DOST Biosafety Committee

The Philippines Biosafety Guidelines for Contained Use of Genetically Modified Organisms (GMOs)

Revised Edition

September 2014

NCBP 1990

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The Philippines Biosafety Guidelines for Contained Use of Genetically Modified Organisms (GMOs)

Revised Edition

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PREFACE

Pursuant to the mandates under Executive Order No. 514: *Establishing the National Biosafety Framework, prescribing Guidelines for its Implementation, Strengthening the National Committee on Biosafety of the Philippines, and for Other Purposes*, issued on 17 March 2006, the Department of Science and Technology (DOST) constituted its Biosafety Committee (DOST-BC) composed of scientists representing the biological, physical, environmental, health and social sciences and ex-officio members from the Departments of Agriculture, Health, Environment and Natural Resources, and DOST itself. The DOST-BC is established to evaluate and regulate experiments on genetically modified organisms (GMOs) under contained use (i.e. laboratory, screenhouse, greenhouse and glasshouse) and confined test.

This manual is designed to contain the DOST-BC guidelines and procedures to serve its primary purpose. It is intended for scientists, researchers, and private and public institutions conducting GMO experiments under the aforementioned conditions.

Specifically, the DOST-BC guidelines provides policies and procedures for application and monitoring of contained use and confined tests of GMOs. Hence, this manual aims to facilitate the process of ensuring that the best available science is adopted in assessing proposals to minimize risks posed by GMOs to the environment, animal and human health.

This manual further provides the specific functions of DOST-BC as a regulatory body, the roles and responsibilities of the Institutional Biosafety Committee (IBC) as a regulator of the institution undertaking GM experiments, the proponents, and other external experts and consultants. It also includes the required level of containment for any particular activity, packaging and transport of regulated materials and basic instructions, monitoring, and appropriate measures in case of incidents resulting from the use of GMOs. Moreover, it features forms that are useful for the preparation of project proposals, IBC assessments, and submission of reports.

The preparation of this manual is a rigorous and complex effort engaging a number of experts from different fields of science. The implementation of the system behind this document is recognized to be a continuous work-in-progress in such way that it has to develop alongside the differing needs and circumstances brought by the rapid expansion of modern biotechnology.



FORTUNATO T. DE LA PEÑA
Undersecretary for S&T Services
and Chairman, DOST-Biosafety
Committee

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EXECUTIVE ORDER 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

MALACAÑANG
MANILA

BY THE PRESIDENT OF THE PHILIPPINES

EXECUTIVE ORDER NO. 514

ESTABLISHING THE NATIONAL BIOSAFETY FRAMEWORK, PRESCRIBING GUIDELINES FOR ITS IMPLEMENTATION, STRENGTHENING THE NATIONAL COMMITTEE ON BIOSAFETY OF THE PHILIPPINES, AND FOR OTHER PURPOSES

WHEREAS, there is rapid expansion of the use of modern biotechnology not only for scientific research but also for products for commercial releases and purposes;

WHEREAS, there is concern over modern biotechnology's potential impacts on the environment, particularly on biological diversity, on human health, and on social and cultural well-being;

WHEREAS, it is the policy of the State to promote the safe and responsible use of modern biotechnology and its products as one of the several means to achieve and sustain food security, equitable access to health services, sustainable and safe environment and industry development;

WHEREAS, the Cartagena Protocol on Biosafety to the United Nations Convention on Biological Diversity which the Philippines signed on 24 May 2000 entered into force on 11 September 2003;

WHEREAS, the National Committee on Biosafety of the Philippines (NCBP), Department of Science and Technology, Department of Agriculture, Department of Health, and Department of Environment and Natural Resources have played, since 1987, a pioneering and important role in developing and establishing the current biosafety system;

WHEREAS, there is a need to enhance the existing biosafety framework to better respond to the challenges presented by further advances in modern biotechnology and to comply with the administrative requirements of the Cartagena Protocol on Biosafety;

NOW, THEREFORE, I, GLORIA MACAPAGAL-ARROYO, President of the Philippines, by virtue of the powers vested in me by law, do hereby order:





SECTION 1. Adoption and Operationalization of the National Biosafety Framework. The National Biosafety Framework (NBF) for the Philippines, attached hereto as Annex A, is hereby adopted.

SECTION 2. Scope and Objectives. The NBF shall have the following scope and objectives:

2.1 Scope. The NBF shall apply to the development, adoption and implementation of all biosafety policies, measures and guidelines and in making biosafety decisions concerning the research, development, handling and use, transboundary movement, release into the environment and management of regulated articles.

2.2 Objectives. The NBF shall have the following objectives:

2.2.1 Strengthen the existing science-based determination of biosafety to ensure the safe and responsible use of modern biotechnology so that the Philippines and its citizens can benefit from its application while avoiding or minimizing the risks associated with it;

2.2.2 Enhance the decision-making system on the application of products of modern biotechnology to make it more efficient, predictable, effective, balanced, culturally appropriate, ethical, transparent and participatory; and

2.2.3 Serve as guidelines for implementing international obligations on biosafety.

SECTION 3. Administrative Framework and Decision-Making Processes. In making biosafety decisions, the administrative system and decision-making processes established in the NBF shall be complied with.

SECTION 4. Strengthening the National Committee on Biosafety of the Philippines (NCBP). The NCBP is hereby strengthened. Its mandate, functions, composition and organization are set forth in the NBF.

SECTION 5. General Mandate on Departments, Offices and Agencies. The mandates, jurisdictions and other powers of all departments and agencies in relation to biosafety and biotechnology shall be guided by the NBF and coordinated with the NCBP and each other in exercising such powers.





SECTION 6. Funding. The DOST, DENR, DA, and DOH shall allocate funds from their present budgets to implement the NBF, including to support the operations of the NCBP and its Secretariat. Starting 2006 and thereafter, the funding requirements shall be included in the General Appropriations Bill submitted by each of said departments to Congress.

These concerned departments shall enter into agreement on the sharing of financial and technical resource to support the NCBP and its Secretariat.

SECTION 7. Transition. The NCBP and its present members shall continue to exercise their present functions under Executive Order No. 430, s. 1990 until such time that it has completely reorganized under the NBF. The reorganization shall commence immediately after the DOST, DENR, DA, and DOH have entered into an agreement on the sharing of financial and technical resources to support the NCBP and its Secretariat on a sustainable basis, and shall be completed within one year from effective date of such agreement.

All members of the NCBP to be appointed by the President, as required by the NBF, shall assume their positions upon completion of the reorganization.

SECTION 8. Repealing and Amending Clause. All orders, rules and regulations or parts thereto which are inconsistent with any of the provisions of this Order are hereby repealed or amended accordingly. For the avoidance of doubt, the following issuances, unless amended by the respective issuing departments or agencies, shall continue to be in force and effect: Department of Agriculture Administrative Order No. 008, s. 2002; the NCBP Guidelines on the Contained Use of Genetically Modified Organisms, except for provisions on potentially harmful exotic species which are hereby repealed; and all Bureau of Food and Drugs issuances on products of modern biotechnology.

SECTION 9. Effectivity. This Order shall take effect fifteen days after publication in two newspapers of general circulation.

DONE, in the City of Manila, this 17th day of March in the year of our Lord two Thousand and Six.

Gloria Arroyo

By the President:

EDUARDO R. ERMITA
Executive Secretary

PHILIPPINE HOLOGRAM # 34636

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LAMBERTO R. BARBIN
Officer-in-Charge
Malacañang Records Office
3-22-06

DEFINITION OF TERMS

For purposes of this Manual, the following terms shall be defined as follows:

Animal - any living stage or form of any member of the animal kingdom. This includes all terrestrial, aquatic and subterranean macroscopic vertebrates and invertebrates, whether parasitic or free-living, and sessile or motile

Applicant - 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 Order and the conditions specified in the relevant permit. An applicant shall be: (i) any of the departments or agencies of the Philippine Government; (ii) a university-based research institution in the Philippines; (iii) an international research organization duly recognized by the Philippine government and based in the Philippines; (iv) a corporation registered with the Securities and Exchange Commission of the Philippines; or, (v) a cooperative registered with the Cooperative Development Authority of the Philippines.

Auto-Ecology - ecological context of both local and imported strains

Biohazard - potential danger posed by a living or biologically-derived material

Bioremediation - any process that uses microorganisms, fungi, plants or their products (e.g. enzymes) to bring back the natural environment altered by contaminants, close to its original condition

Biosafety - a 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

Biosafety Clearing-House or **BCH** - an information exchange mechanism established by the Cartagena Protocol on Biosafety to assist parties in the implementation of its provisions and to facilitate sharing and exchange of scientific, technical, environmental and legal information on, and experience with, regulated articles

Biosafety decisions - apply 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

Biotechnology - any process that uses living organisms, in their entirety, or parts or subparts thereof, to make or modify products or to improve or develop plants, animals or microorganisms for specific use

Confined Tests (CT) - a field test of GM 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

Confinement - restriction of an organism and its genetic traits to a specific and defined area of the environment herein called the “Confined test site” or the “test site”

Contained use - any operation, undertaken within a facility, installation or other physical structure, which involves genetically modified organisms that are controlled by specific measures that effectively limit their contact with, and their impact on, the external environment. It involves the use of a regulated article for research and development inside a physical containment facility which has been inspected and approved by DOST-BC.

Containment - act of restricting or preventing the spread, leak or escape of an experimental object

Decontamination - process of removing, destroying, or reducing the activity of materials such as toxic chemicals, pathogenic microorganisms, etc. that could endanger an individual or the environment

Department Biosafety Committee – a biosafety committee established by a Competent National Authorities (Department of Science and Technology, Department of Agriculture, Department of Environment and Natural Resources, Department of Health) that shall undertake necessary actions in the implementation of biosafety policies, measures, guidelines, and decisions

Donor organism - the organism from which genetic material is obtained for transfer to the recipient organism

Ecosystem - means a dynamic complex of plant, animal and microorganism communities and the non-living environment interacting as a functional unit

Environment - totality of the surrounding air, water (both ground and surface), land, flora, fauna, human and their interrelations that is likely to come into contact with a regulated article

Field test - any intentional introduction into the environment of a regulated article for purposes of research and development and for which no specific physical containment measures are used to limit the contact of the regulated article with, and to provide for a high level of safety for, the general population and the environment. Field testing may be conducted in a single site or in multiple sites

Fusion - the joining of the cell membranes of two cells to create a daughter cell that contains genetic material from both parents

Genetic engineering - the genetic modification of organisms by any process using modern biotechnology techniques

Genetically modified organism or **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 to make them capable of producing new substances or perform new functions

Habitat - means place or environment where species or subspecies naturally occur or has naturally established its population

Handling and Use - process by which regulated articles are moved, carried, transported, delivered, stored or worked with

Hazard - traits inherent to or activities of a regulated article that may cause harm to human or animal health or to the environment

Host or Recipient organism - the organism (e.g. plants, microorganism, animals, etc.) which receives genetic material from a donor organism. It is an organism whose genetic material has been altered by modification of a part of its own genetic material by the insertion of foreign genetic material or both.

Host-vector (HV) system - a microbial strain (host) and its compatible DNA carrier(s) (vector). The host may be a strain of the bacterium *Escherichia coli* or *Bacillus subtilis*, the yeast *Saccharomyces cerevisiae* or other such organisms that have been genetically manipulated to allow the multiplication and expression of the vector. The vector may be a plasmid, a bacteriophage or a virus, and other carriers of genetic materials all designed to carry readily selectable marker(s) and unique restriction sites for inserting DNA segments.

Importation - the act of bringing into the Philippines a regulated article for use in research and development (whether for contained use or for field testing) or for release into the environment (whether for propagation or for direct use as food or feed, or for processing)

Introduce (or introduction) - to bring into or in-transit through the Philippines, to release into the environment, or to cause inter-island movement

Management - measures adopted after the release of regulated articles to ensure their safe use and, in cases of commercial release, shall also include product monitoring and product identification

Microorganism - any microscopic or ultramicroscopic organism able to replicate its own genetic material. This includes fungi, protozoa, bacteria, and viruses.

Modern Biotechnology - (i) recombinant nucleic acid techniques involving the formation of new combinations of genetic material by the insertion of nucleic acid molecules produced by whatever means outside an organism, into any virus, bacterial plasmid or other vector system and their incorporation into a host organism in which they do not naturally occur but in which they are capable of continued propagation; (ii) techniques involving the direct introduction into an organism of heritable material prepared outside the organism including micro-injection, macro-injection and micro-encapsulation; and (iii) cell fusion, including protoplast fusion, or hybridization techniques where live cells with new combinations of heritable genetic material are formed through the fusion of two or more cells by means of methods that do not occur naturally

Move (moving, movement) - to ship, offer for shipment, offer for entry, import, receive for transportation, carry, or otherwise transport or allow to be transported into, through, or within the Philippines

New species - a single distinct kind of animal, plant or microorganism having certain previously undescribed but distinguishing characteristics as determined by taxonomical classification

Organism - any entity able to replicate its own genetic material. It includes any active, infective, or dormant stage or life form of an entity characterized as living, including plants, bacteria, fungi, mycoplasmas, mycoplasma-like entities, vertebrate and invertebrate animals, as well as entities such as viroids, viruses, or any living entity related thereto

Pathogen - any organism that can cause disease

Permit - a written document issued by competent national authorities for the introduction of a regulated material under conditions that it will not present a risk of pest introduction/movement

Permittee - any applicant who has been granted by competent national authorities a permit to import or to release into the environment a regulated article

Person - any natural person or juridical entity such as a corporation or cooperative

Pest – any living stage, whether in active or dormant form, of insects, mites, nematodes, slugs, annelids, snails, protozoa, bacteria, fungi and other parasitic plants or reproductive parts thereof; viruses; any plants or animals that can damage aquatic and terrestrial ecosystems; or any infectious agents or substances which can directly or indirectly injure or cause disease or damage in or to humans, plants or animals or any processed, manufactured or other products of plants or animals

Pest-protected plant – refers to any plant that has been genetically modified with modern molecular techniques (recombinant DNA technology, commonly referred to as genetic engineering) to express a pesticidal trait

Phage - eating or destroying characteristic of a bacterial virus

Pathogens or pathogenic microorganisms - refer to the cellular or acellular organisms that are too small to be seen by an unaided eye and have the ability to cause infections or infectious diseases, as recognized or established to be present by the Department of Health in the Philippines, and the World Health Organization and World Organization for Animal Health

Pharmaceuticals for Human - products derived from modern biotechnology that are engineered to express pharmaceutical products intended for human

Plant - any living stage or form of any member of the plant kingdom, including aquatic, terrestrial or subterranean eukaryotic algae, mosses, club mosses, ferns, angiosperms, gymnosperms, lichens which contain algae, and any part (e.g., pollen, seeds, cells, tubers, stems) thereof including pollen, seeds, cells, stems, rhizomes, tubes, bulbs and corms, leaves, roots, scions and others that may be used for propagation

Plant pest - any form of plant or animal life, or any pathogenic agent, injurious or potentially injurious to plants or plant products

Plant product - any product derived from plants in their natural state or in processed form and are capable of harboring plant pests

Plasmid - a self-replicating, circular, extra-chromosomal DNA molecule

Port of entry - airport, seaport or land border point open to foreign and/or domestic trade. It includes principal ports and subports of entry

Product - anything made by, or formed, or derived from an organism, living or dead

Product identification - 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

Product monitoring - 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.

Project Leader - any person who, under the project proposal, shall be primarily responsible for the implementation of the approved experiments

Propagation - 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

Proponent - any person or group of persons who submits a project proposal to the Competent National Authorities through the Institutional Biosafety Committee for the purpose of conducting experiments on GMOs

Protoplast - a plant, bacterial or fungal cell that has its outer cell wall removed

Public hearing - the face-to-face meeting with relevant stakeholders to inform them of, and give them the opportunity to submit their comments on, any application for field testing of a regulated article which may pose significant risks to human health and the environment

Public consultation - the process of informing relevant stakeholders of, and giving them the opportunity to submit their comments on, any application for field testing, propagation or importation for food or feed, or for processing of a regulated article

Recombinant DNA - a DNA molecule into which a foreign DNA has been inserted

Region - a political unit or administrative entity designated to a certain place of the country

Regulated article - an approved genetically modified organism and its products subject to regulation, according to the process of regulatory agency

Release into the environment - the use of a regulated article outside the physical confinement found in a laboratory, a contained greenhouse, a fermenter or other contained structure. It includes confined field test, field test, propagation, or direct use as food, feed, or for processing of any regulated article.

Responsible person - any natural person or juridical entity who has control and who will maintain control over the introduction of the regulated article and will assure that all conditions contained and requirements set in the permit are complied with. The responsible individual shall be a resident of the Philippines or may be a designated representative who is a resident of the Philippines.

Reproductive isolation - measures taken to prevent principally, pollen-mediated gene flow from plants in the trial site to nearby sexually compatible species. Also known as “genetic confinement”.

Risk - the combination of the likelihood that an adverse consequence of a bio-hazardous activity or trait will occur and the magnitude of such a consequence

Risk assessment - the procedure that identifies, evaluates and predicts the occurrence of possible hazards to human and animal health and the environment and designs mitigating measures to avert or minimize these hazards

Risk management - 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. It includes the measures designed to ensure safety in the handling, use and release of GMOs.

Secretariat – an administrative unit responsible for maintaining records and other secretarial duties

Sexually Compatible - capable of cross-pollinating and forming viable offspring without human intervention

Spatial Isolation - a method of achieving reproductive isolation by separating plants in the test site by a defined distance from prohibited plants

SPS - **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 stuff

IBC (Institutional Biosafety Committee) –responsible for evaluating project proposals involving GMOs. The IBC is also responsible for supervising, monitoring and reporting to the appropriate DB

Temporal Isolation - a method of achieving reproductive isolation by separating plants from prohibited plants in terms of time in such a way that the reproductive stage of both plants will not be synchronized

Test Site – The area of a field test that is confined by one or more continuous method of reproductive and / or material isolation. Also called the “Experimental area”.

Transboundary movement - the movement of a regulated article from another country to the Philippines and from the Philippines to another country

Transformation event - one 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

Transgenic - an organism whose cells, including the germline cells, contain foreign DNA. In the case of animals, it refers to one produced by inserting a foreign DNA into the newly fertilized egg or embryo.

Vector or vector agent - any organism or molecular vehicle used to transfer genetic material from the donor organism to the host or recipient organism

Wildlife - means wild forms and varieties of flora and fauna, in all developmental stages, including those which are in captivity or are being bred or propagated

I. DOST-BIOSAFETY COMMITTEE MANDATE AND COMPOSITION

In compliance with the mandate of the Department of Science and Technology (DOST) under Executive Order No. 514, s. 2006, the DOST-Biosafety Committee is established to 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.

1. **Coverage**. The DOST-BC shall oversee applications for contained use (laboratory/screenhouse/glasshouse/ greenhouse) and confined test (CT) of GMOs.

2. **Composition of the DOST-BC.** The DOST-BC shall be composed of the following:

Chair	-	the DOST Secretary or his/her duly designated representative
Members	-	one (1) biological scientist one (1) environmental scientist one (1) health scientist one (1) physical scientist one (1) social scientist one (1) legal adviser/expert two (2) community representatives one (1) representative each from the Department of Agriculture, Department of Environment and Natural Resources and Department of Health to be designated by the respective Head of Offices

The DOST Secretary may appoint additional members to the Committee as necessary.

3. **Terms of Office of the DOST-BC.** The members of the DOST-BC shall have the following terms of office:

   3.1. The term of office of the Chair shall be co-terminus with his/her appointment as Secretary of the DOST; and,

   3.2. All members, excluding the Chair, shall serve for a term of three (3) years, renewable for another term or more under exceptional circumstances. The members representing DA, DENR and DOH shall hold the positions for the duration of the term of their appointments in their respective agencies.

4. **Qualifications of the DOST-BC**. The members of the DOST-BC should have the following qualifications:

   4.1. Filipino citizens of unquestionable integrity who reside permanently in the Philippines;

4.2. the five (5) scientist-members shall possess a minimum of seven (7) years of collegiate and post-collegiate training (degree and/or non-degree) in their respective fields; and,

4.3. the Community Representative members must be respected members of the community.

5. **Functions of the DOST-BC**. The powers and functions of the DOST-BC, as embodied in Executive Order No. 514, are as follows:

5.1. Ensure that biosafety policies, measures, guidelines and decisions are made on the basis of the best scientific information available;

5.2. Undertake independent risk assessment on proposed activities under containment (laboratory/screenhouse/greenhouse/glasshouse) and confinement (confined tests), review risk assessment undertaken by IBCs, review qualification of research personnel, adequacy of containment/confinement facilities, and when necessary, prescribe additional measures to eliminate or at least minimize risks;

5.3. Issue an approval letter specifying the terms and conditions under which the proposed activities should be carried out;

5.4. As necessary, coordinate with concerned departments and agencies in the implementation of rules pertaining to import permits, monitoring requirements, transparency, and information dissemination;

5.5. Verify that activities involving GMOs are carried out by competent personnel following the prescribed biosafety measures in appropriate containment/confinement facilities;

5.6. As necessary, impose additional measures to enhance the soundness of containment/confinement, material management and other safety measures already in place;

5.7. Review completion reports of the proponent, the IBC, and monitors relevant government regulatory agencies;

5.8. Issue a certificate of completion, indicating among others the specific objectives that have been achieved, summary of the results, and compliance with all the conditions set by the DOST-BC;

5.9. Identify information gaps and possible additional risks associated with larger-scale use of GMOs and recommend mitigation/intervention measures to the concerned Department Biosafety Committee;

5.10. Upon request of concerned Department Biosafety Committee, issue a transmission letter addressing the information gaps identified in (9); and,

5.11. Undertake other duties assigned by the NCBP.

6. **Heads of Institutions**. The responsibility of ensuring that activities involving GMOs are in full compliance with the existing biosafety guidelines ultimately lies with the Head of the Institution. In order to guarantee compliance, the Head of the Institution shall be responsible for the following:

6.1 Create/establish an IBC by endorsing members and submitting the respective curriculum vitae of the proposed members to the NCBP for its approval;

6.2 Provide the IBC with resources necessary to enable it to perform its functions;

6.3 Ensure that resources are provided to employees or researchers for safe work within and outside the institution; and,

6.4 Designate a Biological Safety Officer (BSO), when necessary.

7. **Institutional Biosafety Committee(s) (IBCs)**. Any institution intending to undertake any activity involving GMOs must first set up an Institutional Biosafety Committee (IBC). The IBC shall be responsible for evaluating project proposals involving GMOs under contained use and confined test, and endorsing the project proposals to the DOST-BC for appropriate action.

After the project is approved, the IBC shall be responsible for supervising, monitoring and reporting to the DOST-BC its progress.

More importantly, the IBC shall make sure that the environment and human health are safeguarded in the conduct of any activity involving GMOs by the institution or by any of its employees or researchers. It shall also inform the surrounding communities of any plans for confined tests, including the concomitant risks thereof, if any.

7.1 **Composition of the IBC.** The IBC shall be composed of at least five (5) members, all of whom must first be approved by the NCBP through the DOST-BC:

7.1.1. At least three (3) members shall be designated as the **"scientist-members"**, one of which shall not be affiliated with the applicant. They must possess scientific or technological knowledge and expertise sufficient to enable them to properly evaluate and monitor any work involving GMOs conducted by the institution.

7.1.2. The other members, not less than two (2) individuals, shall be designated as **"community representatives"**. They must not be affiliated with the institution apart from their affiliation with the IBC. They must be in a position to represent the interests of the communities surrounding the institution or which may be affected by the planned activities involving the use of GMOs.

7.1.3. One (1) of the community representatives shall be an elected official (an individual holding an elective position in the community). Additional members may be recommended by the Head of the Institution subject to the approval of the NCBP through the DOST-BC.

7.1.4. When the site is within an ancestral domain, a representative from Indigenous Peoples (IPs) shall be selected through the local IP (IPRA Law-NCIP) process in consultation with the National Commission on Indigenous Peoples (NCIP).

7.2. **Responsibilities of the IBC**. The IBC shall comply with the following responsibilities set forth by the DOST-BC:

7.2.1. Apply the best scientific information available in undertaking the initial risk assessment of the proposed activities involving GMOs;

7.2.2. Identify potential hazards to human health and the environment and to advise the Project Leader on their proper management;

7.2.3. Review the qualifications and experience of personnel involved in the projects;

7.2.4. Ensure competence, acceptable professional practices and adequate supervision of project staff;

7.2.5. Together with the proponent, take the necessary steps to inform the community of the proposed activities for confined test involving GMOs, and provide the community the opportunity to comment. The IBC shall collate the comments elicited from the community and advise the DOST-BC accordingly;

7.2.6. Submit all required project documents for review and approval;

7.2.7. Ensure that all communications from the DOST-BC are conveyed to, and if applicable, complied with by the proponent;

7.2.8. Ensure that all relevant regulatory agencies have been consulted and necessary permits, licenses or approvals have been obtained before any activities on GMOs are carried out;

7.2.9. Develop and implement appropriate contingency and/or mitigation plans to address situations when containment/confinement measures will be compromised due to natural disasters and calamities and other unavoidable circumstances;

7.2.10. Determine and inform the DOST-BC of the actual date of project implementation without compromising the purpose of which the activity was designed;

7.2.11. Monitor the implementation of the proposed activities and continuously evaluate compliance with the conditions set by the DOST-BC and recommend additional biosafety measures, if necessary;

7.2.12. Conduct periodic inspections of containment/confinement facilities to ensure compliance with established containment procedures;

7.2.13. Ensure that accesses to restricted facilities are limited to authorized personnel;

7.2.14. Report immediately all unexpected observations, accidents, and unexplained illnesses or absences of personnel which may be attributed to the activities involving GMOs;

7.2.15. Notify immediately the DOST-BC of any untoward incident or breach of biosafety measures related to the activities involving GMOs;

7.2.16. Keep records of all procedures, decisions and directives related to the activities involving GMOs;

7.2.17. Endorse the activity report and material management report of the project within 15 working days upon completion of such activity;

7.2.18. Endorse the technical completion report of the project within 120 calendar days after completion of the contained or confined test *(Annex 5/Annex 13)*;

7.2.19. Submit the IBC Report after completion of any project involving GMOs at the end of the activities *(Annex 6/Annex 14)*; and,

7.2.20. Submit an annual report to the DOST-BC, who shall furnish copies to the NCBP.

7.3. **Authority to Formulate Rules.** The IBC shall have the power to draft rules and regulations to supplement this Monograph. These rules and regulations may include, but are not limited to, containment procedures and operations and the handling, transport and storage of GMOs by and within the institution.

7.4. **IBC of Small Institutions**. The NCBP recognizes the difficulty that small institutions may have in setting up a competent IBC due to the limited number of scientists who can serve in the IBC. Hence, subject to the prior approval of the NCBP, through the DOST-BC, potentially bio-hazardous activities of these institutions may be supervised by the IBC from another institution.

However, this arrangement, which shall be in writing, must specify, among others, the following:

7.4.1. the Heads of both institutions shall be jointly responsible in ensuring compliance with these guidelines; and,

7.4.2. a senior member of the supervised institution shall liaise closely with the supervising IBC throughout the conduct of the proposed activity.

7.5. **Biological Safety Officer(s) (BSOs).** If the proposed activities will be conducted using GMOs that require special containment/confinement conditions, a Biological Safety Officer (BSO) shall be designated by the Head of the Institution. More than one BSO

may be appointed, depending on the needs of the Institution. The BSO(s) may or may not be a member of the IBC.

Responsibilities of the BSO. The BSO shall have the following responsibilities:

7.5.1. Supervise the implementation of special containment/confinement measures necessitated by scale of activity and/or biohazard level of the GMO that will be used;

7.5.2. Investigate laboratory accidents and report problems, violations and injuries or illnesses associated with any activity involving GMOs to the IBC; and,

7.5.3. Carry out other functions assigned by the IBCs and Head of the Institution.

8. **Project Leader(s)/Proponent(s)**. For each activity involving GMOs, there shall be a designated Project Leader who shall have the overall responsibility of all aspects of the planned work. The Project Leader must be thoroughly familiar with the provisions of existing biosafety guidelines. The Project Leader must ensure that the project complies with existing guidelines and with all the conditions imposed by the DOST-BC. In particular, the Project Leader shall:

8.1. Prepare the project proposal in accordance with the prescribed formats as appropriate for the type of intended application (contained use or confined test) and submit to the IBC for proper action;

8.2. Conduct an initial evaluation of the project proposal to determine if the same falls within the coverage of the existing biosafety guidelines. In case of doubt, the Project Leader shall consult the IBC;

8.3. Provide additional information on the project proposal and its conduct which the IBC and/or the DOST-BC may require for its assessment and monitoring activities;

8.4. Comply with the advice, recommendations and requirements of the IBC and the DOST-BC on the project proposal;

8.5. Carry out work under conditions approved by the IBC and the DOST-BC;

8.6. Ensure that all personnel involved in the project are aware of biosafety requirements of the work and that they have received appropriate training in safety and emergency procedures;

8.7. Seek the approval of the IBC and the DOST-BC of all changes in the conduct of activities and in the composition of the personnel involved in the project;

8.8. Report immediately to the IBC all unexpected observations, results or accidents and unexplained illnesses or absences of personnel which may be attributed to the activities involving GMOs;

8.9. Advise the IBC of any intention to import or transport biological materials covered by the existing biosafety guidelines;

8.10. Keep necessary records appropriate for each activity pertaining to work with GMOs;

8.11. Submit progress report(s) of all ongoing projects to the IBC every end of February, for inclusion in the annual report of the IBC, in accordance with *Annex 4/Annex 12*, in soft and 15 hard copies; and,

8.12. Submit a completion report of the project to the IBC 90 days after its completion, in accordance with *Annex 5/Annex 13*, in soft and 15 hard copies.

II. SCOPE OF THE DOST-BIOSAFETY COMMITTEE GUIDELINES FOR CONTAINED USE AND CONFINED TEST OF GENETICALLY MODIFIED ORGANISMS

1. **Coverage.** This Manual shall apply to all applications of genetically modified organisms (GMOs) under contained use (i.e. laboratory, screenhouse, glasshouse, greenhouse) and confined test (*Appendix 2*).

   This Manual shall cover the following GMOs:
   1.1. Plants (Agricultural crops)
   1.2. Pharmaceutical Plants
   1.3. Animals
   1.4. Forest Trees
   1.5. Microorganisms

2. **Exclusions.** The following activities are not covered by this Manual:

   2.1. Exclusions for Contained use which includes experiments of all GMOs inside the laboratory/screenhouse/ greenhouse/glasshouse:

      2.1.1. Classic molecular biology experiments done in schools and teaching laboratories. The following recombinant DNA molecules are exempted, and therefore, registration with the Institutional Biosafety Committee is not required:

         2.1.1.1. those that consist entirely of DNA segments from a single nonchromosomal or viral DNA source, though one or more segments may be a synthetic equivalent;

         2.1.1.2. those that are not in organisms or viruses;

         2.1.1.3. those that consist entirely of DNA from a prokaryotic host including its indigenous plasmids or viruses when propagated only in that host (or a closely related strain of the same species), or when transferred to another host by well-established physiological means;

         2.1.1.4. those that consist entirely of DNA from a eukaryotic host including its chloroplasts, mitochondria, or plasmids (but excluding viruses) when propagated only in that host (or a closely related strain of the same species);

         2.1.1.5. those that consist entirely of DNA segments from different species that exchange DNA by known physiological processes, though one or more of the segments may be a synthetic equivalent; and,

         2.1.1.6. those that do not present a significant risk to health or the environment.

      2.1.2. Importation of non-viable products of GMOs

      2.1.3. Importation of non-GM organisms for bio-remediation and other purposes

      2.1.4. Importation of non-GM species

   2.2. Other activities in the future that the DOST-BC may declare to be excluded.

III. PHYSICO-CHEMICAL AND BIOLOGICAL CONTAINMENT PROCEDURES AND FACILITIES

1. Physical Containment

1.1. Standard Practices and Training

The first principle of containment is strict adherence to good biosafety practices. Consequently, all personnel directly or indirectly involved in experiments on recombinant DNAs (rDNAs), pests, and potentially harmful microorganisms must receive adequate instruction. This shall include, at the least, instructions in aseptic techniques and in the biology of the organisms used in the experiments so that the potential biohazards can be understood and appreciated.

Any group working with regulated materials should have an emergency plan which describes the procedures to be followed if an accident contaminates personnel or the environment. Everyone should know about this plan. Physical Containment Level I (PI) must ensure that everyone in the laboratory is familiar with both the potential hazards of the work and the emergency plan. If a group is working with a known pathogen for which there is an effective vaccine, such vaccine should be made available to all workers.

Where serological monitoring is clearly appropriate, it should be provided. The "Laboratory Safety Monograph" and "Biosafety in Microbiological and Biomedical Laboratories" booklets describe practices, equipment, and facilities in detail. (See References for details)

1.2. Physical Containment Levels

The objective of physical containment is to confine harmful organisms and those containing rDNA molecules and thus reduce the risk of exposure of the laboratory worker, persons outside of the laboratory, and the environment. The primary means of physical containment is achieved through proper laboratory practices and containment equipment. Special laboratory design provides a secondary means of protection against the accidental release of organisms outside the laboratory or to the environment. Special laboratory design is used primarily in facilities wherein experiments of moderate to high potential hazards are performed.

Combinations of laboratory practices, containment equipment, and special laboratory design can be made to achieve different levels of physical containment. Four levels of physical containment, which are designated as BL1, BL2, BL3, and BL4, are described in succeeding paragraphs. It should be emphasized that the descriptions and assignments of physical containment detailed below are based on existing approaches of pathogenic organisms.

It is recognized that several different combinations of laboratory practices, containment equipment, and special laboratory design may be appropriate for containment of specific research activities. The Guidelines, therefore, allow alternative selections of primary containment equipment within facilities that have been designed to provide BL3 and BL4 levels of physical containment. The selection of alternative methods of primary containment depends however, on the level of biological containment provided by the

host-vector system used in the experiment. Consideration will also be given by the DOST-BC to other combinations that achieve an equivalent level of containment.

1.2.1. **Biosafety Level 1 (BL1)**

BL1 is suitable for work involving agents of no known or minimal potential hazard to laboratory personnel and environment. The laboratory is not separated from the general traffic patterns in the building. Work is generally conducted on open bench tops. Special containment equipment is not required or generally used. Laboratory personnel work in the laboratory and are supervised by scientist(s) with general training in microbiology or a related science.

1.2.1.1. *Procedures*

1.2.1.1.1. When experiments are in progress, access to the laboratory is limited or restricted at the discretion of the laboratory director;

1.2.1.1.2. Work surfaces are decontaminated once a day and after any spill of viable material;

1.2.1.1.3. All contaminated liquid or solid wastes are decontaminated before disposal;

1.2.1.1.4. Mechanical pipetting devices are used; mouth pipetting is prohibited;

1.2.1.1.5. Eating, drinking, smoking, and applying cosmetics are not permitted in the work area. Food may be stored in cabinets or refrigerators designated and used for that purpose only;

1.2.1.1.6. Persons wash their hands after they handle materials involving organisms containing rDNA molecules, and animals, and before leaving the laboratory;

1.2.1.1.7. All procedures are performed carefully to minimize the creation of aerosols;

1.2.1.1.8. Laboratory personnel wear laboratory coats, gowns, or uniforms to prevent contamination or soiling of street clothes;

1.2.1.1.9. Contaminated materials that are to be decontaminated at a site away from the laboratory should be placed in a durable, leakproof container, which is closed before being removed from the laboratory. An insect and rodent control program is in effect, as certified by a licensed pest control officer.

1.2.1.2. *Containment Equipment*

Special containment equipment is generally not required for manipulations of agents assigned to BL1.

1.2.1.2.1. *Laboratory Facilities*

1.2.1.2.2. The laboratory is designed so that it can be easily cleaned;

1.2.1.2.3. Bench tops are impervious to water and resistant to acids, alkalis, organic solvents, and moderate heat;

1.2.1.2.4. Laboratory furniture is sturdy. Spaces between benches, cabinets, and equipment are accessible for cleaning;

1.2.1.2.5. Each laboratory contains a sink for hand-washing;

1.2.1.2.6. If the laboratory has windows that open, they are fitted with fly screens.

1.2.2. **Biosafety Level 2 (BL2)**

BL2 is suitable for work involving agents of moderate potential hazard to personnel and the environment. It requires that (1) laboratory personnel are specifically trained to handle pathogenic agents and are directed by experienced scientists, (2) access to the laboratory is limited when work is being conducted, and (3) certain procedures in which infectious aerosols are created are conducted in biological safety cabinets or other physical containment equipment.

1.2.2.1. *Procedures*

1.2.2.1.1. Access to the laboratory is limited or restricted by the laboratory director when work with organisms containing rDNA molecules is in progress;

1.2.2.1.2. Work surfaces are decontaminated at least once a day and after any spill of viable material;

1.2.2.1.3. Mechanical pipetting devices are used; mouth pipetting is prohibited;

1.2.2.1.4. Eating, drinking, smoking, and applying cosmetics are not permitted in the work area. Food may be stored in cabinets or refrigerators designated and used for that purpose only;

1.2.2.1.5. Persons wash their hands after handling materials involving animals and organisms containing rDNA molecules, and when they leave the laboratory;

1.2.2.1.6. All procedures are performed carefully to minimize the creation of aerosols;

1.2.2.1.7. Experiments of lesser biohazard potential can be carried out concurrently in carefully demarcated areas of the same laboratory;

1.2.2.1.8. Contaminated materials that are to be decontaminated at a site away from the laboratory are placed in a durable, leak-

proof container as specified by the DOST-BC, which is closed before being removed from the laboratory;

1.2.2.1.9. The laboratory director limits access to the laboratory. The director has the final responsibility for assessing each circumstance and determining who may enter or work in the laboratory;

1.2.2.1.10. The laboratory director establishes policies and procedures whereby only persons who have been advised of the potential hazard and who meet specific entry requirements (e.g., immunization) can enter the laboratory or animal rooms;

1.2.2.1.11. When the organisms containing rDNA molecules in use in the laboratory require special provisions for entry (e.g., vaccination), a hazard warning sign incorporating the universal biohazard symbol *(Appendix 5)* is posted on the access door to the laboratory work area. The hazard warning sign identifies the agent, lists the name and telephone numbers of the laboratory director or other responsible persons, and indicates the special requirements for entering the laboratory. An insect and rodent control program is in effect as certified by a licensed pest control operator;

1.2.2.1.12. Laboratory coats, gowns, smocks, or uniforms are worn by personnel while in the laboratory. Before personnel leave the laboratory for non-laboratory areas (e.g., cafeteria, library, administrative offices), this protective clothing is removed and left in the laboratory or is covered with a clean coat not used in the laboratory;

1.2.2.1.13. Animals not involved in the work being performed are not permitted in the laboratory;

1.2.2.1.14. Special care is taken to avoid skin contamination with organisms containing rDNA molecules; gloves should be worn when handling experimental animals and when skin contact with the agent is unavoidable;

1.2.2.1.15. All wastes from laboratories and animal rooms are appropriately decontaminated according to acceptable minimum standards for proper disposal;

1.2.2.1.16. Hypodermic needles and syringes are used only for parenteral injection and aspiration of fluids from laboratory animals and diaphragm bottles. Only needle-locking syringes or disposable syringe-needle units (i.e., needle is integral to the syringe) are used for injection or aspiration of fluids containing organisms that have rDNA molecules. Extreme caution should be observed when handling needles and syringes to avoid auto-inoculation and

generation of aerosols during use and disposal. Needles should not be bent, sheared, replaced in the needle sheath

or guard, or removed from the syringe following use. The needle and syringe should be promptly placed in a puncture-resistant container and decontaminated, preferably by autoclaving, before discard or reuse;

1.2.2.1.17. Spills and accidents that result in overt exposures to organisms containing rDNA molecules are immediately reported to the laboratory director and the IBC. Medical evaluation, surveillance, and treatment are provided as appropriate and written records are maintained;

1.2.2.1.18. When appropriate, considering the agent(s) handled, baseline serum samples for laboratory and other personnel at-risk are collected and stored. Additional serum specimens may be collected periodically, depending on the agents handled or the function of the facility;

1.2.2.1.19. A biosafety manual is prepared or adopted. Personnel are advised of special hazards and are required to read instructions on practices and procedures and to follow them.

1.2.2.2. *Containment Equipment*

1.2.2.2.1. Biological safety cabinets (Class I or II) *(see Section 9)* or other appropriate personal protective or physical containment devices are used whenever necessary;

1.2.2.2.2. Procedures with a high potential for creating aerosols are conducted in biological safety cabinets or other physical containment equipment. These may include centrifuging, grinding, blending, vigorous shaking or mixing, sonic disruption, opening containers of materials whose internal pressures may be different from ambient pressures, inoculating animals intranasally, and harvesting infected tissues from animals or eggs;

1.2.2.2.3. High concentrations or large volumes of organisms containing rDNA molecules may be centrifuged in the open laboratory but must have sealed heads or centrifuge safety cups and are opened only in a biological safety cabinet.

1.2.2.3. *Laboratory Facilities*

1.2.2.3.1. The laboratory is designed so that it can be easily cleaned;

1.2.2.3.2. Bench tops are impervious to water and resistant to acids, alkalis, organic solvents, and moderate heat;

1.2.2.3.3. Laboratory furniture are sturdy and spaces between benches, cabinets, and equipment are accessible for cleaning;

1.2.2.3.4. Each laboratory contains a sink for hand-washing;

1.2.2.3.5. If the laboratory has windows that open, they are fitted with fly screens;

1.2.2.3.6. An autoclave for decontaminating laboratory wastes is available.

1.2.3. **Biosafety Level 3 (BL3)**

BL3 is applicable to clinical diagnosis, teaching, research, or production facilities where work is done with indigenous or exotic agents that may cause serious or potentially lethal diseases as a result of exposure by inhalation. Laboratory personnel have specific training in handling pathogenic and potentially lethal agents and are supervised by competent scientists who are experienced in working with these agents. All procedures involving manipulation of infectious material are conducted within biological safety cabinets or other physical containment devices. Personnel wear appropriate personal protective clothing and devices. The laboratory has special engineering and design features. It is recognized, however, that many existing facilities may not have all the facility safeguards recommended for BL3 (e.g., access zone sealed penetrations and directional airflow, etc.). In such cases, the proponent must show proof of access to BL3 facilities. Under these circumstances, acceptable safety may be achieved for routine or repetitive operations (e.g., diagnostic procedures involving the propagation of agent for identification, typing, and susceptibility testing) in laboratories where facility features satisfy BL2 recommendations, provided the recommended "standard Microbiological Practices", "Special Practices" and "Containment Equipment" for BL3 is rigorously followed. The decision to implement this modification of BL3 recommendations should be made only by the laboratory director.

1.2.3.1. *Procedures*

1.2.3.1.1. Work surfaces are decontaminated at least once a day and after any spill of viable material;

1.2.3.1.2. All contaminated liquid or solid wastes are decontaminated before disposal;

1.2.3.1.3. Mechanical pipetting devices are used; mouth pipetting is prohibited;

1.2.3.1.4. Eating, drinking, smoking, storing food, and applying cosmetics are not permitted in the work area;

1.2.3.1.5. Persons wash their hands after handling animals and materials involving organisms containing rDNA molecules, and when they leave the laboratory;

1.2.3.1.6. All procedures are performed carefully to minimize the creation of aerosols;

1.2.3.1.7. Persons under 16 years of age are not allowed to enter the laboratory;

1.2.3.1.8. If experiments involving other organisms that require lower levels of containment are to be conducted in the same laboratory concurrently with work requiring BL3 level physical containment, such experiments shall be conducted in accordance with all BL3 level practices;

1.2.3.1.9. Laboratory doors are kept closed when experiments are in progress;

1.2.3.1.10. Contaminated materials that are to be decontaminated at a site away from the laboratory are placed in a durable, leak proof container, which is sealed before being removed from the laboratory;

1.2.3.1.11. The laboratory director controls access to the laboratory and restricts access to persons whose presence are required for program or support purposes. The director has the final responsibility of assessing each circumstance and determining who may enter or work in the laboratory;

1.2.3.1.12. The laboratory director establishes policies and procedures whereby only persons who have been advised of the potential biohazard, who meet any specific entry requirements (e.g., immunization), and who comply with all entry and exit procedures enter the laboratory or animal rooms;

1.2.3.1.13. When organisms containing rDNA molecules or experimental animals are present in the laboratory or containment module, a hazard warning sign incorporating the universal biohazard symbol *(Appendix 5)* is posted on all laboratory and animal room access doors. The hazard warning sign identifies the agent, the list and telephone number of the laboratory director or other responsible persons, and indicates any special requirements for entering the laboratory, such as the for immunization, respirators, or other protective measures;

1.2.3.1.14. All activities involving organisms containing rDNA molecules are conducted in biological safety cabinets or other physical containment devices within the containment module. No work in open vessels is conducted on the open bench;

1.2.3.1.15. The work surfaces of biological safety cabinets and other containment equipment are decontaminated after work with organisms containing rDNA molecules is finished. Plastic-backed paper towel shall be used on non-perforated work

surfaces within biological safety cabinets. An insect and rodent program is in effect as certified by a licensed pest control operator;

1.2.3.1.16. Laboratory clothing that protects street clothing (e.g., solid front or wrap-around gowns, scrub suits, cover-alls) is worn in the laboratory. Laboratory clothing is not worn outside the laboratory, and is decontaminated before being laundered;

1.2.3.1.17. Special care is taken to avoid skin contact with contaminated materials; gloves should be worn when handling infected animals and when skin contact with infectious materials is unavoidable;

1.2.3.1.18. Molded surgical masks or respirators are worn in rooms containing experimental animals;

1.2.3.1.19. Animals and plants not related to the work being conducted are not permitted in the laboratory;

1.2.3.1.20. Laboratory animals held in a BL3 area are housed in partial-containment caging systems, such as Horsfall units, open cages placed in ventilated enclosures, solid-wall and bottom cages covered by filter bonnets, or solid-wall and bottom cages placed on holding racks equipped with ultraviolet radiation lamps and reflectors;

(NOTE: Conventional caging systems may be used provided that all personnel wear appropriate personal protective devices. These shall include, at a minimum, wrap-around gowns, head covers, gloves, shoe covers, and respirators. All personnel shall shower on exit from areas where these devices are required.)

1.2.3.1.21. All wastes from laboratories and animal rooms are appropriately decontaminated before disposal;

1.2.3.1.22. Vacuum lines are protected with High Efficiency Particulate Air (HEPA) filters and liquid disinfectant traps;

1.2.3.1.23. Hypodermic needles and syringes are used only for parenteral injection and aspiration of fluids from laboratory animals and diaphragm bottles. Only needle-locking syringes or disposable syringe-needle units (i.e., needle is integral to the syringe) are used for the injection or aspiration of fluids containing organisms that have rDNA molecules. Extreme caution should be observed when handling needle and syringes to avoid auto-inoculation and the generation of aerosols during use and disposal. Needles should not be bent, sheared, replaced in the needle sheath or guard, or removed from the syringe following use. The needle and syringe should be promptly placed in a puncture-resistant container and

decontaminated, preferably by autoclaving, before discard or reuse;

1.2.3.1.24. Spills and accidents which result in overt or potential exposures to organiss containing rDNA molecules are immediately reported to the laboratory director and to the IBC. Appropriate medical evaluation, surveillance, and treatment are provided and written records are maintained;

1.2.3.1.25. Baseline serum samples for all laboratory and other personnel at-risk should be collected and stored for reference purposes. Additional serum specimens may be collected periodically depending on the agents handled or the function of the laboratory;

1.2.3.1.26. A biosafety manual is adopted. Personnel are advised of special hazards and are required to read and follow instructions on practices and procedures;

1.2.3.1.27. Alternative selection of containment equipment is possible. Experimental procedures involving a host-vector system that provides a one-step higher level of biological containment than that specified can be conducted in the BL3 laboratory, using containment equipment specified for the BL4 level of physical containment. Experimental procedures involving a host-vector system that provides a one-step lower level of biological containment than that specified can be conducted in the BL3 laboratory using containment equipment specified for the BL2 level of physical containment.

1.2.3.2. *Containment Equipment*

Biological safety cabinets (Class I, II, or III) *(see Section 9)* or other appropriate combinations of personal, protective or physical containment devices (e.g., special protective clothing, masks, gloves, respirators, centrifuge, safety cups, sealed centrifuge rotors, and containment caging for animals) are used for all activities with organisms containing rDNA molecules, which pose a threat of aerosol exposure. These include: manipulation of cultures and of clinical or environmental materials which may be a source of aerosols; the aerosol challenge of experimental animals, harvesting infected tissues or fluids from experimental animals and embryonate eggs, and necropsy of experimental animals;

1.2.3.3. *Laboratory Facilities*

1.2.3.3.1. The laboratory is separated from areas which are open to unrestricted traffic flow within the building. Passage through two sets of doors is the basic requirement for entry into the laboratory from access corridor or other contiguous areas. Physical separation of the high containment laboratory from access corridors or other laboratories or activities may also be provided by a double-doored clothes

change room (showers may be included), air lock, or other access facility which requires passage through two sets of doors before entering the laboratory;

1.2.3.3.2. The interior surfaces of walls, floors, and ceilings are water resistant so that they can be easily cleaned. Penetrations in these surfaces are sealed or capable of being sealed to facilitate decontamination of the area;

1.2.3.3.3. Bench tops are impervious to water and resistant to acids, alkalis, organic solvents, and moderate heat;

1.2.3.3.4. Laboratory furniture are sturdy and spaces between benches, cabinets, and equipment are accessible for cleaning;

1.2.3.3.5. Each laboratory contains a sink for hand washing. The sink may be operated by foot, by elbow, or automatically and is located near the laboratory exit door;

1.2.3.3.6. Windows in the laboratory are closed and sealed;

1.2.3.3.7. Access doors to the laboratory or containment module are self-closing;

1.2.3.3.8. An autoclave for decontaminating laboratory waste is available, preferably within the laboratory;

1.2.3.3.9. A ducted exhaust air ventilation system is provided. This system creates directional airflow that draws air into the laboratory through the entry area. The exhaust air is not re-circulated to any other area of the building, is discharged to the outside, and is dispersed away from the occupied areas and air intakes. Personnel must verify that the direction of the airflow (into the laboratory) is proper. The exhaust air from the laboratory room should be filtered before it is discharged to the outside to be sure it is not contaminated;

1.2.3.3.10. The HEPA-filtered exhaust air from Class I or Class II biological safety cabinets may be re-circulated within the laboratory if the cabinet is tested and certified at least every 12 months. If the HEPA-filtered exhaust air from Class I or II biological safety cabinets is to be discharged to the outside through the building exhaust air system, it should be connected in a manner [e.g., thimble unit connection] that avoids any interference with the air balance of the cabinets or building exhaust system.

1.2.4. **Biosafety Level 4 (BL4)**

BL4 provides the most stringent containment conditions. All requirements listed in BL3 are applicable to BL4. Standard microbiological practices should be followed.

1.2.4.1. *Procedures*

1.2.4.1.1. Work surfaces are decontaminated at least once a day and immediately after any spill of viable material;

1.2.4.1.2. Only mechanical pipetting devices are used;

1.2.4.1.3. Eating, drinking, smoking, storing food, and applying cosmetics are not permitted in the laboratory;

1.2.4.1.4. All procedures are performed carefully to minimize the creation of aerosols;

1.2.4.1.5. Biological materials to be removed from the Class III cabinets or from the maximum containment laboratory in a viable or intact state are transferred to a non-breakable, sealed primary container, and then enclosed in a non-breakable, sealed secondary container, which is removed from the facility through a disinfectant dunk tank, fumigation chamber, or an air lock designed for this purpose;

1.2.4.1.6. No material, except biological materials that are to remain in a viable or intact state, is removed from the maximum containment laboratory unless it has been autoclaved or decontaminated. Equipment or material that might be damaged by high temperatures or steam is decontaminated by gaseous or vapor methods in an airlock or chamber designed for that purpose;

1.2.4.1.7. Only persons whose presence are required for program or support purposes in the facility or individual laboratory rooms are authorized to enter. The laboratory director has the final responsibility for assessing each circumstance and determining who may enter or work in the laboratory. Access to the facility is limited by means of secure, locked doors; accessibility is managed by the laboratory director, biohazards control officer, or other persons responsible for the physical security of the facility. Before entering, persons are advised of the potential biohazards and instructed on appropriate safeguards to ensure their safety. Authorized persons comply with these instructions and all other applicable entry and exit procedures. A logbook signed by all personnel indicates the date and time of each entry and exit. Practical and effective protocols for emergency situations are established;

1.2.4.1.8. Personnel enter and leave the facility only through the clothing change and shower rooms. Personnel shower every time they leave the facility; personnel use the airlocks to enter or leave the laboratory only in an emergency;

1.2.4.1.9. Street clothing is removed in the outer clothing change room and kept there. Complete laboratory clothing, including undergarments, pants, and shirts or jumpsuits, shoes, and gloves, is provided and used by all personnel entering the facility. Head covers are provided for personnel who do not wash their hair during the exit shower. When leaving the laboratory and before proceeding into the shower area, personnel remove their laboratory clothing and store it in a locker or hamper in the inner change room;

1.2.4.1.10. When materials that have organisms containing rDNA molecules or experimental animals are present in the laboratory or animal rooms, a hazard warning sign incorporating the universal biohazard symbol *(Appendix 5)* is posted on all access doors. The sign identifies the agent, lists the name of the laboratory director or other responsible person(s), and indicates any special requirements for entering the area (e.g., the need for immunization or respirators);

1.2.4.1.11. Supplies and materials needed in the facility are brought in through the double-doored autoclave, fumigation chamber, or airlock which is appropriately decontaminated between each use. After securing the outer doors, personnel within the facility retrieve the materials by opening the interior doors or the autoclave, fumigation chamber, or airlock. These doors are secured after materials are brought into the facility. An insect and rodent control program is in effect as certified by a licensed pest control operator for all levels;

1.2.4.1.12. Materials (e.g. plants, animals, and clothing) not related to the experiment being conducted are not permitted in the facility;

1.2.4.1.13. Hypodermic needles and syringes are used only for parenteral injection and aspiration of fluids from laboratory animals and diaphragm bottles. Only needle-locking syringes or disposable syringe-needle units (i.e., needle is integral part of unit) are used for the injection or aspiration of fluids containing organisms that contain rDNA molecules. Needles should not be bent, sheared, replaced in the needle sheath or guard, or removed from the syringe following use. The needle and syringe should be placed in a puncture-resistant container and decontaminated, preferably by autoclaving before discard or reuse. Whenever possible, cannulas are used instead of sharp needles (e.g. gavage);

1.2.4.1.14. A system is set up for reporting laboratory accidents and exposures and employee absenteeism, and for the medical surveillance of potential laboratory-associated illnesses. Written records are prepared and maintained. An essential adjunct to such a reporting-surveillance system is the

availability of a facility for quarantine, isolation, and medical care of personnel with potential or known laboratory-associated illnesses;

1.2.4.1.15. Laboratory animals involved in experiments requiring BL4 level physical containment shall be housed either in cages contained in Class III cabinets or in partial containment caging systems such as Horsfall units (11), open cages placed in ventilated enclosures, or solid-wall and bottom cages placed on holding racks equipped with ultraviolet irradiation lamps and reflectors that are located in a specially designed area in which all personnel are required to wear one-piece positive pressure suits.

1.2.4.2. *Containment Equipment*

All procedures within the facility with agents assigned to BL4 are conducted in the Class III biological safety cabinet; or in Class I or II biological safety cabinets used in conjunction with one-piece positive pressure personnel suits ventilated by a life-support system.

1.2.4.3. *Laboratory Facilities*

1.2.4.3.1. The maximum containment facility consists of either a separate building or a clearly demarcated and isolated zone within a building. Outer and inner change rooms separated by a shower are provided for personnel entering and leaving the facility. A double-doored autoclave, fumigation chamber, or ventilated air lock is provided for passage of materials, supplies, or equipments that are not brought into the facility through the change room;

1.2.4.3.2. Walls, floors, and ceilings of the facility are constructed to form a sealed internal shell that facilitates fumigation and is animal and insect-proof. The internal surfaces of this shell are resistant to liquids and chemicals, thus making it easier to clean and decontaminate the area. All penetrations in these structures and surfaces are sealed. Any drains in the floors contain traps filled with a chemical disinfectant of demonstrated efficacy against the target agent, and these are connected directly to the liquid waste decontamination system. Sewer and other ventilation lines contain HEPA filters;

1.2.4.3.3. Internal facility appurtenances, such as light fixtures, air ducts, and utility pipes are arranged to minimize the horizontal surface area on which dust can settle;

1.2.4.3.4. Bench tops have seamless surfaces that are impervious to water and resistant to acids, alkalis, organic solvents, and moderate heat;

1.2.4.3.5. Laboratory furniture are made of simple and sturdy material, and spaces between benches, cabinets, and equipment are accessible for cleaning;

1.2.4.3.6. A hand-washing sink operated by foot, by elbow, or automatically is provided near the door of each laboratory room in the facility;

1.2.4.3.7. If there is a central vacuum system, it does not serve areas outside the facility. In-line HEPA filters are placed as near as practicable to each use point or service cock. Filters are installed to permit in-place decontamination and replacement. Other liquid and gas services to the facility are protected by devices that prevent backflow;

1.2.4.3.8. If water fountains are provided, they are foot-operated and are located in the facility corridors outside the laboratory. The water service to the fountain is not connected to the backflow-protected distribution system supplying water to the laboratory areas;

1.2.4.3.9. Access doors to the laboratory are self-closing and can be locked. All windows are breakage resistant;

1.2.4.3.10. A double-doored autoclave is provided for decontaminating materials passing out of the facility. The autoclave door, which opens to the area external to the facility, is sealed to the outer wall and automatically controlled so that the outside door can be opened only after the autoclave "sterilization" cycle has been completed;

1.2.4.3.11. A pass-through dunk tank, fumigation chamber, or an equivalent decontamination method is provided so that materials and equipment that cannot be decontaminated in the autoclave can be safely removed from the facility;

1.2.4.3.12. Liquid effluents from laboratory sinks, biological safety cabinets, floors, and autoclave chambers are decontaminated by heat treatment before being released from the maximum containment facility. Liquid wastes from shower rooms and toilets may be decontaminated with chemical disinfectants or by heat in the liquid waste decontamination system. The procedure used for heat decontamination of liquid wastes is evaluated mechanically and biologically by using a recording thermometer and an indicator microorganism with a defined heat susceptibility pattern. If liquid wastes from the shower room are decontaminated with chemical disinfectants, the chemical used should be of demonstrated efficacy against the target or indicator microorganisms;

1.2.4.3.13. An individual supply and exhaust air ventilation system is provided. The system maintains pressure differentials and directional airflow as required to assure flows inward from

areas outside of the facility toward areas of highest potential risk within the facility. Manometers are used to sense pressure differentials between adjacent areas maintained at different pressure levels. If a system malfunctions, the manometers sound an alarm. The supply and exhaust airflow is interlocked to assure inward (or zero) airflow at all times;

1.2.4.3.14. The exhaust air from the facility is filtered through HEPA filters and discharged to the outside so that it is dispersed away from occupied buildings and air intakes. Within the facility, the filters are located as near the laboratories as practicable in order to reduce the length of potentially contaminated air ducts. The filter chambers are designed to allow in situ decontamination before filters are removed and to facilitate certification testing after they are replaced.

Coarse filters and HEPA filters are provided to treat air supplied to the facility in order to increase the lifetime of the exhaust HEPA filters and to protect the air supply system should air pressures become unbalanced in the laboratory;

1.2.4.3.15. The treated exhaust air from Class I and II biological safety cabinets can be discharged into the laboratory room environment or outside through the facility air exhaust system. If exhaust air from Class I or II biological safety cabinets is discharged into the laboratory, the cabinets are tested and certified at 6 month intervals. The exhaust air from Class III biological safety cabinets is discharged, without recirculation through two sets of HEPA filters in series, via the facility exhaust air system. If the treated exhaust air from any of these cabinets is discharged to the outside through the facility exhaust air system, the treated exhaust air is connected to this system in a manner [e.g., thimble unit connection] that avoids any interference with the air balance of the cabinets or the facility exhaust air system;

1.2.4.3.16. A specially designed suit area may be provided in the facility. Personnel who enter this area wear a one-piece positive pressure suit that is ventilated by a life-support system. The life-support system includes alarms and emergency backup breathing air tanks. Entry to this area is through an airlock fitted with airtight doors. A chemical shower is provided to decontaminate the surface of the suit before the worker leaves the area. The exhaust air from the suit area is filtered by two sets of HEPA filters installed in series. A duplicate filtration unit, exhaust fan, and an automatically starting emergency power source are provided. The air pressure within the suit area is lower than that in any adjacent area. Emergency lighting and communication systems are provided. All penetrations into the internal shell of the suit area are sealed. A double-

doored autoclave is provided for decontaminating waste materials to be removed from the suit area.

2. Biological Containment

In considering biological containment, the vector (plasmid, organelle, or virus) for the rDNA and the host (bacterial, plant or animal cell) in which the vector is propagated in the laboratory will be considered together. In any combination of vector and host, the biological containment must be chosen or constructed so that the following types of "escape" are minimized: (i) survival of the vector in its host outside the laboratory, and (ii) transmission of the vector from the propagation host to other non-laboratory hosts.

Host-vector systems of which a high level of safety (requires P1 level containments) has been confirmed when primitive eukaryote or prokaryote not listed in 3.9.1, 3.9.2, and 3.9.3 and their viruses are used as a DNA donor;

AA (a host-vector system with *Acetobacter aceti* as a host and plasmid or bacteriophage as a vector)

BA (a host-vector system with *Bacilus amloliquefaciens* as a host and plasmid or bacteriophage as a vector)

BB (a host-vector system with a *Bacillus brevis* as a host and plasmid or bacteriophage as a vector)

BF (a host-vector system with *Brevibacterium flavum* as a host and plasmid or bacteriophage as a vector)

BL (a host-vector system with *Brevibacterium lactofermentum* as a host and plasmid or bacteriophage as a vector)

Bst (a host-vector system with *Bacillus stearothermolhilus* as a host and plasmid or bacteriophage as a vector)

CH (a host-vector system with *Corynebacterium herculis* as a host and plasmid or bacteriophage as a vector)

PP (a host-vector system with *Pseudomonas putida* as a host and plasmid or bacteriophage as a vector)

SK (a host-vector system with *Bacillus stearothermolhilus* as a host and plasmid or bacteriophage as a vector)

SL (a host-vector system with *Streptomyces lividans* as a host and plasmid or bacteriophage as a vector)

SP (a host-vector system with *Schizossacharomyces pombe* as a host and plasmid or bacteriophage as a vector)

ZR (a host-vector system with *Zygosaccharomyces rouxii* as a host and plasmid or bacteriophage as a vector)

3. Classification of Host Organisms

3.1. Host Category P1

3.1.1. Microorganisms

3.1.1.1. *Escherichia coli* strain K12 to K102 or *E. coli B* or their derivatives, provided such strains do not contain configuration-proficient autonomous or integrated plasmids or generalized transducing phages;

3.1.1.2. Asporogenic strains of *Bacillus subtilis* or *B. lichenformis,* whose reversion frequencies are less than 10-7, provided these strains are indigenous to the area and are known to be non-pathogenic;

3.1.1.3. Laboratory strains of *Neurospora crassa* and *Saccharomyces cerevisiae*;

3.1.1.4. All other indigenous, non-pathogenic bacterial, parasitic, fungal, viral, rickettsial, and chlamydial agents not included in higher categories.

3.1.2. Plants

Plant cell and tissue cultures; provided the said culture(s) were derived from indigenous species.

3.1.3. Animals

3.1.3.1. Vertebrate cell lines (including human cell lines).

3.1.3.2. Invertebrate cell cultures such as *Spodoptera frugiperda* cell lines, *Drosophila* cell lines, etc.

3.1.3.3. All indigenous unicellular animals which are non-pathogenic, and which are not included in the higher categories.

3.2. Host Category P2

3.2.1. Bacterial Agents

Acinetobacter calcoaceticus
Actinobacilus – all species
Actinomycetes (including Nocardia species, Actinomyces species, and Arachnia propionica)
Aeromomonas hydrophila
Bacillus anthracis
Bordetella – all species
Borrelia recurrentis, B. vicenti
Campylobacter fetus
Campylobacter jejuni
Chlamydia trachomatis
Clostridium botulinum

Cl. chauvoei, Cl. haemolyticum,
Cl. histolyticum, Cl. novyi,
Cl. septicum, Cl. tetani
Edwardsiella tarda
Erysipelothrix rhusiopathiae
Escherichia coli – all enteropathogenic, enterotoxigenic, and enteroinvasive strains bearing K1 antigen
Haemophilus ducreyi, H. influenzae
Legionella pneumophila
Leptospira interrogans – all serotypes
Klebsiella – all species and all serotypes
Listeria – all species
Moxarella – all species
Mycobacterium – all species except those listed in P3
Mycoplasma – all species except *Mycoplasma mycoides and Mycoplasma agalactiae,* which are in P5
Neisseria gonorrheae, N. meningitides
Pasteurella – all species except those listed in P3
Salmonella – all species and all serotypes including Arizona
Shigella – all species and all serotypes
Sphaerophorus necrophorus
Staphylococcys aureus
Streptococcus moniliformis
Streptococcus pyogenes
Treponema carateum, T. pallidum, and T. pertenue
Vibro cholerae
Yersinia enterocolitica

3.2.2. **Fungal Agents**

Blastomyces dematitidis
Cryptococcus neoformans
Paracoccidioides brasiliensis

3.2.3. **Parasitic Agents**

Entamoeba histolytica
Leishmania sp.
Naegleria gruberi
Nosema bombycis
N. apis
Schistosoma mansoni
Toxoplasma gondi
Toxocara canis
Trichinella spiralis
Trypanosoma cruzi

3.2.4. **Viral, Rickettsial, and Chlamydial Agents**

Adenoviruses – human – all types
Cache Valley virus
Coxsackie A and B viruses
Echoviruses – all types
Encephalomyocarditis virus (EMC)

Flanders virus
Hart Park virus
Hepatitis-associated antigen material
Herpes viruses – except *Herpesvirus simiae* (Monkey B virus) which is in P4
Corona viruses
Influenza viruses – all types except A/PRB/34, which is in P1
Langat virus
Lymphogranuloma venereum agent
Measles virus
Mumps virus
Parainfluenza virus – all types except *Parainfluenza virus 3,* SF4 strain, which is P1
Polioviruses – all types, wild and attenuated
Poxviruses – all types except *Alastrim, Smallpox, and* Whitepox which are P5 and *Monkeypox* which depending on experiments, is in P3 or P4
Rabies virus – all strain except Rabies street virus which should be classified in P3
Reovirus – all types
Respiratory syncytial virus
Rhinoviruses – all types
Rubella virus
Simian viruses – all types except *Herpesvirus simiae (Monkey B virus)* and *Marburg virus* which are in P3
Sindbis virus
Tensaw virus
Turlock virus
Vaccinia virus
Varicella virus
Vesicular stomatitis virus
Vole rickettsia
Yellow fever virus, 170 vaccine strain

3.3. **Host Category P3**

3.3.1. **Bacterial agents**

Bartonella – all species; P4 in text
Brucella – all species
Francisella tularensis
Mycobacterium avium, M. bovis, M. tuberculosis
Pasteurella multocide type B (“buffalo” and other foreign virulent strains)
Pseudomonas mallei – P4 in text
Pseudomonas pseudomallei – P4 in text
Yersinia pestis – P4 in text

3.3.2. **Fungal Agents**

Coccidiodes immitis
Histoplasma capsulatum
Histoplasma capsulatum var. duboisii

3.3.3. **Parasitic Agents**

None

3.3.4. **Viral, Rickettsial, Chlamydial Agents**

Monkey pox when used in vitro
Arboviruses – all strains except those in P2 and P4
Dengue virus, when used for transmission or animal inoculation experiments
Lymphocytic choriameningitis (LCM)
Rickettsia – all species except Vole rickettsia when used for transmission or animal inoculation experiments
Yellow fever virus – wild when used in vitro

3.4. **Host Category P4**

3.4.1. **Bacterial Agents**
None

3.4.2. **Fungal Agents**
None

3.4.3. **Parasitic Agents**
None

3.4.4. **Viral, Rickettsial, Chlamydial Agents**

Ebola fever virus
Monkey pox when used for transmission or animal inoculation experiments
Hemorrhagic fever agents including Crimean hemorrhagic fever (Cango), Junin, and *Mcchupo viruses*, and others as yet undefined
*Herpesvirus simiae (*Monkey B virus)
Lassa virus
Marburg virus
Tick-borne encephalitis virus complex including Russian spring summer Encephalitis*, Kyasanur forest disease*, Omak hemmorhagic fever, and Central European encephalitis viruses
Venezuelan equine encephalitis virus, epidemic strains when used for transmission or animal inoculation experiments
Yellow fever virus – wild when used for transmission or animal inoculation experiments

3.5. **Host Category P5**

3.5.1. Animal disease organism whose entry into the Philippines is forbidden by law:

Foot-and-mouth disease virus

3.5.2. Animal disease organisms and vectors whose entry into the Philippines is forbidden

African horse sickness virus
African swine fever virus
Besnoitia besnoiti
Borna disease virus
Bovine infectious petechial fever
Camel pox virus
Ephemeral fever virus

Fowl plague virus
Goat pox virus
Hog cholera virus
Louping ill virus
Lumpy skin disease virus
Nairobi sheep diseases virus
Newcastle disease virus (Asiatic strains)
Mycoplasma mycoides (contagious bovine peuropneumonia)
Mycoplasma agalactiae (contagious agalactia of sheep)
Rickettsia reminantium (heart water)
Rift valley fever virus
Rinderpest virus
Sheep pox virus
Swine vesicular disease virus
Teschen disease virus
Trypanosama vivax (Nagana)
Trypanosama evansi
Theileria parva (East Coast Fever)
Theileria lawrencei
Theileria bovis
Theileria hirci
Versicular axanthema virus
Wesselsborn disease virus
Zyonema

3.5.3. Organisms that may not be studied in the Philippines except at specified facilities

Smallpox virus
Alastrim
White pox virus

3.6. **Vector Category P1**

3.6.1. Non-conjugative *E. coli* plasmids (e.g. PSC101, Co(F), pBR322) and their derivatives, phagemids derived from M13 (e.g., pUC series, pBS series, pBluescript series, etc.) and their derivatives, and variants of the commercially available lambda, lambdoid, Fd or F1 series bacteriophage series;

3.6.2. Indigenous non-toxin-bearing plasmids and phages of asporogenic *Bacillus subtilis* or *B. lichenformis,* whose host ranges do not include *B. cereus* or *B. anthracis;*

3.6.3. Non-tumorigenic, disarmed Ti plasmid vectors in *Agrobacterium tumefaciens;*

3.6.4. All other indigenous, non-toxin-bearing non-invasive and non-viral vectors not included in the higher categories;

3.7. **P1 DNA Donor Organisms**

Classification of DNA donors would largely depend on the size and nature of specific DNA sequences under study. The nature of the DNA insert and the predicted translation products must be generally classified as safe to merit a P1 classification. All the organisms classified as P1 hosts are also classified as P1 DNA donors provided the

DNA sequences under study do not encode full sequences of functional proteins and provided the gene fusions do not produce fully functional proteins.

3.8. Safety level as DNA donors or primitive eukaryotes and prokaryotes

3.8.1. *Organisms used as DNA donor that require P2 containments:*

Actinomyces	*A. bovis*
	A. israeili
	A. naeslundii
Aeromonas	*A. hydrophila* (Toxin producing strains)
	*A. punctate (*Toxin producing strains)
Arizona	*A. hinshawii* (all antigenic type)
Bacillus	*B. cereus* (Toxin producing strains)
Blastomyces	*B. Dematitidis*
Bordetella	*All spps.*
Borrelia	*All spps.*
Brucella	*B. canis*
Calymmatobacterium	*C. granulomatis*
Campylobacter	*All spps.*
Clostridium	*C. chauvoei*
	C. difficile
	C. haemolyticum
	C. histolyticum
	C. novyi (Toxin producing strain)
	C. septicum
Corynebacterium	*C. equie*
	C. pseudotuberculosis
	C. pyogenes
	C. renale
Entamoeba	*E. histolyca*
Erysipelothrix	*E. rhusiopathiae*
	E. insidiosa
Escherichia	*E. coli* (all antigenic types with pathogenecity to intestine)
Fusibacterium	*F. necrophorium*
Haemophilus	*H. ducreyi*
	H. influenzae
Hartmanella	*All spps.*
Herellea	*H. vaginicola*
Klebsiella	*All spps.*
Legionella	*L. pneumophila*
Leishmania	*All spps.*
Leptospira	*L. interrogans* (all antigenic type)
Listeria	*L.monocytogenes*
Mima	*M. polymorpha*
Moraxella	*All spps.*
Mycobacterium	*M. avium*
	M. intracellulare complex
	M. kansasii
	M. marinum
	M. paratuberculosis
	M. acrofulaceum
	M. ulcerans

Mycoplasma	*M. pneumonia*
Naegleria	*All spps.*
Neisseria	*N. gonorrhoeae*
	N. meningitides
Nocardia	*N. asteroids*
	N. brasiliensis
	N. caviae
	N. farcinica
Pracoccidioedes	*P. brasiliensis*
Pasteurella	*All spps. except P. multocida*
Plasmodium	*P. falciparum*
	P. malariae
	P. ovale
	P. vivx
Simian malarial parasites	
Plesiomonas	*P. shigelloides*
Salmonella	All serotypes except *S. paratyphi-A* and *S. typhi*
Shigella	All spps. except *S. dysenteriae*
Staphylococcus	*S. aureus*
Streptococcus	*S. pneumonia*
	S. pyogenes
Treponema	*T. carateum*
	T. pallidum
	T. pertenue
Trichinella	*T. spiralis*
Toxocara	*T. canis*
Toxoplasma	*T. gondii*
Trypanosoma	*T. cruzi*
	T. gambiense
	T. rhodosiense
Vibrio	*V. cholera (*including BiotypeEl Tor)
Yersinia	*Y. enterocolitica*

3.8.2. *Organisms used as donor that require P3 containments:*

Brucella	*B. abortus*
	B. melitensis
	B. suis
Cocciodioides	*C. immitis*
Cryptococcu	*C. neoformans*
Francisella	*F. tularensis*
Histoplasma	*H. capsulatum*
Mycobacterium	*M. afrinacum*
	M. bovis
	M. tuberculosis
Salmonella	*S. paratyphi-A*
	S. typhi

3.8.3. *Organisms used as DNA donor that require P4 containments:*

Bartonella	*B. bacilliformis*
Clostridium	*C. botulinum*
	C. tetani
Corynebacterium	*C. diptheriae*

Mycoplasma	*M. mycoides*
Pasterella	*P. multocida (B:6, E-6, A:5, A:8, A:9)*
Pseudomonas	*P. mallei*
	P. pseudomallei
Shigella	*S. dysenteriae*
Yersinia	*Y. pestis (Y. pseudotuberculosis subsp. Pestis)*

3.9. **Safety level for DNA donor of Virus, Rickettsia, and Chlamydia of Prokaryotes excluding primitive organisms**

3.9.1. *Organisms used as DNA donor that require P1 containment*

Aino virus
Akabane virus
Avian adenovirus
Avian encehalomyelitis virus
Avian enterovirus
Avian influenza virus
Avian poxvirus
*Avian retrovirusa (*except *Avian reticuloendoasis* virus)
Bluetongue virus
Bovine adenovirus
Bovine enterovirus
Bunyamwera virus
Canine distemper virus
Coronavirus
Duck hepatitis vrus
Equine influenza virus
Getah virus
Langat virus
*Live virus vaccine strains (*except *Rinderpest vaccine strain*)
Lucke virus
Marek's disease virus
Parvovirus
Poikilothermal vertebrate retrovirus
Porcine adenovirus
Reovirus (1-3)
Ross River virus
Shope fibtroma virus
Simbu virus
Sindbis virus
Swine influenza virus
Swinepox virus
Viroids
Fish viruses (limit to IPN, IHN, EVA, EVE, LV)
*Insect viruses (*except insect viruses such as arbovirus, which are pathogenic to vertebrate)
Plant viruses

3.9.2. *Organisms used as DNA donor that require P2 containment*

Avian reticuloendotheliosis virus
Batai virus
BK virus

Bovine papilloma virus
Chlamydia trachomatis
Cowpox virus
Coxsackie virus (A, B)
Cytomegalovirus (human, animal)
Dengue virus (1-4)
Eastern equine encephalitis virus
EB virus
Echovirus (1-34)
Extromelia virus
Enterovirus (68-71)
Equine infectious anemia virus
Equine rhinopneumonitis virus
Hepatitis A virus
Hepatitis B virus
Hepatitis non A non B virus
Herpes simplex virus (1, 2)
Human adenovirus
Human influenza virus (A, B, C)
Human wart virus (Human papilloma virus)
HVJ
JC virus
Mammalian retrovirus (except HIVm HTLV-1 (ATLV) and HTLV-II)
Measles virus
Molluscan contagiosum virus
Mouse hepatitis virus
Mumps virus
NDV
Parainfluenza virus (1-4)
Pichinde virus
Poliovirus (1-3)
Polyoma virus
Pseudorabies virus
Rabies (fixed, attenuated) virus
Rhinovirus
Rotavirus
Rubella virus
Emsliki Forest virus
SSPE agent
SV 40
Tanapox virus
Vacinia virus
Varicella virus
Western equine encephalitis virus

3.9.3. *Organisms used a DNA donor that require P3 containments*

California encephalitis virus
Chikungunia virus
Chlamydia psittaci
Herpes virus ateles
Herpes virus saimiri
HIV
Hog choleravirus

HTLV-ATLV
HTLV-1
Japanese encephalitis virus
Las Crosse virus
LCM virus
Monkeypox virus
Murray Valley encephalitis virus
O'nyong-nyong virus
Powassan virus
Rabies street virus
St. Louis encephalitis virus
Tacaribe virus
Vesicular somatitis virus
West Nile virus

4. Classification of Oncogenic Viruses on the Basis of Potential Hazard

4.1. Low-risk Oncogenic Viruses

Rous sarcoma
SV-10
CELO
Ad2-SV40
Polyoma
Bovine papilloma
Rat mammary tumor
Avian leucosis
Murine leukemia
Murine sarcoma
Mouse mammary tumor
Rat leukemia
Hamster leukemia
Bovine leukemia
Dog sarcoma
Mason-Pfizer monkey virus
Marek's
Guinea pig herpes
Lucke (Frog)
Adenovirus
Shope fibroma
Shope papilloma

4.2. Moderate-Risk Oncogenic Viruses

Ad2-SV40
FelV
HV Saimiri
EBV
SSV-1
GaLV
HV Ateles
Yaba
FeSV

5. The following levels of biological containment for host-vector systems (HV) for prokaryotes will be established; and specific criteria will depend on the organisms to be used:

5.1. HV1. A host-vector system that requires a moderate level of containment.

Specific systems follow:

EK1: The host is always E. coli K-12 or a derivative thereof, and the vectors include non-conjugative plasmids (e.g., PSC101, Co(F) or derivatives thereof (1-7), and variants of bacteriophage such as lambda (8-15). The E. coli K-12 hosts should not contain configuration proficient plasmids, whether autonomous or integrated or generalized transducing phages.

Other HV1. Hosts and vectors shall be, at a minimum, comparable in containment to E. coli K-12 with a non-conjugative plasmid or bacteriophage vector. The data to be considered and a mechanism for approval of such HV1 systems are described in Section 5.2.

5.2. HV2. These are host vector systems shown to provide a high level of biological containment as demonstrated by data from suitable tests performed in the laboratory. Escape of the rDNA either via survival of the organisms or via transmission of rDNA to other organisms should be less 1/104 under specified conditions. Specific systems are as follows:

EK2: For EK2 host vector systems in which the vector is a plasmid, no more than in 104 host cells should be able to perpetuate a cloned DNA fragment under the specified non-permissive laboratory conditions designed to represent

the natural environment, either by survival of the original host or as a consequence of transmission of the cloned DNA fragment.

For EK2 host vector system in which the vector is a phage, no more than one in 104 phage particles should be able to perpetuate a cloned DNA fragment under the specified non-permissive laboratory conditions designed to represent the natural environment either (i) as a prophage (in the inserted or plasmid form) in the laboratory host used for phage propagation or (ii) by surviving in natural environments and transferring a cloned DNA fragment to other hosts (or their resident prophages).

6. Certification of Host-Vector Systems

6.1. Responsibility. HV1 systems other than *E. coli* K-1 and HV2 host-vector systems may not be designated as such until they have been certified by the DOST-BC Chairman. Request for certification should be addressed to:

The Chairman
DOST-Biosafety Committee (DOST-BC)
Department of Science and Technology (DOST)
Gen. Santos Ave., Bicutan, Tagig City

6.2. Host vector systems that are proposed for certification will be reviewed by the DOST-BC. Prior to this, a review of the data on construction, properties, and testing of the proposed host-vector system will be made by a working group composed of one or more members of the DOST-BC and other persons chosen because of their expertise in evaluating such data. The DOST-BC will then evaluate the report of the working group and any other available information at a regular meeting.

The DOST-BC chairman is responsible for certification after receiving the advice of the working group. Minor modifications of existing certified host-vector systems, i.e., those of minimal or no consequence to the properties relevant to containment, may be certified by the DOST-BC chairman;

6.3. When a new host-vector system is certified, the DOST-BC sends a notice of the certification to the applicant and to all IBCs and publishes it. Copies of a list of all currently certified host- vector systems may be obtained from the DOST-BC at any time;

6.4. The DOST-BC may, at any time, rescind the certification of any host-vector system. If certification of a host-vector system is rescinded, the DOST-BC will instruct investigators to transfer cloned DNA into a different system or use the clones at a higher physical containment level unless the DOST-BC determines that the already constructed clones have adequate biological containment;

6.5. Certification of a given system does not extend to modifications of either the host or vector component of that system. Such modified systems must be independently certified by the DOST-BC Chairman. If modifications are minor, it may only be necessary for the investigator to submit data showing that the modifications have either improved or not impaired the major phenotypic traits on which the containment of the system depends. Substantial modifications of a certified system require the submission of complete testing data;

7. Data to be Submitted for Certification

7.1. HV1 systems other than E. coli K-12. The following types of data shall be submitted, modified as appropriate for the particular system being considered: (i) a description of the organism and vector, the strain's natural habitat and growth requirements; its physiological properties, particularly those related to its reproduction and survival and the mechanisms by which it exchanges genetic information; the range of organisms with which this organism normally exchanges genetic information and what sort of information is exchanged; and any relevant information on its pathogenicity or toxicity; (ii) a description of the history of the particular strains and vectors to be used, including data on any mutations that render this organism less able to survive or transmit genetic information; and (iii) a general description of the range of experiments contemplated with emphasis on the need for developing such an HV1 system;

7.2. HV2 Systems. Investigators planning to request HV2 certification for host-vector systems can obtain instructions from DOST-BC concerning data to be submitted. In general, the following types of data are required: (i) description of construction steps with indication of source, properties, and manner of introduction of genetic traits; (ii) quantitative data on the stability of genetic traits that contribute to the containment of the system; (iii) data on the survival of the host-vector system under non-permissive laboratory conditions designed to represent the relevant natural environment; (iv) data on transmissibility of the vector and/or a clone DNA fragment under both permissive

and non-permissive conditions; (v) data on all other properties of the system which affect containment and utility, including information on yields of phage or plasmid molecules, ease of DNA isolation, and ease of transfection or transformation. In some cases, the investigator may be asked to submit data on survival and vector transmissibility from experiments in which the host vector is fed to laboratory animals and human subjects. Such in vivo data may be required to confirm the validity of predicting in vivo survival on the basis of in vitro experiments. Data must be submitted in writing to DOST-BC. A period of 10 to 12 weeks is normally required for review and circulation of the data. Investigators are encouraged to publish their data on the construction, properties, and testing of proposed HV2 systems before the system is considered by the DOST-BC and its sub-committee;

8. Physical Containment for Large Scale Uses of Organisms Containing Recombinant DNA Molecules

This part of the Guidelines specifies physical containment guidelines for large scale (greater than 10 liters of culture) research or production involving viable organisms containing rDNA molecules. It shall apply to large scale research or production activities.

All provisions of the Guidelines shall apply to large scale research or production activities, with the following modifications:

The institution shall appoint Biological Safety Officer(s) (BSO) if it engages in large scale research or production activities involving viable organisms containing rDNA molecules.

The institution shall establish and maintain a health surveillance program for personnel engaged in large scale research or production activities involving viable organisms containing rDNA molecules, which require BL3 containment at the laboratory scale. The program shall include pre assignment and periodic physical and medical examinations; collection, maintenance, and analysis of serum specimens for monitoring serologic changes that may result from the employee's work experience; and provisions for investigating any serious, unusual, or extended illnesses of employees to determine possible occupational origin.

8.1. Selecting Physical Containment Levels

The selection of the physical containment level required for rDNA research or production involving more than 10 liters of culture is based on the containment guidelines established in Section 10. For large scale research or production, three physical containment levels are established: BL1-LS, BL2- LS, and BL3-LS;

The BL1-LS level of physical containment level required for large-scale research or production of viable organisms containing rDNA molecules that require BL1 containment at the laboratory scale. The BL2-LS level is required for large scale research or production of viable organisms containing rDNA molecules that require BL2 containment at the laboratory scale;

The BL3-LS level is required for large scale research or production of viable organisms containing rDNA molecules the require BL3 containment at the laboratory scale;

No provisions are made for large scale research or production of viable organisms containing rDNA molecules that require BL4 containment at the laboratory scale. If necessary, these requirements will be established by DOST-BC on an individual basis.

8.2. **BL1-LS Level**

8.2.1. Cultures of viable organisms containing rDNA molecules shall be handled in a closed system (e.g., closed vessel used for propagating and growing cultures) or other primary containment equipment (e.g., biological safety cabinet containing a centrifuge used to process culture fluids) designed to reduce the potential for escape of viable organisms. Volumes less than 10 liters may be handled outside of a closed system or other primary containment equipment, provided all physical containment requirements specified in Section 1.2.1 are met;

8.2.2. Culture fluids (except as allowed in Section 8.2.3) shall not be removed from devised system or other primary containment equipment unless the viable organisms containing rDNA molecules have been inactivated by a validation inactivation procedure. A validation inactivation procedure is one that has been demonstrated to be effective using the organism that will serve as the host for propagating the rDNA molecules;

8.2.3. Sample collection from a closed system and transferring culture fluids from closed system to another shall be done in a manner which minimizes the release of aerosols or contamination of exposed surfaces;

8.2.4. Exhaust gases removed from a closed system or other primary containment equipment shall be treated by filters that have efficiencies equivalent to HEPA filters or by other equivalent procedures (e.g., incineration) to minimize the release of viable organisms containing rDNA molecules;

8.2.5. A closed system or other primary containment that has held viable organisms containing rDNA molecules shall not be opened for maintenance or other purposes unless it has been sterilized by a validated sterilization procedure. A validated sterilization procedure is one that has been demonstrated to be effective using the organism that will serve as the host for propagating the rDNA molecules;

8.2.6. Emergency plans required to cover accidental spills and personnel contamination shall include methods and procedures for handling large losses of culture on an emergency basis.

8.3. **BL2-LS Level**

8.3.1. Cultures of viable organisms containing rDNA molecules shall be handled in a closed system (e.g., closed vessel used for propagating and growing cultures) or other primary containment equipment (e.g., Class III biological safety cabinet containing a centrifuge used to process culture fluids) designed to prevent the escape of viable organisms. Volumes less than ten (10) liters may be handled outside of a closed system or other primary containment equipment, provided all physical containment requirements specified in Section 1.2.2 are met;

8.3.2. Culture fluids (except as allowed in Section 8.3.3) shall not be removed from a closed system or other primary containment equipment unless the viable organisms containing rDNA molecules have been inactivated by a validated inactivation procedure. A validated inactivation procedure is one that has been demonstrated to be effective using the organisms that will serve as the host for propagating the rDNA molecules;

8.3.3. Sample collection from a closed system, the addition of materials to a closed system, and the transfer of culture fluids from one closed system to another shall be done in a manner that prevents the release of aerosols or contamination of exposed surfaces;

8.3.4. Exhaust gases removed from a closed system or other primary containment equipment shall be treated by filters that have efficiencies to HEPA filters or by other equivalent procedures (e.g., incineration) to prevent the release of viable organisms containing rDNA molecules to the environment;

8.3.5. A close system or other primary containment equipment that has held viable organisms containing rDNA molecules shall not be opened for maintenance or other purposes unless it has been sterilized by a validated sterilization procedure. A validated sterilization procedure is one that has been demonstrated to be effective using the organisms that will serve as the host for propagating the rDNA molecules;

8.3.6. Rotating seals and other mechanical devices directly associated with a closed system used for propagating and growing viable organisms containing rDNA molecules shall be designed to prevent leakage or shall be fully enclosed in ventilated housings that are exhausted through filters that have efficiencies equivalent to HEPA filters or through other equivalent treatment devices;

8.3.7. A closed system/containment equipment used for propagating and growing viable organisms containing rDNA molecules shall include monitoring or sensing devices that monitor the integrity of containment during operations;

8.3.8. A closed system used for propagating and growing viable organisms containing the rDNA molecules shall be tested for integrity of the containment features using the organism that will serve as the host for propagating rDNA molecules. Testing shall be conducted before viable organisms containing rDNA molecules are introduced and after essential containment features have been modified or replaced. Procedures and methods used in the testing shall be appropriate for the equipment design and for recovery and demonstration of the test organism. Records of tests and results shall be maintained on file;

8.3.9. A closed system used for propagating and growing viable organisms containing rDNA molecules shall be permanently identified. This identification shall be used in all records reflecting testing, operation, and maintenance, and in all documentation relating to use of this equipment for research or production activities involving viable organisms containing rDNA molecules;

8.3.10. The universal biohazard symbol *(Appendix 5)* shall be posted on each closed system and primary containment equipment when used to contain viable organisms containing rDNA molecules;

8.3.11. Emergency plans required to cover accidental spills and personnel contamination shall include methods and procedures for handling large losses of culture on an emergency basis.

8.4. **BL3-LS Level**

8.4.1. Cultures of viable organisms containing rDNA molecules shall be handled in a closed system (e.g., closed vessels used for propagating and growing cultures)

or other primary containment equipment (e.g., Class III biological safety cabinet containing a centrifuge used to process culture fluids) which is designed to prevent the escape of viable organisms. Volumes less than 10 liters may be handled outside of a closed system, provided all physical containment requirements specified in Section 1.2.3 are met;

8.4.2. Culture fluids (except as allowed in Section 8.4.3 shall not be removed from a closed system or other primary containment equipment unless the viable organisms containing rDNA molecules have been inactivated by a validated inactivation procedure. A validated inactivation procedure is one which has been demonstrated to be effective using the organisms that will serve as the host for propagating the rDNA molecules;

8.4.3. Sample collection from a closed system, the addition of materials to a closed system, and the transfer of culture fluids from one closed system to another shall be done in a manner which prevents the release of aerosols or contamination of exposed surfaces;

8.4.4. Exhaust gases removed from a closed system or other primary containment equipment shall be treated by filters which have efficiencies equivalent to HEPA filters or by other equivalent procedures (e.g., incineration) to prevent the release of viable organisms containing rDNA molecules to the environment;

8.4.5. A closed system or other primary containment equipment that has held viable organisms containing rDNA molecules shall not be opened for maintenance or other purposes unless it has been sterilized by a validated sterilization procedure. A validated sterilization procedure is one that has been demonstrated to be effective using the organisms that will serve as the host for propagating the rDNA molecules;

8.4.6. A closed system used for propagating and growing viable organisms containing rDNA molecules shall be operated so that the space above the culture level will be maintained at a pressure as low as possible, consistent with equipment design, to maintain the integrity of containment features;

8.4.7. Rotating seals and other mechanical devices directly associated with a closed system used to contain viable organisms containing rDNA molecules shall be designed to prevent leakage or shall be fully enclosed in ventilated housings that re exhausted through filters that have efficiencies equivalent to HEPA filters or through other equivalent treatment devices;

8.4.8. A closed system used for propagating and growing viable organisms containing rDNA molecules, and other primary contain- ment equipment used to contain operations involving viable organisms containing rDNA molecules shall include monitoring or sensing devices that monitor the integrity of containment during operations

8.4.9. A closed system used for propagating and growing viable organisms containing rDNA molecules shall be tested for integrity of the containment features using the organisms that will serve as the host for propagating the rDNA molecules. Testing shall be conducted before viable organisms containing rDNA molecules are introduced and after essential containment features have been modified or replaced. Procedures and methods used in the testing shall be appropriate for

the equipment design and for recovery and demonstration of the test organism. Records of tests and results shall be maintained on file;

8.4.10. A closed system used for propagating and growing of viable organisms containing rDNA molecules shall be permanently identified. This identification shall be used in all records reflecting testing, operation, and maintenance and in all documentation relating to the use of this equipment for research production activities involving viable organisms containing rDNA molecules;

8.4.11. The universal biohazard symbol *(Appendix 5)* be posted on each closed system and primary containment equipment when used to hold viable organisms containing rDNA molecules;

8.4.12. Emergency plans required to cover accidental spills and personnel contamination shall include methods and procedures for handling large losses of culture on an emergency basis;

8.4.13. Closed systems and other primary containment equipment used in handling cultures of viable organisms containing rDNA molecules shall be located within a controlled area that meets the following requirements:

8.4.13.1. The controlled area shall have a separate entry area. The entry area shall be a double doored space such as an air lock, anteroom, or change room that separates the controlled area from the balance of the facility;

8.4.13.2. The surfaces of walls, ceilings, and floors in the controlled area shall be such that they can be readily cleaned and decontaminated;

8.4.13.3. Penetrations into the controlled area shall be sealed to permit liquid or vapor phase space decontamination;

8.4.13.4. All utilities and service or process piping and wiring entering the controlled area shall be protected against contamination;

8.4.13.5. Hand-washing facilities equipped with valves that can be operated by foot, by elbow, or automatically shall be located at each major work area and near each primary exit;

8.4.13.6. A shower facility shall be provided. This facility shall be located near the controlled area;

8.4.13.7. The controlled area shall be designed to preclude release of culture fluids outside the controlled area when an accidental spill or release from the closed systems or other primary containment equipment occurs;

8.4.13.8. The controlled area shall have a ventilation system that is capable of controlling air movement. The movement of air shall be from areas of lower contamination potential to areas of higher contamination potential. If the ventilation system provides positive pressure air supply, the system shall operate in a manner that prevents the reversal of the direction of air movement or shall be equipped with an alarm that would be activated when reversal in the direction of air movement occurs. The

exhaust air from the controlled area shall not be re-circulated to other areas of the facility. The exhaust air from the controlled area may be discharged to the outdoors without filtration or other means of effectively reducing an accidental aerosol burden, provided that it can be dispersed clear of occupied buildings and air intakes.

8.4.14. The following personnel and operational practices shall be required:

8.4.14.1. Personnel entry into the controlled area shall be through the entry area specified in Section 8.4.13.1;

8.4.14.2. Persons entering the controlled area shall exchange or cover their personal clothing with work garments such as jumpsuits, laboratory coats, pants and shirts, head cover, and shoes or shoe covers. On exit from the controlled area, the work clothing may be stored in a locker separate from that used for personal clothing or discarded for laundering. Clothing shall be decontaminated before laundering;

8.4.14.3. Entry into the controlled area when work is in progress shall be restricted to those persons required to meet program or support needs. Prior to entry, all persons shall be informed of the operating practices, emergency procedures, and the nature of the work conducted;

8.4.14.4. Access doors to the controlled area shall be kept closed, except as necessary for access, while work is in progress. Service doors leading directly outdoors shall be sealed and locked while work is in progress;

8.4.14.5. Persons under 18 years of age shall not be permitted to enter the controlled area;

8.4.14.6. The universal biohazard symbol *(Appendix 5)* shall be posted on entry doors to the controlled area and all internal doors when any work involving the organism is in progress. This includes periods when decontamination procedures are in progress. The sign posted on the entry doors to the controlled area shall include a statement of agents in use and personnel authorized to enter the controlled area;

8.4.14.7. Persons shall wash their hands when leaving the controlled area;

8.4.14.8. The controlled area shall be kept neat and clean;

8.4.14.9. Eating, drinking, smoking, and storage of food are prohibited in the controlled area;

8.4.14.10. An effective insect and rodent control program shall be maintained;

8.4.14.11. Persons working in the controlled area shall be trained in emergency procedures;

8.4.14.12. Equipment and materials required for the management of accidents involving viable organisms containing rDNA molecules shall be available in the controlled area;

8.4.14.13. The controlled area shall be decontaminated in accordance with established procedures following spills or other accidental release of viable organisms containing rDNA molecules.

9. Biological safety cabinets are classified as Class I, Class II, or Class III cabinets.

9.1. A **Class I cabinet** is a ventilated cabinet for personnel protection; air in it flows inward, away from the operator. The exhaust air from this cabinet filters through a HEPA filter. This cabinet is used in three operational models: (1) with full-width open front, (2) with an installed front closures panel (having four 5 inch diameter openings) without gloves, and (3) with an installed front closure panel equipped with arm-length rubber gloves. The face velocity of the inward flow of air through the full width open front is 75 feet per minute or greater;

9.2. A **Class II cabinet** is a ventilated cabinet for personnel and product protection; it has an open front with inward airflow for personnel protection, and HEPA filtered mass recirculated airflow for product protection. The cabinet exhaust air is filtered through a HEPA filter. The face velocity of the inward flow of air through the full width open front is 75 feet per minute or greater;

9.3. A **Class III cabinet** is a closed front ventilated cabinet of gas-tight construction, which provides the highest level of personnel protection among biohazard safety cabinets. The interior of the cabinet is protected from contaminants outside of the cabinet. The cabinet is fitted with arm length rubber gloves and is operated under a negative pressure of at least 0.5 inch water gauge. All air supply is filtered through HEPA filters. Exhaust air is filtered through two HEPA filters or one HEPA filter and incinerator before being discharged to the outside environment.

10. Container Requirements

10.1. **Plants and plant parts**

All plants or plant parts, except seeds, cells, and sub cellular elements shall be packed in a sealed plastic bag of at least 5 mil thickness, inside a sturdy, sealed, leakproof, outer shipping container made of corrugated fiberboard, corrugated cardboard, or other material of equivalent strength.

10.2. **Seeds**

All seeds shall be transported in a sealed plastic bag of at least 5 mil thickness, inside a sealed metal container, which shall be placed inside a second sealed metal container. Shock absorbing cushioning material shall be placed between the inner and outer metal containers. Each metal container shall be independently capable of protecting the seeds and preventing spillage or escape. Each set of metal containers shall then be enclosed in a sturdy outer shipping container made of corrugated fiberboard, corrugated cardboard, wood or other material of equivalent strength.

10.3. **Live microorganisms and/or etiologic agents, cells, or sub cellular elements**

All regulated materials which are live (non-inactivated) microorganisms, or etiologic agents, cells, or sub cellular elements shall be packed as specified below:

10.3.1. *Volume not exceeding 50 ml*

Regulated materials not exceeding 50 ml shall be placed in a securely closed watertight container, primary container (test tube, vial, etc.) which shall be enclosed in a second, durable watertight container (secondary container). Several primary containers may be enclosed in a single secondary container, if the total volume of all the primary containers so enclosed does not exceed 50 ml. The space at the top, bottom, and sides between the primary and secondary containers shall contain sufficient nonparticulate absorbent material (e.g., paper towel) to absorb the entire contents of the primary container(s) in case of breakage or leakage. Each set of primary and secondary containers shall then be enclosed in an outer shipping container made of corrugated fiberboard, corrugated cardboard, wood, or other material of equivalent strength.

10.3.2. *Volume exceeding 50 ml*

Regulated materials that exceed a volume of 50 ml shall comply with requirements enumerated in Section 10.3.1. In addition, a shock absorbing material, in volume at least equal to that of the absorbent material between the primary and secondary containers, shall be placed at the top, bottom, and sides between the secondary container and the outer shipping container. Single primary containers shall not contain more than 1,000 ml of material. However, two or more primary containers whose combined volumes do not exceed 1,000 ml may be placed in a single, secondary container. The maximum amount of microorganisms of etiologic agents, cells, or sub cellular elements which may be enclosed within a single outer shipping container shall not exceed 4,000 ml.

10.4. **Insects, Mites, and Related Organisms**

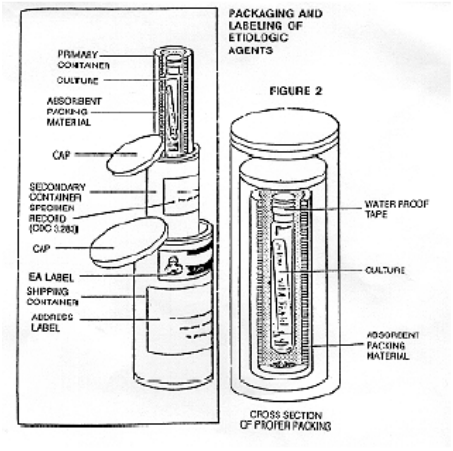
Insects (any life stage) shall be placed in an escape proof primary shipping container (insulated vacuum container, glass, metal, plastic, etc.) and sealed to prevent escape. Such primary container shall be placed securely within a secondary shipping container of crushproof styrofoam or other material of equivalent strength. One or more rigid ice packs may also be placed within the secondary shipping container, and sufficient packing material shall be added around the primary container to prevent movement of the primary shipping container. The secondary (styrofoam or other) container shall be placed securely within an outer shipping container made of corrugated fiberboard, corrugated cardboard, wood, or other material of equivalent strength.

10.5. **Other Macroscopic Organisms**

All macroscopic organisms that are not plants and which requires continuous access to atmospheric oxygen shall be placed in primary shipping made containers made of a sturdy, crushproof frame of wood, metal, or material of equivalent strength, surrounded by escaped proof mesh or netting of a strength and mesh size sufficient to prevent the escape of the smallest organism in the shipment, with edges and seams of the mesh or netting sealed to prevent escape organisms. Each primary shipping container shall be securely placed within a larger secondary shipping container made of wood, metal, or equivalent strength material. The primary and secondary shipping containers shall then be placed securely within an outer shipping container made of corrugated cardboard, wood, or other material of equivalent strength. The outer container may have air holes or spaces in the sides and/or ends of the container, provided that the outer shipping

container must retain sufficient strength to prevent crushing of the primary and secondary shipping containers.

10.6. **Illustration of suitable packaging and labeling of regulated materials**



IV. Policy and Procedures for Application for Contained Use of Genetically Modified Organisms

1. Application for contained use of GMOs. Application for contained use, which include experiments inside laboratory, screenhouse, greenhouse, and glasshouse shall be regulated by the DOST-BC.

The research laboratory/screenhouse/greenhouse/glasshouse and its location must be certified by the IBC/DOST-BC as having complied with biosafety standards and requirements. Its operation should be monitored monthly by the IBC.

After proper evaluation, the DOST-BC can delegate the regulation of contained experiments under the mandate of other department biosafety committees, i.e. Departments of Agriculture, Health, and Environment and Natural Resources.

1.1. **DOST-BC Approval.** No person or institution shall conduct any experiment involving any GMO inside the laboratory/screenhouse/greenhouse/glasshouse without the prior approval of the DOST-BC. However, approval by the DOST-BC does not in any way exempt the project Proponent from complying with any rules, regulations or requirements of other government regulatory authorities. It is the sole responsibility of the Proponent to determine if the proposed activities require any permit, license or approval of such regulatory authorities, and to obtain the same if required.

1.2. **The Proposal**

1.2.1. The proposal shall be in writing and in accordance with the prescribed format shown in *Annex 3 - Project Proposal for Contained Use of GMOs* of this Manual. The Proponent must answer all questions including the sub-questions. The answers must be supported by data and relevant scientific literature, all of which shall be appended to the proposal. The Proponent must disclose all data or literatures that allude to potential adverse effects on human health or the environment by the GMO to be used.

1.2.2. If the proposal contains any information which the Proponent wishes to be kept confidential, the pages containing such information shall be conspicuously marked as “Commercial-in-Confidence”. The Proponent shall specify in writing why the marked pages should be held in confidence. However, no information pertaining to the potential adverse effects of the GMOs on human health or the environment shall be considered confidential.

1.2.3. The proposal shall then be submitted by the Proponent to the IBC for assessment.

1.3. **IBC Evaluation**

1.3.1. The IBC shall evaluate the proposal, specifically whether data obtained in the laboratory or under contained conditions provide sufficient basis to authorize the contained test of the GMO. The IBC should also make an initial assessment of the suitability of the proposed research facility. In making such an evaluation, the IBC must ensure that the proposed activities do not pose any unnecessary risks to the environment or human health.

1.3.2. During the evaluation, the IBC shall consult and discuss with the Proponent and, when appropriate, make suggestions for revisions.

1.3.3. The IBC may require the Proponent to state in his or her proposal any information in addition to those required by the DOST-BC.

1.3.4. The IBC may consult with experts in the scientific disciplines relevant to the proposed contained test of the GMO or knowledgeable in the policies of the institution, relevant laws, standards of professional conduct or practice, community attitudes and practices, and the potential environmental and human health impact of the proposed activity.

1.3.5. After evaluation, the IBC shall decide whether or not to endorse the proposal to the DOST-BC. The proposal must be endorsed by the majority of the IBC members. At least one (1) community representative must approve before the proposal may be endorsed by the IBC to the DOST-BC. Dissenting members of the IBC must indicate the reasons for disapproving the proposal.

1.4. **Endorsement of Proposal by IBC to the DOST-BC**

1.4.1. Approval by a majority of the IBC members, which must include at least one (1) community representative, shall be necessary before any proposal may be endorsed for approval by the IBC to the DOST-BC. Dissenting members of the IBC must indicate the reasons for disapproving the proposal.

1.4.2. The IBC endorsement shall be submitted to the DOST-BC through the DOST-BC Secretariat, and shall include the following:

1.4.2.1. Cover Sheet, in accordance with the form shown in *Annex 1 – Cover Sheet for Application for Contained Use of GMOs*, duly signed and dated by the IBC members (1 soft copy and 15 hard copies);

1.4.2.2. Proposal in two versions:

1.4.2.2.1. Full blown/complete version (1 soft copy and 15 hard copies);

1.4.2.2.2. Commercial-in-Confidence (CIC) deleted version (1 soft copy and 1 hard copy); and,

1.4.2.2.3. An executive summary (1 soft copy and 15 hard copies).

1.4.2.3. Attachments, as applicable: Gantt chart and detailed schedule of activities, plasmid map, references and relevant scientific publications, location map of the screenhouse/greenhouse/glasshouse, Biosafety Contingency Plan, Summary of Introduced Genes (All attachments in 1 soft copy and 15 hard copies);

1.4.2.4. List of all personnel (*Annex 3-J)* who will be involved in the project together with their corresponding curriculum vitae *(Annex 3-JA)* and roles in the proposed experiment (1 soft copy and 15 hard copies);

1.4.2.5. Filled out *Checklist of Requirements for Application for Contained Use of GMOs (Annex 3-A)* for the DOST-BC Secretariat's use.

(The documents should be properly paginated and tables/figures be labeled.)

The DOST-BC reserves the right not to act on any proposal or endorsement which does not comply with the prescribed format or fails to include all the required attachments.

1.4.2.6. Materials marked as Commercial-in-Confidence (CIC) by the Proponent shall be treated as such by the DOST-BC, except in the following conditions:

1.4.2.6.1. they contain information pertaining to the potential adverse effects of the organisms on human health or the environment; or,

1.4.2.6.2. the DOST-BC, in its sole discretion, determines that there is nothing proprietary with the information as would require confidentiality. In the event that the DOST-BC decides that some disclosure is necessary, the DOST-BC shall notify the Proponent, through the IBC, in writing for the purpose of negotiating an acceptable resolution. If agreement is not reached, the Proponent must withdraw the proposal; in which case, the DOST-BC shall be duty bound not to disclose the information deemed confidential by the Proponent.

1.5. **Initial Assessment by DOST-BC Secretariat**

1.5.1. Upon receipt of the documentary submissions from the IBC, the DOST-BC Secretariat shall check whether or not the required format and attachments have been complied with. If the proposal complies with the required format and has all the necessary attachments, the DOST-BC Secretariat shall schedule the review of the proposal by the DOST-BC and notify the IBC accordingly.

1.5.2. On the other hand, if the proposal is incomplete or the format is not complied with, the DOST-BC Secretariat shall immediately inform the Proponent through the IBC of the missing requirements. The Proponent shall then be given a reasonable period within which to complete these requirements. No proposal shall be submitted to the DOST-BC for review unless in the proper format and all required documents are appended.

1.6. **Review by External Expert(s)**

1.6.1. Upon receipt of the proposal from the DOST-BC Secretariat, the DOST-BC may refer the proposal to individual expert(s) to evaluate the potential adverse effects of the project to human health and environment. The expert shall be chosen from the NCBP pool of experts or from the pool of experts of the DOST Sectoral Councils or any appropriate body duly recognized by the DOST.

1.6.2. The selected Technical Expert shall be provided with the copy of the proposal after executing the Oath of Confidentiality to maintain and respect the confidentiality of information declared by the Proponent, and approved by the DOST-BC, to be “Commercial-in-Confidence” (CIC). The Technical Expert shall submit to the DOST-BC its recommendations in writing not later than thirty (30) days from receipt of the proposal from the DOST-BC Secretariat; or,

1.6.3. The DOST-BC may create a Scientific and Technical Review Panel (STRP) to evaluate potential adverse effects of the project to human health and environment. The STRP shall be appointed by the Chairman of the DOST-BC. The STRP shall be composed of at least three (3) members chosen, if possible, from the NCBP pool of experts or from the pool of experts of the DOST Sectoral Councils or any appropriate body duly recognized by the DOST. As far as practicable, no member of the DOST-BC and other department biosafety committees shall be part of the STRP.

1.6.4. The STRP shall be provided copies of the proposal after executing the Oath of Confidentiality to maintain and respect the confidentiality of information declared by the Proponent, and approved by the DOST-BC, to be "Commercial-in-Confidence" (CIC). The STRP shall submit to the DOST-BC its recommendations in writing not later than thirty (30) days from receipt of the proposal from the DOST-BC Secretariat.

1.7. **DOST-BC Assessment and Decision**

1.7.1. The DOST-BC shall act on the proposal for contained use inside the laboratory/screenhouse/greenhouse/glasshouse within sixty (60) days from receipt of the documents mentioned in Item 1.4.2. above.

1.7.2. The DOST-BC shall base its evaluation on the following:

1.7.2.1. Proposal, including amendments and attachments;
1.7.2.2. IBC assessment;
1.7.2.3. External Technical Expert review or STRP review, if any; and,
1.7.2.4. Such other documents or information, from whichever source, deemed relevant by the DOST-BC.

1.7.3. The DOST-BC shall notify the Proponent, through the IBC, in writing of its decision. The approval will be subject to the adherence to the procedures stated in the approved proposal and observance of the limited access to the contained facilities policy.

1.7.4. Any change in the approved proposal shall be subject to the consideration and approval of the IBC/DOST-BC. The approval may also be subject to additional conditions which the DOST-BC deems as necessary. If the proposed activity requires a permit or authority from other government regulatory agencies, and the issuance of the same is conditioned upon approval of the proposal by the DOST-BC, the DOST-BC shall issue an endorsement to facilitate the issuance of the said permit or authority. In case a proposal is disapproved, the DOST-BC shall state the reason or reasons for disapproval.

1.8. **Request for Reconsideration.** The Proponent, through the IBC, may request the DOST-BC for reconsideration within sixty (60) days from receipt of the notice of disapproval. The request shall state all the grounds for reconsideration. The DOST-BC shall have sixty (60) days to act on the request for reconsideration. Unless otherwise stated in writing, failure on the part of the DOST-BC to act within the said period shall be considered as denial of the request. The decision of the DOST-BC relative to the request for reconsideration shall be final.

1.9. **New Data or Information on Risks.** In case new data or information that will reduce significantly biosafety risks that caused the disapproval of the proposal later becomes

available, the Proponent may re-submit the proposal to the IBC together with the new data or information. The re-submitted proposal shall be evaluated in the same manner as that of a new proposal.

2. Implementation of approved proposal to be supervised by DOST-BC in cooperation with line agencies. The implementation of the proposal shall be in accordance with activities submitted by the Proponent and duly approved by the DOST-BC.

2.1. **Responsibilities of Proponent.** The Proponent shall be responsible for the overall implementation of the approved proposal for contained experiments of GMOs to be done inside laboratory/screenhouse/greenhouse/glasshouse. The Proponent must be thoroughly familiar with the provisions of existing biosafety guidelines. During the conduct of the approved project, the Proponent shall:

2.1.1. Comply with the additional advice, recommendations and requirements of the DOST-BC on the approved project;

2.1.2. Ensure that the project complies with existing guidelines and with all the conditions imposed by the DOST-BC as stipulated in the DOST-BC approval letter;

2.1.3. Ensure that all personnel involved in the project are aware of biosafety requirements of the work and that they have received appropriate training in safety and emergency procedures;

2.1.4. Seek the approval of the IBC and the appropriate DOST-BC of all changes in the conduct of activities and in the composition of the personnel involved in the project; and

2.1.5. Report immediately to the IBC all unexpected observations, results or accidents and unexplained illnesses or absences of personnel which may be attributed to the activities involving GMOs.

2.2. **Responsibilities of DOST-BC in cooperation with other agencies**

Monitoring

2.2.1. The IBC, DOST-BC and appropriate government authorities shall monitor the contained experiments of GMOs. The IBC and DOST-BC monitors shall submit to the DOST-BC the results of monitoring activities at intervals specified in the approved monitoring schedule.

2.2.2. In accordance with agreements with line agencies:

2.2.2.1. the Department of Agriculture shall be responsible for monitoring the movement and effects of GMOs approved for the contained experiments;

2.2.2.2. the Department of Environment and Natural Resources shall be responsible for monitoring the environmental effects of the contained experiments; and,

2.2.2.3. the Department of Health shall be responsible for monitoring the effects of contained experiments to human health.

2.2.2.4. The DOST-BC reserves the right to inspect the laboratory/screenhouse/greenhouse/glasshouse facilities and confined test area at any time. Site inspections shall be carried out in such a manner as to avoid interfering with the activities of the Proponent, unless intervention is necessary to avert any imminent danger to human health or the environment.

2.3. **Reportorial Requirements**

2.3.1. *Reports from the IBC*

2.3.1.1. **Annual report of projects under supervision during the year.** The IBC shall submit a report to the DOST-BC not later than the 15th day of March of each year. The report shall be for the period January to December of the preceding year, and shall include the following information:

2.3.1.1.1. Composition of the IBC;

2.3.1.1.2. All activities using GMOs (contained/confined field tests) conducted during the year, including any changes of Proponents and associated personnel;

2.3.1.1.3. Modifications in the test activities of GMOs vis-a-vis the original proposals submitted to the DOST-BC;

2.3.1.1.4. Description of unexpected results from the test activities involving GMOs and their adverse impact to health or the environment;

2.3.1.1.5. Description of accidents or incidents attributable to the test activities involving GMOs and the adverse effects thereof;

2.3.1.1.6. Fate of materials generated from supervised activities; and,

2.3.1.1.7. Any other matters which the IBC may wish to bring to the attention of the DOST-BC.

2.3.1.2. **Completion report** of each supervised experiment under contained experiment in laboratory/screenhouse /greenhouse/glasshouse.

The IBC shall submit a report upon completion of a contained experiment in laboratory/screenhouse/greenhouse/glasshouse and confined test to the DOST-BC in accordance with the format in *Annex 6 – IBC Repot after Completion of Contained Use of GMOs*, not later than one hundred twenty (120) days from completion date.

2.3.1.3. **Incident report**. In case of any accident or untoward incident that may put human health or the environment at risk, the Proponent shall immediately report the same to the IBC and the DOST-BC. 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 DOST-BC relieve the Proponent and the institution of their obligations under the law. The DOST-BC may require the IBC to submit follow-up reports on the long-term effects of the contained experiment.

2.3.2. *Reports from the Proponent*

2.3.2.1. **Progress report**. The Proponent 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, in accordance with *Annex 4*, in one (1) soft and 15 hard copies.

2.3.2.2. **Incident report**. The Proponent shall report immediately to the IBC and DOST-BC any unexpected observations, untoward incidents, results or accidents and unexplained illnesses or absences of personnel which may be attributed to the activities involving GMOs. The Proponent shall ensure that appropriate measures have been applied based on their submitted biosafety contingency plan and best laboratory practices. The Proponent must ensure the safety of their personnel and account for the experimental materials in the occurrence of untoward incidents. Such incidents and action taken shall be reported by Proponent, through the IBC, to the DOST-BC. The DOST-BC shall also inform the NCBP as appropriate.

2.3.2.3. **Completion report.** The Proponent shall submit a completion report of the laboratory/screenhouse/greenhouse/glasshouse to the IBC 90 days after its completion, in accordance with the format in *Annex 5*, in one (1) soft and 15 hard copies to the IBC. The completion report cannot be submitted unless the post-harvest monitoring activities have been accomplished. The report shall specify, among others, whether the objectives of the experiment were achieved; the nature and consequences of the adverse effects, if any, of the contained experiments; and the fate of the GMO after the contained or confined test. The IBC shall review the completion report of the Proponent and endorse it to the DOST-BC within 120 days from completion date of the project.

2.3.3. *Reports from the Monitor*

2.3.3.1. **Inspection report.** The DOST-BC shall assign an Inspection team who shall inspect a proposed new laboratory/screenhouse/ greenhouse/glasshouse to check the appropriateness of the facility/area for the proposed activities. The DOST-BC may also assign an Inspection team to re-inspect or validate a previously approved contained facility. After the inspection, the Inspection team shall submit the inspection report which shall include its observations and recommendations to the DOST-BC for approval.

2.3.3.2. **Monitoring activity report.** The monitors from the Post-Entry Quarantine Service (PEQS) of the Bureau of Plant and Industry and DOST-BC shall:

2.3.3.2.1. Submit monitoring report for each activity, including but not limited to, compliance to contained biosafety requirements, activities undertaken, pest/disease monitoring, staff/persons involved in the activity, and other observations. The report shall be signed by the monitor, IBC representative and the Proponent present during the activity;

2.3.3.2.2. Submit lists of authorized persons including the date and purpose of the activity;

2.3.3.2.3. Include the materials management for the specific activity, *e.g.* report quantity of viable materials, in the monitoring report;

2.3.3.2.4. Report immediately any unexpected observations, untoward incidents, violations, non-compliance to the DOST-BC. The DOST-BC shall take appropriate action. Such incidents and action taken shall be reported by the DOST-BC to the NCBP as appropriate;

2.3.3.2.5. Submit the report for the specific activity to the identified focal person for monitoring, documentation and filing 3 days after the activity; and,

2.3.3.2.6. Submit to the DOST-BC a copy of the monitoring report.

2.3.3.3. **Incident report.** The monitors shall report immediately any unexpected observations, untoward incidents, violations, and non-compliance to the DOST-BC. The DOST-BC shall take appropriate action. Such incidents and actions taken shall be reported by the DOST-BC to the NCBP as appropriate.

2.3.3.4. **Completion report**. The monitors shall submit the completion report to the DOST-BC 60 days after the experiment.

2.3.4. *Report from the DOST-BC.* For every completed project, the DOST-BC will have an analysis for future reference and use for subsequent related experiments and may also be forwarded to the appropriate department biosafety committee as needed.

2.4. Endorsements and Certificates

2.4.1. If the proposed activity requires a permit or authority from other government regulatory agencies, and the issuance of the same is conditioned upon approval of the proposal by the DOST-BC, the DOST-BC shall issue an endorsement to facilitate the issuance of the said permit or authority *(e.g.*, DOST-BC endorsement to the Bureau of Plant Industry for the issuance of permit to import the regulated materials).

2.4.2. The DOST-BC may also endorse and delegate regulation of contained experiments under the mandate of the appropriate department biosafety committees depending on its assessment.

2.4.3. A *Certificate of Completion* shall be issued by the DOST-BC for completed contained experiments which have met the objectives set, regardless of whether they have plans of conducting further experimentation or not.

2.5. **Withdrawal of the DOST-BC Approval**

2.5.1. *Grounds for Revocation of Approval.* The following are the grounds for revocation of any project approval:

2.5.1.1. Failure of the Proponent to comply with the Philippine Biosafety Guidelines or any of the conditions imposed by the DOST-BC for approval of the project, including, but not limited to failure to adhere to restrictions and schedule of activities and protocols imposed by the DOST-BC;

2.5.1.2. Receipt by the DOST-BC of reliable data or information indicating that the activity involving GMOs may pose a threat to human health or the environment; and,

2.5.1.3. Such other grounds as the DOST-BC may deem reasonable to protect human health or the environment.

2.6. **Procedure for Revocation**

2.6.1. The DOST-BC shall advise the Proponent, through the IBC, in writing of the existence of grounds to revoke the project approval. The Proponent shall have a period of not more than ten (10) days within which to explain in writing why the approval should not be revoked. The DOST-BC shall render its decision within ten (10) days from receipt of the explanation of Proponent.

2.6.2. In case of imminent danger to human health or the environment, the DOST-BC Chair may immediately revoke any project approval on his or her own accord, without need of consulting the other members. Thereafter, the DOST-BC, after deliberation, shall either confirm or lift, in writing, the revocation order issued by the Chair. The DOST-BC shall have sixty (60) days therefrom to furnish the Proponent, through the IBC, a written explanation of its action.

2.6.3. **Effect of Revocation.** In the event of revocation, any permit or authority issued by other government authorities on the strength of the previous DOST-BC approval may also be revoked immediately. Further, the DOST-BC may order the Proponent or any government authority to destroy the GMO.

2.7. **Penalties and Sanctions**. In addition to revocation of the project approval, any violation of the provisions of this Manual or the concealment or withholding by the Proponent of any information necessary to evaluate risks to human health or the environment shall be ground for the forfeiture of government research grants. Further, any incentives that may have been granted the Proponent or institution for contributing to advanced scientific or technological research and development may be withheld. These penalties are exclusive of any other penalties that may be imposed under existing laws, including, but not limited to, civil, criminal and administrative liabilities for gross negligence.

ANNEX 1

COVER SHEET[1]

IBC ASSESSMENT OF THE PROJECT PROPOSAL FOR CONTAINED USE OF GMOS IN LABORATORY/SCREENHOUSE/GREENHOUSE/GLASSHOUSE

Fields marked with an asterisk (*) are mandatory

General Information	
DOST-BC Reference number (To be filled out by DOST BC Secretariat)	
Project Title*	
Name of Organization*	
Supervising IBC*	
Other IBCs involved	
Project Duration*	

Project Leader(s) *	
Name	
Position	
Address	
Telephone/Fax Number	
Mobile Number	
E-mail Address	
Name	
Position	
Address	
Telephone/Fax Number	
Mobile Number	
E-mail Address	

[1] The DOST-BC prohibits any modification (removal/deletion of any section/item) to the prescribed format of this document.

Other Organization(s)	
Government Authority(ies) Consulted about this Project, if applicable. (Use extra sheet if necessary)	
Name and Address of Organizatio	
Contact Person	
Contact Details (Telephone Numbe / Email address)	
Government Authority(ies) to whom DOST-BC Approval, Endorsement or Advice on the proposal should be sent, if applicable. (Use extra sheet if necessary)	
Name of Authority	
Addressee/Contact Person	
Telephone and Fax Numbers	
E-mail Address	

Additional Information	
Give an evaluation of the project including a comment on the projec supervisor's capability to manage the work, the adequacy of the project design, site selection, and contingency plans*	
On what specific points does the IBC seek the Committee's advice?	

IBC Assessment		
Name of IBC Chairman / Signature Date	**Decision (Approved / Disapproved)**	**Reason for abstaining** (use additional sheet if necessary
Name of IBC Members and Community Representatives / Signature / Date	**Decision (Approved / Disapproved)**	**Reason for abstaining** (use additional sheet if necessary

Over-All IBC Assessment

☐ Approved ☐ Approved subject to the following conditions : ☐ Disapproved

Name of the IBC Chairperson	
Signature	
Date	

ANNEX 2

EXECUTIVE SUMMARY[1]

FOR CONTAINED USE (LABORATORY/SCREENHOUSE/GREENHOUSE/GLASSHOUSE)

Project Title	
Name(s) of Project Leader(s)	
Name of Institution(s):	
Cooperating Institution	

EXECUTIVE SUMMARY (Brief description of proposed activity, site, duration, GM crop and specific objectives.)

[1] The Executive Summary should not contain any Confidential Business Information (CBI)

ANNEX 3

PROJECT PROPOSAL[1]
FOR CONTAINED USE OF GMOS
(LABORATORY/SCREENHOUSE/GREENHOUSE/GLASSHOUSE)

Project Title	
Name(s) of Project Leader(s)	
Name of Institution(s):	
Cooperating Institution	

A. OBJECTIVES	
What are the objectives of the proposed activity?	
B. MATERIALS AND METHODS	
b.1. Degree of genetic manipulation	
b.2. Methodology/Protocol (including timetable of activities)	
b.3. Location of Experiment[2]	
b.4. Characteristics of Research Organism[3]	
b.4.1 Local Strains	
b.4.1.1 Collected within the region (mention exact location)	
b.4.1.2 Collected from other regions – origin of strains	
b.4.2 Strains to be imported (if any)	
b.4.2.1 Not present in the country	
b.4.2.2 Present but of restricted distribution in the country	
b.4.2.3 Widely distributed in the country	
b.4.3. Genetically Modified Strains	
b.4.4. Auto-Ecology	

[1] The DOST-BC prohibits any modification (removal/deletion of any section/item) to the prescribed format of the proposal. If the proposal is found to have deviated from the prescribed format, the proposal shall not be accepted for evaluation by the DOST-BC and will be returned to the proponent through the IBC for modifications for strict compliance with the DOST-BC requirements.

[2] Please provide the location map of the contained facility on a separate sheet *(Annex 3-G)*

[3] Please indicate point of origin, amount / volume of all materials that will be used in the experiment *(Annex 3-I)*

C. FOR EXPERIMENTS INVOLVING rDNA PLANT	
c.1. Host Organism for rDNA experiment	
c.1.1 Nomenclature	
c.1.2 The state of cultivation or distribution in nature	
c.1.3 Reproductive cycle	
c.1.4 Possibility of natural crossing to related species	
c.1.5 Producibility of toxic substances	
c.1.6 Weediness/effect on environment (soil, water, etc.)	
c.1.7 Auto-Ecology	
c.2 Characteristics of Donor DNA	
c.2.1 Constitution and Origin	
c.2.2 Functions of the target gene	
c.2.3 Characteristics of donor organism	
c.2.3.1. Taxonomy, identification, source culture	
c.2.3.2. The state of cultivation, distribution in nature	
c.2.3.3. Reproductive cycle	
c.2.3.4. Possibility of natural crossing to related species	
c.2.3.5. Producibility of toxic substances	
c.2.3.6. Weediness	
c.2.3.7. Auto-Ecology	
c.2.3 Name, designation, origin and characteristics of the vector	
c.2.4 Construction method of the rDNA organisms (where applicable):	
c.2.4.1 Structure and construction method of the recombinant molecule	
c.2.4.2 Method to introduce target genes into recipient cells	
c.2.5 Characteristics of the rDNA organisms (where applicable):	

c.2.5.1 Comparison with recipient organisms	
c.2.5.2 Localization, copy number and stability of the target gene in recipient cell	
c.2.5.3 Stability of the introduced gene expression	
c.2.6 Other important points obtained in the rDNA experiment to develop the rDNA organisms	
c.2.7 Characteristics of the plant for breeding material	
c.2.7.1 Form of heredity of the target phenotype	
c.2.7.2 Genetic stability of the target phenotype	
c.2.7.3 Reproductive cycle	
c.2.7.4 Natural crossing possibility to related species	
c.2.7.5 Producibility of toxic substances	
c.2.7.6 Weediness/effect on environment (soil, water, etc.)	
c.2.7.7 Auto-Ecology	
c.2.8 Object of the breeding	
c.2.9 Other important points obtained in the rDNA experiment or in the process of growing into breeding material	
D. FOR EXPERIMENTS INVOLVING rDNA MICROORGANISM	
d.1 Characteristics of the recipient organisms	
d.1.1 Nomenclature (scientific name and strain)	
d.1.2 Genetic properties (Characteristics)	
d.1.1.1 History of prior genetic manipulation, if any	
d.1.1.2 Factors which might limit the reproduction, growth and survival of the recipient organisms; stability of genetic traits.History of prior genetic manipulation, if any	
d.1.3 Characteristics and stability of plasmids, phages, viruses, in the recipient organisms	

d.1.4 Reproductive cycle (sexual or asexual).	
d.2 Pathogenicity, active compounds	
d.2.1 Pathogenicity (details and availability of appropriate prophylaxis and therapies, if any)	
d.2.2 Producibility of biological active compounds	
d.2.3 Adventitious agents;	
d.2.4 Prior reports of a history of industrial use, if any.	
d.2.1 Pathogenicity (details and availability of appropriate prophylaxis and therapies, if any)	
d.3 Characteristics of the related strain of recipient organisms:	
d.3.1 Natural habitat and geographic distribution	
d.3.2 Genetic traits	
d.3.2.1 Characteristics and stability of plasmids, phages, viruses, in the recipient organisms	
d.3.2.2 Crossing possibility.	
d.3.3 Pathogenicity, active compounds	
d.3.3.1 Pathogenicity (details and availability of appropriate prophylaxis and therapies, if any)	
d.3.3.2 Producibility of biological active compounds	
d.4 Characteristics of the related strain of recipient organisms:	
d.4.1 Construction origin	
d.4.2 Functions of the objective genes	
d.4.3 Properties of DNA donor	
d.4.3.1 Nomenclature (scientific name and strain);	
d.4.3.2 Pathogenicity, producibility of biological active compounds.	
d.5. Name, designation, origin, characteristics of the vector	
d.6 Construction method of the rDNA organisms	
d.6.1 Structure and construction method of the recombinant molecules	

d.6.2 Method to introduce target genes into recipient cells.	
d.7 Characteristics of the rDNA organisms	
d.7.1 Comparison with recipient organisms	
d.7.1.1 Characteristics with respect to survival, growth and reproduction;	
d.7.1.2 Crossing possibility;	
d.7.1.3 Pathogenicity, infectivity	
d.7.1.4 Producibility of biological active compounds	
d.7.2 Target Gene	
d.7.2.1 Localization, copy number and stability of the target gene in recipient cells	
d.7.2.2 Stability of the introduced gene expression;	
d.7.2.3 PathoGenetic manipulations applied to already modified rDNA organisms;genicity, infectivity	
d.7.2.4 Method to restrict the multiplicating ability in open environment	
d.8 Other important remarks obtained in the rDNA experiment or during the preliminary application in the controlled model environment.	
E. OTHER CONSIDERATIONS IN ASSESSING CHARACTERISTIC OF ORGANISMS	
e.1 Known potential of natural variants to cause epidemics (survival rates, reproduction, dispersal, etc.)	
e.2 Known potential to cause losses (plant part affected, phenological stage affected, etc.)	
e.3 Known potential hosts and their economic or social importance	
e.4 Known natural ability to evolve	
e.5 Known carriers of organism and abundance	
e.6 Epidemiological factors	
e.6.1 mode of spread including vectors and other transport hosts	
e.6.2 environmental conditions needed for epidemics	
e.6.3 history of epidemic.	
e.7 Laboratory Environment	

e.7.1 containment capabilities of laboratory	
e.7.2 sterilization procedures	
e.7.3 personnel awareness of biosafety procedures	
e.7.4 past history of biosafety in laboratory;	
e.7.5 labeling/designation of "risk" areas	
e.7.6 decontamination facilities	
e.7.7 "biosafetiness" of equipment	
F. HOST RANGE	
Host Range	
G. ADDITIONAL CONSIDERATIONS OR END USES SPECIFIC TO PARTICULAR ORGANISM	
g.1 Microorganisms	
g.1.1 Live Vaccines	
g.1.1.1 Specify/give the identification characteristics or markers, the growth requirements, and the genetic modification of the vaccine strain of the organism	
g.1.1.2 Specify the proposed doserate(s). Give the period when the vaccine organism can be detected in the vaccinated animals and their excretions.	
g.1.1.3 Indicate if the vaccine organisms spreads from vaccinated to in-contact, non-vaccinated animals of the same or other animal species. If so, state the mechanisms and frequency.	
g.1.1.4 Give the vaccine strain's frequency of reversion to wild type characteristics	
g.1.1.5 For pentrials, specify arrangements proposed for disposal of waste containing any vaccine organisms and of the vaccinated animals at the conclusion of the trial.	
g.1.1.6 Give the clinical effects of the vaccine organism target and non-target species in the test area and surrounding environment.	
g.1.1.7 Specify the level and duration of immunity produced in the target species.	

g.1.1.8 State challenge or other tests using virulent field strains to be carried out on vaccinated animals.	
g.1.1.9 Indicate the probability of the host vaccine organism being used in other human or animal vaccines. Specify if the use of this vaccine precludes the future use of the host vaccine organism for immunization purposes	
g.1.2 Microorganisms on Soil/Water Associated with Plants	
g.1.2.1 Specify the survival and reproduction characteristics of the organism in the rhizosphere of the plant species of interest and other plant species in the test site and surrounding environment.	
g.1.2.2 Give the effects on organisms likely to be in the test area which are known to be beneficial to plants (e.g. Rhizobium, Frankia and mycorrhizal fungi).	
g.1.3 Microorganisms on Soil/Water Associated with Plants	
State the effects that the unmodified and modified organism has on the biological control target, the plant or animal being protected and non-target species (including humans) in the test area and surrounding environment. State, in particular, if there are any growth or quality reductions in the protected organism	
g.2 Animals - Domesticated or farmed (terrestrial, aquatic)	
g.2.1 Indicate the desirable effects expected to result from the use of the modified animal (e.g. improved reproduction, weight gain, disease resistance and production gains).	
g.2.2 State the undesirable effects that may result from the release of the modified organism like alteration of nutritional quality (e.g. difficult birth, fertility reduction, increased disease prevalence, tumorgenicity and production losses). Indicate if any of the likely gains are directly linked to losses in other characteristics of the species (e.g., an increased growth rate being accompanied by a decrease in	

wool or milk production).	
g.2.3 Indicate if the genetic trait can be transmitted other than thru their normal reproduction (e.g., from animal to animal via virus or insect transmission).	
g.3 Plants	
g.3.1 Specify if any member of the genus of the modified plant is known to be harboring weeds or diseases.	
g.3.2 Indicate if the experimental plot is isolated from plants of the same species, with regard to the pollination characteristics of the plant.	
g.3 Plant Quarantine Significance	
g.3.1 Provide data on the credentials of the principal investigator / researcher.	
g.3.2 Provide data on any previous information on risk assessment of the organism	
g.3.2 Provide data on any markers available to track the organism if it escapes.	
H. ADDITIONAL INFORMATION	
h.1 Will the experiment involve conventional breeding of Plants and Animals (Selective Breeding, Mutagenesis; Protoplast, Cell and Embryo Fusion) (NOTE: If 'yes', it shall be covered by the stipulations of existing plant and animal quarantine laws, including implementing guidelines issued by duly constituted authority.)	
h.2 Experiment Involving Conventional Breeding of Microorganisms (Selective Breeding, Mutagenesis; Protoplast, Cell and Embryo Fusion) (NOTE: These experiments shall be covered by provisions of these guidelines for evaluation where appropriate, especially in Sections D, E, G)	
h.3 The proponent must demonstrate - taking into consideration scientific, ecological, economic, social and ethical concerns - which the proposed objectives of the research, as stated in Section A, cannot be addressed/realized adequately and achieved by alternative approaches.	
h.4 Any other relevant information[4]	

[4] Please use this field to provide any other relevant information that may not have been addressed elsewhere in the proposal

RECORD VALIDATION

Important Notice:

Complete every applicable item on this form or write "N/A" or "Not Applicable" if otherwise. The answers must be supported by data and relevant scientific literature, all of which shall be appended to the proposal.

The Project Leader(s) must affix his signature/initial at the lower right corner of every page of the proposal and its annexes.

The DOST Biosafety Committee (DOST-BC) requires the submission of 1 soft copy *in PDF* and 15 hard copies of the proposal together with the attachments. Annexes must be printed separately.

The DOST-BC reserves the right not to act on any proposal or endorsement which does not comply with the prescribed format or fails to include all the required attachments.

"*Commercial-In-Confidence*" must be stamped at the upper right corner of the page, should the section contain such information.

I hereby confirm that the above information is correct and request its endorsement to the DOST Biosafety Committee.

Name(s) of Project Leader(s)	Signature	Date

ANNEX 3-A

CHECKLIST OF REQUIREMENTS
FOR APPLICATION FOR CONTAINED USE OF GMOS (LABORATORY/SCREENHOUSE/GREENHOUSE/GLASSHOUSE)

DOST-BC Reference Number: (to be filled out by DOST-BC Secretariat)

1	Project Title				
2	Name(s) of Project Leader(s)				
3	Name of Institution:				
4	The following information have been submitted/provided		To be filled out by DOST-BC Secretariat		
			YES	NO	Remarks
a.	Coversheet – Assessed and Duly Endorsed by the IBC		☐	☐	
b.	Executive Summary of the Project Proposal		☐	☐	
c.	Proposal in accordance with prescribed format for evaluation of proposal for contained experiment		☐	☐	
d.	Soft copy of the proposal (full blown proposal and CBI-portion deleted version)		☐	☐	
e.	Annex 3-B Gantt chart of activities		☐	☐	
f.	Annex 3-C Detailed schedule of activities		☐	☐	
g.	Annex 3-D Map of Plasmid, Southern blot		☐	☐	
h.	Annex 3-E Map of Construct				
i.	Annex 3-F Summary of introduced genetic elements		☐	☐	
j.	Annex 3-G Experimental Layout/Floor plan and Location Map		☐	☐	
k.	Annex 3-H Biosafety contingency plan		☐	☐	
l.	Annex 3-I List of Materials to be Utilized		☐	☐	
m.	Annex 3-J List of personnel involved in the project and their duties		☐	☐	

n. Annex 3-JA Personal Data Sheet of project personnel	☐	☐	
o. Annex 3-K Summary of the Project for posting in the DOST-BC website	☐	☐	
p. Annex 3-L Scientific literature/references[1]	☐	☐	

[1] *One complete set of hard copy, including list of citations must be provided for the original proposal and just a list of citations for the remaining copies of the proposal to be submitted*

If any of the above requirements has not been provided, the DOST-BC Secretariat will request the proponent/s through the IBC to complete the required information.

Submitted by		**Verification of Submission** (to be filled out by DOST-BC Secretariat)	
Name of the IBC Chairperson		Received by	
Date		Date and time Received	
Signature		Remarks	

ANNEX 3-B

GANTT CHART OF ACTIVITIES

Project Title	
Name(s) of Project Leader(s)	
Name of Organization:	

Activities (i.e. materials preparation to post-harvest monitoring)	**Week**																			
	1	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**	**14**	**15**	**16**	**17**	**18**	**19**	**20**

ANNEX 3-C

DETAILED SCHEDULE OF ACTIVITIES

Project Title	
Name(s) of Project Leader(s)	
Name of Organization:	

Activity	**Date**	**Location**	**Involved Project Personnel**	**Presence of IBC and/or DOST-BC/ PQS Monitors** (To be filled out by the DOST-BC)

ANNEX 3-D

MAP OF PLASMID / SOUTHERN BLOT

The plasmid must be clearly and properly labeled, indicating the major parts (promoter, terminator, enhancer etc.) and the name, size (kb) and source of the gene(s). Figures showing the stable integration of the introduced gene(s) (Southern blot) must also be properly labeled.

ANNEX 3-E

MAP OF CONSTRUCT

The construct must be clearly and properly labeled, indicating the major parts (promoter, terminator, enhancer etc.) and the name, size (kb) and source of the gene(s). Figures showing the stable integration of the introduced gene(s) must also be properly labeled.

ANNEX 3-F

SUMMARY OF INTRODUCED GENETIC ELEMENTS

PUTATIVE CONSTRUCT DESIGNATION	GENETIC ELEMENTS INTRODUCED *(promoter, terminator, etc.)*	COPY NO. (if known)	DESCRIPTION / FUNCTION	SOURCE	GENEBANK IDENTIFIER/ ACCESSION NUMBER	REFERENCE

ANNEX 3-G

EXPERIMENTAL LAYOUT / FLOORPLAN AND LOCATION MAP
(LABORATORY/SCREENHOUSE/GREENHOUSE/GLASSHOUSE)

The floor plan / layout of the facility that will be used must be clearly and properly labeled. A separate location map must also be provided indicating the dimensions of the facility and its exact location relative to the other facilities of the Institution. If possible, the map should be drawn to scale. If codes/symbols will be used, legends must be provided.

ANNEX 3-H

BIOSAFETY CONTINGENCY PLAN
FOR CONTAINED USE OF GMOS

Project Title	
Name(s) of Project Leader(s)	
Name of Institution:	
Location of Experiment	

BIOSAFETY CONTINGENCY PLAN (e.g. typhoon, flooding, brownouts)	**RAPID TERMINATION PLAN** (e.g. typhoon, flooding)	**CONTACT DETAILS OF THE PERSON TO BE CONTACTED IN CASE OF EMERGENCIES**
		Name Designation Address: Tel. No Mobile No. E-mail

ANNEX 3-I

LIST OF MATERIALS TO BE UTILIZED

Materials (Please indicate the type of material e.g seeds, leaf etc)	**Availability** *Please mark (x) as appropriate*		**Classification** *Please mark (x) as appropriate*		**Quantity**	**Point of Origin**	**Exporter Contact Details** (Applicable only for imported materials)		
	Locally available /developed	**To be Imported**	**Transgenic**	**Non-Transgenic**			**Name**	**Address**	**Contact Number / Email Address**

ANNEX 3-J

LIST OF AUTHORIZED PERSONNEL

Project Title	
Name(s) of Project Leader(s)	
Name of Organization:	

Name	Designation	Responsibilities in the conduct of the activity

ANNEX 3-JA

PERSONAL DATA SHEET
PROJECT PERSONNEL

Full Name	

Current Employment	
Position/Job Title	
Department / Division / Unit	
Employer/Organization	
Mailing Address	
Phone/Fax Number(s)	
Email Address	
Main area(s) of responsibility	

Employment History *(please provide details of your previous employment for the last 5 years starting with the most recent one.)*	
Previous professional experience (a)	
Position/Job Title	
Department / Division / Unit	
Employer/Organization	
Starting to Ending Date	*From* <YYYY> *to* <YYYY>
Previous professional experience (b)	
Position/Job Title	
Department / Division / Unit	
Employer/Organization	
Starting to Ending Date	*From* <YYYY> *to* <YYYY>

Education			
	Name of Academic Institution	Degree Course (Write in Full)	Year Graduated
Secondary		-	
Vocational / Trade Course			
College			
Graduate Studies (M.Sc, Ph.D.)			

Professional qualifications	
Specialized training, certifications *List a maximum of three other relevant professional qualifications*	1. 2. 3.
Publications *List a maximum of three most important publications related to the main field of expertise*	1. 2. 3.

Professional Membership	
Professional memberships *List up to three relevant professional societies or organizations of which you are a member:*	1. 2. 3.
Technical committees, expert panels or advisory bodies served *List up to three relevant technical committees, expert panels or advisory bodies on which you have served and briefly describe your specific responsibilities:*	1. 2. 3.

ANNEX 3-K

SUMMARY OF THE PROJECT FOR POSTING AT THE DOST-BC WEBSITE

Project Title	
Project Type	<Contained Use>
Institution	
Cooperating Institution	
Supervising IBC	
Project Leader(s)	
Location of the experiment	
Objectives of the Study	
Biosafety Measures	

ANNEX 3-L

SCIENTIFIC LITERATURE / REFERENCES[1]

All relevant literature/references must be appended to the original proposal. A summarized list of all the references/literature must likewise be provided and enumerated for the remaining copies of the proposal using the proper format[2]. If information was accessed in the internet, the web page, author and date of access must be indicated[3].

[1] One complete set of hard copy, including list of citations must be provided for the original proposal and just a list of citations for the remaining copies of the proposal to be submitted

[2] Please use the Modern Language Association (MLA) formatting style: Last Name of Author, First Name of Author. Book Title. Publication City: Publisher, Publishing Date

[3] Please provide the URL of the website (e.g. http://dost-bc.dost.gov.ph), name of the website and date accessed (dd-mmm-yyyy)

ANNEX 4

PROGRESS / STATUS REPORT

PROGRESS/STATUS REPORT FOR CONTAINED USE FOR THE YEAR

Project Information	
DOST-BC Reference number	
Project Title	
Project Leader(s)	
Name of Institution	
Location of experiment (Indicate the type of facility)	
Date Approved by the DOST-BC	
Reporting Period	

- IBC Endorsement[1]		
Name of IBC Chairman	**Signature**	**Date**
Name of IBC Members and Community Representatives / Signature / Date	**Signature**	**Date**

[1] Must be signed by all IBC Members

DOST-BC Reference number	
Project Title	

Abstract

Introduction

Objectives

Materials and Methods[2]

Status and Discussion

References

Record Validation

Important Notice:

The DOST Biosafety Committee (DOST-BC) requires the submission of 1 soft copy and 15 hard copies of the Progress / Status Report. Please note that the soft copy submitted to the DOST-BC must be in PDF.

I hereby confirm that the above information is correct and request its endorsement to the DOST Biosafety Committee.

Name of Project Leader(s)	Signature	Date

[2] Include imported materials and source, as well as Inventory of all the biological materials (Fill out *Annex 1* for this purpose)

INVENTORY OF BIOLOGICAL MATERIALS

Materials	Classification		Parentage	Number of Materials Generated	Stored		Other Remarks
	GM	Non-GM			Yes	No	

ANNEX 5

COMPLETION REPORT[1]
FOR CONTAINED USE OF GMOs

Project Information	
DOST-BC Reference number	
Project Title	
Project Leader(s)	
Name of Institution	
Name of Supervising IBC	
Location of experiment (Indicate the type of facility)	
Date Approved by the DOST-BC	
Date of Completion	

IBC Endorsement[2]		
Name of IBC Chairman	**Signature**	**Date**
Name of IBC Members and Community Representatives / Signature / Date	**Signature**	**Date**

[1] The Completion Report is submitted by the proponent to the IBC within 90 days after the completion of the project. *The completion report cannot be submitted unless the post-harvest monitoring activities have been accomplished.* The IBC shall then review the completion report of the Proponent and endorse it to the DOST-BC within 120 days from completion date of the project.

[2] All IBC Members must sign. Otherwise please state reason for abstaining.

DOST-BC Reference number	
Project Title	

Abstract

Introduction

Objectives

Materials and Methods[3]

Results and Discussion

Conclusion and Recommendation

References

Annexes

Record Validation		
I hereby confirm that the above information is correct and request its endorsement to the DOST Biosafety Committee.		
Name of Project Leader(s)	Signature	Date

[3] Include imported materials and source, as well as: a) Status / Fate of Biological Materials and b) Inventory of Materials

ANNEX 6

IBC REPORT
AFTER COMPLETION OF CONTAINED USE OF GMOs

IBC Information	
IBC Name	
Address	

Project Information	
DOST-BC Reference number	
Project Title	
Project Leader(s)	
Agency(ies) which have issued approval(s)/permit(s) and date(s) of issuance	
Location of experiment (Indicate the type of facility)	
Date of Commencement	
Date of Completion	

1. Summary of the Results

2. What monitoring procedures were undertaken?

3. Were the procedures undertaken according to the protocol submitted for review? If not, specify deviations and why.

4. Were the aims of the contained test/CFT achieved? Describe.

5. Were there any unexpected effects? Describe.

6. What is the number of organisms surviving at the site of the experiment? What will be the fate of these organisms? Explain.

7. Will the project be continued to a further stage? If yes, provide details.

8. Were any viable material stored for future use? If yes, provide details.

IBC Concurrence		
Name of IBC Chairman	**Signature**	**Date**
Name of IBC Members and Community Representatives	**Signature**	**Date**

V. Policy and Procedures for Application for Confined Tests of Genetically Modified Organisms

1. **Application for Confined Test (CT**). Putative transgenic events may be evaluated within a small confined test site. Activities under Confined Test must follow specific isolation strategies and practice stringent material management to prevent dispersal or escape of viable reproductive materials (seeds, pollen, viable vegetative parts). For putative transformation event to be eligible for Confined Test, they must fall under one of the following classifications:

- GM crops already commercially available in the country where they were developed, if sufficient information relevant to Philippines is available
- Locally developed GM crops with sufficient information generated in the lab/screenhouse-data sufficient for risk assessment
- GM crops whose size & growth habits require areas not afforded by standard screenhouse, *e.g. papaya*
- Other crops and events that warrant limited release under confined conditions

The data generated from the CT may be utilized in complying with the requirements for Field Test (FT) under the Department of Agriculture and Department of Environment and Natural Resources.

1.1. **DOST-BC Approval.** No person or institution shall conduct CT work with GMOs without the prior approval of the DOST-BC. However, approval by the DOST-BC does not in any way exempt the Proponent from complying with any rules, regulations or requirements of other government regulatory authorities. It is the sole responsibility of the Proponent to determine if the proposed CT requires any permit, license or approval of such regulatory authorities, and to obtain the same if required.

1.2. **The Proposal**

1.2.1. The proposal shall be prepared in accordance with the prescribed format in *Annex 9-Project Proposal for Confined Test of GMOs* of this Manual. The Proponent must answer all questions relevant to this application. The answers must be supported by data and scientific literature, all of which shall be appended to the proposal. The Proponent must disclose all data or literature on potential adverse effects of GMOs on human health or the environment.

1.2.2. If the proposal contains any information which the Proponent wishes to be kept confidential, the pages containing such information shall be conspicuously marked as “Commercial-Business Information (CBI)”. The Proponent shall specify in writing why the marked pages should be held in confidence. However, no information pertaining to the potential adverse effects of the organisms on human health or the environment shall be considered confidential.

1.2.3. The proposal shall then be submitted by the Proponent to the IBC for assessment.

1.3. **Institutional Biosafety Committee (IBC).** – Any institution intending to undertake CT activities must have an active Institutional Biosafety Committee (IBC) established, as specified in Chapter I, Section 7.

1.4. **IBC Evaluation**

1.4.1. The IBC shall evaluate the proposal using the risk assessment table of *Annex 9-Project Proposal for Confined Test of GMOs* of this Manual. Specifically, the IBC shall evaluate whether data obtained in the laboratory or under contained conditions provide sufficient basis to authorize the CT of the GMO. The IBC should also make an initial assessment of the suitability of the proposed CT site. In making such evaluation, the IBC must ensure that the CT of the GMO does not pose any unnecessary risks to the environment or human health.

1.4.2. During the evaluation, the IBC shall consult and discuss with the Proponent and, when appropriate, make suggestions for revisions.

1.4.3. The IBC may require the Proponent to state in his or her proposal any information in addition to those required by the DOST-BC.

1.4.4. The IBC may consult with experts in the scientific disciplines relevant to the proposed CT of GMO or knowledgeable in the policies of the institution, relevant laws, standards of professional conduct or practice, community attitudes and practices, and the potential environmental and human health impact of the proposed activity.

1.4.5. After the evaluation, the IBC shall decide whether or not to endorse the proposal to the DOST-BC. The proposal must be approved by majority of the IBC members. At least one (1) community representative must approve the proposed activity before the proposal may be endorsed by the IBC to the DOST-BC. Dissenting members of the IBC must indicate their reasons for disapproving the proposal.

1.5. **Endorsement of Proposal by IBC to the DOST-BC.** The IBC shall endorse the proposal to the DOST-BC through the DOST-BC Secretariat. The submission shall include the following:

1.5.1. Cover Sheet, in accordance with *Annex 7-Cover Sheet for Application for Confined Test of GMOs*, duly signed and dated by the IBC members (1 soft copy and 15 hard copies);

1.5.2. The following versions of the proposed CT activity, with attachments that include but are not limited to:

1.5.2.1. Executive Summary (1 soft copy and 15 hard copies);
1.5.2.2. Complete version of the proposal with Commercial-Business-Information (CBI) clearly marked (1 soft copy and 15 hard copies);
1.5.2.3. CBI deleted version (1 soft copy and 1 hard copy;

1.5.3. Gantt chart and detailed schedule of activities, plasmid map, references and relevant scientific publications, location map of the CT site, Biosafety Contingency Plan, Summary of Introduced Genes *(see Annexes)*;all attachments in 1 soft copy and 15 hard copies);

1.5.4. The IBC Site assessment report on indicative conditions of the proposed test site for CT *(Annex 11)*;

1.5.5. Project Information Sheet (PIS) for public notification and comment, in accordance with the form shown in *Annex 10* (1 soft copy and 15 hard copies); and,

1.5.6. List of all personnel *(Annex 9-J)* who will be involved in the project together with their curriculum vitae *(Annex 9-JA)* and roles in the proposed experiment (1 soft copy and 15 hard copies);

(The documents should be properly paginated and tables/figures be labeled.)

The DOST-BC reserves the right not to act on any proposal or endorsement which does not comply with the prescribed format or fails to include all the required attachments.

1.6. **Initial Assessment by DOST-BC Secretariat.** Upon receipt of the documentary submissions from the IBC, the DOST-BC Secretariat shall check whether or not the required format and attachments have been complied with. If the project proposal complies with the required format and has all the necessary attachments, the DOST-BC Secretariat shall calendar the proposal for review by the DOST-BC and acknowledge its receipt. On the other hand, if the project proposal is incomplete or the format is not complied with, the DOST-BC Secretariat shall immediately inform the Proponent through the IBC of the missing requirements. The Proponent shall then be given a reasonable period within which to complete these requirements. No proposal shall be submitted to the DOST-BC for review unless in the proper format and all the required documents are appended.

1.7. **Initial Review by DOST-BC**

1.7.1. *Designation of Site Inspection Team.* The DOST-BC shall assign an Inspection Team who shall inspect a proposed new CT site to check the appropriateness of the facility for the proposed activities. The DOST-BC may also assign an Inspection Team to re-inspect or validate a previously approved CT site.

1.7.2. *Report of the Site Inspection Team*. After the inspection, the Inspection Team shall submit the inspection report which shall include its observations and recommendations to the DOST-BC for approval.

1.8. **Formal Review by the DOST-BC**

Review by External Expert(s) as needed.

1.8.1. Upon receipt of the proposal from the DOST-BC Secretariat, the DOST-BC has the option to create a Scientific and Technical Review Panel (STRP), as needed, to evaluate potential adverse effects of the project to human health and environment. The STRP shall be appointed by the Chairman of the DOST-BC. The STRP shall be composed of at least three (3) members chosen, if possible, from the NCBP pool of experts or from the pool of experts of the DOST Sectoral Councils or any appropriate body duly recognized by the DOST. As far as practicable, no member of and Department Biosafety Committee shall be part of the STRP.

1.8.2. The STRP shall be provided copies of the proposal after executing the Oath of Confidentiality to maintain and respect the confidentiality of information declared by the Proponent, and approved by the DOST-BC, to be Confidential

Business Information (CBI). The STRP shall submit to the DOST-BC its recommendations in writing not later than thirty (30) days from receipt of the project proposal from the DOST-BC Secretariat.

1.8.3. Or the DOST-BC may refer the proposal to individual expert(s) to evaluate the potential adverse effects of the project to human health and environment. The expert shall be chosen either from the NCBP specialists, from the pool of experts of the DOST Sectoral Councils or any appropriate body duly recognized by the DOST.

1.8.4. Similar to the process with the STRP, the selected expert shall be provided with the copy of the proposal after executing the Oath of Confidentiality to maintain and respect the confidentiality of information declared by the Proponent, and approved by the DOST-BC, to be Confidential Business Information (CBI). The selected expert shall submit to the DOST-BC its recommendations in writing not later than thirty (30) days from receipt of the project proposal from the DOST-BC Secretariat.

1.9. **Approval of Project Information Sheet (PIS)**

1.10. **Posting of the Project Information Sheet (PIS) for Purposes of Public Notification and Comment.** The Proponent shall prepare in addition to the project proposal the Project Information Sheet (PIS) for Purposes of Public Comment/Notification as shown in *Annex 10*, in English and one vernacular version, for approval of the DOST-BC. The vernacular version shall be written using simpler terms of the very basic information about the technology so that it will be more understandable by the people in the locality.

1.10.1. Concurrent with the optional review by the STRP or individual external expert(s) and the DOST-BC, the Proponent through the facilitation of the IBC, shall take steps to notify the public of the CT and to invite comments thereon. The following shall be the procedure for the public notification and comment:

1.10.1.1. The Proponents through the facilitation of the IBC will be required to brief the local officials at the barangay level about the proposed CT activities.

1.10.1.2. The IBC shall post, for three (3) consecutive weeks, copies of the DOST-BC-approved Project Information Sheet (PIS) for CT *(Annex 10)* in a language understood by the locality and in English, in at least three (3) conspicuous places in the barangay and/or city/municipal halls where the proposed activities will be conducted. Proof of posting, which may either be a certification from the duly authorized barangay leader(s) or an affidavit executed by the Proponent, shall be submitted to the DOST-BC within ten (10) days from the last day of posting.

1.10.1.3. Concomitant to the posting in barangays, the DOST-BC-approved Project Information Sheet shall be posted in the internet through the websites of the NCBP/DOST-BC and the National Biosafety Clearing-House (BCH Pilipinas).

1.10.1.4. If in the judgment of the IBC the proposed CT of GMO carries potentially significant risks to human health and the environment, the IBC shall conduct a public hearing not later than ten (10) days from the

last day of publication of the Project Information Sheet as required under Section 1.5.5 above.

1.10.2. The IBC shall allow at least thirty (30) days from the last day of posting, for the public to comment on the proposed CT. The public shall be asked to direct all its inquiries to the Proponent, whose name and complete address shall be stated in the Project Information Sheet (PIS). The Proponent shall provide additional information about the project to any requesting party not later than fifteen (15) days from receipt of such request.

1.10.3. All comments on the proposed CT shall be sent by personal service, courier or registered mail to: The Secretariat, DOST-Biosafety Committee, Department of Science and Technology, Gen. Santos Avenue, Bicutan, Taguig City, Metro Manila.

1.10.4. The DOST-BC shall collate and forward all public comments to the Proponent through the IBC for appropriate response. The Proponent shall respond, in writing, to all public comments within fifteen (15) days from receipt thereof. The IBC shall furnish the DOST-BC a copy of all its responses within the same period. Should there be opposition or comments on environmental issues, said comments shall be referred to the Ecosystems Research and Development Bureau (ERDB) of the Department of Environment and Natural Resources by the DOST-BC for information and appropriate action, decision on which should be received by the DOST-BC within fifteen (15) working days upon receipt.

1.10.5. The Proponent, if he so desires, may amend his or her proposal in response to the public comments. The amendments to the project proposal, public comments and the responses thereto shall be immediately transmitted to the DOST-BC and shall form part of the record to be used by the DOST-BC in its deliberations.

1.10.6. Public comments, opinions, positions, submitted following posting of the PIS, where relevant shall be considered in the decision making process. The final decision shall be posted in the NCBP/DOST-BC website and the BCH Pilipinas website.

1.10.7. All expenses incurred in the public notification and comment shall be for the account of the Proponent.

1.11. **DOST-BC Assessment and Decision**

1.11.1. In the event that no public comment has been received, the DOST-BC shall act on the proposal for CT of GMOs within sixty (60) days from the end of the period for public comment. Otherwise, it shall act on the proposal within sixty (60) days from submission of the documents mentioned in Section 1.5 above.

1.11.2. The DOST-BC shall base its evaluation on the following:

1.11.2.1. Project proposal, including amendments and attachments;
1.11.2.2. IBC assessment;
1.11.2.3. Suitability of the proposed CT site as attested by the DOST-BC designated Inspection Team;
1.11.2.4. Comments and recommendations of the STRP or external technical expert, if appropriate;

1.11.2.5. Public comments; AND,

1.11.2.6. Other documents or information deemed relevant by the DOST-BC.

1.11.3. The DOST-BC shall notify the Proponent through the IBC in writing of its decision. Approval may be subject to conditions such as, but not limited to, a detailed description of the CT and mitigating measures, specific time period for the CT, specific geographical areas for use as test sites, and additional monitoring and reporting requirements. If the proposed activity requires a permit or authority from other government regulatory agencies and the issuance of the same is conditioned upon approval of the project proposal by the DOST-BC, the DOST-BC shall issue an endorsement to facilitate the issuance of the said permit or authority. In case a project proposal is disapproved, the DOST-BC shall state the reason or reasons for disapproval.

1.12. ***Request for Reconsideration.*** The Proponent through the IBC may request the DOST-BC for reconsideration within sixty (60) days from receipt of the notice of disapproval. The request shall state all the grounds for reconsideration. The DOST-BC shall have sixty (60) days to act on the request for reconsideration. Unless otherwise stated in writing, failure on the part of the DOST-BC to act within the said period shall be considered as denial of the request. The decision of the DOST-BC relative to the request for reconsideration shall be final.

1.13. ***New Data or Information on Risks.*** In case new data or information that will reduce significantly biosafety risks that caused the disapproval of the project proposal later becomes available, the Proponent may re-submit the project proposal to the IBC together with the new data or information. The re-submitted project proposal shall be evaluated in the same manner as that of a new proposal.

2. Oversight and Supervision of the approved activity. The oversight and supervision of the approved activity shall be carried out by the DOST-BC in collaboration with the Department of Agriculture (DA), Department of Environment and Natural Resources (DENR) and Department of Health (DOH). The Proponent, the IBC and the DA, DENR AND DOH shall meet and agree to adopt a mutually acceptable implementation and monitoring scheme and schedule.

2.1. In accordance with agreements with line agencies, (i) the Department of Agriculture shall be responsible for monitoring the movement and effects of GMOs approved for the CT; (ii) the Department of Environment and Natural Resources shall be responsible for monitoring the environmental effects of the CT; and, (iii) the Department of Health shall be responsible for monitoring the effects of the CT to human health.

2.2. The DOST-BC reserves the right to inspect the CT facilities at any time. Site inspections shall be carried out in such manner to avoid interfering with the activities of the Proponent, unless intervention is necessary to avert any imminent danger to human health or the environment.

2.3. In case of accident or untoward incident, breach in isolation or material management requirements, the DOST-BC shall require the immediate implementation of specific contingency plans to mitigate any possible adverse effects.

2.4. ***Responsibilities of Proponent.*** The Proponent shall be responsible for the overall implementation of the approved activities for work on GMOs done inside the CT site. The Proponent must be familiar with the provisions of this Manual.

During the conduct of the approved activity, the Proponent shall:

2.4.1. Comply with the additional advice, recommendations and requirements of the DOST-BC on the approved activity;

2.4.2. Ensure that the guidelines and conditions imposed by the DOST-BC as stipulated in the DOST-BC approval letter is complied with;

2.4.3. Ensure that all personnel involved in the activity are aware of the biosafety requirements of the work and that they have received appropriate training in safety and emergency procedures;

2.4.4. Seek the approval of the IBC and DOST-BC of any changes in activities and the composition of the personnel involved in the activity; and,

2.4.5. Report immediately to the IBC all unexpected observations, results or accidents and unexplained illnesses or absences of personnel which may be attributed to the activities involving GMOs.

2.4.6. In case of accidents, intrusions, untoward incidents, or breach in isolation or material management requirements, whether *force majeure* or anthropogenic, the proponent and the IBC shall immediately implement the specific contingency plans and corrective measures to mitigate any possible adverse effects and prevent the escape of viable regulated materials from the CT site.

2.4.7. The Proponent and the IBC shall also immediately report the same to the DOST-BC. The report shall describe in detail the nature of the accident, untoward incident, intrusions or breach of confinement and the specific contingency measures and corrective measures implemented. Reporting to the DOST-BC does not necessarily relieve the Proponent and the Institution of their obligations under the law.

3. Reportorial Requirements

3.1. *Reports from the IBC*

3.1.1. **Annual report of projects under supervision during the year.** The IBC shall submit a report to the NCBP copy furnished the DOST-BC not later than the 15th day of March of each year. The report shall be for the period January to December of the preceding year, and shall include the following information:

3.1.1.1. Composition of the IBC;

3.1.1.2. All activities using GMOs (contained/confined tests) conducted during the year, including any changes of Proponents and associated personnel;

3.1.1.3. Modifications in the test activities of GMOs vis-a-vis the original proposals submitted to the DOST-BC;

3.1.1.4. Description of unexpected results from the test activities involving GMOs and their adverse impact to health or the environment;

3.1.1.5. Description of accidents or incidents attributable to the test activities involving GMOs and the adverse effects thereof;

3.1.1.6. Fate of materials generated from supervised activities; and,

3.1.1.7. Any other matters which the IBC may wish to bring to the attention of the NCBP and the DOST-BC.

3.1.2. **Completion report of each supervised CT project.** The IBC shall submit a report upon completion of a CT to the DOST-BC in accordance with the format in *Annex 14-IBC Report after Completion of Confined Test of GMOs*, not later than one hundred twenty (120) days from completion date.

3.1.3. **Incident report***.* In case of any accident or untoward incident that may put human health or the environment at risk, the Proponent shall immediately report the same to the IBC and the DOST-BC. 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 DOST-BC relieve the Proponent and the institution of their obligations under the law. The DOST-BC may require the IBC to submit follow-up reports on the long-term effects of the CT.

3.2. *Reports from the Proponent*

3.2.1. **Progress report.** The Proponent 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, in accordance with *Annex 12*, in soft and 15 hard copies.

3.2.2. **Incident report.** The Proponent shall report immediately to the IBC and DOST-BC any unexpected observations, untoward incidents, results or accidents and unexplained illnesses or absences of personnel which may be attributed to the activities involving GMOs. The Proponent shall ensure that appropriate measures have been applied based on their submitted biosafety contingency plan and best CT practices. The Proponent must ensure the safety of their personnel and account for the experimental materials in the occurrence of untoward incidents. Such incidents and action taken shall be reported by Proponent through the IBC to the DOST-BC. The DOST-BC shall also inform the NCBP as appropriate.

3.2.3. **Completion report.** The Proponent shall submit a completion report of the CT project to the IBC 90 days after its completion, in accordance with the format in *NNEX 13*, in soft and 15 hard copies to the IBC. The completion report cannot be submitted unless the post-harvest monitoring activities have been accomplished. The report shall specify, among others, whether the objectives of the experiment were achieved; the nature and consequences of the adverse effects, if any, of the CT; and the fate of the GMO after the CT. The IBC shall review the completion report of the Proponent and endorse it to the DOST-BC within 120 days from completion date of the project.

3.3. *Reports from the Monitor*

3.3.1. **Inspection report.** The DOST-BC shall assign an Inspection team who shall inspect a proposed new CT site to check the appropriateness of the facility for the proposed activities. The DOST-BC may also assign an Inspection team to

re-inspect or validate a previously approved CT site. After the inspection, the Inspection team shall submit the inspection report which shall include its observations and recommendations to the DOST-BC for approval.

3.3.2. **Monitoring activity report**. The monitors from the PEQS and DOST-BC shall:

3.3.2.1. Submit monitoring report for each activity, including but not limited to, compliance to CT biosafety requirements, activities undertaken, pest/disease monitoring, staff/persons involved in the activity, and other observations. The report shall be signed by the monitor, IBC representative and the Proponent present during the activity.

3.3.2.2. Submit lists of authorized persons including the date and purpose of the activity.

3.3.2.3. Include the materials management for the specific activity, e.g. report quantity of viable materials, in the monitoring report.

3.3.2.4. Report immediately any unexpected observations, untoward incidents, violations, non-compliance to the DOST-BC. The DOST-BC shall take appropriate action. Such incidents and action taken shall be reported by the DOST-BC to the NCBP as appropriate.

3.3.2.5. Submit the report for the specific activity to the identified focal person for monitoring, documentation and filing 3 days after the activity.

3.3.2.6. Submit to the DOST-BC a copy of the monitoring report.

3.3.3. **Incident report.** The monitors shall report immediately any unexpected observations, untoward incidents, violations, non-compliance to the DOST-BC. The DOST-BC shall take appropriate action. Such incidents and action taken shall be reported by the DOST-BC to the NCBP as appropriate.

3.3.4. **Completion report.** The monitoring lead shall submit the completion report to the DOST-BC 60 days after the experiment.

3.4. *Report from the DOST-BC.* For every completed project, the DOST-BC will have an analysis for future reference and use for subsequent related experiments and may also be forwarded to the appropriate DBC as needed.

4. Endorsements and Certificates. If the proposed activity requires a permit or authority from other government regulatory agencies, and the issuance of the same is conditioned upon approval of the project proposal by the DOST-BC, the DOST-BC shall issue an endorsement to facilitate the issuance of the said permit or authority *(e.g., DOST-BC endorsement to the Bureau of Plant Industry for the issuance of permit to import the regulated materials).*

The DOST-BC may also endorse and delegate regulation of contained experiments under the mandate of the appropriate Department Biosafety Committee depending on its assessment.

A *Certificate of Completion* shall be issued by the DOST-BC for completed CT projects which have met the objectives set, regardless of whether they have plans of conducting further experimentation or not.

5. Withdrawal of the DOST-BC Approval

5.1. ***Grounds for Revocation of Approval.*** The following are the grounds for revocation by the DOST-BC of any project approval:

5.1.1. Failure of the Proponent to comply with the Philippine Biosafety Guidelines or any of the conditions imposed by the DOST-BC for approval of the project, including, but not limited to failure to adhere to restrictions and schedule of activities and protocols imposed by the DOST-BC;

5.1.2. Receipt by the DOST-BC of reliable data or information indicating that the activity involving GMOs may pose a threat to human health or the environment; and,

5.1.3. Such other grounds as the DOST-BC may deem reasonable to protect human health or the environment.

5.2. **Procedure for Revocation**

5.2.1. The DOST-BC shall advise the Proponent through the IBC in writing of the existence of grounds to revoke the project approval. The Proponent shall have a period of not more than ten (10) days within which to explain in writing why the approval should not be revoked. The DOST-BC shall render its decision within ten (10) days from receipt of the explanation of Proponent.

5.2.2. In case of imminent danger to human health or the environment, the DOST-BC Chair may immediately revoke any project approval on his or her own accord, without need of consulting the other members. Thereafter, the DOST-BC, after deliberation, shall either confirm or lift, in writing, the revocation order issued by the Chair. The DOST-BC shall have sixty (60) days there from to furnish the Proponent through the IBC a written explanation of its action.

5.2.3. **Effect of Revocation.** In the event of revocation, any permit or authority issued by other government authorities on the strength of the previous DOST-BC approval may also be revoked immediately. Further, the DOST-BC may order the Proponent or any government authority to destroy the GMO.

6. Penalties and Sanctions. In addition to the revocation of the project approval, any violation of the provisions of this Manual or the concealment or withholding by the Proponent of any information necessary to evaluate risks to human health or the environment shall be ground for the forfeiture of government research grants. Further, any incentives that may have been granted the Proponent or Institution for contributing to advanced scientific or technological research and development may be withheld. These penalties are exclusive of any other penalties that may be imposed under existing law, including, but not limited to, civil, criminal and administrative liabilities for gross negligence.

ANNEX 7

COVER SHEET[1]
IBC ASSESSMENT OF THE PROJECT PROPOSAL FOR THE CONFINED TEST OF GMOS

Fields marked with an asterisk (*) are mandatory

General Information	
DOST-BC Reference number (To be filled out by DOST BC Secretariat)	
Project Title*	
Name of Organization*:	
Supervising IBC*	
Other IBCs involved	
Project Duration*	
Expected Date of Public Notification*	

Project Leader(s) *	
Name	
Position	
Address	
Telephone/Fax Number	
Mobile Number	
E-mail Address	
Name	
Position	
Address	
Telephone/Fax Number	
Mobile Number	
E-mail Address	

[1] The DOST-BC prohibits any modification (removal/deletion of any section/item) to the prescribed format of this document.

Confined Test Site Details*	
Location of Confined Test Site	
Locality/Municipality/Province	
Global Position System (GPS) Coordinates.	
Person in charge of the Confined Test Site	
Name	
Address	
Tel. and Fax Numbers	
E-mail Address	
Brief Description of the Confined Test Site	
Please use this field to provide the brief description of the Confined Test Site	
Please provide information on the size, scale and frequency of release	

Other Organization(s)	
Government Authority(ies) Consulted about this Project, if applicable. (Use extra sheet if necessary)	
Name and Address of Organization:	
Contact Person	
Contact Details (Telephone Number / Email address)	
Government Authority(ies) to whom DOST-BC Approval, Endorsement or Advice on the proposal should be sent, if applicable. (Use extra sheet if necessary)	
Name of Authority	
Addressee/Contact Person	
Telephone and Fax Numbers	
E-mail Address	

IBC Assessment		
Name of IBC Chairman / Signature / Date	**Decision (Approved / Disapproved)**	**Reason for abstaining** (use additional sheet if necessary)
Name of IBC Members and Community Representatives / Signature / Date	**Decision (Approved / Disapproved)**	**Reason for abstaining** (use additional sheet if necessary)

Over-All IBC Assessment

☐ Approved ☐ Approved subject to the following conditions : ☐ Disapproved

Name of the IBC Chairperson	
Signature	
Date	

ANNEX 8

EXECUTIVE SUMMARY[1]
FOR CONFINED TEST OF GMOS

Project Title	
Name(s) of Project Leader(s)	
Name of Institution(s):	
Cooperating Institution	

EXECUTIVE SUMMARY (Brief description of proposed activity, site, duration, GM crop and specific objectives.)

[1] The Executive Summary should not contain any Confidential Business Information (CBI)

ANNEX 9

PROJECT PROPOSAL[1]
FOR CONFINED TEST OF GMOS

This Section consists of three parts.

Part I. contains the core questions. The proponent must answer core questions applicable to his or her project.

Part II. contains questions on the specific types of organisms or applications. The proponent should answer all questions relevant to his or her proposal.

Part III. pertains to risk analysis. The proponent should answer all questions relevant to his or her proposal.

To the extent possible, answers to the following questions should be supported by data acquired under previous contained work and published scientific literature, or both. If unsupported by such, the basis for the answers should be specified. References should be fully documented and attached to the proposal submitted to DOST-Biosafety Committee (DOST-BC) as appropriate. When a matter is controversial or there is some doubt about the answer, both sides of the issue should be presented.

The following questions may not cover all possible impacts. However, it remains the responsibility of the proponent to give the fullest and best consideration to the possible impacts of the proposed release, and to make full disclosure of relevant matters to the Institutional Biosafety Committee (IBC) and the DOST-BC. Such impacts include, but are not limited to, those on public health and safety, occupational safety, biodiversity, agricultural production and the quality of the environment.

Project Title	
Name(s) of Project Leader(s)	
Name of Institution:	
Cooperating Institution:	

CORE QUESTIONS:

Part I. GENETICALLY-MODIFIED ORGANISMS (GMOs)

A. OBJECTIVES		
a.1	What are the objectives of the proposed activity?	
a.2	What is the intended eventual use of the organism to be released?	

[1] The DOST-BC prohibits any modification (removal/deletion of any section/item) to the prescribed format of the proposal. If the proposal is found to have deviated from the prescribed format, the proposal shall not be accepted for evaluation by the DOST-BC and will be returned to the proponent through the IBC for modifications for strict compliance with the DOST-BC requirements.

a.3. What alternative technologies can accomplish the same purpose?	
a.4 What advantage does this technology have over existing technologies?	
a.5 What are the other consequences or spin-offs on the use of the organism or new technology?	
B. SPECIES TO BE RELEASED	
b.1 What species is/are to be released? (taxon, strain, cultivar, breed, variety, etc. of the GMO?	
b.2 Is/are the wild type or the modified organism(s) capable of causing human, animal or plant disease? If so, what are the possible diseases / effects / symptoms.	
b.3. Prior to genetic manipulation, is the organism found in the country? If so, state the geographical distribution of the said organism. Otherwise, state country of origin, and give a brief description of site of collection / breeding / production	
b.4 Is the wild type organism found at the site of release?	
C. TEST SITE	
c.1 Physical Environment	
c.1.1 Location	
c.1.2 Size of Experimental Site	
c.1.3 Climatic type (rainfall pattern; prevailing wind directions; wind velocity; average temperature; relative humidity sunlight duration)	
c.1.4 Details of the history of test site Location	
c.1.5 Legal or descriptive land location of the test site	
c.1.6 Distance to the nearest crop of the same species	
c.1.7 Distance to the nearest crop of any kind	
c.1.8 Distance to bodies of water	
c.1.9 Distance of populated areas	
c.1.10 Is there an area of special ecological interest (protected or sanctuary) near the trial site. If yes, describe briefly	

c.1.11 What is the anticipated post-trial land use?	
c.1.12 Is the test proposed isolation area and vicinities under the proponent's control? If no, give details as to how to maintain the isolation area.	
c.1.13 Does the site fall under ECA of DENR (Environmentally Critical Areas) per DENR Admin. Order 96-37?	
c.2 Biological Environment	
c.2.1 Vegetation	
c.2.1.1 Dominant weed species present	
c.2.1.2 Tree species in the vicinities	
c.2.1.3 Other crops growing in the vicinities	
c.2.2 Entomological Communities	
c.2.2.1 Insects/Pests Observed	
c.2.2.2 Predator/Beneficial Insects	
c.2.1.3 Other crops growing in the vicinities	
c.2.3 Plant Diseases Observed	
c.2.4 Other Species Observed	
c.2.4.1 Livestock/migratory Species	
c.2.4.2 Avian Species	
c.2.4.3 Reptiles, amphibians, crustaceans, fisheries, mollusks	
c.2.4.4 Are there any endangered or threatened species or near the trial site? If yes, please list	
c.3 Social Environment	
c.3.1 Local population near the trial site	
c.3.2 Cultural Profile	
c.3.3 Livelihood/economic activities	
c.3.4 Health Facilities	

c.3.5 Security (intruders, fence, etc.)	
c.3.6 Other infrastructure	
D. TEST SITE MAP *A map of the test site will be prepared by the proponent and appended to the record of planting. The following details should be included to allow regulators to locate each test site during the current and post-harvest season:* *1. the map should be legible and precise* *2. should be on a blank page with crisp line drawings and block letters* *3. the following information must be clearly printed:*	
d.1 General location of the test site (barangay/town/city/region)	
d.2 Legal or descriptive land location	
d.3. Global Positioning System (GPS) coordinates. The use of GPS locator numbers for each corner of the test site is recommended to provide the most accurate information to enable verification of the location test site. All GPS coordinates should be obtained using units with accuracy of at least plus or minus 5 meters.	
d.4 Compass directions, with North at the top of the page (drawn to scale)	Please provide the map of the test site (Annex 4)
d.5 Distances to permanent markers or surrounding landmarks such as telephone poles, road	
d.6. Indicate closest fields of same species and crop of any kind in the experimental area	
d.7 Total dimensions of the test site	
d.8 Include any natural ecosystems adjacent to the test site (natural habitats, waterways, forests and hedgerows)	
E. HABITAT AND ECOLOGY (please provide separate information for each organism)	
e.1 What is/are the natural habitat(s) of the wild type organism?	
e.2 What is the distribution range of the wild type organism (or its closest taxonomic relative) in the Philippines?	
e.3. Is the wild type organism or its closest taxonomic relative present at or near the site of release? State the geographical distribution of the wild type organism or its closest taxonomic relative.	

e.4	Is the modified organism capable of interbreeding or genetic exchange with its wild type counterpart, or with other species found at or near the site of planned release? Describe any intra and interspecific genetic interactions involved. Predict possible adverse effects of such genetic interactions.	
e.5	Are there any natural enemies (predators, pathogens, parasites, parasitoids) of the wild type organism in the Philippines? If so, identify and describe the natural enemies of the organism.	
e.6	Could the release prejudice any beneficial function of other organisms in the local environment? If so, explain.	
F. GMO GENETICS		
f.1	What genetic manipulations have been made? Provide details on the method(s) used to produce the organism.	
f.2	Give the characteristics of the GMO and specify how it differs from its wild type counterpart.	
f.3.	Where in the genome is the genetic manipulation made (chromosomal, mitochondria, chloroplast, chlamydia, transposon, unintegrated DNA, etc.)?	
f.4	How many copies of the manipulated gene/DNA sequence are present?	
f.5	What morphological or biochemical markers differentiate the GMO from its wild type counterpart?	
f.6	Will the genetic marker differentiate the GMOs from other organisms in the laboratory? In the open environment?	
f.7	Is any vector used in the genetic manipulation? Provide a description of the vector, its genotype, and a map. Show also the points of insertion/deletion/mutation of DNA in the final construct, including any control sequences and genetic markers added to the vector.	
f.8	Can the vector transfer to the other hosts? Provide information on the host range of the vector.	
f.9	Is the recombinant vector present (whole or partial vector sequences) in the final construct? If not, describe how the vector was removed from the final construct.	

f.10	If no vector was involved, how was the genetic material introduced?	
f.11	How many copies of the genetic sequence was inserted / deleted / mutated in the GMO?.	
f.12	What secondary genetic effects may be anticipated (horizontal transfer, reversions, loss of introduced trait, etc.)	
f.13	How does the modification alter the phenotype of the organism?	
f.14	What is the level of expression of the manipulated gene?	
f.15	How is the level of expression regulated?	
f.16	What intrinsic genetic features regulate the survival of the GMO in the open environment? How stable are these features?	
f.17	What genetic changes have been introduced into the GMO to limit its reproduction or the transfer of its genes to other organisms?	
G. DATA ON STABILITY, SURVIVAL AND TRANSFER UNDER CONTAINED CONDITIONS		
g.1	Was this organism studied under containment?	
g.2	What containment level was used in the study of this organism? Describe the containment measures.	
g.3.	Based on literature data and on the results of contained experiments, how long does the GMO survive in habitats relevant to the confined test?	
g.4	Give the growth rate or generation time of the GMO under conditions relevant to the release (physical environment, season, moisture, etc.)	
g.5	What is the frequency of reversion or loss of the introduced trait under conditions relevant to the confined test?	
g.6	What is the expected or known dispersal range of the GMO?	
g.7	What are the dispersal mechanisms used by the GMO or its wild type counterpart in air, water and soil?	
g.8	Can the GMO form long-term survival structures (seeds, spores, conidia, cysts, etc.)? If so, identify the type of structures and describe conditions that induce formation of such structures.	
g.9	Is there evidence of horizontal gene transfer to other organism(s) found at the release site and the surrounding	

	environment? If so, provide details on species specificity of transfer, transfer mechanism(s) involved, techniques used to monitor horizontal transfer, and possible adverse effects of transfer.	
g.10	Does the introduced trait confer any selective advantage on the organism under certain conditions? If so, what are these conditions? Provide data on growth rates and survival in the presence and in the absence of selection pressure.	
g.11	Would you expect the organism to have any competitive advantage over related taxa in mixed populations under the conditions of the test site? If so, what are these competitive advantages?	
H. EXPERIMENTAL PROCEDURES		
h.1	Describe in detail the overall experimental design for the release, including methodology, layout of site for release, schedule of release and duration of entire activity (excluding the required post-activity monitoring). On a separate page, provide Gantt chart for the activities involved in the said release. Indicate in the Gantt chart the season (dry, wet or rainy) when the proposed confined test will be conducted.	
h.2	How many organisms will be released?	
h.3.	How many releases are proposed?	
h.4	How will the organism be produced in bulk for the confined test?	
h.5	How will the organism be transported to the test site?	
h.6	What methods will be used to test batch to batch variability of organisms? Where will such tests be conducted?	
h.7	How will the survival of the organism and horizontal gene transfer be monitored? Give methodology and frequency of monitoring at the primary site and beyond?	
h.8	Give details on the specificity and sensitivity of monitoring methodology. Include a description of the equipment to be used.	
h.9	What other parameters will be monitored? Give details on how these	

	parameters will be monitored, and rationale for this monitoring activity.	
h.10	What methods will be used to minimize the organism's dispersal and survival beyond the primary site of release?	
h.11	What methods will be used to minimize horizontal gene transfer?	
h.12	Will the organism be allowed to remain in the environment after the release? If so, state expected duration and possible consequences of retaining the organism on site.	
h.13	Will measures be taken to reduce populations or eliminate the organism once the activity is completed? Provide details and rationale for choice of methodology.	
h.14	What monitoring will be undertaken after the release is completed and the activity is terminated?	
h.15	Describe site supervision procedures and safety protocols to be instituted on site of release.	
h.16	Describe your contingency plan in the event of an emergency (e.g. sabotage, accidental release, unanticipated risks necessitating cessation of additional releases, etc.).	
I. OTHERS		
i.1	Has the organism been previously cleared by the DOST-BC for laboratory use?	
i.2	Have similar releases been performed in other countries? Provide references and furnish a copy of the final report of previous releases.	
i.3	What are the organisms/materials that will be used for the experiment?	Please fill out Annex 6
i.4	Are there additional data that may be relevant to the proposed release?	

Part II. THE ORGANISMS AND APPLICATIONS

A. PLANTS		
a.1	Has the wild type or parent plant an extended history of cultivation and safe use? Provide details.	
a.2	What pleiotropic effects (desirable or otherwise) on the agronomic characteristics of the plant may result from the expression of the introduced	

	trait?	
a.3.	How is pollen dispersal accomplished by the plant? Provide data on pollen longevity and viability. Are potential pollinators present in or within the range of the confined test site?	
a.4	Is there a potential for weediness of the unmodified parent or of the modified plant? If so specify conditions that may encourage unwanted proliferation of such plants.	
a.5	Are there literature reports on cross-pollination between the GMO and wild relatives that are known to be weeds?	
a.6	Are sexually compatible plants present at or near the site of release? Are these plants within the expected pollen dispersal range? Should cross-pollination occur, would the resulting plant survive/compete well?	
a.7	Up to what stage would the plants be grown (e.g., vegetative stage only, up to the reproductive stage, up to senescence, etc.)?	
a.8.	If plants will be grown up to the seed stage, how are the seeds dispersed? Specify the size of the seeds. Are the seeds capable of prolonged dormancy? Specify conditions that may encourage dormancy and germination.	
a.9	Can the plant be dispersed by vegetative propagation? Describe conditions for vegetative propagation of the plant.	
a.10	What factors may contribute to the integration of the released plant into the vicinity?	
a.11	What attempts have been made or will be made to mitigate integration of the introduced plant in the local environment (e.g., male sterility, polyploidy, etc.)	
a.12	What factors may contribute to any competitive edge of the introduced plant? What mitigating activities would be done to limit the expression of such competitive edge?	
a.13.	Does the plant have extraordinary capabilities of adding or extracting nutrients from the soil?	
a.14	Does the plant possess higher levels of toxins as compared to that of wild types or closest taxonomic relative?	

	Could any products of the plant concentrate in the food chain? Is the biodegradability of the plant changed?	
a.15	What secondary ecological effects are expected from the confined test (effect on endangered species, selection for resistant pest populations, effects on natural enemies, etc.)?	
a.16	Is the plant resistant to an agricultural chemical or biological control agent(s)? Provide data on the activity, selectivity, persistence, and mode of application of the chemical or biological agent(s) concerned.	
a.17	What impacts will the release of the plant have on the agricultural uses of the said control agent? On integrated pest management?	
a.18.	Has the wild type or parent plant an extended history of cultivation and safe use? Provide details.	
B.	**MICROORGANISMS ASSOCIATED WITH PLANTS OR MICROORGANISMS THAT MODIFY THE PHYSICAL AND CHEMICAL ENVIRONMENT**	
b.1.	For microorganisms associated with plants, what is the partner species of plant? Describe the specificity of the interaction and indicate the range of plant species with which the introduced microorganism can interact.	
b.2.	Does the organism have an extended history of use in agriculture? Provide details of agricultural usage, including conditions of use.	
b.3.	For microorganisms associated with plants, what is the effect of the introduced organism on the partner plant species and how will this effect be monitored?	
b.4.	What other secondary effects might the organism have on the plant?	
b.5.	If the organism has been genetically modified, does the modification cause any change to the range of host plant species available to the organism?	
b.6.	What effects are anticipated regarding the distribution and abundance of the host plant species and other species with which the organism can interact?	
b.7.	If the organism is associated with plant species which are food crops, could the organism affect sustainability of the resultant produce for human or animal consumption? If so, explain.	

b.8. What are the effects expected on the soil chemistry (e.g., pH, mineral leaching, chelation, and nutrient levels)?	
b.9. What is the survival and dispersal of the organism in natural waters and soil?	
b.10. Does the organism produce spores, chlamydia or other resilient reproductive structures? Are these structures resistant to desiccation, heat-treatment, or disinfection?	
b.11. Are beneficial organisms (e.g., *Rhizobium, Azospirillum, Frankia* and *mycorrhiza)* present in the area/plants? What effects might the organism have on beneficial soil organisms? What is known about the interactions between the organism and closely related microorganisms in the partner plant (if applicable) or the environment of the release site?	
b.12. For microorganisms associated with plants, what effects might the organism have on insects, birds and animals (including humans) which may consume the plant?	
b.13. Is the organism known to exchange genetic material with plant pathogens? If so, elaborate.	
b.14. What sterilization methods, disinfectants and anti-microbial agents are active against the organism? Is the organism susceptible to UV or ionizing radiation?	
C. MICROORGANISMS LIVING IN OR ON ANIMALS	
c.1. What is the animal host species?.	
c.2. Does the organism have an extended history of use in agriculture, industry or medicine? Provide details of usage, including conditions of use.	
c.3. Is there any evidence that the organism might be capable of establishing in or on other animals, including feral animals? If so, what are these animals and what are the effects?	
c.4. What new capacity will the organism provide for the host species (e.g., ability to degrade plant or pasture toxins)? What secondary effects can be postulated from conferring the said capacity on the host?	

c.5. Will the competitive advantage or ecological fitness of the host be altered? Explain, providing data to support your answer..	
c.6. What effects (including secondary effects) are likely on the other plants or animals in the agricultural and natural environments?	
c.7. What secondary effects can be postulated from the introduction of the organism into or onto the host? (For example, is there a possibility of the genetic insert being transferred to other organisms in the host, or host cells?)	
c.8. For microorganisms living in animals, will the organism be excreted or otherwise leave the animal? If so, does the organism survive outside the host animal? Give details on the survival rate, longevity and persistence of the organism outside its host.	
c.9. What are the mechanisms for the survival and dispersal of the organism in natural waters and soil?	
c.10. Does the organism produce spores or other resilient resting/reproductive structures?	
c.11. What could be the effects of the organism on water quality?	
c.12. Is the organism resistant to desiccation?	
c.13. What sterilization and disinfection methods and anti-microbial agents are active against the organism? Is the organism susceptible to UV and ionizing radiation?	
D. MICROORGANISMS AS LIVE VACCINES	
d.1. What disease is to be controlled by the use of this vaccine?	
d.2. In what host species is the vaccine to be used?	
d.3. What is the host range of the parent organism from which the vaccine was constructed?	
d.4. If the vaccine is intended for humans, what are the proposed target groups for the vaccine? Specify age range, risk factor groups, and geographic area of residence, if applicable.	
d.5. Provide data regarding level and duration of immunity produced in the host species after vaccination with the organism.	

d.6	Over what period can the vaccine organism be detected in the vaccinated animals or their excretions? Provide supporting data.	
d.7	Can the vaccine organism spread from the vaccinated to non-vaccinated animals or other species (including humans)? If so, what is the mechanism and frequency? Provide data, if available.	
d.8.	If there are any evidence to indicate whether the susceptibility of the host to the vaccine organism could be affected by the current state of the host (e.g., immunosuppression or superimposition's of other disease) or by other treatments (e.g., drugs)? If so, elaborate.	
d.9.	Does the genetic material of the vaccine organism have the potential to become incorporated in whole or in part into the genome of any cells of the vaccinated host?	
d.10.	If this is a viral vaccine, can the nucleic acid of the virus in the vaccine be rescued, or be restored to wild type, by recombination or complementation with intracellular viruses?	
d.11.	In trials, is it proposed to dispose of waste, which contains vaccine organisms? If so, describe arrangements.	
d.12.	What is the fate of the vaccinated animals at the conclusion of the trial?	
d.13.	Will the vaccinated humans or animals carry live vaccine organisms at the end of the trial?	
d.14.	Will they be likely to disseminate the live vaccine organisms to their family contacts or to the general population?	
d.15.	What measures if any will be taken too minimize this probability?	
d.16.	Will the organisms be able to cross the placenta?	
d.17.	Is the use of this vaccine organism likely to preclude its use for vaccination against other disease subsequently? Will its usefulness for other vaccinations be affected?	
d.18.	Is the vaccine likely to have any deleterious effects on pregnant humans or animals? If so, specify. For humans, provide data from animal models.	

d.19. Is the vaccine teratogenic (i.e. causing developmental defects) for the fetus at any stage of gestation? If so, elaborate.	
d.20. Does the organism produce spores?	
d.21. Is the organism resistant to desiccation?	
d.22. What sterilizing and anti-microbial agents are active against the organism?	
d.23. Is the organism susceptible to UV and ionizing radiation?	
E. ANIMALS (VERTEBRATES, NOT INCLUDING FISH)	
e.1. What unintended effects (environmental, animal welfare or economic) may result from the release, and what is their likelihood?	
e.2. Are any of the intended gains directly linked to changes in other characteristics of the species? If so, specify.	
e.3. Will the animals in this experiment be allowed to breed? If not, is breeding planned for later experiments in the commercial phase?	
e.4. Are the arrangements for handling any offspring the same as those for the experimental animals? If not, please specify the arrangements.	
e.5. Do feral populations of the species exist in the Philippines? If so:	
e.6. Do the feral populations cause agricultural, environmental or disease-control problems? Specify the problems.	
e.7. Can feral populations interbreed with the organism? What is the likelihood of the novel genetic material entering the feral gene pool.	
e.8. What effect might the entry of novel genetic material into a feral gene pool have on the distribution and abundance of the feral population or on its ability to cause agricultural or environmental problems, or to contribute to the spread of infectious disease? Provide data to support your answer.	
e.9. If no feral populations exist in the Philippines, comment on the likelihood that the imparted characteristic may enhance the ability of the species to	

establish feral populations.	
e.10. Can the organism interbreed with any species native to the Philippines?	
e.11. What management procedures and environmental factors, if any, are required for the optimal survival of the organism? Provide data to support you answer.	
e.12. What management procedures and environmental factors, if any, are required for the total annihilation of the organism to be introduced? Provide data to support you answer.	
F. FISH AND AQUATIC ORGANISMS SUCH AS CRUSTACEANS	
f.1. Could the organism produce any metabolites or toxins likely to have deleterious effects on parasites or predators? If so, elaborate.	
f.2. What other unintended effects may result from the release? Your answer should include consideration of the effect of the organism on the community ecology at the release site.	
f.3. Are any of the likely gains directly linked to losses in other characteristic of the organisms?	
f.4. Will the organisms in this release be allowed to breed? If not, is breeding planned for later releases or commercial use?	
f.5. Are the arrangements for handling any offspring the same as those for the experimental organisms? If not, please specify the arrangement.	
f.6. Can the genetic material of the organism be transmitted by means other than by reproduction normal for the species or to any other species? If so, specify, and elaborate its effects.	
f.7. Do natural populations of the related organisms exist in the Philippines (including in rivers, lakes, dams, or coastal waters)? If so, do the natural population cause problems with other organisms? Specify the organisms and the problems.	
f.8. Could the organism establish competitive populations in aquatic habitats?	
f.9. What is the likelihood that the genetic material of the introduced organism will enter the gene pool of natural	

populations?	
f.10. Could the entry of novel genetic material into the gene pool significantly affect the distribution and abundance of other organisms? Describe such effects.	
f.11. What mechanisms will be used to prevent dispersal of the organism into other ecosystems?	
G. INVERTEBRATES	
g.1. What effects might the organism have on the food chain?	
g.2. Could the organism produce any metabolites or toxins likely to have deleterious effects on parasites or predators? If so, elaborate.	
g.3. What other unintended effects may result from the release? Your answer should include consideration of the effect of the organism on the community ecology at the release site.	
g.4. Will the organisms in this release be fertile? If not, is it intended to use fertile organisms in later releases?	
g.5. Are the genotype and phenotype of the offspring the same as those of the organisms to be released? If not, please specify the differences.	
g.6. Do populations of similar or related organisms exist in the Philippines? If so, do these populations cause agricultural, environmental or public health problems or benefits? Specify the problems or benefits.	
g.7. Can the novel genetic material be transmitted by means other than reproduction normal for the species? If so, specify and elaborate its effects.	
g.8. What is the likelihood of the novel genetic material entering gene pools of natural populations?	
g.9. Can the novel genetic material be transmitted to any other species? If so, specify the mechanism of transfer and list the species.	
g.10. What is the likelihood that the genetic material of the introduced organism will enter the gene pool of natural populations?	
g.11. Could the entry of novel genetic material into the gene pool significantly affect the distribution and abundance	

of other organisms? Describe such effects.	
g.12. What mechanisms will be used to prevent dispersal of the organism into other ecosystems?	
H. ORGANISMS FOR BIOLOGICAL CONTROL	
h.1. What is the species targeted for biological control?	
h.2. What direct effects does the organism have on the target species?	
h.3. What is the host range of the organism?	
h.4. What non-target organisms have been tested for susceptibility to the organism?	
h.5. What is the rationale for the choice of species tested?	
h.6. How is the GMO transferred from one target individual to another and what factors affect the transferability?	
h.7. What secondary effects can be envisaged on predators, prey or parasites of the target species?	
h.8. Explain the consequences of the removal or reduction of the target species on the management of agriculturally significant plants or farm animals.	
h.9. Predict any changes in the ecosystem resulting from a reduction in the population of the target organism.	
h.10. Does the organism produce metabolites, which may have deleterious effects directly on other organisms or indirectly through concentration in the food chain? If so, elaborate.	
h.11. If novel genetic traits can be transmitted to other organisms, which are likely to be in the environment, are these other organisms likely to affect non-targeted species?	
h.12. What genetic response might be invoked in populations of the target organisms as a result of the use of the organism (e.g., increased resistance to the introduced organism)?	
I. ORGANISMS TO BE CONSUMED AS FOOD OR FEED	
i.1. Is the organism (genetically modified or otherwise) already used in food production or eaten as food? If so, At	

	what level of daily/weekly intake, and Is any processing needed or commonly used before consumption?	
i.2.	Identify countries that use of the organism as food or feed. Was registration of the organism required prior to marketing of the organism as food? Provide details.	
i.3.	Does the organism produce metabolites, which may have adverse effects on the consumer (humans or animals)? If so, elaborate.	
i.4.	Provide available data on toxicology, allergenicity and other possible adverse effects.	
i.5.	Can any products of the organism concentrate in the food chain to levels, which may become toxic? If so, elaborate.	
i.6.	Is the organism to be processed during the production of the food or feed? If so, elaborate on the processing.	
i.7.	Is the organism the major component of the food as eaten, or is it in small numbers in the final product (e.g., yeast cells in beer)?	

Part III. RISK ANALYSIS

Identify all potential risks of your confined test work and describe the corresponding mitigation measures that will be implemented in the table provided below. Tick/mark field with 'x' as appropriate.

	Applicable	**Not Applicable**	**Mitigating Measure**
A. Parent (Wild type) Organism			
1. Domestication			
a. No reproduction without human aid			
b. Semi-domesticated: wild or feral populations known			
c. No reproduction without human aid			
2. Agents for control			
a. Known			
b. None Known			
3. Origin			

	Applicable	Not Applicable	Mitigating Measure
a. Indigenous			
b. Exotic			
c. Unknown (Not Sure)			
4. Pest / Pathogen			
a. Relatives not pests/pathogens			
b. Relatives are pests/pathogens			
c. Organism is pest/pathogen itself			
5. Survival under adverse conditions			
a. Ultra short term			
b. Short term			
c. Long term (e.g. spores, cysts, seeds, dormancy)			
6. Distribution / Habitat			
a. Narrow range			
b. Broad range			
c. Long term (e.g. spores, cysts, seeds, dormancy)			
7. Gene exchange in natural populations			
a. None			
b. Frequent			
c. Unknown			
B. Genetic Constituents			
1. Donor DNA			
1.1. Source of insertion			
a. Same species			
b. Closely related species			

	Applicable	Not Applicable	Mitigating Measure
c. Unrelated			
1.2. Characterization			
a. Full			
b. Poor			
c. Unknown			
2. Vector			
1.1. Source of vector			
a. Same species; non-pathogen			
b. Closely related species; non-pathogen			
c. Unrelated species or pathogen			
1.2. Vector DNA/RNA in altered genome			
a. Absent			
b. Present but non-functional			
c. Functional			
C. Phenotype Organism			
1. Fitness			
a. Reduced irreversibility			
b. Reduced reversibility			
c. Increased			
2. Infectivity, virulence, pathogenicity or toxicity			
a. Reduced irreversibility			
b. Reduced reversibility			
c. Increased			
3. Host range			

	Applicable	**Not Applicable**	**Mitigating Measure**
a. Unchanged			
b. Broadened or shifted			
4. Substrate resource			
a. Unchanged			
b. Altered			
c. Expanded			
5. Environmental limits to growth or reproduction (habitat, microhabitat)ost range			
a. Narrowed but not shifted			
b. Broadened or shifted			
6. Resistance to disease, parasitism, herbivory, or predation			
a. Decreased			
b. Unchanged			
c. Increased / Unknown			
7. Susceptibility			
7.1. To agents of control			
a. Increased			
b. Unchanged			
7.2. To absence of substrate			
a. Increased			
b. Unchanged			
c. Decreased			
7.3. To destruction by mechanical means			
a. Increased			
b. Unchanged			

	Applicable	Not Applicable	Mitigating Measure
c. Decreased			
8. Similarity to phenotypes previously used safely			
a. Identical			
b. Similar			
c. Dissimilar			
D. Attributes of the Environment			
1. Positive Selection			
a. Absent			
b. Present			
2. Possible dispersal to wild, weedy, or feral relatives			
a. No			
b. Yes			
3. Vectors or agents of dissemination or dispersal (mites, insects, rodents, birds, humans, machines, wind, water, etc.)			
a. Absent			
b. Present but controllable			
c. Present and uncontrollable			
3. Vectors or agents of dissemination or dispersal (mites, insects, rodents, birds, humans, machines, wind, water, etc.)			
a. Absent			
b. Present but controllable			
c. Present and uncontrollable			
4. Direct involvement in basic ecosystem processes (e.g. nutrient cycling)			
a. Not involved			
b. Marginally Involved			
c. Involved / Key Species			

	Applicable	Not Applicable	Mitigating Measure
5. Range of environments for use or testing; potential geographical range			
a. Very restricted			
b. Restricted			
c. Broad / Widespread			
6. Simulation of Test conditions			
a. can simulate realistically			
b. very difficult to stimulate realistically			
c. Broad / Widespread			
7. Public access to test site			
a. Tightly controlled			
b. controlled			
c. uncontrolled			
8. Effectiveness of monitoring and mitigation plans			
a. Proven Effective			
b. Likely to be effective			
c. Untested or unlikely to be effective			

RECORD VALIDATION

Important Notice:

Complete every applicable item on this form or write “N/A” or “Not Applicable” if otherwise. The answers must be supported by data and relevant scientific literature, all of which shall be appended to the proposal.

The Project Leader(s) must affix his signature/initial at the lower right corner of every page of the proposal and its annexes.

The DOST Biosafety Committee (DOST-BC) requires the submission of 1 soft copy *in PDF* and 15 hard copies of the proposal together with the attachments. Annexes must be printed separately.

The DOST-BC reserves the right not to act on any proposal or endorsement which does not comply with the prescribed format or fails to include all the required attachments.

“*Commercial-In-Confidence*” must be stamped at the upper right corner of the page, should the section contain such information.

I hereby confirm that the above information is correct and request its endorsement to the DOST Biosafety Committee.

Name(s) of Project Leader(s)	Signature	Date

ANNEX 9-A

CHECKLIST OF REQUIREMENTS
FOR APPLICATION FOR CONFINED TEST OF GMOS

DOST-BC Reference Number:
(to be filled out by DOST-BC Secretariat)

1	Project Title	
2	Name(s) of Project Leader(s)	
3	Name of Institution:	

4	The following information have been submitted/provided	To be filled out by DOST-BC Secretariat		
		YES	NO	Remarks
a.	Coversheet – Assessed and Duly Endorsed by the IBC	☐	☐	
b.	Proposal in accordance with prescribed format for evaluation of proposal for contained experiment	☐	☐	
c.	Executive Summary of Project Proposal	☐	☐	
d.	Soft copy of the proposal (full blown proposal and CBI-portion deleted version)	☐	☐	
e.	Project Information Sheet (PIS) in English and Local Dialect Versions	☐	☐	
f.	Site Inspection Report for validation of the DOST-BC Inspection Team	☐	☐	
g.	Annex 9-B Gantt chart of activities	☐	☐	
h.	Annex 9-C Detailed schedule of activities	☐	☐	
i.	Annex 9-D Map of Plasmid, Southern blot	☐	☐	
j.	Annex 9-E Map of Construct	☐	☐	
k.	Annex 9-F Summary of Introduced Genetic Elements	☐	☐	
l.	Annex 9-G Location Map of the Confined Test Site	☐	☐	
m.	Annex 9-H Biosafety Contingency Plan	☐	☐	
n.	Annex 9-I List of Materials Utilized	☐	☐	
o.	Annex 9-J List of personnel involved in the project and their duties	☐	☐	
p.	Annex 9-JA – Personal Data Sheet of project personnel	☐	☐	
q.	Annex 9-K Summary of Project for posting in the DOST-BC website	☐	☐	
r.	Annex 9-L Scientific literature/references[1]	☐	☐	

[1] *One complete set of hard copy, including list of citations must be provided for the original proposal and just a list of citations for the remaining copies of the proposal to be submitted*

If any of the above requirements has not been provided, the DOST-BC Secretariat will request the proponent/s through the IBC to complete the required information.

Submitted by		**Verification of Submission** (to be filled out by DOST-BC Secretariat)	
Name of the IBC Chairperson		Received by	
Date		Date and time Received	
Signature		Remarks	

ANNEX 9-B

GANTT CHART OF ACTIVITIES

Project Title	
Name(s) of Project Leader(s)	
Name of Organization:	

Activities (i.e. materials preparation to post-harvest monitoring)	**Week**																			
	1	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**	**14**	**15**	**16**	**17**	**18**	**19**	**20**

ANNEX 9-C

DETAILED SCHEDULE OF ACTIVITIES

Project Title	
Name(s) of Project Leader(s)	
Name of Organization:	

Activity	**Date**	**Location**	**Involved Project Personnel**	**Presence of IBC and/or DOST-BC/ PQS Monitors** (To be filled out by the DOST-BC)

ANNEX 9-D

MAP OF PLASMID / SOUTHERN BLOT

The plasmid must be clearly and properly labeled, indicating the major parts (promoter, terminator, enhancer etc.) and the name, size (kb) and source of the gene(s). Figures showing the stable integration of the introduced gene(s) (Southern blot) must also be properly labeled.

ANNEX 9-E

MAP OF CONSTRUCT

The construct must be clearly and properly labeled, indicating the major parts (promoter, terminator, enhancer etc.) and the name, size (kb) and source of the gene(s). Figures showing the stable integration of the introduced gene(s) must also be properly labeled.

ANNEX 9-F

SUMMARY OF INTRODUCED GENETIC ELEMENTS

PUTATIVE CONSTRUCT DESIGNATION	**GENETIC ELEMENTS INTRODUCED** *(promoter, terminator, etc.)*	**COPY NO. (if known)**	**DESCRIPTION / FUNCTION**	**SOURCE**	**GENEBANK IDENTIFIER/ ACCESSION NUMBER**	**REFERENCE**

ANNEX 9-G

LOCATION MAP OF THE CONFINED TEST SITE

A Location map must be provided indicating the dimensions of the Confined Test Site and its exact location relative to the other facilities of the Institution. The map must be drawn to scale with the North compass direction at the top of the page. If codes/symbols will be used, legends must be provided.

ANNEX 9-H

BIOSAFETY CONTINGENCY PLAN
FOR CONFINED TEST OF GMOS

Project Title	
Name(s) of Project Leader(s)	
Name of Institution:	
Location of Experiment	

BIOSAFETY CONTINGENCY PLAN (e.g. typhoon, flooding, brownouts)	**RAPID TERMINATION PLAN** (e.g. typhoon, flooding)	**CONTACT DETAILS OF THE PERSON TO BE CONTACTED IN CASE OF EMERGENCIES**
		Name Designation Address: Tel. No Mobile No. E-mail

ANNEX 9-I

LIST OF MATERIALS TO BE UTILIZED

Materials (Please indicate the type of material e.g seeds, leaf etc)	**Availability** *Please mark (x) as appropriate*		**Classification** *Please mark (x) as appropriate*		**Quantity**	**Point of Origin**	**Exporter Contact Details** (Applicable only for imported materials)		
	Locally available /developed	**To be Imported**	**Transgenic**	**Non-Transgenic**			**Name**	**Address**	**Contact Number / Email Address**

ANNEX 9-J

LIST OF AUTHORIZED PERSONNEL

Project Title	
Name(s) of Project Leader(s)	
Name of Organization:	

Name	Designation	Responsibilities in the conduct of the activity

ANNEX 9-JA

PERSONAL DATA SHEET
PROJECT PERSONNEL

Full Name	

Current Employment	
Position/Job Title	
Department / Division / Unit	
Employer/Organization	
Mailing Address	
Phone/Fax Number(s)	
Email Address	
Main area(s) of responsibility	

Employment History *(please provide details of your previous employment for the last 5 years starting with the most recent one.)*	
Previous professional experience (a)	
Position/Job Title	
Department / Division / Unit	
Employer/Organization	
Starting to Ending Date	*From* <YYYY> *to* <YYYY>
Previous professional experience (b)	
Position/Job Title	
Department / Division / Unit	
Employer/Organization	
Starting to Ending Date	*From* <YYYY> *to* <YYYY>

Education			
	Name of Academic Institution	Degree Course (Write in Full)	Year Graduated
Secondary		-	
Vocational / Trade Course			
College			
Graduate Studies (M.Sc, Ph.D.)			

Professional qualifications	
Specialized training, certifications *List a maximum of three other relevant professional qualifications*	1. 2. 3.
Publications *List a maximum of three most important publications related to the main field of expertise*	1. 2. 3.

Professional Membership	
Professional memberships *List up to three relevant professional societies or organizations of which you are a member:*	1. 2. 3.
Technical committees, expert panels or advisory bodies served *List up to three relevant technical committees, expert panels or advisory bodies on which you have served and briefly describe your specific responsibilities:*	1. 2. 3.

ANNEX 9-K

SUMMARY OF THE PROJECT
FOR POSTING AT THE DOST-BC WEBSITE

Project Title	
Project Type	<Confined Test>
Institution	
Cooperating Institution	
Supervising IBC	
Project Leader(s)	
Location of the experiment	
Objectives of the Study	
Biosafety Measures	

ANNEX 9-L

SCIENTIFIC LITERATURE / REFERENCES[1]

All relevant literature/references must be appended to the original proposal. A summarized list of all the references/literature must likewise be provided and enumerated for the remaining copies of the proposal using the proper format[2]. If information was accessed in the internet, the web page, author and date of access must be indicated[3].

[1] One complete set of hard copy, including list of citations must be provided for the original proposal and just a list of citations for the remaining copies of the proposal to be submitted

[2] Please use the Modern Language Association (MLA) formatting style: Last Name of Author, First Name of Author. Book Title. Publication City: Publisher, Publishing Date

[3] Please provide the URL of the website (e.g. http://dost-bc.dost.gov.ph), name of the website and date accessed (dd-mmm-yyyy)

ANNEX 10

PROJECT INFORMATION SHEET (PIS)
FOR CONFINED TEST

FOR PURPOSES OF PUBLIC NOTIFICATION AND COMMENT
(ENGLISH VERSION)

1. Name if institution

2. Address of Institution

3. Project Leader(s) – Name, Address, Telephone/Fax Numbers, Email Address

4. Organism to be tested

5. Purpose(s) of the Confined Test

6. Advantages/Disadvantages of the Proposed Strategy over Existing Methods

7. Brief Summary of the Nature and Effects of the Organisms to be Tested

8. Location and Size of the Confined Test Site

PUBLIC INFORMATION SHEET
Approved for Purposes of Public Information and Comments Only

Chairman, DOST Biosafety Committee

Date

9. Duration of the Project involving Confined Test. Start/End.

10. Government Agencies Consulted Before Release

11. Additional information may be obtained from the proponent or his organization.

We invite the public to comment on this confined test.

Please address comments to:

OFFICE OF THE CHAIRMAN
DOST-Biosafety Committee
c/o the Head Secretariat
2nd Floor, Room 212, DOST Main Bldg.
Department of Science and Technology
Gen. Santos Ave., Bicutan, Taguig City, Metro Manila

Telefax Number: (02) 837-2930 or (02) 837-2943
E-mail: secretariat@dost-bc.dost.gov.ph

PUBLIC INFORMATION SHEET
Approved for Purposes of Public Information and Comments Only

Chairman, DOST Biosafety Committee _____ Date

ANNEX 11

INSPECTION REPORT
ON INDICATIVE CONDITIONS OF THE PROPOSED CONFINED TEST SITE

Project Title	
Location of Confined Test site	

Site Component	Description	Inspector's Remarks
A. PHYSICAL ENVIRONMENT		
• Area		
• Soil Type / Topography		
• Climatic Type		
Meteorological Data (PAGASA)		
• Rainfall Pattern		
• Prevailing wind Directions		
• Wind Velocity		
• Average Temparature (°C – min & max)		
• Relative Humidity (%)		
Component / Description		
• Normal Planting Schedule		
Distance to:		
• Bodies of Water		
• Populated Areas		
• Center of Agricultural Activity		
• Protected Areas / Habitat and endangered Species		
Does it fall under ECA of DENR (Environmental Critical Areas) Per DENR Administrative Order 96-37		
B. BIOLOGICAL ENVIRONMENT		
Vegetation		
• Weed species present in the field		
• Tree species planted in the vicinities of the site		

Site Component	Description	Inspector's Remarks
• Other Crops growing in the vicinities of the area		
Entomological Communities and Population Behavior		
• Insect pests observed in the area field		
• Pests Damage		
• Predator/Beneficial insects		
• Livestock / migratory species		
• Avian population		
• Reptiles, Amphibians, Crustaceans, Fisheries, Mollusks		
• Profile of Microorganisms (diseases observed in the area)		
C. SOCIAL ENVIRONMENT		
• Local population near the site		
• Ecological support system		
• Economic activities		
• Health facilities		
• Security		

DATA COLLECTION AND SUBMISSION (To be filled up by the Proponent)			
Data gathered and submitted by:		Designation	
Signature and Date		Company / Institution	

RECORD VALIDATION (To be filled up by the DOST-BC Inspection Team)			
Date of Inspection			
Inspector	**Institution**	**Signature**	**Remarks**

RECOMMENDATIONS (To be filled up by the DOST-BC Inspection Team)

☐ Approved ☐ Disapproved

☐ Approved after complying with the following conditions:

ANNEX 12

PROGRESS / STATUS REPORT
PROGRESS/STATUS REPORT FOR CONFINED TEST FOR THE YEAR

Project Information	
DOST-BC Reference number	
Project Title	
Project Leader(s)	
Name of Institution	
Location of experiment (Indicate the type of facility)	
Date Approved by the DOST-BC	
Reporting Period	

- IBC Endorsement[1]		
Name of IBC Chairman	**Signature**	**Date**
Name of IBC Members and Community Representatives / Signature / Date	**Signature**	**Date**

[1] Must be signed by all IBC Members

DOST-BC Reference number	
Project Title	

Abstract

Introduction

Objectives

Materials and Methods[2]

Status and Discussion

References

Record Validation

Important Notice:

The DOST Biosafety Committee (DOST-BC) requires the submission of 1 soft copy and 15 hard copies of the Progress / Status Report. Please note that the soft copy submitted to the DOST-BC must be in PDF.

I hereby confirm that the above information is correct and request its endorsement to the DOST Biosafety Committee.

Name of Project Leader(s)	Signature	Date

[2] Include imported materials and source, as well as Inventory of all the biological materials (Fill out *Annex 1* for this purpose)

INVENTORY OF BIOLOGICAL MATERIALS

Materials	Classification		Parentage	Number of Materials Generated	Stored		Other Remarks
	GM	Non-GM			Yes	No	

ANNEX 13

COMPLETION REPORT[1]
FOR CONFINED TEST OF GMOs

Project Information	
DOST-BC Reference number	
Project Title	
Project Leader(s)	
Name of Institution	
Name of Supervising IBC	
Location of experiment (Indicate the type of facility)	
Date Approved by the DOST-BC	
Date of Completion	

IBC Endorsement[2]		
Name of IBC Chairman	**Signature**	**Date**
Name of IBC Members and Community Representatives / Signature / Date	**Signature**	**Date**

[1] The Completion Report is submitted by the proponent to the IBC within 90 days after the completion of the project. *The completion report cannot be submitted unless the post-harvest monitoring activities have been accomplished.* The IBC shall then review the completion report of the Proponent and endorse it to the DOST-BC within 120 days from completion date of the project.

[2] All IBC Members must sign. Otherwise please state reason for abstaining.

DOST-BC Reference number	
Project Title	

Abstract

Introduction

Objectives

Materials and Methods[3]

Results and Discussion

Conclusion and Recommendation

References

Annexes

[3] Include imported materials and source, as well as: a) Status / Fate of Biological Materials and b) Inventory of Materials

Record Validation		
I hereby confirm that the above information is correct and request its endorsement to the DOST Biosafety Committee.		
Name of Project Leader(s)	Signature	Date

ANNEX 14

IBC REPORT
AFTER COMPLETION OF CONFINED TEST OF GMOs

IBC Information	
IBC Name	
Address	

Project Information	
DOST-BC Reference number	
Project Title	
Project Leader(s)	
Agency(ies) which have issued approval(s)/permit(s) and date(s) of issuance	
Location of experiment (Indicate the type of facility)	
Date of Commencement	
Date of Completion	

1. Summary of the Results

2. What monitoring procedures were undertaken?

3. Were the procedures undertaken according to the protocol submitted for review? If not, specify deviations and why.

4. Were the aims of the contained test/CFT achieved? Describe.

5. Were there any unexpected effects? Describe.

6. What is the number of organisms surviving at the site of the experiment? What will be the fate of these organisms? Explain.

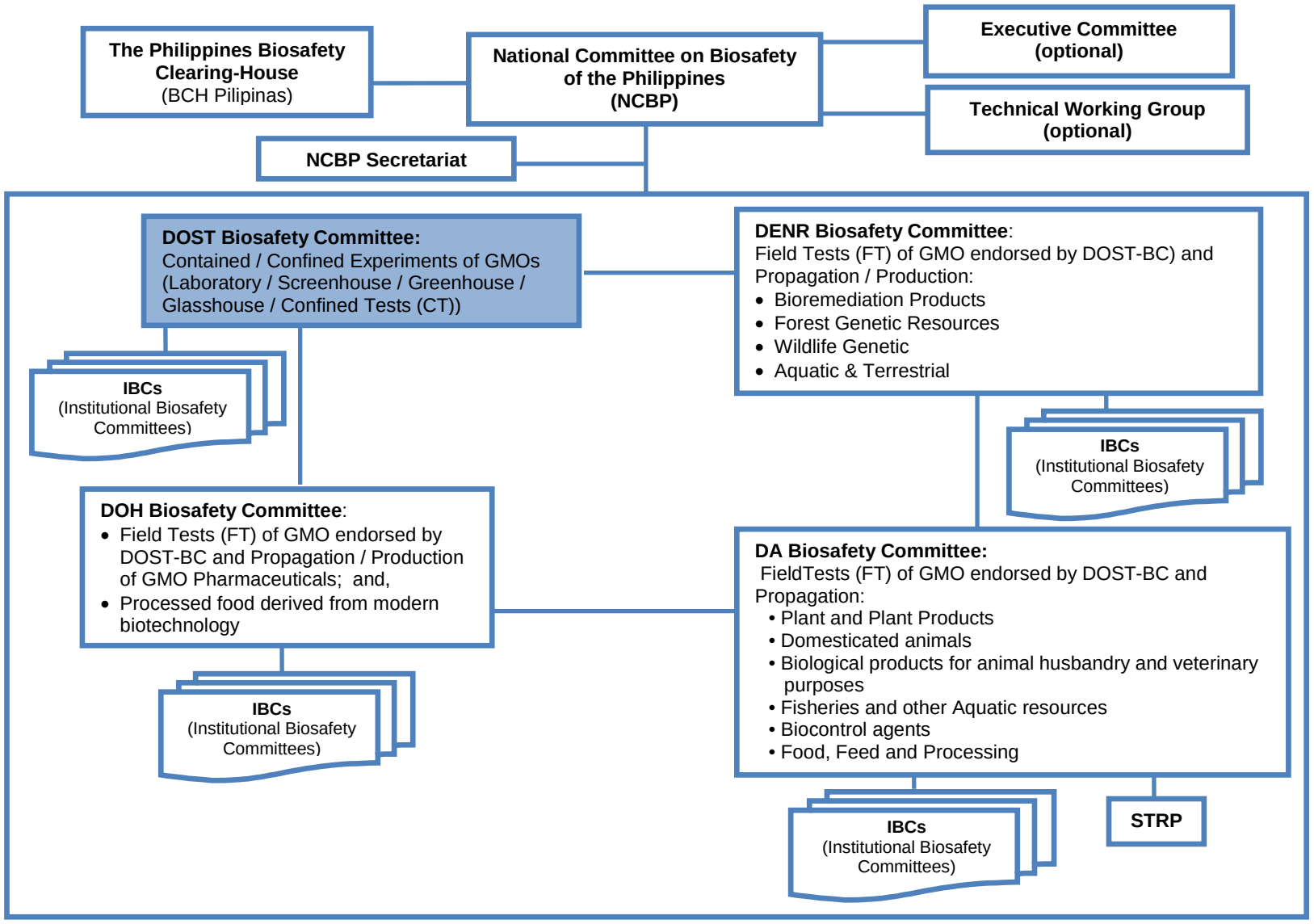
7. Will the project be continued to a further stage? If yes, provide details.

8. Were any viable material stored for future use? If yes, provide details.

IBC Concurrence		
Name of IBC Chairman	**Signature**	**Date**
Name of IBC Members and Community Representatives	**Signature**	**Date**

APPENDIX 1

The Philippines Biosafety Organizational Structure

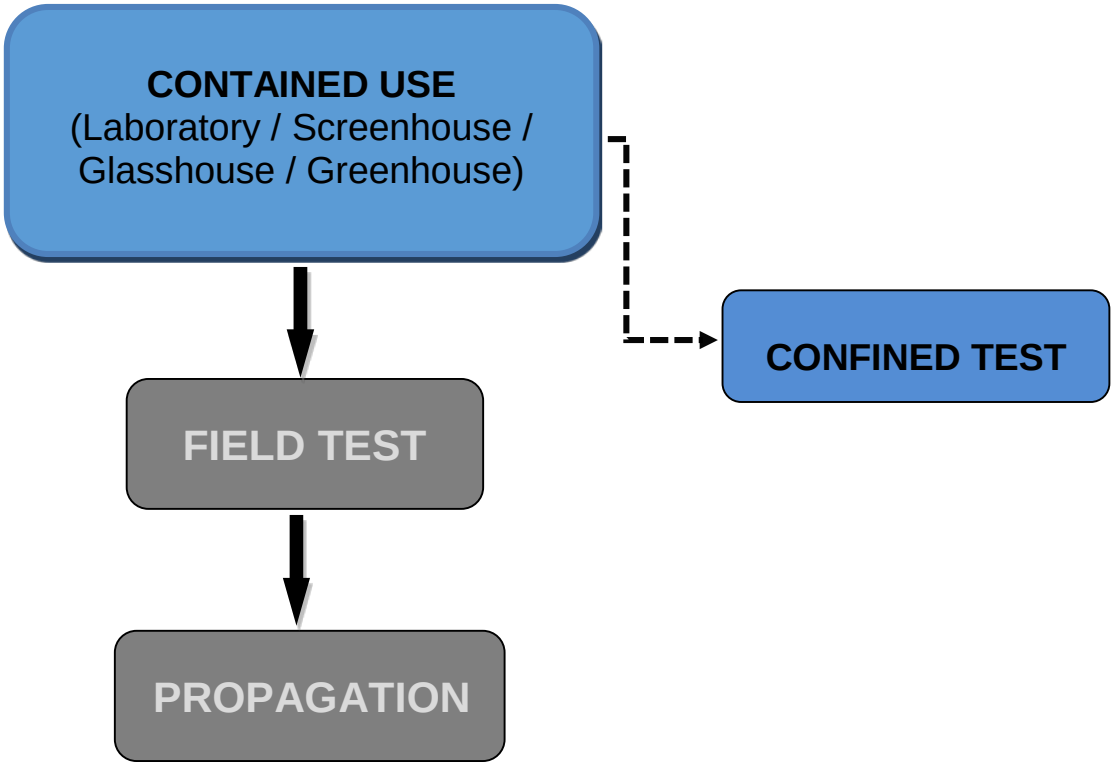


NCBP : National Committee on Biosafety of the Philippines
DA-BC : Department of Agriculture-Biosafety Committee
DOH-BC : Department of Health-Biosafety Committee
IBC : Institutional Biosafety Committee

BCH : Biosafety Clearing-House
DENR-BC : Department of Environment and Natural Resources-Biosafety Committee
DOST-BC : Department of Science and Technology-Biosafety Committee
STRP : Scientific and Technical Review Panel

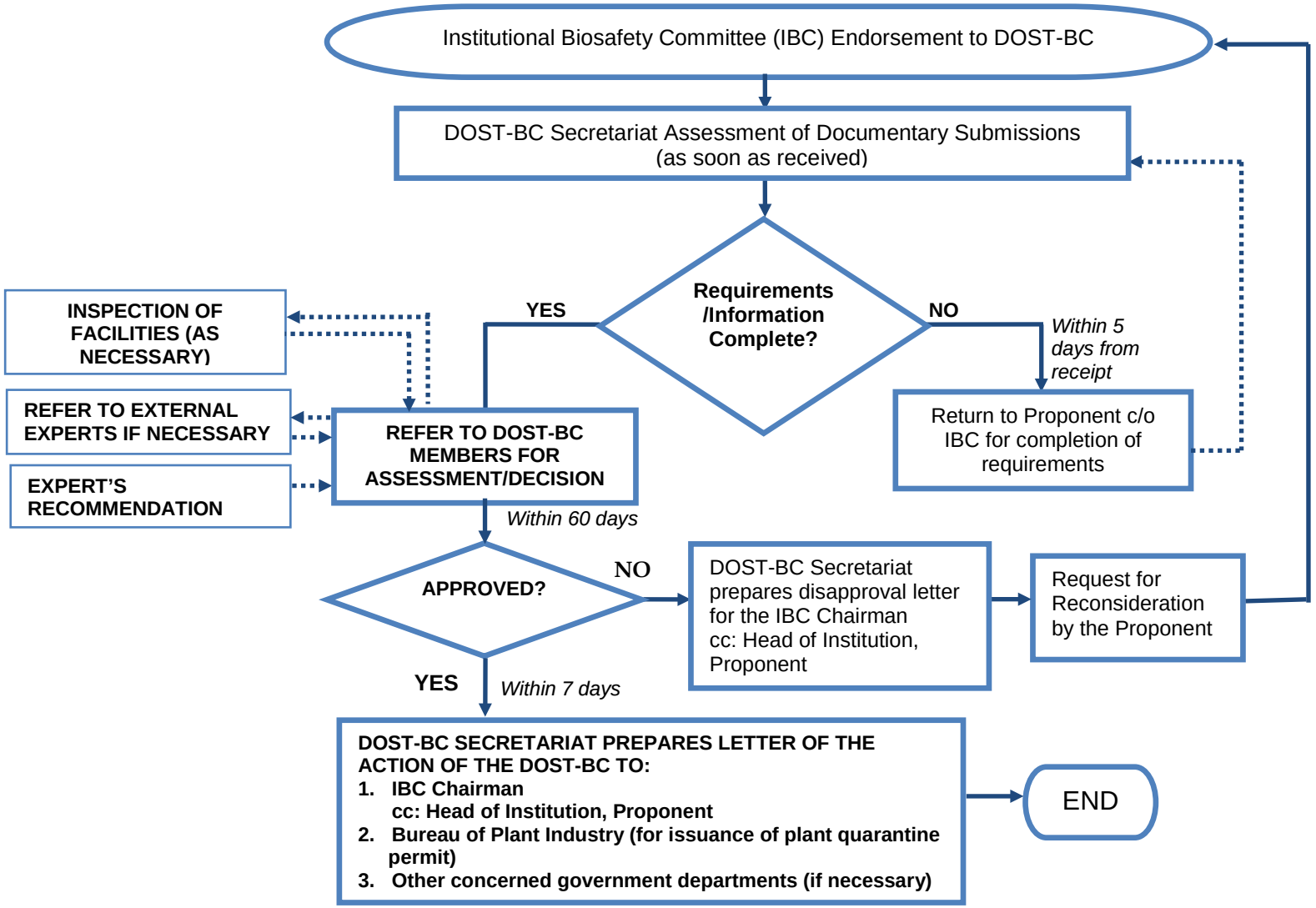
APPENDIX 2

STAGES OF GMO DEVELOPMENT



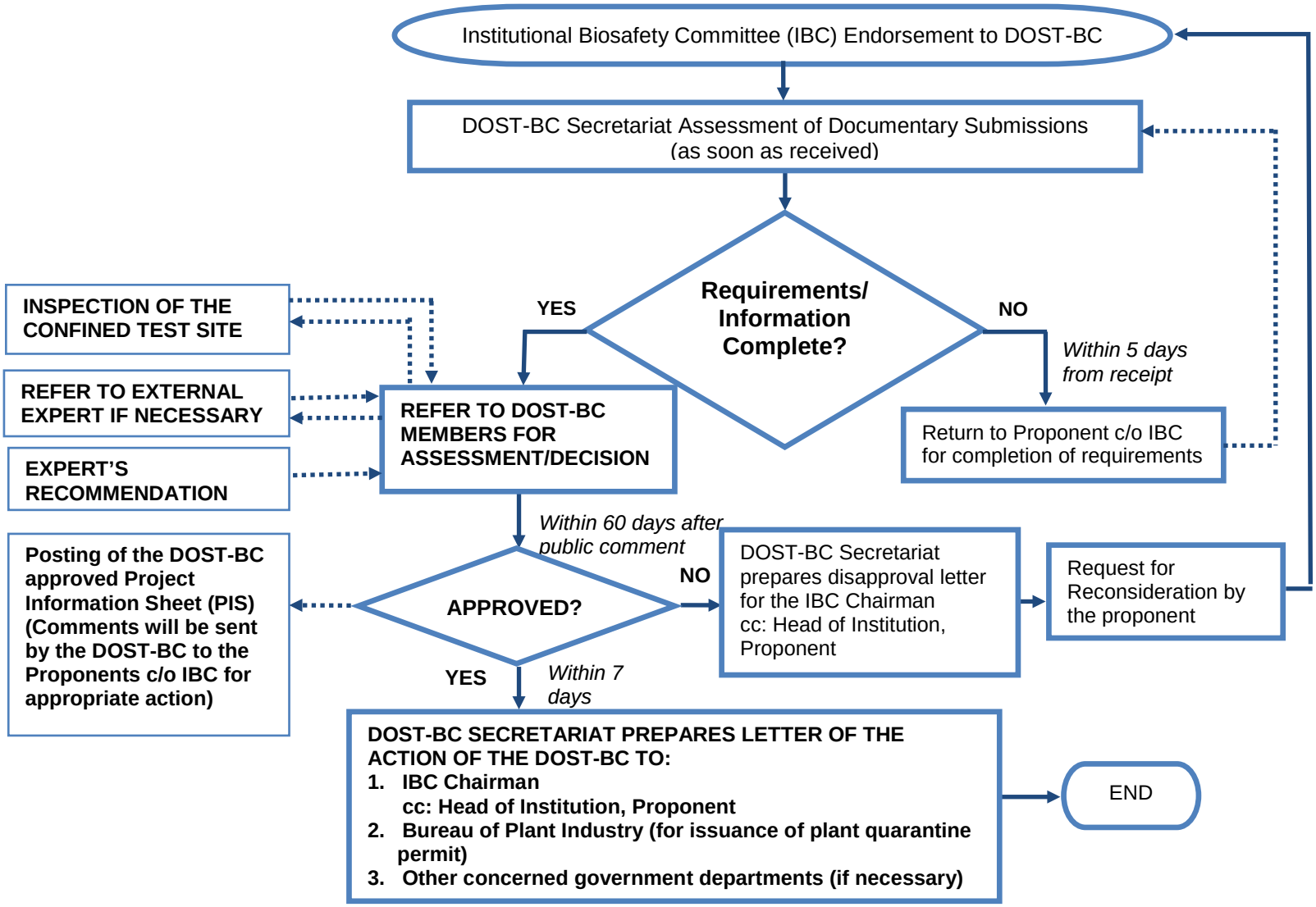
APPENDIX 3

Flowchart for the Review of Applications for Contained Use of GMOs
in Laboratory/Screenhouse/Greenhouse/Glasshouse



APPENDIX 4

Flowchart for the Review of Applications for Confined Test of GMOs



APPENDIX 5

THE UNIVERSAL BIOHAZARD SYMBOL



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Adopted on the 13th day of September Two Thousand and Fourteen in Diliman, Quezon City by the Department of Science and Technology Biosafety Committee (DOST-BC):

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Undersecretary for S&T Services
Department of Science and Technology
and Chair, DOST-BC

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