

NIGERIA BIOSAFETY GUIDELINES

1. INTRODUCTION

It is generally accepted that biotechnology both traditional and modern could contribute substantially to sustainable development by improvements in the fields of agriculture, food and feed production and supply, industry, health care (human and animal) and environmental protection. Traditional biotechnology has been in use for centuries notably in the brewing and fermentation industries and in the production of animal vaccines. Modern biotechnology, however, includes, among other technologies, cell and tissue culture, monoclonal antibodies, and recombinant DNA (rDNA) or “genetic engineering” techniques. The increased precision and shorter time required in producing results with modern biotechnology make these new techniques particularly attractive.

The development of new techniques of genetic modification in the early 1970’s introduced a new dimension to biotechnology. Scientists can now recombine DNA from different organisms, giving rise to Living Modified Organisms (LMOs)/Genetically Modified Organisms (GMOs). Recombinant DNA (rDNA) organisms are derived by introducing a section of DNA from a “donor” organism to a “recipient” organism. The genome of the recipient organism is, therefore, modified. While recognising the potential benefits of this new molecular technique which allows a greater diversity of genes to be introduced into organisms, the relative lack of familiarity with such modified organisms and the gaps in knowledge as regards the effect of the interaction of these LMOs with the environment, make it necessary to institute measures to ensure that the technology is developed in a precautionary and judicious manner. The results of this modification need to be assessed for risks to human health, conservation of biodiversity and the environment before the intentional release of the modified organism.

In recognition of the tremendous benefits of modern biotechnology and the risks inherent thereto, the guidelines contained in this document seek to provide appropriate regulatory measures to assist all stakeholders in the establishment and maintenance of national and institutional capacities to provide for safety in biotechnology, development of expert human resources and efficient exchange of information.

2. BACKGROUND

Nigeria in 1992 together with about 168 countries adopted Agenda 21 and the Convention on Biological Diversity (CBD) at the United Nations Conference on Environment and Development (UNCED) held in Rio de Janeiro, Brazil. Both Agenda 21 and the CBD while recognising that biotechnology is essential for the attainment of conservation and sustainable use of biological diversity, particularly by improvements in agriculture, food and feed production and supply, health care and environmental protection, cautioned that its development and application be pursued judiciously.

In particular, the CBD in Article 8(g) encourages Parties to the Convention to “establish or maintain means to regulate, manage or control the risks associated with the use and release of living modified organisms (LMOs) resulting from biotechnology which are likely to have adverse environmental impacts that could affect the conservation and sustainable use of biological diversity taking also into account risks to human health”.

Article 19(3) of the CBD calls upon “Parties to consider the need for and the modalities of a protocol setting out appropriate procedures, including in particular, advance informed agreement for the safe transfer, handling and use of any LMOs resulting from biotechnology that may have adverse effect on the conservation and sustainable use of biological diversity”. “Article 19(4) makes it obligatory for Parties to directly or indirectly provide available information about the use and safety regulations required by these Parties in handling such organisms as well as any available information on the potential adverse impact of the specific organism to the receiving Party”.

To facilitate the implementation of the aforementioned objectives, Nigeria participated in the negotiation and drafting of the Cartagena Protocol on Biosafety with specific focus on transboundary movement of any LMOs/GMOs resulting from modern biotechnology that may have adverse effects on the conservation and use of biodiversity and the adoption of appropriate procedure for Advance Informed Agreement (A. I. A). Nigeria signed the Cartagena Protocol in May 2000 during the 5th Conference of Parties in Nairobi, Kenya.

In order to fulfil Nigeria’s commitments under the CBD and the Environmental Impact Assessment (EIA) Decree No. 86, 1992 and to achieve the goals expressed in the National Policy on Environment, a group of experts under the then Ministry of Agriculture and Natural Resources put together the **Guidelines on Biosafety for Nigeria** which was published in 1994.

Recognising the dynamic nature of the field of molecular biology research and techniques and the new developments thereof, it has become necessary to review and update the 1994 Guidelines.

3. OBJECTIVES AND GENERAL PRINCIPLES

Mindful of the precautionary principle embodied in Agenda 21, the CBD and the Cartagena Protocol on Biosafety, the revised Guidelines provide a general framework for safety in the research, development, release, transboundary movements, use and application of biotechnology products containing organisms with novel traits and is based on the principle that preventive action should be taken to preserve, protect and improve the environment and human health irrespective of whether or not such concerns are justified by available scientific data.

The Guidelines seek to facilitate the establishment and development of national capacities to assess and manage potential risks, associated with Biotechnology. These would be achieved by:

- (a) Development of regulations, standards, codes of practice, monitoring capacities and other instruments for research and development (R&D), and the risks associated with release of LMOs and GMOs into environment. The Guidelines address human and environmental safety of all types of applications of biotechnological products containing or consisting of organisms with novel traits including but not limited to LMOs/GMOs. The Guidelines further recognize and address the need for such products to comply with any specific product requirement such as food safety, efficacy and quality before their release into the environment.
- (b) Establishment and strengthening of national and institutional Biosafety mechanism.
- (c) Development and establishment of a comprehensive and up-to-date scientific database, infrastructure for information exchange upon which risk assessment and evaluation of products can be made and mechanisms for effecting advance informed agreements.
- (d) Provision of regulations and safety procedures for the research, manufacture, transportation and handling, accident prevention, release, containment, and waste

disposal and end-use of biotechnology products. The need to prevent accidents is even more imperative where released organisms could easily reproduce in the environment and spread into neighbouring countries.

- (e) Assessment and identification of priorities in human resources development and the implementation of national capacity building programmes for biosafety.
- (f) Establishment of adequate measures for developing and accelerating innovation for sustainable biotechnology processes.
- (g) Promotion and use of regular monitoring to verify the assumptions made in risk assessment and to evaluate whether the recommended risk management procedures are appropriate and effective.
- (h) Promotion of public awareness on Biosafety through initiatives involving the community, policy makers, legislators, administrators, the private sector and the industry.

4. SCOPE AND METHODOLOGY

These guidelines shall cover the following:

- (a) Safety in Genetic transformation of micro-organisms, plants and animals
- (b) Safety in rDNA technology in vaccine and pharmaceutical products development.
- (c) Large -scale production and deliberate or accidental release of LMOs/GMOs and products derived therefrom.
- (d) Appropriate measures to avoid adverse effects on human health, biodiversity and the environment, which might arise from the deliberate or accidental release of LMOs/GMOs.
- (e) Export, importation and use of LMOs/GMOs and other biotechnology products.
- (f) Liability and redress in the use, handling, transportation of LMOs/GMOs.

The Guidelines shall deal essentially with:

Notification and Authorization - covering procedures for the Advance Informed Agreement, Acknowledgement, Decision-making and Review of decisions.

Risk Assessment - involves the identification of possible hazards and the projection or estimation of the combined consequences of the hazard and the likelihood of the actual occurrence of such hazard.

Risk Management - guided by the result of the risk assessment, it involves the application of adequate management strategies, procedures and methods to minimise the risks and their consequences or complete cancellation of the project.

Capacity Building - essentially entails human resource development, adequate funding, provision and maintenance of appropriate infrastructure to implement the recommendations contained in the Guidelines.

5. NOTIFICATION

(a) Applications for the movement of LMOs/GMOs into Nigeria shall be based on the Advance Informed Agreement. For the purpose of compliance with the provisions of the Guidelines, notification shall cover import, export, research and development activities. For import, notification should be prior to the first intentional transboundary movement for all that fall within the scope of the Guidelines and should address the relevant information contained in the Annex I.

(b) Notification should be sent to Nigeria's Focal Point (Federal Ministry of Environment) using the appropriate form. The Party of export shall ensure that legal requirements for the accuracy of information provided by the exporter are met.

6. ACKNOWLEDGEMENT OF NOTIFICATION

(a) Acknowledgement of notification shall be made in accordance with the details as may be set out from time to time by the National Biosafety Committee which is Competent National Authority, through the National Focal Point.

(b) Failure by the Focal Point to acknowledge receipt of notification shall not imply its consent to an intentional release or transboundary movement of LMOs/GMOs.

7. DECISION MAKING PROCEDURES

(a) The decision-making procedures shall take into consideration risk assessment, which involves scientific, socio-economic, cultural and ethical concerns. The decision to permit

research and development in rDNA, import and release of LMOs/GMOs for whatever purpose shall be on a case by case basis.

(b) Lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects of an LMO/GMO on the conservation and sustainable use of biological diversity and risk to human health shall not prevent the relevant authorities from taking appropriate decision, with regard to the release or importation of the LMO/GMO.

(c) As part of the requirement for taking decisions, the applicant is obliged to provide accurate information on the LMO/GMO in question.

(d) The decision making procedure shall cover field trials, releases for domestic use as food or feed, or for processing, and placing in the market of an LMO/GMO including those that are subject to transboundary movement.

(e) A decision taken pursuant to this Guidelines by the relevant authorities shall not render it liable for any adverse impact directly or indirectly resulting from the use of the LMOs/GMOs and does not exclude the applicant from the requirements of other applicable regulatory instruments.

(f) Approval to import, export or carry out releases shall be given by the Minister of Environment in consultation with other Ministries based on advice from the National Competent Authority.

8. REVIEW OF DECISIONS

(a) A decision may be reviewed by the appropriate authority dealing with LMO/GMO based on new information on adverse effects on conservation and sustainable use of biological diversity, also taking into consideration the risks to human health.

(b) The National Focal Point shall take steps to inform applicants and the Biosafety Clearing House of the Convention on Biological Diversity as appropriate.

(c) An applicant, notifier, exporter may request for review of a decision taken by the appropriate agency under the following conditions:

- i) a change in a piece of relevant information or
- ii) other circumstance has become available.

9. TRANSIT

- (a) Any person who wishes to use a port in Nigeria for transit purposes in connection with the transboundary movement of LMOs/GMOs shall notify the National Focal Point accordingly in writing.
- (b) A written consent, stating the conditions under which transit is granted, must be obtained before the transit can take place.
- (c) Failure to acknowledge receipt of the request for transit should not be regarded as consent.

10. UNINTENTIONAL TRANSBOUNDARY RELEASE AND EMERGENCY

- (a) All cases of unintentional transboundary release of LMO/GMO must be reported immediately to the NFP.
- (b) Information accompanying such declaration should include, at a minimum:
 - i) quantities and details provided for in annex 1 of this guideline
 - ii) details of circumstances, estimated date of the release, and the use in the country of origin
 - iii) possible harmful effects on conservation and sustainable use of biodiversity, taking also into consideration risks to human health as well as risk management measures
 - iv) any other relevant information and points of contact for further information.

11. RISK ASSESSMENT

- (a) The risk assessment shall take the following into consideration:

the guiding principle of risk assessment is the precautionary approach. Where the transboundary movement, use or handling of GMO(s)/LMOs or products thereof may cause, or has a proven or theoretical potential to cause harm to biodiversity, ecosystems, human or animal health, the lack of full scientific certainty or consensus regarding the level of risk should not be interpreted as the lack of risk, or as acceptable risk.
- (b) The risk assessment should take into account, inter alia, all relevant scientific theory, evidence and experience, including previous risk assessments (see details in Annex 1). This enables the risk assessment to evolve in the light of new evidence and knowledge. For example, a GMO or product thereof previously considered acceptable may no longer be acceptable, and vice versa.

- (c) It should be accepted as a principle underlying the risk assessment that every transgenic line is different because of random insertion, even if they are made with the same vector system, the same gene constructs and the same variety, and that it has to be well characterised to be stable for at least five generations under a reasonable range of environmental conditions that it may encounter. If the risk assessment at first shows that the level of risk of the intended use is not acceptable, additional risk-management measures are to be taken and assessed until the risks have been minimised to an acceptable level. If the risk cannot be minimised in this way, it might be concluded that the intended operation should not proceed, or a risk/benefit analysis might be carried out to determine whether a higher level of risk is acceptable and whether the intended operation should proceed.
- (d) Risk assessment shall be carried out by person(s) approved by the NBC.
- (e) The cost of risk assessment and other administrative charges shall be borne by the applicant.

12. RISK MANAGEMENT

(a) Risk management is employed during the development and evaluation of an organism in a systematic fashion, for example from the laboratory, through stages of field testing, to commercialisation. The number and forms of these stages are not fixed, but depend on the outcome of risk assessment at the different stages.

(b) The type of risk management procedure to be adopted will depend on the Genetically Modified Organism/Living Modified Organism and the particular application. For contained use, the degree of containment achieved depends primarily on the type of physical barriers and the application of appropriate work procedures. In the case of controlled release, different types of barriers, such as biological, chemical, physical or temporal barriers can be used to minimise or limit the dissemination and impacts of organisms with novel traits and/or to provide genetic isolation as required. Different risk-management practices may be applied, depending on the scale of the proposed release and its duration.

Measures for Controlled Releases

Appropriate risk management measures for releases will vary considerably from case to case. They will be determined by the risk assessment, the organisms involved and the method of release. In addition to general precautions to control release, risk management measures often focus on the control of the dissemination of the released organisms and control of the gene flow from the released organisms (See Annex 1 section 3). The type of risk management measures to be employed should be commensurate with the risk identified.

13. HANDLING, PACKAGING AND IDENTIFICATION

(a). All LMOs/GMOs should be handled, packaged and transported under conditions of safety taking into consideration local and international requirements.

(b). All LMOs/GMOs and derivatives as well as products made from LMOs/GMOs irrespective of their use should be properly identified and labelled.

14 LIABILITY AND REDRESS

(a) Any person who carries out any activity in relation to LMOs/GMO(s) or products thereof shall be strictly liable for any harm, injury or loss caused directly or indirectly by such LMOs/GMO(s) or products thereof or any activity in relation to them. The harm, injury or loss includes personal injury, damage to property, financial loss and damage to the environment or to biological diversity.

(b) Liability shall attach to the applicant, the person responsible for the activity, which results in the damage, injury or loss, as well as to the provider, supplier or developer of the LMOs/GMO(s) or products thereof.

(c) Where liability under this section is incurred by a corporate body, any director, manager, secretary or similar officer of the corporate body shall be similarly liable unless he/she can show that he/she did everything in his/her power to prevent the import, deliberate release, placing on the market or contained use which caused the damage in question.

(d) If there is more than one person responsible for the damage, injury or loss, the liability shall be joint and several.

- (e) Where proceedings are brought against more than one person it shall not be a requirement for the person bringing the proceedings to identify the person who caused the damage in question, provided that he/she can prove that one or more of the persons so proceeded against could have caused the damage.
- (f) In the case of harm to the environment or to biological diversity, redress shall include the costs of reinstatement, rehabilitation or clean-up measures actually incurred or to be incurred and, where applicable, the costs of preventive measures and any loss or damage caused by the taking of the preventive measures; provided that the person responsible may be required to carry out the reinstatement or rehabilitation at its own cost and to the satisfaction of the competent authorities.
- (g) Liability shall also extend to harm or damage caused directly or indirectly by the LMOs/GMO(s) or products thereof to the economy, social or cultural practices, livelihoods, indigenous knowledge systems, or indigenous technologies. Such harm includes the following: disruption or damage to production systems, agricultural systems, reduction in yields, and damage to the economy of an area or community.
- (h) An applicant shall indemnify:
 - (i) Any other person who deliberately releases or markets LMOs/GMO(s) or products thereof; and
 - (ii) Any person who manufactures, processes or markets food, food ingredients or animal feed containing or derived from LMOs/GMO(s) against any civil liability where the LMOs/GMO(s) or products thereof in question was first imported, deliberately released, used in contained conditions, or placed on the market by the applicant.
 - (iii) Any person who fails to label seeds, food, a food ingredient or animal feed containing or derived from LMOs/GMO(s), against any civil liability.
- (i) The right to bring any action to redress the harm caused by the LMOs/GMO(s) or products thereof shall lapse only after a reasonable period from the date on which the affected person or community could reasonably be expected to have learned of the harm, taking due account of:

- (a) the time the harm may take to manifest itself; and
 - (b) the time that it may reasonably take to correlate the harm with the GMO(s) or products thereof, having regard to the situation or circumstance of the person or community affected.
- (j) Any person or group of persons may be entitled to bring a claim and seek relief in respect of the breach or threatened breach of any provision of this draft Guidelines, including any provision relating to damage to the environment and biological diversity:
- (i) in that person's or group of persons' interest;
 - (ii) in the interest of or on behalf of, a person who is, for practical reasons, unable to institute such proceedings;
 - (iii) in the interest of or on behalf of, a group or class of persons whose interests are affected;
 - (iv) in the public interest; and
 - (v) in the interest of protecting the environment or biological diversity.
- (k) No costs shall 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 the environment or biological diversity.
- (l) It shall not be a defence to any claim for compensation or damage that the activity had been consented to by the competent authorities.

15. PROTECTED DISCLOSURES

- (a) Notwithstanding the provisions of any other law, no person is civilly or criminally liable or may be dismissed, disciplined, prejudiced or harassed on account of having disclosed any information, if the person in good faith reasonably believed at the time of the disclosure that he/she was disclosing evidence of any risks posed by LMOs/GMO(s) or products thereof to human or animal health, the environment or biological diversity in accordance with section 11.b.
- (b) Section 16.a applies only if the person concerned
 - disclosed the information to:

- any authority which has the jurisdiction over matters pertaining to the protection of human or animal health, the environment or biological diversity;
 - any authority having powers of prosecution or enforcement; or
 - parliament including state legislatures or any committees thereof.
- (c) The person disclosing the information concerned to one or more news media and on clear and convincing grounds believes at the time of the disclosure:
- (i) it was necessary to avert an imminent and serious threat to human or animal health, the environment or biological diversity, to ensure that such a threat was properly and timely investigated, or to protect himself/herself against serious or irreparable harm from reprisals; or
 - (ii) giving due weight to the importance of open, accountable and participatory administration, that the public interest in disclosure of the information clearly outweighed any need for non-disclosure; or
 - (iii) The person disclosing information, which, before the time of the disclosure of the information, had become available to the public, whether in the country or elsewhere.
- (d) Section 16 (a) applies whether or not the person disclosing the information concerned has used or exhausted any other applicable external or internal procedure to report or otherwise remedy the matter concerned.
- (e) No person may induce any other person to exercise or refrain from exercising his/her right as aforesaid by giving or promising any advantage.
- (f) No person may threaten to take any action against any other person for exercising or intending to exercise his/her right as aforesaid.

16. INSTITUTIONAL ARRANGEMENTS

A. NATIONAL FOCAL POINT

There shall be one National Focal Point for Biosafety in Nigeria. The National Focal Point is the Federal Ministry of Environment and shall be responsible for liaison with the Secretariat

of the Convention on Biological Diversity for the administrative functions required under the Cartagena Protocol on Biosafety

National Focal Point shall be responsible for all correspondence with importers, exporters and applicants on movement of LMOs/GMOs.

B. COMPETENT NATIONAL AUTHORITY

A National Biosafety Committee (NBC) is instituted and shall serve as the Competent National Authority for Biosafety in Nigeria. National Biosafety Committee shall be responsible for the safe management of biotechnology activities, including research, development, introduction and the use of LMOs/GMOs.

Subcommittees shall be established by the NBC for sectoral interests such as agriculture, health, industry and environment.

(i) Membership

Membership of NBC should comprise the following:

(ii) Relevant Ministries/Agencies	<i>Number</i>
Federal Ministry of Environment	(1)
Federal Ministry of Agriculture	(1)
Federal Ministry of Science & Tech.	(1)
Federal Ministry of Industry	(1)
Federal Ministry of Health (NAFDAC)	(1)
Federal Ministry of Justice	(1)
Federal Ministry of Commerce	(1)
Federal Ministry of Foreign Affairs	(1)
Nigerian Customs Service	(1)
NACCIMA/Organised private sector	(1)
Biologist	(1)
Physical scientist	(1)
Social scientist	(1)

A representative of NGOs distinguished in environmental matters and

biodiversity conservation

(1)

The Federal Ministry of Environment will provide the secretariat and the chairman shall be appointed from among the members.

(iii) Appointment

Relevant Ministries shall appoint their representatives.

(iv) Tenure

Non-civil servant members of the NBC shall be appointed by the Minister of Environment in consultation with other Ministries. They shall serve for four years in the first instance and are eligible for reappointment for a second term of three years only.

(v) Functions of the NBC

In recognition of the need to provide advice to government on Biosafety, the NBC shall:

- (a) be responsible for risk assessment and risk management.
- (b) Establish and review, as necessary, guidelines for both physical and biological containment and/or control procedures appropriate to the level of assessed risk involved in relevant research, development and application activities.
- (c) Consult with relevant government agencies and other organisations as appropriate.
- (d) Advise, where appropriate, on the training of personnel with regard to safety procedures.
- (e) Maintain an inventory of laboratories with physical and human capacities to conduct research in rDNA, undertake risk assessment and create a database of experiences in the releases of LMOs/GMOs in the country.
- (f) Be responsible for advising Government on the release of LMOs and GMOs
- (g) Assess applications and send to Technical Committee.
- (h) Monitor and validate information provided to it by the applicant
- (i) Submit an annual report of its activities to the National Focal Point (NFP).

B. NATIONAL BIOSAFETY TECHNICAL SUBCOMMITTEE:

The National Biosafety Technical Sub-committee shall:

- (i) Be formed, one each for the various disciplines (e.g. agriculture, health, industry, environment) to support the work of the NBC.

- (ii) Review proposals for research and recommend the conditions under which experiments should be conducted.
- (iii) Provide technical advice to the NBC and contribute to its functions in relation to contained use.

C. INSTITUTIONAL BIOSAFETY COMMITTEE (IBC)

All institutions in Nigeria, both private and public (e.g. research institutes, universities and polytechnics, international research centres, industrial research and development units which plan to undertake biotechnology research and/or development), shall each establish an Institutional Biosafety Committee (IBC), which will be responsible to, and co-operate with the NBC.

(i) **Actions and Responsibilities of Institutions**

Responsibilities of the institution will include:

- (a) Formulation of policies and guidelines for biotechnology research in the respective institutions consistent with the Nigeria Biosafety Guidelines;
- (b) Establishment of an IBC. Where a critical mass of scientists to constitute the IBC is not available, the institution may jointly form one committee with other institutions, or rely on the IBC of another institution;
- (c) Assistance to Principal Investigators (PIs) responsible for research to make sure that the research is conducted in accordance with established guidelines;
- (d) Appointment of a Biosafety Officer (BO) who will monitor and advise on biosafety issues on day-to-day basis;
- (e) Establishment of provisions to make available to the public information on experiments conducted at the institution, subject to established guidelines, unless it contains confidential business information or its disclosure is prohibited by law, and to make available a general description of information withheld;
- (f) Assurance that the IBC reports promptly to the NBC any significant problems with implementation of established guidelines.
- (g) Establish and oversee the work of scientific subcommittees, whose role and function include research performed under contained laboratory conditions.

(ii) Composition of the IBC

The IBC should include:

- (a) Five members from the respective institution, including the Biosafety Officer.
- (b) Two other members not affiliated with the institution but knowledgeable in biotechnology or related fields, and representing the interests of the community, such as:
 - (i) Members of governments' public health or environmental agencies;
 - (ii) Persons active in human, plant or animal health concerns and,
 - (iii) Persons or NGOs active in environmental concerns.
- (c) The IBC may invite any Principal Investigator (PI) or representative of NBC or any other person to its meetings.

(iii) Functions of the IBC

The IBC shall perform the following functions:

- (a) Consult with and seek approvals from the NBC;
- (b) Implement the recommendations of the NBC;
- (c) Review and recommend to the NBC applications from PIs;
- (d) Create and maintain a central reference file and library of catalogues, books, articles, news letters and other communications as a source of advice and reference, including such items as the availability of safety equipment, the availability and level of biological containment for various host: vector systems, suitable training of personnel and data on the potential biohazards associated with certain technologies;
- (e) Facilitate the exchange of scientific, technical, environmental and legal information on, and experience with LMOs/GMOs;
- (f) Develop a safety and operation manual and assist PIs in the required staff training;
- (g) Certify the safety of facilities, procedures, and practices as well as the level of training and expertise of the personnel;
- (h) Review and monitor all biotechnology research conducted and sponsored by the institution to ensure compliance with established guidelines;
- (i) Maintain a list of PIs, project supervisors, approved by the IBC as competent to perform supervisory duties for particular projects;
- (j) Maintain records and files of each research project;

- (k) Investigate and report promptly to the NBC all accidents and unexplained absence due to illness;
- (l) Submit an annual report to the NBC.

(D) BIOSAFETY OFFICER (BO)

The institution's authorities will appoint the Biosafety Officer. It is expected that the biosafety officer will be familiar with biosafety requirements for rDNA work. In addition the BO should be sufficiently independent to exercise some authority as related to responsibilities of this office.

- (i) Responsibilities of the Biosafety Officer:
 - (a) Make checks and advise on biosafety issues on a day-to-day basis;
 - (b) Ensure that biosafety is not compromised by any other considerations;
 - (c) Appointment as a member of the IBC;
 - (d) Provision of a report, which should form part of the IBC's annual report to the NBC.

(E) PRINCIPAL INVESTIGATOR (PI)

The PI who is responsible for conducting biotechnology research is the agent of an institution. The PI is accountable to the IBC and leads the efforts in a safe manner and in compliance with the appropriate research guidelines and all applicable regulations.

- (i) Functions of the PI

The PI shall perform the following functions:

- (a) Ensure that experiments, for which the PI is responsible, are carried out in strict compliance with institutional and national guidelines;
- (b) Ensure that safety procedures and practices are complied with;
- (c) Report promptly to the IBC on any significant problems with respect to the implementation of relevant guidelines and regulations;
- (d) Immediately notify the IBC on any research-related accidents that have resulted or could result in human illness, in unanticipated plant or animal disease, or in the escape of organisms under study from the intended confinement;

- (e) Obtain approval of the IBC before embarking on, or modifying biotechnology research projects requiring prior approval of the IBC.
- (f) Ensure compliance with applicable shipping requirements regarding human, plant, and animal health protection policies, permit requirements and containment conditions for possession of certain organisms.

ANNEX I

INFORMATION REQUIRED FOR THE APPLICATION

I. GENERAL INFORMATION

A. Name and Address of applicant

B. Information on personnel and training

- (a) Name of person(s) responsible for planning and carrying out the release, including those responsible for supervision, monitoring and safety, and qualification(s) of the responsible scientist(s).

II. Information relating to the GMO(s) or products thereof

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

- (a) Scientific name;
- (b) Taxonomy;
- (c) Other names (usual name, strain name, cultivar name etc);
- (d) Phenotypic and genetic markers;
- (e) Degree of relatedness between donor and recipient or between parental organisms;
- (f) Description of identification and detection techniques;
- (g) Sensitivity, reliability (in quantitative terms) and specificity of detection and identification techniques;
- (h) 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;
- (i) Potential for genetic transfer and exchange with other organisms;
- (j) Verification of the genetic stability of the organism and factors affecting it, taking into account the relevance of the laboratory experiments undertaken for the authentic ecological conditions under which the organisms live or are used;
- (k) Pathological, ecological and physiological strains:
 - (i) Classification of hazards according to existing national rules concerning the protection of human health and/or environment;

- (ii) Generation time in natural ecosystems, sexual and asexual reproductive cycles;
 - (iii) Information on survival, including seasonality and the ability to form survival structures e.g., seeds, spores or sclerotia;
 - (iv) Pathogenicity: infectivity, toxicity, virulence, allergenicity, carrier (vector) of pathogen, possible vectors, host range including non-target organisms, possible activation of latent viruses (proviruses) and ability to colonise other organisms;
 - (v) Antibiotic resistance, and potential use of these antibiotics in humans and domestic animals for prophylaxis and therapy;
 - (vi) Involvement in environmental processes: Primary production, nutrient turnover, decomposition of organic matter, respiration, etc.
- (l) Nature of indigenous vectors:
 - (i) Sequence
 - (ii) Frequency
 - (iii) Specification
 - (iv) Presence of genes which confer resistance
 - (m) History of previous genetic modifications.

B. Characteristics of the vector

- (a) Nature and source of the vector;
- (b) Genetic map of the vector(s), position of the gene(s) intended for transfer, other coding and non-coding sequences affecting the expression of the introduced gene(s), and marker(s);
- (c) Frequency of mobilisation of inserted vector and/or genetic transfer capabilities and methods of determination;
- (d) Information on the degree to which the vector is limited to the DNA required to perform the intended function;
- (e) 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

- (a) Methods used for the modification
- (b) Purpose of the modification and intended use in relation to need or benefit;
- (c) Methods used to construct and introduce the insert(s) into the recipient or to delete a sequence;
- (d) Description of the insert and/or vector construction;
- (e) 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;
- (f) Number of intact and truncated vector inserts. Sequence, functional identify and location of the altered/inserted/deleted nucleic acid segment(s) in question with particular reference to any known harmful sequence;
- (g) Sequence and methylation pattern of the recipient DNA as far as 100kbp up and down stream from all DNA inserts.
- (h) Description of genetic trait(s) or phenotypic characteristics and in particular any new traits and characteristics which may be expressed or no longer expressed;
- (i) Structure and amount of any vector and/or donor nucleic acid remaining in the final construction of the GMO(s) or product thereof;
- (j) Stability of the organism in terms of genetic traits;
- (k) Rate and level of expression of the new genetic material. Method and sensitivity of measurement;
- (l) Activity of the expressed protein(s);
- (m) Expression levels for the recipient's genes situated as far as 100kbp up and down stream from all DNA inserts;
- (n) Sensitivity, reliability (in quantitative terms) and specificity of detection and identification techniques;
- (o) History of previous releases or uses of the GMO(s) or products thereof;
- (p) Health consideration:
 - (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 colonisation;
- (v) If the organism is pathogenic on humans who are immuno-competent:
 - 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;
 - Antibiotics-resistance patterns;
 - Allergenicity;
 - Availability of appropriate therapies.

III. Information relating to the conditions of release and the receiving environment

A. Information on the release

- (a) Description of the proposed deliberate release, including the purpose(s) and foreseen products;
- (b) Foreseen dates of the release and time of planning the experiment including frequency and duration of releases;
- (c) Preparation of the site previous to the release;
- (d) Size of the site;
- (e) Method(s) to be used for the release;
- (f) Quantities of GMO(s) or products thereof to be released;
- (g) Disturbance on the site (type and method of cultivation, mining, irrigation or other activities);
- (h) Worker protection measures taken during the release;

- (i) Post-release treatment of the site;
- (j) Techniques foreseen for elimination or inactivation of the GMO(s) or products thereof at the end of the experiment;
- (k) Information on, and result of, previous releases of the GMO(s) or products thereof, especially at different scales and in different ecosystems.

B. Information on the environment (both of the site and the wider environment)

- (a) Geographical location and grid reference of the site(s) (in case of notifications the site(s) of release will be the foreseen areas of use of the product);
- (b) Physical or biological proximity to humans and other significant biota;
- (c) Proximity to significant biotypes or protected areas;
- (d) Size of local population;
- (e) Economic activities of local population which are based on the natural resources of the area;
- (f) Distance to closest areas protected for drinking water and/environmental purpose;
- (g) Climatic characteristics of the region(s) likely to be affected;
- (h) Geographical, geological and pedological characteristics;
- (i) Flora and fauna, including crops, livestock and migratory species;
- (j) Description of target and non-target ecosystems likely to be affected;
- (k) A comparison of the natural habitat of the recipient organism with the proposed site(s) of release;
- (l) 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

- (a) Biological features which affect survival, multiplication and dispersal;
- (b) Known or predicted environmental conditions which may affect survival, multiplication and dissemination (wind, water, soil, temperature, pH, pollutants such as pesticides, heavy metals and others etc.);

- (c) Sensitivity to specific agents.

B. Interactions with the environment

- (a) Predicted habitat of the GMO(s) or products thereof;
- (b) Studies of the behaviour and characteristics of the GMO(s) or products thereof and their ecological impact carried out in simulated natural environment, such as microcosms, growth rooms, greenhouses;
- (c) Genetic transfer capability:
 - (i) Post-release transfer of genetic material from GMO(s) or products thereof into organism in affected ecosystems;
 - (ii) Post-release transfer of genetic material from indigenous organism to the GMO(s) or products thereof;
- (d) Likelihood of post-release selection leading to the expression of unexpected and/or undesirable traits in the GMO(s) or products thereof;
- (e) Measures employed to ensure and to verify genetic stability. Description of genetic traits which may prevent or minimise dispersal of genetic material. Methods to verify stability;
- (f) Routes of biological dispersal, known or potential modes of interaction with the disseminating agent, including inhalation, ingestion, surface contact, burrowing, etc.;
- (g) Description of ecosystem to which the GMO(s) or products thereof would be disseminated.

C. Potential environmental impact

- (a) Potential for excessive population increases in the environment;
- (b) Competitive advantage of the GMO(s) or products thereof in relation to the unmodified parental organism(s);
- (c) Identification and description of the target organisms;
- (d) Anticipated mechanism and result of interaction between the released GMO(s) or products thereof and the target organism;
- (e) Identification and description of non-target organisms which may be affected unwittingly;

- (f) Likelihood of post-release shifts in biological, or in host range;
 - (g) Known or predicted effects on non-target organisms in the environment, impact on population levels of competitors, preys, hosts, symbionts, predators, parasites and pathogens;
 - (h) Known or predicted involvement in biogeochemical processes;
 - (i) Other potentially significant interaction with the environment.
- (v). Characteristics of resuscitated organisms and gene(s) and fossil DNA sequences:**
- A. Resuscitated organism**
- (a) Scientific name and taxonomy;
 - (b) Identity of nearest species and their characteristics which are of relevance to the intended use;
 - (c) Site at which it was found;
 - (d) Method used for resuscitation;
 - (e) Purpose of introducing the organism and benefits, if any;
 - (f) Impacts on human and animal health and the environment;
 - (g) Measures for counteracting adverse impacts;
 - (h) Length of time the organism has been in use;
 - (i) Genetic stability;
 - (j) Likelihood of gene transfer to other organisms;
 - (k) Fossil and living nearest related species;
 - (l) Biological and biochemical differences from related living species;
 - (m) Information on previous uses since resuscitation.
- B. DNA sequences from fossils or from resuscitated organism**
- (a) Scientific name and taxonomy of the species whether resuscitated or a fossil;
 - (b) Site of origin of the fossil;
 - (c) Site of the gene in the resuscitated genome, if known;
 - (d) Base sequence of the extracted gene;
 - (e) Method used in extracting the gene;
 - (f) Function of gene, if known;
 - (g) Purpose of use and benefits, if any;

- (h) Environment in which it lived before fossilisation;
- (I) Fossil species related to the species from which the gene was taken;
- (j) Living species related to the species from which the gene was taken;

2. SOCIO-ECONOMIC CONSIDERATIONS:

- (a) Anticipated changes in the existing social and economic patterns resulting from the introduction of the GMO or product thereof;
- (b) Possible threats to biological diversity, traditional crops or other products and, in particular, farmers' varieties and sustainable agriculture;
- (c) 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;
- (d) 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 GMO or product thereof;
- (e) Possible countries and/or communities to be affected in terms of disruptions to their social and economic welfare;
- (f) Possible effects which are contrary to the social, cultural, ethical and religious values of communities arising from the use or release of the GMO or product thereof.

3 Risk Management Measures

A. General precautions

- (a) Appropriate information and training is provided for those involved in handling the organisms;
- (b) Monitoring procedures are applied in such a way that appropriate measures can be taken in case of unexpected effects during or after the release;
- (c) The dissemination of the released organisms and/or gene flow from the released organisms is controlled;
- (d) Controlling access to the release site.

(i) PLANTS

(a) Applying reproductive isolation, by:

- Spatial separation;
- Temporal separation: use of plants that will flower either earlier or later than plants of nearby reproductively compatible species;
- Biological prevention of flowering (e.g. by omitting vernalisation);
- Removal of the male or female reproductive structures’;
- Bagging of flowers;
- Making use of sterility;

(b) Controlling the persistence or dispersal of reproductive structures such as propagules or seeds.

(c) Destroying volunteer plants after harvest;

(ii) ANIMALS

(a) Confining by appropriate means such as fences, filters, islands, and ponds;

(b) Applying reproductive isolation by using sterile animals

(c) Isolation from feral animals of the same species

(d) Controlling the persistence or dispersal of reproductive structures such as larvae or eggs.

(iii) MICRO-ORGANISMS

(a) Using organisms with impaired ability to grow or persist in the environment;

(b) Minimising gene transfer by:

- using organisms that do not contain known self-transmissible mobilisation or transposable genetic elements;
- ensuring that introduced traits is stably located on the chromosome.

B. Monitoring techniques

a. Methods for tracing the GMO(s) or products thereof, and for monitoring their effects;

- b. Specify (to identify the GMO(s) or products thereof, and distinguish them from the donor, recipient or, where appropriate, the parental organisms) sensitivity and reliability of the monitoring techniques;
- c. Techniques for detecting transfer of the donated genetic material to other organisms;
- d. Methods to detect aberrant gene expression.

C. Waste treatment

- (a) Types of waste generated;
- (b) Expected amount of waste;
- (c) Possible risks;
- (d) Description of treatment envisaged.

D. Emergency response plan

- (a) Methods and procedures for controlling the GMO(s) or products thereof in case of unexpected spread;
- (b) Methods for decontamination of the areas affected, e.g. eradication of the GMO(s) or products thereof;
- (c) Methods for disposal or sanitation of plants, animals, soil, etc. that were exposed during or after the spread;
- (d) Methods for the isolation of the area affected by the spread;
- (e) Plans for protecting human health and the environment in case of the occurrence of an undesirable effect.

Annex II

CONTAINMENT FACILITIES & BIOSAFETY PRACTICES

Containment is the term used to describe the safety methods for managing infectious agents or hazardous compounds in the laboratory environment where they are being handled or maintained in order to prevent their distribution outside the prescribed space. The purpose of containment is to reduce exposure of laboratory workers, other persons and the outside environment to potentially hazardous agents.

A. BIOSAFETY LEVELS

Different levels of physical containment, designated BL1, BL2, BL3 and BL4 can be achieved with combinations of laboratory practices, containment equipment and special laboratory design. The onus of proof of the Biosafety level designation and the level of hazards posed by any biological entity for a given biosafety level and the consequences thereof rest with the applicant/ researcher/facility owner.

BIOSAFETY LEVEL 1 (BL1)

This level is suitable for work, which involves agents of no known or minimal potential hazard to laboratory personnel and the environment. No special accommodation or equipment is required but the laboratory personnel have specific training in laboratory procedures and are supervised by a scientist in a related field. Special containment equipment is generally not required for manipulation of agents assigned to Biosafety level 1.

(i) LABORATORY FACILITIES

- (a) The Laboratory should be designed so that it can be easily cleaned.
- (b) Bench-tops should be impervious to water, and resistant to acids, alkalis, organic solvents, and moderate heat.
- (c) Each laboratory should contain a sink for hand washing preferably near the exit.
- (d) Safety systems covering fire, electrical, shower and eyewash should be provided.
- (e) Laboratory furniture should be sturdy.
- (f) If the laboratory has windows that open, they should be fitted with fly screens.

- (g) Doors should have appropriate fire ratings, be self-closing and have vision panels.
- (h) Facilities for storing outer garments and personnel items and for eating, drinking and smoking should be provided outside the working areas.
- (i) First aid rooms suitably equipped and readily accessible should be provided.
- (j) An autoclave for decontamination of infectious laboratory wastes should be provided in the same building as the laboratory.

B. BIOSAFETY LEVEL 2 (BL2)

This level is suitable for work involving a broad-spectrum of moderate-risk agents. Safety guidelines similar to that for the BL1 have to be observed. In addition the following special practices should be adhered to:

(i) LABORATORY FACILITIES

These are same as for BL1

(ii) SPECIAL PRACTICES

- (a) Laboratory personnel should have specific training in handling pathogenic agents and must be under competent supervision.
- (b) Access to the laboratory should be limited or restricted by the laboratory director who should ensure that only persons that have been advised of the potential hazard and meet the specific entry requirements (e.g. immunisation) could enter the laboratory or animal rooms.
- (c) Contaminated materials meant for disposal are to be decontaminated. Before decontamination they are to be placed in leak-proof durable containers which are closed and labeled.
- (d) All wastes from the laboratories and animal rooms should be properly decontaminated before disposal.
- (e) When organisms containing DNA molecules are handled in the laboratory a hazard warning sign such as the biohazard symbol must be boldly displayed on the access door to the laboratory.

- (f) Special care should be taken to avoid skin contact with organisms containing rDNA molecules; gloves should be worn when handling experimental animals and when skin contact with the agent is unavoidable.
- (g) Spills and accidents, which result in overt exposures to organisms containing rDNA molecules must be immediately, reported to the laboratory director. Medical evaluation, surveillance, and treatment are provided as appropriate, while written records are also maintained.
- (h) A biosafety manual should be prepared and adopted for use by laboratory personnel. Personnel are advised of special hazards and are required to be conversant with practices and procedures and adhere to them at all times.

(iii) CONTAINMENT EQUIPMENT

Biological safety cabinets or other personal protective or physical containment devices are used whenever:

- (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 or materials whose internal pressure may be different from ambient pressures, inoculating animals intra-nasally, 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 open laboratory if sealed heads or centrifuge safety caps are used and if they are opened only in a biological safety cabinet.

C. BIOSAFETY LEVEL 3 (BL3)

These practices are applicable to clinical, diagnostic, research or production facilities in which work is done with indigenous or exotic agents, which may have adverse effects on the environment and biodiversity, human health, cause serious or potentially lethal disease due to exposure, by ingestion, inhalation, or other contact. In addition to the conditions required for BL2, it is necessary that the under-listed special guidelines be strictly adhered to.

(i) LABORATORY FACILITIES

- (a) The laboratory is separated from areas, which are open to unrestricted human traffic flow. Passage through two sets of doors is the basic requirement for entry into the laboratory from access corridors or other contiguous areas. Physical separation of the high risk 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 laboratory is designed so that it can be easily cleaned, and sealing must block penetrations in the interior surfaces of walls, floors and ceilings or be capable of being sealed to facilitate decontaminating the area.
- (c) Windows in the laboratory must be closed and sealed.
- (d) The access door to the laboratory or containment module should be self-closing.

(ii) SPECIAL PRACTICES

- (a) All activities involving organisms containing rDNA molecules should be conducted in Biological Safety Cabinets or other physical containment devices within the containment module. No work in open vessels should be conducted on the open bench.
- (b) The work surfaces of Biological Safety Cabinets and other containment equipment must be decontaminated when work with organisms containing rDNA molecules is finished.
- (c) Laboratory clothing (e.g. wrap-around gowns) that protects street clothing must be worn in the laboratory; front button laboratory coats are unsuitable. Laboratory clothing must be decontaminated before being laundered.
- (d) Extreme caution should be used when handling needles and syringes to avoid autoinoculation 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 being discarded.
- (e) Laboratory animals kept in the BL3 areas shall be housed in partial – containment caging systems, such as 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.

(iii) CONTAINMENT EQUIPMENT

As in BL2

D. BIOSAFETY LEVEL 4 (BL4)

These practices, safety equipment and facilities are applicable to work with highly pathogenic or exotic agents, which pose a high individual risk resulting in life-threatening disease.

In addition to the conditions required for BL3, it is necessary that following practices be strictly complied with:

(i) 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 airlock should be provided for passage of those materials, supplies or equipment which are not brought into or out of the facility through change room.
- (b) The autoclave door, which opens to the area external to the facility, should be sealed to the outer wall and automatically controlled so that the outside can only be opened after the autoclave sterilization cycle has been completed.
- (c) Walls, floors and ceilings of the facility should be constructed to form a sealed internal shell, which facilitates fumigation and is animal and insect proof. The internal surfaces of this shell should be resistant to liquids and chemicals and thus facilitates cleaning and decontamination of the area. All penetrations in these structures and surfaces are sealed. Any drains in the floors should contain traps filled with a chemical disinfectant of proven efficacy against the target agent. They should be connected directly to the liquid wastes decontamination system. Sewer and other ventilation lines should contain in-line HEPA filters.

- (d) A pass-through “drunk” tank, fumigation chamber, or an equivalent decontamination method should be provided so that materials and equipment that cannot be decontaminated in the autoclave can be safely removed from the facility.
- (e) Liquid effluents from the sinks, biological safety cabinets, floors and autoclave chambers should be decontaminated by heat treatment before release from the maximum containment facility. Liquid wastes from shower rooms and toilets should be decontaminated with chemical disinfectants or by heat in a liquid waste decontamination system. The procedure used for heat decontamination of liquid wastes should be 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 proven efficacy against the target or indicator microorganisms.
- (f) A specially designed suit area may be provided in the facility. Personnel who enter this facility or area wear a one-piece positive pressure suit that is ventilated by a self-support system. The life support system includes alarms and emergency backup breathing air tanks. Entry to this area should be through an airlock fitted with airtight doors. A chemical shower should be provided to decontaminate the surface of the suit before the worker leaves the area. The exhaust air from the suit area should be filtered by two sets of HEPA filters installed in series. A duplicate filtration unit, exhaust fan and a power source with an automated switching system should be provided. The design should be such that air pressure within the suit area is lower than that of any adjacent area. Emergency lighting and communication systems are provided. All penetrations into the internal shell of the suit are sealed. A double-doored autoclave should be provided for decontaminating waste materials to be removed from the suit area.

(ii) SPECIAL PRACTICES

- (a) Access to the facility is highly restricted and the Laboratory Director or the Biohazard Control Officer manages accessibility. A logbook signed by all personnel indicates the date and time of each entry and exit.
- (b) Street clothing should be removed in the outer clothing change room and kept there. Complete laboratory clothing including undergarments, pants and shirts or jumpsuits,

shoes and gloves should be 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 should remove their laboratory clothing and store it in a locker or hamper in the inner change room.

- (c) Biological materials to be removed from the class III Biological Safety Cabinets or from the Maximum containment laboratory in a viable or intact state should be transferred to a non-breakable, sealed primary container and then closed in a non-breakable, sealed secondary container which is removed from the facility through a disinfectant “dunk” tank, fumigation chamber, or an airlock designed for this purpose.
- (d) No materials, except for biological materials that are to remain in a viable or intact state are removed from maximum containment laboratory unless they have been autoclaved or decontaminated before they leave the facility. Equipment or material which might be damaged by high temperatures or steam is decontaminated by gaseous or vapour methods in an airlock or chamber designed for this purpose.
- (e) A system should be set up to report laboratory accidents and exposures and employee absenteeism and for medical surveillance for potential laboratory – associated illness. Written records should be prepared and maintained. An essential adjunct to such a reporting – surveillance system is the availability of a facility for a quarantine, isolation and medical care of personnel with potential or known laboratory – associated illnesses.

(iii) CONTAINMENT EQUIPMENT

All procedures within the facility with agents assigned to BL4 can be conducted in Class III Biological Safety Cabinets or in Class I or II Cabinets used in conjunction with one-piece positive pressure personnel suits ventilated by a life-support system.

GLOSSARY

Accident: Any incident involving a significant and unintended release of genetically modified organism in the course of their contained use, which could present an immediate or delayed hazard to human health or the environment.

Biosafety: The policies and procedures adopted to ensure the environmentally safe applications of modern biotechnology in medicine, agriculture, and the environment, and to avoid endangering public health or environmental safety.

Biotechnology: Any technique that uses living organisms or substances from these organisms to make or modify a product, to improve plants or animals, or to develop microorganisms for specific uses.

Cell: The smallest component of life. A membrane-bound protoplasmic body capable of carrying on all essential life processes. A single-cell unit is a complex collection of molecules with many different activities.

Confinement/Containment: Measures to limit the interaction of the regulated organisms with the environment or with human, procedures include but are not limited to isolation from related species, destruction of residues, and sterilisation using, physical, chemical and/or biological barriers to limit their contact with the general population and the environment.

Deliberate release: Any intentional introduction into the environment of a GMO or a combination of GMOs without provision for containment, such a physical barriers or a combination of physical barriers together with chemical and/or biological barriers used to limit their contact with the general population and the environment.

Environment: Components of the earth, including air, land, water, all layers of the atmosphere, all organic and inorganic matter and living organisms, and all interacting natural systems that include components referred to above. Includes the natural and managed ecosystems, including agricultural ecosystems.

Environmental Release: The controlled, intentional resting of genetically engineered living organisms, outside of a confinement structure.

Environment Risk Assessment: The evaluation of the risk to human health and the environment (which includes plants and animals) connected with the release of GMOs or products containing GMOS.

Gene: The fundamental physical and functional unit of heredity, the portion of a DNA molecule that is made up of an ordered sequence of nucleotide base pairs that produce a specific product or have an assigned function.

Genetic Engineering: Technologies (including rDNA technologies) used to isolate genes from an organism, manipulate them in the laboratory, and insert them into another organism.

Genetically Modified Organism (GMO): An organism in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination.

Notification: The presentation of documents containing the requisite information to the component authorities of a national state. The person making the presentation shall be referred to as the notifier.

Organism: Any biological entity capable of replication or of transferring genetic material.

Phenotype: The physical appearance of an organism as distinguished from its genetic constitution (genotype).

Product: A preparation consisting of, or containing, a GMO or a combination of GMOs, which is placed on the market.

Shipping: Movement of materials, which includes transportation, exchange, introduction, acquisition and transfer.

Tissue Culture: The propagation of tissue removed from organisms in a laboratory environment that has strict sterility, temperature, and nutrient requirements.

Transformation: Introduction and assimilation of DNA by one organism from another.

Use: The deliberate application of a product, which has been placed on the market. The persons carrying out this use shall be referred to as users.

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(1)

Risk assessment shall be carried out in accordance with Annex I. Risk assessment shall be carried out by a person(s) approved by the NBC

The cost of risk assessment and any other administrative charges shall be borne by the applicant.

Notification should be sent to the National Focal Point as defined in the 12B1

14 ANFP

There shall be one National Focal Point for biosafety in Nigeria. The focal point is the Federal Ministry of Environment. The National Focal Point shall be responsible for liaison with the Secretariat Convention on Biological Diversity.

A Competent Authority shall be responsible for performing the administrative functions.

~~Transit - Notification~~

~~Review of decision~~

~~Unintentional transboundary movement (release and Emergency appeal)~~

~~Public awareness and Participation~~

~~Capacity building~~

~~Biosafety Clearing House.~~

Party of export is the country of origin of the LMO/GMO
RDNA recombinant Deoxyribose Nucleic Acid