. Name of Responsible Officer/Authorized Representative
5. Description of the Regulated Article for Direct Use (mention the crop, transformation event, new trait conferred, name of the gene transferred, method of transformation, and advantages of the trait conferred)
6. If to be imported, Country (ies) of Origin of the Regulated Article
7. Brief Summary of Potential Effects on Human and Animal Health and the Environment (summarize human and animal health and environmental assessments done and studies implemented indicating potential effects on human and animal health and the environment)
8. Brief Summary of Potential Benefits (Describe how the new trait will benefit farming, the farmer, the environment, and society as a whole)
9. Countries Where Approvals Have Been Granted (for FFP; for Commercial Propagation)

The public is hereby invited to submit their comments to the BPI Director (within 60 days from date of publication) on the Proposal for the Importation of Name Transformation Event for direct use as food and feed, or for processing

Director
Bureau of Plant Industry
San Andres, Malate, Manila
Telephone Number 521-1080
Fax Number 521-1080
E-Mail bpibitechsecretariat@yahoo.com

Approved for Publication: _____

Director
Bureau of Plant Industry
Date:

ANNEX G

**LIST OF REGULATED ARTICLES WITH VALID BIOSAFETY PERMIT
UNTIL THEIR EXPIRATION DATE**

I. Regulated Articles (single transformation event) for Direct Use

Regulated Article	Date of Expiration
Corn MON88017	March 20, 2016
Soybean A5547-127	June 22, 2016
Alfalfa J101 and J163	August 8, 2016
Corn 59122	August 8, 2016
Liberty Link (LL) 62 Rice	May 15, 2017
Soybean MON87701	May 15, 2017
Corn MIR604	October 4, 2017
Corn MON87460	November 14, 2017
Soybean MON89788	November 15, 2017
Corn MON810	December 2, 2017
Corn 3272	February 6, 2018
Corn BT11	July 18, 2018
Soybean 40-3-2	July 18, 2018
Soybean 305423	September 8, 2018
Corn NK603	September 9, 2018
Corn TC1507	October 6, 2018
Canola RT73	October 21, 2018
Corn BT176	October 23, 2018
Corn GA21	November 19, 2018
Corn T25	December 4, 2018
Cotton 1445	December 4, 2018
Cotton 15985	December 4, 2018
Soybean A2704-12	January 22, 2019
Cotton 531	February 4, 2019
Corn MON89034	April 28, 2019
Soybean MON 87708	May 4, 2019
Soybean MON87705	November 27, 2019
Corn MON87427	November 27, 2019
Corn MIR162	February 10, 2020
Canola MON88302	April 23, 2020
Soybean MON87769	April 23, 2020
Corn 5307	June 10, 2020
Sugarbeet H7-1	July 27, 2020
Cotton COT102	September 8, 2020
Soybean FG72	September 8, 2020
Soybean CV127	October 28, 2020
Cotton MON88913	November 25, 2020

II. Regulated Articles (stacked transformation events) for Direct Use

Regulated Article	Date of Expiration
Cotton 15985 x RR Flex Cotton (MON88913)	April 19, 2016
Corn MON88017 x Corn MON810	June 30, 2016
Corn Bt11 x Corn DAS59122 x Corn MIR604 x Corn TC1507 x Corn GA21	August 2, 2016
Corn Bt11 x Corn GA21	January 22, 2017
Corn 59122 x Corn NK603	February 6, 2017
Corn TC1507 x Corn 59122	February 6, 2017
Corn 59122 x Corn TC1507 x Corn NK 603	February 6, 2017

Corn TC1507 X Corn MON810 x Corn NK603	May 15, 2017
Corn Bt11 x Corn MIR604	December 12, 2017
Corn MIR604 x Corn GA21	December 12, 2017
Corn Bt11 x Corn MIR604 x Corn GA21	February 28, 2018
Corn Bt11 x Corn MIR162	October 28, 2018
Corn Bt11 x Corn TC1507 x Corn GA21	January 22, 2019
Soybean 305423 x Soybean 40-3-2	April 29, 2019
Corn 87460 x Corn MON89034 x Corn NK603	July 9, 2019
Corn MON89034 x Corn NK603	July 21, 2019
Soybean MON87701 x Soybean MON89788	September 25, 2019
Corn MON87460 x Corn MON89034 x Corn MON88017	September 25, 2019
Corn MON89034 x Corn MON88017	Oct. 18, 2019
Corn TC1507 x Corn DAS59122 x Corn MON810 x Corn MIR604 x Corn NK603	October 27, 2019
Corn GA21 x Corn T25	December 8, 2019
Corn TC1507 x Corn MON810 x Corn MIR162 x Corn NK603	Jan. 7, 2020
Corn MON810 x Corn NK603	Jan. 7, 2020
Cotton 531 x Cotton 1445	Jan. 7, 2020
Cotton 15985 x Cotton 1445	Jan. 7, 2020
Corn MON89034 x Corn 1507 x Corn 88017 x Corn 59122	Feb. 8, 2020
Corn Bt11 x MIR162 x GA21	February 11, 2020
Corn Bt11 x MIR162	February 11, 2020
Corn NK603 x Corn T25	April 21, 2020
Corn Bt11 x Corn MIR162 x Corn GA21	July 27, 2020
Corn 3272 x Corn Bt11 x Corn MIR604 x Corn GA21	July 27, 2020
Corn BT11 x Corn MIR162 x Corn MIR604 x Corn GA21	July 27, 2020
Corn MON89034 x Corn 1507 x Corn NK603	Jul 27, 2020
Corn BT11 x Corn MIR162 x Corn TC1507 x Corn GA21	Jul 27, 2020
Corn Bt11 x Corn MIR162	December 6, 2020
Corn Bt11 x Corn MIR162 x Corn GA21	December 6, 2020
Corn Bt11 x Corn TC1507 x Corn GA21	December 6, 2020

III. Regulated Articles (single transformation events) for Propagation

Regulated Article	Date of Expiration
Corn MON810	Nov. 18, 2016
Corn TC1507	Dec. 2, 2017
Corn GA21	December 8, 2018
Corn NK603	Nov. 23, 2019
Corn Bt11	Mar. 15, 2020
Corn MON89034	Apr. 22, 2020

IV. Regulated Articles (stacked transformation events) for Propagation

Regulated Article	Date of Expiration
Corn MON89034 x Corn NK603	March 3, 2016
Corn TC1507 x Corn MON810 x Corn NK603	March 30, 2019
Corn TC1507 x Corn MON810	August 6, 2019

Corn TC1507 x Corn NK603	August 6, 2019
Corn MON810 x Corn NK603	July 15, 2020
Corn Bt11 x Corn GA21	Sept. 5, 2020
Corn Bt11 x Corn TC1507 x Corn GA21	October 25, 2020