THE UNITED REPUBLIC OF TANZANIA

The National Biosafety Guidelines for Tanzania

VICE PRESIDENT'S OFFICE

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PREFACE

Biosafety can simply be referred to as avoidance of risk to human health and conservation of the environment as a result of research and commerce of GMOs and products thereof by instituting legal, administrative and policy instruments. Many new products in agriculture, aquaculture, health, industry and environmental remediation have emerged via modern biotechnological process. However, these techniques must be applied according to a number of precautions to ensure safe and effective applications. It also requires negotiations between stakeholders to bridge the different interests between the proponents of this powerful new science who argue that biotechnology has potential, among others, to boost food security, reduce the need for clearing more land for farms, improve health care, reduce the need for irrigations and agrochemicals. However, other are concerned over the possible risk that GMOs can pose for biological diversity, ecosystems, species and genetic resources whose interactions form the web of life on earth and human health.

As a result, there exists an immediate need for Biosafety Guidelines to be designed to contribute in ensuring an adequate level of protection in the field of the safe transfer, handling and use of GMOs resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, protection of human health taking also into account socio-economic cultural and ethical concerns and specifically focusing on transboundary movements. Currently, the Government is implementing the Cartagena Protocol on Biosafety focusing on developing the National Biosafety Framework that provide a foundation in developing appropriate policies, legislation, regulations and guidelines to achieve an adequate level of safety in biotechnology through UNEP-GEF funded project spearheaded by Vice President's Office. These Biosafety Guidelines have been designed with accordance to the precautionary approach contained in Principle 15 of the Rio Declaration on Environment and Development (1992) and also draws extensive experience from the Cartagena Protocol on Biosafety, African Model Law on Biosafety and Biosafety Guidelines of several other countries including Uganda, Kenya, Philippines, Namibia, South Africa and Egypt.

The guidelines outline the procedures and steps to be followed by the importer who arranges for importation of a Genetically Modified Organism (GMO) in the country, as well as identifying the basic requirements in fulfilling the same including facilities to be in place. Also goes further to offer technical guidance on issues such as risk assessment and risk management just to mention a few. These Biosafety guidelines are meant to facilitate the importation and use of Genetically Modified Organisms (GMOs) and their products thereof in Tanzania.

It is anticipated that the guidelines would be revised periodically, for more effective and efficient implementation. Therefore, any suggestion for improvement from all stakeholders would be highly appreciated.

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ABBREVIATIONS AND ACRONYMS

BL	Biosafety Level
CBD	Convention on Biological Diversity
CPB	Cartagena Protocol on Biosafety
DNA	Deoxyribonucleic Acid
CBD	Convention on Biological Diversity
CPB	Cartagena Protocol on Biosafety
GEF	Global Environmental Facility
GMO	Genetically Modified Organism
HEPA	High Efficiency Particulate Air
HV	Host-Vector
IBC	Institutional Biosafety Committee
MARI	Mikocheni Agricultural Research Institute
NBAC	National Biotechnology Advisory Committee
NBC	National Biosafety Committee
NBF	National Biosafety Framework
SUA	Sokoine University of Agriculture
rDNA	recombinant Deoxy ribonucleic acid
UNEP	United Nations Environment Program
NBFP	National Biosafety Focal Point
VPO	Vice President's Office

GENERAL PROVISIONS

A. Key Features

(i) These guidelines may serve as inputs when developing, drafting or revising legislative, administrative or policy measures that relate to ensuring adequate level of protection in the field of safe transfer, handling and use of genetically modified organisms resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health.

(ii) These guidelines take into account socio-economic, cultural and ethical considerations that may arise from the introduction of genetically modified organisms into the country.

(iii) These guidelines will be reviewed, revised and improved as experience is gained in biosafety.

B. Definition of Terms

Applicant The applicant should be a permanent resident of Tanzania or in the case of a non-resident, should designate an agent who is a permanent resident of Tanzania. In the case of a corporation, permanent resident means a company incorporated in Tanzania, and in the case of a natural person, permanent resident means a citizen of Tanzania, either by birth or acquisition. The applicant need not be the breeder or owner of the genetically engineered plant, in which case a signed statement is required from the breeder or owner authorizing representation by the applicant. All correspondence with respect to the application for confined field trial, including the notification of authorization, will be addressed to the applicant.

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

Biosafety Avoidance of risk to the protection of the environment and to human health, as a result of the use for research and commerce of GMOs, by instituting legal, administrative and policy instruments.

Confinement A measure to restrain or limit the spread and survival of organisms and their products in research involving planned introductions of organisms into the environment.

Contained use any operation, undertaken within a facility, installation or other physical structure, which involves GMOs that are controlled by

specific measures that effectively limit their contact with, and their impact on, the external environment.

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 and pathogenic microorganisms that could endanger an individual or the environment.

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

Export intentional transboundary movement from Tanzania to another country;

Exporter any legal or natural person, who arranges for a genetically modified organism to be exported.

Genenetic engineering: Technologies (including rDNA technologies) used to isolate genes from an organism, manipulate them in the laboratory and insert them in another organism to produce a product in form of a protein or organism

Genetically Modified Organism any organism which has been altered or produced through genetic engineering, or any product which contains such an organism, or any other organism or product altered or produced through genetic engineering. For the purpose of this guidelines the terms genetically engineered plants, genetically modified plants and transgenic plants should be used interchangeably.

Environment humans and their surroundings including the earth's sub-surface.

Import intentional transboundary movement into Tanzania.
Importer any legal or natural person, who arranges for a genetically modified organism to be imported into Tanzania.

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

Living modified organism any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology.

Living organism `any biological entity capable of transferring or replicating genetic material, including sterile organisms, viruses and viroids.

Minister Minister responsible for environment.

Modern biotechnology - the application of:

a. In vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (rDNA) and direct injection of nucleic acid into cells or organelles, or

b. Fusion of cells beyond the taxonomic family, that overcome natural physiological reproductive or recombination barriers and that are not techniques used in traditional breeding and selection.

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 Tanzania.

Organism 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 a disease-causing organism.

Permit a written document issued by the appropriate authority for the introduction of a GMOs under conditions that it will not present a risk of pest introduction/movement.

Person any individual, partnership, corporation, company, society, association, or other organized group.

Plant any living stage or form of any member of the plant kingdom including, but not limited to, eukaryotic algae, mosses, club mosses, ferns, angiosperms, gymnosperms, and lichens (which contain algae) including any parts (e.g. pollen, seeds, cells, tubers, stems) thereof, and any cellular components (e.g. plasmids, ribosomes, etc.) thereof.

Pest any living stage (including active and dormant forms) of insects, mites, nematodes, slugs, snails, protozoa, or other animals, bacteria, fungi, other parasitic plants or reproductive parts thereof; viruses; other plants and 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.

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

Phage eating or destroying characteristic of a bacterial virus.

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

Recipient organism the organism that receives genetic material from a donor organism.

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

Regulatory body: An institution that has a legal mandate to enforce a piece of legislation

Release into the environment the use of a GMOs outside the physical confinement found in a laboratory, a contained greenhouse, a fementer or other contained structure.

Responsible individual someone 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 should be a resident of Tanzania or may be a designate representative who is a resident of Tanzania.

Risk Assessment a process of ascertaining necessary safety measures before introduction of GMOs as defined and described in the guidelines;

Risk Management a process of ensuring safe introduction of GMOs as defined and described in the guidelines;

Transboundary movement means the movement of a living modified organism from another country into Tanzania and vice versa.

Transgenic organism An organism whose hereditary DNA has been transformed through modern biotechnology techniques.

Transformation: The process of gene modification of an organism through incorporation and assimilation of foreign DNA using modern biotechnology

Vector or vector agent organisms or objects used to transfer genetic material from the donor organism to the recipient organism.

C. Scope

These guidelines apply to the development within the country, import, export, transit and handling, contained or confined use, release or placing on the market of any genetically modified organism whether intended for release into the environment, for use as a pharmaceutical, food, feed or for processing, or a product of a genetically modified

organism. The guidelines basically apply to GMOs that may have adverse effects on the environment and human health, taking into account socio-economic, cultural and ethical considerations.

D. Relationship with Relevant Policies and Legislation

The guidelines should not be interpreted as replacing any existing policies and legislation. The present guidelines were prepared with the view to ensuring their complementarity and mutual supportiveness with national policies and legislation. Where gaps with existing policies and legislation occur, the guidelines could be a useful input to review, revision and improvement of such policies and legislation.

E. Objectives

The main objective of these guidelines is to contribute in ensuring adequate level of protection in the field of safe transfer, handling and use of GMOs resulting from modern biotechnology that may have adverse effects on human health and the environment as well as taking into account socio-economic, cultural and ethical concerns. The specific objectives of the Guidelines are to:

(i) Encourage and assist the establishment of an appropriate national regulatory framework;

(ii) Ensure that national authorities and institutions, distributors and users are informed or have access to information on safety and risk thereby facilitating the safe use and handling of GMOs and products containing, or consisting of GMOs;

(iii) Develop mechanisms for co-operation and consultation among governmental and non-governmental institutions to ensure safe research, development, and use of GMOs;

(iv) Ensure the safety of all types of research, development and marketing of GMOs and products containing or consisting of GMOs by providing mechanisms to obtain consultation and advice on risk assessment and management as required;

(v) Stimulate the development of mechanisms for obtaining and disseminating information in a timely and efficient manner;

(vi) Emphasize the need for and responsibility of all national authorities and other parties involved to ensure that the public is well informed and consulted;

(vii) Supplement the existing general regulations and relevant legislation and assess requirements on amendments to the regulations and legislation related to biosafety.

1.0 INSTITUTIONAL ARRANGEMENTS FOR IMPLEMENTATION OF THE NBF

The proposed institutional structure is summarized in Figure 1. However, in the meantime, it is proposed to use the draft guidelines developed by the Vice President's Office with UNEP-GEF support. On the onset, it is important to note that the proposed structure should recognize mandates of ministries and competent authorities in their respective disciplines.

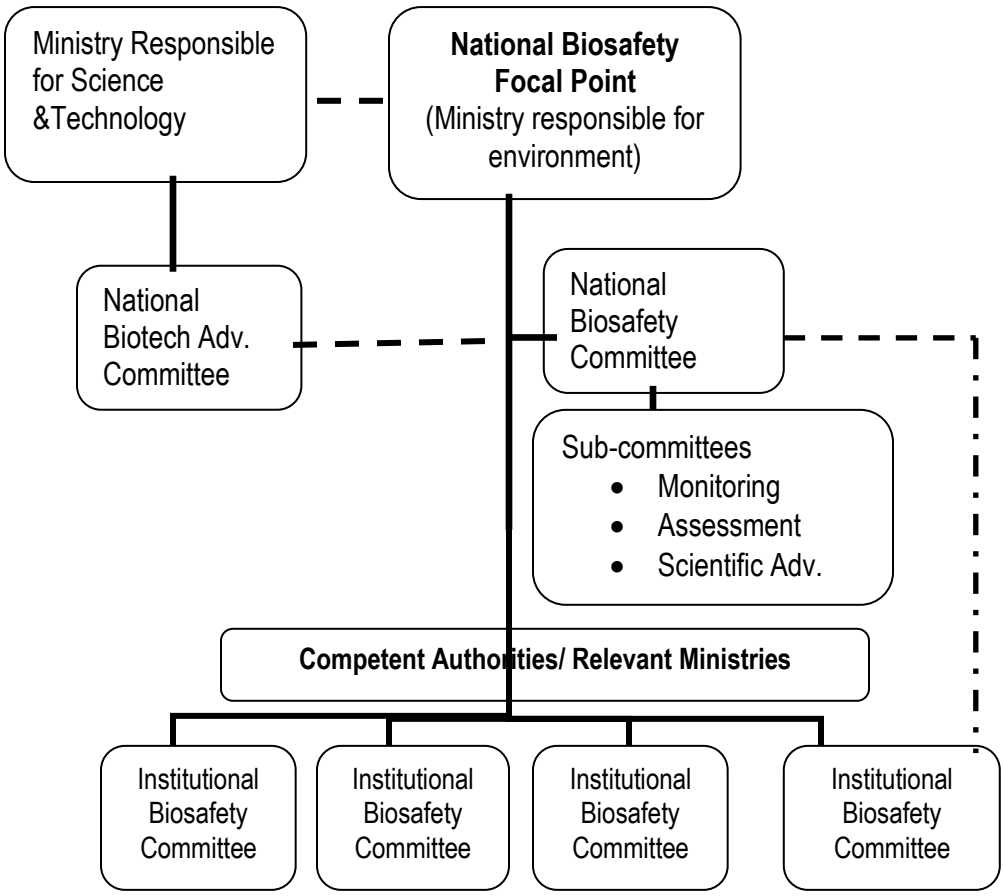

Figure 1: Proposed institutional structure

1.1 National Biosafety Focal Point

The National Biosafety Focal Point should be the Ministry responsible for environment. Its roles and responsibilities should include the following:

(i) To review and approve biosafety applications for research, confined release, pre-commercial release or putting on the market;
(ii) To oversee the implementation of biosafety issues;
(iii) To receive and forward applications to the competent authorities;

(iv) To collect and disseminate biosafety information to the public;
(v) To establish contacts and linkages within the country as well as regional and international agencies and institutions
(vi) To establish a database for the purpose of facilitating collection, storage, retrieval and dissemination of information relevant to biosafety;
(vii) To establish and update a register of experts in biotechnology and biosafety;
(viii) To decide whether to accept or reject an application based on the advice by the competent authority and NBC;
(ix) To notify the project chief/ proponent/investigator about the results of the review;
(x) To initiate diplomatic actions as may be necessary for appropriate compensation to Tanzania inhabitants or organizations who may suffer damage as a consequence of the exposure to imported biotechnology products;
(xi) To liaise with the Secretariat of Cartagena Protocol and the Biosafety Clearing-House and for facilitating exchange of information among the relevant bodies and authorities.

1.2 National Biosafety Committee (NBC)

The role of the NBC is to advise on policies, legislation and other policy instruments. The committee would also provide other technical advice to the National biosafety focal point for biosafety and the institutions responsible for biotechnology and biosafety in the country.

The NBC should play an advisory role to relevant Ministries/competent authorities that have mandate to regulate GMO related materials and their products.

The NBC should, in its operations, take into consideration the participation of the private sector and the public at large.

The NBFP should establish NBC that should perform the following functions.

(a) To ensure that adequate testing of GMOs developed elsewhere has been performed in the country of origin before it is introduced in a local trial programme;
(b) To propose mitigation measures to be undertaken in case of any accident; and
(c) To review biosafety regulations and guidelines from time to time as necessary.
(d) To facilitate socio-economic impact,
(e) To initiate scientific and technical review biosafety applications,
(f) To perform any other function as may be directed by the NBFP.

The NBC may establish an independent body of experts drawn from, but not limited to, the disciplines and fields of experts set out in sub-regulation (3) to assist it to carry out its functions of risk assessment.

A National Biosafety Committee should comprise representatives from both Tanzania and Zanzibar of governmental and non-governmental organizations, and the private

sector that are relevant to the issues of biotechnology and biosafety should be established by the government to provide, as appropriate, policy recommendations and guidelines to the competent authority.

The National Biosafety Scientific Advisory Sub-Committee should be answerable to the NBC. The sub-committee should advise the NBC on scientific biosafety concerns. Such functions should include to review and ascertain the suitability of both physical and biological containment, confinement and control procedures appropriate at the level of assessed risk involved in relevant research, development and application activities.

The National Biosafety Focal Point should designate the Sub-committee. The committee should be comprised of multidisciplinary team of experts in the field of biotechnology and biosafety.

1.3 Relevant Ministries/ Competent Authorities

The National Biosafety focal point should designate/request Competent Authorities to follow up, supervise and control the implementation of the biosafety regulations.

The roles and responsibilities of the Competent Authorities should include:

(a) To review relevant applications or proposals for development, introduction, import, export, transit, contained use, release or placing on the market;
(b) To advise the NBFP; and
(c) To undertake assessment of socio-economic impacts;

1.4 Institutional Biosafety Committee (IBC)

Institutions that are involved in the import, export, handling, contained use, release or placing on the market of GMOs or products of GMOs should establish Institutional Biosafety Committees to institute and control safety mechanism and approval procedures at the institutional level. These committees should have multidisciplinary teams.

The roles and responsibilities for IBC should include:

(a) To review the containment and confinement levels required by the Guidelines for the proposed research;

(b) To hold discussions on the comparative ecological, economic and social impacts of alternative approaches to attain the purpose/objectives of the proposed GMO and other services;

(c) Report immediately to the relevant Ministries/Competent Authorities and appropriate official in the concerned organization, any significant GMO activities, problems with or violations of the regulations and any significant research related accidents and illness; and

(d) Perform other functions as may be delegated by the relevant Ministries/Competent Authorities.

2.0 PROCEDURE FOR IMPORTATION AND FIELD RELEASES OF GMOs

2.1 Transboundary Movement of GMOs

(a) The notification procedure should be undertaken such that:-
    (i) The Party of export should notify, or require the exporter to ensure notification to, in writing, the competent national authority in Tanzania, prior to the importation of GMOs into Tanzania for those GMOs that are not intended for direct use as food, feed or for processing.
    (ii) The Party of Export should ensure that there is a legal requirement for the accuracy of information provided by the exporter.
    (iii) The notification should contain, at a minimum the information specified in Annex 9.

(b) The competent authority should acknowledge receipt of the notification, in writing, to the notifier within ninety days of its receipt.

(c) The acknowledgement should state:-

    (i) The date of receipt of the notification;
    (ii) Whether the nofication, prima facie, contains the information referred to under “Notification” above;
    (iii) Whether to proceed according to the domestic regulatory framework of Tanzania that is consistent with the Cartagena Protocol on Biosafety.

(d) Failure by Tanzania to acknowledge receipt of a notification should not imply its consent to an intentional importation of a GMO into the country.

(e) All persons who desire to import GMOs should apply for import permit from approporiate regulatory agency as required by law.
(f) A written application should respond to all items listed in the course of action for transboundary movement of GMOs. Application(s) should be submitted four (4) months before importation.
(g) The appropriate authorities should make any and all information on the organism available to the regulatory bodies and should ask specific advice on any aspect of the organism or GMOs and recommendation on conditions which should be applied. Applications for importation of organisms modified by rDNA techniques should be referred to regulatory bodies for review by the concerned agency.
(h) If portions of the application contain trade secret or confidential business information, each page of the application containing such information should be marked "Commercial-in-Confidence" or "CIC Copy" by the principal investigator/project manager.
(i) After review of the application and the data submitted to the National Biosafety Focal Point (NBFP) should make the appropriate decision. If a permit is issued, it should specify applicable conditions for introduction of GMOs. If the application is denied, the applicant should be promptly informed of the reasons.
(j) Any person whose application has been denied or whose permit has been withdrawn may appeal the decision in writing to the appropriate authorities within thirty (30) days of

receipt of the written notice. The appeal should clearly state all the facts and reasons to show that the permit was wrongfully withdrawn or denied. All appeals including application documents should be referred back to regulatory bodies for final comments and suggestions.

(k) Permit should be issued in quadruplicate. The original should be given to the permitee for presentation to the Quarantine Officer at the port of entry; the duplicate should be sent by the permitee to the shipper in the country of origin for their guidance relative to the terms and conditions; the triplicate should be presented to the Collector of Customs at the point of entry, and the fourth copy should be filed with the application.

(l) A person who is issued a permit should comply with conditions specified in it. Non-compliance with the conditions should be ground for revocation of permit. It will remain revoked until such time that the specified conditions are fully complied with.

(m) No GMOs should be introduced and moved unless guidelines on packaging and container requirements including marking and identification requirements are fully complied with.

(n) All introduction of organism should be addressed to the appropriate quarantine officers.

(o) Movement from the Quarantine to the final destination should be under guard of a Quarantine Officer at the importer's expense. No further movement of genetically modified organisms should be made unless authorized by appropriate authorities.

(p) All the guidelines for movement should be applied in the domestic transport or within and between institutions.

Documentation requirements for transboundary movement of GMOs

The application to introduce or release GMOs should include the following:

(a) Description of applicant and developer/ supplier/importer:-

- (i) Name, title, address, telephone number, and signature of the applicant;
- (ii) Name, address, and telephone number of the person(s) who developed and/or supplied the GMO ;
- (iii) Quantity of the GMO(s) to be introduced and proposed schedule and number of introductions;
- (iv) All scientific, common, and, where available, commercial names, and all designations necessary to identify the GMO; and
- (v) Country and locality where the GMO was collected, developed, and produced.

(b) Description of the modified microorganisms**:-**

- (i) Nomenclature and characteristics of donor, recipient, and vector organisms;
- (ii) A detailed description of the molecular biology of the systems (e.g., donor-recipient-vector) that is or will be used to produce the GMOs;
- (iii) A description of the anticipated or actual expression of the altered genetic material in the GMOs;
- (iv) An explanation of how that expression differs from the expression in the non-modified parental organism such as morphological or structural characteristics, physiological activities and processes, number of copies inserted in the genetic material;
- (v) The physical state of this material inside the recipient organism, products and secretions, growth characteristics; and

(vi) A detailed description of the processes, procedures, and safeguards that have been used or will be used in the country of origin and in Tanzania to prevent contamination, release, and dissemination in the production of the donor organism, recipient organism, vector or vector agent, GMOs, and a constituent of each genetically modified organism which is a product.
(vii) Known potential to cause an epidemic (survival and reproductive rates, dispersal, etc.);
(viii) Known potential to cause losses;
(ix) Known potential hosts or alternative hosts;
(x) Known ability to evolve;
(xi) Known vector of organisms;
(xii) Known mode of spread and conditions for epidemic;
(xiii) History of epidemics; and
(xiv) The GMO's transformation event code; or where available, its unique identifier code.

(c) Others
(i) A detailed description of the uses and the purpose for introducing the GMO, including a detailed description of the proposed experimental and/or production design;
(ii) History of similar introductions;
(iii) A description of transfer of the genetically modified organisms (e.g., mail, common carrier, baggage, or hand carried);
(iv) A detailed description of the intended destination (including final and all intermediate destinations), and/or distribution of the genetically modified organisms (e.g. greenhouse, laboratory, or growth chamber location; field trial location; pilot project location; production, propagation, and manufacture location; proposed sale and distribution location);
(v) A detailed description of the proposed procedures, processes, and safeguards that will be used to prevent escape and dissemination of the genetically modified organism at each of the intended destinations;
(vi) A detailed description of any biological material (e.g. culture medium or host material) accompanying the genetically modified organisms during movement; and
(vii) A detailed description of the proposed method of final disposition of the GMOs.

(d) Marking and identification of GMO shipment:-
(i) General nature and quantity of the content;
(ii) Country and locality where collected, developed, manufactured, reared, cultivated, or cultured;
(iii) Name and address of shipper, owner, or person shipping or forwarding the organism;
(iv) Name, address, and telephone number of consignee;
(v) Identifying shipper's mark and number;
(vi) Written permit number authorizing the importation; and
(vii) Container (refer to container requirements).

(e) GMOs intended for direct use as food or feed or for processing:-

Information required concerning GMO intended for direct use as food, feed, or for processing should be:-

(i) Exporters should be required to declare in the documentation that accompanies the GMOs that the shipment contains genetically modified organisms, and that they are not intended for intentional introduction into the environment;
(ii) The name and contact details of the applicant for a decision for domestic use;
(iii) The name and contact details of the authority responsible for the decision;
(iv) Name and identity of the GMO;
(v) Description of the gene modification, the technique used, and the resulting characteristics of the GMO;
(vi) Any unique identification of the GMO;
(vii) Taxonomic status, common name, point of collection or acquisition, and characteristics of the donor organism or organisms related to biosafety;
(viii) Centres of origin and centers of genetic diversity, if known, of the recipient organism and/or the parental organisms and a description of the habitats where the organisms may persist or proliferate;
(ix) Taxonomic status, common name, point of collection or acquisition, and characteristics of the donor organism or organisms related to biosafety;
(x) Approved uses of the GMO;
(xi) A risk assessment report consistent with section 3.0
(xii) Suggested methods for the safe handling, storage, transport and use, including packaging, labeling, documentation, disposal and contingency procedures, where appropriate.

2.2 Field releases

a) No person is allowed to release any GMOs unless he has a permit.
b) Application for a permit and a proposed procedure for release of GMOs into the environment duly endorsed by NBFP should be submitted to the regulatory bodies 120 days in advance of the scheduled release. The application and research proposal should respond to all items listed in the guidelines for release.
c) The appropriate authorities, in coordination with the NBFP, should grant a permit, if warranted. If an application is denied, appropriate explanation should be given.
d) All persons who are granted permit to release GMOs should be required to submit periodic reports as specified by and to the appropriate authorities.
e) The relevant ministries/Competent Authorities should be responsible for monitoring the progress of the work and should immediately report any significant outcome to NBFP for any remedial action.

3.0 RISK ASSESSMENT

3.1 Definition

Risk assessment is a process of gathering diverse data to identify possible risk in research and development involving GMOs or processes. Risk assessment is, *inter alia,* used by Competent Authorities to make informed decisions regarding GMOs.

Depending on the case, risk assessment takes into account the relevant technical and scientific details regarding the characteristics of the following subjects:

(i) *Recipient organism or parental organisms.* The biological characteristics of the recipient organism or parental organisms, including information on taxonomic status, common name, origin, centers of origin and centers of genetic diversity, if known, and a description of the habitat where the organisms may persist or proliferate;

(ii) *Donor organism or organisms*. Taxonomic status and common name, source, and the relevant biological characteristics of the donor organisms;

(iii) *Vector.* Characteristics of the vector, including its identity, if any, and its source or origin, and its host range;

(iv) *Insert or inserts and/or characteristics of modification*. Genetic characteristics of the inserted nucleic acid and the function it specifies, and/or characteristics of the modification introduced

(v) *Detection and identification of the genetically modified organism*. Suggested detection and identification methods and their specificity, sensitivity and reliability;

(vi) *Information relating to the intended use*. Information relating to the intended use of the genetically modified organism, including new or changed use compared to the recipient organism or parental organisms; and

(vii) *Receiving environment*. Information on the location, geographical, climatic and ecological characteristics, including relevant information on biological diversity and centers of origin of the likely potential receiving environment.

3.2 Objective

The objective of the risk assessment is to identify and evaluate the potential adverse effects of GMOs on the conservation and sustainable use of biological diversity in the likely potential receiving environment taking also in account risk in human health.

3.3 General Principles

(i) Risk assessment should be carried out in a scientifically sound and transparent manner, and can take into account expert advice of, and guidelines developed by relevant international organizations.

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

(iii) Risks associated with GMOs or products thereof, namely, processed materials that are of GMOs origin, containing detectable novel combinations of replicable genetic material obtained through the use of modern biotechnology, should be considered in the context of the risks posed by the non-modified recipients or parental organisms in the likely potential receiving environment.

(iv) Risk assessment should be carried out on a case-by-case basis. The required information may vary in nature and level of detail from case to case, depending on the GMOs concerned, its intended use and the likely potential receiving environment.

3.4 Methodology for Risk Assessment

The process of risk assessment may give rise to a need for further information about specific subjects, which may be identified and requested during the assessment process.

To fulfil its objective, risk assessment entails the following steps:

(i) An identification of any novel genotypic and phenotypic characteristics associated with the genetically modified organism that may have adverse effects on biological diversity, environment, human health, taking also into account socio-economic, cultural and ethical concerns;

(ii) An evaluation of the likelihood of these adverse effects being realized, taking into account the level and kind of exposure of the likely potential receiving environment to the genetically modified organism;

(iii) An evaluation of the consequences should these adverse effects be realized;

(iv) An estimation of the overall risk posed by the genetically modified organism based on the evaluation of the likelihood and consequences of the identified adverse effects being realized;

(v) A recommendation as to whether or not the risks are acceptable or manageable, including, where necessary, identification of strategies to manage the risks; and

(vi) Where there is uncertainty regarding the level or risk, it may be addressed by requesting further information on the specific issues of concern or by implementing appropriate risk management strategies and/or monitoring the GMOs in the receiving environment.

3.5 Socio-economic, Cultural and Ethical Considerations

The social economic, cultural and ethical impact of GMOs covers a wide range of non-safety issues, which are relevant for general release of GMOs (refer to Annex VI G).

4.0 RISK MANAGEMENT

The objective of risk management is to establish and maintain appropriate mechanisms, measures and strategies to regulate, manage and control risks identified in the risk assessment regarding the use, handling, introduction and field release of GMOs.

In current agricultural research development practices, conventionally modified organisms are generally extensively tested prior to commercialisation. Similar procedures are appropriate in

the development of GMOs for agricultural applications. This testing typically involves a stepwise process, which includes the following:

- Greenhouse (or other type of specialized containment);
- Limited scale controlled field plots and;
- Large scale multiple field plots in various geographical sites.

Evaluations and data collection at each incremental stage are conducted both to ascertain efficacy and to eliminate any organism or application resulting in unwanted environmental effects. All experiments involving genetic manipulation of plant or animal pathogens and the use of such genetically manipulated pathogens will require approval of the National Biosafety Committee. A permit should be required for introduction into the environment of any organism or product, which has been altered or produced through genetic engineering.

4.1 Containment Procedures

Containment is used to describe safe methods for managing infectious agents or hazardous compounds in the laboratory environment, growth room and greenhouse where they are being handled or maintained in order to prevent their escape outside the prescribed spaces. The purpose of containment is thus to reduce exposure of laboratory workers and other persons and the outside environment to potential hazardous agents. There are two types of containment: biological and physical.

4.1.1 Physical Containment

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 to these harmful organisms. 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 regulatory bodies to other combinations that achieve an equivalent level of containment.

4.1.1.1 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 scientists with general training in microbiology or a related science.

Procedure

a) When experiments are in progress, access to the laboratory should be limited or restricted at the discretion of the laboratory in charge;
b) Work surfaces should be decontaminated once a day and after any spill of viable material;
c) All contaminated liquid or solid wastes should be decontaminated before disposal;
d) When mechanical pipetting devices are used; mouth pipetting should be prohibited;
e) Eating, drinking, smoking, and applying cosmetics are not permitted in the work area. Food should be stored in cabinets or refrigerators designated and used for that purpose only;
f) Persons should wash their hands after handling materials involving organisms containing rDNA molecules, and animals, and before leaving the laboratory;
g) All procedures should be performed carefully to minimize the creation of aerosols;
h) Laboratory personnel should be wear laboratory coats, gowns, or uniforms to prevent contamination or soiling of street clothes;
i) Contaminated materials that are to be decontaminated at a site away from the laboratory should be placed in a durable, leak-proof 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.

Containment Equipment

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

Laboratory Facilities

a) The laboratory is designed so that it can be easily cleaned;
b) Bench tops are impervious to water and resistant to acids, alkalis, organic solvents, and moderate heat;
c) Laboratory furniture is sturdy. Spaces between benches, cabinets, and equipment are accessible for cleaning;
d) Each laboratory contains a sink for hand-washing;
e) If the laboratory has windows that open, they are fitted with fly screens;

4.1.1.2 Biosafety Level 2 (BL2)

BL2 is similar to BL1 and is suitable for work involving agents of moderate potential hazard to personnel and the environment. It differs in 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 and conducted in biological safety cabinets or other physical containment equipment.

Procedure

a) Access to the laboratory is limited or restricted by the laboratory in charge when work with organisms containing rDNA molecules is in progress;
b) Work surfaces are decontaminated at least once a day and after any spill of viable material;
c) Mechanical pipetting devices are used; mouth pipetting is prohibited;
d) 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;
e) Persons wash their hands after handling materials involving animals and organisms containing rDNA molecules, and when they leave the laboratory;
f) All procedures are performed carefully to minimize the creation of aerosols;
g) Experiments of lesser biohazard potential can be carried out concurrently in carefully demarcated areas of the same laboratory;
h) 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 regulatory bodies, which is closed before being removed from the laboratory;

i) The officer in charge of the laboratory 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;
j) The officer in charge of the laboratory 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;
k) 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 is posted on the access door to the laboratory work area. The hazard warning sign identifies the agent, lists the name and telephone number of the laboratory in charge 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;
l) Personnel working in the laboratory should wear coats, gowns, smocks, or uniforms. Before personnel leaves 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;
m) Animals not involved in the work being performed are not permitted in the laboratory;
n) 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;
o) All wastes from laboratories and animal rooms are appropriately decontaminated according to acceptable minimum standards for proper disposal;
p) 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;

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

Containment Equipment

Biological safety cabinets (Class I or II) or other appropriate personal protective or physical containment devices are used whenever necessary;

a) Procedures with a high potential for creating aerosols are conducted. 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;

b) High concentrations or large volumes of organisms containing rDNA molecules are used. Such materials may be centrifuged in the open laboratory if sealed heads or centrifuge safety cups are used and if they are opened only in a biological safety cabinet.

Laboratory Facilities

a) The laboratory is designed so that it can be easily cleaned.
b) Bench tops are impervious to water and resistant to acids, alkalis, organic solvents, and moderate heat.
c) Laboratory furniture is sturdy and spaces between benches, cabinets, and equipment are accessible for cleaning;
d) Each laboratory contains a sink for hand washing.
e) If the laboratory has windows that open, they are fitted with fly screens.
f) An autoclave for decontaminating laboratory wastes is available.

4.1.1.3 Biosafety Level 3 (BL3)

Biosafety level 3 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 are rigorously followed. The decision to implement this modification of BL3 recommendations should be made only by the laboratory in charge.

Procedure

a) Work surfaces are decontaminated at least once a day and after any spill of viable material;
b) All contaminated liquid or solid wastes are decontaminated before disposal;
c) Mechanical pipetting devices are used; mouth pipetting is prohibited;
d) Eating, drinking, smoking, storing food, and applying cosmetics are not permitted in the work area;
e) Persons wash their hands after handling animals and materials involving organisms containing rDNA molecules, and when they leave the laboratory;
f) All procedures are performed carefully to minimize the creation of aerosols;
g) Persons under 18 years of age are not allowed to enter the laboratory;
h) 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 should be conducted in accordance with all BL3 level practices;
i) Laboratory doors are kept closed when experiments are in progress;
j) Contaminated materials that are to be decontaminated at a site away from the laboratory are placed in a durable,

leak-proof container, which is closed before being removed from the laboratory;

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

l) The laboratory in charge 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;

m) 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 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 in charge or other responsible persons, and indicates any special requirements for entering the laboratory, such as the for immunization, respirators, or other protective measures;

n) 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;

o) The work surfaces of biological safety cabinets and other containment equipment are decontaminated when work with organisms containing rDNA molecules is finished. Plastic-backed paper towelling used on non-perforated work surfaces within biological safety cabinets facilitates cleaning up. An insect and rodent program is in effect as certified by a licensed pest control operator.

p) 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;

q) 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;

r) Molded surgical masks or respirators are worn in rooms containing experimental animals;

s) Animals and plants not related to the work being conducted are not permitted in the laboratory;

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

u) All wastes from laboratories and animal rooms are appropriately decontaminated before disposal;

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

w) 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 needles 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;

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

y) 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;

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

aa) 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 BL2 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 BL4 level of physical containment.

Containment Equipment

Biological safety cabinets (Class I, II, or III) 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;

Laboratory Facilities

a) 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;
b) 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;
c) Bench tops are impervious to water and resistant to acids, alkalis, organic solvents, and moderate heat;
d) Laboratory furniture is sturdy and spaces between benches, cabinets, and equipment are accessible for cleaning;
e) 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;
f) Windows in the laboratory are closed and sealed;
g) Access doors to the laboratory or containment module are self-closing;
h) An autoclave for decontaminating laboratory waste is available, preferably within the laboratory;

i) 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;

j) 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 (12)] that avoids any interference with the air balance of the cabinets or building exhaust system.

4.1.1.4 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.

Procedure

a) Work surfaces are decontaminated at least once a day and immediately after any spill of viable material;
b) Only mechanical pipetting devices are used;
c) Eating, drinking, smoking, storing food, and applying cosmetics are not permitted in the laboratory;
d) All procedures are performed carefully to minimize the creation of aerosols;
e) 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;
f) 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;

g) Only persons whose presence are required for program or support purposes in the facility or individual laboratory rooms are authorized to enter. The laboratory in charge 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 in charge, 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 the 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;

h) 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;

i) 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;

j) 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 is posted on all access doors. The sign identifies the agent, lists the name of the laboratory in charge or other responsible person(s), and indicates any special requirements for entering the area (e.g., the need for immunization or respirators);

k) 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;

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

m) 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);

n) 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;

o) Laboratory animals involved in experiments requiring BL4 level physical containment should be housed either in cages contained in Class III cabinets or in partial containment caging systems such as Horsfall units, 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;

p) 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 BL4 facility using containment equipment requirements specified for the BL3 level of physical containment. Alternative combinations of containment safeguards.

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.

Laboratory Facilities

a) 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 equipment that are not brought into the facility through the change room;
b) 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 facilitating cleaning and decontamination of 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;
c) 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;
d) Bench tops have seamless surfaces that are impervious to water and resistant to acids, alkalis, organic solvents, and moderate heat;
e) Laboratory furniture is made of simple and sturdy material, and spaces between benches, cabinets, and equipment are accessible for cleaning;
f) A hand-washing sink operated by foot, by elbow, or automatically is provided near the door of each laboratory room in the facility;
g) 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;
h) 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;
i) Access doors to the laboratory are self-closing and can be locked. All windows are breakage resistant; 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;

j) 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;

k) 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;

l) 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;

m) 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;

n) 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;

o) 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.

4.1.2 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.
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:

4.1.2.1 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 should 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 2.3.

4.1.2.2 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 10^4 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).

4.1.2.3 Safety Level as DNA donors of Primitive Eukaryotes and Prokaryotes

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Organisms used as DNA donor that require P4-B1 containment:
Bartonella: *B. bacilliformis ,*
Clostridium: C. botulinum *, C. tetani*
Corynebacterium: *C. diphtheriae*
Mycoplasma *M. mycoides*
Pasteurella: *P. multocida* (B:6, E:6, A:5, A:8, A:9)
Pseudomonas: *P. mallei (Actinobacillus mallei), P. pseudomallei*
Shigella : *S. dysenteriae*
Yersinia : *Y. pestis* (*Y. pseudotuberculosis* subsp. pestis)

Organisms used as donor that require P3-B1 or P2-B2 containment:
Bacillus: *B. abortus*

Brucella: *B. abortus, B. melitensis, B. suis*
Coccidioides: *C. immitis*
Cryptococcus: *C. neoformans*
Francisella: *F. tularensis*
Histoplasma: *H. capsulatum, H. duboisii*
Mycobacterium: *M. africanum, M. bovis , M. tuberculosis*
Salmonella: *S. paratyphi-A, S.typhi*

Organisms used as DNA donor that require P2-B1 or P2-B2 containment :

Actinobacillus: *A. mallei (Pseudomonas mallei)*
Actinomyce: *A. bovis, A. israelii, A. naeslundii*
Aeromonas: *A. hydrophila*.rm67 (Toxin producing strains), *A. punctata* (Toxin producing strains)
Arizona: *A. hinshawii* (all antigenic type)
Bacillus: *B. cereus* (Toxin producing strains)
Blastomyces: *B. dermatitidis*
Bordetella: All spp.
Borrelia: All spp.
Brucella: B. canis
Calymmatobacterium: *C. granulomatis*
Campylobacter: All spps.
Clostridium: *C. chauvoei, C. difficile, C. haemolyticum, C. histolyticum, C. novyi, C. perfringens* (Toxin producing strain) C. septicum
Corynebacterium: *C. equiC. Haemolyticum C. Pseudotuberculosis C. Pyogenis C. renale*
Entamoeba *E. histolytica*
Erysipelothrix: *E. rhusiopathiae, E. insidiosa*
Escherichia *E. coli* (all antigenic types with pathogenicity to intestine)
Haemophilus: *H. ducreyi, H. influenzae*
Hartmanella: All spps.
Herellea: *H. vaginicola*
Klebsiella: All spps.
Legionella *L. pneumophila*
Leishmaniao 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. pneumoniae*
Naegleria All spps.
Neisseria *N. gonorrhoeae N. meningitidis*
Nocardia *N. asteroides N. brasiliensis N. caviae N. farcinica*
Paracoccidioide P. brasiliensis
Pasteurella All spps. Except *P. multocida*

Plasmodium	*P. falciparum P. malariae P. ovale P. vivax*.rm67 Simian malarial parasites
Plesiomonas	*P. shigelloides*
Salmonella	All serotypes except *S. paratyphi-A and S. typhi Shigella* All sops. Except, *S. dysenteriae*,
Sphaerophorus	*S. necrophorus*
Staphylococcus	*S. aureus*
Streptococcus	*S. pneumoniaeS. pyogenes*
Treponema	*T. carateum T. pallidum T. pertenue*
Trichinella	*T. spiralis*
Toxocara	T. canis
Toxoplasma	T. gondii
Trypanosoma,	*T.cruzi,T.gambiense, T. rhodesiense*
Vibro	*V. cholera* (including Biotype El Tor
Yersinia	*Y. enterocolitica Y. pseudotuberculosis* (except *Y. pestis*) (*Y. pseudotuberculosis* subsp. pestis)

4.1.2.4 Safety level for DNA donor of virus, Rickettsia, and Chlamydia of Protokaryota excluding Primitive Organisms

Organisms used as DNA donor that require P3-B1 or P2-B2 containment:
California encephalitis virus, Chikungunia virus, Chlamydia psittaci, Herpes virus, ateles Herpes virus, saimiri HIV Hog choleravirus, HTLV – ATLV HTLV – I, Japanese encephalitis virus, La 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 stomatitis virus and West Nile virus

Organisms used as DNA donor that require P2-B1 or P1-B2 containment:
Avian reticuloendotheliosis virus, Batai virus, BK virus, Bovine papilloma virus, Chlamydia trachmatics, Cowpox virus, Coxsackie virus (A, B), Cytomegalovirus (human, animal), Dengue virus (1-4), Eastern equine encephalitis virus, EB virus, Echovirus (1.-34), Ectromelia virus, Enterovirus (68-71), Equine infectious anemia virus, Equine rhinopneumonitis virus, Hepatitis A virus, Hepatitis B virus, Hepatitis non A non B virus, Herpo simplex virus (1, 2), Human adeno virus, Human influenza virus (A, B, C), Human wart virus (Human papilloma virus), HVJ JC virus, Mammalian retrovirus (except HIV, HTLV-I, (ATLV) and HTLV-II) Measles virus, Molluscum 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, Rinderpest virus (vaccine strain), Rotavirus, Rubella virus, Semliki Forest virus, SSPE agent SV 40, Tanapox virus, Vaccinia virus, Varicella virus, Western equine encephalitis virus.

Organisms used as DNA donor that require P1-B1 or P1-B2 containment:
Aino virus, Akabane virus, Avian adenovirus, Avian encephalomyelitis virus, Avian enterovirus, Avian influenza virus, Avian poxvirus, Avian retrovirus (except Avian reticuloendoasis virus), Bluetongue virus, Bovine adenovirus, Bovine enterovirus, Bunyamwera virus, Canine distemper virus, Coronavirus,

Duck hepatitis virus, 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 fibroma 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 vertebrate), Plant viruses.

4.1.2.5 Host-vector systems

Host-vector systems of which a high level of safety (requires PI level containment) has been confirmed when primitive eukaryote or prokaryote not listed above and their viruses are used as a DNA donor:

AA: (a host-vector system with *Azotobacter aceti* as a host and plasmid or bacteriophage as a vector)
BA: (a host-vector system with *Bacillus amyloliquefaciens* as a host a and plasmid or bacteriophage as a vector)
BB: (a host-vector system with *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 stearothermophilus* 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 *Streptomyces kasugaensis* 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 *Schizosaccharomyces 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)

4.1.2.6 Certification of Host-Vector Systems

- 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 chairperson of the National Biosafety Focal Point as advised by the Competent Authorities. Application for certification of a host-vector system should be addressed to:

Permanent Secretary,
Vice President's Office,

National Biosafety Focal Point,
P. .O Box 5380, Dar es Salaam, Tanzania
FAX (255) 22 2125297
E-mai:biosafetytz@vpdoe.go.tz; sotchair@africaonline.co.tz.

- Host vector systems that are proposed for certification will be reviewed by the Prior to this, a review of the data on construction, properties, and testing of the proposed host-vector system will be made by the National Biosafety Scientific Advisory Sub-Committee in evaluating such data. The National Biosafety Committee will then evaluate the report of the National Biosafety Scientific Advisory Sub-Committee and any other available information at a regular meeting.
- The NBFP is responsible for certification after receiving the advice of the NBC. 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 NBFP.
- When a new host-vector system is certified, NBFP sends a notice of the certification to the applicant and to all IBCs through Competent Authorities and publishes it. Copies of a list of all currently certified host- vector systems may be obtained from regulatory bodies at any time.
- The NBFP may, at any time, rescind the certification of any host-vector system. If certification of a host-vector system is rescinded, Competent Authorities will instruct investigators to transfer cloned DNA into a different system or use the clones at a higher physical containment level unless the National Biosafety Scientific Advisory Sub-Committee determines that the already constructed clones have adequate biological containment.
- 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 NBFP. 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.

4.1.2.7 Data to be Submitted for Certification

HV1 systems other than E. coli K-12. The following types of data should 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.

HV2 Systems. Investigators planning to request HV2 certification for host-vector systems can obtain instructions from Competent Authorities 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 Competent Authorities. 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 Competent Authorities.

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

The National research institutions should appoint Biosafety Inspectors if they engage in large scale research or production activities involving viable organisms containing rDNA molecules.

The institutions should establish and maintain a health surveillance programs 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 should 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.

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. 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 Competent Authorities on an individual basis.

BL1-LS Level

a) Cultures of viable organisms containing rDNA molecules should 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 are met.
b) Culture fluids should 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.
c) Sample collection from a closed system and transferring culture fluids from closed system to another should be done in a manner which minimizes the release of aerosols or contamination of exposed surfaces.
d) Exhaust gases removed from a closed system or other primary containment equipment should 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.

e) A closed system or other primary containment that has held viable organisms containing rDNA molecules should 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.
f) Emergency plans required to cover accidental spills and personnel contamination should include methods and procedures for handling large losses of culture on an emergency basis.

BL2-LS Level

a) Cultures of viable organisms containing rDNA molecules should 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 are met.
b) Culture fluids should 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.
c) 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 should be done in a manner that prevents the release of aerosols or contamination of exposed surfaces.
d) Exhaust gases removed from a closed system or other primary containment equipment should 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.
e) A close system or other primary containment equipment that has held viable organisms containing rDNA molecules should 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.

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

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

h) A closed system used for propagating and growing viable organisms containing the rDNA molecules should be tested for integrity of the containment features using the organism that will serve as the host for propagating rDNA molecules. Testing should 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 should be appropriate for the equipment design and for recovery and demonstration of the test organism. Records of tests and results should be maintained on file.

i) A closed system used for propagating and growing viable organisms containing rDNA molecules should be permanently identified. This identification should 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.

j) The universal biohazard sign should be posted on each closed system and primary containment equipment when used to contain viable organisms containing rDNA molecules.

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

BL3-LS Level

a) Cultures of viable organisms containing rDNA molecules should 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 are met.

b) Culture fluids should 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.

c) 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 should be done in a manner which prevents the release of aerosols or contamination of exposed surfaces.

d) Exhaust gases removed from a closed system or other primary containment equipment should 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.

e) A closed system or other primary containment equipment that has held viable organisms containing rDNA molecules should 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.

f) A closed system used for propagating and growing viable organisms containing rDNA molecules should 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.

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

h) 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 should include monitoring or sensing devices that monitor the integrity of containment during operations.

i) A closed system used for propagating and growing viable organisms containing rDNA molecules should be tested for integrity of the containment features using the organisms that will serve as the host for propagating the rDNA molecules. Testing should 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 should be appropriate for the equipment design and for recovery and demonstration of the test organism. Records of tests and results should be maintained on file.

j) A closed system used for propagating and growing of viable organisms containing rDNA molecules should be permanently identified. This identification should 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.

k) The universal biohazard sign be posted on each closed system and primary containment equipment when used to hold viable organisms containing rDNA molecules.

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

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

    (i) The controlled area should have a separate entry area. The entry area should 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;

    (ii) The surfaces of walls, ceilings, and floors in the controlled area should be such that they can be readily cleaned and decontaminated;

    (iii) Penetrations into the controlled area should be sealed to permit liquid or vapor phase space decontamination;

    (iv) All utilities and service or process piping and wiring entering the controlled area should be protected against contamination;

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

    (vi) A shower facility should be provided. This facility should be located near the controlled area;

(vii) The controlled area should 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;

(viii) The controlled area should have a ventilation system that is capable of controlling air movement. The movement of air should be from areas of lower contamination potential to areas of higher contamination potential. If the ventilation system provides positive pressure air supply, the system should operate in a manner that prevents the reversal of the direction of air movement or should 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 should not be recirculated 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.

(n) The following personnel and operational practices should be required:

(i) Personnel entry into the controlled area should be through the entry area specified in the above Sections (sub bullet one);

(ii) Persons entering the controlled area should 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 should be decontaminated before laundering;

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

(iv) Access doors to the controlled area should be kept closed, except as necessary for access, while work is in progress. Service doors

leading directly outdoors should be sealed and locked while work is in progress;

(v) Persons under 18 years of age should not be permitted to enter the controlled area;

(vi) The universal biohazard sign should 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 should include a statement of agents in use and personnel authorized to enter the controlled area;

(vii) Persons should wash their hands when leaving the controlled area;

(viii) The controlled area should be kept neat and clean;

(ix) Eating, drinking, smoking, and storage of food are prohibited in the controlled area;

(x) An effective insect and rodent control program should be maintained;

(xi) Persons working in the controlled area should be trained in emergency procedures;

(xii) Equipment and materials required for the management of accidents involving viable organisms containing rDNA molecules should be available in the controlled area; and

(xiii) The controlled area should be decontaminated in accordance with established procedures following spills or other accidental release of viable organisms containing rDNA molecules.

4.1.3.1 Biological Safety Cabinets Are Classified As Class I, Class II, Or Class III Cabinets.

a) 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 more.

CLASS I SAFETY CABINETS

- Open fronted design protects worker by continuously drawing air in through front
- Simple, cheap, effective.
- Suitable for Hazard Group 3 work
- Also acceptable for lower risk Hazard Group 3work

b) 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 more.

CLASS II SAFETY CABINETS

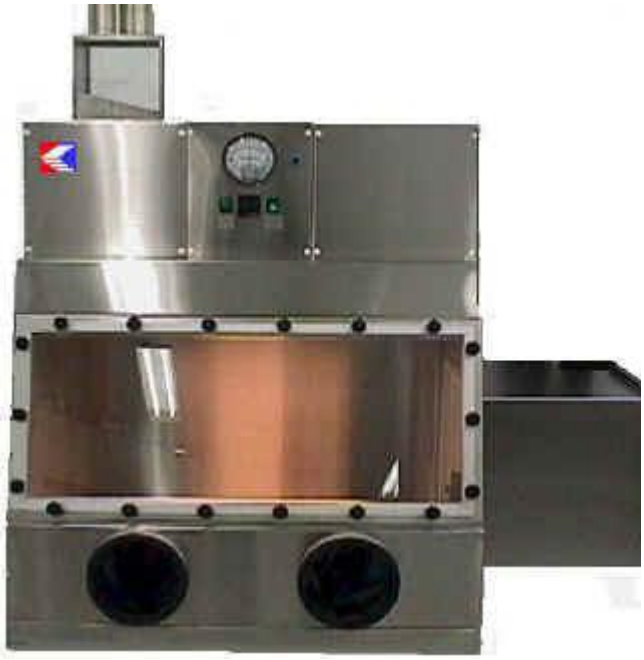
- Operator & product protection
- Air drawn down and filtered before directing into work areas as a clean vertical laminar flow
- Need good working experience
- Air flow can be upset by external air movements
- Electric, vertically lifting screen
- Stainless steel working area

c) 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.

CLASS III SAFETY CABINETS

- Operator protection (barrier protection) working through gloves or gauntlets
- Excellent product protection
- HEPA filtered air drawn from rear and extracted
- Ducted to atmosphere
- Suitable for high risk Hazard Group 3 e.g. highly concentrated samples



4.1.3.2 Container Requirements

a) Plants and plant parts

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

b) Seeds

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

c) Live microorganisms and/or etiologic agents, cells, or sub cellular elements.

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

Volume not exceeding 50 ml

GMO materials not exceeding 50 ml should be placed in a securely closed watertight container, primary container (test tube, vial, etc.) which should 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 should 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 should then be enclosed in an outer shipping container made of corrugated fiberboard, corrugated cardboard, wood, or other material of equivalent strength.

Volume exceeding 50 ml

GMO materials that exceed a volume of 50 ml should comply with requirements enumerated above. In addition, a shock absorbing material, in volume at least equal to that of the absorbent material between the primary and secondary containers, should be placed at the top, bottom, and sides between the secondary container and the outer shipping container. Single primary containers should 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 should not exceed 4,000 ml.

d) Insects, Mites, and Related Organisms

Insects (any life stage) should be placed in an escape proof primary shipping container (insulated vacuum container, glass, metal, plastic, etc.) and sealed to prevent escape. Such primary container should 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 should be added around the primary container to prevent movement of the primary shipping container. The secondary (styrofoam or other) container should be placed securely within an outer shipping container made of corrugated fiberboard, corrugated cardboard, wood, or other material of equivalent strength.

e) Other Microscopic Organisms

All microscopic organisms that are not plants and which requires continuous access to atmospheric oxygen should 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 should be securely placed within a larger secondary shipping container made of wood, metal, or equivalent strength material. The primary and secondary shipping containers should 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.

4.1.3.3 Health and Medical Surveillance

a) The objectives of health and medical surveillance programmes for basic laboratories apply to containment laboratories, except where modified as follows:

b) Medical examination of all laboratory personnel working in the containment laboratory is mandatory. This examination should include a detailed past medical history and clinical examination.

c) A baseline serum sample should be obtained and stored for future reference.

d) Employees being treated with immunosuppressive drugs should not be employed in containment laboratories.

e) Following a satisfactory clinical assessment report, the examinee should be provided with the medical contact card that he/she is employed in a containment laboratory. It is suggested that the card should be wallet sized and the holder should always carry it.

f) The contact persons to be entered on the front of the card would need to be agreed locally but might include the laboratory in charge, the medical adviser, or the biosafety officer.

4.1.3.4 Emergency Procedures

Emergency contingency plans should be prepared for each individual laboratory as well as for the institution. The individual laboratory supervisor in conjunction with his staff and the safety officer should prepare emergency contingency plans. This procedure offers the best prospect of success, as it is the immediate staff that are most familiar with the hazards associated with the particular laboratory. For example any research group working with agents known to be potential bio-hazards should have an emergency plan which describes the procedures to be followed if an accident contaminates personnel or the environment. For example, if a research group is working with a known pathogen for which there is an effective vaccine, the vaccine should be made available to the workers before commencing work and at prescribed intervals thereafter. Where serological monitoring is appropriate it should be provided. Once the emergency plan is formulated, it should be posted in a conspicuous place in the laboratory for immediate reference. Emergency plans should provide for:

a) Breakage and spillage;

b) Accidental injection, cuts and abrasions;
c) Accidental ingestion of potentially hazardous material;
d) A potential hazardous aerosol release (other than in a safety cabinet);
e) Breakage of tubes in centrifuges not having safety cups;
f) Fire, floods, and natural disaster;
g) Vandalism;
h) Emergency services, whom to contact; and
i) Emergency equipment and its location.

4.1.3.5 Decontamination and Disposal

Decontamination and disposal in laboratories are closely interrelated acts, since disinfections or sterilisation constitute the first phase of disposal. All materials and equipment will ultimately be disposed of. However, in terms of daily use in laboratories of Biosafety Level I to III, only a portion of these will require actual removal from the laboratory or destruction. The remainder will be recycled for use within the laboratory, examples being re-usable laboratory glassware, instruments and laboratory clothing. Disposal should therefore be interpreted in the broad sense rather than in the restrictive sense of a destructive process. In the case of Biosafety Level IV laboratories, equipment and instruments should be confined into special, leak proof chambers, In addition disposable ware containers, clothing and shoes should be used.

Decontamination should be carried out by an autoclaving process. The autoclave should be of the gravity displacement type and worked upon at 1.4 kg/cm^2 pressure for 30 minutes. If an autoclave is not available, alternative methods of decontamination should be used as detailed in the Biosafety Guidelines. These include boiling for 30 minutes, preferably in water containing sodium bicarbonate, or use of a pressure cooker at the highest attainable working pressure. Alternatively, contaminated waste should be placed in specially marked containers and transported directly to an incinerator. Incineration for this purpose must be approved by public health, air pollution authorities, and the safety officer. Where incinerators are not approved for such use, final disposal, appropriate methods must be established in cooperation with public health and community authorities. Prior disposal, identification and separation system for contaminated materials (and their containers) should be established. Categories may be:

a) non-contaminated waste that can be disposed of with general wastes,
b) “sharps” needles, syringes, etc.
c) contaminated material for autoclaving and recycling,
d) contaminated material for disposal.

Hypodermic needles should be placed in containers with walls that are not readily penetrable. When full, these should be placed in contaminated waste containers and incinerated, even if laboratory practice requires that they are autoclaved first.
Disposable syringes, placed in a container, should be incinerated, even if they are autoclaved first.

Disinfectants
A disinfectant known to be effective for microbes in use should be available in the laboratory at all times. The work surfaces should be disinfected and cleaned after work with a suitable disinfectant. Sodium hypochlorite and formaldehyde are the disinfectants recommended for general laboratory use.

For special purposes, phenolic compunds, various surface-active and/or lipid-destroying agents, including alcohols, iodine iodophors, and other oxidizing agents, as well as very high or extremely low pH compounds should be used provided that the agent to be destroyed is not resistant to the procedure.

4.1.3.6 Chemicals, Electrical, Fire and Radiation Safety for Biotechnology Facilities

All biotechnology facilities should be constructed in a manner that is suitable for their intended activities to avoid accidents resulting from fire, chemical, electrical, or radiation accidents. A preliminary assessment of the status of the laboratory in respect to these hazards can be made using the Industries should also conform to guidelines in addition to the Industrial Safety Standards and Good Manufacturing Practices (GMP).

(i) Chemical safety

The following requirements will apply to all laboratories where hazardous, flammable, toxic or corrosive chemicals are handled or stored.

(ii) Eye protection

Eye protection using appropriate equipment is required at all times in laboratories where hazardous chemicals are stored or handled.

(iii) Chemical storage and traceability

Flammable and other hazardous chemicals should be securely stored. Small amounts (less than one litre) may be stored in laboratory cabinets or on shelves with a safety chain. Large amounts, or extra hazardous materials such as ethyl ether, should be stored in a separate storage building. No flammable or corrosive chemicals should be stored in commercial or household type refrigerators. The biosafety officer should keep an updated record of all chemicals/specimens in use, amounts remaining after use and those that have expired and should recommend appropriate disposal for the latter.

(iv) Chemical Disposal
Small quantities (less than one litre) of inert, water-soluble, non-volatile neutral chemicals may be flushed down the drain with large quantities of water. Water-immiscible, flammable and radioactive chemicals should be disposed of by the laboratory biosafety officer.

(v) Laboratory attire

Clothing providing full body protection should be worn when working with flames or chemicals. Suitable apron, gloves, and eye-face shields should be worn when working with strong acids, bases, bromine and similar corrosive chemicals.

(vi) Chemical carcinogens

Suspected carcinogens should be handled with appropriate precautions. For example, benzene and carbon tetrachloride should be used in approved hoods only. Chemical with carcinogenic properties should be handled after specific approval by the biosafety officer.

4.2 Confinement Procedures

4.2.1 Procedures

The level of confinement corresponds to the level of safety concern. Therefore, the level of confinement is related to the potential for maintaining or increasing pest/pathogen status, the nature of ecological relationships in the environment, the potential for establishment in the environment, the potential for inducing genetic change in natural or managed populations, the potential for monitoring and control, the characteristics of the accessible environment, and the design of the research.

Confinement procedures be grouped into five types: physical, biological, environmental, chemical and scale. Some examples are as follows:

Physical

Physical barriers are used to limit the survival and dissemination of organisms outside the research site. Physical barriers include border rows, geographical isolation, dams, soil terraces, tillage, fences, screens, meshes and impervious or plastic barriers.

Biological

Biological barriers limit survival and dissemination of organisms outside the research site and limit the transfer of genetic information from the research organism to other organisms. Biological barriers include genetic modifications that disable the organism: render it sterile, and reduce its ability to survive or escape predators. Removal of reproductive organs and removal of organisms that are hosts for the research organism as well as natural biological decay, e.g. normal death, can be used to aid confinement.

Environmental

Environmental conditions can be varied to limit reproduction of organisms and to limit survival or dissemination of organisms outside the research site. Environmental variables, which are reproduction- limiting, include climate, geography or location of research site, water supply, humidity, photoperiod and seasonal or temporal factors, e.g., time of the year-

Chemical
Chemical treatments can be used to limit survival and reproduction of organisms outside the research site and to limit transfer of genetic information from the research organism to other organisms. Chemical treatments include application of pesticides, disinfectants, fumigants and other materials toxic to the research organisms, pH alterations, use of gametocides, and other chemicals which act as reproductive control agents, and elimination of essential nutrients.

Scale
By decreasing the number of organisms or the size of the research site, the possibility of rapid and widespread dissemination may be reduced and remedial actions, easier to implement.

4.2.2 Confinement Levels

Four levels of confinement are prescribed, ranging from good agricultural research practices (Confinement Level 1) to very stringent measures (Confinement Level 4). There is a continuous progression from minimum confinement and each confinement level is based upon good agricultural research practices.

Confinement should be designed for each particular organism and specified accessible environment, based on the ability of the organism to escape confinement and cause adverse effects on managed or natural ecosystems. The increased number and variety of confinement practices (e.g., use of more than one type of biological and physical barriers) will result in greater assurance of safe confinement.

4.2.2.1 Confinement Level 1

Confinement Level 1 applies to modified organisms for which the level of safety concern is 1, the lowest level of risks. Level of safety concern 1 applies to organisms whose ecological attributes are known with reasonable certainty that the parental organisms has virtually no potential adverse effects on human health or on managed or natural ecosystems. Some attributes of organisms that may be classified under Level of Safety Concern 1 are as follows:

a) No history of adverse effects in the accessible environment or similar environments.
b) Low evolutionary potentials to become harmful organism in the accessible environment.
c) Low probability of survival in the accessible environment beyond the time necessary for the particular research.
d) Low probability of exchange of genetic information with native populations of organisms.
e) Indigenous status in the accessible environment.
f) Existence of practical techniques to minimize escape of viable organisms from accessible environments.
g) Existence of practical techniques to recapture or kill escaped organisms before adverse effects occur.

Confinement Level 1 consists of good agricultural research practices for the organism in accessible environment. These practices have evolved from experience in conducting agricultural field research over the past 100 years. Confinement Level 1 applies to all organisms and the good agricultural practices include the following:

a) Acceptable experimental design
b) Definition of source, type, and name of research organisms
c) Maintenance of beginning and ending inventories
d) Careful record keeping, including significant alterations of research protocols
e) Description of site design and lay-out
f) Utilization of appropriate statistical analysis design
g) Clear statements of objectives, procedure and methods
h) Control and maintenance of integrity of sites and organisms
i) Training, instruction, and oversight of personnel on research and emergency procedures
j) Appropriate termination of research and disposal of organisms and experimental materials in excess of that retained for further research.

4.2.2.2 Confinement Level 2

This confinement level is appropriate for Level of Safety Concern 2 modified organisms. This includes organisms that may cause adverse effects on human health or on managed or natural ecosystems, the consequences of which are predictably low. The confinement requirements of each group of organisms are the following:

Domestic, Terrestrial Plants. Level of Safety Concern 2 of this group will include plants that do not hybridize or cross with indigenous plants. The Confinement Level 2 requirements are:

a) All of Confinement Level 1, and
b) Confine all plants to research site.
c) Control seeds, plant stocks, and their movement by wind or water, and secure seeds and plant stocks.
d) Exclude birds, other animals, and unauthorized persons.
e) Estimate the biomass and number of plants in the plot weekly.
f) Record all persons entering and leaving the research site.
g) Monitor for escaped plants and survivors.

Domestic, Terrestrial Animals. This group includes animals that contain genes for growth promotion, other hormones or enzymes, produce modified animal food products, but are not sexually mature or have been surgically rendered sterile. Confinement Level 2 requirements include:

a) All of Level 1, and
b) Isolate with locked fence
c) Clip wings of fowls and band
d) Tattoo or eartag animals

e) Exclude predators, other animals and unauthorized persons
f) Record all persons entering and leaving the research site
g) Record initial number of animals, deaths and final numbers.

Microorganisms. This group include microorganisms that are soil-borne, non-motile, do not readily exchange genetic information, are not vectored by insects, and do not form endospores. Confinement Level 2 requirements include:

a) All Level 1, and
b) Prevent movement by wind and water
c) Prevent movement by contamination of hands, clothing and shoes
d) Disinfect upon entry and exit
e) Exclude animals that can carry soil, other animals, and unauthorized persons
f) Monitor for movement.

Insects, Nematodes and Other Arthropods. Included in this group are insects that are non-flying or migratory, will not cross with native species, are not sexually mature or are sterile. Requirements for Confinement Level 2 includes:

a) All of Level 1, and
b) Isolate and fence research site
c) Control movement
d) Limit the number of organisms used in the field research
e) Monitor movement and invasion of hosts
f) Monitor trap hosts outside, but adjacent to the research site
g) Exclude non-target hosts, predators, other animals and unauthorized persons.
h) Clean or sterilize tools and clothing removed from the research site
i) Destroy at termination, including target host and all alternate hosts
j) Burn, fumigate, or deactivate as required.

Aquatic and Marine Animals. This group includes animals that do not cross or hybridize with related species, are not sexually mature, or are chemically or physically made non-fertile. The Level 2 requirements are:

a) All of Level 1, and
b) Isolate from any connecting water ways or drains
c) Require pumping of all inlet and outlet water so no gravity or natural siphoning can normally occur
d) Screen all inlets and outlets to prevent escape
e) Have sufficient freeboard to prevent overflow from storm
f) Have sufficient berm design to prevent accidental failure
g) Utilize barriers and liners to prevent burrowing animals from penetration
h) Have overflow area that can contain twice the volume of any catastrophic breach of berms, and keep water levels low at all times
i) Mark, brand, or otherwise uniquely identify animals
j) Exclude wildlife, other animals and unauthorized persons from the research site with screens and locked fence
k) Patrol surveillance and have emergency termination procedure
l) Record the numbers of animals stocked, deaths and removals, and number present at termination

m) Destroy all animals not needed for further research at termination and report number and identification of those retained
n) Monitor wild population of unmodified stock for presence of modified animals for two (2) years following field research.

Aquatic Plants. This group include aquatic plants that are not capable of sexual reproduction or cannot cross with indigenous plants. Confinement Level 2 requirements are:

a) All of Level 1, and
b) Isolate research area
c) Exclude wildlife, predators, other animals, and unauthorized persons
d) Prevent loss through drainage waters
e) Clean tools and clothing before leaving plot.

4.2.2.3 Confinement Level 3

Organisms classified under Level of Safety Concern 3 or those which may cause adverse effects on human health or on managed or natural ecosystems, the consequences of which are predictably moderate.

Domestic, Terrestrial Plants This group include plants that hybridize or cross with indigenous plants. Confinement Level 3 requirements include:

a) All Level 2 requirements, and
b) Isolate research site from all cross pollinators
c) Control pollen or sterilize
d) Monitor with trap crops for pollination
e) Controlled access
f) Provide patrolled security
g) Provide locked security fence
h) Destroy plants at termination and fumigate plot to kill seeds or plant parts.

Domestic, Terrestrial Animals. Level of Safety concern 3 of this group includes animals that contain genes from other species and are capable of producing compounds that have pharmaceutical activity in animals or humans and are sexually mature and capable of reproduction. Confinement Level 3 includes:

a) All of Level 2, and
b) Maintain double security fence and locks to prevent breaking in or out
c) Provide continuous monitoring of the animals
d) Provide maximum security
e) Collect, record, and incinerate all animal products, e.g. milk, eggs, etc
f) Control reproduction by segregation or sterilization
g) Destroy all animals and residues at termination

Microorganisms. This group includes microorganisms that are arboreal and are soil colonizers, motile with limited movement, vectored by insects, form endospores, contain toxins for some life forms. Confinement Level 3 includes:

a) All of Level 2, and
b) Exclude vectors, and trap and monitor potential vectors in the vicinity
c) Double security fence locked

d) Patrol area and have procedures if security is breached
e) Monitor organisms both inside and outside confinement
f) Monitor for exchange in organisms reported to have exchanged genetic information
g) Record all persons entering and leaving the research site
h) Fumigate plot upon termination and employ techniques to destroy all endospores.

Insect, Nematodes, and Other Arthropods. Included in this group are insects that move or migrate, are sexually mature, are pests of indigenous plants, animals or humans, and will establish interbreeding colonies with natural parents. Requirements of Confinement Level 3 are:

a) All of Level 2, and
b) Prevent movement that will allow crossing or interbreeding with parental insects
c) Confine insects to research site
d) Monitor movement of insects for escape from research plot
e) Provide patrolled security on integrity of confinement
f) Record all persons entering and leaving the research site
g) Monitor unmodified insects for two (2) years for movement of genetic information from the research site
h) Destroy all insects, hosts, and habitat on research site and in near vicinity.

Aquatic and Marine Animals. Included in this group are animals that are sexually mature, can cross or hybridize with large numbers of native species, or contain genetic material from unrelated animals, plants, or microorganisms, or with modifications that enhance their competitive advantage with wild forms or increase their nuisance. Confinement Level 3 requirements are:

a) All of Level 2, and
b) Monitor animals for sexual maturity and spawning
c) Collect all drainage water during spawning period, and check for evidence of eggs, fry, and milt
d) Recycle or retain all drainage water during the spawning period and for two weeks prior to and following spawning
e) Biologically deactivate all non-recycled drainage water
f) Monitor and retain samples of roe, milt, and fry for post experimental analysis
g) Determine if crossing and hybridization can occur with native populations and genetic fingerprint such crosses
h) Provide 24 hour surveillance and security
i) Record all persons entering and leaving research site
j) Estimate numbers produced
k) Destroy all excess animals at termination and incinerate
l) Record and uniquely identify all animals removed or retained for research purposes.

Aquatic Plants. This group includes aquatic plants that reproduce sexually, that produce pollen, seed or tubers, and may be weeds or nuisance in the environment. Confinement Level 3 requirements are:

a) All of Level 2, and
b) Isolate from natural drainage and waterways
c) Prevent pollen dispersal by wind, water and insects
d) Remove plants from the near environment that can be cross pollinated
e) Screen all inlets and outlets to prevent movements of seeds or plant parts
f) Recycle water when possible
g) Maintain catchment basins for drainage waters and pump all outlet water so no gravity drainage or siphoning can occur
h) Construct all beams and dams with liners or barriers to prevent burrowing animals from penetrating
i) Provide patrolled surveillance
j) Monitor surrounding environment for escaped plants, seed and pollen
k) Monitor unmodified plants for transfer of genetic information
l) Develop and test plants for emergency termination of experiment if catastrophic breach occurs
m) Destroy all plants at termination, drain plots or pools, monitor for regrowth, treat or fumigate as required.

4.2.2.4 Confinement Level 4

Level of Safety Concern 4 modified organisms should be released under Confinement Level 4. These organisms may cause adverse effects on human health or on managed or natural ecosystems, the consequences of which are predictably high.

Domestic, Terrestrial Plants. Confinement level 4 will be appropriate for plants that hybridize, outcross, and contain genes that could be transferred to noxious weeds, e.g., genes for resistance to herbicides. Confinement requirements include:

a) All of level 3, and
b) Provide isolation at least three (3) times greatest distance that natural pollination has been reported to occur.
c) Provide beams to contain all run off
d) Provide 24 hour surveillance during pollen shedding period
e) Provide locked security fences with alarms
f) Exclude with double measures all pollinators, other animals and insects
g) Monitor pollen collected in the area for genetic markers
h) Use methods of hand pollination and sterilization whenever possible
i) Monitor research site for two (2) years/seasons after termination of experiment for genetic escapes.

Domestic, Terrestrial Animals. Confinement Level 4 is appropriate for animals that contain unique genes or combination of genes not including infectious agents, but which may require higher levels of confinement because there is no familiarity with the potential effects on human health or on managed or natural ecosystems. Confinement Level 4 requirements include:

1. All of Level 3, and
2. Provide alarm on all fences and gates
3. Permanently identify all animals
4. Equip animal with location devices such as radio transmitters.
5. Develop and test system for immediate termination if confinement is breached.

Microorganisms. Level of Safety Concern 4 of modified organisms include microorganisms that are arboreal and soil colonizers which are motile and have been reported to readily exchange genetic information and which form endospores or have other long term methods of survival, produce toxins or other biocides or are readily vectored or spread by insects, wildlife, wind or water. Confinement Level 4 requirements include:

a) All of Level 3, and
b) Double confinement fences, barriers, screens and netting
c) 24-hour surveillance
d) Monitor to demonstrate that expected exchange of genetic information has occurred
e) Use double deactivation techniques for materials and personnel entering and leaving the plot
f) Emergency termination and monitoring procedures if security is breached
g) Destroy all organisms and all endospores or other long term survival bodies at termination of experiment
h) Monitor site for three (3) years.

Insects, Nematodes, and Other Arthropods. This group includes insects that move, migrate, are sexually mature, contain genetic information from non-insect sources and would likely be more competitive or successful in the environment, if they are able to escape. Confinement Level 4 requirements are:

a) All of Level 3, and
b) Double screen research site
c) Lock all entries and maintain 24-hour surveillance
d) Mark or uniquely identify (genetic markers) the experimental insect
e) Estimate by census the insect populations at weekly intervals
f) Monitor the immediate environment for escapes with sticky boards and trap hosts
g) Provide a means to destroy or secure insects if impending weather conditions threaten the security of the plot
h) Develop and demonstrate the ability to terminate and destroy all organisms immediately, if security is breached
i) Develop a plan to destroy all escaped insects if a breach occurs
j) Destroy at termination and repeat at two intervals to destroy any insects that might have persisted
k) Monitor for three (3) years for escaped insects and native insects for transfer of genetic information.

Aquatic and Marine Animals. Confinement Level 4 is appropriate for animals that contain genetic information from unrelated organisms, are sexually mature, contain characteristics which are known to increase their competitive advantage and nuisance characteristics. Requirements include:

a) All of Level 3, and
b) Secure and have 24-hour on-site monitoring by trained, qualified personnel
c) Use triple screened drains and inlets
d) Maintain berms and freeboard in excess of twice the average rainfall for the last 100 years

e) Perform blind deliberate releases of marked unmodified animals into the drains and retention system to test the integrity of the retention. Terminate upon failure
f) Destroy all animals at the termination of the research, except for those to be retained for research purposes, which must be clearly marked and have prior notification of intention to retain
g) Incinerate destroyed animals and verify by a third party
h) Develop, demonstrate, and test an emergency termination plan and system prior to and during the research
i) Monitor site and surrounding for three (3) years following termination.

Aquatic Plants Confinement Level 4 is appropriate for plants that both sexually and asexually reproduce and contain genetic information from non-plant sources and have a high likelihood of adversely affecting the environment and human health or producing toxic materials. Requirements include:

a) All of Level 3, and
b) Locate pools or plots in areas where water and plants will not reach natural drains or bodies of water if ruptures or failures occur
c) Test system with unmodified plants prior to research to ensure integrity of confinement. Terminate upon failure
d) Fence and screen plots with double fences and screens as required
e) Maintain free board in all plots or pools to contain water in excess twice the average rainfall in the last 100 years
f) Provide 24-hour surveillance
g) Develop and test a plan to monitor severe weather conditions; secure or terminate, if imminent conditions could breach confinement and spread plants
h) Inventory plants weekly to estimate number of plants, pollen, seeds, and other reproductive organs
i) Record wet biomass, number of plants, number of seeds, tubers and other reproductive organs, and method of destruction of materials not retained for future research

Monitor research site for four (4) years and unmodified plants for six (6) years for transfer of genetic information

5.0 MONITORING AND ENFORCEMENT OF THE GUIDELINES

5.1 Introduction

The purpose of monitoring and evaluation is to gather data concerning the GMOs in order to assess the extent, to which transgenic have impacted on the biological diversity, environment and human health. When referring to the environment, the main focus is on confined field trials and commercial release of GMOs. Thus, monitoring would determine effects, which could be categorized as severe, moderate, low, negligible or no harm. In the case of plants, monitoring should be undertaken to determine the level of horizontal gene transfer and to develop a monitoring and

evaluation prospectus. Monitoring of the GMOs should be undertaken at different levels. Initial monitoring should be done at the project initiation phase to ensure that all things are organized according to the plan. At several stages during the execution of the project, monitoring should be undertaken to ensure compliance. Two types of evaluations should be undertaken, namely at the formative and the final stages. There are two different types of monitoring which can be associated with the release of GMOs:

a) Monitoring which is required by the government and is intended to confirm any assumptions made in the risk assessment procedures and
b) Voluntary monitoring which is undertaken by the applicant in order to provide further information for his or her own purposes.

5.2 Methodology

It is necessary to establish a common methodology to carry out the environmental risk assessment based on independent scientific advice. It is also important to establish common objectives for the monitoring of GMOs after their deliberate release and/or after placing GMO in the market or products of GMOs. Monitoring of potential cumulative long-term effects should be considered as compulsory part of the monitoring plan. The objective of monitoring plan is to:

a) confirm that any assumption regarding the occurrence and impact of potential adverse effects of the GMO or its use in the environmental risk assessment are correct, and
b) identify the occurrence of adverse effects of the GMO or its use on human health or the environment which were not anticipated in the environmental risk assessment.

5.2.1 Monitoring Plan Design

The National Biosafety Focal Point (NBFP) in collaboration with the competent authorities should prepare monitoring plan for each release of specific GMO. The design of the monitoring plan should:

a) Be detailed on case by case basis taking into account the environmental risk assessment and risk management;

b) Take into account the characteristics of the GMO, the characteristics and scale of its intended use and the range of relevant environmental conditions where the GMO is expected to be released;

c) Incorporate general surveillance for unanticipated adverse effects and, if necessary, (case) specific monitoring focusing on adverse effects identified in the environmental risk assessment;

d) Be carried out for a sufficient period of time to detect immediate and direct as well as, where appropriate, delayed or indirect effects which have been identified in the environmental risk assessment;

e) Make use of already established routine surveillance practices such as to how relevant information collected through established routine surveillance practices will be made available to the consent-holder;

f) Facilitate the observation, in a systematic manner, of the release of a GMO in the receiving environment and the interpretation of these observations with respect to safety to human health or the environment;

g) Identify who will carry out the various tasks the monitoring plan requires and who is responsible for ensuring that the monitoring plan is set into place and carried out appropriately, and ensure that there is a route by which the consent holder and the competent authority will be informed on any observed adverse effects on human health and the environment.

h) Give consideration to the mechanisms for identifying and confirming any observed adverse effects on biodiversity, human health and environment and enable the consent holder or the Competent Authority, where appropriate, to take the measures necessary to protect human health, biodiversity and the environment.

5.2.2 Types of Monitoring

For the purpose of this NBF monitoring is used to gather additional scientific data to assist the assessment of risk and decision-making. Monitoring is carried out for specific reasons and at specific times in the development of GMOs. The various types of monitoring that may be used by monitoring agencies are listed below.

a) Case-specific monitoring

Case specific monitoring should be used to confirm any assumption derived from risk assessment regarding potential adverse effects of the GMO or its use on human health or the environment. It deals with the observation of certain adverse effects, i.e. "immediate and direct as well as delayed or indirect effects which have been identified in the environmental risk assessment" relating to individual approvals for placing on the market over a limited period of time.

b) General surveillance monitoring

Used for the long-term observation in Good Manufacturing Practices (GMPs) and covers the observation of adverse effects of the GMO or its use for human health and the environment that were not predicted in the risk assessment for one particular product. To be able to identify these adverse effects, general surveillance should consist of elements based on effect-hypotheses and elements not based on clear defined hypotheses. If changes in the environment are identified further examination is required. An additional component could be existing observation programmes which could be adapted to the needs of monitoring GMPs. In a first range this could be environment observation programmes as well as programmes in the field of agriculture food surveys, nature conservation, soil observation and veterinary surveys.

c) Voluntary monitoring

Might include data collection for the further development of a program of release proposals, e.g. by accumulation of data on survival of the GM plant in the environment. It might also mean obtaining data to better understand the probability or impact of risk and thus allow informed relaxation of unnecessary safeguards in future releases.

d) Monitoring by applicants

Monitoring by an applicant is done at the field level following terms and conditions set by the competent authority. It enables the applicant to take measures to ensure that the implementation of trials/projects on release of GMO are proceeding as expected and if unexpected problems arise, the applicant should immediately take action and notify the authorities.

For the purpose of this NBF, monitoring should cover all types of activities starting from laboratory to commercial release. Some of the important things to consider are:

i) develop monitoring indicators;
ii) develop target outputs ;
iii) develop performance measures;
iv) determine at what stage the evaluation will be undertaken and timelines for both formative and final evaluation; and
v) provide for the resources which will be needed for both monitoring and evaluation.

e) Experimentation

Experimentation refers to that exercise that is part of early stage, research and development procedures. In small scale field tests, monitoring might be designed to answer specific questions about product performance or provide basic information on the biology of organisms and their interactions with the environment. With regard to biosafety issues, a monitoring program might be designed to test pre-release evaluations of gene flow or the potential impacts of gene exchange should it occur. Any of these issues may have been raised at the risk assessment stage of an application review. If there are restrictions imposed as a condition for application approval, a monitoring procedure may be proposed to fulfill some or the entire requirement.

f) Tracking

Tracking is used primarily to monitor the movement and dispersal of the organisms and their genes. For most crop plants which do not survive well beyond cultivated fields, this has not been of great concern. For those crop plants that have close relatives in proximity to the cultivated plots, however, there has been concern for out crossing of the engineered genes. It is the responsibility of the authorized party to ensure that the conditions for reproductive isolation of all trial plants/organism are met during current release period and the post release/harvest periods.

g) Surveillance

For the purpose of this frame work, Surveillance implies post-release observation, often for the survival and dispersal of an organism or for some environmental impact when predetermined sampling regimes are often impractical. The implications of large distances (e.g., kilometers) and long time intervals (e.g., years) to monitor wind driven pollen or seed dispersal, for example, might challenge the most robust budget. Additionally, deciding upon what to look for and devising a meaningful surveillance program may present insurmountable difficulties when there may only be speculation as to what environmental impacts a GMO release might impose. This might result in good faith arguments where responsible investigators suggest 'looking under the lamp post'.

5.2.3 Monitoring During Release

Monitoring during release aims to assess the efficacy of any risk management safeguards applied to the release. This should detect whether there is any risk of harm, caused for example by introgression with potential recipients. For example, if the presence of available pollen recipients within the dispersal area is essential to be a risk, their number should be kept below the level at which harm might occur.

The frequency of monitoring should take account of the nature of GMOs. Monitoring data obtained during and after the release from such voluntary experiments to test survival could help address the uncertainty. A more precise risk assessment could then be made for a subsequent release proposal, and consequently, could allow risk management safeguards to be reduced.

It is possible that, despite a thorough risk assessment, unforeseen events will still occur. The monitoring regime may or may not be able to detect whether this is the case. If an unforeseen effect is detected, its significance should be assessed. If there is a significant adverse impact on the environment, pre-planned emergency control will be required.

5.2.4 Post Release Monitoring

Monitoring of post emergence should be implemented following post emergency time periods established by the NBFP.

Post release/harvesting monitoring is necessary where the risk assessment determines that the continuous presence of the released GMO presents risk of harm. Post-release monitoring will need to concentrate on confirming the removal of the released GMOs. Where appropriate, monitoring should concentrate on detecting and controlling any volunteer GMOs arising form the release. In some cases there may be uncertainty regarding the risk of harm from continued presence of an organism, especially over the long term. Post-release monitoring should then be designed to provide data to enable the uncertainty to be resolved. In case of plants, factors to be taken into account include:

i) Seasonal effects, such as flowering and likely germination times;
ii) Post-trial treatment of the release site; and
iii) Longevity of seed or tubers in soil.

5.3 Reporting Requirements

The authorized party should comply to the reporting format set in the terms and conditions of authorization. However, for every GMO introduction , there is a need to determine when to undertake monitoring and when to evaluate the work. The same process would explicitly identify who would undertake the monitoring and evaluation, and who would receive the reports.

5.4 Inspection and Enforcement

In accordance to section of the draft Environmental Management Act and Biosafety Regulations, inspection and supervision shall be performed by the Inspectorate of Competent Authorities/key Ministries. Authorised party shall pay inspection fees that will be established by the competent authorities. Inspectors have the authority to inspect sites containing GMOs like field trial sites etc for compliance with terms and conditions of authorization. Inspectors also have the authority to inspect contained facilities that may be used for research or storage of GMOs. Competences for the inspection supervision will be specified in permits or approvals.

The proposed system has flexibility to appoint different competent inspectorates on the case by case basis. On the other hand, the competent bodies already have other mandates, therefore, separation of the competences will have to be formalized for GMO regulation.

If an inspector during the performance of work or on the basis of a notification establishes that because of unfulfilled required conditions and requirements, the environment, human health or socio-economic and ethical issues are at risk shall order the following measures:

(a) prohibit contained use, deliberate release of a GMO into the environment or placing a product on the market,
(b) order the temporary suspension of contained use, the deliberate release of GMOs into the environment or placing a product on the market,
(c) order the rectifying of established irregularities within a time limit that the inspector specifies, and
(d) order remediation and other measures for rectifying or reducing the consequences of adverse effect that have occurred because of GMO management.

In order for the inspectors to discharge their duties effectively, it is necessary to:-

(a) Carry out a capacity needs assessment;

Develop and implement capacity building programme including training, infrastructure, equipment and tools.

6.0 HANDLING, TRANSPORT, PACKAGING AND IDENTIFICATION OF GMOS

6.1 General

In order to avoid adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, these guidelines stresses the importance of documentation accompanying living modified organisms that are intended for direct use as food or feed, or for processing, clearly identifies that the shipment may contain living modified organisms that are intended for direct use as food or feed, or for processing, and states that they are not intended for intentional introduction into the environment; also provides the details of a contact point for further information: the exporter, the importer, or any appropriate authority. The accompanying document should include (i) the common, scientific and where available, commercial names, and (ii) the transformation event code of the LMO's or where available, as a key to accessing information in the Biosafety Clearing-House, its unique identifier code.

Documentation accompanying living modified organisms. In a case where:-

(a) Living modified organisms that are destined for contained use clearly identifies them as living modified organisms; and specifies any requirements for the safe handling, storage, transport and use, the contact point for further information, including the name and address of the individual and institution to whom the living modified organisms are consigned; and

(b) Living modified organisms that are intended for intentional introduction into the environment of the Party of import and any other living modified organisms within the scope of the Protocol, clearly identifies them as living modified organisms; specifies the identity and relevant traits and/or characteristics, any requirements for the safe handling, storage, transport and use, the contact point for further information and, as appropriate, the name and address of the importer and exporter; and contains a declaration that the movement is in conformity with the requirements of this protocol applicable to the exporter.

6.2 GMO Specimens

The handling, transfer and shipment of improperly packed specimens and infectious agents carry a risk of infection to all people directly engaged in, or in contact with, any part of the process. Improper handling within the laboratory endangers not only the immediate staff but also administrative and other support personnel. Transfer of materials between laboratories or institutions widens the scope of risk to the public and the environment.

Specimen containers should be leak proof. No material should remain on the outside after the cap/lid has been closed.

To avoid accidental leakage or spillage into the environment special secondary containers should be provided for the transport of specimens between wards or

departments and laboratories. These should be strong, thermo-chemical resistant and leak proof.

Where large numbers of specimens are received a separate room should be provided for their receipt. In a small facility, this may be a designated part of the laboratory.

All packages received should be opened in a biological safety cabinet.

Infectious substances and their products are classified as dangerous goods by the United Nations Committee of Experts on the Transport of Dangerous Goods, the International Air Transport Association (IATA), the Universal Postal Union (UPU), the International Civil Aviation Organisation (ICAO), and the World Health Organisation (WHO, 1993). These organisations have developed common definitions, packaging, and labels requirements.

The IATA Shipper's Declaration for Dangerous Goods must also be completed for shipment by either airfreight or airmail. The Universal Postal Union (UPU) requires that containers for international shipment of non-infectious diagnostic specimens and other biological materials bear the standard international violet coloured "matieres biologiques perishables" (perishable biological substances). Below are examples of containers for biological transport.

i) Mini Tube

ii) Biofreeze –1ltr

6.3 Food, Feed or for Direct Processing

Donor providing genetically modified food and feed should comply with the prior informed consent principle and the notification requirements in accordance with Article 8 of the Cartagena Protocol on Biosafety

Food and feed consignment involving grain that contains GMO should be milled prior to distribution to beneficiary populations. Food and feed in transit that contain GMO should be cleared identified and labelled in accordance to national legislation.

7.0 LIABILITY AND REDRESS

The liability provisions impose strict liability for any damage caused by the introduction of a GMO or product thereof. Liability is imposed to any person or entity responsible for the harm. Liability also imposed to officers of a corporation unless they can prove beyond any reasonable doubt that they did all that was possible to prevent damage/injury/financial loss due to the activity in relation to the GMO or product thereof.

The time limit to bring an action should be extended to a reasonable time after the affected person could reasonably expected to have learnt of the harm. In ascertaining this, due account must be taken of the time the harm takes to manifest itself as well as time it takes to correlate the harm caused with the GMOs or product thereof.

A person who imports, arranges transit, makes contained use of, releases or places on the market a genetically modified organism or product thereof should be strictly liable for any harm caused by such a genetically modified organism or product thereof. The harm should be fully compensated.

If there is more than one person responsible for the damage, injury or loss, then the liability should be joint and several.

Liability also extends to harm or damage caused directly or indirectly to the economic, social, or cultural practices, including negative impacts on the livelihoods and local systems and technologies of a community or communities or damage or destruction arising from the incidence of public disorder triggered by the GMO or the product thereof, disruption or damage to production or agricultural systems, reduction in yields, soil contamination, damage to biological diversity, damage to the economy of an area or community, and any other consequential damage.

In the case of harm to the environment or biological diversity, compensation should include the costs of reinstatement, rehabilitation or clean up measures which actually are being incurred and, where applicable, the costs of preventive measures.

In the case of harm to human health, compensation should include;

- all costs and expenses incurred in seeking and obtaining the necessary and appropriate medical treatment;
- compensation for any disability suffered, for diminished quality of life; and
- compensation for loss of life and all costs and expenses incurred for funeral and other related expenses.

A wide category of persons is given the right to institute legal action. This includes, in addition to those directly affected, groups which bring an action on behalf of those who are unable to do so. Any person may also bring an action in the public interest or for protecting the environment or biological diversity.

No costs should be awarded against any of the above persons who fail in any action as aforesaid if the action was instituted reasonably out of concern for the public interest or

in the interest of protecting human health, biological diversity and the environment as well as socio-economic, cultural and ethical concerns.

8.0 PUBLIC AWARENESS AND PARTICIPATION

8.1 Introduction

Tanzania has experienced lively public debates on a wide range of issues related to science and technology but not on GMOs. However, the debates on GMOs coincided with growing public awareness on societal issues such as environment and sustainable development. This reflects the fact that involvement of the general public is crucial in the formulation and implementation of national policies.

The level of public awareness on biotechnology and biosafety in the country is extremely low, even amongst the scientific community. Possible explanations for low awareness include:

a) Recent nature of GMO technology;
b) Limited knowledge on GMO technology at all levels;
c) Limited access to relevant publications, the internet and other information sources; and
d) Low level of awareness by the general public on benefits and risks associated with GMOs.

Therefore, it is very crucial to involve a wide range of stakeholders through a consultative process in order to promote and facilitate public awareness and public participation as stipulated in Article 23 of the CPB, which states that parties shall promote and facilitate public awareness, education and participation concerning the safe transfer, handling and use of GMOs in relation to the conservation of biological diversity, taking into account the risks to human health. Parties shall further endeavour to ensure public awareness and education encompassing access to information on GMOs identified in accordance with this protocol that may be imported, should consult the public in the decision making process regarding GMOs, and should make the results of such decisions available to the public.

8.1.1 Why Public Awareness and Participation

As biotechnology develops rapidly, more and more GMOs and their products will be released into the environment and may thus pose potential risks to the environment and human health. A proper mechanism should be established to create awareness and enable the public to participate in implementation of the biosafety measures. Awareness and participation are important:

a) For consensus-building on issues that affect people directly or indirectly;
b) To build a sense of ownership and collective responsibility;
c) To promote sustainable development;
d) To promote smooth implementation of the decisions;
e) To build transparency and accountability;
f) To provide balanced information in terms of pros and cons; and
g) To harmonize institutions that provide awareness activities.

Proposed Biosafety Regulations compel the NBFP to provide information to the public and provide for public consultation mechanisms. The NBFP shall endeavor to make available to the public:

a) Information on all GMOs or their products which have received, or have been denied, authorization, as the case may be, for import, deliberate release (including the location of the release), placing on the market or contained use;
b) The risk assessment report in respect of the GMOs or products thereof; and
c) The report on the evaluation of the outcome of the risk assessment.

The Competent Authorities and other agencies, in making biosafety decisions, should promote and facilitate public awareness, education, and participation concerning the research, development, handling, transboundary movement, transport, use, transfer, release and management of GMOs. They should incorporate into their respective administrative issuances and processes best practices and mechanisms on public awareness and participation.

8.1.2 Scope of Public Awareness and Participation

Public awareness should be promoted in terms of:

a) Imparting relevant information to stakeholders about specific issues;
b) Providing balanced information in terms of pros and cons;
c) Providing universal access to information;
d) Providing relevant information for informed participation; and
e) Translating available information.

Public participation on the other hand should be promoted in terms of:

a) Involving stakeholders (at all levels of society) in decision-making and all processes
b) Obtaining opinion from other people, passing on the information; and
c) Using a democratic process in reaching a common understanding and coming out with a common solution.

8.2 Access to information

a) **Right of access to information:** The right of the public and the relevant stakeholders to information about applications for the research, development, handling, transboundary movement, transport, use, transfer, release and management of GMOs shall be respected. Concerned government departments and agencies should, subject to reasonable limitations, protect confidential information as provided in the Proposed Regulations, and should disclose all information on such applications in a prompt and timely manner.

b) **Confidential Business Information (CBI):** All ministries agencies and institutions handling GMO applications shall ensure that they have procedures to protect confidential business information. The protection of confidential business information is subject to the following requirements:
    i) The declaration of confidentiality of commercial information is subject to proof that the information specified in the application is: a trade secret; or

any other information that has a commercial or other value that could be destroyed or diminished if the information were disclosed; or other information that concerns the lawful financial and commercial affairs of a legal or physical person and that if it were disclosed it could reasonably affect that person;

ii) The NBFP, Competent Authorities and other agencies may refuse declaring the confidentiality of such information if it is satisfied that the public interest in disclosure outweighs the prejudice that the disclosure would cause to any person;

iii) If an application is withdrawn, the concerned NBFP, Competent Authorities and other agencies should respect the confidentiality of commercial and industrial information, including research and development information;

iv) In no case shall the following information be considered confidential:

- The name and address of the applicant.
- A general description of the GMOs.
- A summary of the scientific risk assessment conducted by the applicant.
- Where applicable, any methods and plans for emergency response; and

v) For information claimed as CBI, applicant must provide written justification.

c) **Information on Biosafety Decisions:** The public and relevant stakeholders should have access to all biosafety decisions approving or denying applications for the research, development, handling, transboundary movement, transport, use, transfer, release and management of GMOs. Such decisions need to summarize the application; the results of the scientific risk assessment and the evaluation of socio-economic risks; the public participation process followed; and the basis for approval or denial of the application.

8.3 Minimum Requirements

Public awareness and participation shall apply to all stages of the biosafety decision-making process from the time the application is received. In conducting these processes, the following minimum requirements should be followed:

a) Notice to all concerned stakeholders, in a language understood by them and through media to which they have access. Such notice must be adequate, timely, and effective.
b) Adequate and reasonable time frames for public participation procedures.
c) Public consultations, as a way to secure wide input into the decisions that are to be made. These could include public hearings in certain cases, particularly where there is public concern about the proposed measures. These

consultations should encourage exchanges of information between applicants and the public before the application is acted upon. Dialogue and consensus building among all stakeholders should be encouraged.

d) Procedures for public participation should include mechanisms that allow public participation in writing or through public hearings, and which allow the submission of any comments, information, analyses or opinions.

Public opinion as gauged through the procedures for public participation must be taken into account in the decision. The public must be informed of the final decision promptly, have access to the decision, and must be provided with the reasons and considerations resulting in the decision.

8.4 Tools and Processes

Tools that are used for both public awareness and participation are inter-linked; a mix of tools and processes will assist in achieving the goals. Following are the mechanisms that will be used.

a) **National Biosafety Clearing House:** National Biosafety Clearing House should be established in order to facilitate exchange of scientific, technical, legal and administrative information.

b) **Public consultative meetings:** Public meetings and open days in accordance with the local practice in each community, such as Farmers' Day, stakeholder tours, and demonstration projects. Other public gatherings for meetings with local leaders could also be used to disseminate information. Public meetings should be age and gender-sensitive, accessible, convenient to all and as much as possible use the *Kiswahili* language.

c) **Workshops and seminars:** Workshops and seminars targeted at particular stakeholders e.g., awareness workshops involving groups of consumers, farmers, scientists etc..

d) **Public debates and forums:** Provision of information and public debate should be encouraged between companies and institutions working with GMOs and public interest groups. Follow-up general meetings should be conducted with smaller groups of opinion leaders (key informants) to further explain and exchange ideas. Independent forums may be conducted to identify particular needs of different groups.

e) **Capacity building for various stakeholders:** Implementation of the NBF requires the building of biosafety capacities by concerned government departments and agencies. (Annex I), capacity building programs on biosafety are needed for relevant stakeholders including policymakers, regulators, research scientists, media, NGOs and the general public.

f) **Supporting NGOs or civil society groups:** Interest groups (NGOs, etc) should be supported in promoting public awareness or mobilizing public involvement.

g) **Create awareness about opportunities to participate**: Advertising events and meetings in local media. Make the public aware of forthcoming events or meetings, so that people can raise issues before the meeting.

h) **Mass media:** Using radio, newspapers and television.
   - Printed information on biosafety e.g., leaflets, brochures, fact-sheets, posters, newsletters in accessible style and format.
   - Electronic communication technologies such as internet discussions and e-mail news-group.
   - Theatre art and other performances to raise awareness and convey information in an accessible and engaging way. Information dissemination and advertising.

i) **Committees:** Stakeholders participation in committees

8.5 Challenges and way forward

Among the key challenges of participation in the implementation of National Biosafety Framework were issues such as how to simplify highly scientific information to facilitate and increase the comprehension of the concepts by the general public. The key issue is to how to define the limits of confidentiality for the provision of information to the public. Another view held that the responsibility for deciding what represented confidential product information lay with the national government, in consultation with the company concerned, since a government needed to have the right to ask for all relevant information. To communicate the given message to the chosen audience one needed to know that audience, to see the message from their point of view, and to engage them. To communicate effectively, it is also necessary to listen to what is said, and what to be left unsaid.

Dialogue required honesty, openness, transparency and inclusiveness, with mutual respect and an absence of condescension. The public had valid points of view which needed to be voiced and understood, taking into account room for variance. In that context, it is necessary to see how information could be packaged and communicated, and to bear in mind the rule that “no size fits all”.

Enabling environment for public awareness and participation is a requirement to ensure smooth implementation of National Biosafety Framework. There is a need for:-

a) Capacity building;
b) Establishment and implementation of appropriate programmes and policy guidelines on participatory approaches;
c) Networking among stakeholders;
d) Regional/sub-regional and global cooperation; and
e) Effective participation at all levels, public, government and private.

ANNEXES

ANNEX I: BIBLIOGRAPHY

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http//www.bdt.fat.org.br/binas/regulations.full.regs/Egypt/biosafety.htm.

Anon (1994b) Guidelines on Biosafety for Nigeria
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Anon (1998) National Guidelines for Release of Genetically Modified Organisms (GMOs) to the Environment *http//www.bdt.fat.org.br/binas/regulations.htm.*

Anon (2000). Biosafety Guidelines for Uganda. Uganda National Council for Science and Technology, Kampala Uganda

Convention of Biological Diversity, (1992). *United Nations Conference on Environment and Development*. Rio de Janeiro, Brazil, 3 – 14th June 1992.

OAU and Institute for Sustainable Development (2002). *African Model Law on Safety in Biotechnology*

Mabileletsa, P (2003). *South African Food and Agriculture Import Regulations and Standards*

ANNEX II: GMOs THAT SHOULD NOT BE INTRODUCED IN TANZANIA

Level of Safety Concern 5 include organisms whose ecological attribute indicate that they may cause adverse effects on human health or on managed natural ecosystems, the consequences of which are predictably high, and that no feasible types of confinement will allow safe conduct of research outside contained facilities. Some attributes that alone or in combination might indicate Level 5 are:

1. History of adverse effects in the accessible environment or in similar environments

2. Ability to survive and proliferate in the accessible environment

3. Non-indigenous status in the accessible environment

4. High frequency of exchange of genetic information with native populations of organisms

5. Lack of effective techniques to minimize escape of viable organisms or active products of the organism from the research site

6. Lack of adequate techniques to recapture or kill escaped organisms before adverse effects occur.

ANNEX III: APPLICATION TO INTRODUCE OR RELEASE GMOs INTO TANZANIA

PREAMBLE

Following is the information required for the application to authorize the release to the environment of GMOs or product thereof, including use in a close system in quantities, import, export for food, feed or processing and pharmaceuticals which have no certification to the effect that they have authorized by an agency with the mandate to do so, both in the context of human health and country''s biological diversity

Applicants are required to provide further information as may be requested by the National Biosafety Focal Point.

I. General Information

A. Name and detailed contact address of applicant

B. Information on personnel and Training

Name, training and other qualifications of person(s) responsible for planning and carrying out the implementation of the project, including those responsible for supervision, monitoring and safety, in particularly the name and qualifications of the responsible scientists.

II. Information Relating to the GMO(s) or Product Thereof

A. Characteristics of a) the donor, b) the recipient or c) (where appropriate) parental organism(s)

(1) Scientific name
(2) Additional taxonomic information
(3) Other names (usual name, strain name, cultivar name etc).
(4) Phenotypic and genetic markers
(5) Degree of relatedness between donor and recipient or between parental organisms
(6) Description of identification and detection techniques
(7) Sensitivity, reliability (in quantitative terms) and specificity of detention and identification techniques
(8) Description of the geographic distribution and of the natural habitat of the organisms including information on natural predators, preys, parasites and competitors, symbionts and hosts
(9) Potential for genetic transfer and exchange with other organisms
(10) Verification of the genetic stability of the organisms and factors affecting it, taking into account the relevance of the laboratory experiments undertaken to the authentic ecological conditions under which the organisms live or are used.
(11) Pathological, ecological and physiological traits:
    - Classification of hazard according to existing national rules concerning the protection of human health and/or environment

- Generation time in natural ecosystems, sexual and asexual reproductive cycle
- Information on survival, including season ability and the ability to form survival structures e.g. seeds, spores or sclerotia
- Pathogenicity: infectivity, toxigenicity, virulance, allergenicity, ability to be a carrier (vector) of pathogen, possible vectors, host range including non-target organisms. Possible activation of latent viruses (proviruses). Ability to colonize other organisms
- Antibiotic resistance, and potential use of these antibiotics in humans and domestic organisms for prophylaxis and therapy
- Involvement in environmental processes: primary production, nutrient turnover, decomposition of organic matter, respiration, etc

(12) History of previous genetic modifications

B: Characteristics of the vector

(1) Nature and source of the vector
(2) Sequence of transposons, vectors and other non-coding genetic segments used to construct the GMO(s) or products thereof and to make the introduced vector and insert function in the GMO(s) or products thereof
(3) Frequency of mobilization of inserted vector and/or genetic transfer capabilities and methods of determination
(4) Information on the degree to which the vector is limited to the DNA required to perform the intended function.
(5) Factors (chemical, biological, climatic, etc) influencing the functional level of the promoter/enhancer, and how the functional level is changed.

C: Characteristics of the GMO(s) or products thereof

(1) Information relating to the genetic modification:
   a) Methods used for the modification
   b) Methods used to construct and introduce the insert(s) into the recipient or to delete a sequence
   c) Description of the insert and/or vector construct.
   d) Purity of the insert from any unknown sequence and information on the degree to which the inserted sequence is limited to the DNA required to perform the intended function.
   e) Number of intact and truncated vector inserts sequence, functional identity and location of the altered/inserted/deleted nucleic acid segment(s) in question with particular reference to any known harmful sequence
   f) Sequence and methylation pattern of the recipient DNA as far as 100 kbp up and down stream from all DNA inserts

(2) Information on the final GMO:
   a) Description of genetic trait(s) of phenotypic characteristics and in particular any new traits and characteristics which may be expressed or no longer expressed

b) Structure and amount of any vector and/or donor nucleic acid remaining in the final construction of the GMO(s) or product thereof
c) Stability of the genetic traits of organism in terms of both expressing and structure
d) Rate and level of expression of the new genetic material. Method and sensitivity of measurement
e) activity of the expressed protein(s)
f) expression levels for the recipient's genes situated as far as 100 kbp up and down stream from all DNA inserts
g) Sensitivity, reliability (in quantitative terms) and specificity of detection and identification techniques
h) History of previous releases or uses of the GMO(s) or products thereof
i) Health considerations:
    (i) Toxic or allergenic effects of the non-viable GMO(s) or products thereof and/or their metabolic products
    (ii) Product hazards
    (iii) Comparison of the GMO(s) or products thereof to the donor, recipient or (where appropriate) parental organism regarding pathogenicity
    (iv) Capacity for colonization
    (v) If the organism is pathogenic to humans who are immunocompetent
        - Diseases caused and mechanism of pathogenicity including invasiveness and virulence
        - Communicability
        - Infective dose
        - Host range, possibility of alteration
        - Possibility of survival outside of human
        - Presence of vectors or means of dissemination
        - Biological stability
        - Antibiotic-resistance patterns
        - Allergenicity
        - Availability of appropriate therapies.

III: Information Relating to the Conditions of Release and the Receiving Environment

A. Information on the release

(1) Description of the proposed deliberate release, including the purpose(s) and foreseen products
(2) Foreseen dates of the release and time planning of the experiment including frequency and duration of releases
(3) Preparation of the site previous to the release
(4) Size of the site
(5) Method(s) to be used for the release
(6) Quantities of GMO(s) or products thereof to be released

(7) Disturbance on the site (type and method of cultivation, minimum irrigation, or other activities)
(8) Workers protection measures taken during the release
(9) Post-release treatment of the site
(10) Techniques foreseen for elimination or inactivation of the GMO(s) or products thereof at the end of the experiment
(11) Information on, and results of, previous releases of the GMO(s) or products thereof, especially at different scales and in different eco-systems.

B: Information on the environment

This should be for both the site and the wider environment. Note that in the case of GMOs or their products destined to be used as food or feed or for processing, the environment includes the transportation routes and the market places as well as all the catchment areas of the market places.

(1) Geographical location and grid reference of the site(s) (in case of notifications under part C the site(s) of release will be the foreseen areas of use of the product)
(2) Physical or biological proximity to humans and other significant biodata
(3) Proximity to significant biotypes or protected areas
(4) Size of local population
(5) Economic activities of local populations which are based on the natural resources of the area
(6) Distance to closest areas protected for drinking water and/or environmental purpose
(7) Climatic characteristics of the region(s) likely to be affected
(8) Geographical, geological and pedological characteristics
(9) Flora and fauna, including crops, livestock and migratory species
(10) Description of target and non-target ecosystems likely to be affected
(11) A comparison of the natural habitat of the recipient organism with the proposed site(s) of release
(12) Any known planned developments or changes in land use in the region, which could influence the environmental impact of the release.

IV: Information relating to the interactions between the GMO(s) or products thereof and the environment

A. Characteristics and factors affecting survival, multiplication, gene expression and dissemination

(1) Biological features which affect survival, multiplication and dispersal
(2) Known or predicted environmental conditions which may affect survival, multiplication and dissemination (wind, water, soil, temperatures, pH, pollutants such as pesticides, heavy metals and others, etc.)
(3) Sensitivity to specific agents

B. Interactions with the environment

(1) Predicted habitat of the GMOs
(2) Studies of the behaviour and characteristics of the GMOs or products thereof and their ecological impacts carried out in simulated natural environments, such as microcosms, growth rooms, greenhouses
(3) Genetic transfer capability:
    a) post-release transfer of genetic material from GMOs or products thereof into organisms in affect ecosystems;
    b) post-release transfer of genetic material from indigenous organisms to the GMO(s) or products thereof;
(4) Likelihood of post-release selection leading to the expression of unexpected and/or undesirable traits in the GMOs or products thereof
(5) Measures employed to ensure and to verify genetic stability. Description of genetic traits which may prevent or minimize dispersal of genetic material. Methods to verify stability
(6) Routes of biological dispersal, known or potential modes of interaction with the disseminating agent, including inhalation, ingestion, surface contact, burrowing, etc.
(7) Description of ecosystems to which the GMO(s) or products thereof could be disseminated

C. Potential environmental impacts

(1) Potential for excessive population increase in the environment
(2) Competitive advantage of the GMO(s) or products thereof in relation to the unmodified recipient or parental organism(s)
(3) Identification and description of the target organisms
(4) Anticipated mechanism and result of interaction between the released GMO(s) or products thereof and the target organism
(5) Identification and description of non-target organisms which may be affected indirectly.
(6) Likelihood of post-release shifts in biological, or in host range
(7) Known or predicted effects on non-target organisms in the environment, impact on population levels of competitors, preys, hosts, symbionts, predators, parasites and pathogens
(8) Known or predicted involvement in biogeochemical processes
(9) Other potentially significant interactions with the environment.

V: Information on Monitoring, Control, Waste Treatment and Emergency Response Plans

A: Monitoring techniques

(1) Methods for tracing the GMO(s) or products thereof, and for monitoring their effects
(2) Specificity (to identify the GMO(s) or products thereof, and to distinguish them from the donor, recipient or, where appropriate, the parental organisms), sensitivity and reliability of the monitoring techniques
(3) Techniques for detecting transfer of the donated genetic material to other organisms

(4) Methods to detect aberrant gene expression.

B. Control of the release

(1) Methods and procedures to avoid and/or minimize the spread of the GMO(s) or products thereof beyond the site of release or the designated area for use
(2) Methods and procedures to protect the site form intrusion by unauthorized individuals
(3) Methods and procedures to prevent other organisms from entering the site.

C. Waste treatment

(1) Type of waste generated
(2) Expected amount of waste
(3) Possible risks
(4) Description of treatment envisaged

D. Emergency response plan

(1) Methods and procedures for controlling the GMO(s) or products thereof in case of unexpected spread
(2) Methods for decontamination of the areas affected, e.g. eradication of the GMO(s) or products thereof
(3) Methods for disposal or sanitation of plants, animals, soils, etc, that were exposed during or after the spread
(4) Methods for the isolation of the area affected by the spread
(5) Plans for protecting human health and the environment in case of the occurrence of an undesirable effect
(6) Recommended mitigation options

ANNEX IV: INFORMATION REQUIRED CONCERNING GMOs INTENDED FOR DIRECT USE AS FOOD OR FEED, OR FOR PROCESSING

a) The name and contact details of the applicant for a decision for domestic use;

b) The name and contact details of the authority responsible for the decision;

c) Name and identity of the GMO;

d) Description of the genetic modification, the technique used, and the resulting characteristics of the GMO;

e) Any unique identification of the GMO;

f) Taxonomic status, common name, point of collection or acquisition, and characteristics of recipient organism or parental organisms related to biosafety;

g) Centers of origin and centers of genetic diversity, if known, of the recipient organism and/or the parental organisms and a description of the habitats where the organisms may persist or proliferate;

h) Taxonomic status, common name, point of collection or acquisition, and characteristics of the donor organism(s) related to biosafety;

i) Approved uses of the GMO;

j) A risk assessment report consistent with the Annex III of the Cartagena Protocol on Biosafety; and

k) Suggested methods for the safe handling, storage, transport and use, including packaging, handling, labeling, documentation, disposal and contingency procedures, where appropriate.

ANNEX V: ADDITIONAL INFORMATION REQUIRED IN THE CASE OF PLACING GMOs ON THE MARKET

A. The following information should be provided in the notification for placing on the market products, in addition to that of Annex III:

(1) Name of the product and name(s) of GMO(s) contained therein
(2) Name of the manufacturer or distributor and has address, including address in the country
(3) Specificity of the product, exact conditions of use including, when appropriate, the type of environment and/or the geographical area(s) of the country for which the product is suited
(4) Type of expected use; industry, agriculture and skilled trades, consumer use by public at large.

B. The following additional information should be provided when required/relevant

(1) Measures to take in case of unintended release or misuse
(2) Specific instructions or recommendations for storage and handling
(3) Estimated production in and/or imports to the country
(4) Proposed packaging. This must be appropriate so as to avoid unintended release of the GMO(s) during storage, or at a later stage
(5) Proposed labeling. This must include, at least in summarized form, the information referred to in points A(1), A(2), A(3), B(1) and B(2).

C. The following information concerning labeling of products thereof should be provided on a label and/or in accompanying documents

(1) The words "This product contains GMO(s)" whenever there is evidence of the presence of GMO(s) in the product
(2) The words "This product may contain GMO(s)" where the presence of GMO(s) in a product cannot be excluded but there is no evidence of any presence of GMO(s)
(3) The words "This product may cause… (speify the particular reactions, allergies or other side-effects)" where it is known that a particular reaction, allergy or other side-effect may be caused by the product
(4) Where applicable, further or as a qualification to C.1 or C.2, the words "This product contains genetic material (nucleic acids) from GMO(s)" or "This product is based on raw materials from GMO(s)"

ANNEX VI: RISK ASSESSMENT PARAMETERS

The user should carry out an assessment prior to the use or release of GMOs or products thereof as regards the risks to human and animal health, biological diversity, the environment and the socio-economic welfare of societies,. This assessment should take the following parameters into consideration including any other parameter deemed to be relevant:

A. Characteristics of donor and recipient organisms or parental organisms:

(1) Scientific name and taxonomy;
(2) Strain, cultivar or other name;
(3) Species it is related to and degree of relatedness;
(4) The degree of relatedness between the donor and recipient organisms, or between the parental organisms;
(5) All sites from where the donor and recipient organisms or parental organisms were collected, if known;
(6) Information on the type of reproduction (sexual/asexual) and the length of reproductive cycle or generation time, as appropriate, as well as the formation of resting and survival stages;
(7) History of prior genetic manipulation, whether the donor or recipient organisms are already genetically modified;
(8) Phenotypic and genetic markers of interest;
(9) Description of identification and detection techniques for the organisms, and the sensitivities of these techniques;
(10) Geographic distribution and natural habitats of the organisms including information on natural predators, prey, parasites, competitors, symbionts and hosts;
(11) Climatic characteristics of original habitats;
(12) Ability of the organisms to survive and colonize the environment to which release in intended or otherwise;
(13) Genetic stability of the organisms, and factors affecting the stability;
(14) The presence of endogenous mobile genetic elements of viruses likely to affect the genetic stability;
(15) The potential of the organisms to transfer or exchange genes with other organisms, either vertically or horizontally;
(16) Pathogenicity to humans or animals, if any;
(17) If pathogenic, their virulence, infectivity, toxicity and modes of transmission;
(18) Known allogenicity and/or toxicity of biochemical and metabolic products;
(19) Availability of appropriate therapies for pathogenicity, allergenicity and tocixity.

B. Characteristics of the vector(s)

(1) Nature and source of the vector(s)
(2) Genetic map of the vector(s), position of the gene(s) inserted for the transfer, other coding and non-coding sequences affecting the expression of introduced gene(s), and marker gene(s);
(3) Ability of the vector(s) to mobilize and transfer genes by integration and methods for determining the presence of the vecto(s);
(4) History prior genetic manipulation, whether the donor or recipient organisms are already genetically modified;
(5) Potential for pathogenicity and virulence;

(6) Natural and host range of vectors;
(7) Natural habitat and geographic distribution of natural and potential hosts;
(8) Potential impacts on human and animal health and the environment;
(9) Measures for counteracting adverse impacts;
(10) Potential to survive and multiply in the environment, or to form genetic recombinants;
(11) Genetic stability of vectors, such as hypermutability.

C. Characteristics of genetically modified organism:

(1) The description of the modifications made using gene technology;
(2) The function of the genetic modifications and/or the new insert, including any marker gene(s);
(3) Purpose of the modification and intended use in relation to need or benefit;
(4) Method of modification and in case of transgenic organisms, the methods for constructing inserts and to introduce them into the recipient organism;
(5) Whether introduced gene(s) integrated or extra chromosomal;
(6) Number of insert(s), positions in the host genome, and its/their structure(s), for example, the copy number whether in tandem or other types of repeats;
(7) Product(s) of the transferred gene(s), levels of expression and methods for measuring expression;
(8) Stability of the introduced gene(s) in terms of expression(s), structure(s) and site(s) of integration;
(9) Biochemical and metabolic differences of genetically modified organism compared with the unmodified organism;
(10) Probability of vertical or horizontal gene transfer to other species;
(11) Probability of inserts or transferred gene(s) to generate pathogenic recombinants with endogenous viruses, plasmids and bacteria;
(12) Allergenicities, toxicities, pathogenicities and unintended effects;
(13) Autecology of the genetically modified organism compared with that of the unmodified organism;
(14) Susceptibility of the genetically modified organism to diseases and pests compared with the unmodified organism;
(15) Detailed information on past uses including results on all experiments leading to previous releases;

D. Characteristics of resuscitated organism(s) and gene(s) and fossil DNA sequences

D.1 Resuscitated organism

(1) Scientific name and taxonomy;
(2) Identity of nearest species and their characteristics which are of relevance to the intended use;
(3) Site at which it was found;
(4) Method used for resuscitation;
(5) Purpose of introducing the organism and benefits, if any;
(6) Impacts on human and animal health and the environment;
(7) Measures for counteracting adverse impacts;
(8) Length of time the organism has been in use;

(9) Genetic stability;
(10) Likelihood of gene transfer to other organisms;
(11) Fossil and living nearest relative species;
(12) Biological and biochemical differences form related living species;
(13) Information on previous uses since resuscitation.

D.2 DNA sequences form fossils or from resuscitated organism

(1) Scientific name and taxonomy of the species whether resuscitated or a fossil;
(2) Site of origin of the fossil;
(3) Site of the gene in the resuscitated genome, if known;
(4) Base sequence of the extracted gene;
(5) Method used in extracting the gene
(6) Function of gene, if known;
(7) Purpose of use and benefits, if any;
(8) Environment in which it lived before fossilization;
(9) Fossil species related to the species from which the gene was taken;
(10) Living species related to the species from which the gene was taken

E. Safety considerations for human and animal health

Information on the genetically modified organism and when it is genetically engineered, information on the donor and recipient organisms as well as the vector before it was disarmed or disabled in cases where it has been disarmed or disabled regarding;

(1) Capacity for colonization;
(2) If the genetically modified organism is pathogenic to humans or animals the following information is required:
    (a) diseases caused and mechanism of pathogenicity, including invasiveness and virulence, and property of virulence;
    (b) communicability;
    (c) infective dose;
    (d) host range and possibilities of alteration;
    (e) ability to survive outside of the human or animal host;
    (f) the existence of vectors or other means of transmission;
    (g) biological stability;
    (h) allergenicity;
    (i) availability of appropriate therapies.

F. Environmental considerations

Information on the genetically modified organism, and when it is genetically engineered, information on the donor and recipient organizations as well as the vector before it was disarmed or disabled in cases where it has been disarmed or disabled, regarding:

(1) Factors affecting the survival, reproduction and spread of the genetically modified organism in the environment;
(2) Available techniques for detection, identification and monitoring of the GMOs;

(3) Available techniques for detecting transmission of genes from the genetically modified organism to other organisms;
(4) Known and predicted habitats of the genetically modified organism;
(5) Description of the ecosystems which could be affected by accidental release of the genetically modified organism;
(6) Possible interactions between the genetically modified organism and other organisms in the ecosystem which might be affected by accidental release;
(7) Known or predicted effects on plants and animals such as pathogenicity, infectivity, toxicity, virulence, being a vector or pathogens, allergenicity, and colonization;
(8) Possible involvement in biogeochemical processes;
(9) Availability of methods for decontamination of the area in case of accidental releases;
(10) Effects on agricultural practices with possible undesirable impacts on the environment.

G. Socio-economic considerations

In parallel to and simultaneous with the scientific risk assessment, an evaluation of the socio-economic risks should be undertaken by relevant Ministries in consideration of the following, but not limited to:

(1) Anticipated changes in the existing social and economic patterns resulting from the introduction of the genetically modified organism or product thereof;
(2) Possible threats to biological diversity, traditional crops or other products and, in particular, farmers' varieties and sustainable agriculture;
(3) Impacts likely to be posed by the possibility of substituting traditional crops, products and indigenous technologies through modern biotechnology outside of their agro-climatic zones;
(4) Anticipated social and economic costs due to loss of genetic diversity, employment, market opportunities and, in general, means of livelihood of the communities likely to be affected by the introduction of the GMOs or products thereof;
(5) Possible countries and/or communities to be affected in terms of disruptions to their social and economic welfare;
(6) Possible effects which are contrary to the social, cultural, ethical and religious values of communities arising from the use or release of the genetically modified organism or the product thereof.

ANNEX VII: RISK MANAGEMENT SCHEMES

The user should employ the following risk management schemes and procedures from the development, through all stages of testing of the genetically modified organism or the product thereof, to its intended use or commercialisation.

(1) Imported products of GMOs used for human or animal health (e.g. antibodies, drugs and hormones):
    (a) observation to ensure that changes in food habits, nutrition and other factors that could conceivably modify the expected impacts are insignificant;
    (b) such observation can be limited in scope when it is shown that adequate trials on the specific products have been made on humans or animals, as appropriate, in areas other than the state of import.

(2) Imported microbial genetically modified organisms for human and animal health;

    Besides the limited observation specified in 1, experiments should be carried out to evaluate viability and risks of reacquiring virulence or lending virulence to other micro-organisms when in the body and in the environment, since some spilling is inevitable.

(3) Imported GMOs for contained use:
    (a) The products of GMOs will be treated as in 1 above;
    (b) Experiments will be made in complete laboratory containment to determine: (i) longevity of the genetically modified organism in cases of unintended release in the premises and in the surrounding environment, and (ii) genetic transfer into other micro-organisms and implications thereof on human and animal health and the environment; and
    (c) Methods of counteracting adverse impacts resulting from unintended releases should be specified.

(4) Products of genetically modified organism made locally:
    (a) Trial on experimental animals will be made when the product of the GMOs in intended to be used on humans;
    (b) In all other cases, trials will be made on species for which the product of the genetically modified organism has been designed.

(5) GMOs made locally for use as human or animal vaccines:
    (a) Initial molecular, tissue culture, serological and other related studies in the laboratory in complete containment;
    (b) Trials with experimental animals under strict containment;
    (c) Experiments in complete containment to evaluate the extent of transfer of the genes of the vector introduced or of other genes through the agency of the vector to the genetically modified organism or to other species which will be found in association with the genetically modified organism to ensure that virulence is not acquired by the genetically modified organism in question or by other micro-organisms;
    (d) Trials on animals completely contained from their species and from related species and species known to be susceptible to the gene recipient micro-organism from which the GMOs has been made;

(e) Statistically valid trials in conditions in which the vaccinated individuals live in their communities.

(6) Imported genetically modified plant or microbel for release:
   (a) The reports from releases in areas other than the state of import should be thoroughly evaluated by the National Biosafety Committee. Particular emphasis should be given to whether the applicable regulations in the previous release have been adequate to ensure safety;
   (b) If the regulations mentioned in (a) above have not been found adequate, the National Biosafety Committee will decide at which step in item 8 the observations should begin;
   (c) If it is decided that the previous release mechanisms have been rigorous enough, observations should be made in experimental conditions completely contained from the outside environment, but otherwise kept at the same soil community, moisture, air temperature and plant and animal community conditions as the intended area of release;
   (d) The observations will include the health of the genetically modified organism, the health of the organism within the area or limited release, and the biological diversity and the ecology the area;
   (e) Nationally approved limited field releases will be carried out with appropriate emergency procedures in place to deal with possible cases of escape.

(7) Imported genetically modified animal for release:
   (a) The reports from releases in areas other than the state of import should be thoroughly evaluated by the National Biosafety committee. Particular emphasis should be given to whether the applicable regulations in the previous release have been adequate to ensure safety;
   (b) If the regulations mentioned in (a) above have not been found adequate, the National Biosafety Committee will decide a which step in item 9 the observations should begin;
   (c) If it is decided that the regulations used in the previous release have been rigorous enough, then observations will be made in complete containment in the expected ambient climatic nutritional and other environmental conditions to monitor physiological functions, adaptations and gene transfers;
   (d) When the results have met the stated requirements, then a trial release may be authorized with adequate emergency plans put in place to deal with cases of escape.

(8) Genetically modified plant or microbes produced locally for eventual release;
   (a) Laboratoryr experiments on transformation of resuscitation and other phenomena will be carried out in complete containment;
   (b) Tissue culture experiments to develop the genetically modified organism, when required, will be carried out in complete containment;
   (c) Observations aimed at understanding the nature of the genetically modified organism should be carried out in complete containment;
   (d) Experiments with the soil, soil micro-organisms, plant and animals species, under the environmental conditions of the area of intended release, will be carried out in complete containment;
   (e) Complete observations of the interactions of the genetically modified organism with the environment (soil including micro-organisms and terrestrial

communities) will be made in enclosed fields but not fully contained. At the end of the experiment, the products of the genetically modified micro-organisms may be used on an experimental basis, otherwise they should be destroyed;

(f) The product form the genetically modified organism should be subjected to the procedure in 4;

(g) The monitoring of the spread and behaviour of any released plant or micro-organism genetically modified organism should continue for at least 150 years in the case of trees, and for at least 30 years in the case of annuals and micro-organisms, the duration for perennials which live shorter than trees being in between. The user who was responsible for releasing the GMOs or its successor should provide annual reports to the competent authority.

(9) Genetically modified animal produced locally for eventual release

(a) Laboratory bimolecular experiments on transformation for resuscitation if it is possible) and other phenomena will be carried out in complete containment;

(b) Methods of incubating the transformed generative cell or the resuscitated animal will be carried out in complete containment;

(c) The rearing of and observations on the genetically modified organism will be carried out under complete containment;

(d) The genetically modified organism should be observed under complete containment in an experimental environment which simulates the intended area of release in climatic, microbial, animal and plant communities. The observations should include the condition of the transgenic animal and those of its micro-organisms especially in the context of gene transfer and those of the microbial, plant and animal communities in the experiment, again including gene transfer:

(e) A limited release will be carried out in an area with appropriate enclosure and emergency measures put in place to prevent escape. Observations will include the condition of the genetically modified organism, its micro-organisms focusing on gene transfer, and the ecology of the microbial, plant and animal communities in the area, again including gene transfer;

(f) If the animal is intended to yield a product, the regulation of the production will follow the procedure in item 4;

(g) The monitoring of the spread and behaviour of any genetically modified animal will continue for at least 30 years.

(10) General Requirements

(a) All trials, experiments or observations specified in all the above cases (1-9) are put in their logical sequence and should be subjected to the hierarchical procedures of approval by the lower institutional and the higher national level bodies, namely the Institutional Biosafety Committees or the National Biosafety Scientific Advisory Sub-Committee and the National Biosafety Committee;

(b) Experiments starting form transformation of living organisms or resuscitation of fossil organisms carried out under completely contained laboratory conditions laboratory conditions and continuing in the development of GMOs or products thereof should be subject to approval by the Institutional Biosafety Committee or by national Biosafety Committee as the case may be. All experiments outside of strict laboratory isolation and initial experiments involving imported GMOs or products thereof should be subject to approval by the National

Biosafety Committee. All final approval for the use of GMOs or products thereof should be made by the National Biosafety Committee;

(c) Once approval from the National Biosafety Committee is obtained at the completion of the final stage of the trials, experiments or observations, the genetically modified organism in question or the product thereof can be employed for its intended use. The National Biosafety Committee should notify its decision in writing to the competent authority

ANNEX VIII: GROUPS OF ORGANISMS THAT ARE OR CONTAIN ANIMAL, HUMAN, OR PLANT DISEASES

The lowest unit of classification actually listed is the taxon or group that may contain organisms that are regulated. Organisms belonging to all lower taxa contained within the group listed are included as organisms that may be or may contain animal, human, or plant diseases.

The following partial list may be expanded when new information is available.

GROUP

Virus
All members of groups containing plant viruses, and all other plant and insect viruses

Viroids
Superkingdom Prokaryote
Coryneform group
Genus Arthrobacter Genus Corynebacterium
Kingdom Monera
Division Bacteria
Family Pseudomonadaceae
Genus Pseudomonas
Genus Xanthomonas
Family Rhizobiaceae
Genus Rhizobium
Genus Bradyrhizobium
Genus Agrobacterium
Genus Phyllobacterium
Family Enterobacteriaceae
Genus Erwinia
Family Streptomycetaceae
Genus Streptomyces
Family Actinomycetaceae
Genus Actinomyces
Coryneform group
Genus Clavibacter
Genus Arthrobacter
Genus Curtabacterium
Genus Coiynebacterium
Gram-negative phloem-limited bacteria associated with plant diseases
Gram-negative xylem-limited bacteria associated with plant diseases
And all other bacteria associated with plant or insect diseases
Rickettsiaceae
Rickettsial-like organisms associated with insect diseases
Class Mollicutes
Order Mycoplasmatales
Family Spiroplasmataceae
Genus Spiroplasma

Mycoplasma-like organisms associated with plant diseases
Mycoplasma-like organisms associated with insect diseases
Superkingdom Eukatyote
Kingdom Mycota
Class Plasmodiophoromycetes
Division Mastigomycota
Class Chytridiomycetes
Order Chytridiales
Class Oomycetes
Order Lagenidiales
Family Lagenidiaceae
Family Olpidiopsidaceae
Order Peronosporales
Family Albuginaceae
Family Peronosporaceae
Family Pythiaceae
Order Saprolegniales
Family Saprolegniaceae
Family Leptolegniellaceae
Class Zygomycetes
Order Mucorales
Family Choanephoraceae
Family Mucoraceae
Class Ascomycetes
Subclass Hemiascomycetidae
Order Protomycetales
Family Taphrinales
Subclass Loculoascomycetidae
Order Myriangiales
Family Elsinoeaceae
Family Myriangiaceae
Order Asterinales
Order Dothideales
Order Chaetothyriales
Order Hysteriales
Family Parmulariaceae
Family Phillipsiellaceae
Family Hysteriaceae
Order Pleosporales
Order Melanommatales
Subclass Plectomycetidae
Order Eurotiales
Family Ophiostomataceae
Subclass Hymenoascomycetidae
Pyrenomycetes
Order Erysiphales
Order Meliolales
Subclass Hymenoascomycetidae
Pyrenomycetes

Order Xylariales
Order Diaporthales
Order Clavicipitales
Subclass Hymenoascomycetidae IV
Discomycetes
Class Discomycetes
Order Phacidiales
Order Helotiales
Family Ascocorticlceae
Family Hemiphacidiaceae
Family Dermateaceae
Family Sclerotiniaceae
Order Cyttarriales
Order Medeolariales
Order Pezizales
Family Sarcosomataceae
Family Sarcoscyphaceae
Class Basidiomycetes
Subclass Teliomycetidae
Subclass Phragmobasidiomycetidae
Family Auriculariaceae
Family Ceratobasidiaceae
Subclass Holobasidiomycetidae
Hymenomycetes
Order Exobasidiales
Order Agaricales
Family Corticiaceae
Family Hymenochaetaceae
Family Echinodantiaceae
Family Fistulinaceae
Family Clavariaceae
Family Polyporaceae
Family Tricholomataceae
Class Hyphomycetes
Class Coelomycetes
And all other fungi associated with plant or insect diseases
Sub-kingdom Embryobionta

Division Magnoliophyla
Family Balanophoraceae - parasitic species
Family Cuscutaceae - parasitic species
Family Hydnoraceae - parasitic species
Family Krameriaceae - parasitic species
Family Lauraceae - parasitic species
Genus Cassytha
Family Lennoaceae - parasitic species
Family Loranthaceae - parasitic species
Family Myzodendraceae - parasitic species
Family Olacaceae - parasitic species

Family Orobanchaceae - parasitic species
Family Rafflesiaceae - parasitic species
Family Santalaceae - parasitic species
Family Scrophulariaceae - parasitic species
- Genus Alectra
- Genus Bartsia
- Genus Buchnera
- Genus Buttonia
- Genus Castilleja
- Genus Centranthera
- Genus Cordylanthus
- Genus Dasistoma
- Genus Euphrasia
- Genus Gerardia
- Genus Harveys
- Genus Hyobanche
- Genus Lathraea
- Genus Melampyrum
- Genus Melasma
- Genus Orthants
- Genus Orthocarpus
- Genus Pedicularis
- Genus Rhamphicarpa
- Genus Rhinanthus
- Genus Schwalbea
- Genus Seymeria
- Genus Siphonostegia
- Genus Scpubia
- Genus Striga
- Genus Tozzia

Family Viscaceae - parasitic species
Kingdom Protista
Phylum Sarcomastigophora
Subphylum Masfigophora
Class Zoomastigophora
Subphylum Sarcodina
Superclass Rhizopoda
Phylum Apicomplexa
Phylum Microspore
Genus Phytomonas
And all Protozoa associated with insect diseases
Kingdom Animalia
Phylum Nematoda
Class Secementea
Order Tylenchida
Family Anguinidae
Family Be!onolaimidae
Family Caloosiidae
Family Criconematidae

Family Dolichodoridae
Family Fergusobiidae
Family Hemicycliophoridae
Family Heteroderidae
Family Hoplolaimidae
Family Meloidogynidae
Family Nacobbidae
Family Neotylenchidae
Family Nothotylenchidae
Family Paratylenchidae
Family Pratylenchidae
Family Tylenchidae
Family Tylenchulidae
Order Aphelenchida
Family Aphelenchoidlciie
Class Adenophorea
Order Dorylaimida
Family Longidoridae
Famlly Trichodoridae
Phylum Mollusca
Class Gastropoda
Sub-class Pulmonata
Order Basommatophora
Superfamily Planorbacea
Order Stylommatophora
Sub-family Strophacheilacea
Family Succiineidae
Sub-family Strophacheilacea
Family Achatinacea
Superfamily Arionacea
Super family Limacacea
Order Systellommatophora
Superfamily Veronicellacea
Phylum Arthropoda
Class Arachnida
Order Parasitiformes
Sub-order Mesostigmata
Superfamily Ascoidea
Superfamily Dermanyssoidea
Order Acariformes
Sub-order Prostigmata
Superfamily Eriophyoidea
Superfamily Tetranychaidea
Superfamily Eupodoidea
Superfamily Tydeoidea
Superfamily Erythraenoidea
Superfamily Trombidioidea
Superfamily Hydryphantoidea
Superfamily Pyemotoidea

Sub-orderAstigmata
Superfamily Arcoptoidea
Superfamily Acaroidea
Class Diplopoda
Order Polydesmida
Class Insects
Order Collembola
Family Sminthoridae
Order Isoptera
Order Thysanoptera
Order Orthopthera
Family Acrididae
Family Gryllidae
Family Gryllacrididae
Family Gryllotalpidae
Family Phasmatidae
Family Ronaleidae
Family Tettigoniidae
Family Tetrigidae
Order Hemiptera
Family Thaumastocoridae
Family Aradidae
Superfamily Piesmatoidea
Superfamily Lygaeoidea
Superfamily Idiostoloides
Superfamily Coreoidea
Superfamily Pentatamoidea
Superfamily Pyrrhocoroidea
Superfamily Tingoidea
Superfamily Miroidea
Order Homoptera
Order Coleoptera
Family Anobiidae
Family Apionidae
Family Anthribidae
Family Bostrichidae
Family Brentidae
Family Brunchidae
Family Buprestidae
Family Byturidae
Family Cantharidae
Family Carabidae
Family Cerambycidae
Family Chrysomelidae
Family Coccinellidae
Sub-family Epilachninae
Family Curculionidae
Family Dermestidae
Family Elateridae

Genus Helophorus
Family Lyctidae
Family Meloidae
Family Mordellidae
Family Platypodidae
Family Scarabaeidae
Sub-family Melolonthinae
Sub-family Rutelinae
Sub-family Cetoniinae
Sub-family Dynastinae
Family Scolytidae
Family Selhytidae
Family Tenebrionidae
Order Lepidoptera
Order Diptera
Family Agromyzidae
Family Anthomyiidae
Family Cecidomyiidae
Family Chloropidae
Family Ephydridae
Family Lonchaeidae
Family Muscidae
Genus Atherigona
Family Otitidae
Genus Euxeta
Family Syrphidae
Family Tephritidae
Family Tipulidae
Order Hymenoptera
Family Apidae
Family Caphidae
Family Chalcidae
Family Cynipidae
Family Eurytomidae
Family Formicidae
Family Psilidae
Family Siricidae
Family Tenthredinidae
Family Torymidae
Family Xylocopidae

Unclassified organisms and/or organisms whose classification is unknown.

ANNEX IX: CLASSIFICATION OF MICROORGANISMS ON THE BASIS OF HAZARD

Classification of Etiologic Agents

Class I Agents

All bacterial, parasitic, fungal, viral, rickettsial, and chlamydial agents not included in higher classes.

Class 2 Agents:

Bacterial Agents

Acinetobacter calcoaceticus Actinobacillus - all species
Aeromonas hydrophila Arizona hinshawii - all serotypes
Bacillus anthracis Bordetella - all species Borrelia
recurrentis, B. vincenti Campylobacter fetus
Campylobacterjejuni Chlamydia trachomatis Clostridium
botulinum
Cl. chauvoei, Cl. haemolyticum,
Cl. histolyticum, Cl. novyi,
Cl. septicum, Cl. tetani
Corynebacterium diphtheriae
C. equi, C. haemolyticum
C. pseudotuberculosis
C. pyogenes, C. renale
Edwardsiella tarda
Eiysipelothrix insidiosa
Escherichia coli - a,fl enteropathogenic, enterotoxigenic,
and enteroinvasive
Strains bearing Kl antigen
Haemophilus ducreyi, H. influenzas
Legionella pneumophila
Leptospira interrogans - all serotypes
Klebsiella - all species and all serotypes
Listeria - all specl. es
Moraxella - all species
Mycobacterium - all species except those listed in Class 3
Mycoplasma - all species except
Mycoplasma mycoides and Mycoplasma agalactiae, which are in Class 5
Neisseria gonorrhoeae, N. meningitidis
Pasteurella - all species except those listed in Class 3
Salmonella - all species and all serotypes
Shigella - all species and all serotypes
Sphaerophorus necrophorus
Staphylococcus aureus
Streptobacillus moniliformis
Streptococcus pneut-rioniae
Streptococcus pyogenes

Treponema carateum, T. pallidum, and T. pertenue
Vibrio choleras
Vibrio parahemolyticus
Yersinia enterocolitica

Fungal Agents

Actinomycetes (including Nocardia species,
Actinomyces species, and Arcichnia propionica)
Blastomyces dermatitidis
Cryptococcus neoformans
Paracoccidioides braziliensis

Parasitic Agents

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

Viral, Rickettsial, and Chiamydial 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 Class 4
Corona viruses
Influenza viruses - all types except AIPRB134, which is in Class 1
Langat virus
Lymphogranuloma venereum agent Measles virus
Mumps virus
Parainfluenza virus - all types except Parainfluenza virus 3, SF4 strain, which is in Class 1
Polioviruses - all types, wild and attenuated Poxviruses - all types except Alastrim, Smallpox, and Whitepox which are Class 5, and Monkey pox which depending on experiments, is in Class 3 or Class 4 Rabis virus - all strains except Rabies street virus which should be classified in Class 3
Reoverus - 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 Class 4
Sindbis virus
Tensaw virus
Turlock virus

Vacclnia virus
Varicella virus
Vesicular stomatitis virus
Vole rickettsia
Yellow fever virus, 170 vaccine strain

Class 3 Agents

Bacterial agents

Bartonella - all species
Brucella - all species
Francisella tularensis
Mycobacterium avium, M. bovis, M. tuberculosis
Pasteurella multocide type B ("buffalo" and other foreign virulent strains)
Pseudomonas mallei
Pseudomonas pseudomallei Yersinia pestis

Fungal Agents

Coccidioldes immitis
Histoplasma capsulatum
Histoplasma capsulatum var. duboisii

Parasitic Agents

None

Viral, Rickettsial, and Chiamydial Agents

Monkey pox when used in vitro
Arboviruses - all strains except those in Class 2 and 4
Dengue virus, when used for transmission or animal inoculation experiments
Lymphocytic choriameningitis virus (LCM)
Rickettsia - all species except Vole rickettsia when used for transmission or animal inoculation experiments
Yellow fever virus - wild when used in vitro

Class 4 Agents

Bacterial Agents

None

Fungal Agents

None

Parasitic Agents

None

Viral, Rickettsial, and Chlamydial Agents

Ebola fever virus
Monkey pox when used for transmission or animal inoculation experiments
Hemorrhaoic 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-home encephalitis virus complex including Russian spring summer encephalitis, Kyasanur forest disease.
Omak hemorrhagic 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.

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

2.1 Low-Risk Oncogenic Viruses

Rous sarcoma
SV-10
CELO
Ad2-SV40
Polyoma
Bovine papilloma
Rat mammary tumor
Avian leukosis
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

2.2 Moderate-Risk Oncogenic Viruses

Ad2-SV40
FeLV
HV Saimiri
EBV
SSV-i
GaLV
HV ateles
Yaba
FeSV

3. Class 5 Agents

3.1 Animal disease organism whose entry into the Tanzania is forbidden by law

Foot-and-mouth disease virus

3.2 Animal disease organisms and vectors whose entry into the Tanzania is forbidden

African horse sickness virus
African swine fever virus
Besnoitia besnoiti
Boma disease virus
Bovine infectious petechial fever

Camel pox virus
Ephemeral fever virus
Fowl plague virus
Goat pox virus Hog cholera virus Looping ill virus Lumpy skin disease virus Nairobi sheep diseases virus
Newcastle disease virus (Asiatic strains)
Mycoplasma mycoides (contagious bovine pleuropneumonia)
Mycoplasma agalactiae (contagious agalactia of sheep)
Rickettsia ruminatium (heart water)
Rift valley fever virus Rinderpest virus Sheep pax virus
Swine vesicular disease virus Teschen disease virus
Trypanosoma vivax (Nagana)
Trypanosoma evansi Theileria parva (East Coast fever)
Theileria annulata Theiteria lawrencei Theileria bovis
Theileria hirci Vesicular axanthema virus Wesselsbron disease virus Zyonema

3.3 Organisms that may not be studied in Tanzania except at specified facilities

Smallpox virus
Alastrim
White pox virus

The NBFP, in consultation with regulatory bodies reserve the right to alter categorization of any of these organisms based on:

1. The pathogenicity of the agent.
2. Modes of transmission and host range of the agent.
3. Whether the micro-organism is widely prevalent and/or incidence is significant in Tanzania and;
4. Availability of effective preventive or curative treatment.
5. New knowledge
6. Any other relevant considerations.

ANNEX X: INFORMATION REQUIRED IN NOTIFICATIONS

(a) Name, address and contact details of the exporter.

(b) Name, address and contact details of the importer.

(c) Name and identity of the living modified organism, as well as the domestic classification, if any, of the biosafety level of the living modified organism in the State of export.

(d) Intended date or dates of the transboundary movement, if known.

(e) Taxonomic status, common name, point of collection or acquisition, and characteristics of recipient organism or parental organisms related to biosafety.

(f) Centres of origin and centres of genetic diversity, if known, of the recipient organism and/or the parental organisms and a description of the habitats where the organisms may persist or proliferate.

(g) Taxonomic status, common name, point of collection or acquisition, and characteristics of the donor organism or organisms related to biosafety.

(h) Description of the nucleic acid or the modification introduced, the technique used, and the resulting characteristics of the living modified organism.

(i) Intended use of the living modified organism or products thereof, namely, processed materials that are of living modified organism origin, containing detectable novel combinations of replicable genetic material obtained through the use of modern biotechnology.

(j) Quantity or volume of the living modified organism to be transferred.

(k) A previous and existing risk assessment report consistent with Annex III.

(l) Suggested methods for the safe handling, storage, transport and use, including packaging, labelling, documentation, disposal and contingency procedures, where appropriate.

(m) Regulatory status of the living modified organism within the State of export (for example, whether it is prohibited in the State of export, whether there are other restrictions, or whether it has been approved for general release) and, if the living modified organism is banned in the State of export, the reason or reasons for the ban.

(n) Result and purpose of any notification by the exporter to other States regarding the living modified organism to be transferred.

(o) A declaration that the above-mentioned information is factually correct..